Planning For The Pandemic
Selected Privacy Related Legal Concerns

Association of State and Territorial Health Officials Workshop

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Develop & Begin Exploration of:

- What Personal Data Needs Are Likely To Arise & When
- What Types of Rules & Practical Constraints Are Likely To Impact the Ability To Use, Access or Disclose This Data
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Presented by
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Public Health Response by WHO Phase

- **Phase 3** –
  - Human infection with new subtype (e.g. H5N1) but no human to human spread, or at most rare with close contact

- **Phase 4** –
  - Small clusters, limited human to human, highly localized, not well adapted
Public Health Response by WHO Phase

- **Phase 5** –
  - Large clusters, still localized, but showing better transmissibility, but not all the way to sustained yet

- **Phase 6** –
  - Pandemic phase, sustained human to human transmission

- **Phase 7??** –
  - Pandemic over, getting back to normal
Phase 3 – Public Health Activities

- Phase 3 - Phase we’re in now.
- **WHO** - Providing guidance, confirming human infections with testing and typing, establishing global case definition, pub updates on international EPI situation
- **Federal** - Deploying rapid response teams to support WHO, Helping with genetic sequencing, Pre-positioning US contribution to international anti-viral stockpile
- States - where you are now - planning!
Phase 3 – Legal and Privacy Issues

- Pandemic Planning – Creating Sound Protocols
  - Collecting disease information?
  - Tracking employee health?
  - Providing employee treatment?
  - Responding to third party inquiries?
    - Press
    - Private citizens
    - Legislative
Phase 4 – Public Health Activities

- **WHO** - Requests reports from members on enhanced surveillance, advocates monitoring international travelers, deploys global stockpile as part of rapid operation to contain protocol, continued EPI updates and case def development

- **Federal** - Asks for departure screening / implements entry screening, I&Q protocols initiated for ports of entry, diversion of vaccine production when seed available, possible revision of priority list, calls to states to activate plans (including regular calls with governors and health officers)

- **SNS** – Recent Guidance - Delivery of anti-virals begins! Prior to request!
Phase 4 – State Public Health Activities

- Emergency Management
  - Activating Agency situation rooms or EOCs

- Pharmaceuticals
  - Receiving SNS anti-viral shipments and distributing
  - Getting a fix on #s of HCW in Tier 1A

- Surveillance and Investigation
  - Enhancing - Pushing suspect case screening protocols/patient interview forms
  - Investigating suspect cases

- Public Info
  - Infection Control, Specimen collection and shipping to PH labs, I&Q, EPI Investigation, Case Definitions, home care
Phase 4 – State Public Health Activities

➤ Testing
  ▪ Requesting specimens for PH Lab Testing
  ▪ Receiving control samples from CDC thru LRN

➤ Containment
  ▪ Isolate initial cases if Phase 4 is local
  ▪ Quarantine close contacts of initial cases
  ▪ Activate I&Q sites as appropriate

➤ Health Care Facilities
  ▪ Partial activation of HICS
  ▪ Identify Triage areas for ILI patients
Phase 5 – Public Health Activities

➤ WHO
  • Tracking spread, refining case definition, assessing extent of transmissibility, forecasting trends for characteristics of first wave, recommending travel restrictions

➤ Federal
  • Screening travelers from affected countries, possibly expanding screenings, developing and deploying control samples for LRN (if not done already), reviewing guidelines, distributing revised versions if disease characteristics warrant
Phase 5 – State Public Health Activities

- Phase 4 activities begin if we jump from 3 to 5 quickly.
- If not, Phase 5 in your state plans looks a lot like Phase 4
  - Enhanced Surveillance
  - EPI Investigations
  - Pharmaceutical PODs open?
  - Local isolation of suspect/confirmed case with quarantine of close contacts
  - Public Info continues
Phases 4 and 5 – Legal and Privacy Issues

- Collecting disease information
  - Is ILI or pan flu reporting voluntary or mandatory now?

- Tracking employee health, in action
  - Working quarantine for field staff
    - How do you collect?
    - Who collects?
    - How do you handle the information?
    - Who can see the info?
    - Does this lead to treatment?

- Containment
  - Who tracks persons in I&Q? Who monitors health status? Are you health care provider?
  - SNS PODs? – Are you health care provider? Public health agency?
Phases 4 and 5 – Legal and Privacy Issues

- Providing medical treatment
  - E.g., anti-viral prophylaxis, also HCFs’ plans to treat staff
  - Are you health care provider or employer?

- Responding to third party requests
  - Movement from 3 to 4 will be big story
  - Who is asking?
  - What role did you play in collecting info?
  - Are there circumstances where you should release without request?
    - Private health care partners?
    - Business?
Phases 4 and 5 – Legal and Privacy Issues

- Tracking employee health, in action
- COOP plans will have large impact on scope of this issue
- Working quarantines for field staff
  - EPI Investigations, Public Health Clinic Workers, Home Health Staff, SNS Distribution Staff
- How do you collect info?
- Who collects?
- How do you handle the information?
- Who can see the info?
- What do you do with it?
- Does this lead to treatment?
Phases 4 and 5 – Legal and Privacy Issues

- Tracking employee health
- What about non-field staff?
- Absenteeism will rise - both legit and not legit
  - Can you track who gets the flu?
  - Can you track who stays home with sick family?
  - How do you factor into leave policies?
Phase 6 – Public Health Activities

- WHO and Feds
  - Good info on disease characteristics, treatment guidance, anti-viral resistance, etc.
  - BUT, actual response will be very localized now

- States
  - Surveillance - individual reporting probably stopped with statewide counting taking its place
  - EPI investigations - stopped, except for special clusters
  - Testing - limited specimen testing, but watching for antigenic shift

- Public Info
  - Disease, EPI, Infection control info
  - Continued home care and deceased disposal info
Phase 6 - Public Health Activities

- **States – Pharmaceuticals**
  - PODs will certainly be operational now with staff in field, dispensing drugs

- **Containment**
  - Individual isolation and quarantine will cease - no longer effective
  - Voluntary/mandatory I&Q at home based on symptoms
  - School closings
  - Canceling and limiting “large” public gatherings
Phase 6 – Legal and Privacy Concerns

- Surveillance and Containment
  - Activities will be shifting away from collection of persona data

- Third Party Requests
  - Intense interest from all sectors, press, legislative, citizens, business
  - At some point shifting to interest in vital records info on deaths
Phase 7?? – After the Pandemic

BIG ISSUE – How do you declare pandemic over?
- How do handle space between waves?
- Probably lots of guidance from WHO and CDC

Activities?
- Reopening schools
- Allowing “large” public gatherings again
- Emerging out of COOP Plans, restarting normal operations
Phase 7?? – After the Pandemic

- Resuming normal activities
- How will staff who have been infected with pan flu and recovered be identified so that they can return to their normal activities without undue burden and still have their privacy maintained?
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MEETING THE MISSION REQUIRES

- Your Agency Legally & Effectively Obtain, Use & Safeguard Necessary Personal & Other Sensitive Data
- Manage Data Requests & Disclosure To Promote Desired Individual & Organizational Response/Cooperation
- Manage Data Requests & Disclosures To Deter Undesirable Third Party Behavior
- Manage Public Image
Privacy Concerns Can Undermine Required Data Access

I completed the confidential questionnaire. You won’t share this with my employer or anyone else, right?!!
Jury & Public Sensibilities

Trump Yours

Do you promise to tell the truth, the whole truth, and nothing but the truth, so help you whatever your personal beliefs are?
Personal Health & Other Data Use

Peeking Into Private Matters Is Sensitive Stuff Regardless of The Legitimacy or Importance Behind The Inquiry
Your Agency Must Both:

- Understand Your Agency’s Many Hats, Requirements & Concerns

+ 

- Understand/Manage Others Hats, Requirements & Concerns
The Cast of Characters
Your Public Agency’s Many Hats

- Disaster Preparedness/Recovery Agency
- Health Care Provider
- Federal Government Contractor
- Employer
  - Managing Communicable Disease
  - Managing Absences
  - Cost Containment Issues
- Employee Benefit Plan Sponsor/Contributor
- Contractual
- Public Actor
The Cast of Characters
Third Parties

- Other Coordinating Agencies
  - Agency Mission – Not Same As Yours
  - Agency Rules – Not Same As Yours
  - Employers
  - Health Plan Sponsor
  - Other Employee Benefit Plan Sponsor
  - Public Image
The Cast of Characters
Third Parties

- Health Care Providers
  - HIPAA & Other Medical Privacy Obligations
  - Employers
  - Health Plan Sponsor
  - Other Employee Benefit Plan Sponsor
  - Public Image
The Cast of Characters
Third Parties

- Private Sector Businesses
  - Commercial Product/Service Providers
  - Employers
  - Health Plans
  - Other Employee Benefit Plans
  - Worker’s Compensation & Other Insurance Policy Holders
  - Shareholder/Equity/Member Accountability
  - Public Entity
The Cast of Characters
Third Parties

- The Press, The Regulators & The Plaintiff’s Lawyers

- WESTMORELAND
- CBS
- THE LAWYERS ($13.5 MILLION IN LEGAL FEES)
Health Care Provider Privacy

- HIPAA
- If Governmental Agency, Specific Requirements, e.g.:
  - Federal & State Constitutional Privacy Rights
  - Other Specific Statutory/Regulatory Mandates
- State HIPAA & Medical Privacy Laws
- Ethical Obligations/Professional Standards of Practice
- Contractual/Promised Privacy Including Business Associate and Other Subcontracted Responsibilities
- Public Expectations
- Other
HIPAA Privacy & Data Security

- Apply To
  - Heath Care Providers
  - Health Plans
  - Health Care Clearinghouses

- Covered Entities Responsible For Business Associates & Workforce Compliance
HIPAA “Health Care Provider”

... a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

45 C.F.R. § 160.103
Arrangement that is an individual or group plan, or combination thereof, that provides, or pays for the cost of, medical care, including:

- Diagnosis, cure, mitigation, treatment or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body;
- Amounts paid for transportation primarily for and essential to medical care; and
- Amounts paid for insurance covering medical care; and

Listed plan.

45 C.F.R. § 160.103
HIPAA “Health Plan”

✓ Group health plan (50 or more participants or insured)
✓ Health insurance issuer
✓ HMO
✓ Certain specified federal government programs
✓ State child health plan
✓ Medicare supplemental policy issuer
✓ Long term care policy issuer
✓ Employee welfare benefit program
✓ Any other individual or group plan that provides or pays for the cost of medical care
Could Your Agency Be a HIPAA Health Care Clearinghouse?

Does the business or agency process, or facilitate the processing of, health information from nonstandard format or content into standard format or content or from standard format or content into nonstandard format or content? (4)

YES

Does the business or agency perform this function for another legal entity?

YES

STOP! The business or agency is a health care clearinghouse

NO

STOP! The business or agency is not a health care clearinghouse
Privacy & Security Standards: A Nutshell

- **Privacy Rule:** A covered entity cannot use or disclose protected health information (PHI) except as permitted or required by the final Privacy Standards.

- **Security Rule:** Covered entities receiving, maintaining or transmitting electronic PHI must safeguard data against improper use, access, disclosure or destruction.

- **Privacy Rights:** Covered entities must honor specified individual HIPAA Privacy rights.

- **Privacy Officer & Compliance Plan Requirements.**
HIPAA Protects “Protected Health Information”

- Information relates to:
  - past, present, or future mental or physical condition;
  - the provision of health care; or
  - payment for the provision of health care
- Created by a:
  - Provider
  - Plan
  - Clearinghouse
  - Employer
- Identifies the Individual or creates a reasonable basis to believe that the individual’s identity may be revealed
- No de-identified or otherwise excluded
HIPAA Personal Identifiers:

- Name
- Address
- Zip Code
- Names of relatives
- Name of employer
- DOB
- Telephone number
- Fax number
- E-mail address

- Finger or voice prints
- Photographic images
- SSN
- Medical record #
- Health Plan #
- Account #
- Driver’s license #
- Vehicle #
- Any other unique identifier or code
HIPAA ALLOWED PERMITTED USES/DISCLOSURES

- Limited availability
- Must meet all technical requirements
- Must have/be in Privacy Notice
- Generally limit to meet “minimum necessary”
- Generally must account – requires documentation
HIPAA PHI Use/Disclosure Permitted

- With valid authorization;
- Treatment, Payment, & Operations
- To individuals involved in care with opportunity to object;
- In an emergency;
- For law enforcement purposes;
- For public health activities;
- For health oversight activities
- Serious threat to public health/safety
- Required of disclosing covered entity by law

- To provide information to coroners, funeral directors, etc.;
- Research purposes;
- For organ, eye, or tissue donation purposes; and
- Judicial/administrative procedure;
- Law enforcement purposes;
- Specialized government functions;
- Worker’s compensation;
- For use by business associates with BA Agreement.
Valid Authorization Elements

- Specific and meaningful description of the information to be used or disclosed;
- Identification of the entity authorized to make the requested use or disclosure;
- Identity of the entity authorized to receive the use or disclosure;
- Expiration date or event that terminates the authorization;
- Statement of the right to revoke the authorization, including exceptions and a description of the revocation process;
- Inform the individual that the information used or disclosed pursuant to the authorization may be subject to redisclosure by the recipient and no longer protected;
- Signature of the individual and date;
- Special conditions for psychiatric notes; and
- If the authorization is signed by a personal representative of the individual, a description of such representative’s authority.

45 C.F.R. § 164.508
Valid Authorization

CAUTIONARY NOTE ABOUT RELIANCE ON AUTHORIZATIONS

- Must Limit Use To Authorized Purpose Unless Otherwise Permitted Without Authorization
- Language Of Authorization May Forfeit Otherwise Allowable Alternative Use By Unduly Restrictive Language

45 C.F.R. § 164.508
Treatment, Payment & Operations

Accounting Mandate Generally N/A

- **Treatment** - the provision, coordination, or management of health care and related services by one or more health care providers.
- **Payment** - activities by a health plan to obtain premiums or to determine or fulfill obligations for coverage and the provision of benefit and activities by a provider to obtain or provide reimbursement for the provision of health care.
- **Health Care Operations** - activities such as quality assessment and improvement, training, accreditation, credentialing, medical review, etc.

45 C.F.R § 164.506
Public Health Authority
Special Rules 45 C.F.R. § 164.512(b)

Public health authority means “an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.”

45 C.F.R §§ 164.501

Distinguish from acting as research entity
CE May Disclose PHI For Following The Public Health Activities And Purposes

45 C.F.R. § 164.512(b)

➢ A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation;
CE May Disclose PHI For Following The Public Health Activities And Purposes

45 C.F.R. § 164.512(b)

➢ To employer about individual member employer’s workforce if:
  ▪ CE is health care provider who is a member of employer’s workforce or provides health care to individual at employer’s request as part of evaluation (1) relating to medical surveillance of the workplace or (2) if individual has work-related illness or injury;

  ▪ Only disclosed PHI is findings concerning a work-related illness or injury or a workplace-related medical surveillance;

  ▪ Employer needs findings to comply with its obligations to record illness or injury or other workplace medical surveillance duties under OSHA or other similar federal or state workplace safety laws; and

  ▪ The covered health care provider provides written notice as required by the Privacy Standards to the individual that PHI relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer.
CE May Disclose PHI For Following The Public Health Activities And Purposes

45 C.F.R. § 164.512(b)

- A public health authority authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

- A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

- A person subject to FDA jurisdiction with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity

- If CE also is a public health authority, CE may use PHI in all cases in which it is permitted to disclose such information for public health activities above.
CE may disclose PHI to a health oversight agency for health system or government health condition based benefit program oversight or civil rights laws enforcement for which health information is necessary for determining compliance.

Health oversight activity ≠ investigation where subject of info is the subject of the investigation unless investigation relates either to receipt of health care; a claim for public benefits related to health; or qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.

If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted above.
PHI To Avert Serious Threat To Public Safety
45 C.F.R. § 164.512(j)

- CE may, consistent with applicable law and standards of ethical conduct, use or disclose PHI, if the covered entity, in good faith, believes the use or disclosure:
  - Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and
  - Disclosure is either to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat or necessary for law enforcement authorities to identify or apprehend a violent criminal or suspected criminal or criminal escapee;  
  - CE did not get the information in the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure, or counseling or therapy or through a request by the individual for that treatment; and
  - The disclosure is limited in scope as required by Privacy Standards.
Government health plan providing public benefits may disclose PHI relating to eligibility/enrollment to another agency administering a government public benefits program:
- Where info-sharing among agencies required or expressly authorized by statute or regulation;
- Programs serve the same or similar populations and the disclosure of PHI necessary to coordinate the covered functions of such programs or to improve administration and management relating to the covered functions of such programs.
Privacy In Workplace

- Maintaining Workplace Health/Safety
- Managing Absenteeism
- Managing Benefits & Costs
- Responding To Requests for Information From Government Agencies & Others
Monitoring Workplace Health/Safety

HERE'S YOUR NEW CUBICLE: THE "CUBORG 2000."

IT'S A SELF-SUFFICIENT WORK SPACE AND LIFE-SUPPORT SYSTEM!

THESE TUBES ATTACH TO VARIOUS PARTS OF YOUR BODY SO YOU NEVER HAVE TO LEAVE.

"VARIOUS PARTS"?

LET'S JUST SAY YOU DON'T WANT TO GET THESE TWO TUBES MIXED UP.

WE'LL MONITOR YOUR VITAL SIGNS FROM A CENTRAL LOCATION.

NO, THE HUMAN RESOURCES DEPARTMENT, IN CASE WE HAVE TO DO SOME EMERGENCY HIRING.

THE COMPANY NURSE?

IS IT UPGRADEABLE?

YEAH, THE CUBORG 3000 IS EXPECTED TO HAVE AIR HOLES.
Managing Absenteeism

“I know it’s your first time in 38 years, but what would happen if everyone was ten minutes late for work?”
Employers Face Many Federal/State Mandates To Protect Information

- Government Employers, Statutory & Constitutional Privacy Rules
- Americans With Disabilities Act
- Tax Code
- Social Security Act & State Laws Restricting Social Security # Use & Disclosure
- Drug Treatment Records
- ERISA
- Other Federal & State Laws
- Collective Bargaining Agreements
- State Law
- Proof of Other Discrimination or Other Bad Acts
Common Law Claims

- Contractual
- Intrusion On Seclusion Of Private Affairs,
- Disclosure of Embarrassing Private Facts
- Appropriation of Name/Likeness
- Place In False Light
- Intentional Infliction of Emotional Distress
- Defamation
Health Plan Privacy & Data Security Mandates Include

- HIPAA
- Medical Risk Contractors and Other Governmental Contractor Patient Confidentiality Regulations
- The Federal Privacy Act of 1974
- Federal HMO Regulations
- ERISA Fiduciary Duty To Protect Patient Confidentiality
- Contractual
- Other
Federal Criminal Code Data Security & Identity Theft Laws Require Data Protection

- 18 U.S. C. § 1028. Identity Theft And Assumption Deterrence Act
- 18 U.S.C. § 1030. Fraud and Related Activity in Connection with Computers
Examples Of Other Federal Laws Requiring/Recommending Business/Government Protect Personal Information Include:

- 18 U.S. C. § 1028 - Identity Theft And Assumption Deterrence Act
- Privacy Mandates For Government Agencies
- Electronic Discovery Rules
- FACTA
- Sarbanes-Oxley
- Graham Leech
- Fair Credit Reporting Act/FACTA
- Securities
Proposed S.1326, “Notification Of Risk To Personal Data Act” (SEN. JEFF SESSIONS)

Would require agencies and persons in possession of computerized data containing sensitive personal information, to disclose security breaches where such breach poses a significant risk of identity theft.
States With Personal Data Breach Notification Laws

Source: The University of Georgia
Athens, GA 30602
STATE COMMON LAW CLAIMS

- Negligence
- Invasion of Privacy
- Intentional Infliction of Emotional Distress
- Breach of Contract
- Deceptive Trade Practices
- Other
Individual Privacy Rights
Special Government Issues

- 4th Amendment Search & Seizure, Due Process & and Other Constitutional Issues
- Statutory & Regulatory Requirements
- Federal Government Subcontractor & Other Program Participation Requirements
- Contractual
- Common Law
- Other
Privacy Risk-Management Program Planning

- Consider Attorney-Client Privilege Before Starting
- Legal & Operational Inventory To Define Minimum Requirements
- Audit Policies, Procedures and Practices
- Assess Compliance Status and Risks
- Design and Document Tailored Risk-management Program
- Document Decisions
- Implement Risk-Management Program
- Oversee Compliance
- Consistently Enforce Standards Through Appropriate Disciplinary Mechanisms
- When Detect Violation, Respond Appropriately Including Appropriate Compliance Plan Adjustments To Minimize Future Risks
- Responsibility To Monitor Compliance To Specific High Level Person, Not To Individuals That Maintain Programs
- Communicate and Conduct Training Tailored To Ensure Effectiveness
- Establish/Communicate Compliance Standards and Procedures Reasonably Capable of Being Followed
- Oversight & Enforcement
- Continuous Quality Improvement
PRIVACY RISK-MANAGEMENT PROGRAM PLANNING
WHAT DO YOU NEED PEOPLE TO DO?

- Operational requirements to control/monitor access and usage
- Laws and regulations requiring/recommending control/monitor access & usage
- Contractual/external relations requiring/recommending control/monitor access & usage
- Documented oversight, enforcement and correction
Who Do You Need To Do It?

- People To Be Granted Access With Documentation For Rationale and Scope
- Permitted Access and Usage
- Required Credentials For Maintaining Access & Usage
- Operational requirements to control/monitor access and usage
- Training Safeguards
- Oversight
- Monitoring & Redress of Attempted & Actual Violations
- Termination of Access
- Documentation
HAVE A DISASTER RECOVERY PLAN

“Remember son, if at first you don’t succeed, make it look like someone else’s fault then sue them.”
The world is a scary place at times...
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