

Track C, Day 1

Legal and Regulatory Issues



Scattered State Law: A Three-Year Plan for Consolidating Statutes

Privacy and Security Project
National Meeting
March 5-6, 2007

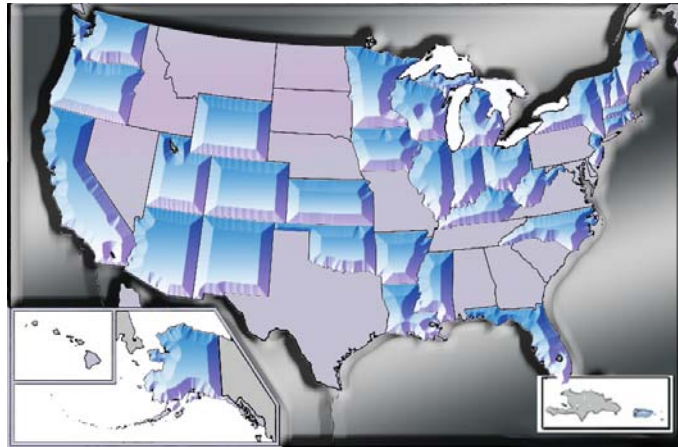


Project Overview

Florida is one of 34 states and U.S. Territories awarded a contract by RTI, Inc. to conduct a study of the variations in business practices and laws related to electronic health information exchange (E-Health Exchange).



Other States . . .



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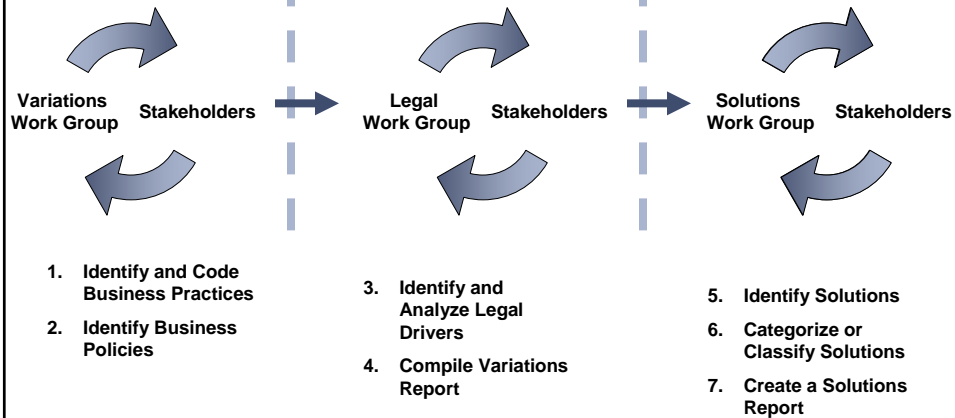
Privacy and Security Project Objectives

- To identify business practices and policies related to electronic health information exchange (HIE).
- To analyze the policies and laws that are “barriers” to HIE.
- To identify solutions to the “barriers.”
- To develop a plan for implementing the solutions.

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Assessment of Business Practices—Process



1. Identify and Code Business Practices
2. Identify Business Policies

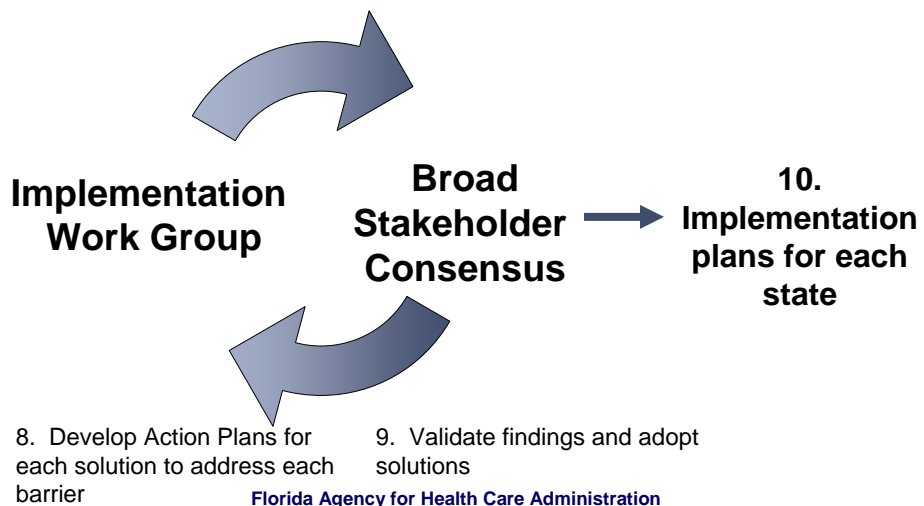
3. Identify and Analyze Legal Drivers
4. Compile Variations Report

5. Identify Solutions
6. Categorize or Classify Solutions
7. Create a Solutions Report

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Implementation of Solutions



8. Develop Action Plans for each solution to address each barrier

9. Validate findings and adopt solutions

10. Implementation plans for each state

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Stakeholder Representation

- FHIN Grantees/ RHIO Representatives
- State Agencies & Medicaid
- Provider Associations
- Payers
- Academia including a Student
- Medical Board
- Health Law Attorneys
- Legislative Staff
- Florida Alcohol and Drug Abuse Association
- AARP
- Vanderbilt Center for Better Health
- Florida Health Information Management Association

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Special Guest to the Project

- The Florida Privacy and Security Project also invited the participation of the National Conference of Commissioners on Uniform State Laws (NCCUSL) to monitor the discussion and serve as a resource for the national implementation of privacy and security solutions including the development of a model state law for electronic health.
- *The National Conference of Commissioners on Uniform State Laws (NCCUSL)*
<http://www.nccusl.com/Update>

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Steering Committee Input

- The Project's Steering Committee is the Governor's Health Information Infrastructure Advisory Board which was responsible for:
 - Serving as chairs for each of the working groups
 - Approving all deliverables while ensuring the plans meet Florida's overarching HIT goals



Major "Barriers" to HIE

- Inconsistent or contradictory laws at state and federal level.
- Misunderstanding or misinterpretation of policies and laws – "HIPAA Folklore"
- Mistrust of other health care entity and liability concerns -- "Battle of Forms"
- Limited use of technology or electronic health information.



Legal Analysis

- In 2002, the Florida Hospital Association identified over 200 separate citations related to health information exchange. [\[1\]](#)

[\[1\]](#) See, *Florida HIPAA Preemption Analysis - A Comprehensive Review of Florida Statutes and Regulations*, Florida Hospital Association, December 2002.



Legal Analysis

- In the review of the scenarios conducted by the Privacy and Security Project over forty-five (45) different sections of Florida law were identified as potentially applicable. [\[2\]](#)

[\[2\]](#) See, *Florida's Interim Assessment of Variations Report*, Agency for Health Care Administration, November 2006.



Legal Analysis -- Example

- Two Florida statutes apply to the majority of disclosures of protected health information for treatment and payment purposes.
- §395.3025(4), F.S., provides the applicable requirements for treatment and payment disclosures by hospitals; and,
- §456.057(7)(a), F.S., provides the applicable requirements for treatment and payment disclosures by health care practitioners.



Legal Analysis -- Example

- §456.057(7) (a), F.S., is broader than §395.3025(4), F.S., in the sense that patient consent is not required for the exchange of health formation for treatment purposes.
- Although §395.3025(4), F.S., also allows the disclosure of patient information for treatment purposes such disclosure is limited to “licensed facility personnel” and “attending physicians.”



Burden Placed on Providers

- Health care providers must understand multiple laws governing health information exchange.
- Health care providers must determine which laws are applicable in the often ambiguous context of events.
- Health care providers must rely on the other provider making the request for facts, context, that determines applicable law.



Model State Law

- Health care surrogate
- Ownership of data
- Security issues & standards for electronic transmission of data
- Informed consent
- Securing sensitive information (HIV, SA, MH) within an electronic medical record



Proposed Solutions

- Consolidate statutes related to the exchange of health information among physicians, hospitals and other health care entities including,
 - the storage, transmission, security, and confidentiality of medical records and specifically,
 - electronic health information exchange.



Proposed Solutions

- Adopt uniform standards for consent and person consenting on behalf of patient;
- Address emergency care when no one is available to consent;
- Conform language to widen and simplify determination of applicability; and
- Analyze and adopt effective standards.



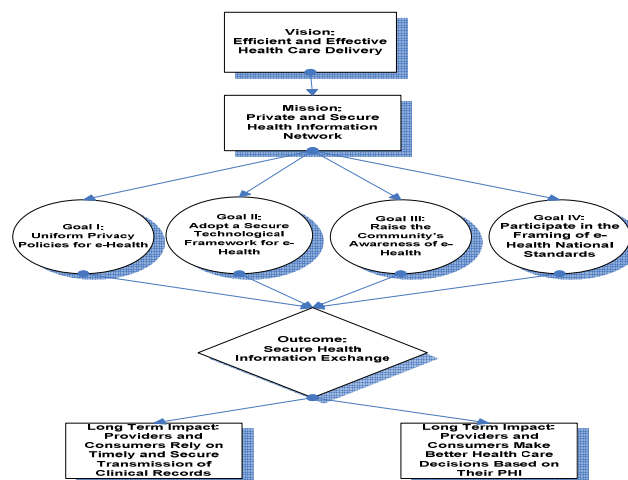
Proposed Solutions

- Facilitate electronic patient consent;
- Address electronic signatures;
- Create penalties for medical identity theft; and,
- Adopt recommendations of Florida Health Information Network.

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Proposed Implementation Strategy



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Next Steps

- Create Florida Health Information Network as a Statutory Entity
 - Uniform policies, procedures, forms
- Create Privacy and Confidentiality of Medical Records Chapter in Statutes



For More Information

Lisa Rawlins, Bureau Chief
Carolyn Turner, Government Analyst
Florida Center for Health Information
and Policy Analysis
Agency for Health Care Administration

http://ahca.myflorida.com/dhit/Privacy_ss.shtml

Establishing a Health Information Committee under the Louisiana State Law Institute

Louisiana Health Information Security and Privacy Collaboration

Major Themes

- Large resource and capability gaps exist between payers, hospitals, and smaller providers;
- Differences in identity verification, authorization, access control and auditing processes may produce security and privacy gaps;
- Lack of regulatory guidance and case law results in widely different interpretations of simple HIPAA driven procedures;
- Consumers are largely unaware of the issues surrounding health information privacy and security;
- "Sensitive" PHI is hard to define, and is procedurally and sometimes technically difficult to carve out;
- The type, size, volume, regularity, and clinical importance of information exchanges vary by stakeholder type.

Implementation Plans 1 & 2

- Establish a collaborative Louisiana Health Information Technology and Exchange forum to promote HIT/HIE use and the adoption of a common HIT/HIE framework and principles.
- Immediately convene current Louisiana HIE/HIT projects to adopt a common security and privacy framework.

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Implementation Plans 3-5

- Promote the adoption of Electronic Medical Records and best in class privacy and security practices in small and rural providers.
- Revise Louisiana state statutes regarding the authorization of release of health information.
- Establish a Health Information Committee under the Louisiana State Law Institute.

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Context for the Solution

- Laws relevant to health information exchange and security and privacy are scattered throughout Louisiana civil and criminal code, are often unclear or purposefully vague, may conflict, may not represent the technical advances of recent years, or may simply not exist.
- The LSIS is chartered by the state Legislature to:

"promote and encourage the clarification and simplification of the law of Louisiana and its better adaptation to present social needs; to secure the better administration of justice and to carry on scholarly legal research and scientific legal work."

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Proposed Solution

- Establish a committee of the LSLI to begin a review, rationalization, consolidation and update of Louisiana laws governing health information. This committee would be responsible for recommending changes in the law to the Louisiana State Legislature with the intent of reducing barriers to HIE while promoting health information privacy and security.

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Implementation Steps

- ✓ Contact LSLI to verify process for forming a new committee and gain their support;
 - Outline list of issues to be considered as a starting point;
 - Draft resolution language;
 - Obtain sponsor for the final resolution;
 - Submit.

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Starting Point Issues

- Current law:
 - Consolidation of all health information privacy and security related laws
 - Reconciliation of all current health information privacy and security laws
- Interpretation of laws in a paper vs. electronic environment
- Ownership of PHI
- Distribution of liability among covered entities
- Consent

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Questions & Contacts

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- Louisiana State Law Institute
 - www.lslri.org

OUTDATED/FRAGMENTED LAWS

- Health laws enacted in piecemeal fashion
- Enacted without consideration of benefits of EHR or HIE

OUTDATED/FRAGMENTED LAWS

- New Mexico– More than 30 separate Acts that potentially deal with EHR and HIE
- Enacted various times, dating to early 70's
- Some Disease-Specific

OUTDATED/FRAGMENTED LAWS

- Some Acts -- no reference to electronic records
- Some Acts-- prohibit retention of records

OUTDATED/FRAGMENTED LAWS

- All state laws, to the extent more restrictive than HIPAA must be complied with
- Compliance difficult to impossible -- creating barrier to EHR and HIE

OUTDATED/FRAGMENTED LAWS

- Revision of all existing Acts not feasible
- Solution – Enactment of a single Act governing EHR and HIE

OUTDATED/FRAGMENTED LAWS

- Affirmatively allows EHR & HIE
- Supersedes other Acts
- Provides clarity and one-stop shopping for rules

OUTDATED/FRAGMENTED LAWS

- Wish us Luck!

**Developing a single
set of rules to govern
PHI exchange –
Arkansas’
recommendation**

Kevin W. Ryan JD, MA



HISPC National Meeting

March 5 - 6, 2007

**Development and
implementation of a single
set of rules to govern PHI
exchange:**

Why is this needed?



Why a single set of rules?

- **Consistency – different technologies currently in use do not ‘talk’ to each other, thus limited sharing of information across systems**
 - In development
 - In application
- **Security / privacy considerations**
 - In transmission of PHI
 - Different internal policies due to litigation fears



Development and implementation of a single set of rules to govern PHI exchange:

What is needed to accomplish this?



What is needed?

- **Identification of all applicable Arkansas state laws / regulations on point**
- **Development of a single set of laws / regulations governing PHI exchange**
 - **Focus: Electronic transmission parameters and encryption guidelines**
 - **Clarify what is required and expected**
 - Medical community
 - Patients
 - Vendors

Development and implementation of a single set of rules to govern PHI exchange:

Who should develop and administer?

Development and administration considerations

- **Federal v. state based**
 - **Federal potential**
 - Office of Information Technology
 - **State potential**
 - **Executive branch**
 - Division of Information Systems
 - Governor's Office
 - » Engagement / partnering with proposed EHR taskforce
 - **Arkansas General Assembly**



Development and implementation of a single set of rules to govern PHI exchange:

Who should be included?



Who should be at the table?

- **Stakeholders for all areas MUST be included!**
 - Hospitals
 - Insurers
 - Pharmacies
 - Physicians
 - Consumers
 - Community Health Centers
 - Quality Improvement Organizations
 - Vendors



Development and
implementation of a single
set of rules to govern PHI
exchange:

Essential areas to address



Essential areas to address

- **Technology**
 - Electronic signature
 - Encryption and authentication Issues
 - Potential for shared software development (restricted “open source”)
 - Infrastructure
 - Lines
 - Band width
 - Equipment
- **HIPPA**
 - Training and support



Development and
implementation of a single
set of rules to govern PHI
exchange:

Arkansas specific challenges



Arkansas' specific challenges

- Rural state
- Geographic diversity
- Limited funds
- Limited connectivity / infrastructure



Development and
implementation of a single
set of rules to govern PHI
exchange:

Thoughts and questions?



Thank you.

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OVERCOMING BARRIERS TO LAB RESULT EXCHANGE

NC: Clinical Laboratory Improvement Amendments (CLIA) Issue and Proposed Solutions

Donald E. Horton, Jr.

Associate Vice President, Public Policy & Advocacy

LabCorp

March 5, 2007

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What's the Problem?

- Clinical laboratories face significant legal obstacles in delivering test results to persons other than the "authorized person" who ordered the test
- These obstacles exist even when test results are sought for legitimate purposes:
 - Quality Improvement
 - Patient Safety
 - Case Management
 - Disease Management
 - Elimination of Duplicative Testing
 - Reducing Health Care Costs
- To achieve these goals, labs must be able to deliver real-time and historical test results to entities who are not currently "authorized persons"

2

The Issue, Part 1: CLIA

- Clinical laboratories are comprehensively regulated under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA)
- 42 CFR § 493.1291(f): "Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test."
- 42 CFR § 493.2: "Authorized person means an individual authorized under State law to order tests or receive test results, or both."
- "Individual responsible for using the test results" is undefined.

3

The Issue, Part 2: State Law

- Many State laws narrowly define those who are authorized to order tests or receive test results
 - Arizona: The result of a test must be reported to the person who authorized it, and only podiatrists, chiropractors, dentists, physicians, or a person licensed to practice medicine in another state are authorized (A.R.S. § 370-40 (A) and (B))
 - Georgia: Test results must be reported only to, or as directed by, a licensed physician, dentist or other authorized person requesting the test (GA Rules & Regulations § 290-9-8-.25)
 - North Carolina: Law is silent on issue of who is authorized to receive test results; by default, CLIA limits result recipients to those authorized to order tests under NC law

4

The Result of Current Law

- Many persons or entities that need test results for legitimate reasons are not “authorized persons” for the purpose of receiving test results directly from labs:
 - Non-ordering physician specialists to whom a patient is referred by an ordering primary care physician
 - Regional Health Information Organizations (RHIOs)
 - Quality Improvement Organizations (QIOs)
 - Disease Management Companies
 - Health Plans
 - CMS
- Current workarounds are very inefficient and often ineffective
 - Labs need authorization from the ordering physician to send results to a third party - try that for millions of results and thousands of physicians
 - Contractual authorizations may not exist, difficult to obtain and interpret

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Potential Solutions

- Amend laws in 50 States and a number of territories and districts to expand the list of permissible recipients of lab test results
 - Huge undertaking
 - Long time horizon for completion
 - Significant variation likely
- Amend CLIA regulations to expand the list of permissible recipients of lab test results
 - Effort focused with HHS / CMS
 - Reasonable time horizon for completion
 - Promotes national uniformity

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Proposed Solutions

- CLIA Amendment Alternative 1: Revision of 42 CFR § 493.1291(f)
 - Current Law: Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.
 - **Proposed Revision**: *Test results must be released to the authorized person who ordered the test. In addition, notwithstanding any contrary State law defining who is an individual authorized to order tests or receive test results or both, test results may be released to:*
 - *The laboratory that initially requested the test, if applicable;*
 - *Any person designated to receive the test results by the authorized person who ordered the test;*
 - *A “covered entity” as defined in 45 CFR § 160.103; and*
 - *A “business associate” of a covered entity as defined in 45 CFR § 160.103. This section shall not be construed to permit the disclosure of any specific type of test result to any of the persons or entities named herein where the disclosure of test results of that type is otherwise prohibited by State or Federal law.*

Proposed Solutions

- CLIA Amendment Alternative 2: Addition to 42 CFR § 493.2
 - Current Definition of “Authorized Person”: Authorized person means an individual authorized under State law to order tests or receive test results, or both.
 - **Proposed Definition of “Authorized Person”**: *Authorized person means an individual authorized under State law to order tests or receive test results, or both. In addition, notwithstanding any contrary State law defining who is an individual authorized to order tests or receive test results or both, authorized person means:*
 - *Any person designated to receive the test results by the authorized person who ordered the test;*
 - *A “covered entity” as defined in 45 CFR § 160.103; and*
 - *A “business associate” of a covered entity, as defined in 45 CFR § 160.103. This definition shall not be construed to permit the disclosure of any specific type of test result to any of the persons or entities named herein where the disclosure of test results of that type is otherwise prohibited by State or Federal law.*

Proposed Solutions

- CLIA Amendment Alternative 3: Addition to 42 CFR § 493.2
 - Current definition of "Individual responsible for using the test results": None.
 - **Proposed definition of "Individual responsible for using the test results"**: *Individual responsible for using the test results means, notwithstanding any contrary State law defining who is an individual authorized to order tests or receive test results or both:*
 - Any person designated to receive the test results by the authorized person who ordered the test;
 - A "covered entity" as defined in 45 CFR § 160.103; and
 - A "business associate" of a covered entity, as defined in 45 CFR § 160.103. This definition shall not be construed to permit the disclosure of any specific type of test result to any of the persons or entities named herein where the disclosure of test results of that type is otherwise prohibited by State or Federal law.

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Intent, Rationale and Implications

- Intent of Proposed CLIA Amendments: Solely to expand the list of permissible recipients of lab test results - NOT to expand the purposes for which test results may be disclosed. Aimed at scenarios where the disclosure would be permitted by HIPAA but prohibited by State law merely because the recipient is not defined as an "authorized person".
- Rationale of Proposed CLIA Amendments:
 - To responsibly expand the list of permissible recipients of test results by ensuring that those who receive the results are either closely associated with the patient's care or are governed by HIPAA safeguards
 - To assure everyone that particularly sensitive types of test results (e.g., HIV) that are currently confidential will remain confidential despite these amendments (*i.e.*, the State law pre-emption does not apply to confidentiality laws relating to particular types of sensitive test results)

Intent, Rationale and Implications

- Rationale of Proposed CLIA Amendments, continued:
 - Alternative 1: Enhances 42 CFR 493.1291(f) by distinguishing between mandatory and permissive test result disclosures and eliminating any reference to the undefined term “individual responsible for using the test results”
 - Alternative 2: Clarifies the meaning of both “Authorized Person” and 42 CFR 493.1291(f) in which it appears
 - Alternative 3: Clarifies the meaning of both “individual responsible for using the test results” and 42 CFR 493.1291(f) in which it appears

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Intent, Rationale and Implications

- Implications of Proposed CLIA Amendments:
 - Labs will no longer have to obtain ordering physician authorization to send results to non-ordering covered entities and business associates, assuming the disclosure is otherwise permissible under HIPAA
 - Would continue to permit States to define those to whom test results must be disclosed, but would prohibit States from disallowing (by omission or otherwise) result delivery to the persons or entities named in the revised CLIA regs
 - Would responsibly facilitate and expedite lab result exchange to accomplish consensus public policy objectives

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Framing the Issue: WV State Medicaid Plan Amendment

Potential Impacts upon Privacy

Animating Principle

Any perceived “leakage” of confidential data will negatively impact public perception and acceptance of HIT.

Background and Context

- WV one of first states to use Deficit Reduction Act of 2005 (DRA) flexibility.
- Used “Secretary-approved” option to make significant changes to specific eligibility groups.
 - Infants with incomes below 150% of poverty
 - Children 1 to 6, incomes below 133%
 - Children 6 to 19, incomes below 100%
 - Working parents, incomes below 37%
 - Non-working parents, incomes below 19%

Basic vs. Enhanced Services

- Differential between “Basic” and “Enhanced” is substantial; some examples below:
 - Behavioral health/substance abuse services
 - Basic vs. intensive/rehab
 - Skilled nursing care
 - Orthotics/Prosthetics
 - Diabetes Education
 - Cardiac Rehab
- Parents must sign and comply with “Member Agreement” to receive and maintain Enhanced benefits.

Member Agreement: Core Elements

- Broad Range of new Business Practices
- Contract with “Medical Home”
 - Attend health improvement programs.
 - Go to Medical Home when sick, for check ups.
 - Take prescribed medications.
 - Show up on time for appointments; call if not.
 - Use ER only for emergencies.
- Number of “Rights” also included.

Medical Information: Privacy Issues

- Compliance review claims-based.
- Medical records remain with provider.
- Medicaid is encouraging use of EMRs.
- Appeals, audits of program, of necessity, may involve review of medical records and member agreements.