

# Wisconsin Security and Privacy Project

## *Interim Solutions Report*

Subcontract No.  
RTI Project No. 9825

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January 10, 2007

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# Section 1 - Background

## 1.1 Purpose and scope

The Wisconsin Solutions Workgroup was convened to propose solutions to security and privacy issues that present challenges to the implementation of health information exchange. This report documents the solutions and barriers that were previously identified and analyzed by the Variations and Legal workgroups. The barriers presented to the Solutions Workgroup became apparent as the result of analysis of organization-level business policies and practices and the underlying laws and regulations.

Nearly all the barriers identified during the assessment process were presented to the Solutions Workgroup for consideration and representatives from all of the stakeholder groups participated in the meetings. In order to bring representatives from all stakeholder groups, and keep the membership at a manageable level for the Solutions Workgroup meetings, several participants served more than one role. A limitation to this approach was that the Workgroup was dominated by hospital staff, legal experts, and professional associations.

## 1.2 HIT development in Wisconsin

By Executive Order in November 2005, Governor Doyle created the eHealth Care Quality and Patient Safety Board. The goal of the Board is to have 100% adoption of electronic health records systems by health care providers and the appropriate exchange health information from these systems within five years.

The eHealth Board submitted the Wisconsin *eHealth Action Plan* to the Governor in December 2006. This plan addresses the following challenges:

- Ensuring health information is available at the point of care for all patients.
- Reducing medical errors and avoiding duplicative medical procedures.
- Improving coordination of care between hospitals, physicians and other health professionals.
- Furthering health care research.
- Providing consumers with their health information to encourage greater participation in their health care decisions.

In the process of creating the *eHealth Action Plan*, the eHealth Board conducted research in the areas of current technology and health information technology (HIT) adoption in Wisconsin. The following information regarding HIT development was taken from *eHealth Action Plan*.

There is much work underway in Wisconsin being led by health care provider organizations, physicians, public health, technologists, scholars, and public and private health care purchasers. Many large health systems are already moving ahead with electronic health records and other investments. The Wisconsin Collaborative for Healthcare Quality, the Wisconsin Health Information Organization, the Wisconsin Medical Society and the Wisconsin Hospital Association, major insurers and provider organizations are collaborating on these efforts.

In 2005, MetaStar surveyed Wisconsin primary care practices and supplemented the results with field staff knowledge and identified that 38% of primary care practice sites boasted an EMR<sup>1</sup>. In addition, two studies recently examined hospital HIT adoption in Wisconsin. The state has several well-established, integrated health care delivery networks with extensive HIE infrastructure in place. In 2005 MetaStar and the Wisconsin Hospital Association examined adoption of two technologies: Computerized Physician Order Entry (CPOE) and Telemedicine<sup>1</sup>. The results of this survey identified that of those responding 82% are planning or considering CPOE, and 33% are planning Telemedicine; 12% have partially implemented CPOE while 39% have partially implemented Telemedicine with 7% fully implemented Telemedicine.

A 2006 survey of HIT adoption in 30 rural or very small hospitals (22% of all Wisconsin Hospitals) conducted by the Rural Wisconsin Health Cooperative (RWHC) discovered that:

- Every hospital has a core Master Patient Index database
- 80% of respondents had installed electronic pharmacy, lab, or order entry systems
- Few hospitals have interface engines, which inhibit information flow inside the hospital and may hinder participation in HIEs.

Wisconsin now has an opportunity to deploy technology to transform health care to achieve a better, safer, and more efficient health system and thereby improve the overall health of the state's population. Technology provides a platform to manage and access information to transform the health care sector. The Wisconsin *eHealth Action Plan* presented to Governor Doyle on December 1, 2006, lays out a five-year roadmap to achieve this vision. The policy work that is underway with the support of this project sets out the steps to address privacy and security issues that are a barrier to health information exchange.

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<sup>1</sup> MetaStar, Inc. Environmental Scan, December 1, 2005 and Simmons G. The prevalence of EHI Technology in Wisconsin, eHealth Board, March 26, 2006.

## **Section 2 – Summary of Interim Assessment of Variations Report**

### **2.1 Results of the interim assessment**

The Variations and Legal Workgroups found several barriers to health information exchange (HIE) that are driven by the following:

- Wisconsin state law
- Both Wisconsin state and federal law
- Federal law
- Policy and practice

#### **2.1.1 BARRIERS DRIVEN BY WISCONSIN STATE LAW**

Wisconsin statutory requirements that are more restrictive than federal requirements cause barriers to the exchange of information.

Some of the greatest barriers to HIE are the regulations associated with the treatment of sensitive information, defined as information pertaining to mental health, alcohol and drug abuse and developmentally disabled. The requirements include:

- Consent for all disclosures (payment and treatment)
- Verification of the requestor for this information
- Additional documentation of these disclosures

HIV test results are also treated as sensitive information, except that they can be disclosed from provider to provider for treatment purposes.

Other barriers driven by Wisconsin state law include:

- Documentation of all disclosures made with or without patient consent
- Requirements prohibiting re-disclosure of health information

#### **2.1.2 BARRIERS DRIVEN BY STATE AND FEDERAL LAW**

Consent requirements, governed by state and federal law, present the greatest hurdles to health information exchange. The barriers are caused by:

- The process to obtain a consent, including determination of who is able to sign
- Validation of the statutorily required elements of the consent
- Analysis required of state and federal law to determine which law controls
- Variation between states in requirements

#### **2.1.3 BARRIERS DRIVEN BY FEDERAL LAW**

In some cases, federal law is more stringent than state law. In all of these cases, both the law and the varying interpretations of the law cause barriers to exchange. The federal requirements identified by the workgroups that pose barriers to exchange include:

- Verification of requester

- Minimum necessary
- Business associate agreements
- Federal Privacy Rule

## **2.1.4 BARRIERS DRIVEN BY POLICIES AND PRACTICES**

The Variations and Legal Workgroups identified several barriers to HIE that are driven by policies and practices. Most often, variation in policy and practice implementation lead to barriers to HIE.

Barriers driven by policies and practices include:

- Consent – varying interpretations of when consent is required for disclosure
- Method of requesting information – varying methods for making requests
- Method of disclosure – varying methods for disclosing information

The final barrier to exchange identified by the workgroups is technology. In generally, current technology used in Wisconsin cannot limit access to relevant parts of the record or to specific records to comply with minimum necessary requirements. Furthermore, currently employed technology often cannot specify the type of access (read-only, edit/modify, delete) granted to the user. For those who do not have electronic medical records, the lack of technology creates a barrier to exchange.

## **2.2 Effective practices**

In discussing the various business practices with stakeholders, it became clear that some organizations have identified unique ways of working within the restrictions imposed by both state and federal law to exchange health information. Many of these practices drastically improve organizational ability to exchange health information, particularly in relation to exchanging for treatment purposes. Generally, these practices would translate to an electronic environment.

Effective practices promote the exchange of health information within an organization and between unrelated organizations. Some effective business practices identified by the stakeholders include:

- Creation and maintenance of a database containing known providers and health agencies users with their contact information for identifying the agency requesting information.
- Creation and use of an algorithm or unique patient identifier.
- Using a set of unique patient identifiers, at least two, both to determine when to release information and when incorporating information into a patient's medical record.
- Employing role-based access for electronic medical records.
- Implementation of written business associate agreement, which allows for the exchange of information. This can also hinder exchange, because it requires the legal document prior to exchange.
- The added flexibility provided to public health for exchanging information as needed in order protect the interests of the public.

## **2.3 Lessons learned**

### **2.3.1 HEALTH INFORMATION TECHNOLOGY AND EXCHANGE**

While Wisconsin is in a unique position to move forward with health information exchange due to the large number of physicians in large group practices, and the number of organizations that are engaged in

health care quality improvement and the creation of the Wisconsin *eHealth Action Plan*, this will be an incremental process. For the most part, the Variations Workgroup members indicated that they were not using electronic systems to record information. Those organizations that were using electronic medical records were generally not exchanging health information through an electronic means or were only exchanging within a networked health care system. In these organizations, additional resources were needed to incorporate all incoming information from outside organizations into the medical record through a manual process. For one of the stakeholders, information can be accessed by their business associates through a web-based query method, but this information cannot be directly incorporated in another organization's electronic system.

Many policies and procedures currently in place could be used in an electronic environment without too much difficulty. Technology provides the means to overcome many security and privacy barriers, but technological innovations cannot overcome all barriers that exist primarily because of restrictive statutory language. Unless changed, these barriers will continue to present challenges as statewide implementation of health information exchange occurs. The advent of health information exchange presents issues related to redisclosure and documentation that have yet to be resolved. Currently, those organizations using electronic systems often maintain separate log systems for documentation.

### **2.3.2 STATE AND FEDERAL LAW**

The lack of standard application and interpretation of state and federal laws is behind all of the barriers identified through the Health Information Security and Privacy Collaboration (HISPC) process. As a result, "workarounds" are prevalent. Sometimes this means that the state or federal law is interpreted in its broadest sense and sometimes in its most restrictive sense. In some cases, the workgroup members would like to retain the flexibility they currently have to ensure that the patient's information is protected. For example, "minimum necessary" is a key issue where variation exists. Health information managers have the flexibility to determine what information is disclosed under this provision, allowing them to modify requests based on the need identified. One challenge this presents to that there is no standard expectation for the set of information that health care providers can expect when "minimum necessary" applies.

In discussing these situations with stakeholders, it was apparent that health information managers take protection of patient information very seriously. They are not interested in compromising that security for the sake of rapid exchange of information. In addition, there are many advocates and consumers who want to retain the added protection afforded by Wisconsin law for sensitive health information, such as mental health records and HIV test results.

As the discussion moves from high-level policy about the exchange of health information to more detailed discussions of actual practice, solutions for making the new electronic environment a reality are not simple. The challenges of transitioning from a paper environment to an electronic environment involve rethinking the workflow, staff skills, resources, habits, and culture of an organization all while functioning within the limitations of the law. Many business organizations' practices are driven by provisions in federal and state law, and in some cases extend beyond what the law technically requires.

## **Section 3 - Review of State Solution Identification and Selection Process**

### **3.1 Overall process to develop solutions**

Following the completion of the *Interim Assessment of Variations Report*, the Wisconsin Security and Privacy Project team determined that the Solutions Workgroup should include existing members of the Variations and Legal workgroups as well as additional new members. These members were chosen to represent all of the stakeholder groups identified by RTI as well as a few other groups the team felt should be represented. The goals of the Workgroup were to analyze the barriers identified by the Legal and Variations Workgroup, to determine which barriers should be eliminated or modified and to develop solutions to the barriers to improve the exchange of health information while maintaining privacy mechanisms that protect consumers.

The Solutions Workgroup began by considering the variations in organizational-level business practices and relevant state and federal laws that affect and/or pose barriers to health information exchange documented in the work of the Legal and Variations workgroups. The challenge to the Workgroup was to seek solutions to perceived or real barriers to HIE that will improve patient care while considering the impact of the solutions to consumer protection and patient privacy.

With 35 diverse members representing a variety of perspectives, the Solutions Workgroup used a multi-faceted approach that allowed participation from all members and the capture of varied viewpoints. Sessions were designed with a series of small break-out groups and large group discussions to develop and refine solutions. Once the initial solutions were developed, the Workgroup evaluated them based on feasibility and impact. This process allowed for critical re-evaluation of the solutions and further development of critical discussions that balanced the need for exchange against the patient's right of privacy. The balance of impact versus feasibility also provided the Workgroup with an opportunity to address the commitment and impact of what may be a difficult and less feasible solution against the local and national impact of a barrier whose elimination or modification would ultimately provide better patient care and possibly save lives. The results are the prioritized solutions detailed in this report.

### **3.2 Solutions Workgroup**

The Solutions Workgroup was comprised of 35 individuals who represent organizations in the various stakeholder groups identified by RTI that would be impacted by the proposed solutions, as well as individuals with legislative policy, technical, policy and procedure and legal expertise. Every stakeholder group identified by RTI was represented in the Workgroup. Roughly half of the members previously participated in the Variations and/or Legal workgroups and were extremely knowledgeable about the identified variations and barriers evolving from those Workgroups.

The charge of the Solutions Workgroup was to:

1. Identify and develop solutions that reduce or eliminate the barriers identified by the Variations and Legal workgroups while preserving necessary protections to patient privacy and security.

2. Evaluate proposed solutions by assessing:
  - a. The impact of the solutions on consumer protection and privacy
  - b. The impact of the solutions on health care organizations' operations and resources
  - c. The feasibility of solutions under current state and federal law
  - d. The relationship of the solutions to national standards
3. Prioritize proposed solutions and determine which solutions should be further developed.

### 3.3 Process used to identify solutions

Before the Solutions Workgroup commenced, staff organized an approach to analyze the barriers identified by the Variations and Legal workgroups that proceeded chronologically, so the barriers were approached as they would develop in the health information process. The barriers were then grouped so that each of three Workgroup meetings would focus on a group of barriers while following the chronological approach. The groupings included:

Meeting 1: Method of Request, Verification of Requester and Verification of Patient

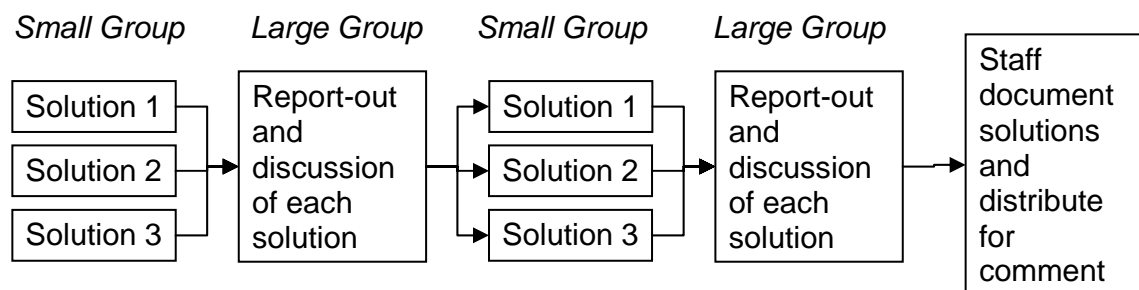
Meeting 2: Patient Consent for Disclosure, Business Associate Agreements and Exchange of Sensitive Information

Meeting 3: Method of Disclosure, Re-Disclosure, Documentation of Disclosure and Minimum Necessary

Meeting 4 was reserved to prioritize and refine the prioritized solutions.

Prior to each meeting, participants were given documents that outlined the barriers associated with each topic as identified in the Variations and Legal workgroups. The first part of each meeting was spent as a large group reviewing and discussing the barriers, including discussion of why barriers exist and why some should remain as controls on inappropriate release of information. In one meeting, Workgroup members performed a skit to demonstrate issues with patient consents. In other meetings, the project privacy consultant gave a presentation on the barriers the group would cover at that meeting. Once the barriers were presented, the Workgroup discussed which barriers to address and which ones should be maintained. Barriers determined to be necessary to provide adequate patient privacy protections were reviewed, re-discussed and modified in a manner that allowed them to be re-entered into the proposed solutions.

Once the Workgroup determined which barriers would be analyzed, the Workgroup used a series of small break-out groups, followed by large group report-outs and discussion to develop solutions to the barriers.



The small break-out groups allowed all individuals on the Workgroup the opportunity to participate in the development of the solutions and also allowed the group to simultaneously work on multiple solutions to maximize the work completed in the short timeframe available. By preparing report-outs to the larger group, small break-out groups were forced to pull thoughts from their discussion into presentable work, receive feedback in the large group discussion and work through the solution again before getting another round of feedback from the large group. In the second round of work, members of the small break-out groups were often mixed to bring additional perspectives and varied stakeholder opinions to refine the solution.

Each solution went through two rounds of development at the Workgroup meetings. Following the Workgroup meetings, staff documented the solutions and distributed them for additional comment.

### **3.4 Determination of feasibility of identified solutions**

In the final Workgroup meeting, the group voted to identify the solutions considered most critical to the reduction of barriers to HIE, while considering the feasibility and impact of the solutions. The Workgroup considered the importance of the removal or modification of the barrier to an improvement in patient care processes in addition to the impact of each solution. Each Workgroup member voted for feasibility and for impact.

The process of voting on feasibility and impact caused the group to change the way they were looking at the solutions. Instead of looking at each solution as the removal of a single barrier, the Workgroup looked for ways the solutions could be grouped to ensure that the group's top priorities were implemented.

Once the critical solutions were identified, the group reviewed those with the highest priority. The group used relevant scenarios designed by RTI to create skits to demonstrate the solutions. Each skit was performed as it would be done today; then again as it would be with the solution implemented. A discussion followed. By really seeing the impact of what was being proposed, in some cases, the group decided to alter or add to the solution.

The final Solutions Workgroup meeting was completed with a strong feeling of success at having identified, analyzed and modified processes that will bring state and national improvement to HIE. Following the final meeting, the solution write-ups were revised for distribution at the first Implementation Workgroup meeting.

### **3.5 Organization of identified solutions for this report**

As described in Section 3.3, in the final meeting of the Solutions Workgroup, the members grouped solutions designed to eliminate or reduce specific barriers into broader solutions that would be implemented together; then prioritized the broad solutions. The four solutions outlined in the next section are the results of that process and are presented in the order in which they were prioritized by the Workgroup. Following the detailed descriptions of each solution are matrices that allow the reader to look across all solutions to see the barriers that were addressed and the domains that are impacted.

## Section 4 – Analysis of State Proposed Solutions

These solutions address each of the barriers identified by the Variations and Legal workgroups in earlier phases of the Security and Privacy project. These barriers include:

- Barriers driven by Wisconsin State Law
  - Sensitive information (per Wisconsin Statute 51.30)
  - Documentation of all disclosures with or without consent
  - Requirements prohibiting re-disclosure
- Barriers driven by state and federal law
  - Consents
- Barriers driven by federal law
  - Verification of requester
  - Minimum necessary
  - Business associate agreements
  - Federal Privacy Rule
- Barriers driven by variations in policy or practice
  - Consent
  - Method of requesting information
  - Method of disclosure

The Solutions Workgroup emphasized that the proposed solutions to each barrier are important components of Wisconsin’s ability to transition smoothly to electronic health information exchange and participate in exchange at the national level. However, the Workgroup recognizes that these solutions are not the only steps necessary for this transition. Wisconsin’s eHealth Care Quality and Patient Safety Board is considering numerous steps outside the scope of this project.

### 4.1 Change Wisconsin Statute 146 to mirror HIPAA for treatment purposes

#### 4.1.1 CONTEXT FOR PROPOSED SOLUTION

The Wisconsin legislature protected “sensitive” health care information in 1977, and general patient health care information in 1980. The Wisconsin privacy laws were intended to balance the patient’s right to have their health care information remain confidential with the need to allow disclosure without patient consent when the legislature determined that the societal need to know was greater than the patient’s right of protection. An example of this balance is allowing a patient’s health care provider to access patient information from other health care sources when providing care and treatment for the patient without the patient’s consent.

Many of the barriers to health information exchange result from strict privacy protection requirements in the current Wisconsin privacy laws. While some of the restrictions clearly interfere with or prohibit information exchange, others are so complex in their application that health care practices relating to disclosures are very different between health care providers. While some health care providers prefer more general statutory language that allows greater flexibility in disclosure

practices, the result is often wide variability and inconsistency in disclosure practices. The strictness of the regulations, complexity of interpretation and variability in practices result in some health care providers allowing disclosure while others deny disclosure. This variability in practice creates significant and often unanticipated barriers to health information exchange.

HIPAA creates additional privacy protections in many of the same areas as Wisconsin Statutes 146.81-146.84. This creates additional barriers because in order to exchange information within Wisconsin, one must first determine which law applies (HIPAA or Wisconsin Privacy laws); then determine the statutory requirements of the exchange. The requirement of analysis between state and federal law creates significant complexity to the information disclosure process and creates additional barriers to exchange. In addition, when Wisconsin law is more restrictive than HIPAA, the state law interferes with the more accepted national HIPAA standards for exchange. Consequently, when someone outside the state attempts to exchange information with an entity in Wisconsin, different regulations may apply, further complicating the exchange.

There are four main areas in which Wisconsin Statute 146 is more restrictive than HIPAA:

1. Documentation requirements
2. Re-disclosure restrictions
3. Limitation on disclosure to family
4. Limitation on disclosure to law enforcement

#### **4.1.2 PROPOSED SOLUTION**

The workgroup advocates changing four main areas of Wisconsin statute 146 to mirror the language in HIPAA:

1. Expanding disclosures to family (Wis. Stat. 146.82, 146.83)
2. Expanding disclosures to law enforcement
3. Modifying re-disclosure restrictions (Wis. Stat. 146.82(2)(b))
4. Modifying the documentation of disclosure requirements (Wis. Stat. 146.82 (2) (d), 146.83(3))

#### **4.1.3 SOLUTION DESCRIPTION**

The section that follows presents each element of this four-part solution in detail, summarizing the topic area as it applies in Wisconsin today as well as the proposed solution.

*Disclosure to Family* (Wis. Stat. 146.82) – add exception for family involved with care and treatment of patient.

Wisconsin Statute 146.82 has no exceptions to its requirement for patient consent to disclose to families: family members are generally not allowed access to a patient's health information without that patient's consent. Under Wisconsin Statute 51.30, however, disclosure to families is allowed

under certain circumstances without patient consent.<sup>2</sup> By requiring patient consent in most circumstances, Wisconsin statutes differ from Federal Regulations under HIPAA, which allow disclosure to family members involved in the care and treatment of a patient with that patient's agreement (rather than formal consent).<sup>3</sup>

The restrictions within the Wisconsin privacy laws requiring patient consent to disclose to family members create barriers to the exchange of health information. Furthermore, the differences between Wisconsin and federal laws create additional barriers to exchanges across state lines.

**The proposed solution standardizes Wisconsin privacy laws (and other states utilizing the HIPAA Privacy Rule standard) to mirror HIPAA by allowing family members and other individuals involved with patient care access to patient health information with patient agreement (vs. formal written consent).**

#### *Disclosure to Law Enforcement*

When comparing the state exceptions for access to law enforcement to those in HIPAA, the Wisconsin privacy laws are generally more protective and will control. In many cases, this requires law enforcement to obtain a consent from the patient in order to obtain protected health information (PHI). Workgroup members have rarely seen law enforcement provide a patient consent for access. More often the information is provided to law enforcement without consent contrary to state law, or a court order is obtained. Nonetheless, the requirement to obtain a consent or a court order imposes a barrier to information exchange. Furthermore, the elements in the consent that are required by the state privacy laws vary between state laws and those required by HIPAA.

In summary, the steps it takes to determine whether or not a consent is needed and then which elements are required in that consent pose barriers to the exchange of information. There are also great variations in business practices associated with release of information to law enforcement that are likely caused by the complexity of determining which law applies; then applying the requirements of the controlling law.

**The proposed solution allows Wisconsin (and other states adopting the HIPAA standard) to adopt the national HIPAA Privacy Rule standard for access to protected health information by law enforcement and would provide consistency in approach and implementation of law enforcement access.**

#### *Re-disclosure (Wis. Stat. 146.82(2)(b))*

Wisconsin Statute 146.82(2)(b) requires that when patient information is disclosed without patient consent, the recipient must keep the information confidential and may not disclose identifying information about the patient. This statutory language effectively prohibits re-disclosure of protected health information (PHI) received without patient consent. That is, when organization A receives PHI from organization B without patient consent, organization B cannot send the information on to

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<sup>2</sup> Wis. Stat. 51.30(4)(b)20. allows providers to share a patient's presence in an inpatient treatment facility with family members without patient consent if the spouse, parent, adult child or sibling is directly involved in providing care to or monitoring the treatment of the subject individual

<sup>3</sup> 45 CFR 164.510(b)

(re-discloses to) organization C—with or without patient consent. This prohibition does not apply to PHI received *with* patient consent under s 146.83. Wisconsin statutes 51.30 and 252.15 regulating sensitive information do not contain re-disclosure prohibitions and allow re-disclosure in compliance with the consent or statutory exception requirements.<sup>4</sup>

Variation in Wisconsin Statutes governing re-disclosure complicates health information exchange in both paper and electronic environments. In order to comply with current law, providers must be able to identify the source of each element of a patient’s record prior to disclosing PHI. Elements received under Wis. Stat. 146.82(b) without patient consent (e.g., disclosure to providers for treatment purposes) cannot be re-disclosed. In contrast, elements received under Wis. Stat. 146.83 with patient consent *can* be re-disclosed with patient consent. Such variation makes it difficult for the recipient of information to determine whether the patient information may be disclosed. Disclosure is further complicated by variations in the type of information received and the type of consent (e.g., oral vs. written).

**The proposed solution allows Wisconsin (and other states utilizing the HIPAA standard) to adopt a nationally consistent standard for re-disclosure and allows a provider who receives health information from one provider, to release the information received to another provider, for treatment purposes.**

*Documentation Requirements* (Wis. Stat. 146.82 (2) (d), 146.83(3))

Wisconsin Statutes 146.82 (2) (d) and 146.83(3) require documentation of all disclosures of health care information. The federal Privacy Rule<sup>5</sup> requires documentation of disclosures to enable the patient to determine who has accessed their information and when. These statutes vary in when documentation must occur and also what elements are required to be documented. Therefore, in order to document correctly, there must be a determination of what law applies to the disclosure, whether documentation of the disclosure is required and finally what elements need to be documented.

**The proposed solution allows Wisconsin (and other states utilizing the HIPAA standard) to adopt the national HIPAA standard for documentation that modifies the Wisconsin documentation of disclosure requirements to match HIPAA and still enables the patient to determine who has accessed their information and when.**

#### **4.1.4 BARRIERS ADDRESSED**

*Disclosure to Family* (146.82)

By standardizing Wisconsin privacy laws to allow family members and other individuals involved with patient care access to patient health information with patient agreement (vs. formal consent), this solution eliminates the variance in the state and federal law noted above. These proposed changes are consistent with federal HIPAA regulations, thereby eliminating the variance between state and federal regulations in this regard. If this solution, to follow HIPAA, were adopted nationally, it would eliminate inter-state variation as well. Eliminating or reducing these legal

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<sup>4</sup> Wis. Stat. 51.30 covers mental health, alcohol and other abuse treatment, and developmental disabilities; Wis. Stat. 252.15 covers HIV test results.

<sup>5</sup> 45 CFR 164.528

variations will minimize the complexity of process and variation in interpretation noted above, enhance information exchange and reduce barriers to information exchange processes.

This solution offers additional benefits to providers and recipients of care; first, it increases provider efficiency by streamlining the release process, and second, it increases the transparency of provider activities to patients, family members, and other designated caregivers.

#### *Disclosure to Law Enforcement*

The proposed solution allows Wisconsin (and other states utilizing the HIPAA standard) to adopt the national standard for access to protected health information by law enforcement and would provide consistency in approach and implementation of law enforcement access. The solution also continues to provide solid protection to patient privacy by allowing access without consent only when society's need to know overrides the patient's right of privacy.

Standardization of access by law enforcement would decrease variation in deciding which and how the varying controlling laws are applied. Administrative and cost savings would result from a standardized approach to requests for health information by law enforcement. Exchanges between states would be simplified if each state adopted the national standard. With a standard approach, business processes would be streamlined and education and training costs would decrease.

#### *Re-disclosure*

This solution eliminates a barrier to information exchange created by a strict prohibition on re-disclosure of PHI received without patient consent under Wisconsin Statute 146.82(b). This solution also eliminates the need to identify the source of specific elements of a patient's record prior to disclosing PHI, thereby reducing the complexity of the disclosure process. It will also eliminate variations in practice caused by variations in interpretation of the legal requirements.

This solution offers a number of other benefits to health care providers and recipients: it increases provider access to patient information for treatment purposes, decreases the chances of an erroneous disclosure, and increases consistency of information disclosed. In addition, by simplifying the Wisconsin law, this solution will increase compliance, control costs, and improve patient safety.

#### *Documentation*

By eliminating the statutory requirement to document disclosures of health information, the barriers caused by these regulations are removed. This would result in significant cost savings as employees would no longer need to determine which law applies and the elements required to be documented, then document the elements required for the release of information. Training costs would be greatly reduced as well. This cost savings could potentially be passed along to patients.

Removing the documentation requirements would not reduce patient privacy. There are very few cases in which a patient requests to view access by others to their records and for the very few who do; the current requirements are extremely burdensome and costly.

There is concern that current IT systems do not have the capability to collect the necessary elements for documentation. Under current state law, those organizations that rely on audit trails created by

their IT systems for documentation could be liable for not documenting the required elements, as could their vendors.

#### **4.1.5 TYPES OF HEALTH INFORMATION EXCHANGE ADDRESSED**

*Expansion of disclosure to family:* All types of health care information would be affected by this solution including scheduling of appointment, medications, patient health care services, immunizations and other clinical information, laboratory reports, etc. exchanged by a provider and family caretaker through verbal interaction, phone calls, face-to face exchanges or the provision of copies of patient information.

*Expansion of disclosure to law enforcement:* Information from all types of health care providers to law enforcement in all health care environments would be affected by this solution. Although many of these exchanges typically occur in emergency departments, the law should clearly state how to handle all requests by law enforcement for health information - by phone or in writing, in addition to in person.

*Removal of Re-disclosure:* The exchange of PHI that is received without patient consent under Wis. Stat. 146.82.

*Modification of Documentation requirements:* Current documentation requirements (Wisconsin state law and federal Privacy Rules) apply to all disclosures of health information (not internal uses of information). Therefore all disclosures of health information would be impacted by a change in the regulations.

#### **4.1.6 STAKEHOLDERS IMPACTED AND INVOLVED**

The grid below indicates the stakeholder groups identified by RTI that have a role in the development of, or are impacted by, this proposed solution:

	Stakeholder Group																
	Clinicians	Physician groups	Federal health facilities	Hospitals	Payers	Public health agencies	Community clinics and health centers	Laboratories	Pharmacies	Long term care facilities and nursing homes	Homecare and hospice	Correctional facilities	Professional associations and societies	Medical/public health schools that conduct research	Quality improvement organizations	Patients, Consumers, Advocacy Organizations	State government
<b>Documentation</b>																	
Impacted by Solution	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Involved in Solution	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>Re-disclosure</b>																	
Impacted by Solution	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Involved in Solution	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>Family</b>																	
Impacted by Solution	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Involved in Solution	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>Law Enforcement</b>																	
Impacted by Solution	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Involved in Solution	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

In addition, employers will be impacted by this solution. As well, legislators, vendors, and standards generating organizations (e.g., CCHIT, HITSP, etc.) will be critical partners in the development and implementation of this solution.

#### 4.1.7 STAGE OF DEVELOPMENT

None of the proposed changes to Wis. Stat. 146 have been initiated although workgroup study of current processes indicate that the restrictive requirements are not being met by many health care providers.

#### 4.1.8 EXTENT SOLUTION IS IN USE

None of the proposed changes to Wis. Stat. 146 have been initiated. However, workgroup study business practices indicate that many providers are utilizing the proposed solutions rather than complying with the more restrictive law.

#### 4.1.9 SCALABILITY

The changes to Wis. Stat. 146 apply to all organizations who exchange PHI in Wisconsin. The overriding concept of the solution is to change state law to mirror HIPAA to allow for better

exchange of information both within the state of Wisconsin and across state boundaries. That concept can, and should, be applied across states to facilitate HIE.

#### **4.1.10 POSSIBLE BARRIERS**

This solution removes a perceived privacy protection provided by Wis. Stat. 146. As with any legislative change, the process to change the law will be a barrier. There also may be lobbying groups who lobbied to create the law in the first place, who will have to be persuaded.

#### **4.1.11 DOMAINS ADDRESSED**

- 1 - User and entity authentication
- 2 - Information authorization and access controls
- 3 - Patient and provider identification
- 4 - Information transmission security or exchange protocols
- 5 - Information protection (against improper modification)
- 6 - Information audits that record and monitor activity
- 8 - State law restrictions
- 9 - Information use and disclosure policy

## **4.2 Modify Wisconsin Statute 51.30 in relation to access for treatment**

### **4.2.1 CONTEXT FOR PROPOSED SOLUTION**

Wisconsin statutes governing disclosure of personal health information to providers for treatment purposes vary by the type of health information disclosed. General health information and HIV test results can be released to providers for treatment purposes without patient consent.<sup>6</sup> Information regarding mental health, alcohol or drug abuse, and developmental disabilities can be released only with a patient's written informed consent except in a medical emergency or for medications, allergies and diagnosis to health care providers within a related health care entity.<sup>7</sup> By requiring patient consent to release information regarding mental health, alcohol and drug abuse (AODA) and developmental disabilities, Wisconsin statutes differ from federal HIPAA regulations, which allow release of information between providers for treatment purposes without patient consent.<sup>8</sup> Like Wisconsin law, the federal law that controls AODA treatment records requires patient consent to provide this information to a provider for treatment purposes.<sup>9</sup>

The lack of uniformity between Wisconsin privacy laws and between state and federal regulations present a number of barriers to the disclosure of health information to providers for treatment purposes in paper and electronic environments. Most notably:

- Before treatment information may be shared, there must be a determination of which state privacy law applies and a determination of whether consent is required.

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<sup>6</sup> Wis. Stat. 146.82(2)(a)2.; Wis. Stat. 252.15(5)(a)2

<sup>7</sup> Wis. Stat. 51.30(4)(a)8

<sup>8</sup> 45 CFR 164.506

<sup>9</sup> 42 CFR Part 2

- Before the treatment information exchange can occur, there must be a determination of whether HIPAA applies and then whether state or federal law controls and whether consent is required.
- Before the treatment information exchange can occur, there must be a determination of whether the federal AODA law applies and whether consent is required.

#### **4.2.2 PROPOSED SOLUTION**

The Workgroup advocates changing Wisconsin Statute 51.30 clauses governing access for treatment purposes to mirror the language in HIPAA. This proposed solution would allow the exchange of all personal health care information, with the exception of psycho-therapy notes as defined by HIPAA and AODA treatment information governed by 42 CFR Part 2, between providers for treatment purposes without patient consent.

The workgroup discussed a number of additional areas where adjusting Wis. Stat. 51.30 to match HIPAA could positively impact health information exchange, and recommends further consideration of modification of the following areas of the statute: disclosure to family; disclosure to law enforcement; and documentation requirements.

#### **4.2.3 SOLUTION DESCRIPTION**

Wisconsin Statute 51.30 should be changed to be consistent with HIPAA, such that all treatment records are disclosed to providers for treatment purposes without patient consent, with the exception of psycho-therapy notes as defined by HIPAA. Moreover, HIPAA should become the national standard for disclosures/exchanges between providers for treatment purposes, making all such exchanges allowable without patient consent in all states. This change would enable all states to utilize the HIPAA definitions and requirements, creating uniform definitions of ‘treatment,’ ‘consent,’ and ‘health care provider.’

#### **4.2.4 BARRIERS ADDRESSED**

This solution eliminates variation in Wisconsin law by removing the requirement to secure patient consent to release certain types of health information to providers for treatment purposes. It also eliminates variation between Wisconsin law and the HIPAA Privacy law. (It does not address the variation between the federal AODA law and HIPAA).

This solution provides a number of added benefits for providers and patients. Consistency in the regulations governing disclosure and consent of health information will remove barriers to health information exchange, eliminating treatment delays due to unavailable or incomplete information and associated risks to patient safety. Moreover, clearer definitions of ‘treatment,’ ‘health care,’ and ‘provider’ will reduce ambiguities in release practices, leading to more efficiency in the exchange of health care information. The Workgroup feels that these changes will lead to dramatic improvements in patient care, decreases in costs for providers and patients, and improvements in providers’ ability to share patient information across states.

## 4.2.5 TYPES OF HEALTH INFORMATION EXCHANGE ADDRESSED

This solution impacts all exchanges of all health information among providers for treatment purposes.

## 4.2.6 STAKEHOLDERS IMPACTED AND INVOLVED

The grid below indicates the stakeholder groups identified by RTI that have a role in the development of, or are impacted by, this proposed solution:

	Stakeholder Group																
	Clinicians	Physician groups	Federal health facilities	Hospitals	Payers	Public health agencies	Community clinics and health centers	Laboratories	Pharmacies	Long term care facilities and nursing homes	Homecare and hospice	Correctional facilities	Professional associations and societies	Medical/public health schools that conduct research	Quality improvement organizations	Patients, Consumers, Advocacy Organizations	State government
<b>Impacted by Solution</b>	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X
<b>Involved in Solution</b>	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X

## 4.2.7 STAGE OF DEVELOPMENT

Wisconsin laws regulating general health and HIV record release for treatment do not require patient consent for exchange and are consistent with HIPAA. One of the networked organizations also uses the HIPAA standard that allows disclosure without consent. These processes have worked well in Wisconsin and provide a possible template to handle mental health and developmentally disabled records as proposed by this solution. (Note: Release of AODA treatment records will still require patient consent per 42 CFR Part 2.)

The Workgroup noted a number of steps towards implementing this solution, including: gaining the support of appropriate professional associations and consumer organizations, including finding common ground with advocates; drafting model legislation; working toward legislative changes; and providing provider and consumer education.

## 4.2.8 EXTENT SOLUTION IS IN USE

As noted above, this solution already governs the release of general health and HIV records in Wisconsin. In addition, the networked organization use the HIPAA standard that allows disclosure without consent.

## **4.2.9 SCALABILITY**

This solution reduces barriers to health information exchange, and should be feasible for organizations of all types and sizes. Changing Wisconsin law to mirror HIPAA would simplify the process for providing patient care across state lines.

## **4.2.10 POSSIBLE BARRIERS**

This solution removes a perceived privacy protection provided by Wis. Stat. 51.30. There are very strong lobbying groups in Wisconsin who fought to create the legislation. Removing these privacy protections will be difficult at the state level. Thus, involving a broad variety of consumers in the decision-making and implementation process will be critical to bring this solution to the implementation phase. Recent modifications to Wis. Stat. 51.30 have allowed expanded access to patient health care information by providers, so this may be an opportune time to consider discussing further modification to this law.

Residual variability in other states laws would hinder the exchange of health information for treatment purposes. Thus, additional research should be done to determine which other states have laws that are more restrictive than HIPAA regarding the disclosure of health information to providers for treatment purposes.

As Wisconsin transitions to an electronic environment, additional consideration should be given to the regulations governing ‘access’ as opposed to ‘disclosure.’ These efforts should examine what is disclosed to whom under which circumstances, with serious consideration directed toward the establishment of uniform access controls within Wisconsin and between states.

## **4.2.11 DOMAINS ADDRESSED**

- 1 - User and entity authentication
- 2 - Information authorization and access controls
- 8 - Laws
- 9 - Information use and disclosure policy

## **4.2.12 ALTERNATIVE SOLUTION**

In the event that this solution is not feasible, an alternate solution was proposed. This alternate solution would expand on the recent changes to Wis. Stat. 51.30, such that the data elements outlined under Wis. Stat. 51.30(4)(b)8g could be exchanged for treatment purposes without consent by health care providers that are not part of the same network.

## **4.3 Verification of patient identity**

### **4.3.1 CONTEXT FOR PROPOSED SOLUTION**

Currently there is no standard method for verifying that, when information is exchanged, it is exchanged on the correct patient. All Variations Workgroup members stated that they had processes for verifying they were exchanging information on the correct patient, but all of the verification

methods were different. Without a standard method for identifying patients, parameters used to distinguish patients in one provider practice might not be available in another, making exchange of information difficult. Furthermore, it might not be easy to determine, when receiving information from another practice, that it is information regarding the correct patient. Effectively the only legal control for verification of the patient is the application of penalties for a privacy violation when the wrong patient's information is disclosed.

When moving into an electronic world where information is exchanged from one electronic health care system to another, this lack of standard patient identifiers will cause even greater problems than it does today.

### **4.3.2 PROPOSED SOLUTION**

The Workgroup advocates a two part solution to improve the identification and verification of the patient:

1. Create front-end policies to ensure appropriate capture of patient identifiers
2. Adopt patient identifiers that are defined at a national level

### **4.3.3 SOLUTION DESCRIPTION**

We propose development of a standard set of patient identifiers that can be utilized at a national level, in a standardized and consistent process to assure the identity of the patient. This includes a clearly defined approach to ensuring that the identifiers are obtained and reviewed each time the patient receives care or treatment. The standard set of identifiers could also be clearly written on the patient consent form or any other standardized documents used to request patient information to ensure that patients can clearly be identified prior to releasing information. To assure correct verification of the patient, the identifiers should include:

- The patient's full name (the group did not discuss including middle names or honorifics)
- Gender
- Date of birth
- Address
- Zip code
- Phone number

Other additional identification methods might include a driver's license or photograph.

A workgroup should be set up to refine the identifiers and determine the best way to ensure compliance with the regulations prior to implementing a national standard.

### **4.3.4 BARRIERS ADDRESSED**

With the appropriate parameters, this solution would greatly simplify the process for identifying the patient and would also improve the accuracy with which the patient is identified. This would lead to

improvements in safety and quality, reduce the administrative burden of resolving the identification of patients and prevent confidentiality violations.

### 4.3.5 TYPES OF HEALTH INFORMATION EXCHANGE ADDRESSED

This solution impacts every exchange of patient information involving identifiable patient information.

### 4.3.6 STAKEHOLDERS IMPACTED AND INVOLVED

The grid below indicates the stakeholder groups identified by RTI that have a role in the development of, or are impacted by, this proposed solution:

Section 4.3.6, Table 1. Stakeholder Group																	
	Clinicians	Physician groups	Federal health facilities	Hospitals	Payers	Public health agencies	Community clinics and health centers	Laboratories	Pharmacies	Long term care facilities and nursing homes	Homecare and hospice	Correctional facilities	Professional associations and societies	Medical/public health schools that conduct research	Quality improvement organizations	Patients, Consumers, Advocacy Organizations	State government
<b>Impacted by Solution</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>Involved in Solution</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

The impact for accurate identification of the patient impacts all who use or disclose patient information

### 4.3.7 STAGE OF DEVELOPMENT

There are currently several studies underway on correctly identifying the patient. These include the Markle Foundation, RxHub, Indiana, Washington National Medical Center and Chica.

### 4.3.8 EXTENT SOLUTION IS IN USE

There is no standard approach to verifying patient identity that is in use today. Each organization has its own set of patient identifiers to ensure the appropriate identification of patients, but in order to exchange information, the identifiers must be standard across organizations who share information.

### 4.3.9 SCALABILITY

This solution impacts all who exchange health information and is applicable in every setting in which information is exchanged. It could be implemented state-wide initially but would be much more effective if scaled to the national level. The standards would greatly improve exchanges of information at a national level.

### 4.3.10 POSSIBLE BARRIERS

In order for the solution to be effective, everyone would have to adopt the standards. The vendors would have to be aligned to develop products that comply with the standards. A large effort would be required to conform legacy data to the new standards and very consistent training on new standards would need to be employed to ensure that current data not only had the required elements, but was obtained and/or reviewed each time the patient was treated. Processes and policies would need to be changed at the institution level.

### 4.3.11 DOMAINS ADDRESSED

- 1 – User and entity authentication
- 2 – Information authorization and access controls
- 3 – Patient and provider identification
- 4 – Information transmission security or exchange protocols
- 5 – Information protection (against improper modification)
- 8 – Laws
- 9 – Information use and disclosure policy

## 4.4 Propose changes to HIPAA

This proposed solution suggests a change to the Federal Privacy law.

### PROPOSED SOLUTION

The Workgroup advocates proposing changing the language of the federal Privacy Rule, HIPAA, in three areas:

1. **Business Associate Agreements (BAA):** Remove the requirement to have a BAA, but hold business associates accountable for adhering to state and federal privacy requirements and liable for privacy violations under statutory law.
2. **Research:** Remove the waiver process required to proceed for research without patient consent, but maintain Institutional Review Board (IRB) process requirements.
3. **Minimum Necessary:** Develop model policies and procedures to clarify the Minimum Necessary standard.

This solution is outlined in more depth in Section 5 of this report.

## 4.5 Solution matrices

This section provides an aggregate analysis of Wisconsin's proposed solutions. It allows the reader to compare the proposed solutions to:

1. Barriers identified by the Variations and Legal workgroups

2. Domains defined by RTI.

Matrices comparing solutions to the stakeholders identified by RTI are included in the descriptions of individual solution (section 4 of this report). The first matrix in this section presents a high-level view, or roll-up, of the more detailed matrices that follow.

<b>Section 4.5, Table 1. High level roll-up of Solutions and Barriers</b> (Barriers identified by Variations and Legal Workgroups)				
Solutions	Barriers Driven by....			
	Federal Law Only	State Law Only	Federal and State Law	Variation in Policy or Practice
<b>Change Wis. Stat. 146</b>				
Allow Family Access		X		X
Expand Law Enforcement Access		X		X
Remove Re-disclosure Prohibition		X		X
Remove Documentation Requirements		X		X
<b>Change HIPAA</b>				
Eliminate Business Associate Agreements (BAAs)	X			X
Remove Research Waiver Requirement	X			
Clarify Minimum Necessary			X	X
<b>Change Wis. Stat. 51.30 (sensitive information)</b>				
Allow Access to Providers for Treatment Purposes		X		X
<b>Standardized Method to Verify Patients</b>				
				X

<b>Section 4.5, Table 2. Solutions to Barriers Driven by Federal Law</b>					
Solution	Specific barriers identified by Variations and Legal Workgroups				
	Verification of Requestor*	Research Waiver	Minimum Necessary	BAAs	HIPAA
<b>Change HIPAA</b>					
Eliminate BAAs				X	X
Remove Research Waiver Req.		X			X
Clarify Minimum Necessary			X		X
* The Workgroup chose not to develop a solution for this barrier, because this process would change in an electronic environment. The Workgroup decided instead to focus on barriers that would exist as barriers in both the paper and electronic environments.					

<b>Section 4.5, Table 3. Solutions to Barriers Driven by State Law</b>				
Solutions	Specific barriers identified by Variations and Legal Workgroups			
	Consent	Sensitive Information (Wis. Stat. 51.30)	Documentation	Prohibition on Re-disclosure
<b>Change Wis. Stat. 146</b>				
Allow Family Access	X			
Expand Law Enforcement Access	X			X
Remove Re-disclosure Prohibition				X
Remove Documentation Requirements			X	
<b>Change Wis. Stat. 51.30 (sensitive information)</b>				
Allow Access to Providers for Treatment	X	X		

Section 4.5, Table 4. Solutions to Barriers Driven by Variations in Policy or Practice					
Solutions	Specific barriers identified by Variations and Legal Workgroups				
	Consent	Mis-identification of Patient	Method of Requesting Information*	Method of Disclosure *	Varying Interpretation of Law
<b>Change Wis. Stat. 146</b>					
Allow Family Access	X				X
Expand Law Enforcement Access	X				X
Remove Re-disclosure Prohibition					X
Remove Documentation Requirements					X
<b>Change HIPAA</b>					
Eliminate BAAs					X
Remove Research Waiver Req.					X
Clarify Minimum Necessary					X
<b>Change Wis. Stat. 51.30 (sensitive information)</b>					
Allow Access to Providers for Treatment	X				X
<b>Standardized Method to Verify Patients</b>		X			

\* The Workgroup chose not to develop a solution for this barrier, because this process would change in an electronic environment and is currently driven by organization-level policies. The Workgroup decided instead to focus on barriers that would exist as barriers in both the paper and electronic environments.

The Solutions Workgroup emphasized that the specific solutions proposed would be most feasible to implement if they are bundled by the legislation they impact (i.e., Change Wis. Stat. 146, Wis. Stat. 51.30, or HIPAA). Thus, the RTI domains are compared only to the overall solution, not each individual component (i.e., ‘Change Wis. Stat. 146’ as opposed to ‘Allow Family Access’).

Section 4.5, Table 5. Comparing Proposed Solutions to RTI Domains									
Solutions	RTI Domains								
	1	2	3	4	5	6	7	8	9
<b>Change Wis. Stat. 146</b>	X	X	X	X	X	X		X	X
Allow Family Access									
Expand Law Enforcement Access									
Remove Re-disclosure Prohibition									
Remove Documentation Requirements									
<b>Change HIPAA</b>	X	X	X	X	X	X	X	X	X
Eliminate BAAs									
Remove Research Waiver Req.									
Clarify Minimum Necessary									
<b>Change Wis. Stat. 51.30</b>	X	X						X	X
Allow Access to Providers for Treatment									
<b>Standardize Verification of Patient</b>	X	X	X	X	X			X	X

## 4.6 Categorizing solutions

This section outlines the solution categories and sub-categories as defined by RTI. The first matrix is a roll-up of the subsequent, more detailed matrices.

RTI’s main categories include:

- Solutions affecting variations in organization business practices and policies
- Solution affecting state laws/regulations
- Solutions affecting federal laws/regulations
- Solutions affecting Interstate Health Information Exchanges

It should be noted that the project team chose to define ‘misinterpretation’ broadly to include instances where individuals misunderstand the law as well as instances where individuals understand the law yet interpret it differently.

<b>Section 4.6, Table 1. High Level Roll-up of Solution Categories</b>				
Solutions	Main Solution Categories Defined by RTI			
	Business Practice or Policy	State Law/Regulations	Federal Law/Regulation	Interstate HIE
<b>Change Wis. Stat. 146</b>				
Allow Family Access		X		X
Expand Law Enforcement Access		X		X
Remove Re-disclosure Prohibition		X		X
Remove Documentation Requirements		X		X
<b>Change HIPAA</b>				
Eliminate Business Associate Agreements			X	X
Remove Research Waiver Requirement			X	X
Clarify Minimum Necessary			X	X
<b>Change Wis. Stat. 51.30 (sensitive information)</b>				
Allow Access to Providers for Treatment		X		X
<b>Standardize Verification of Patient</b>	X			X

The table below reflects the Workgroup’s belief that developing a standardized mechanism for verifying a patient’s identity requires technical standards as well as policies and procedures to implement and support the standards.

<b>Section 4.6, Table 2. Solutions affecting variations in business practice or policy (not state or federal law)</b>				
Solution	Solution Sub-categories Defined by RTI			
	Governance-related	Business arrangement	Technical	Guidance or education for misinterpretation
<b>Verification of Patient</b>	X	X	X	X

The table below reflects the changes to Wisconsin State Statutes 146 and 51.30. It is the Workgroup’s belief that these changes will not only reduce barriers to exchange caused by the law, but will also reduce barriers caused by varying interpretations of the law. Although changes in HIPAA will impact practice at the state level, changing HIPAA as proposed will not affect Wisconsin State law.

Section 4.3, Table 3. Solutions affecting state laws/regulations				
Solutions	Solution Sub-categories Defined by RTI			
	Change existing law	Create new law	Address Non-compliance	Address misinterpretation issues
<b>Change Wis. Stat. 146</b>				
Allow Family Access	X		X	X
Expand Law Enforcement Access	X		X	X
Remove Re-disclosure Prohibition	X		X	X
Remove Documentation Requirements	X		X	X
<b>Change Wis. Stat. 51.30 (sensitive information)</b>				
Allow Access to Providers for Treatment	X			

The table below reflects the changes to HIPAA. It is the Workgroup’s belief that these changes will not only reduce barriers to exchange caused by the law, but will also reduce barriers caused by varying interpretations of the law. The Workgroup did not discuss the impact of these changes on state programs (e.g., Medicaid)

Section 4.3, Table 4. Solutions affecting federal laws/regulations				
Solution	Solution Sub-categories Defined by RTI			
	Applies to HIPAA	Applies to State Programs	Address Non-compliance w/Federal Law	Address misinterpretation issues
<b>Change HIPAA</b>				
Eliminate BAAs	X		X	X
Remove Research Waiver Req.	X			
Clarify Minimum Necessary	X		X	X

One of the drivers for these solutions is the Workgroup’s belief that any inconsistencies between Wisconsin and federal law as well as variations in business practices and policies will impede health information exchange. The Workgroup believes that the solutions requiring a multi-state approach will have limited impact if they are not adopted nationally.

Section 4.3, Table 5. Solutions affecting interstate health information exchange		
Solutions	Solution Sub-categories Defined by RTI	
	Involves cross-state exchange	Requires a multi-state approach
<b>Change Wis. Stat. 146</b>		
Allow Family Access	X	
Expand Law Enforcement Access	X	
Remove Re-disclosure Prohibition	X	
Remove Documentation Requirements	X	
<b>Change HIPAA</b>		
Eliminate Business Associate Agreements	X	X
Remove Research Waiver Requirement	X	X
Clarify Minimum Necessary	X	X
<b>Change Wis. Stat. 51.30 (sensitive information)</b>		
Allow Access to Providers for Treatment	X	
<b>Standardize Verification of Patient</b>	X	X

## Section 5 - Solutions that Impact Federal Law

### 5.1 Propose changes to HIPAA

#### 5.1.1 CONTEXT FOR PROPOSED SOLUTION

The HIPAA Privacy Rule introduced a number of requirements intended to protect patient privacy. In some instances, however, the Workgroup feels that HIPAA's requirements increased administrative burdens that impede health information exchange while providing nominal improvements in patient privacy protections. In other instances, HIPAA's requirements provide important protections to patient privacy but are broadly interpreted and implemented with wide variation. In relation to both of these instances, the Workgroup recommends revising HIPAA.

#### 5.1.2 PROPOSED SOLUTION

The Workgroup advocates proposing changing the language of the federal Privacy Rule, HIPAA, in three areas:

1. **Business Associate Agreements (BAA):** Remove the requirement to have a BAA, but hold business associates accountable for adhering to state and federal privacy requirements and liable for privacy violations under statutory law.
2. **Research:** Remove the waiver process required to proceed for research without patient consent, but maintain Institutional Review Board (IRB) process requirements.
3. **Minimum Necessary:** Develop model policies and procedures to clarify the Minimum Necessary standard.

#### 5.1.3 SOLUTION DESCRIPTION

The section that follows presents each element of this three-part solution in detail, summarizing the topic area in Wisconsin today as well as the proposed solution.

##### *Business Associate Agreements*

Prior to HIPAA, when confidential information was exchanged, there was typically 'confidentiality language' in contracts regarding the protection and use of confidential information in services performed. Wisconsin recognized most of these relationships as legal contractual relationships, agency relationships, or employment agreements and applied required privacy protections to those individuals or groups using protected health information to perform services on behalf of health care providers.

HIPAA formalized the contractual relationship formed by this type of language with a mandate for Business Associate Agreements (BAAs) between covered entities that include specific privacy

protection language. This mandate stemmed in part from the HIPAA Privacy Rule's omission of a mechanism that provides accountability for individuals accessing protected health information when performing services for covered entities. The HIPAA BAA requirement allows accountability for activities of the business associate through the covered entity<sup>10</sup> and the contractual arrangement of the BAA.

HIPAA requires that whenever a covered entity is supplying information directly or indirectly to an outside person or entity and that information includes protected health information (PHI), the covered entity must consider whether a business associate relationship is being created and a whether BAA is necessary.<sup>11</sup> There is not a requirement for this type of contractual agreement under Wisconsin law. However, within Wisconsin laws and codes, there are requirements to contractually protect confidential information in certain circumstances.<sup>12</sup>

Determining whether a BAA is needed is an administratively burdensome process. Drafting BAAs is similarly time and resource-intensive: separate, unique BAAs are required for almost every business associate. Although there is a national standard for BAA language, it is not uniformly applied. BAAs can also be confused with trading partner agreements. On balance, Workgroup members consider BAAs to be burdensome and costly undertakings with little gain to operational efficiency or patient privacy. **Thus, the Workgroup recommends eliminating HIPAA's requirement to have a BAA, and creating a mechanism to hold business associates accountable under statutory law in case of breach, state privacy, or HIPAA violation.**

### *Research*

In Wisconsin, prior to HIPAA, access to research information without patient consent was controlled by the statutory exceptions in the state privacy laws.<sup>13</sup> HIPAA's requirements governing access for research purposes are deemed more protective of patient information than state laws and, therefore, the HIPAA requirements control access without consent for research purposes. Under HIPAA, if researchers request access to identifiable health information as part of a research study, they must either obtain a waiver from the Institutional Review Board (IRB) as part of the IRB approval process

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<sup>10</sup> Covered entities include health plans, health care providers, and clearinghouses.

<sup>11</sup> A business associate is a person or company who performs or assists in the performance of a function or activity on behalf of a covered entity (health care provider) involving the use or disclosure of protected health information (PHI). In addition, if any person or company in the following categories is hired by a covered entity and PHI is disclosed to them as part of their agreement with the covered entity they are a business associate: legal, actuarial, accounting, consulting, certain data aggregation services, management, administrative, accreditation, or financial services. Business associates perform a range of functions and activities, including: claims processing or administration, data analysis, utilization review, quality assurance, billing, benefit management, and practice management.

<sup>12</sup> For example, for the purposes of Medicaid administration, the state is required to have some time of agreement unless there is a legal requirement to provide the data. For more, see: HFS 108.01 (5) – HFS 108.01(6)(b).

<sup>13</sup> Wisconsin State statutes generally allowed access if the researcher was affiliated with the health care provider and provided written assurances that the information would only be used for the purpose requested and no identifiable information would be disclosed in the final research product. In addition, Wis. Stat. 51.30, controlling more sensitive information, required that the research project be approved by the Department of Health and Family Services and Wis. Stat. 252.15, regulating HIV test results, required that the project be approved by an Institutional Review Board (IRB). In addition, although not required by the privacy laws, research studies involving human subjects were approved by an IRB. If a researcher did not meet these requirements, a patient consent for research access would be required. For additional information, see Wis. Stats. 146.82(2)(a)6, 51.30(4), 252.15(5)10.

or obtain consent from all patients in the study.<sup>14</sup> Due to the additional waiver criteria required by HIPAA, many facilities have created privacy boards in addition to the IRB to evaluate and grant waivers.

In evaluating a research proposal, an IRB is required to weigh the proposal's risks and benefits, including its impact on the confidentiality of patient health information. It is the Workgroup's consensus that IRB approval is sufficient to protect patient confidentiality. **Thus, the Workgroup proposes eliminating 45 CFR 164.512(i)(2)(ii), the clause in HIPAA that specifically requires the additional waiver criteria.**

### *Minimum Necessary*

The minimum necessary standard, a specific protection of the HIPAA Privacy Rule, is derived from confidentiality codes and practices in common use today.<sup>15</sup> It is based on sound current practice that the disclosure of protected health information should be limited to that which is necessary to satisfy a particular purpose or carry out a function. The minimum necessary standard requires covered entities to evaluate their practices and enhance safeguards as needed to limit unnecessary or inappropriate access to and disclosure of protected health information. The Privacy Rule's requirements for minimum necessary are designed to be sufficiently flexible to accommodate the various circumstances of any covered entity.<sup>16</sup>

The Privacy Rule requires that the minimum necessary standard be applied unless the regulations specifically state that the standard is not required to be applied. The application of the standard is distinctly different for uses other than disclosures and is applied differently for routine and non-routine disclosures. The Privacy Rule generally refers to uses as internal sharing of information and disclosures as a release of information made outside of the facility or system. The Privacy Rule is written such that each covered entity interprets the minimum necessary standard in their own policies and procedures.

The only Wisconsin law that specifically requires the application of a minimum necessary standard is the administrative code defining Wisconsin Statute 51.30, which regulates mental health, alcohol and drug abuse and developmentally disabled information.<sup>17</sup> This state law requires that whenever information is released that is regulated by Wis. Stat. 51.30, the information shall be limited to include only the information necessary to fulfill the request.<sup>18</sup>

Application of the minimum necessary standard creates a significant barrier to health information exchange. The standard makes it difficult to determine what is to be disclosed and allows for subjective decision-making on the amount of information that is disclosed. Moreover, it makes it difficult to know what information will be received.

The Workgroup noted that it may not be feasible to adhere to the minimum necessary standard in many electronic health information systems. In an electronic exchange, minimum necessary may require limitation of access or other technology that allows for layered access. In organizations with paper records, for exchanges subject to the minimum necessary standard, an individual must sort through the chart and copy only the relevant pieces of information before releasing the information. The standard therefore may require specific technology requirements and/or specially trained staff to evaluate records which may increase costs and administration of the disclosure process.

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<sup>14</sup> 45 CFR 164.512(i)(2)(ii)

<sup>15</sup> 45 CFR 164.502(b), 164.514(d)

<sup>16</sup> OCR HIPAA Privacy, December 3, 2002, Revised April 4, 2003

<sup>17</sup> HFS 92.03(1)(n)

<sup>18</sup> HFS 92.03(1)(n)

In addition to the requirements of the law, variation in business practice as a result of varying interpretations of the loosely defined law create further barriers to information exchange. If one organization limits information in one way while the organization it is exchanging with limits it another way, for example, it is difficult to obtain the information required for the intended purpose. The inconsistency in the standard may also result in insufficient information being provided when necessary for patient health care processes.

**Thus, the Workgroup recommends both re-writing the applicable section of Wisconsin Administrative Code 92.03(1)(n) that pertains to Minimum Necessary so that it mirrors HIPAA and developing state and national model policies and procedures for defining and applying the Minimum Necessary standard.**

#### **5.1.4 BARRIERS ADDRESSED**

##### *Business Associate Agreements*

Removing the requirement to have a BAA eliminates the need to dedicate resources to determining when a BAA is necessary and, when necessary, drafting and monitoring BAAs. By doing so, it simplifies the process for exchanging information. Moreover, this solution enables covered entities to redirect resources currently allocated to BAAs to benefit health care operations and patient care. This should reduce costs for everyone involved, possibly contributing to a reduction in health care costs. Once federal law is changed, this solution would be inexpensive to implement and would have nominal impact on patient privacy.

##### *Research*

Maintaining the IRB process but removing the waiver process required to proceed without patient consent eliminates a barrier to exchange for research purposes, thereby enhancing and encouraging research projects that are IRB approved. While the legal solution proposed still maintains the patient privacy protections provided by the IRB, it reduces the administrative costs of conducting research by removing the additional and often redundant step of applying for, reviewing, and ultimately granting waivers to access health information for research purposes.

##### *Minimum Necessary*

This solution does not remove the barrier imposed by the Minimum Necessary standard because the Workgroup believes the standard is necessary for patient privacy protection. The Workgroup maintains that information released should be limited to what is required to meet the intended purpose. Instead, this solution addresses the variability in application of the Minimum Necessary standard with a request for development of model policies and procedures to clarify the standard.

Clarifying and standardizing the minimum necessary requirement has many benefits. First and foremost, it simplifies and streamlines the exchange of information. In addition, it helps guarantee that organizations receive the information they need to meet the purpose of the exchange. Clear standards also reduce the amount of time required to fulfill a request for information as it will be easier to ascertain what information should be released. Finally, with a simplified process, it will become easier and less resource intensive to train staff on the minimum necessary standard. If the

standards are adopted nationally, this will benefit exchanges between all types of organizations, at the state, regional, and national level.

### 5.1.6 TYPES OF HEALTH INFORMATION EXCHANGE ADDRESSED

*Business Associate Agreements:* All exchanges of health information between organizations and individuals that meet the current definition of covered entity and business associate.

*Research:* All types of health care research and those involved in these processes including patients, health care facilities, researchers, health care providers, public health, quality assurance programs and developers of drugs and treatment programs that utilize patient health care information in their research.

*Minimum Necessary:* All exchanges of health care information that are covered by HIPAA will be impacted by this proposed change to HIPAA. Furthermore in Wisconsin, all exchanges of information covered by Wis. Stat. 51.30 (mental health, alcohol and drug abuse and developmentally disabled information) would be impacted.

### 5.1.7 STAKEHOLDERS IMPACTED AND INVOLVED

The grid below indicates the stakeholder groups identified by RTI that have a role in the development of, or are impacted by, this proposed solution:

	Stakeholder Group																
	Clinicians	Physician groups	Federal health facilities	Hospitals	Payers	Public health agencies	Community clinics and health centers	Laboratories	Pharmacies	Long term care facilities and nursing homes	Homecare and hospice	Correctional facilities	Professional associations and societies	Medical/public health schools that conduct research	Quality improvement organizations	Patients, Consumers, Advocacy Organizations	State government
Business Associate Agreements																	
<b>Impacted by Solution</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>Involved in Solution</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Research																	
<b>Impacted by Solution</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>Involved in Solution</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Minimum Necessary																	
<b>Impacted by Solution</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
<b>Involved in Solution</b>	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

## **5.1.8 STAGE OF DEVELOPMENT**

*Business Associate Agreements:* Any health care provider that is not required to comply with HIPAA currently implements this solution. As there is no BAA requirement under Wisconsin law, this solution was also utilized throughout the state before the introduction of HIPAA

*Research:* Before HIPAA, the IRB process was used effectively to protect patient confidentiality in Wisconsin. There were no documented breaches of patient privacy related to research in court proceedings. A return to pre-HIPAA requirements would be a relatively easy transition in Wisconsin.

*Minimum Necessary:* This solution has not been implemented anywhere. The Workgroup is not aware of any initiatives underway to implement it.

## **5.1.9 EXTENT SOLUTION IS IN USE**

This solution is not currently in use.

## **5.1.10 SCALABILITY**

The Workgroup believes that revising HIPAA as proposed will simplify the process of health information exchange in all health care settings at the state, regional and national level. As many BAAs cross state lines, it is critical that the BAA component of this solution is implemented nationally.

## **5.1.11 POSSIBLE BARRIERS**

It is an onerous process to change federal law. Thus, it could take years to achieve this solution. In addition, simplifying the process for providing access without consent for research under federal law may not eliminate more restrictive state laws in other states that would preempt federal law. The national elimination of the waiver requirement may still result in a state-by-state patchwork of variable legal requirements relating to access for research purposes. States that have more restrictive privacy requirements than the proposed IRB approval only process would continue to have difficulty exchanging information for research purposes.

## **5.1.12 DOMAINS ADDRESSED**

- 1 - User and entity authentication
- 2 - Information authorization and access controls
- 3 - Patient and provider identification
- 4 - Information transmission security or exchange protocols
- 5 - Information protection (against improper modification)
- 6 - Information audits that record and monitor activity
- 7 - Administrative or physical security safeguards
- 8 - State law restrictions
- 9 - Information use and disclosure policy

### **5.1.13 ALTERNATIVE SOLUTION**

#### *Research*

Understanding that a change in federal law may be difficult to achieve in a timely manner, another solution might be to obtain a specific type of consent from a patient that would allow access for research that would be ongoing throughout the provision of health care services. This solution could be enhanced by the design of a standardized, nationally-accepted consent form allowing for very broad access and use of health care information for research purposes.

## **Appendices**

## Appendix 1: Solution Workgroup Members

### *Wisconsin Security and Privacy Project*

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#### *Solutions Workgroup*

##### **Members**

**Chair: Jay Gold**, MetaStar

**Paul Baum**, Group Health Cooperative

**Tom Berg**, Marshfield Clinic

**Becky Borchert**, Hospice, Inc.

**Sarah Coyne**, Quarles and Brady

**Beth DeLair**, UW Health, Hospital and Clinics

**Mary Gulbrandsen**, Madison Metropolitan School District

**Stephanie Harrison**, Wisconsin Primary Health Care Association

**John Hartman**, Visonex Corporation

**Peggy Hintzman**, State Lab of Hygiene

**Kathy Johnson**, Department of Health and Family Services

**Lowell Keppel**, Wisconsin Academy of Family Physicians (WAFP)

**Laura Leitch**, Wisconsin Hospital Association

**Chrisann Lemery**, WEA Trust

**Thomas Luetzow**, representing the Wisconsin Medical Society

**Elizabeth Malchetske**, Appleton Medical Center

**Susan Manning**, Privacy Consultant

**Gloria Marquardt**, Department of Corrections

**Lori McDonald**, Wm. S. Middleton Memorial Veterans Hospital

**Thomas Moore**, Wisconsin Health Care Association

**Alice O'Connor**, Murphy Desmond, S.C.

**Barbara Oswald**, Wisconsin Office of the Attorney General

**Patty Pate**, PIC Wisconsin

**John Sauer**, Wisconsin Association of Homes and Services for the Aging

**Thomas Shorter**, Godfrey and Lahn, S.C., Attorneys at Law

**Theresa Smithrud**, Mercy Health System

**Susan Turney**, Wisconsin Medical Society

**Jane Wegenke**, U.W. School of Medicine and Public Health, Comprehensive Cancer Center

**Carol Weishar**, Milwaukee Medical Clinic

**Hugh Zettel**, GE Healthcare

**Sheila Zweifel**, U.W. - Madison University of Health Services

## Appendix 2: Security and Privacy Project Team

### *Wisconsin Security and Privacy Project Team*

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**Alison Bergum**, University of Wisconsin – Madison School of Medicine and Public Health

**Stacia Jankowski**, Division of Health Care Financing, Department of Health and Family Services

**Kathy Johnson**, Office of Legal Council, Department of Health and Family Services

**Susan Manning**, Privacy Consultant

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**Marie Whitsell**, Office of Strategic Finance, Department of Health and Family Services

**Susan Wood**, Department of Health and Family Services