Privacy and Security Solutions for Interoperable Health Information Exchange

Final Implementation Plan Report

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Table of Contents

1.0 Background

1.1 Purpose and Scope of Report

The Health Information Security and Privacy Collaboration (HISPC) is a federal initiative to examine privacy and security related laws, policies and business practices that impact electronic health information exchange (HIE). New York is one of thirty-three states and Puerto Rico charged with bringing together a broad range of stakeholders to develop recommendations to support the private and secure exchange of health information. NYHISPC is led by a statewide steering committee of diverse leaders in health care, business and privacy policy, and is informed by a wide range of stakeholders (including clinicians, physician groups, health facilities and hospitals, payers, public health agencies, government health agencies, pharmacies, long-term care facilities and nursing homes, and consumer organizations) who have been engaged through working groups and other forums. NYHISPC also is supported by a select panel of expert legal advisors, who provide analysis and feedback on all work products. NYHISPC offers an important opportunity to advance the understanding of how State and federal laws and organization-level business practices impact the privacy and security of HIE in New York.

The project included four major phases over the course of ten months, culminating in two final reports. The project tasks are:

- Task 1: Assess Variations in Business Practices and the Law that Present Challenges to the Secure Exchange of Health Care Information
- Task 2: Develop Solutions to Address those Challenges
- Task 3: Develop a Plan to Implement the Solutions
- Task 4: Finalize the Assessment, Analysis and Implementation Plans

The purpose of this *Final Implementation Plan Report* is to document practical approaches and actionable steps for implementing solutions identified in the *Final Assessment of Variations and Analysis of Solutions Report* submitted to RTI on March 30, 2007. This Report documents the process used by the State to create implementation plans to remove or mitigate the barriers identified in the Variations Phase, while preserving essential privacy and security protections for consumers. It identifies implementation plans, including timelines and resources needed, for each approved solution, and illustrates how the implementation plans work together.

1.2 Key Assumptions and Limitations

The breadth of the project scope and the timeline for project deliverables limited the project team's ability to fully research the range of solutions identified in the solutions phase. A longer-term process is also required to detail and gain consensus around each implementation approach.

2.0 Summary of Final Assessment of Variations and Analysis of Solutions Report

2.1 Solutions

The Analysis of Solutions phase of the project documented targeted solutions for maintaining privacy and security protections while enabling the exchange of electronic health information. The solutions were developed in response to a complex web of legal requirements, business and clinical demands, and policy goals governing today's paper-based health information world.

The report identified four main solutions areas:

Patient Engagement and Custodianship	Support the right of patients to expeditiously access their own clinical health information, and to make choices about the collection, storage, use and disclosure of their data; and engage people in taking a more informed and active role in their own health care.
Consent	Ensure that patients are able to make meaningful consent decisions about the disclosure of their health care information, and that custodians of health care information comply with patient consent mandates under State and federal law.
Security/Access/Use	Establish a common set of interoperable policies and technical requirements determining: (i) data access and use; (ii) authentication; and (iii) auditing, compliance, and software and data security.
Patient Identification	Provide for a reliable and secure method to correctly match patients with their health information ensuring access to the right record(s) for the right patient at the point of care.

And proposed an implementation framework consisting of four major approaches:

Leadership	Appoint a Deputy Commissioner of NYSDOH in charge of an Office of Health Information Technology Transformation (OHITT) to lead State and private sector efforts. The Commissioner of Health may appoint an Advisory Body comprised of public and private sector stakeholders to make recommendations for aligning health information exchange (HIE) policies, identify best practices for HIEs, and provide technical, business practice and policy guidance to OHITT.
Accreditation Process	Establish an accreditation process for health information exchanges (HIEs) that includes but is not limited to minimum standards for privacy and security solutions. A private non profit entity could accredit HIEs pursuant to but a State law prohibiting HIEs from operating without accreditation. Accreditation could also confer benefits to accredited HIEs including but not limited to access to Medicaid data.
Clarification of Existing Laws and Regulations	Call on State government to provide guidance and clarification around existing laws that impact HIE to facilitate the smooth exchange of health information.
Promulgation of New Laws	Develop new laws that address emerging issues in the transition to electronic HIE.

As implementation planning progressed, five areas of focus were identified as immediate priorities for moving HIE forward in New York: Leadership, Accreditation Process, Consent, Third-Party Custodian Law and Patient Engagement. The first two areas, Leadership and Accreditation Process, are process-oriented implementation approaches that provide an ongoing framework for addressing a wide range of specific, substantive solutions. A leadership infrastructure provides a platform for statewide discussion, information sharing and ultimately, decision-making related to a wide range of policy issues including accreditation, consent patient engagement, custodianship and patient identification. An accreditation process provides the mechanism for implementing policy decisions related to security, access and use of information. This Implementation Report provides a work plan to ensure that both infrastructures are put in place to continue the work of HISPC and support health care transformation in New York in the years to come.

The remaining areas of focus in this Implementation Report, Consent, Third-Party Custodian Law and Patient Engagement, address substantive solutions in need of immediate guidance or focus. These areas were identified as high priorities for participating stakeholders, including those currently planning and implementing HIE projects throughout the State. Thus, while each area will be integrated into larger planning efforts, this Implementation Report sets forth specific implementation plans for those three areas.

2.2 Implemented Solutions

Although no solutions have yet been fully implemented, on April 9, 2007, the New York State Department of Health (NYSDOH) Commissioner Richard F. Daines, M.D., announced the creation of an Office of Health Information Technology Transformation (OHITT) and appointed

Lori M. Evans[1] as a NYSDOH Deputy Commissioner in charge of this office. Under Ms. Evans leadership, OHITT will be responsible for leading State and private-sector efforts to improve health care quality, accountability and efficiency through widespread deployment of health IT. Staff will be hired to support the work of the Deputy Commissioner.

Additionally, it is anticipated that OHITT will have some responsibility for coordinating the State's substantial funding for health IT projects under the Health Care Efficiency and Affordability Law for New Yorkers (HEAL-NY) Capital Grant Program, as well as the evaluation of those projects in collaboration with the academic consortium known as the Health Information Technology Evaluation Collaborative (HITEC). OHITT will also collaborate with the State Medicaid Program and other NYSDOH programs on a variety of health IT initiatives. The work of NYHISPC will have an impact on HEAL grantees as they implement their projects.

As part of the overall operating budget, the Deputy Commissioner in charge of OHITT will have responsibility for money appropriated for the Health e-Links Program in the 2006 State budget (L. 2006, ch. 57, Part G). A total of $1.5 million has been appropriated (half last year and half this year) "to enhance the adoption of an interoperable regional health information exchange and technology infrastructure that will improve quality, reduce the cost of health care, ensure patient privacy and security, enhance public health reporting including bioterrorism surveillance and facilitate health care research." A portion of the appropriations will be used to continue the work of NYHISPC.

On January 11, 2007, NYSDOH sponsored a stakeholder conference entitled "Promoting Health, Protecting Privacy through Health Information Exchange" and invited HEAL-NY grantees as well as a broad range of health care providers across the continuum. This forum provided an opportunity not only to present the findings from the Assessment of Variations Report but to engage the participants in a practical discussion of Solutions. Experts from the field of information technology, including Alan Boucher from Intel and Nick Augustinos from Cisco were presenters. Representatives from NYSDOH offices of Information Systems, Medicaid and Legal Affairs also addressed issues of patient identification, security, access and consent.

In addition, the New York eHealth Collaborative, Inc. (NYeC) was established in 2006 to continue the work of the New York Health[2]IT Stakeholders Group Planning Committee, which was chaired by a representative from NYSDOH. NYeC held its first meeting in January 2007. The organization was founded, with a $100,000 grant from the United Hospital Fund, by health care leaders across the State based on a shared vision of the urgency to improve health care quality, safety and efficiency in New York, and specifically to foster coordination of health IT implementation efforts in support of that vision.

NYSDOH representatives also presented at a Health Information Exchange Summit for HEAL-NY grantees and other stakeholders sponsored by NYeC on March 16, 2007. The Medicaid Medical Director from the Office of Health Insurance Programs described the Medicaid Medication History Pilot currently underway with the New York City Department of Health and Mental Hygiene (NYCDOHMH), which would allow treating practitioners access to medication histories of Medicaid recipients via the eMedNY system. Other representatives from NYSDOH presented on legal issues relative to HIE consent. A representative from HITEC described preliminary results of organizational surveys conducted with each HEAL-NY grantee across the State.

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[1] Ms. Evans brings significant expertise to OHITT having served as Senior advisor to Dr. David Brailer, the nation's first National Coordinator of health IT as well as VP of the eHealth Initiative and Program Director for Connecting Communities for Better Health. She also has held leadership positions for regional health information organizations in California and New York. It is with this background that she will lead OHITT.

3.0 Review of State Implementation Planning Process

3.1 Implementation Planning Process and Organization

The implementation phase was led by NYHISPC's Steering Committee with support from the project team, and informed by the Legal Committee and HIE stakeholders from across the State. (Appendices A, B, C & D) Representatives from a broad range of organizations involved in New York State health IT activities attended the January 11th conference in Albany, NY, including many recipients of HEAL-NY grants. The conference held implementation workgroup sessions for five areas highlighted in the Solutions Phase of this project: Leadership, Accreditation Process, Patient Engagement, Patient Identification and Consent. The workgroup sessions focused on solution validation and prioritization, feasibility assessments and identification of actionable steps. Stakeholder input was collected from each workgroup and shaped the implementation plans presented in this Report. Additionally, a consumer workshop was led during a working lunch to further engage consumer advocate organizations about the benefits of HIE.

4.0 State-Level Implementation Plans

4.1 Statewide Strategy and Coordination

The implementation plans are organized around five major areas: Leadership, Accreditation Process, Consent, Third-Party Custodian Law and Patient Engagement. The Deputy Commissioner and the Advisory Body will coordinate and implement a Statewide strategy.

4.2 Implementation Plans for Identified Solutions

Detailed implementation plans are presented below for the identified areas referenced above. The State will continue to refine its implementation plans going forward and establish strategies for areas that have been identified previously but have not been addressed in this Report.

4.2.1 Leadership

4.2.1.1 Solution
The Commissioner of NYSDOH appointed the Deputy Commissioner in charge of the new Office of Health Information Technology Transformation (OHITT). The Commissioner may appoint an Advisory Body to convene stakeholders, make recommendations for aligning health information exchange (HIE) policies, identify best practices for HIEs, and provide technical, business practice and policy guidance.

4.2.1.2 Implementation Plan

1. Effective Practice Established or Barrier Eliminated
Until recently, the New York State health IT policy was expressed through grant funding. The State policy will now be implemented through the NYS Office of Health Information Technology Transformation (OHITT) with advice and recommendations from an Advisory Body comprised of public and private sector stakeholders appointed by the Commissioner of Health, Dr Richard Daines.   In November 2005, NYSDOH, as part of the HEAL-NY initiative, released a Request for Grant Applications worth approximately $53 million as a means of fostering the development of HIEs, electronic health records and electronic prescribing. The specific policy NYSDOH was fostering was the development of systems which could communicate with one another. The RGA requested multiple stakeholder participation with easy access to new membership so that regional systems rather that many individual systems would be developed. Grants were awarded to 26 grantees which were charged with using health IT/HIE to reduce costs and/or utilization, improve quality, promote interoperability and demonstrate financial viability and sustainability.

In October 2006, as part of the HEAL-NY initiative, a second Request for Grant Applications was issued for an additional almost $53 million. This RGA was to provide incentives to further the collaboration among regional HIEs, as well as electronic imaging and projects that focused on the creation of bi-directional public health information reporting. (The grant awards on this second RGA are to be announced shortly.) Despite the Department's grant programs, it is evident that providers and other stakeholders continue to struggle with the technical and legal issues involving consent, security, access and use of electronic medical information, and are looking for leadership from the State. Through the appointment of a Deputy Commissioner of NYSDOH in charge of OHITT, the State will provide that direction.

While the OHITT is organized and staffed, NYSDOH has been exchanging ideas and working with the New York eHealth Collaborative, Inc. (NYeC). NYeC, Inc., is a Type B corporation under the New York Not-for-Profit Law section 201. NYeC's mission is to galvanize health care systems improvements by promoting broad use of health IT. This report is recommending that NYeC study and provide recommendations in areas such as accreditation, security, authentication, data access and use. To ensure the integrity of its recommendations, NYeC should abide by appropriate conflict of interest rules.

It is essential to NYSDOH to evaluate the HEAL-NY projects but HEAL-NY funds can only be used for capital expenditures. Thus, HITEC was formed as an academic consortium (participating institutions include Cornell. Columbia and SUNY-Albany) to provide standardized metrics, tools and methodologies to monitor HEAL-NY projects and to quantify their financial, quality and safety impacts. HITEC has obtained a major foundation grant, as well as funding commitments from two health plans, to support its studies. NYSDOH intends to provide additional funds to support the work of HITEC.

In order to further assist the OHITT, the Commissioner of Health is considering appointing an Advisory Body comprised of public and private sector experts in the health IT field. This Advisory Body will provide advice and make recommendations to OHITT regarding issues relative to privacy and security, as well as, other health IT/HIE issues. In this way, NYSDOH would work with all stakeholders to utilize a public-private partnership model to promote health IT and HIE.

2. Planning Assumptions and Decisions

Short Term: NYSDOH recently appointed a Deputy Commissioner for the new Office of Health Information Technology Transformation (OHITT). That individual will also be the "state coordinator" of the "office of Health e-Links" for which the legislature has made appropriations. NYSDOH can contract with NYeC to provide specific deliverables that will continue the work of NYHISPC, as detailed below. Health e-Links funds will also be used to fund HITEC's evaluation of HEAL-NY Projects.

Long Term: The NYSDOH Commissioner may establish a permanent Advisory Body with an official role of making recommendations to the Deputy Commissioner in charge of OHITT. The State can contract as necessary for required services. OHITT will coordinate and facilitate a vast array of existing State health IT projects, including the HEAL-NY grant projects, as well as collaborate on Medicaid Program health IT initiatives.

3. Project Ownership and Decisions

The Deputy Commissioner in charge of OHITT will coordinate State health IT policy. NYeC will provide some consulting services to OHITT in the short term but is also expected to have private funding to work with health IT stakeholders on projects outside of NYSDOH's control. OHITT will collaborate with the NYSDOH Medicaid Program. The HEAL-NY grantees will contract with HITEC to evaluate their projects as required by their HEAL-NY grant contracts, and NYSDOH will provide some funding to subsidize the work of HITEC. The Commissioner of NYSDOH should appoint the Advisory Body to continue OHITT's public-private partnership.

4. & 5. Project Scope and Required Tasks/Work Breakdown Structure

The project scope is to provide guidance to HIEs in the following areas: (1) assessing data

access and use, authentication and security policies among existing HIEs that exchange patient information; and determining a common set of data access and use, authentication and security policies that address remedies for personal health information (PHI) breaches and data errors, appropriate role-based access rights and authentication and audit requirements; (2) make recommendations for a set of model policies and procedures for HIE data access and use, authentication and security; and (3) make recommendations on how to accredit organizations that perform HIE so that a law may be passed prohibiting non-accredited organizations from engaging in HIE.

6. Project Timeline/Milestones
The work noted above will be completed within 6–9 months. The NYSDOH Commissioner will make a decision regarding establishment of an Advisory Body within three months. However, the structure could be implemented in 2007.

7. Projected Cost/Resources Required
OHITT will develop a budget in accordance with its needs. A Health e-Links program budget of $1.5 million currently exists to support that work. Additional funds will be allocated for statewide health IT priorities.

8. Means for Tracking, Measuring & Reporting Success
- Create program goals and objectives and overall program plan. Regularly measure accomplishments against plan.   - Develop communication plan and regular reporting process   - Create escalation structure to identify and resolve priority issues as required.

9. Impact Assessment on All Stakeholders
Impacts all stakeholders involved in health IT and HIE initiatives

10. Feasibility Assessment
The Commissioner's creation of OHITT, which is dedicated to working on health IT and HIE issues and the expertise of the newly appointed Deputy Commissioner, is evidence of commitment to complete this work.

11. Barriers to Implementation
None

4.2.2 Accreditation Process

4.2.2.1 Solution

Establish an accreditation process for health information exchanges (HIEs) that provide minimum policies and standards for privacy and security solutions. A private entity could perform the accreditation but a State law would prohibit HIEs from operating without accreditation.

4.2.2.2 Implementation Plan

1. Effective Practice Established or Barrier Eliminated
Currently, the State holds the HEAL-NY grantees to standards through their grant contracts with DOH. Also, under 1902(a)(7) of the Social Security Act (42 USC § 1396a(a)(7)), a State Plan for medical assistance (Medicaid) must "provide safeguards which restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan." Also, under 42 CFR § 431.303, the "Medicaid agency must have authority to implement and enforce the provisions specified in federal regulations for safeguarding information about applicants and recipients." To ensure that NYSDOH only uses Medicaid data for purposes directly connected with the administration of the State Plan for Medicaid and to ensure the security of that data, the Medicaid program will only release the Medicaid data if the recipient executes a Data Exchange Application and Agreement (DEAA) that explains procedures

to protect the security of the data adequately.

Thus, the Medicaid Program is currently negotiating such a contract with the New York City Department of Health and Mental Hygiene (NYCDOHMH) as part of the Medicaid Medication History Pilot. NYCDOHMH intends to contract with eClinicalWorks to develop an electronic infrastructure that would allow treating practitioners to access the medication history of approximately 200,000 NYC Medicaid recipients via the State's eMedNY system. HIEs such as the Community Health EHR Exchange (CHEX) will be contractually required to adhere to specified technical policies and standards related to the security of Medicaid data. This partnership among NYSDOH, NYCDOHMH, eClinicalWorks and participating HIEs and providers promises to decrease duplicative prescriptions, improve medication compliance monitoring and improve patient safety.

Although NYSDOH can make its standards known to all HIEs in New York State (Appendix E), it is not practical in the long term for NYSDOH to enter into individual contracts to enforce the standards. Also, not all exchanges are or will be under contract with NYSDOH if the information being exchanged does not include Medicaid data.

Therefore, there is a need for a mandatory and uniform set of policies and standards for all HIEs in New York State which align with national standards set through the Health Information Technology Standards Panel (HITSP) and codified or expressed through the Certification Commission for Healthcare Information Technology (CCHIT). With respect to the accreditation process and criteria, alignment with the State Level HIE/RHIO Consensus project funded by the Office of the National Coordinator for Health IT is required.

2. Planning Assumptions and Decisions

There are no minimum standards for non HIPAA-covered entities engaged in the electronic exchange of health information. There is a need to establish standards for consistency and to meet expectations that privacy and security protocols are in place and are being followed.

Short Term:
1) The State will establish a set of minimum security standards for sharing Medicaid data received from the State that will be implemented through contractual relationships between the State and HIEs with which the State is exchanging Medicaid data. These standards will be consistent with federal standards for privacy and security and will be required for the exchange of all individually identifiable health data by such HIEs, not just Medicaid data. This is necessary for the continued protection in the disclosure and re-disclosure of Medicaid data. The goal is that these standards will eventually be incorporated into a set of minimum standards to which all those wishing to exchange electronic health information will be held.
2) NYeC will recommend to OHITT a process to accredit HIEs.

Long Term:
NYSDOH will develop, over a two-year period, a State-level accreditation process for HIEs, incorporating federal standards and creating State-level standards as a minimum for entities to engage in electronic HIE. A law would prohibit non-accredited entities from operating as HIEs. The Advisory Body will make recommendations on an ongoing basis with respect to accreditation issues. The Deputy Commissioner of the Office of Health Insurance Programs (OHIP), who is the state Medicaid Director, reserves the right to establish standards for the Medicaid program.

3. Project Ownership and Decisions

The Deputy Commissioner in charge of OHITT and the Deputy Commissioner in charge of OHIP will evaluate the recommendations submitted by NYeC for the accreditation process. NYSDOH will work with the Governor's office on a bill for consideration by the Legislature that would require HIEs to be accredited. It is anticipated that some private sector entity will conduct the accreditation process and inspect HIE conformance with the accreditation criteria.

4. Project Scope
The project scope includes a study of accreditation process and selection of accrediting body.

5. Required Tasks/Work Breakdown Structure

1) Establish minimum technical standards related to security of Medicaid data in an electronic HIE.
2) Publish standards for the benefit and knowledge of all HIE stakeholders.
3) Require all HIEs who will receive Medicaid data to agree under a contract with NYSDOH to comply with the technical standards for all data exchanged.
4) Require HEAL-NY grantees to agree under their grant contracts to comply with the technical standards as they are developed.
5) NYeC will research and identify models for accreditation with regard to the following issues:
   a) What entities should be accredited?
   b) What criteria should be part of the accreditation process?
   c) What entities currently exist which do accreditation in other areas, which may serve as the accreditation body for health IT?
   d) What is the organizational and governance structure and business model of the accreditation body?
   e) What is the public process for determining and vetting accreditation criteria?
   f) What is the mechanism for ensuring compliance with standards and process for ongoing compliance?
   g) What action should be taken for noncompliance?
   h) What additional benefits may accrue to entities which are accredited, such as government reimbursement for HIE operational costs? By analogy, some Medicare providers must be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
6) Pass legislation prohibiting any person or entity from engaging in HIE unless they are accredited.

6. Project Timeline/Milestones
Within 6 months - one year, recommendations for the accreditation process will be developed

7. Projected Cost/Resources Required
Resources from the Health e-Links budget will be used to complete this work. A business plan for the accrediting entity will be developed.

8. Means for Tracking, Measuring & Reporting Success
• Create program goals and objectives and overall program plan. Regularly measure accomplishments against plan. • Develop communication plan and regular reporting process • Create escalation structure to identify and resolve priority issues as required

9. Impact Assessment on All Stakeholders
Need stakeholder buy-in

10. Feasibility Assessment
There exists a number of models for an accreditation process in other areas of the health care system. It is expected that those models can be utilized in the accreditation process for HIEs.

11. Barriers to Implementation
Developing a model to ensure sustainability for funding accreditation may be a potential barrier.

4.2.3 Consent

4.2.3.1 Solution

Ensure that patients are able to make meaningful consent decisions about the disclosure of their health care information, and that custodians of health care information comply with patient consent mandates under State and federal law.

4.2.3.2 Implementation Plan

1. Effective Practice Established or Barrier Eliminated
Emerging HIE initiatives across the State are struggling to define what constitutes adequate and meaningful patient consent. Broad variation in opinion exists among stakeholders as to what is required legally, what is appropriate for risk management purposes, what constitutes the best public policy and what is feasible from an implementation perspective. How these various legal requirements and procedures are operationalized in an electronic environment is not yet clear. Nevertheless, some limited points of consensus exist. First, the disclosing provider is ultimately responsible for releasing information with appropriate consent. Second, under State law some form of consent is necessary for providers to disclose patient information to third parties, including other providers, even for treatment purposes. Third, stakeholders have different expectations and standards regarding consent when the exchange of health information is for purposes other than treatment. Beyond these broad outlines, diverse and often passionate opinions exist about what is legally required, what is good policy and what can be operationalized. There is an urgent need for guidance, as HIE projects and providers in New York are currently faced with creating the policies that will govern the consent within their projects. NYSDOH believes that a general consent plus notice of the HIE would be adequate to exchange health information that is not specially protected, but the patient must give specific consent for the HIE to exchange specially protected health information, unless an exception applies. This specific consent could be (a) obtained initially, prior to loading the information in the HIE, or (b) if the HIE's use of the data is controlled by the disclosing providers under the terms of an appropriate business associate agreement, obtained after loading but prior to a provider's request for access. Providers that did not obtain a specific consent at any point could access the information only if they were otherwise authorized by law to do so, e.g., in an emergency. However, it is important to note that other options may exist and remain under consideration by State officials and stakeholder projects around the State. Consent solutions are likely to evolve in the coming weeks and months as efforts to arrive at a recommendation that has the broad support of project participants and stakeholders continues. Consents obtained prior to loading would need to be durable until revoked. That is, the consent would need to be effective for repeated or ongoing disclosures.
2. Planning Assumptions and Decisions
Greater clarity is needed to ensure that patients have a willingness to disclose medical information via electronic HIE. Stakeholders need certainty and assurance that they are obeying the laws and regulations; stakeholders want to avoid unduly costly or burdensome procedures. *Short Term:* NYSDOH should clarify that general (not specially protected) identifiable medical information may be uploaded to an HIE and then shared for treatment purposes pursuant to a general release and notification, with an opt-in or opt-out process. NYSDOH should develop, in conjunction with other affected agencies, a universal consent form or language that includes specially protected health care information (HIV, mental health, substance abuse, genetic testing, venereal disease and abortion records) for use in electronic HIE. The State should clarify whether the combined consent form is sufficient for disclosure of sensitive information for treatment purposes. Also, the State should specifically clarify whether this form or language may provide an "all or nothing" consent to participation in the HIE without options that would require specially protected data to be categorized and sorted out of the HIE. *Long Term:* Create a new law governing patient consent for exchange of electronic health information in the context of an HIE, with the intent of protecting patient privacy, facilitating the

exchange of health information and reducing liability exposure for organizations that follow prescribed privacy and security procedures. One option that should be explored is allowing HIEs to load all information (sensitive and non-sensitive) into the exchange for treatment purposes so long as the patient has generally consented to the provider's use and disclosure of health information for the purpose of treatment. This approach might or might not require accessing providers to obtain a second consent to access information from the HIE and would require HIEs to monitor and routinely audit disclosures. While this approach may already be possible under existing law, a new law could clear up the ambiguity created by the variety of provisions now scattered throughout the New York State Public Health Law, Education Law, Mental Hygiene Law and Civil Rights Law, and various State regulations.

Also, continue to explore whether or not technology applications exist to feasibly allow the patient to restrict sensitive information and whether, if so restricted, physicians will chose to participate in HIEs exchanging varying content.

3. Project Ownership and Decisions
NYSDOH can interpret the Public Health Law. The New York State Office of Mental Health can interpret the Mental Hygiene Law. The New York State Office of the Attorney General can interpret the Civil Rights Law. Only the federal government can interpret 42 CFR Part 2. State agency interpretations of laws can be relied upon to constrain State government enforcement action, but only a new State law could provide complete protection from civil liability to private parties.

4. Project Scope
The project scope includes reviewing State and federal laws, and meeting with stakeholders and advocacy groups regarding appropriate policy.

5. Required Tasks/Work Breakdown Structure
- NYSDOH should take the lead in implementation of the guidance and revision of the single consent form in consultation with other State agencies, the Governor's office and, where necessary, federal officials. NYSDOH is charged with interpreting PHL § 17, PHL § 4410(2), PHL § 2803(1)(g), 10 NYCRR 405.7(b)(12), (13), 405.7(a)(1), 405.7(c)(13), PHL § 2803-c(3)(f), 10 NYCRR 415.3(d), PHL Article 27-F, 10 NYCRR §§ 63.1, 63.5(a). DOH OPMC enforces -- but may not issue guidance interpreting -- Education Law § 6530(23). DOH General Counsel may issue opinion letters, including a letter explaining how DOH would interpret or enforce Education Law § 6530(23) under a given set of factual circumstances. The NY OAG interprets Civil Rights Law § 79-l. The NY OMH interprets Mental Hygiene Law §§ 22.05, 33.13 and 33.16. Only the federal government can interpret HIPAA and 42 CFR Part 2.   - Guidance should be released by end of summer, 2007. In spring 2007, NYSDOH should develop the recommendation and vet it with other State agencies and interested parties. By end of summer 2007, the final recommendation should be approved for public release.   - NYSDOH should work with others to convene a working group of State and private sector experts, including representatives from the Consumer Advisory Committee (see Patient Engagement below), to explore options for a new law. This should be addressed in the next 1-3 months. The working group should submit recommendations to NYSDOH within 9-12 months.   - NYSDOH with the input of the Advisory Body should work with the legislature to generate model legislation for introduction in 2008.

6. Project Timeline/Milestones
See above.

7. Projected Cost/Resources Required
Legal resources in existing affected agencies.

8. Means for Tracking, Measuring & Reporting Success
• Create program goals and objectives and overall program plan. Regularly measure accomplishments against plan. • Develop communication plan and regular reporting process • Create escalation structure to identify and resolve priority issues as required • Success measured by passage of new law

9. Impact Assessment on All Stakeholders
The process in the passage of new legislation allows input from all stakeholders.

10. & 11. Feasibility Assessment & Barrier to Implementation
The primary challenge will be to develop a law that meets multiple, pressing and politically sensitive public policy goals. It will be important to ensure the law is feasible from a technical and business process perspective.

4.2.4 Third-Party Custodian Law

4.2.4.1 Solution
Establish a regulatory and policy framework for the development of personal health records (PHRs), maintained by third parties, which are not covered by State or federal law.

4.2.4.2 Implementation Plan

1. Effective Practice Established or Barrier Eliminated
A legal framework that governs third-party custodians is needed to foster the development and use of PHRs by consumers.

2. Planning Assumptions and Decisions
Consumers want the convenience of having all of their medical information from different providers in one place. As a proliferation of products in this area are being developed without knowledge of the risks, consumers may actually believe that these services are regulated or offers certain privacy protections when they may not. It is the expectation that entities providing such services to consumers would be bound by privacy and security standards. Without such protections, the market for PHRs outside HIPAA-covered entities will be limited due to legal uncertainty and consumers' privacy concerns. *Short term*: The Deputy Commissioner in charge of OHITT should convene diverse constituencies to develop a set of best practices to be adopted by third parties not covered by existing law that maintain and use PHRs on behalf of consumers. *Long Term*: Enact new law to regulate the use and disclosure of PHRs by third-party custodians of health information. Elements of the law may include: consumer access to their records in electronic form, consumer control over access and use of identifiable data, procedures for consumers to add and maintain their own health data, and remedies for breaches.

3. Project Ownership and Decisions
OHITT will evaluate the use and development of personal health records, medical records of patients in an electronic format from one or more providers held on behalf of patients by third party custodians. With recommendations from the consumer advisory committee and the Advisory Body, OHITT will determine whether legislation is needed to regulate third party custodians to protect the privacy and security of the information and to ensure that consumers have access to and control over the information.

4. Project Scope and Required Tasks/Work Breakdown Structure
• The Deputy Commissioner should convene diverse health care and consumer stakeholders to address the scope of State and federal law that applies to third-party custodians of PHRs. • The Deputy Commissioner should launch and lead a public education and outreach

campaign on the potential for PHRs to improve health care access and quality, and give people greater control in managing their own care. Outreach efforts should target individual consumers and their representative organizations (such as disability rights and disease groups), as well as health care providers, payers, employers, and others who may offer and use PHRs.

- The Deputy Commissioner, working with affiliated consumer groups, should develop materials and initiatives aimed at informing the public and policymakers about the benefits of PHRs—as well as the risks—with the goal of accelerating the demand for health IT.

5. Project Timeline/Milestones
Recommendations should be submitted in 2007. Legislation should be developed for consideration in 2008 legislative session.

6. Projected Cost/Resources Required
Resources need to be allocated for the development of consumer education materials to advise of the need for oversight of third party custodians.

7. Means for Tracking, Measuring & Reporting Success
Success will be determined based on the passage of legislation.

8 Impact Assessment on All Stakeholders, Feasibility Assessment and Barriers to Implementation
The early stage of market development presents challenges for developing legislation. If there is no national law, individual state laws may cause confusion or unwillingness to participate in New York. Therefore, it will be important to closely monitor this issue in other states and at the federal level to coordinate state action accordingly.

4.2.5 Patient Engagement

4.2.5.1 Solution
Support the right of patients to expeditiously access their own clinical health information, and to make choices about the collection, storage, use and disclosure of their data; and engage people in taking a more informed and active role in their own health care.

4.2.5.2 Implementation Plan

1. Effective Practice Established or Barrier Eliminated
Consumers need to be more fully informed of the risks and benefits of HIE. It will be difficult to implement HIE without a public education campaign and outreach effort to foster awareness of and support of health IT.

2. Planning Assumptions and Decisions
In order for individuals to better manage their health care, and ensure quality outcomes, they need to understand the benefits of health IT and HIE. The Deputy Commissioner in charge of OHITT will convene a coalition or workgroup of consumer and health advocacy groups to provide input on a range of issues concerning HIE to ensure that consumers are informed and engaged at the earliest stages of the policy and design process, and that consumers' interests are considered at the outset, as well as to safeguard against potential backlash and criticism. In addition, NYSDOH should undertake a significant public education role and outreach effort aimed at consumers to foster awareness of and support for health IT.

3. Project Ownership and Decisions
The Deputy Commissioner in charge of OHITT will be responsible for engaging consumers through education and outreach. The Advisory Body and a consumer advisory committee may make recommendations to NYSDOH. Other resources within NYSDOH will be utilized to support

this work.

4. Project Scope
The scope of the project will include public outreach, consumer education and improved communication.

5. Required Tasks/Work Breakdown Structure
The required tasks include: • Convene a Consumer Advisory Committee comprised of a range of groups from around New York State. • Develop materials for consumer organizations and their constituents on the benefits and risks of health IT, encouraging greater public engagement in policymaking and spurring adoption of health IT. • Organize workshops for consumers on the benefits and risks of health IT, providing groups with resources to more actively engage in policymaking initiatives, the crafting of best practices and other opportunities to provide input. • Work with other State agencies such as Office of the Aging to collaborate with meetings already scheduled with consumers. • Create a communications and outreach network aimed at consumer and health care groups, which may include a website, materials, a listserv, and briefings.

6. Project Timeline/Milestones
Deputy Commissioner in charge of OHITT will convene a consumer advisory committee within 90 days. The group will convene bimonthly via teleconference with at least one meeting a year held regionally upstate and downstate.

7. Projected Cost/Resources Required
DOH will host an annual meeting. Organizations must allocate resources to attend but most meetings will be conducted via teleconferencing.

8. Means for Tracking, Measuring & Reporting Success
An annual report will be prepared outlining materials prepared and disseminated, workshops convened, participating organizations, identification of consumer needs and recommendations for revisions to or development of new public policy.

9. Impact Assessment on All Stakeholders
The group will assess the extent to which its efforts reach a broad constituency of State residents, including underserved populations and those in rural areas.

10. Feasibility Assessment and Barriers to Implementation
In order to ensure success, it is important to involve appropriate experts and a broad and diverse consumer constituency, and dedicate enough resources to support the efforts of this group.

5.0 Multi-State Implementation Plans

5.1 Multi-State Strategy and Coordination

NYSDOH and the NJ Department of Banking and Insurance will be working together to explore the creation of a patient identification model in the metropolitan NYC area. The initial strategy is

to begin with the Medicaid and Public Health reporting systems where unique identifiers may already exist. Both states have projects underway to harmonize those systems within their respective states and will use that as the foundation for a coordinated approach between the two states.

Additionally, the NJ Department of Human Services was the recipient of a Medicaid Transformation grant from CMS. The NJ Department of Banking and Insurance was asked to participate relative to privacy and security issues and invited NYSDOH to help create one single electronic health record for Medicaid covered children that will be interoperable over state lines.

New York will pursue working with Massachusetts on a consent protocol based on the pilot being conducted in the North Adams Community. Additionally, New York will pursue a collaboration with the Massachusetts State Medicaid program to develop an interoperability platform for electronic prescribing, utilizing existing technologies and extending their capabilities to include programs such as preferred drug programs, quality care measures, error rate reduction, benefits integrity, privacy, and consent management. The project will also advance progress towards a Northeast (regional) electronic prescription solution.

5.2 Implementation Plans for Identified Solutions

1. Effective Practice Established or Barrier Eliminated
The effective practice to be established is a patient identification system beginning in the metropolitan NYC region, which will serve as a model for the State and coordination with other neighboring states.

2. Planning Assumptions and Decisions
There is a willingness on the part of both states' Medicaid and Public Health Offices to begin the foundation discussions.

3. Project Ownership and Decisions
OHITT will coordinate the efforts of NYSDOH which will bring together the Office of Health Insurance Programs (OHIP), the Center for Community Health (CCH) and the Office of Information Systems.

4. Project Scope
The project scope includes the foundational discussions for the creation of a metropolitan area patient match system and also to harmonize the public health electronic reporting registries that currently exist separately in New York and New Jersey so that each system will synchronize between the two states. A second part of the project is to create one single Electronic Health Record for Medicaid covered children that will be interoperable over state lines.

5. Required Tasks/Work Breakdown Structure
A planning telephone conference was held on April 10, 2007 with another call scheduled for April 30, 2007. A meeting of stakeholders and various state offices and agencies from New York and New Jersey will be held in NYC on May 22, 2007.

6. Project Timeline/Milestones
It is expected that consensus on a patient match model will be reached within a year and a pilot for use in one region will begin after that.

7. Projected Cost/Resources Required
Staff will be dedicated in OHITT and OHIP to attend meetings for further discussion. DOH is seeking resources dedicated to the harmonization of registries within DOH including registries for Congenital Malformation, Newborn Screening, Early Intervention, Immunization and Lead.

8. Means for Tracking, Measuring & Reporting Success
A workgroup of staff from all Registries already exists. Program goals and objectives are being

developed. A communication plan and a regular reporting process will be created. A system for identifying and resolving priority issues will be developed.

9. Impact Assessment on All Stakeholders
A survey will be conducted through the Health Providers Network, an electronic reporting system developed for emergency preparedness, which has capacity to disseminate surveys regarding issues related to patient match and public health reporting.

10. Feasibility Assessment
Previously, NYSDOH had developed a system to harmonize information for the pediatric population. The Integrated Child Health Information System (ICHIS) was put on hold due to problems in funding. There is interest in reactivating the system with participation from the Medicaid Program.

11. Barriers to Implementation
There are strong feelings for and against a Master Patient Index. Some privacy advocates prefer a probabilistic approach which relies on unifying several sources of demographic information rather than a unique identifier. Continued study will be needed to reach consensus.

6.0 National-Level Recommendations

The NY HISPC team has identified certain solutions that would benefit from being implemented at a national level, including:

- Develop and implement model consent forms for loading information (routine and/or specially protected information) into an HIE.
- Develop and implement model consent forms for disclosing Medicare information to and from an HIE.
- Clarify the applicability of 42 CFR Part 2 in connection with the inclusion of patient information regarding alcohol and drug use in an HIE.
- Consider an exception in the 42 CFR Part 2 regulations regarding that when a person gives his/her consent to disclose their information "to a provider for treatment purposes," this operates to disclose any and all information to a treating provider accessing the HIE—not only access to a subset of the patient's information which might be determined to be necessary to treat the particular condition/illness. Potential reconsideration by the federal government of the need for a prohibition on re-disclosure statements for each disclosure a HIE/provider makes in the context of an HIE. Possibly a single statement to this effect when a provider first signs on might be acceptable. The rationale is that if the statement is made routinely, no one will pay attention to it.
- New York State is seeking assurance that an electronic health record which is released to an out-of-state provider receives the same high level of protection that exists if that electronic record were exchanged in New York. It appears to be the sentiment nationwide that consumers want to be given the choice to consent on a specific basis to the disclosure of sensitive medical information, even for purposes of treatment, as is required in New York. New York State expects that any national guidance on this topic will maintain New York's standard. New Yorkers would be reticent to share their information in an electronic exchange if the information would be subject to less protection.
- Discuss further a comprehensive consent to participate in an HIE encompassing various categories of protected information with or without separate check-off opportunities for specific, sensitive types of information. A national model form created by the federal government will assist states and expedite the flow of information among states.
- Develop and implement federal level standards for third party custodians of PHRs that are not HIPAA-covered entities.

Appendices

Appendix A: Steering Committee

Gus Birkhead, M.D.	Director, AIDS Inst. & Center for Community Health
Rick Cotton	VP & General Counsel, NBC Universal Inc.
James Figge, M.D., MBA	Medical Director, Office of Health Insurance Programs
Lisa Wickens	Asst. Director, Office of Health Systems Management
Tom Quinn	CEO, Community General Hospital
Philip Gioia, M.D.	Medical Society of the State of New York (MSSNY)
Michael Caldwell, M.D.	Commissioner of Health, Dutchess County
Wilfredo Lopez	General Counsel Emeritus and Consultant, New York City Dept. of Health & Mental Hygiene
Katie O'Neill	Senior VP & HIV/AIDS Projects Dir., Legal Action Center
Tom Buckley	CEO, Visiting Nurse Association of Albany
John Rugge, M.D.	Hudson Headwaters Health Network
Harriet Pearson	VP Corporate Affairs & Chief Privacy Officer, IBM
Laray Brown	Senior VP, NYC Health & Hospitals
William Cromie	President & CEO, Capital District Physicians' Health Plan
Fred Cohen, Esq.	Senior VP and General Counsel, Independent Health
Bridget Gallagher	Senior VP, Jewish Home & Hospital Lifecare System

Appendix B: Project Team

New York State Department of Health

Jessica Kleinberg, Assistant Director, OSP	Contract Administrator
Bill Schroth, Chairman, NYS HIT Work Group	Project Director
Ellen Flink, Director of Research Patient Safety & Quality	Project Manager
Jean Quarrier, Deputy Director, Bureau of House Counsel	Team Member
Anna Colello, Director, Regulatory Affairs	Team Member
Jonathan Karmel, Associate Counsel	Team Member
Perry Smith, Director, Division of Epidemiology	Team Member
James Miller, Bioterrorism Epidemiology Coordinator	Team Member
Ivan Gotham, Director, HEALTHCOM Ntwk Sys Mgmt	Team Member
Theodore Hagelin, Director	Team Member
Robert Barnett, Director	Team Member
Debra Betor, Secretary	Project Support
Marilyn Soucy, Secretary	Project Support

Manatt, Phelps and Phillips

William Bernstein, Partner & Co-Chair, Government & Regulatory Division	Project Director
Melinda Dutton, Partner	Team Member

Manatt Health Solutions

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Susannah D'Oench, Consultant	Project Support

Columbia University

Janlori Goldman, Research Scholar	Project Director
Sydney Kinnear, Research Assistant	Project Support

Appendix C: Legal Committee

Robert Belfort	Manatt, Phelps & Phillips, LLP
William Bernstein	Manatt, Phelps & Phillips, LLP
Deborah A. Brown	Greater New York Hospital Association
Anna Colello	New York State Department of Health
Melinda Dutton	Manatt, Phelps & Phillips, LLP
Janlori Goldman	Columbia College of Physicians & Surgeons
Jonathan Karmel	New York State Department of Health
Wilfredo Lopez	New York City Department of Health & Mental Hygiene (retired 12/22/06)
Anne Maltz, RN	Herrick, Feinstein LLP
Donald Moy	Medical Society of the State of New York
Katie O'Neill	Legal Action Center
Jean Orzech Quarrier	New York State Department of Health
Sarah D. Strum	Catholic Health Care System
Robert N. Swidler	Northeast Health

Appendix D: Implementation Workgroup

Carol Allocco	Johnson & Johnson
Nick Augustinos	Cisco
Ellen Bagley	NYSHFA
Chris Baldwin	Northeast Health
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Patricia Beato	University of Rochester Medical Center
Maryam Behta	New York Presbyterian Hospital
Beverly Benno	Eden Park Health Care Center
Jo Berger	NYSDOH
Bill Birnbaum	Unlimited Care, Inc.
Erin Blakeborough	New York Association of Health Care Providers, Inc.
Rachel Block	United Hospital Fund
Maura Bluestone	Affinity Health Plan
Jim Botta	NYS DOH- Medicaid
Alan Boucher	Intel
Tammy Breault	Seton Health System
Deborah Brown	GNYHA
Julie Brucker	Saratoga Hospital
Thomas Buckley	VNA of Albany, Inc.
Michael Burgess	New York State Alliance for Retired Americans
Ann Burnett	NYSDOH - AIDS Institute & Uninsured Care Programs
Rachel Burwell	Cerebral Palsy of the North Country
Blair Butterfield	GE Healthcare
Thomas Carpenter	Affinity Health Plan
Diane Carroll	
Scott Casler	North Country Children's Clinic
John Cauvel	Lifetime Care
C. Lynn Chevalier	Next Wave Inc
Nicholas Christiano	Health Quest
Elizabeth Cole	Greene County Public Health Nursing Service
Ellen Cooper	Executive Woods Ambulatory Surgery Center
Rick Cotton	NBC Universal, Inc
William Cromie	CDPHP
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Gregory Dobkins	NYSDOH
Maryann Dubai	Rome Memorial Hospital
Heather Duell	NYSDOH AIDS Institute
Kathleen Duffett	Kathleen Duffett, RN, JD, Attorney at Law
Kevin Dumes	Syracuse University
Craig Duncan	NYeC Board Member
Tom Ellerson	Lourdes Hospital
Simminate Ennever	Stony Brook University Medical Center
Lori Evans	Manatt Health Solutions
Donna Farago	Our Lady of Mercy Medical Center
Debra Feinberg	NYSCHP
James Figge	NYSDOH - Office of Health Insurance Programs
Carol Furchak	Crystal Run Healthcare
Christina Galanis	Southern Tier HealthLink
Beth Gallo	Waiting Room Solutions
Jim Garnham	GRIPA
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Ken Harris	NYAHSA - The Center
Martin Hickey	Excellus BC/BS
Jeffrey Hirsch	Waiting Room Solutions
Susan Huntington	Glens Falls Hospital
Matthew Jarman	American Red Cross
Robin Jones	CMIp
Annette Kahler	Albany Law School
Mary Kenna	Group Health Incorporated
Brett Kessler	Bellevue Woman's Hospital
Al Kinel	Kodak
Irene Koch	Maimonides Medical Center
Susan Koppenhaver	Eden Park Health Care Center
Ted Kremer, MPH	Greater Rochester RHIO

Franklin Laufer	NYSDOH - AIDS Institute
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Arthur Levin	Center for Medical Consumers
Liz Lonergan	Syracuse University College of Law
Joseph Lurin	Group Health Incorporated
Monica Mahaffey	Visiting Nurse Regional Health Care System of Brooklyn
Anthony Mancuso	Maimonides Medcial Center
Glenn Martin	Queens Health Network
Aileen Martin	North Country Children's Clinic
Roberto Martinez, MD	CDPHP
Joseph Martucci	NYS Office of Cyber Security
Mary Ann McGriel	Castle Senior Living at Forest Hills
David McNally	AARP
John Mills	HIP Health Plan
George Mina, Jr.	Canton-Potsdam Hospital
Lanetta Moore	Phase:PiggyBack,Inc.
Farzad Mostashari	New York City Department of Health and Mental Hygiene
Betsy Mulvey	NYHPA
Debra Mussen	CVPH Medical Center
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Carla Novak	Healthcare Association of NYS
Jeong Oh	Syracuse University
Renee Olmsted	Oneida Healthcare Center
Katie O'Neill	Legal Action Center
Michael Oppenheim	North Shore LIJ Health System
Johannes Peeters	Tioga County Health Department
Joe Phillips	Aurelia Osborn Fox Memorial Hospital
Scott Pidgeon	Palladia, Inc.
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Laurie Radler	Montefiore Medical Center
Carol Raphael	Visiting Nurse Service of New York
Rita Reynolds	Memorial Hospital
Cindy Richards	Northeast Health
Salvatore Russo	NYC Health & Hospitals Corporation
John Shaw	Next Wave Inc.
Ben Smith	Greater Rochester IPA
Robin Smith	ARCHIE:Adirondack Regional Community Health Information Exchange
Joseph Sorrenti	Interfaith Medical Center
Keith Stack	Alcoholism and Substance Abuse Providers of NYS
Susan Stuard	New York Presbyterian Hospital
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Deborah Tokos	United Health Services
Asha Upadhyay	THINC RHIO, Inc.
Teresa Yennan	Baptist Health
Daniel Walden	Medco Health Solutions
Mary Welch	Trudeau Health Systems
Robert Westlake, Jr MD	NY Chapter, American College of Physicians
John White	Our Lady Of Lourdes Hospital
Dianne Wilson	American Red Cross, New York-Penn Region
Lynn-Marie Wozniak	Next Wave

Appendix E: Security Requirements for the Medicaid Data Sharing Pilot with NYC

1. Technical Standards for the Physician's Office

- CCHIT Certified EHR (2006 standards), including user and/or role-based security access privileges, audit records, authentication, data backups, disaster recovery;
- Protection against malicious software (malware/spyware) - the physician's office must present documentation of an active software license with an appropriate vendor covering the time-frame of the pilot program;
- Security certificate to be issued by the State's fiscal agent.

2. Technical Security Standards for Transmission of Protected Medicaid Data via the Internet or Other Open Networks

- Web services interoperability model, conforming to the National Institute of Standards and Technology - Federal Information Processing Standards (NIST-FIPS). Features include:
    - Virtual Private Network (VPN) with tunneling and/or https:// protocol;
    - Triple-DES encryption (*)
    - Hashing algorithm for message authentication (e.g., HMAC {FIPS 198}).

* Advanced Encryption Standard (AES) also acceptable.

3. Physical Security

- Safeguards against unauthorized physical access.