

*Illinois Health Information Exchange Authority  
Data Security & Privacy Committee  
Inaugural Meeting  
February 8, 2012*



# **Legal Task Force Overview and Status Report**

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# Task Force Structure

- Formed October 2010
- Assembles approximately 50 seasoned health care attorneys as volunteer advisors to OHIT (See Appendix A.)
- Co-chairs:
  - Bernadette Broccolo, Partner, McDermott Will & Emery
  - Mark Deaton, General Counsel, IL Hospital Association

# Task Force Workgroups

- **10 Workgroups**
  - General Protected Health Information
  - Behavioral Health
  - Substance Abuse
  - HIV/AIDS; STDs
  - Public Health & Abuse Reporting; Medical Research
  - Genetic Testing
  - Disclosure of Clinical Laboratory Test Results; Prescription Drug Information; Payment Claims
  - Liability Issues Arising from Provisions in PA96-1331, Litigation Testimonial Privileges, Enforcement
  - Patient Consent Management/Forms
  - Interstate Issues

# The Executive Committee

- Membership = Co-Chairs of the 10 Workgroups
- Met 9 times beginning on Oct. 27, 2010, to:
  - Monitor the progress of the Workgroups
  - Explore issues and challenges identified by Workgroups
  - Discuss common themes emerging across Workgroups and explore common legislative solutions.

# Background:

## Relevant Illinois Laws and HIPAA

- IL health information confidentiality laws significantly predate HIPAA
- IL Statutes generally require consent for use and disclosure of “Sensitive Information”
  - Drug abuse/alcohol treatment
  - Mental health/ developmental disability
  - HIV/AIDs/sexually-transmitted disease
  - Genetic testing
  - Child abuse or neglect
  - Sexual assault/abuse
- These various laws are not harmonized

# Background:

## Relevant Illinois Laws and HIPAA

- HIPAA permits use and disclosure without consent/authorization for:
  - “**TPO**” – for **T**reatment, **P**ayment or health care **O**perations
  - To a “Business Associate” under contract to assist with Operations
  - To avert a serious threat to health or safety
    - “break the glass”
  - As required by law
- While IL law and HIPAA contain similar concepts, there are gaps, giving rise to uncertainty, increased costs and delay in ILHIE implementation
  - Wording of permitted uses under IL statutes
  - More extensive consent requirements
  - No HIPAA preemption
    - Stricter state laws preempt HIPAA

# Workgroups' Analytical Process

- Each Workgroup was assigned myriad statutes, regulations and case law applicable to its topic area.
  - Over 130 state and federal statutes and regulations were reviewed. (See Appendix B.)
- Efficient and Thoughtful Comparison Across Groups
  - Common Worksheet was used to analyze the statutes, regulations and case law for their topic.
  - Analyses focused on identifying the barriers Illinois and Federal law present to the operation of an HIE in Illinois.
  - Various Workgroups presented findings and recommendations in the form of White Papers.



***Laurel Fleming and Wendy Rubas***

# IMHDDA Barriers to establishment of ILHIE

- Illinois Mental Health and Developmental Disabilities Act
- (“IMHDDA”)
- Scope is broad and unclear
  - Arguably applies to behavioral health issues in non-mental health treatment scenarios
    - E.g., post-partum depression
  - Segregation of behavioral health information presents challenges
  - Clarification is essential to
    - Facilitate proper administration of the ILHIE
    - Avoid excluding the behavioral health population from the scope and patient care benefits of the ILHIE

# IMHDDA Barriers to establishment of ILHIE

- Current consent exceptions do not encompass disclosures for all contemplated ILHIE purposes:
  - IMHDDA restricts behavioral health providers from identifying existence of patient record to the ILHIE
  - Disclosures allowed without consent for treatment, payment, and health care operations (including quality assessment and peer review) are more limited than under HIPAA
- Patient consent requirements do not fit the ILHIE model or will require additional administrative processes
  - Granular specificity required (no blanket consents)
  - Specific expiration dates required
  - Procedure requirements required (e.g., witnesses)

# IMHDDA Barriers to establishment of ILHIE

- Limits the conduct of research
  - With few exceptions, individual patient consent is required
  - Consent is required for types of research HIPAA permits without an authorization
    - Research using de-identified data and limited data sets
    - Preparatory and retrospective chart reviews
- Outdated for application of an electronic medical record
  - No distinction between “use” and “disclosure”
  - No recognition of technical solutions and safeguards
- Does not accommodate current business models
  - Limited role of a “records custodian” does not allow comprehensive services to be provided by a third-party vendor
- Establishes processes that are redundant with HIPAA’s, resulting in administrative inefficiency
  - Amendment of records
  - Accounting of disclosures

# Illinois Licensure Statutes Affecting Behavioral Health Providers

- Individual licensure statutes often require consent for disclosure of patient information unless an exception is provided
- Exceptions
  - Limited to only a few scenarios
  - Scenarios cover far less than the IMHDDA covers or that the ILHIE would need
- Clarification of the interplay between IL licensure statutes is necessary

# Behavioral Health Workgroup Recommendations

- Clarify scope of IMHDDA so as to facilitate identification of behavioral health information in the IHIE. Consider:
  - Define mental health and developmental disability services as those either provided by defined mental health treatment providers or to defined diagnosed conditions (e.g., DSM-listed conditions)
  - Adopt HIPAA's definition of psychotherapy notes
- Make disclosure through the ILHIE an exception to written patient consent or modify consent requirements to facilitate inclusion of mental health information in the ILHIE
- Make IMHDAA consistent with HIPAA with respect to:
  - Research
  - De-identification and limited data sets
  - Business associates
  - Patient rights (amendment, etc.)
- Centralize confidentiality requirements regarding behavioral health information in the IMHDDA

# Substance Abuse Workgroup



*Renée Popovits*

# Substance Abuse Treatment Providers Should Fully Participate in Illinois HIE

- SAMHSA Strategic Initiative on HIT: Ensuring that the behavioral health system, including States, community providers, and peer and prevention specialists, fully participates with the general health care delivery system in the adoption of health information technology (HIT) and interoperable electronic health records (EHRs).

# Substance Abuse Treatment Providers Should Fully Participate in Illinois HIE

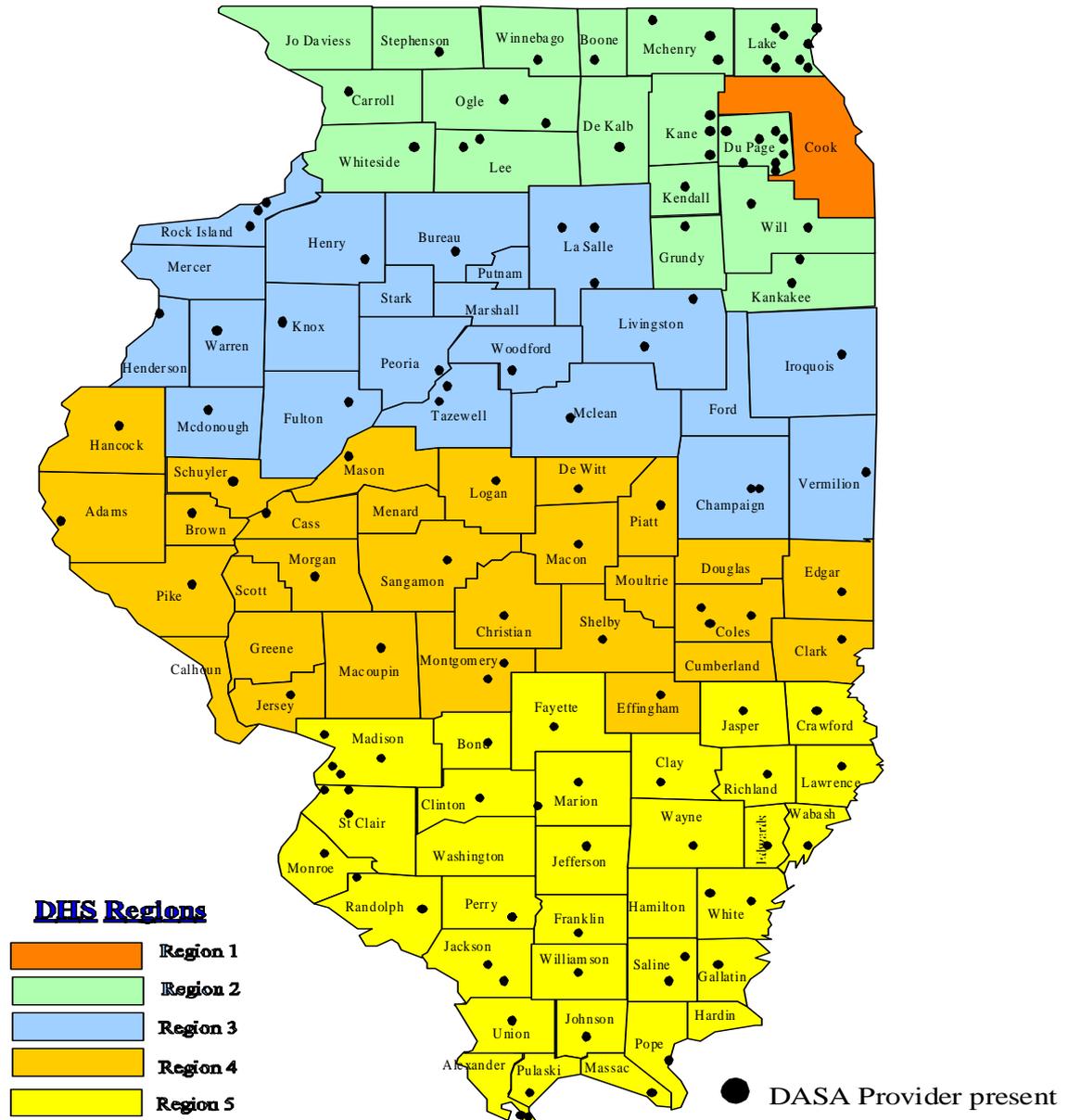
- Knowledge gaps exist among patients and providers in the IL behavioral health community about the use of EHRs and the benefits of HIE.
- Legal barriers and confusion about privacy and exchange of sensitive patient data exist between IL behavioral and physical health providers.
- Our IL Community-Based Addiction Treatment System of Care is critical to our Health Care System.
- We need to eliminate roadblocks!

# Substance Abuse Treatment is Critical to Illinois' Health Care System

- Reduces emergency room utilization
- Provides specialty care for detoxification
- Contributes to better health outcomes
- Enhances economic productivity, reduces public safety costs and increases the effective use of the overall health care system
- Results in financial savings through community based care

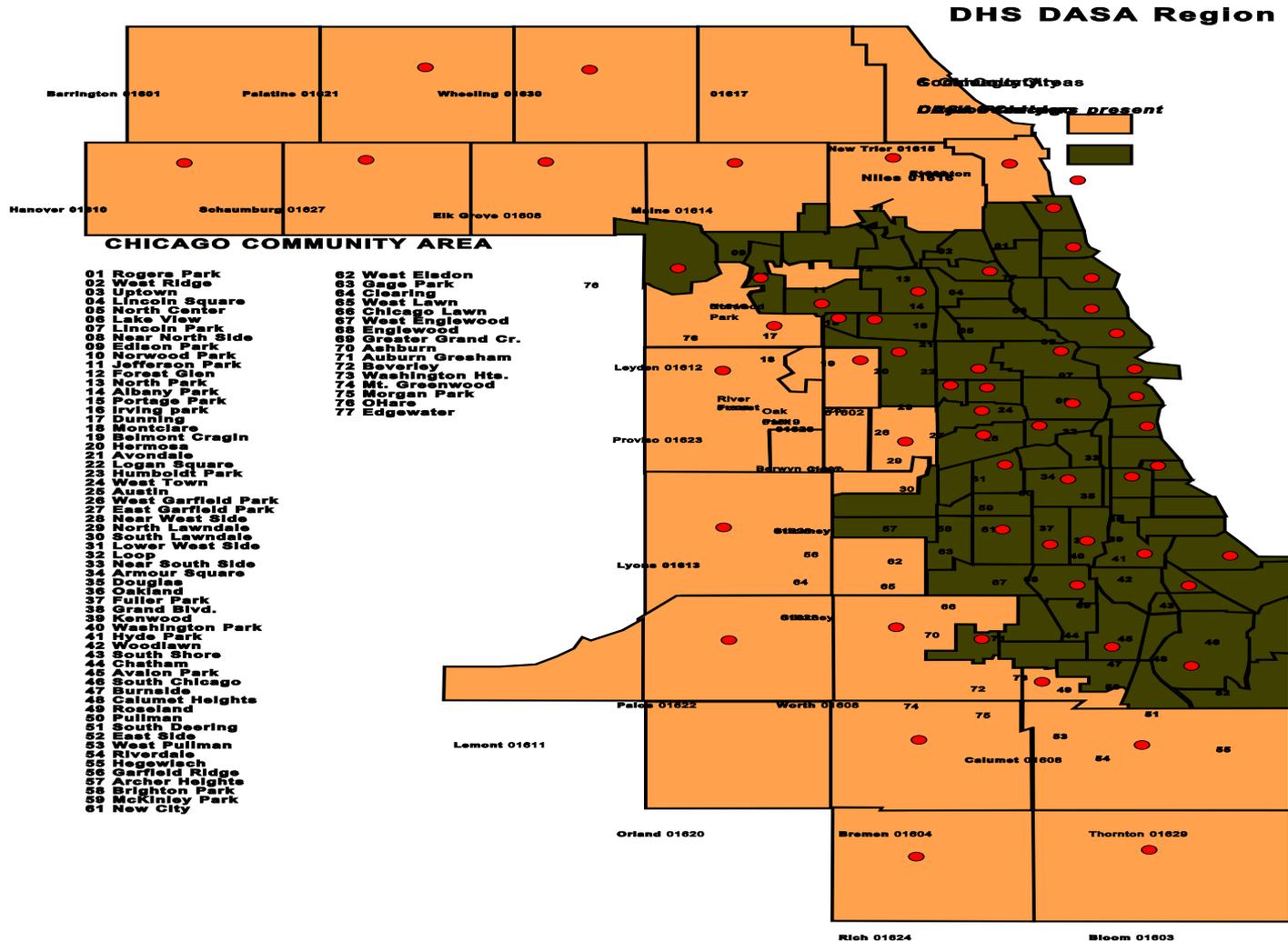
## Illinois Substance Abuse System

- 893 licenses for treatment and DUI
- 494 licenses are held by 147 funded corporations
- 399 licenses are held by 283 unfunded corporations
- Less than 12 DHS Licenses in Hospitals



# DHS DASA Cook County Service Providers

DHS DASA Service Providers Chicago/Cook County by Community Areas



# IL Confidentiality Protections



- Confidentiality specific to substance abuse treatment, diagnosis and referral
- Enacted in early 1970s
- Federal laws: 42 U.S.C. 290dd-2 Federal regs: 42 C.F.R. Part 2
- Illinois statute follows federal laws

# Why Stringent Protections for Addiction Treatment Information?

- Premised on negative stigma historically associated with substance abuse
- Congress assumed individuals would be more motivated to seek treatment if they were assured their treatment remained confidential



# Ways to Share Substance Abuse Information

- Written Authorization by Patient
- Communications within a Program
- Qualified Service Organization (QSO) agreement
- Medical Emergency
- Research purposes
- Court order
- Child abuse exemption
- Crime on program premises
- Audit & evaluation
- Sharing with VA and Armed Forces
- Coroner and vital statistics
- Non-patient identifying

# Substance Abuse Workgroup Recommendations

- Revise IL laws to be consistent with HIPAA where possible and not in conflict with Federal substance abuse confidentiality law (42 CFR Part 2)
- Work within parameters established by SAMHSA and ONC because of Federal law
- Broadly construe medical emergency (“break the glass” exception) under state statute
- Develop a state standardized consent form that meets requirements of Federal substance abuse confidentiality law and other IL laws
- Modify IL MHDDCA consent provisions to create greater flexibility consistent with SAMHSA FAQs

**Recommendation:  
Institute Safeguards to  
Reduce Stigma and Discrimination**

**Preserving Patient Trust is Paramount!**

- Neither federal nor state law expressly include non-discrimination prohibitions or protections
- Additional patient protections addressing penalties for discrimination and improper use and disclosure of sensitive data should be added to the Illinois Alcoholism and Other Drug Dependency Act

## **Recommendation: Strengthen Penalties and Remedies**

- Legal remedies for violations of 42 C.F.R. Part 2 are limited to a \$500 criminal penalty, with additional violations allowing for increases up to \$5,000
- Such amounts do not serve as a deterrent to improper use or resulting discrimination
- Financial penalties and other remedies for improper use or disclosure of sensitive information should be strengthened in our State laws

## **Recommendation: Preserve Stringent Court Orders**

- Addiction treatment information is of potential interest to law enforcement, child welfare, employers and attorneys in civil proceedings.
- Therefore, it is essential that any proposed changes to current law maintain strong confidentiality protections.
- Extensive due process provisions for court orders for substance abuse treatment information should be preserved consistent with 42 CFR Part 2.

# **Recommendation: Limit Use in Criminal and Civil Investigations**

- Retain special due process protections of court orders required under 42 C.F.R. 2.61-2.66 and 20 ILCS 301/305(bb)
- Prohibit use of treatment information in criminal and civil proceedings by the government without a specific court order and include exclusion of evidence as a remedy for illegally obtaining or wrongfully using confidential treatment information

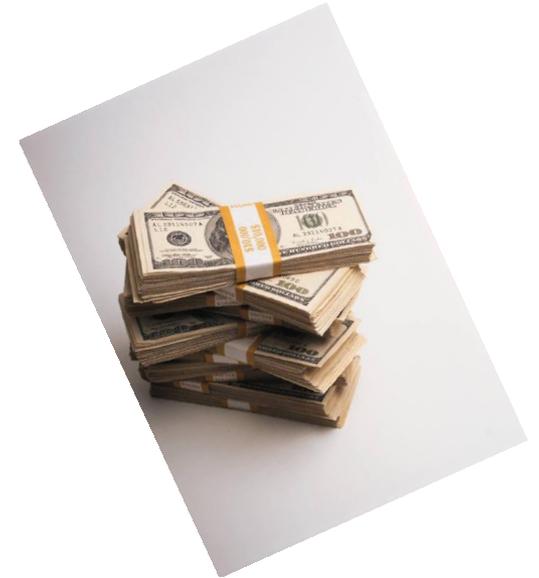
# Recommendation: Fund Behavioral Health EHRs!

- Many small behavioral health providers in Illinois do not have the resources to purchase and implement EHR systems
- Behavioral health facilities are not eligible to participate in the ARRA meaningful use incentive payment program



# Recommendation: Expand HIT Incentives to Behavioral Health

- SB539 (Sen. Whitehouse D-RI) re-introduced a bill to expand federal health information technology payments to mental health professionals, psychiatric hospitals, mental health treatment facilities and substance abuse treatment facilities.
- Illinois should support this legislation.
- Illinois should expand Medicaid incentives to substance abuse providers consistent with our detailed Committee recommendations.



# **Genetic Testing Workgroup**

*Mary Lucie  
Maia Thiagarajan*

# Workgroup Members

- Genetic Counselors
- Health Lawyers
- Law Students
- Physician

# State and Federal Laws Reviewed

- Illinois Genetic Information Privacy Act (GINA)
- Illinois Genetic Counselor Licensing Act (GCLA)
  - Illinois Mental Health And Developmental Disabilities and Confidentiality Act Incorporated by Reference
- Illinois Newborn Metabolic Screening Act
- Federal Genetic Information Nondiscrimination Act of 2008 (GINA)
- Proposed Rule To Implement GINA Within HIPAA Privacy Rule

# Impact of Existing Laws

- Restricted disclosure based on sensitivity of information
  - GIPA intended to encourage individuals to obtain genetic tests
  - GCLA regulates genetic counselors in the use and disclosure of genetic information; referral from MD/PA/NP required
- Genetic test results can be provided to test subject, those specifically authorized by test subject, or as permitted by statute
  - Limited discovery and admissibility of test results
- Restricted use by recipients
  - Need to prevent discrimination
    - Prevent employers from discrimination against employees or applicants
    - Prohibit insurers from restricting enrollment and premium adjustments
  - Limited use by law enforcement and in paternity cases
  - No re-disclosure unless permitted by statute

# Observations

- Current laws would restrict exchange of information through HIE without consent
- Revisions should balance need to protect public vs. need to promote exchange of information through HIE
- Amendments should align language with HIPAA principles

# Recommendations

- Genetic Information Privacy Act
  - Modify to facilitate ability of healthcare providers to share information for treatment purposes
  - Add exception for medical emergency of test subject
  - Modify to allow for the use for payment purposes as long as use for underwriting is prohibited
  - Modify to expand the use for healthcare operations
  - Add exception to address public health activities

# Recommendations (Cont'd)

- Genetic Counselor Licensing Act/Mental Health and Developmental Disabilities Confidentiality Act
  - Modify to enhance disclosure for treatment purposes; incorporate a specific exception for HIE
  - Add exception for medical emergency of test subject
  - Modify to allow for the use for payment purposes as long as use for underwriting is prohibited
  - Expand use for health care operations and peer review purposes
  - Modify to allow disclosure for public surveillance and disease monitoring

# Recommendations (Cont'd)

- Challenges – lack of consistency
  - Definitions vary between state and federal statutes
    - “genetic information”
    - “genetic testing”
    - “genetic services”
    - “family member”
  - De-identification standards
    - Not addressed under current state law
    - Applicable to genetic information?
    - variations between providers
  - Research protocols
    - Independent Review Board (for HIE)

# Conclusion

- Sensitive information
- Current state and federal laws could inhibit the flow of information through HIE
- Opportunities exist for revisions to allow transfer of information through HIE

# October 28, 2011 Executive Committee Meeting

- Reviewed final findings and recommendations of the Workgroups
- Developed “mainstream approach” to achieve an appropriate balance between removing the barriers to the implementation of an HIE and preserving the privacy rights of individuals.
- Concluded that threshold legal question is what kind of patient consent should be required to send health information through the HIE:
  - No consent?
  - Opt-in consent?
  - Opt-out consent?
- Developed a “Grid” for encapsulating the changes needed in each current law to implement each of the three consent models.

# Preliminary Conclusions

1. Harmonize IL law to Federal HIPAA
2. Revise IMHDDA
3. Take steps to facilitate public trust

# Harmonize IL law to HIPAA

- Expressly adopt HIPAA definitions for “TPO”
- Expressly adopt emergency treatment exception (“break-the-glass”)
- Substitute PHI as defined by the HIPAA Privacy Standards for “nature or details of services provided to patients”
- Permit disclosure to Business Associates as defined in HIPAA
- Permit disclosures authorized or required by law as defined in HIPAA

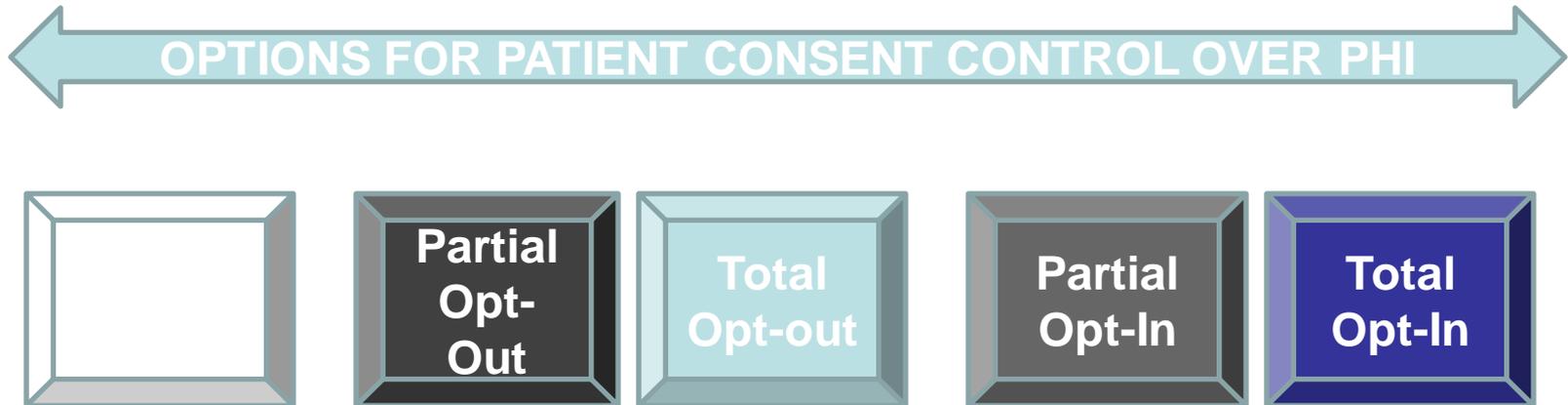
# Other Recommendations

- Consider features of HIE-specific statutes adopted by other states, including:
  - Requiring notice to patients of participation in HIE
  - Delineating patient rights in connection with HIE
  - Definitions such as health information exchange and record locator service

# Steps to Facilitate Public Trust

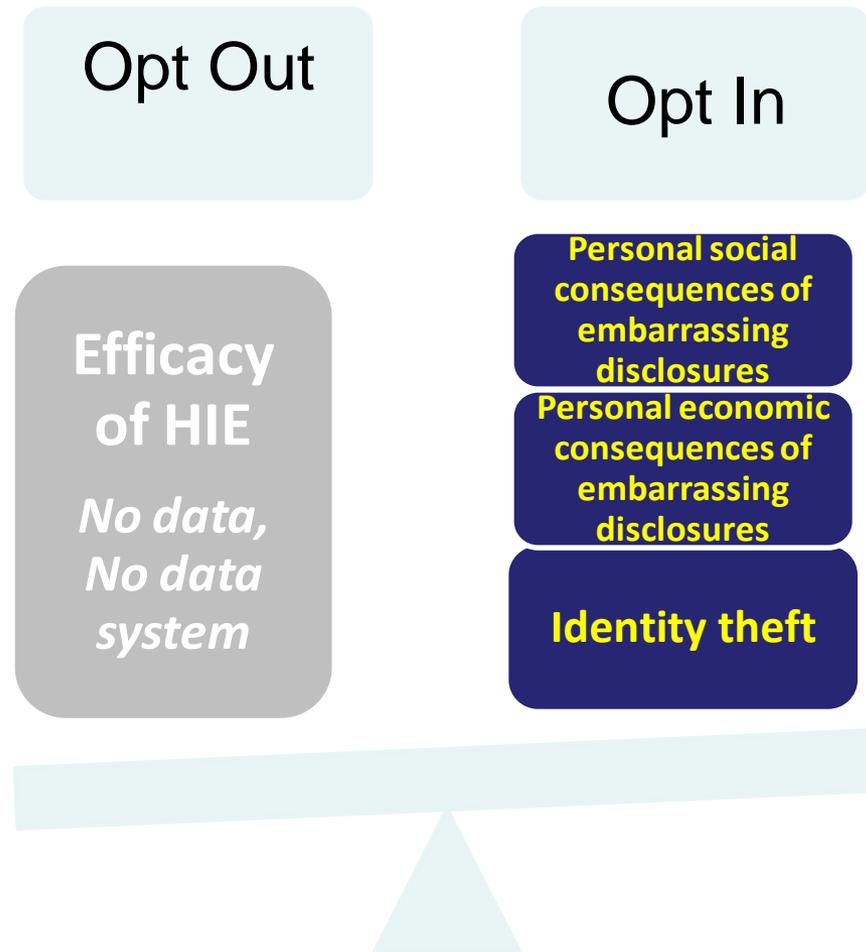
- Authority adopts pro-active approach to protecting patient PHI
  - Appointment of Chief Privacy Officer
  - Establishment of breach notification monitoring
  - Active field auditing of compliance
  - IRB role
  - Coordination of enforcement among IL agencies
- Increased IL penalties for violations
- HIPAA security requirements

# Patient Consent Mgmt Options



- Should each person have absolute control over his/her Personal Health Information (PHI)?
- Does society have a legitimate interest in having certain PHI disclosed? (against patient's wishes)

# Balancing of Privacy Concerns: “Opt-Out”



# Achieving Dual HIE “Trust”

- Clinicians

- Must be confident that the patient record delivered by the HIE is complete and reliable – no “digital Swiss cheese”



- Patients and Associate Interest Groups

- Must be confident that the PHI of patients is adequately protected from unauthorized disclosure or use



# AMA Code of Ethics

- “The physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by law. The obligation to safeguard patient confidences is subject to certain exceptions which are ethically and legally justified because of overriding social considerations.”





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