HIT Report

New Jersey Health Information Technology Commission and The Office for Electronic Health Information Technology Development, Implementation and Deployment

Joint Interim Report

July 2010

Chris Christie
Governor

Kim Guadagno
Lt. Governor

New Jersey
Health Information
Technology Commission

Preface

The Health Information Technology Commission, in collaboration with the Office for e-HIT Development, is statutorily obligated to submit an Interim Report to the Governor and the Legislature. The material in this report reflects the continued work in the priority areas of the New Jersey Health Information Technology Commission as determined by the Commission members with input from the Office for Electronic Health Information Technology (e-HIT) Development and the rapidly-changing national landscape of health IT.

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Executive Summary

The Health Information Technology Commission was formed by the "New Jersey Health Information Technology Act," signed into law by Governor Corzine in January, 2008. (A4044/S2728; PL 2007, Chapter 330). Under the law, the Commission and the Office for e-HIT Development in the Department of Banking and Insurance are responsible for collaborating to "develop, implement, and oversee the operation of a Statewide Health Information Technology Plan."

The Commission is composed of key leaders from the private and public sectors representing the variety of services that compose the New Jersey Healthcare environment. The Commission held its first full meeting in December 2008.

In July, 2009 the Commission realigned its effort in order to respond to the American Recovery and Reinvestment Act of 2009 (ARRA), which contains funding under Part 3010 for the establishment of interoperable systems for Health Information Exchange (HIE). Working with leaders throughout the state, New Jersey submitted a proposal to create four regional health exchanges, for which we received approval in March 2010, resulting in a notice of grant award for $11.4 million.

Also in July, 2009 the Commission voted to form three Committees to develop and track recommendations regarding the important areas of emphasis for the state: Implementation, Policy, and Technology. Each of these committees has completed its first phase and made preliminary recommendations to the full Commission. Efforts to further delineate and refine the recommendations are currently under way. The Commission has also synthesized a variety of reports from both the private and public sectors to better define the healthcare landscape and needs of the residents of New Jersey.

The Health Information Technology Commission, in collaboration with the Office for e-HIT Development, is statutorily obligated to submit this Interim Report to the Governor and the Legislature "concerning its activities and the status of, and actions taken regarding development, implementation, and oversight of the statewide health information technology plan." The material in this report reflects the continued work in the priority areas of the New Jersey Health Information Technology Commission as determined by the Commission members with material contribution from the Office for e-HIT Development and the rapidly-changing national landscape of health IT.

Over the past year and a half, the NJHITC has collected, reviewed and integrated a variety of reports and plans in existence throughout the state including the *Rutgers HIT Landscape Report* commissioned by the Office for e-HIT Development assessing the current state of electronic healthcare information systems, and the *Regional Health Exchange Feasibility Study and Model* for creating a state wide HIE commissioned by the New Jersey Hospital Association. The NJHITC addressed the issues pertinent to emergency preparedness through a review of Hippocrates, New Jersey's state of the art, real-time, electronically integrated emergency preparedness response system program. The NJHITC and Office for e-HIT Development also reviewed the New Jersey Department of Health and Senior Services' plan to rollout technology to Federally Qualified Health Centers, the meaningful use criteria defined by ARRA HITECH regulations, and plans to create an interstate immunization registry with New York and Pennsylvania.

These projects serve as a background for the overall statewide plan. In addition the Commission and the Office for e-HIT Development worked with the Camden Coalition to explore process improvements in health quality and cost savings in underserved urban communities through robust health data collection. The subcommittee on Policy ran a public forum and synthesized a manual of privacy policy needs and recommendations, as well as completed a preliminary analysis of Selected New Jersey Confidentiality and Patient Approval Regulations attached to this Report as Appendix D.

The Implementation subcommittee assembled sound recommendations for the implementation of technology in physician offices and outlined best practices for implementing health information

technology. The Technology subcommittee formed recommendations for standards and infrastructure which are the groundwork for moving the plan forward.

All of this effort afforded the Commission the opportunity to contribute to the ARRA grant funding effort, and facilitate attainment of the grant award by the State of New Jersey.

As we move forward, the Commission subcommittees will further develop recommendations and advance the statewide HIT plan along with the guidelines offered by our federal partners. To encourage continued progress, the Commission will maintain focus on the following foundations for success:

Foster the quality of care

Protect the privacy of individual health information

Ensure the accuracy of health data

Encourage innovation

Incorporate all healthcare related entities

Introduction and Report Scope

The acquisition and deployment of Health Information Technology (HIT) and Health Information Exchange (HIE) throughout the healthcare system(s) in New Jersey offer a momentous opportunity to make substantial progress in improving the health of our citizens. The direct benefits include: improved patient safety and healthcare quality, enhanced public health, healthcare cost reduction, improved access to care, and greater consumer engagement and empowerment. It is vitally important that the State of New Jersey have a strategic vision for both the implementation of information technology and a system of connectivity that will provide for the free exchange of information among providers throughout the state. Health IT is a pillar of our healthcare system—and will be increasingly central to health-care reform.

This Interim Report provides a landscape summary of health IT, a description of long-term goals, initiatives undertaken to date regarding the state plan and its implementation -- including the state's successful ARRA grant application -- and recommendations to help achieve those goals. Working with other state agencies, on Oct. 16, 2009 the Commission submitted to the federal Department of Health and Human Services a State Plan in conjunction with a grant opportunity through the American Recovery and Reinvestment Act for the creation of a statewide Health Information Exchange (HIE). The HIE is one component for a state-based model of digital healthcare. The detailed State Plan is available at the Commission's web site: http://www.nj.gov/health/bc/hitc.shtml.

Our ARRA grant submission was approved for the "Strategic" aspects of our State Health IT Plan and as a result, the State received a notice of grant award in the total amount of $11.4 million. The State has received $1 million of the total award for planning activities, but as with 48 other states, the federal agency is requiring that the State Plan be in full compliance with all requirements before the remaining "Implementation" funds are released. This will require that certain points in the State Plan be modified or clarified, as described below.

This interim report represents a review of a process that will continue to evolve over time. Thus, it is both a “look back” and a projection of “future activity.” The transformation of the healthcare system in New Jersey from a paper based health care environment to a digital health care environment is complex and will require collaboration across multiple parties with potential conflicting interests. It is our belief however that working together with public and private parties the State can sustain the effort to accomplish the transformation and provide access to reliable health care information that improves the quality and efficiency of care.

Working with the Office for e-HIT Development, and the Division of Medical Assistance and Health Services, the New Jersey Health Information Technology Commission (NJHITC) is addressing a broad scope of critical components and workflows in building the blueprint of a statewide health information technology network. These two entities continue to plan a strategy to deploy electronic health records in physician offices, federally qualified health centers, long term care facilities, hospitals, home health agencies, and other health care delivery settings and connect them electronically to laboratories, pharmacies, state registries, and payers. The Commission also recognizes the valuable role technology will play to enable the optimal use of health care data for clinical research, to improve public health outcomes, and to improve the process and outcomes of patient care in New Jersey.

This report focuses on the opportunities and challenges to clinical data exchange at the community and state level and to the adoption of HIT. The American Recovery and Reinvestment Act's HITECH provision and subsequent funding programs prompted the NJHITC and Office for e-HIT Development to focus their attention on developing a plan for health information exchange so that the State of New Jersey could procure the maximum funding for such activities allowed by federal legislation. The Health Information Exchange is the cornerstone of an overall statewide plan but is not the only aspect of the plan that the NJHITC and the Office for e-HIT Development are working on. It is the intent of the two entities to issue interim reports on an 'as needed' basis to inform the

Governor and the Legislature of the State of New Jersey of the ongoing progress to achieve the vision of a statewide HIE and other aspects of the health IT plan.

Accomplishments

The following table provides a list of recent Health Information Technology (HIT) accomplishments by the State of New Jersey. These accomplishments contribute to the state's overall HIT program vision, a foundation upon which the state's health information program will be built and transformed to enable the exchange of Electronic Health Records (EHRs) and improve health outcomes statewide.

The HIT accomplishments table is divided into six focus sections that represent key foundational areas necessary to build a successful statewide HIT program. They are as follows:

- Organization and Governance – This area addresses recent organizational changes and project governance now in place to lead and govern HIT for the state.
- Transformation Planning – This section provides further details on the plans and funding that has been secured to initiate HIT planning activities and supplement HIE technology infrastructure needs.
- Technology and Business Transformation – This area includes several major in-process initiatives to support federal directives to address HIPAA compliance and other major improvements.
- Health Information Exchanges – This area lists all active New Jersey HIEs that have been established, each addressing their specific geography and local patient and physician needs.
- Implementation and Transformation Support – This section includes accomplishments to support HIT implementation and sustain program efforts going forward.
- National Involvement – This section includes communication and coordination of activities with other states, participation in national events to share and exchange HIT related best practices and lessons learned.

HEALTH INFORMATION TECHNOLOGY		
Focus	**Initiative**	**Accomplishment**
Organization & Governance	HIT Commission	The HIT Commission established four subcommittees to focus on core areas of HIT implementation and provide recommendations as the state moves forward with its HIT strategy. • Policy (including Privacy issues) • Implementation • Technical Infrastructure
	HIT Medicaid Strategy & Health Care Reform Focus	The State has recognized the importance of Medicaid in the overall State HIT program as well as the need to embrace healthcare reform in the state's HIT vision and strategy planning. A new Executive Director role has been created within the Department of Human Services to focus specifically on the Medicaid State HIT Plan (SMHP) and analyze recent healthcare reform impact on the overall HIT program. The Executive Director will work in close coordination with the State's HIT Leader.
	HIT Leadership	The State has recently created an HIT office and Leader position as part of the Governor's office. This role will have the responsibility of directing and coordinating all HIT activities across the state. A statewide governance structure will be established and this new office will work in conjunction with the Office for e-HIT within the Department of Banking and Insurance and the HIT Commission.
	Electronic Data Sharing Agreements	Nationally recognized and accepted standard electronic data share agreements were developed and put in place between states. This was endorsed by the National Coordinator for Health IT, CDC and the American Immunization Registry Exchange.
	Accreditation Requirements to Protect Citizen Health Information	DOBI and Office for e-HIT now requires the accreditation of national healthcare clearinghouses, third party billers and third party administrators handling any New Jersey protected health information as to HIPAA and State privacy and security laws, regulations and business practices.

HEALTH INFORMATION TECHNOLOGY		
Focus	**Initiative**	**Accomplishment**
		This will ensure that the protected health information of our citizens is safe and secure.
Transformation Planning	NJ State HIT Plan	The state submitted a statewide planning and implementation plan to the Office of the National Coordinator in response to funds available through the American Recovery and Reconciliation Act. The plan effectively established a foundation that leverages 4 Regional Health Information Exchanges, covering the entire state that would implement electronic health records with a 'bottom-up' approach. The plan also uses Medicaid as a key partner and leverages CMS funding to build the infrastructure for statewide HIE.
	State Medicaid HIT Plan	The State Medicaid HIT Plan (SMHP) establishes the road map for how the Medicaid agency will promote the use of HIT and electronic health records (EHRs) among Medicaid providers. The first phase of this project is nearing completion, with the delivery of a current landscape assessment, and will be followed by the development of a vision and a set of strategies to drive the road map. The landscape assessment is a current view of New Jersey's HIT maturity and will also be leveraged to develop a statewide HIT vision and plan.
	Funding Received - Planning	The state received $4.92M from Centers for Medicare and Medicaid Services (CMS) to support the State Medicaid HIT Planning (SMHP) effort.
	Funding Received – HIEs	The state received $11.4M from the Office of National Coordinator (ONC) for HIT to support four approved regional HIEs.
	Funding Received – Regional Extension Center (REC)	NJIT received more than $23M from ONC to support REC planning and initial implementation support including awareness, training and education. The newly formed REC is called NJ-HITEC, New Jersey Health Information Technology Extension Center.
Technology &	Master Patient Index	This project (started in March 2010) will enable the New Jersey Division of

HEALTH INFORMATION TECHNOLOGY		
Focus	**Initiative**	**Accomplishment**
Business Transformation		Medical Assistance & Health Services (DMAHS) to reliably and accurately maintain a single unique beneficiary identity within the Medicaid enterprise, while also linking Medicaid beneficiary records across various information systems. This will promote the critical interoperable exchange of Medicaid, Immunization and Blood Lead Screening databases among New Jersey's departments of Health and Senior Services and Children and Families, Managed Care Organizations, FQHC Providers, Hospitals and the Department of Human Services.
	Immunization Registry Data Exchange	Electronic exchanges of immunization registry data between States lead by the Office for e-HIT between NJ and many other states. This has become the model for a national public health registry data exchange that is being established by the various Regional Extension Centers (RECs) around the country.
Health Information Exchanges (*Current ONC funded HIE's)	Camden Coalition*	Implementing the HIE infrastructure enables the exchange of health information among the health care organizations and encourages improved efficiency and quality of care. Several HIE's within New Jersey are in various stages of implementation. Significant accomplishments have been made over the last year including four of the HIEs receiving funding from ONC (indicated by the *). A Roadmap for Statewide Implementation was submitted to the Office of the National Coordinator in May 2010.
	Health-e-ciTi*	
	Northern & Central HIE*	
	South Jersey HIE*	
	Clara Maass	
	Central Jersey HIE	
	MOHIE	
	Trenton HIE	
	Virtua HIE	
	Mid-Atlantic States - HIE	NJ e-HIT has established, at the request of ONC, a preliminary mid-Atlantic states health information exchange involving NJ, NY, PA, DE, MD, DC and VA.

HEALTH INFORMATION TECHNOLOGY		
Focus	**Initiative**	**Accomplishment**
Implementation & Transformation Support	Sharing Medication History	NJ Medicaid began sharing medication history data with the Health-e-ciTi HIE in March 2010.
	Regional Extension Center (REC)	NJ-HITEC will support HIT implementation throughout the state including HIT related awareness, training and education. William O'Byrne, former State Coordinator, Office for Electronic Health Information Technology Development, has since retired from the state and has become the REC Executive Director.
	Stakeholder Analysis	Excluding patients, there are more than 100,000 entities in New Jersey who are potentially involved, influence, or are impacted by HIT. It is critical to understand the stakeholder involvement and impact throughout the planning and implementation of the HIT program. The goal of the stakeholder analysis is to provide a strategic view of the human and institutional landscape, and the relationships between the different stakeholders and the issues they care about most.
National Involvement	Multi-State Collaborative	New Jersey has been an active participant in multi-state calls sponsored by CMS to share and exchange HIT best practices, lessons learned, etc. New Jersey is also planning its own multi-state collaboration event with participation from 2-3 nearby CMS regions to further exchange and share information.
	MMIS 2010 National Conference	State of New Jersey is participating and presenting on several topics related to HIT, HIE and SMHP at the 2010 MMIS National Conference in Portland Oregon, mid August.

Challenges and Opportunities

This is an interim report and as a result the proposed solutions are still a work in progress. Because the joint work groups of the NJHITC and Office for e-HIT Development continue to meet to further develop and refine their recommendations, this report can only note the activities completed thus far and describe the planned activities required to fully develop solutions and assess their feasibility.

Of significant note is a challenge we confronted early on during the planning phase, namely a lack of clear decision-making authority with respect to implementing health information technology at the state-government level and participation by the full range of stakeholders. We had consistent, but limited participation of certain stakeholders throughout our work meetings with a very strong contingent of health care sectors and representatives of medical association's state government and provider groups. As a mitigation tactic, the NJHITC scheduled specific meetings with key stakeholder groups, to facilitate both knowledge transfer and consensus; some of which have already occurred, and some of which are part of our projected activity. Without clear leadership proposed solution prioritization is a challenge. We are pleased to report the Governor's office has appointed a State coordinator who can lead this process.

The NJHITC and Office for e-HIT Development shall continue to pursue the study of various governance models that facilitate financial sustainability. Upon finding the optimum solution, the NJHITC shall recommend to the Governor and Legislature various governance models coupled with models of financial sustainability that will effectively underwrite the costs of an interoperable statewide health information network

Advances in information technology systems have dramatically altered the world in which we live. Significantly large resource investments, both public and private, make it virtually impossible to carry out the activities of daily living without utilizing some form of automation. The healthcare industry has traditionally been cautious to take advantage of new technology on a broad scale. Only a small

percentage of healthcare providers have successfully integrated information technology into their own practices. Even fewer have connected their systems with other providers in any meaningful way to improve care coordination and exchange of health information. Consequently most medical records remain paper based, and the vast majority of providers provide ambulatory care in small practices which do not exchange healthcare records on a regular basis with other medical providers. For HIT to be adopted widely, not only must it be affordable, provide value to the practitioner, be easy to implement and cost-effective to maintain over time, it must also engage the public's trust in the safety and security of the system.

New Jersey is positioned to evolve a model of health that can more effectively serve its citizens through the deployment of real-time data at the fingertips of health-care providers. A developing culture of collaboration and innovation statewide, coupled with funded pilot projects and programs virtually ensures sustainable change in HIT in the State of New Jersey.

Status

1. Assessment of in state assets, willingness and capacity — Status: Complete

To date, the NJHITC has reviewed both public and private documentation on the status of information technology throughout the state. New Jersey can be characterized by multiple uncoordinated initiatives, with a wide variety of technology in various stages of deployment. Most health systems and hospitals have electronic health records in place however the functionality of each EHR differs widely. Less than 5% of physician practices in the state have an electronic record and many physicians are searching for the value proposition which would make the installation reasonable and affordable. New Jersey must develop a cohesive HIT strategy by aligning value propositions and focusing on prioritized goals and objectives.

2. Technical Model Development — Status: In Process

Given decreased reimbursement, limited funding and compressed time lines for complying with meaningful use criteria, significant economies of scale across New Jersey must be achieved by leveraging a shared services technical environment through the infrastructure being built by NJ Medicaid. Use of common, comprehensive, scalable, standards based technology solutions will facilitate health information exchange and lay the foundation for achieving meaningful use, as well as participation the Nationwide Health Information Network.

3. Final Governance Model Development — Status: In Process

The Governance Model needs to be created through a multi-stakeholder process. There is an interim governing body that is overseeing the statewide HIE portion of the plan, and the appointment of a state HIT coordinator is helpful but additional resources need to be allocated. The model should include provisions for Policy, Legal, Privacy and Security, Architecture, Evaluation, Business and Technical Operations and Stakeholder engagement.

4. Business Model Development — Status: Not Started

Recent reports by the National Governor's Association and State Level Health Information Exchange (SLHIE) collaborative have explored various governance and financial sustainability models that are currently being reviewed by the NJHITC and Office for e-HIT Development as being applicable in New Jersey. Factors affecting this consideration are the density and economic health of the population, the number of healthcare institutions and providers and the number of health insurance companies and state and federal payers.

Planning: 5. Community Engagement and Organization Model — Status: In Process

Through the efforts of the regional HIE groups community engagement has been good. The overall organizational model needs to be defined and implemented. The newly created Regional Extension Center will be a key player in helping to bring individual physician practices into the digital environment. Significant risk exists for health care systems without robust funding. As costs increase and reimbursement declines, organizations will be hard pressed for the type of capital investments needed to advance and maintain Healthcare information systems. Payers have a participatory role with the commission as well as ancillary services including but not limited to home health agencies, visiting nurse services, pharmacies, and Federally Qualified Health Centers.

6. Development of a consistent Privacy and Security Legal Framework — Status: In Process

Prior analyses of State laws affecting privacy and security have been completed through HISPC projects. These are being reviewed, and a determination as to how they may be best leveraged shall be made. Preliminary identification of laws affecting privacy and security disclosures through the HIE/RHIO environment has been started, and attached hereto as Appendix D. Addition analysis is to be completed before recommendations for regulatory and/or legislative changes are made.

Core Recommendations

1. Designate a State Coordinator for New Jersey Health Information Technology and furnish the appointee with the human and financial resources to be effective. This core recommendation is essential for two reasons: 1) it will delineate clear lines of authority and streamline decision making on policy issues going forward; and 2) it will respond to a direct criterion, established by the Office for the National Coordinator, that must be satisfied before any federal funds are disbursed for the implementation for HIE construction, as was recommended by the Standards subcommittee of HITC. The HITC and the Office for e-HIT recommend that the State Coordinator's office be situated in and report directly to the Governor's Office.

2. Develop an approach for sustainable financing that does not solely rely on federal, state, or private grant-based funds. Explore models for revenue generation through various mechanisms such as membership fees, surcharges on claims transactions (i.e., the "click charge") or direct assessments.

3. Leveraging the Federal funds being used to build a Master Patient Index and Record Locator Service for New Jersey Medicaid should form the cornerstone for the construction of the statewide New Jersey Health Information Network (NJHIN). CMS and ONC have mandated the coordination of federal Medicaid HIT spending and statewide HIE/HIN design and implementation. The coordination of NJ Medicaid HIT implementation with the construction of the broader NJHIN must be a guiding principle.

4. Develop statewide Health Information Exchange capacity that is guided by health outcome goals that incorporate improvement in individual and population health status, and are governed by and implemented cooperatively through collaborative efforts of the public and private sectors. Develop and enforce policy requiring all statewide HIE participants to comply with a common set of privacy and security guidelines and policies.

5. Implement a permanent Governance Framework by the end of 2010. The Governance Framework should address management of the implementation and ongoing maintenance of a statewide health information network and data driven clinical process improvement at the state, county, and municipal levels.

6. Foster an integrated approach with DHS Medicaid and the State's public health programs to enable electronic information exchange and build capacity to support provider participation in HIE as required for Medicaid meaningful use incentives.

7. Work with the Regional Extension Center to educate and deploy electronic medical records in physician practices. Federal funds may not provide more than 50% of the cost required to create and operate a Regional Extension Center. A state must have an HIT strategic plan in place that is consistent with the National HIT Strategic Plan in order to apply for funds under the HITECH portion of ARRA. Although New Jersey is recognized as a national leader in the development of HIT and HIE systems and policies, this comprehensive HIE strategic plan is needed to guide policy decisions and prioritize funding decisions.

8. Expand and Develop a Statewide Health Information Network. The New Jersey Health Information Technology Commission and the Office for e-HIT Development envision a future in which all residents of New Jersey have accurate and secure health records available at the point of care. Technology exists to design and build a fully integrated and connected health information system that will enhance efficiency, quality and effectiveness of the delivery of healthcare. Technology can also enhance the patient's ability to be an engaged consumer of healthcare and an important partner in their health management (consumer-driven health care). Setting aside the issues of cost, there are significant overarching policy decisions and guiding principles upon which such a system must be found (see Appendix B).

9. Develop an HIT framework that helps position eligible providers for the Medicare and Medicaid incentive programs.

Subcommittee Recommendations

Privacy & Security Recommendations

The Commission's Policy Committee held a Privacy & Security forum on April 12, 2010. Topics discussed and comments made include: (i) whether the State should adopt an "opt-in" or "opt-out" HIE policy; (ii) whether certain state law requirements enacted in the "paper medical record" era are still applicable to evolving practices in an electronic age; (iii) whether past analyses of state laws can be leveraged to produce an updated review of state law; (iv) would enactment of a broad, new statute be beneficial for addressing differing state standards pertaining to health information exchange and access, or should the authority already vested in certain State Departments (e.g., DHSS; DOBI; DHS) be utilized to amend current, disparate standards.

The full Commission approved the following main ideas and recommendations May 6:

1. New Jersey should adopt an **"OPT-OUT" approach** to electronic HIE (meaning that patients and their data are in the exchange by default, with proper consent, unless the patient chooses to opt-out). Further decisions will be needed regarding the specifics of any State-mandated right to opt-out – e.g., Is it all or nothing (you are in the HIE or you are out)?; Can patients opt-out of certain HIE-participating *providers*, *facilities*, *episodes of care*, types of *information*?

2. Comprehensive **legislation** or regulation will be needed to update State laws to better enable electronic HIE between private facilities and through the statewide network. Such legislation would address the following key elements:

    a. Access to information through the exchange will be limited to **physicians and other health-care providers authorized** to utilize data for the patients they are **treating**;

b. Aggregated, de-identified data may be accessed by the Department of Health and Senior Services, the Department of Human Services, the Department of Banking and Insurance, the Department of Children and Families, and any departments and agencies with statutory authority;

c. When consenting to the release of data at the point of care, patients will be opted into the exchange, except under circumstances involving sensitive data (e.g., HIV status, genetic information, sexually transmitted infections, etc.). These sensitive data will always be behind a "break glass" requiring a higher level of "proof" of authority to access such information;

d. Patients/consumers have will have a standard right to access the data about themselves that reside in the information exchange/network when they request it;

e. Any existing state law or requirement that conflicts with the enacted legislation would be superseded by the new legislation;

f. New legislation on electronic health information exchange must make clear the permissibility and prohibitions on secondary uses [to be defined] of information in the exchange/network;

g. Requirements related to breach notification through multiple HIE participants should be consistent with HITECH and DHHS regulations;

h. Limited immunity should be granted to providers who are producers of electronic data on their patients, insofar as they are not responsible for future treatment decisions made by providers who use that information to treat the patients for whom the electronic data were collected.

3. To guarantee the privacy and security of patient data, each regional HIE and the NJ statewide network must develop **security standards** consistent with HIPAA and HITECH guidelines, as well as meeting emerging security standards from NIST/HITSP/NHIN. Each new participant that joins an HIE must undergo a screening process to ensure its security standards meet these thresholds.

4. The HIT Commission should evaluate whether a RFP process can be employed to engage a law firm to do a formal and written crosswalk between federal law and existing state law, and among existing state laws, governing data exchange among different types of health-care institutions. The law firm would be hired to identify potential conflicts between state and federal law, and to find possible barriers to data exchange among different types of healthcare providers. The NJHIT Commission should identify all prior efforts to conduct such analyses made through HISPC, Medicaid, NJDHSS, etc. Any extant work products should be consolidated and made accessible at the NJHITC website and should be leveraged for further legal review and final determinations.

5. There must be a State-level multi-disciplinary governing entity entrusted with the **oversight** of the privacy and security of the data in a Statewide health information network, and that entity must include individuals with clinical, policy, and technological expertise. This oversight requirement might also be extended to certain activities of the regional HIEs.

Implementation-Related Recommendations

1. A coordinated decision-making structure is essential to the success of the implementation of the NJ HIT plan. We support the Governor's appointment of a State Coordinator with responsibility for oversight of the implementation of the comprehensive NJ HIT plan. The State Coordinator should have policy making authority and should be responsible for the development of a financial sustainability model. The appointed leader should coordinate activities with all stakeholder groups, patient advocates, state agencies, Regional Extension Centers and State HIEs. The State Coordinator should promote collaboration of the work of the Regional Extension Centers, NJ Medicaid, NJHITC and Office for e-HIT Development to ensure the timely implementation of the state's HIT plan.

2. To foster successful adoption of electronic medical records by physicians, the Regional Extension Centers should develop and implement educational programs for physician offices, consistent with federal guidelines. These programs should detail the value of health information technology and electronic medical records to a physician's office and should train physicians and their staff on best practices for implementation and maintenance of electronic medical records.

3. Development of privacy and security standards should be coordinated with the policy sub-committee of NJHITC and broadly implemented to ensure compliance with all federal and state regulations regarding the protection of personal health information. Education and training sessions that focus on privacy and security standards should be developed and customized for specific target audiences.

4. In collaboration with the Regional Extension Center, NJ Medicaid, and stakeholder professional societies, programs should be developed to update physicians and other

stakeholders on changes to standards and guidelines, such as meaningful use, privacy and security, vendor certifications, grants and other financing opportunities.

5. Where appropriate physicians should be supported and encouraged to provide patients secure, electronic access to their personal healthcare data.

6. NJ Medicaid, the Regional Extension Center and the State Coordinator of HIT should provide a comprehensive overview and timeline for the implementation of health information technology initiatives that could impact the implementation of health information technology by physicians and other stakeholders. Appropriate communication to all stakeholders regarding the implementation of state initiatives for the delivery of data between the state and relevant stakeholders is essential to timely and accurate data exchange. NJ Medicaid and the State HIEs should consult with each other to develop timelines and requirements for deliverables and to ensure interoperability.

7. The coordination of interoperability between service providers, such as laboratories and pharmacy benefit managers, is essential to the successful implementation of the statewide health information technology plan. Service providers, therefore, should be included as key stakeholders in the implementation process.

8. Regional and statewide exchanges and hospital and physician office systems (including EMRs) should comply with nationally accepted standards to ensure interoperability.

Technology Related Recommendations

1. The New Jersey Health IT Commission recommends that the state government of New Jersey establish a Record Locator Service for health-information exchange, using a Master Patient Index (MPI) that employs robust probabilistic matching criteria, subject to the requirements, standards and recommendations of the Statewide HIT Plan.

2. The MPI must be interoperable with current and future regional health-information exchanges, and will ultimately serve as the hub for health-data exchange to be accessed by health-care providers to improve quality and efficiency of care

3. New Jersey leverages the Record Locator Service and Master Patient Index now being built by NJ Medicaid. These technological components, funded by the federal government, will be interoperable with current and future regional health-information exchanges, and will ultimately serve as the hub for health-data exchange to be accessed by health-care providers to improve quality and efficiency of care. This leveraging of existing federal commitments to New Jersey Medicaid will satisfy the requirements of CMS, DHHS, and ONC that all federally-funded state HIT implementation programs make it a priority to maximize the impact of federally funded technology in the construction of the statewide health information network.

4. A statewide Health Information Exchange is developed to facilitate the communication between the HIEs and New Jersey Medicaid within the NJHIN framework. It is recommended for consideration that the following functionality be provided to eliminate redundancy and support the most efficient data exchange possible: Master Patient Index; Record Locator Service; Patient Identifier Cross Reference, Patient Demographic query service, Basic Patient Privacy Consent; Audit Trails and Node Authentication; Provider Directory; connection to NHIN, Public Health Databases and data repositories for labs and medications.

Principles on HIE Governance

Current Governance Structure: New Jersey's current governance structure relies on multiple state agencies to collaborate on health IT, each with a specific role or set of roles and sharing overall leadership and decision-making. That structure has been effective in developing our State Plan and we anticipate that it will continue to be effective in the initial deployment and administration of ONCHIT grant funds to regional HIEs. The Health Care Facilities and Financing Authority (HCFFA) has been enlisted to team with NJHITC and Office for e-HIT Development in the management of the Office of the National Coordinator's Health Information Exchange grant. HCFFA, working closely and directly with the NJHITC and the Office for e-HIT Development, will serve as the applicant and contracting agent for the Cooperative Grant Agreement, will execute all transactions to sub-grantees, and enforce all ARRA and State accountability functions. This collaborative model is multi-disciplinary and multi-stakeholder and it has evolved organically out of the existing state agency functions and competencies. However, as New Jersey has finalized its State Plan and moved towards implementation, both public and private stakeholders have concluded that a more unified HIT chain of command, with more robust staffing and funding, will be needed to bring our State Plan to fruition. A possible new governance entity is described below.

Proposed New Governance Structure: State-level governance must address the diverse, dynamic and often divergent needs of local stakeholders, yet also align statewide strategies with the national vision for Health Information Exchanges. Achieving HIE implementation to meet healthcare improvement goals requires a structure for sustained collaboration and coordination across multiple sectors and among diverse stakeholders. This collaborative structure provides a critical piece of infrastructure – a mechanism for negotiating HIE solutions among diverse interests (e.g., providers, payers, purchasers, consumers, researchers, and policy makers). Such a collaborative structure can also address implementation challenges, balancing these challenges against the public interest in health system improvements, the privacy and security of data, and patients' access to data.

In their conceptualizing of the state governance structure during the planning process, the HITC and Office for e-HIT Development reviewed best practices in Governance from around the nation, including publications from the National Governors Association (NGA) and the State-Level HIE Project. In the Cooperative Agreement Program guidance, ONC noted NGA's three potential paths for Governance. SLHIE has promulgated three similar tracks for State governments to provide or manage the HIE technical infrastructure and oversee its use:

1. HIE Public Utility with Strong Government Oversight: State government serves an oversight role and regulates statewide HIE that is provided by the private sector.

2. Private-Sector-led HIE with Government Collaboration: State government collaborates and contributes as a stakeholder in the private-sector provision of HIE, relying on self- regulation mechanisms like accreditation in concert with statutory and regulatory frameworks.

3. Government-Led HIE: State governments provide or manage the HIE technical infrastructure and oversee its use.

The HIT Commission and Office for e-HIT Development have determined that a combination of options #1 and #2 best suits the state's needs, namely a public-utility model with joint public-private support, management, and implementation. Therefore, over the course of the next 12 months, the New Jersey Office for e-HIT Development and the Health Information Technology Commission propose to help the state form a not-for-profit public-private incorporated partnership of all stakeholders involved in the delivery of health care, to be called the New Jersey Health Information Network (NJHIN). NJHIN would be endowed with organizational capacity that draws on both its public and private character, including:

· Contracting with others to perform its duties in facilitating statewide HIE and employing sufficient staff to do so.

- Establishing a non-appropriated special funds account, in order to receive grants, gifts, departmental funds transfers and donations.
- Reviewing and recommending changes to state health insurance regulations (in conjunction with the Commissioner of Insurance) or State privacy and security laws;
- Governing the policies and procedures of a statewide Health Information Network that provides various enterprise-wide technological services, incorporates regional/community HIEs, and provides data integration for all other contributors and authorized users of clinical data.
- Establishing a New Jersey State Web Portal, through which all New Jersey-based health care claims would be filed to measure conformance with the State's prompt pay and clean claim laws set forth in N.J.S.A. 17B: 30-26 et seq.
- Establishing such processes, procedures and systems as are necessary and appropriate to encourage the implementation and deployment of electronic health records and systems by individual and small group health care providers.

A public-private partnership involving the State of New Jersey and multiple relevant private sector stakeholders would oversee the implementation of the State HIT Plan and facilitate the implementation of a financial sustainability model and a governance structure appropriate for the permanent operation of a statewide health information network.

Conclusions on Governance: The State Health Information Technology Coordinator, acting with the strong support of the Governor's Office, would be responsible for implementing the HIT Plan and policy decisions in a streamlined fashion. While the current governance model of shared leadership has worked, greater efficiency can be achieved by vesting ultimate authority in a single entity. A salutary effect of this change is that it would also put New Jersey in compliance with an ONC requirement that any state that receives ARRA funding for HIE implementation must have a single authority responsible for overseeing implementation of the state's HIT plan and satisfying ONC regulations and federal law.

The Public-Private Partnership overseeing the NJHIN should have a Board of Directors composed of members capable of assembling the economic resources required to build and maintain the state's HIT infrastructure. Such qualified public and private sector Board members of appropriate relevance and competency should include, but not be limited to, representatives of the New Jersey State Health Benefits Program, payers (including property and casualty insurers), NJ Medicaid, major employers in the state, service providers (including laboratories), data clearinghouses, third party administrators, banks, unions, etc. The HITC would continue to function in an advisory and consultative role to the Public-Private Partnership, pursuant to the HIT Act.

NJHIN will be formally designated and function as the New Jersey Qualified Statewide Program for Interoperable Health Information Exchange Infrastructure pursuant to any present or future federally established and/or funded programs for the creation, development and advancement of interoperable health information technology.

Principles of Sustainability

For many, the magnitude of funding from the ARRA has created the impression that the financial obstacles for health IT have been resolved. While the funds represent an unprecedented investment, they will not address the persistent challenges to sustaining a health information infrastructure that meets the demands of a high performing healthcare system. As stakeholders begin the process of creating or updating their statewide plans, it will be critical to avoid the temptation of addressing short term financial needs at the expense of the longer term systemic considerations that will ultimately determine the success of the stimulus investment. States need to act now and engage public and private payers and purchasers in a dialogue to develop the financial mechanisms needed to ensure the long term viability of these efforts.

A long-term sustainability plan is laid out below. But New Jersey based an analysis of financial considerations and sustainability on the "Health Information Exchange: "From Start Up to Sustainability" report (hereafter referred to as the eHI report) and accompanying toolset released by the U.S. Department of Health and Human Services Health Resources and Services Administration on May 22, 2007. These materials, developed under a grant from the Office for the Advancement of Telehealth, provide a template for planning and implementing HIEs that will be sustainable. The eHI report draws on the experience of several organizations and projects, including: HealthBridge of Cincinnati, Ohio, which implemented an HIE for order entry, eligibility verification, portal services, and clinical messaging; IHIE of Indiana, which implemented an HIE for clinical messaging; and THINC of the Hudson Valley in New York, which implemented an HIE for hosted electronic health records (EHRs). The toolkit accompanying the eHI report includes several spreadsheet-based modeling tools that assist HIE planners in developing sustainability plans. These tools take into account aspects of the partners in an HIE such as the services, users, infrastructure and mapping capabilities needed to be incorporated. The State will help HIEs conduct such an analysis to determine short/intermediate-term contributions needed for sustainability as ARRA funds are depleted. That said, the HIEs are, of course, free to develop their own subscription models. Finally, however, we recognize that with

hospital-led coalitions, their financial resources are limited, as are the primary-care physicians who serve as one of the primary HIE-connected destinations. Therefore, the State is undertaking a long-term financial-sustainability initiative to sustain the four HIEs and to embark upon and maintain a statewide exchange.

Long-term sustainability: New Jersey's work on the issue of financial sustainability is a work in progress. Aside from the federal requirements, our HIT Act requires that we build a full self-sustaining, self-sufficient statewide health IT network for all the people of this State. As a result, we have directed considerable thought to looking at the various ways that other state have funded or propose to fund their statewide HIEs in order to understand and apply the work of others and yet develop a plan that will work for New Jersey and is supported by our law. As with any plan, our law requires that we submit our plan, suggestions and recommendations to the Governor and Legislature at the required time. Our expectation is that we will also convene payers, provider, consumer and stakeholder groups to review and comment on our plans and to offer alternatives, if any. What is described below is the financial framework that we are currently vetting but we cannot give any assurance that the Governor and Legislature will accept these suggestions. The HITC and the Office for e-HIT Development do expect New Jersey will have a self-funding mechanism that is supported by New Jersey law and works for our stakeholders.

The federal government and all states are challenged by the ultimate question of economic support for the electronic health information network after it is created and ARRA funding ends. There is no one answer that fits all with the federal authorities relying on each state to adopt a funding mechanism that is supported by local law and does not adversely disrupt the market place. Fortunately, New Jersey has the legal authority and a proposed technical architecture for support of the network once it is constructed. Absent a universal federal solution, every state must consider and resolve self-sufficiency in careful and long term consultation with all health care stakeholders. At a minimum, the following considerations must be addressed: 1) Is there legal support for the solution? 2) Does the solution work within the existing health information infrastructure? 3) Does the solution adequately address and

protect the privacy and security of protected health information? 4) Is any one group or segment of stakeholders being asked to assume a disproportionate share of the costs? 5) Is there a return on investment for all the stakeholders? 6) Will the solution encourage and facilitate the stakeholders to fully use the statewide network? 7) Will the solution include sufficient flexibility to adequately respond to the economic needs of the statewide network? 8) Is there sufficient time and opportunity to launch an operational plan to educate all stakeholders as to the provisions of the plan and to obtain critical "buy-in" by all concerned? These are some but not all of the questions that we have considered in formulating our long term financial stability plan.

Principles of Privacy and Security

A top priority of New Jersey's health information exchange strategy is ensuring that policies protect privacy, strengthen security, ensure affirmative and informed consent and support the right of New Jerseyans to have greater control over and access to their personal health information as foundational requirements for interoperable health information exchange.

These policies will also serve to build consumer trust in health IT and HIE by reassuring consumers that their health information will be shared securely and only for purposes permitted or required by law or as authorized by the consumer. Public confidence in privacy and security standards requires both that the standards fit our principles and the ordinary consumers can readily see that the standards protect their interests in the privacy of their health information. This requirement to be visibly and actually protective from the consumer's viewpoint will foster trust and confidence in health information exchange.

The development of privacy and security policies and standards will ensure that healthcare providers are able to obtain needed patient health information in a timely manner without undue cost and administrative burdens.

One of the first tasks for the Privacy and Security workgroup will be to convene and propose changes necessary to interpret these principles in the context of both existing law and the principles set forth in HHS' "Nationwide Privacy and Security Framework for Electronic Exchange of Individually Identifiable Health Information".

The above principles are aligned with the following HIE principles articulated by the Sub-committee intended to guide the development and implementation of the NJHIE:

Appropriate privacy and security must be guaranteed.

Individual personal health information must be protected. Consumers will accept sharing sensitive personal information if it is done on their behalf to assure that the right information is shared at the right time and for the right reasons. At times this means immediate and secure access to certain critical information from any location in the system.

Adherence to strong ethical standards. The full trust and support of stakeholders will be enhanced by adherence to strong ethical standards, conflict of interest, and full disclosure in all business operations involving HIT.

Use-case scoring matrix. Be guided by a "use-case scoring matrix" that envisioned certain data elements being available to providers in various venues/sites of care. The Commission believes this scoring should inform the State's top priorities for data elements necessary for the development of a statewide health information exchange. Thus, interfaces and key data feeds for those data elements would be required in the state HIE. The priorities should also inform providers as they adopt HIT in their own facilities and engage in contract negotiations with vendors. The results of the matrix are attached to this report (see Appendix C).

This set of clinical priorities will need to be taken into consideration along with the CMS federal guidelines for achieving the phases of "meaningful use".

Conclusions

The New Jersey Health Information Technology Commission believes that progress in implementing health information technology and health information exchange in New Jersey faces several hurdles. Robust and properly-structured governance at the state-government level is needed both to implement and oversee a statewide Health Information Exchange and to generally oversee policy development and implementation in a rapidly changing field. Communications with health-care providers about the utility of Electronic Health Records must be more robust and frequent—an initiative that will be undertaken in large part by the newly-created Regional Extension Center, by New Jersey Medicaid, and by the Commission, but one that needs additional proliferation to all providers and coordination among agencies. Finally, under both the federal requirements and the operational imperative for a statewide health information exchange that integrates all HIE efforts, a dedicated revenue source that derives funding from the health-care system is necessary.

Regional HIE efforts around the country have mostly failed, in large part because of reliance on grant and start-up seed monies, which diminished over time, in turn leaving ongoing software, personnel, and training costs unfunded. The Commission and the Office for e-HIT Development have discussed the necessary components of a statewide HIE, as reflected in the State Health IT Plan and the HIE application both successfully submitted to federal HHS, and strongly believe a statewide exchange is contingent upon a sustainable, dedicated revenue source and adequate governance.

We have heard and discussed the notion that health-care providers are already over-burdened by both requirements and overhead costs, and implementing health IT systems will add to those burdens, even if they are intended for the laudable goals of increased quality and efficiency. The federal “meaningful use” incentive payments through Medicare and/or Medicaid are unlikely to cover the carrying costs of EHR systems beyond a few years, so the Commission and the Office for e-HIT Development want to emphasize the need for the State to implement a funding source for health-information exchange that is

placed squarely on the shoulders of providers. Models have been developed that do not utilize a state's operational budget, and instead derive funding from the health-care system itself.

Exchanging clinical data through HIEs is a critical part of the NJHIT Commission's and the Office for e-HIT Development's overall charge of developing the blueprint for the statewide health information technology plan. The two entities will continue to build a robust plan that accounts for the need for process improvement and efficiencies facilitated by health information technology in many more areas of application. Stakeholder end-users like physicians, nurses, midlevel practitioners (physician's assistants, nurse practitioners), pharmacists, mental health providers and other allied health professionals need to have significantly more input in the functional processes and deliverables of a statewide health network. Stakeholder facilities such as hospitals, long term care facilities, ambulatory surgical centers, radiology/imaging facilities and walk in urgent care centers will all need to have modernization, connectivity and interoperability of their health information systems in such a manner that facilitates optimum information delivery to relevant providers.

Such information is critical for improving clinical decision support that results in better clinical actions that improve the quality of healthcare services that is reflected through the system. Advanced research methodologies and analytics from the biologic through the clinical spectrum can help better inform scientific and clinical processes in the system leading to increased quality of knowledge and services. Such quality improvement will lead to better financial sustainability of the healthcare system and ultimately optimized patient safety in all facets of the healthcare delivery process. This is the ultimate goal of the New Jersey Health Information Technology Commission and the Office for e-HIT Development.

Appendix A - Glossary of Terms

ARRA - American Recovery and Reinvestment Act of 2009

CDC – Centers for Disease Control and Prevention

CMS – Centers for Medicare and Medicaid Services

DHS – Department of Human Services (NJ)

DHSS – Department of Health and Senior Services (NJ)

DMAHS – Division of Medical Assistance and Health Services (NJ)

DOBI – Department of Banking and Insurance (NJ)

eHI – eHealth Initiative

e-HIT – The Office for Electronic Health Information Technology Development, Implementation and Deployment – New Jersey Department of Banking and Insurance

EHR – Electronic Health Record

EMR – Electronic Medical Record

FQHC – Federally Qualified Health Center

HCFFA – Health Care Facilities and Financing Authority (NJ)

HHS – Department of Health and Human Services (Federal)

HIE – Health Information Exchange

HIN – Health Information Network

HIT – Health Information Technology

HITECH - Health Information Technology for Economic and Clinical Health

HIPAA - Health Insurance Portability and Accountability Act of 1996

HISPC – Health Information Security and Privacy Collaboration

IHIE – Indiana Health Information Exchange

LTC – Long Term Care

MMIS – Medicare Management Information Systems

MPI – Medicare Provider Inventory

MPI – Master Patient Index

NGA – National Governors Association

NHIN – National Health Information Network

NIST – National Institute of Standards and Technology

NJ-HIN – New Jersey Health Information Network

NJHITC – New Jersey Health Information Technology Commission

NJ- HITEC – New Jersey Health Information Technology Extension Center at the New Jersey Institute of Technology

ONC/ONCHIT – Office of the National Coordinator for Health Information Technology

REC – Regional Extension Center

RHIO – Regional Health Information Organization

RLS – Record Locator Service

SJHIE – South Jersey Health Information Exchange

SLHIE – State-Level Health Information Exchange

SMHP – Medicare State Health Information Technology Plan

THINC - Taconic Health Information Network and Community (NY)

Appendix B

Guiding Principles for a Health Information Exchange

The HIE solution must be consumer centered. A critical element toward improving health is an engaged consumer who has the means, information, opportunity and the know how to better manage their own health and lifestyle choices. Engaged consumers will have easier access to and more control over their individual health records and they will be able to play a more active role in managing their own health. Sharing information between multiple providers and across disciplines will improve the decisions providers and consumers make and result in better continuity of care.

Better health, not just better healthcare, must be the goal. Better health requires looking beyond just HIT and the traditional practices of healthcare providers and payers to create a virtual "health home" where care is coordinated and collaborative. Prevention is the key. It must be a shared commitment of public and private employers, government non-governmental organizations, communities and individuals.

Privacy and security must be guaranteed. Individual personal health information must be protected. Consumers will accept sharing sensitive personal information if it is done on their behalf to assure that the right information is shared at the right time and for the right reasons. At times this means immediate and secure access to certain critical information from any location in the system.

Automating what we already do will not work. We cannot expect to get better health outcomes by simply applying information technology on top of the existing system of inefficiencies (legacy

systems), silos and uncoordinated care. Achievement of such requires applying evidence-based best practices to improve outcomes of care through improved workflow redesign and application of clinical decision making support systems. These components coupled with the application of clinical information sharing processes lie at the heart of an effective healthcare delivery system. The effect of a reengineered HIT system further seeks to eliminate the costs associated with redundant care or care not supported by clinical/scientific evidence.

HIT investments must support improved individual health as well as population health.

Use the federal stimulus funds to drive the changes needed in the overall system that will create sustainable and continuous quality health improvements. The new HIT system and policies should leverage existing investments in technology, take advantage of innovations, and identify opportunities for new investments, such as the federal support for new technology for NJ Medicaid. This includes utilizing current, leading edge technology already present within New Jersey state government (like the Department of Health and Senior Services CDRSS real-time clinical disease reporting and tracking program) and academic sectors (the health guideline markup language for encoding clinical guidelines done by the Informatics Lab at UMDNJ-Robert Wood Johnson Medical School) into the tapestry of the state health information technology network plan.

The system must inclusive and comprehensive. The system must be standards based.

Whether physical or behavioral health, long term or acute care, public or private provider, insured or uninsured, veteran or civilian, rural or metropolitan, all sectors can be part of the system. The HIT system is provider and insurer-neutral. Its design and implementation do not favor or disadvantage any provider type, practice setting, or insurer.

The system must be collaborative. No single entity can accomplish the HIT vision alone. Working together, New Jersey's hospitals, along with independent medical care providers, therapists, laboratories, pharmacists, in-home care providers, educational institutions, public agencies and non-profit organizations will improve the health of residents and communities. Collaboration among communities will enhance New Jersey's response to public health threats, disasters, and state and national emergencies.

Effectiveness and continuous quality improvement is fundamental. The ability to analyze and share data across entities will reduce duplication of services, identify best practices, better utilize resources, reduce health disparities, lead to better practice management, and inform future policy and planning decisions and expenditures. The evolution of data sources and analytics of large-scale, de-identified data provides the groundwork for comparative effectiveness research (CER).

Innovation will be required. Ongoing research and analysis of changing needs and technologies will keep the system dynamic and timely. Implementation and continuous improvement strategies will require an iterative approach that maximizes resources and follows national standards and certification requirements.

Sustainability is the key. The system will be sustained by a support network providing technical and professional education, training and consultation. The long term stability of HIT will be built upon financial incentives and value-added functionality rather than a mandate to participate.

This is a marathon, not a sprint. HIT systems will be built incrementally. Every stakeholder in the process must be able to move ahead from where they are on the continuum from minimum HIT involvement to fully electronic and interoperable networks. This means that the implementation process will accommodate a broad range of participants including the small independent community practitioner as s/he decides to implement an EHR in the practice, as well as a large hospital health system with an existing sophisticated HIT system.

Assessment of Current HIE Capacities that could be Expanded or Leveraged

At the core of New Jersey's strategy is the "Community HIE". Building upon initiatives with an established collaborative HIE focus and providing these communities with a shared technical service infrastructure for health information exchange creates an optimal deployment environment and is an efficient and cost effective strategy for rapidly expanding capacity across New Jersey. Immediate potential opportunities for leveraging existing initiatives to begin building HIE capacity across the state are described in the State Plan as well as other opportunities that can contribute to building a solid, comprehensive HIE Program.

HIE Readiness

New Jersey's current HIE efforts can be segmented into two categories: 1) large health systems, affiliated providers and ancillary service providers who have implemented integrated EHRs, and 2) community-based HIE efforts focused on ensuring ubiquitous availability of data within a region.

Community HIE Efforts: One community based-HIE initiative is currently operational, which is located in the Central part of the state. However, there are several efforts currently in the planning stage, with some transitioning to an implementation phase of development. Other efforts continue to organize stakeholders and are in the process of assessing various approaches to HIE. Most of the community HIE efforts are in the planning phase of development. While they share a common mission to improve healthcare in their communities through HIE, the efforts do not all share a common technical approach. The majority of these HIE efforts are pursuing some variation of a federated technology model with one initiative pursuing an Application Service Provider (ASP) model. Viable sustainability models remain a challenge and a top priority of community HIEs that are planning to move to the implementation phase.

The multi-departmental committee developed a Request for Application (RFA), informed by priorities set forth by both ONC and the Commission. The RFA issued to the public was necessary because community HIEs will be a critical component of both the application and the State plan. Throughout the nation, regional/local exchanges are seen as a more attainable and, in some ways, more organic layer prior to the establishment of a statewide, and ultimately a national exchange. The multi-departmental committee selected four community/regional HIEs that scored the highest on the objective criteria: South Jersey HIE, Camden HIE, Northern & Central New Jersey HIE Collaborative, and Health-e-Citi, which is starting in Newark and expanding outward in northeast New Jersey. Given the scopes of the projects, the committee felt that the South Jersey, Northern & Central New Jersey, and Health-e-Citi projects would each receive about $3.5 million of the state's total, and Camden, which has already demonstrated improved outcomes but has limited geographic scope, would receive $1 million.

South Jersey HIE: AtlantiCare, as the central partner of SJ-EMRX and SJHIE, is sharing data between primary care providers, and AtlantiCare's two hospitals. Physicians in their practices are e-Prescribing and are sharing lab and radiology results from the hospitals to the EMRs. They are in the process of bringing on the first nursing home within the next six months. Additionally AtlantiCare is looking at including data from their behavioral health facilities though the application in use by their behavioral health clinics. They are also moving toward eventual incorporation of all specialties. Currently AtlantiCare has included primary-care providers, OB-GYN, and cardiologists, and is working on incorporating technology from the first LTC facility in its network (within the next 6 months), on oncologist incorporation (targeted within next 6 months), and on all behavioral-health providers (planned but current privacy hurdles need to be overcome). This process of staged incorporation of outpatient providers into the network will be replicated with all the systems that are partners of SJHIE.

Camden HIE: The first phase of the Camden HIE will target primary care providers, hospitalists, and ER physicians. Future phases will include providing access to health care providers working in other settings- specialists, nursing homes, medical day programs, and mental health facilities in Camden. The first data made available will include: labs, radiology results, discharge summaries, and Medicaid medication data. The Camden HIE has begun discussions with Steininger Behavioral Health about including their organization in the HIE. They are in the midst of adopting a behavioral health EHR system.

Northern & Central Health Information Exchange: NCNJHIE's initial target populations are physicians and hospitals, including emergency departments' access to patient information. The data exchanged in this phase will include lab results, radiology reports, medication data, discharge

summaries and other transcribed reports as available. The second phase of this project would look to include data from other care settings such as post acute and long term care. Many of the partners operate long-term care or other outpatient facilities that are ripe for incorporation into the network

Health-e-Citi: Health-e-cITi NJ is interested in exchanging clinical information between the highest Medicaid users in the state. Currently the Counties of Essex, Passaic and Hudson are the 3 highest Medicaid users and the exchange has commitments from the hospitals in those regions to participate. In addition, there are close to 1000 priority primary-care providers in those counties and the amount of data delivered to them will increase incrementally as the hospitals go live on the exchange. They also plan on connecting to one of the largest behavioral health hospitals in the state (Bergen Regional Medical Center) once the policy committee develops the necessary documentation related to privacy and mental health patients. Since the exchange is currently up and running between Newark Beth Israel and the five Federally Qualified Health Centers in the City of Newark, the pilot is in the process of connecting to the Visiting Nurse Association of Central New Jersey and MONOC Ambulance Services, which is moving its emergency records into an electronic format, while it waits for federal funding for larger connectivity.

Appendix C

NJHITC/Office for e-HIT Development- Use Case Matrix Scores

VENUES	Emergency Dept		Physician Office		Hospital-to-post-acute		Hospital-to-community physicians		Personal Health Records		FQHC/Urban medical homes		Public Health Researchers		Public Emergency Response	
DATA																
Basic transfer data: demographics, allergies, advance directives, problem lists, discharge summaries, test results	SCORE:	8.6	SCORE:	7.1	SCORE:	8.1	SCORE:	7.6	SCORE:	7.2	SCORE:	7.9	SCORE:	6.0	SCORE:	6.9
Labs (including decision support)	SCORE:	8.0	SCORE:	8.0	SCORE:	7.9	SCORE:	7.8	SCORE:	6.8	SCORE:	7.7	SCORE:	5.9	SCORE:	6.1
Radiology/imaging (with notes)	SCORE:	7.4	SCORE:	7.6	SCORE:	7.2	SCORE:	7.4	SCORE:	5.9	SCORE:	7.0	SCORE:	4.8	SCORE:	5.0
Longitudinal claims	SCORE:	6.2	SCORE:	6.0	SCORE:	5.3	SCORE:	6.0	SCORE:	5.1	SCORE:	6.1	SCORE:	4.9	SCORE:	3.9
Public surveillance registries: birth, immunization, communicable disease, cancer, etc.	SCORE:	4.6	SCORE:	7.9	SCORE:	7.2	SCORE:	7.3	SCORE:	5.4	SCORE:	5.8	SCORE:	6.1	SCORE:	5.3

VENUES	Emergency Dept		Physician Office		Hospital-to-post-acute		Hospital-to-community physicians		Personal Health Records		FQHC/Urban medical homes		Public Health Researchers		Public Emergency Response	
DATA																
E-prescribing	SCORE:	6.2	SCORE:	7.6	SCORE:	6.8	SCORE:	6.7	SCORE:	3.9	SCORE:	5.9	SCORE:	4.8	SCORE:	5.6
Rx Drug data exchange (incl. drug 'frequent fliers')	SCORE:	5.9	SCORE:	6.5	SCORE:	7.7	SCORE:	7.8	SCORE:	4.9	SCORE:	6.5	SCORE:	4.6	SCORE:	5.3
Bed reporting/Diversion status	SCORE:	4.6	SCORE:	2.8	SCORE:	4.0	SCORE:	4.0	SCORE:	3.1	SCORE:	4.1	SCORE:	3.4	SCORE:	4.2
Clinical/Progress notes	SCORE:	7.0	SCORE:	7.7	SCORE:	6.7	SCORE:	6.5	SCORE:	5.0	SCORE:	7.4	SCORE:	5.4	SCORE:	5.2
Connectivity of existing electronic systems to a statewide network	SCORE:	9.6	SCORE:	8.9	SCORE:	8.1	SCORE:	8.2	SCORE:	6.4	SCORE:	7.6	SCORE:	6.8	SCORE:	7.0

APPENDIX D

to the Joint Interim Report of the New Jersey Health Information Technology Commission and Office of Electronic Health Information Technology Development, Implementation and Deployment

ANALYSIS OF SELECTED NEW JERSEY CONFIDENTIALITY AND PATIENT APPROVAL REGULATIONS

Prepared by:
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Appendix D – Analysis of Selected New Jersey Confidentiality and Patient Approval Regulations

PROVIDER TYPE	RULE and EXCEPTION(S)	COMMENTS	Recommended Considerations
ACUTE CARE HOSPITALS	**N.J.S.A. 26:2H-12.8f, 12.8g - Confidentiality** Every person admitted to a general hospital as licensed by the State Department of Health and Senior Services…**shall have the right:** f. **To privacy** to the extent consistent with providing adequate medical care to the patient. *This shall not preclude discussion of a patient's case or examination of a patient by appropriate health care personnel*; g. To **privacy and confidentiality** of all records pertaining to his treatment, *except as otherwise provided by law or third party payment contract*….	Statute requires privacy and confidentiality of information, but does not expressly require prior patient consent for exchange to occur between two treating providers. Should not be a barrier to Opt-Out approach.	No recommendations.
	N.J.A.C. 8:43G-4.1(a)(21) – Patient Approval. Information in the patient's records shall not be released to anyone outside the hospital without the **patient's approval**, **unless** another health care facility to which the patient was transferred requires the information, or the release of the information is required and permitted by law, a third-party payment contract, a medical peer review, or the New Jersey State Department of Health. The hospital may release data about the patient for studies containing aggregated statistics when the patient's identity is masked.	This regulation generally requires HOSPITALS to obtain **"patient approval"** before releasing information to "*anyone outside the hospital*". The author is aware that many hospitals capture such approval by obtaining a "blanket consent" from patients upon admission/registration. Those who do not, however, will need to either: rely on the regulation's "disclosures exceptions," or obtain patient approval prior to releasing any information through a HIE/RHIO. **This *could* create barriers and an *uneven implementation* of an Opt-Out approach State-wide.** **Disclosure Exceptions** (*no patient approval*): #1 to another (transferee) **health care facility** #2 required and permitted by **law** #3 required & permitted by **3rd party payment K** #4 required and permitted **medical peer review**	• Does Exception #1 need to be limited to disclosures *only* to other health care facilities? Can/should the exception be **expanded** to allow HOSPITALS to also disclose information to other non-facility providers involved in the patient's treatment or care? • If **NJDOHSS promulgates rules** (under Exception #5) that "require and permit" disclosures between participants in a HIE/RHIO for treatment of a patient (or other permissible purposes), then HOSPITALS would be permitted to make such disclosures without having to obtain prior patient approval. • In addition, the regulations to not address "disclosures" to a third party HIE/RHIO as a conduit/business partner for purposes of effectuating the transmission of information between providers. Additional clarification on this point could also be beneficial.

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		#5 required and permitted **NJDOHSS** #6 de-identified aggregated data	
	N.J.A.C. 8:43G-15.2(f) – Transfer Records If the patient is transferred to another health care facility (including a home health agency) on a nonemergency basis, the **hospital shall** maintain a transfer record reflecting the patient's immediate needs **and send a copy of this record to the receiving facility at the time of transfer.** The transfer record shall contain at least the following information: (1) Diagnoses, including history of any serious physical conditions unrelated to the proposed treatment which might require special attention to keep the patient safe; (2) Physician orders in effect at the time of discharge and the last time each medication was administered; (3) the patient's nursing needs; (4) Hazardous behavioral problems; (5) Drug and other allergies; and (6) A copy of the patient's advance directive, where available.	This is a "**required by law**" disclosure (e.g., hospital *shall*.. send a copy). It provides another Disclosure Exception under which HOSPITALS can release information through a HIE/RHIO (to receiving facility) without prior patient approval.	No recommendations.
	N.J.A.C. 8:43G-15.2(h)(i) – Medical Records. (h)[…](i) Original medical records **or components of medical records** shall not leave hospital premises unless they are under court order or subpoena or in order to safeguard the record in case of a physical plant emergency or natural disaster.	This regulation generally prohibits HOSPITALS from releasing components of "original medical records". This regulation was likely intended to prohibit patients' *paper medical charts* from being removed from HOSPITAL premises. However, as electronic medical records (EMR) become more prevalent, the EMR may become the "original" medical record. As such, the "***shall not leave the hospital premises***" restriction could have an unintended consequence of acting as a barrier to release of information through a HIE/RHIO.	• Should the **definition of Electronic Medical Record** be added to HOSPITAL regulations? • Can/should this restriction be removed or its applicability be limited to paper charts only?

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AMBULATORY CARE FACILITIES (ACF)	**N.J.A.C. 8:43A-13.5(a), (b) – Medical Records.** (a) The facility shall establish and implement written policies and procedures regarding medical records including, but not limited to, policies and procedures for the following: (1)….The **patient's written consent** shall be obtained for **release of medical record information**….	This regulation generally requires ACFs to obtain the **"patient's written consent"** before releasing "medical record" information. Some ACFs may capture the required written consent upon registration of patients. However, for those who do not, this ***could* create an administrative barrier for ACFs** participation in a HIE/RHIO implementing an Opt-out approach. However, under a separate section of the ACF regulations (see next section), only "patient approval" is required and "Disclosure Exceptions" similar to the hospital licensing regulations are included.	• Can/should the "**prior written consent**" requirement be **removed**, or at least revised to read consistent with NJAC 8:43A-16.2(a)9 (*see next section*)?
	N.J.A.C. 8:43A-16.2(a)9 - Patient Rights. Each patient receiving services in an ambulatory care facility shall have the following rights . . . 9. To confidential treatment of information about the patient. i. Information in the patient's medical record **shall not be released to anyone outside the facility without the patient's approval**, unless another health care facility to which the patient was transferred requires the information, or unless the release of the information is required and permitted by law, a third-party payment contract, or a peer review, or unless the information is needed by the Department for statutorily-authorized purposes. ii. The facility may release data about the patient for studies containing aggregated statistics when the patient's identity is masked;	This regulation generally requires ACFs to obtain **"patient approval"** before releasing information to "*anyone outside the facility*". As noted above, ACFs may capture such approval by obtaining a "blanket consent" from patients upon registration, but those who do not will need to either: rely on the regulation's "disclosures exceptions," or obtain patient approval prior to releasing any information through a HIE/RHIO. **This *could* create barriers and an *uneven implementation* of an Opt-Out approach State-wide for HIE/RHIOs.** **Disclosure Exceptions** (*no patient approval*): #1 to another (transferee) health care facility #2 required and permitted by law #3 required and permitted by 3rd party payment K	• Can/should Exception #1 be **expanded** to authorize ACFs to also disclose information to other non-facility providers involved in the patient's treatment or care?

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PROVIDER TYPE	RULE and EXCEPTION(S)	COMMENTS	Recommended Considerations
		#4 required and permitted medical peer review #5 needed by NJDOHSS for statutory purposes #6 de-identified aggregated data	
CLINICAL LABORATORIES	**N.J.S.A. 45:9-42.27** "Person" means any individual, partnership, limited partnership, corporation or other legal entity	**CLIA, 42 CFR 493.1241(a)** "**Authorized person"** means an individual authorized under State law to order tests or receive test results, or both." i (see Endnotes)	No recommendations.
	N.J.S.A. 45:9-42.34 Where feasible such rules and regulations shall equal or exceed minimum standards for laboratory certification contained in Federal rules and regulations promulgated pursuant to [CLIA] of 1967.	None.	No recommendations.

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	N.J.S.A 45:9-42.42(c) **No person shall**: (c) Accept specimens for tests from and make **reports to** persons who are not **legally qualified or authorized** to submit specimens to clinical laboratories and to receive such reports, *but this shall not prohibit the referral of specimens from one licensed clinical laboratory to another similarly licensed under the laws of the state in which it is located, providing the report indicates clearly the clinical laboratory performing the test and the name of the director of such clinical laboratory.* **N.J.A.C. 8:44-2.7(g), (i)** (g) **The laboratory** shall examine specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations and **shall report only to those authorized by law to receive such results.** (1) If a patient is sent to the laboratory, a written request for the desired laboratory procedures must be obtained from a person authorized by law to use findings of laboratory examination. (2) If only a specimen is sent, it must be accompanied by a written request. (i) The **original or true duplicate of the laboratory report shall be sent promptly to the licensed physician** or other authorized person who requested the test…. (3) The **results of laboratory tests or procedures** or transcripts thereof **shall be sent to the licensed physician**, dentist or other person authorized by law to use the findings of laboratory examinations. ***The patient may request a copy of such reports….*** (6) If the laboratory refers specimens to another laboratory, the physician ordering an examination shall receive the original reference laboratory report or a true duplicate of that report. The reference laboratory must report its findings on report forms of the reference laboratory. *If the physician so requests,* **the referring laboratory may authorized the testing laboratory to report directly to the physician or other authorized person who requested the test,** *in which even the testing laboratory must send a duplicate of the report to the referring laboratory.*	The State CLIA law could be interpreted as creating a barrier with regard to **HIE/RHIOs** receiving/transmitting test results by implementing an Opt-Out approach (without prior patient consent), as well as the **patient accessing** test results directly through a HIE/RHIO/PHR. Under Federal CLIA any individual authorized by state law to *order* tests or receive test results is considered an "authorized individual" for federal purposes. "Individuals responsible for ***using*** test results" may also receive test results from a laboratory. Although this is undefined by CLIA, it is understood that this means those individuals who need test results in order to provide treatment to patients such as healthcare providers. Federal CMS guidance provides that an authorized person ***may contract with an EHR vendor or HIE*** *as an* ***agent*** and therefore, the HIE could receive the test results directly from the laboratory. There is no language under federal CLIA suggesting that a patient must provide consent in order for these test results to be sent to an HIE so long as it is designated to receive the results by the authorized person. However, New Jersey CLIA does not reference designation of agents by an authorized person to receive test results, although the relevant statutory and regulatory provisions do not seem to exclude HIEs from	• Other States have enacted legislation to clarify **that a HIE/RHIO is "legally authorized" to receive or transmit lab test results** to the ordering physician. It could be beneficial for New Jersey to further review whether similar clarification should be added to the NJ-CLIA statute and regulations. • Another area of legislative clarification that could be beneficial is with regard to **whether the patient is or is not considered "legally authorized"** to access his/her own test results under State law, and **when** (timing of access e.g., "after physician receives" or can it immediately be transmitted to a patient's PHR?). ****PRIORITY**** Transmission of laboratory results are a primary focus of many HIE/RHIOs as one of the first data elements for transmitting. As such, **it is RECOMMENDED that some form of NJ-CLIA "TASK GROUP" resolve the policy for this area of law, and make any recommendations for legislative changes to support and clarify the issues surrounding NJ-CLIA identified here.**

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		those "authorized by law to receive such results" and therefore from patients or physicians designating them to receive the reports. It is unclear however whether the patient's consent, written or otherwise, would be required before an authorized person could designate release of test information to the HIE. **If prior consent is determined to be required, then this could be an administrative barrier to releasing lab test results through HIE/RHIOs based upon a Opt-Out approach.**	
LONG TERM CARE FACILITIES (LTCF)	**N.J.S.A. 30:13-5** g. ….Every resident shall have the **right to confidentiality** and privacy concerning his medical condition and treatment, *except that records concerning said medical condition and treatment* ***may be disclosed*** *to another nursing home or health care facility on transfer, or as* ***required by law*** *or third-party payment contracts.*	None.	No recommendations.
	N.J.A.C. 8:39-4.1(a) Each resident shall be entitled to the following rights: 18. To confidential treatment of information about the resident. Information in the resident's records **shall not be released to anyone outside the nursing home without the resident's approval,** *unless the resident transfers to another health care facility, or unless the release of the information is required by law, a third-party payment contract, or the New Jersey State Department of Health and Senior Services.*	This regulation generally requires LTCF to obtain **"resident approval"** before releasing information to "*anyone outside the nursing home*". LTCFs that do not capture such approval upon admission or registration will need to either: rely on the regulation's "disclosures exceptions," or obtain resident approval prior to releasing any information through a HIE/RHIO. **This *could* create barriers and an *uneven implementation* of an Opt-Out approach State-wide.** **Disclosure Exceptions** (*no resident approval*): #1 to another (transferee) *health care facility* #2 required by law #3 required by 3rd party payment contract	• Can/should **Exception #1** be **expanded** to allow LTCFs to also disclose information to other *non-facility* providers involved in the patient's treatment or care? • If **NJDOHSS promulgates rules** (under Exception #4) that "require and permit" disclosures between participants in a HIE/RHIO for treatment of a patient (or other permissible purposes), then LTCFs would be permitted to make such disclosures without having to obtain prior resident approval. • *In addition, the regulations to not address "disclosures" to a third party HIE/RHIO as a conduit/business partner for purposes of effectuating the transmission of information between providers. Additional clarification on this point could also be beneficial.*

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		#4 required by NJDOHSS	
ASSISTED LIVING FACILITIES (ALF)	**N.J.A.C. 8:36-4.1** ….Each resident is entitled to the following rights: 27. The right to receive **confidential treatment** of information about the resident. Information in the resident's **records shall not be released to anyone outside the facility** without the **resident's approval,** *unless the resident transfers to another health care facility, or unless the release of the information is required by law, a third-party payment contract, or the New Jersey State Department of Health and Senior Services.*	This regulation generally requires ALF to obtain **"resident approval"** before releasing information to "*anyone outside the facility*". ALFs that do not capture such approval upon admission or registration will need to either: rely on the regulation's "disclosures exceptions," or obtain resident approval prior to releasing any information through a HIE/RHIO. **This *could* create barriers and an *uneven implementation* of an Opt-Out approach State-wide.** **Disclosure Exceptions** (*no resident consent*): #1 to another (transferee) *health care facility* #2 required by law #3 required by 3rd party payment contract #4 required by NJDOHSS	• Can/should **Exception #1** be **expanded** to allow ALFs to also disclose information to other *non-facility* providers involved in the patient's treatment or care? • If **NJDOHSS promulgates rules** (under Exception #4) that "require and permit" disclosures between participants in a HIE/RHIO for treatment of a patient (or other permissible purposes), then ALFs would be permitted to make such disclosures without having to obtain prior resident approval. • *In addition, the regulations to not address "disclosures" to a third party HIE/RHIO as a conduit/business partner for purposes of effectuating the transmission of information between providers. Additional clarification on this point could also be beneficial.*
RESIDENTIAL HEALTHCARE FACILITIES (RHF)	**N.J.A.C. 8:43-4.6(a)** A policy and procedure manual(s) for the organization and operation of the facility shall be developed, implemented, and reviewed at intervals specified in the manual(s)….The manual(s) shall include at least the following: 5. Policies and procedures for maintaining **confidentiality** of resident records, including policies and procedures for examination of resident records by the resident and other authorized persons and **for release of the resident's records** to any individual outside the facility, ***as consented to by the resident*** *or as required by law or third party payor*.	See next section.	See next section.

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	N.J.A.C. 8:43-13.1(b) Records and information regarding the individual resident shall be considered confidential and the resident shall have the opportunity to examine such records, in accordance with facility policies. *The* ***written consent of the resident shall be obtained for release of his or her records*** to any individual not associated with the facility, except in the case of the resident's transfer to another health care facility, or as required by law, third-party payor, or authorized government agencies.	This regulation generally requires RHFs to obtain **"written consent" of the resident** before releasing **records** to "*anyone not associated with the facility*". **Unclear** whether this restriction can be interpreted to be limited to ***physical "records"*** -- in which case the requirement would not be a barrier in the EMR/HIE context. However, if "records" are viewed to also mean EMR records, **then the requirement to obtain prior written consent could be a barrier for implementing an Opt-Out approach in the HIE/RHIO context if the RHF does not obtain such consents routinely upon admission/registration.** **Disclosure Exceptions** (*no resident consent*): #1 to another (transferee) *health care facility* #2 required by law #3 required by third party payor #4 required by authorized government agencies	• Can/should **Exception #1** be **expanded** to allow ALFs to also disclose information to other *non-facility* providers involved in the patient's treatment or care? • If **the appropriate agency promulgates rules** (under Exception #4) that "require and permit" disclosures between participants in a HIE/RHIO for treatment of a patient (or other permissible purposes), then RHFs would be permitted to make such disclosures without having to obtain prior resident written consent. • *In addition, the regulations to not address "disclosures" to a third party HIE/RHIO as a conduit/business partner for purposes of effectuating the transmission of information between providers. Additional clarification on this point could also be beneficial.*
Emergency Medical Services (EMS)	**N.J.A.C. 8:40-3.5(b)** 1. Each provider shall develop a policy to ensure that all patient information, including patient identifiable data, remains **confidential** and **private**. This policy shall be part of the SOP manual, and shall be provided to each of the provider's employees. ***Patient information shall only be disclosed or released*:** i. If the *patient, guardian, executor or other legally authorized person* **has requested in writing** that the information be released **to a specific person, entity or company;** ii. In compliance with a *subpoena, judicial order or applicable law,*	Generally requires EMS providers to obtain a specific **"written request"** from a patient (or legal representative) **before releasing** any "patient information" to a specific person, entity, company. The **Disclosure Exceptions** are limited to: #1 subpoena, judicial order, required by law #2 processing claims for insurance #3 audits/inspections by DHSS #4 **"transfers"** of patient to **another**	• *The regulations to not address "disclosures" to a third party HIE/RHIO as a conduit/business partner for purposes of effectuating the transmission of information between providers. Additional clarification on this point could be beneficial.*

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	rule and/or regulation; iii. To process a *claim for insurance*, including Medicare or Medicaid, if authorized by the patient, guardian, executor or other legally authorized person; iv. To *Department staff* in the performance of their duties and/or while conducting inspection, audit and/or investigation; and v. To effect the *transfer of the patient to another health care professional* receiving the patient.	**health care *professional*** Exception #4 should permit EMS to disclose information through a HIE/RHIO to treating providers in accordance with an Opt-out approach.	
Home Health Agencies (HHA)	**N.J.A.C. 8:42-11.2(a), (g), (h)** (a) The facility shall have written policies and procedures for medical/health records that… shall include at least: 3. Procedures for the **protection of medical record** information against loss, tampering, alteration, destruction, or unauthorized removal or use; 5. Release and/or provision of copies of the patient's medical/health record to the patient and/or the patient's authorized representative… (g) The agency shall develop policies and procedures for the **removal of the medical/health record, *which shall occur only under the following conditions*:** 1. No **medical/health record** or **parts thereof** shall be removed from the agency ***except for purposes of providing clinical patient care and treatment*;** 2. If there is a *court order or subpoena* for its release; or 3. To *safeguard the record* in case of a physical plant emergency or natural disaster; and 4. There shall be a system to protect the security and confidentiality of all components of the medical/health record at all times.	Exception (g)1. can be interpreted to allow HHAs to disclosure patient information to other providers in a HIE/RHIO for treatment purposes and should not be a barrier to implementing an Opt-Out approach for the State.	• *Clarification that "medical record" includes information maintained in an EMRs could be beneficial for HIE/RHIO context*

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Physicians	**N.J.A.C. 13:35-6.5(d), (e) – Treatment Records.** (d) Licensees shall maintain the **confidentiality** of **professional treatment records**, except that: 1. The licensee shall release patient records as directed *by a subpoena* issued by the Board of Medical Examiners or the Office of the Attorney General, or by a *demand for statement in writing under oath*, pursuant to N.J.S.A. 45:1-18. Such records shall be originals, unless otherwise specified, and shall be unedited, with full patient names. […] All x-ray films and reports maintained by the licensee, including those prepared by other health care professionals, shall also be provided. 2. The *licensee shall release information as required by law or regulation*, such as the reporting of communicable diseases or gunshot wounds or suspected child abuse, etc., or when the patient's treatment is the subject of peer review. 3. The licensee, in the exercise of professional judgment and in ***the best interests* of the patient** (even absent the patient's request), **may *release pertinent information* about the patient's treatment to another *licensed health care professional* who is providing or has been asked to *provide treatment to the patient,*** or whose expertise may assist the licensee in his or her rendition of professional services. 4. The licensee, in the exercise of *professional judgment*, who has had a good faith belief that the patient because of a mental or physical condition may pose an imminent danger to himself or herself or to others, *may release pertinent information to a law enforcement agency or other health care professional in order to minimize the threat of danger*. Nothing in this paragraph, however, shall be construed to authorize the release of the content of a record containing identifying information about a person who has AIDS or an HIV infection, without patient consent, for any purpose other than those authorized by N.J.S.A. 26:5C-8. If a licensee, without the consent of the patient, seeks to release information contained in an AIDS/HIV record to a law enforcement agency **or other health care professional in order to minimize the threat of danger to others, an application to the court shall be made pursuant to** N.J.S.A. 26:5C-5 et seq.	Exception (d)3. can be interpreted to generally ***allow*** physicians to disclosure patient information to other providers in a HIE/RHIO for **treatment** purposes and, so, the Board of Medical Examiner (BME) regulations **should not be a barrier** to implementing an Opt-Out approach for the State. In addition, however, it could be **IMPORTANT** for the BME and/or the State to consider clarifying the definition of an EMR as it may need to be /should be limited to the EMR maintained by the *respective* physician practice, and NOT the aggregated information that may make up an "Electronic Health Record" (EHR) maintained by any centralized HIE data model. **Such clarification is important where the physician regulations *require* physicians to release patient records pursuant to a subpoena (see Disclosure Exception (d)(1)), and there is concern that this provision not be used as a bases to compel disclosure by a physician practice of information maintained by the HIE and belonging to another participating provider of the HIE/RHIO.**	• **Clarify definitions so it is clear that "professional treatment record" includes information maintained in an EMR.** • Definition should further clarify that **disclosures pursuant to a subpoena would be limited to the EMR maintained in and by the *respective* physician/ practice,** and **NOT** the EHR aggregated by any centralized HIE repository.

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	e) Where the ***patient*** ***has requested the release*** of a professional treatment record or a portion thereof to a(specified individual or entity, in order to protect the confidentiality of the records, the licensee shall: 1. Secure and maintain a current **written authorization**, bearing the signature of the patient or an authorized representative; 2. Assure that the scope of the release is consistent with the request; and 3. Forward the records to the attention of the specific individual identified or mark the material "Confidential."	This provision should not be a barrier to implementing an Opt-Out model for HIE/RHIOs. However, **it would require administrative tracking of written authorizations for patient-initiated access requests,** including when a patient asks the provider to "transmit" information to the patients Personal Health Record (PHR,) or to another provider. In addition, a "Confidential" mark would need to be worked-in to the HIEs technology functionality in order to meet this technical requirement if interpreted to extend to EMRs. Yet, while marking documents as "confidential" may have provided an additional safeguards" for confidential information in the paper record world, it likely adds little in the HIE/RHIO context.	• **Consider modifying the technical requirement of making records marked as "Confidential", or confirm that interpretation would only apply to forwarding of paper records.**
Psychologists	**N.J.S.A. 45:14B-28 - Privileged Communication.** The **confidential relations** and communications between and among a licensed practicing psychologist and individuals, couples, families or groups in the course of the practice of psychology are placed on the *same basis as those provided between attorney and client*, and ***nothing in this act shall be construed to require any such privileged communications to be disclosed by any such person.*** There is *no privilege* under this section for any communication: (a) upon an issue of the client's condition in an action to *commit the client or otherwise place the client under the control of another or others because of alleged incapacity*, or in an action in which the *client seeks to establish his competence* or in an *action to recover damages on account of conduct of the client which constitutes a crime*; or (b) upon an issue as to the *validity of a document as a will of the client*; or (c) upon an *issue between parties claiming by testate or intestate succession* from a deceased client.	Information maintained by a psychologist could not be disclosed through a HIE/RHIO without prior patient consent. Such information would need to be treated as a **"Special Category" of Information** in the HIE/RHIO context, and at a minimum safeguarded from access (e.g., put behind "break glass").	No recommendations.
	N.J.S.A. 45:14B-32 A patient who is receiving or has received treatment from a licensed, practicing psychologist *may* ***be requested to authorize*** *the*		

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	psychologist to disclose certain confidential information ***to a third-party payor*** for the purpose of obtaining benefits from the third-party payor for psychological services, *if the disclosure is pursuant to a valid authorization as described in section 6 of this act and the information is limited to*: a. Administrative information; b. Diagnostic information; c. The status of the patient (voluntary or involuntary; inpatient or outpatient); d. The reason for continuing psychological services, limited to an assessment of the patient's current level of functioning and level of distress (both described by the terms mild, moderate, severe or extreme); e. A prognosis, limited to the estimated minimal time during which treatment might continue.		
	N.J.S.A. 45:14B-39 Information disclosed pursuant to section 2 of this act **shall not be further disclosed by the third-party payor or to any other party or in any legal proceeding without valid authorization,** *unless disclosure is otherwise required by law* or when *relevant to legal disputes* between the third-party payor and the patient with regard to a determination of the entitlement to, or the amount of, payment of benefits for psychological services. **N.J.A.C. 13:42-8.5(a)-(g)** (a) A licensee shall preserve the confidentiality of information obtained from a client in the course of the licensee's teaching, practice or investigation. *However, the licensee shall reveal the information to appropriate professional workers, public authorities and the threatened individual(s) or their representatives only, if in the licensee's judgment, exercised in accordance with the standards of the profession, any one of the following circumstances occur*: 1. There is a *clear and imminent danger* to the individual or the public; 2. There is *probable cause* to believe that an *identifiable potential victim of a client* is *likely to be in danger*; or 3. Release of such information is *otherwise mandated by law*, such as, but not limited to, N.J.S.A. 2A:62A-17.	** **Note that the restriction extends to RE-DISCLOSURES of such information** as well, so if consent is obtained by psychologist to disclosure to a third party, the third party must similarly protect and not redisclose the information without obtaining an addition episodic consent from the patient.	

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	(b) In the case of a client's death: 1. *Confidentiality survives the client's death and a licensee shall preserve the confidentiality of information obtained from the client in the course of the licensee's teaching, practice or investigation*; 2. The disclosure of information in a deceased client's records is governed by the same provisions for living patients set forth in N.J.A.C. 13:42-8.3, 8.4 and 8.5; and 3. A licensee shall retain a deceased client's record for at least seven years from the date of last entry, unless otherwise provided by law. (c) A licensee may *discuss* the information obtained in clinical or consulting relationships, or in evaluating data concerning children, students, employees and others, *only for professional purposes and only with persons clearly connected with the case*. (d) A licensee *may reveal, in writing, lectures or other public forums*, personal information obtained during the course of professional work *only as follows*: 1. With *prior consent* of the clients or persons involved; or 2. Where the *identity* of the client or person involved is *adequately disguised*. (e) A licensee may share confidential communications with other parties interested therein, in a non-public forum, *only where the original source and other persons involved have given their express permission to do so*. (f) A licensee may reveal the *identity of research subjects only if the subjects have granted explicit permission*. (g) A licensee may release confidential documents, testimony or other information contained in the client record *only in accordance with the provisions of N.J.A.C. 13:42-8.3 and this section.*		
Pharmacists	**N.J.A.C. 13:39-7.6; N.J.A.C. 13:39-7.19** **Patient records** shall be kept **confidential**, but shall be made available to **persons authorized** to inspect them under State and Federal statutes and regulations.	The regulations governing pharmacies *should not be a barrier* to exchange of information through an HIE/RHIO implementing an Opt-Out approach. However, clarification whether "patient records" includes an EMR could be beneficial. In addition,	• **Clarify definition of "patient record" to include EMR.** • **Clarify who are "Authorized Persons" for purposes of accessing EMRs.**

PROVIDER TYPE	RULE and EXCEPTION(S)	COMMENTS	Recommended Considerations
		clarification with regard to who are "persons authorized" to inspect an EMR maintained by a pharmacists could be beneficial.	
Marital & Family Therapists	**N.J.S.A. 45:8B-29 – Privileged Communications.** A **communication** between a marriage and family therapist and the person or persons in therapy **shall be confidential and its secrecy preserved.** This **privilege** shall not be subject to waiver, *except where* the marriage and family therapist is a party defendant to a civil, criminal or disciplinary action arising from the therapy, in which case, the waiver shall be limited to that action. **N.J.A.C. 13:34-8.3(a)-(c)** (a) A licensee **shall preserve the confidentiality** of information obtained from a client in the course of performing marriage and family therapy services for the client, *except in the following circumstances*: 1. Disclosure is required by *Federal or State law or regulation*; 2. Disclosure is required by the *Board* or the *Office of the Attorney General* during the course of an investigation; 3. Disclosure is required by a *court of competent jurisdiction* pursuant to an *order*; 4. The licensee has information that the client presents a *clear and present danger to the health or safety of self and/or others*; 5. The licensee is a *party defendant* to a civil, criminal or disciplinary action *arising from the marriage and family therapy services provided*, in which case disclosure shall be limited to that action; or 6. *The* **patient or client agrees, in writing, to waive the privilege accorded by this section.** In circumstances when more than one person in a family is receiving marriage and family therapy services, *each family member who is at least 18 years of age or older must agree to the waiver*. Where required by Federal or State law, persons under the age of 18 years of age must agree to the waiver. Absent a waiver by each family member, a licensee shall not disclose any information received from any family member. (b) A licensee shall establish and maintain procedures to protect	Information maintained by such therapists could not be disclosed through an HIE/RHIO without prior patient consent. **Disclosure Exceptions** are limited to: 1 - required by law 2 – required by AG for investigation 3 – court order 4 – clear and present danger 5- judicial proceedings Such information would need to be treated as a **"Special Category" of Information** in the HIE/RHIO context, and at a minimum safeguarded from access (e.g., put behind "break glass").	No recommendations.

PROVIDER TYPE	RULE and EXCEPTION(S)	COMMENTS	Recommended Considerations
	client records from access by unauthorized persons. (c) A licensee shall establish procedures for maintaining the confidentiality of client records in the event of the licensee's relocation, retirement or death and shall establish reasonable procedures to assure the preservation of client records.		
Social Workers	**N.J.S.A. 45:15BB-13 – Privileged Communication.** A social worker licensed or certified pursuant to the provisions of this act **shall not be required to disclose any confidential information that the social worker may have acquired from a client or patient** while performing social work services for that client or patient unless: a. Disclosure is **required by other *State* law**; b. Failure to disclose the information presents a *clear and present* ***danger to the health or safety*** *of an individual*; c. The social worker is a ***party defendant*** to a civil, criminal or disciplinary action *arising from the social work services provided*, in which case a waiver of the **privilege** accorded by this section shall be limited to that action; d. The patient or client is a *defendant in a criminal proceeding* and the use of the privilege would violate the defendant's right to a compulsory process or the right to present testimony and witnesses on that person's behalf; or e. A patient or client ***agrees to waive the privilege*** accorded by this section, and, in circumstances where more than one person in a family is receiving social work services, *each such member agrees to the waiver*. Absent a waiver from each family member, a social worker shall not disclose any information received from any family member.	This statutory provision prevents social workers from disclosing confidential information through an HIE/RHIO without prior patient consent. **Disclosure Exceptions** are limited to: 1 - required by State law 2 – to avert danger to health or safety 3 – certain judicial proceedings Such information would need to be treated as a **"Special Category" of Information** in the HIE/RHIO context, and at a minimum safeguarded from access (e.g., put behind "break glass").	
	N.J.A.C. 13:44G-12.3(a)-(c) – Privileged Communication (a) A social worker **shall preserve the confidentiality** of information obtained from a client in the course of performing social work services for the client, **including after the death** of a client, except in the following circumstances. 1. Disclosure is **required by *Federal or state* law** or regulation. 2. Disclosure is **required by the *Board or the Office of the Attorney***	This regulatory provision prevents social workers from disclosing confidential information through an HIE/RHIO without prior patient consent. **Disclosure Exceptions** are limited to: 1 - required by law 2 – to AG for investigation	

PROVIDER TYPE	RULE and EXCEPTION(S)	COMMENTS	Recommended Considerations
	General during the course of an investigation. 3. Disclosure is **required by a *court*** *of competent jurisdiction* pursuant to a judge's order. 4. The client would present a ***clear and present danger*** *to the health or safety of an individual* if the social worker fails to disclose the information. 5. The social worker is a ***party defendant*** to a **civil, criminal or disciplinary action** *arising from the social work services provided*, in which case a waiver of the privilege accorded by this section shall be limited to that action. 6. The patient or client is a ***defendant in a criminal*** *proceeding* and the use of the privilege would violate the defendant's right to a compulsory process or the right to present testimony and witnesses on that person's behalf. 7. *The patient or* ***client agrees to waive the privilege*** *accorded by this section*. In circumstances **when more than one person** in a family is receiving social work services, *each family member who is at least 14 years of age or older must agree to the waiver*. Absent a waiver of each family member, a social worker shall not disclose any information received from any family member. (b) A social worker shall establish and maintain a procedure to protect the client record from access by unauthorized persons. (c) The social worker shall establish procedures for maintaining the confidentiality of client records in the event of the social worker's relocation, retirement or death and shall establish reasonable procedures to assure the preservation of client records in accordance with the time frame set forth in N.J.A.C. 13:44G-12.1(e) in the event of the social worker's separation from a group practice.	3 - to avert danger to health or safety 4 – certain judicial proceedings Such information would need to be treated as a **"Special Category" of Information** in the HIE/RHIO context, and at a minimum safeguarded from access (e.g., put behind "break glass").	
Physical Therapists	**N.J.A.C. 13:39A-3.3(d)** **Where the patient has requested** the release of a professional treatment record or a portion thereof to a specified individual or entity, in order to protect the confidentiality of the records, the licensed physical therapist shall: 1. Secure and maintain **a current written authorization**, bearing the signature of the patient or an authorized representative;	This provision should not be a barrier to implementing an Opt-Out model for HIE/RHIOs. However, **it would require administrative tracking of written authorizations for patient-initiated access requests,** including when a patient asks the physical therapist to "transmit" information to the PHR, or to another provider. In	• Consider modifying the technical requirement of making records marked as "Confidential", or confirm that interpretation would only apply to forwarding of paper records.

PROVIDER TYPE	RULE and EXCEPTION(S)	COMMENTS	Recommended Considerations
	2. Assure that the scope of the release is consistent with the request; and 3. Forward the records to the attention of the specific individual or entity identified and mark the material "**Confidential**."	addition, a "Confidential" mark would need to be worked-in to the HIE's technology functionality in order to meet this technical requirement if interpreted to extend to EMRs. Yet, while marking documents as "confidential" may have provided an additional safeguards" for confidential information in the paper record world, it likely adds little in the HIE/RHIO context.	
Dentists	**N.J.A.C. 13:30-8.7(e),(f)** (e) Licensees shall provide patient records to the patient or the patient's authorized representative or another dentist of the patient's choosing in accordance with the following: 1. Upon receipt of a written request from a patient or the patient's authorized representative…duplicates of models and copies of radiographs, shall be furnished to the patient, the patient's authorized representative, or a dentist of the patient's choosing. "Authorized representative" means a person who has been designated by the patient or a court to exercise rights under this section. An authorized representative shall include the **patient's attorney** or an agent of an **insurance carrier** with whom the patient has a contract which provides that the carrier be given access to records to assess a claim for monetary benefits or reimbursement. If the patient is a minor, a parent or guardian who has custody (whether sole or joint) shall be deemed an authorized representative. (f) Licensees shall maintain the **confidentiality** of patient records, *except that*: 1. The licensee **shall release** patient records *as directed by the Board of Dentistry or the Office of the Attorney General*, or by a *Demand for Statement in Writing under Oath*, pursuant to N.J.S.A. 45:1-18….. 2. The **licensee, in the *exercise of professional judgment and in the best interests* of the patient *(even absent the patient's request),* may release pertinent information about the patient's treatment to *another licensed health care professional*** who is providing or who has been asked to provide treatment to the patient,	Exception (f)2. can be interpreted to generally ***allow*** dentists to disclosure patient information to other providers in a HIE/RHIO for **treatment** purposes and, so, the Board of Density (BOD) regulations **should not be a barrier** to implementing an Opt-Out approach for the State. Again, clarification that "patient record" may include EMR could be beneficial.	• Clarify definitions so it is clear that "patient record" includes information maintained in an EMR.

PROVIDER TYPE	RULE and EXCEPTION(S)	COMMENTS	Recommended Considerations
	or whose expertise may assist the licensee in his or her rendition of professional services. 3. The licensee shall release information *as required by statute or rule*, such as the reporting of communicable diseases or gunshot wounds or suspected child abuse, or when the *patient's treatment is the subject of peer review*.		
Chiropractors	**N.J.A.C. 13:44E-2.2(e)** (e) Licensees shall maintain the confidentiality of patient records, *except that*: 1. **Upon receipt of a *written request from a patient*** *or an authorized representative*…copies of radiographs, shall be furnished to the patient or an authorized representative or another designated health care provider. […] 2. **The licensee, in the *exercise of professional judgment and in the best interests* of the patient (*even absent the patient's request*), may release pertinent information about the patient's care to another *licensed health care professional*** who is providing or who has been asked to provide care to the patient, or whose expertise may assist the licensee in his or her rendition of professional services. 3. A licensee shall provide *copies of records in a timely manner to a patient or another designated health care provider* where the *patient's continued care is contingent upon their receipt.*[…]	Exception (e)2. can be interpreted to generally ***allow*** chiropractors to disclosure patient information to other providers in a HIE/RHIO for **treatment** purposes and, so, the regulations **should not be a barrier** to implementing an Opt-Out approach for the State. Again, clarification that "patient record" may include EMR could be beneficial.	• Clarify definitions so it is clear that "patient record" includes information maintained in an EMR.

Appendix D – Analysis of Selected New Jersey Confidentiality and Patient Approval Regulations

INFORMATION-TYPE	RULE and EXCEPTION(S)	COMMENTS	Recommended Considerations
HIV/AIDS Records	**N.J.S.A. 26:5C-7** A record maintained by: d. **a provider** of health care or a **health care facility** as defined by [N.J.S.A.26:2H-2]; or h. **any other institution** or **person**; *which contains identifying information about a person who has or is suspected of having AIDS or HIV infection is confidential and* ***shall be disclosed only for the purposes authorized by this act.***	The restrictions in the HIV/AIDS statute applies to EVERYONE (all facilities and persons handling any such information).	None.

	N.J.S.A. 26:5C-8. a a. The **content** of a record referred to in section 3 of this act *may be disclosed in accordance with the* ***prior written informed consent*** of the person who is the subject of the record or if the person is legally incompetent or deceased, in accordance with section 8 of this act. **N.J.S.A. 26:5C-8. b** b. If the prior written consent of the person who is the subject of the record is not obtained, the person's records *shall be disclosed only under the following conditions* (1) To *qualified personnel for the purpose of* ***conducting scientific research,*** but a record shall be released for research only following review of the research protocol by an Institutional Review Board constituted pursuant to federal regulation 45 C.F.R. 46.101 et seq. *The person who is the subject of the record* ***shall not be identified****, directly or indirectly, in any report of the research and research personnel shall not disclose the person's identity in any manner.* (2) To *qualified personnel for the purpose of conducting* ***management audits, financial audits or program evaluation***, but the personnel *shall not identify, directly or indirectly, the person who is the subject of the record in a report of an audit or evaluation, or otherwise disclose the person's identity in any manner.* ***Identifying information shall not be released to the personnel unless it is vital to the audit or evaluation.*** (3) To ***qualified personnel involved in medical education or in the diagnosis and treatment of the person who is the subject of the record.*** Disclosure is limited to only personnel **directly involved** in medical education or in the diagnosis and **treatment of the person.** (4) *To the department as required by State or federal law.* (5) As permitted *by rules and regulations adopted by the commissioner for the purposes of disease prevention and control.* (6) In all other instances ***authorized by State or federal law.***	The law requires **"prior written informed consent"** of the patient before releasing HIV/AIDS information to any third party. Generally, "informed consent" suggests a higher duty to make sure the patient is fully informed of the benefits/ risks of disclosing information to a third party. In general, such information should be treated as a **"Special Category" of Information** in the HIE/RHIO context, and at a minimum safeguarded from access (e.g., put behind "break glass"). **Disclosure Exceptions**: #1 Scientific IRB-approved research #2 Certain audit functions, but info must be de-identified unless vital to the audit or evaluation #3 Qualified personnel directly involved in medical education #4 Qualified personnel directly involved in treatment of the person. #5 Reporting to NJDOHSS as required by law #6 As permitted by NJDOHSS for disease prevention and control #7 If authorized by State or federal law. Some the restrictions in the HIV/AIDS statute are **unclear as to whether certain third parties can access or receive such HIV/AIDS information without the patient's prior informed consent,** and therefore could be a barrier to such information being made available or being contained in the HIE/RHIO pursuant to an Opt-out approach.	• Consider clarifying that **direct treatment provider** could include providers that are not necessarily treating the patient HIV/AIDS, but may have a **legitimate need to know/access such information** in connection with treating the patient for other conditions. • Consider clarifying whether **ancillary support staff** may be permitted access to support treatment by physician. • Consider clarifying that **HIE/RHIO is permitted to facilitate the transmission of such information to an authorized recipient** without having to obtain prior written informed consent of the patient. • Consider clarifying **whether the statute required prior informed consent of the patient to disclose certain HIV/AIDS pharmaceutical drugs contained in a patient's record and disclosed to providers and others in connection with patient care.** If interpreted that the statute requires prior patient consent before such drugs are identified anywhere throughout the HIE/RHIO, this could cause substantial compliance challenges of tagging such HIV/AIDS-specific pharmaceuticals anywhere they are referenced throughout an EMR.

	N.J.S.A. 26:5C-9 a. The record of a person who has or is suspected of having AIDS or HIV infection may be disclosed by ***an order of a court*** *of competent jurisdiction* which is granted pursuant to an application showing *good cause* therefor. […] b. A court may authorize disclosure of a person's record for *the purpose of* ***conducting an investigation of or a prosecution for a crime of which the person is suspected*****,** only if the crime is a first degree crime and there is a reasonable likelihood that the record in question will disclose material information or evidence of substantial value in connection with the investigation or prosecution. c. Except as provided in subsections a. and b. of this section, a record shall not be used to initiate or substantiate any criminal or civil charges against the person who is the subject of the record or to conduct any investigation of that person.	**Additional Disclosure Exceptions**: #1 court order #2 investigation of crimes	No recommendations.
	N.J.S.A. 26-5C-10 The limits on disclosure set forth in this act shall continue to apply to a record relating to AIDS and HIV infection concerning a person who has been a patient or a participant in a program, whether that person remains a patient or participant or ceases to be a patient or participant.	None.	No recommendations.
	N.J.S.A. 26:5C-11 Any record disclosed under this act **shall be held confidential by the recipient of the record and shall not be released by said recipient unless the conditions of this act are met.**	** **Note that the restriction extends to RE-DISCLOSURES of such information** as well, so if consent is obtained to disclosure to a third party, the third party must similarly protect and not re-disclose the information without obtaining an additional informed consent from the patient.	No recommendations.

Venereal Diseases	**N.J.S.A. 26:4-41** **No person shall disclose the name or address or the identity of any person known or suspected to have a venereal disease** except to the person's physician or to a health authority, or, in the event of a prosecution under this article or under the criminal law of this State, to a prosecuting officer or to the court; provided, *however, that the person's physician or a health authority may disclose the name, address or identity of such person when and only when the physician or health authority shall deem such disclosure necessary in order to protect the* ***health or welfare of the person*** *or of his family or of the public;* and provided further, that nothing herein shall be construed as in any way *restricting such disclosures to the State Department of Health*. Documents, records or reports which contain or would reveal the name, address or identity of a person known or suspected to have a venereal disease or treated for such a disease **shall not be open to inspection** *except by an authorized representative of the State Department of Health or, in the event of a prosecution under this article or under the criminal laws of this State, by a prosecuting officer or the court*; provided, however, that the *custodian* of any such documents, records or reports ***may permit*** inspection of them by a **licensed physician** or a health official *whenever said custodian shall deem such inspection* ***necessary in order to protect the health or welfare of the person*** *or of his family or of the public* and the custodian of any hospital record *shall permit examination of such record in connection with any claim for compensation or damages for personal injury or death* resulting therefrom by any person authorized by any other law to make such examination.	The law requires prohibits information regarding venereal diseases about a patient from being disclosed. Generally, patient authorization will be required and such information should be treated as a "**Special Category" of Information** in the HIE/RHIO context, and at a minimum safeguarded from access (e.g., put behind "break glass"). Some the restrictions in the statute are **unclear as to whether certain third parties can access or receive such information without the patient's prior authorization,** and therefore could be a barrier to such information being made available or being contained in the HIE/RHIO pursuant to an Opt-out approach.	• Consider clarifying that **direct treatment provider** could include providers that are not necessarily treating the patient for venereal disease, but may have a **legitimate need to know/access such information** in connection with treating the patient for other conditions. • Consider clarifying whether **ancillary support staff** may be permitted access to support treatment by physician. • Consider clarifying that **HIE/RHIO is permitted to facilitate the transmission of such information to an authorized recipient** without having to obtain prior written informed consent of the patient. • Consider clarifying **whether the statute will require prior informed consent of the patient to disclose certain venereal pharmaceutical drugs contained in a patient's record and disclosed to providers and others in connection with patient care.**
Genetic Privacy Act	**N.J.S.A. 10:5-43** b. Genetic information is personal information that **should not be collected, retained or disclosed** without the individual's authorization.	The law requires prohibits certain genetic information from being disclosed without prior patient authorization. Generally, such information should be treated as a "**Special Category" of Information** in the HIE/RHIO context, and at a minimum safeguarded from access (e.g., put behind "break glass").	No recommendations.

	N.J.S.A. 10:5-45 No person shall obtain genetic information from an individual, or from an individual's **DNA sample**, *without first obtaining* ***informed consent from the individual*** *or the individual's representative* according to regulations promulgated by the Commissioner of Health and Senior Services, in consultation with the Commissioner of Banking and Insurance, pursuant to subsection b. of section 9 of P.L.1996, c.126 (C.10:5-48). a. The requirements of this section *shall not apply to genetic information obtained*: (1) By a State, county, municipal or federal law enforcement agency for the purposes of establishing the *identity of a person in the course of a criminal investigation or prosecution*; (2) To determine *paternity* in accordance with the provisions of section 11 of P.L.1983, c.17 (C.9:17-48); (3) Pursuant to the provisions of the "*DNA Database and Databank Act of 1994*," P.L.1994, c.136 (C.53:1-20.17 et seq.); (4) To determine *the identity of deceased individuals*; (5) For *anonymous research* where the identity of the subject will not be released; (6) Pursuant to *newborn screening requirements* established by State or federal law; or (7) As authorized by *federal law for the identification of persons*. b. In the case of a policy of life insurance or a disability income insurance contract, informed consent shall be obtained pursuant to the provisions of P.L.1985, c.179 (C.17:23A-1 et seq.).		

	N.J.S.A. 10:5-46 a. No person shall *retain* an individual's genetic information *without first obtaining authorization under the informed consent requirement* of section 6 of P.L. 1996, c. 126 (C. 10:5-45) from the individual or the individual's representative, *unless*: (1) Retention is *necessary for the purposes of a criminal or death investigation or a criminal or juvenile proceeding*; (2) Retention is *necessary to determine paternity* in accordance with the provisions of section 11 of P.L.1983, c.17 (C.9:17-48); (3) Retention is *authorized by order of a court of competent jurisdiction*; (4) Retention is made pursuant to the provisions of the "*DNA Database and Databank Act of 1994*," P.L. 1994, c. 136 (C. 53:1-20.17 et seq.); or (5) Retention of information is for *anonymous research* where the identity of the subject will not be released. e. An individual or an individual's representative, promptly upon request, may inspect, request correction of and obtain genetic information from the records of the individual unless the individual directs otherwise by informed consent pursuant to section 6 of P.L. 1996, c. 126 (C. 10:5-45); *except that, in the case of a policy of life insurance or a disability income insurance contract, the provisions of P.L. 1985, c. 179 (C. 17:23A-1 et seq.) shall apply*.		

	N.J.S.A. 10:5-47 a. Regardless of the manner of receipt or the source of genetic information, including information received from an individual, *a person may not disclose or be compelled, by subpoena or any other means*, to disclose the identity of an individual upon whom a genetic test has been performed or to disclose genetic information about the individual in a manner that permits identification of the individual, *unless:* (1) Disclosure is *necessary* for the purposes of a *criminal or death investigation* or a *criminal or juvenile proceeding*; (2) Disclosure is necessary to *determine paternity* in accordance with the provisions of section 11 of P.L.1983, c.17 (C.9:17-48); (3) Disclosure is *authorized by order of a court* of competent jurisdiction; (4) Disclosure is made pursuant to the provisions of the "*DNA Database and Databank Act of 1994*," P.L.1994, c.136 (C.53:1-20.17 et seq.); (5) Disclosure is *authorized by the tested individual or the tested individual's representative* by *signing a consent* which complies with the requirements of the Department of Health and Senior Services; (6) Disclosure is for the purpose of *furnishing genetic information relating to a decedent for medical diagnosis of blood relatives of the decedent*; (7) Disclosure is for the purpose of *identifying bodies*; (8) Disclosure is pursuant to *newborn screening* requirements established by State or federal law; (9) Disclosure is authorized by *federal law* for the *identification of persons*; or (10) Disclosure is by an *insurer* pursuant to the requirements of P.L.1985, c.179 (C.17:23A-1 et seq.). b. The provisions of this section apply to any subsequent disclosure by any person after another person has disclosed genetic information or the identity of an individual upon whom a genetic test has been performed.		

	RULE and EXCEPTION(S)	COMMENTS
Medicaid	**N.J.A.C. 10:49-9.7(a)-(c)** (a) All information concerning applicants and beneficiaries acquired under this program shall be confidential and *shall not be released without the written consent of the individual or his or her authorized representative*. If, because of an emergency situation, time does not permit obtaining consent before release, the program shall notify the individual, his or her family, or authorized representative, *immediately after releasing the information*. (b) The restriction on the disclosure of information *shall not preclude* the release of *statistical or summary data or information in which applicants or beneficiaries are not, and cannot be, identified*; nor shall it preclude the *exchange of information among providers furnishing services*, *Fiscal Agent of the program*, and *State or local government agencies*, for purposes *directly connected* with *administration of the program*. Disclosure without the consent of the applicant or beneficiary shall be limited to purposes directly connected with the administration of the program in accordance with Federal and State law and regulations. 1. Purposes *directly connected* with the administration of the program shall include but are not limited to: i. Establishing eligibility; ii. Determining the amount of medical assistance; iii. Providing services for beneficiaries; and iv. Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the program. (c) The type of information about applicants and beneficiaries that shall be safeguarded by the program includes, but is not limited to: 1. Name and address; 2. Medical services provided; 3. Social and economic conditions or circumstances; 4. Program evaluations of personal information; 5. Medical data, including diagnosis and past history of disease or disability; 6. Any information received for verifying income eligibility and amount of medical assistance payments. Income information received from SSA or the Internal Revenue Service shall be safeguarded according to the requirements of the agency that	

	RULE and EXCEPTION(S)	COMMENTS
	furnished the data; and 7. Any information received in connection with the identification of legally liable third party resources as required under applicable Federal Regulations (42 C.F.R. 433.138).	
Mental Health "Provider Agency Programs"	**N.J.A.C. 10:37-6.79(a),(b),(e),(f),(h),(i)** (a) All certificates, applications, information and records directly or indirectly identifying persons who are receiving or have received mental health services from a provider licensed by the Department, or for whom such services were sought, shall be kept confidential and shall not be disclosed by any person, *except under the following circumstances*: 1. Upon *authorization of the consumer*: 2. Pursuant to a *court order directing disclosure*, upon its determination that disclosure is necessary for the conduct of its proceedings before it and that failure to make such disclosure would be contrary to the public interest; or 3. To *carry out any of the provisions of Title 30 or Article 9 of Chapter 82 of Title 2A of the New Jersey Statutes* (N.J.S.A. 2A:82-41), or as required by other *Federal or State law*. (b) Consumer records **may also be disclosed** to the following persons, upon presentation of appropriate credentials, *under these circumstances*: 1. *Employees of the agency* who are involved in the care of the consumer provided, however, that when a consumer enters treatment(s) he or she will be informed that agency staff will have access to his or her records. 2. *Clinical records audit teams, monitoring and site review staff* designated by the Department, the Office of Legislative Services, the New Jersey Department of Health and Senior Services, and the Center for Medicaid & Medicare Services; 3. A *person participating in a Professional Standards Review Organization*; and 4. *Officials within the offices of the State Medical Examiner or a County Medical Examiner* making investigations and conducting autopsies, pursuant to N.J.S.A. 52:17B-78 et seq.	

	RULE and EXCEPTION(S)	COMMENTS
	(e) Nothing in this section shall preclude disclosure, upon proper inquiry and after the consumer has had the opportunity to object and does not express an objection, of *information as to a consumer's current medical condition to any relative or friend*. (f) Information may be disclosed to *any licensed mental health provider or medical health care provider* who has a *contract with the Division of Mental Health Services or the Department of Human Services*, or to the consumer's *personal physician* if it appears that the information is to be used for the benefit of the consumer. (h) Where disclosure to third parties is authorized pursuant to (b) above, [certain specified] conditions shall be observed.[…] (i) Consent to disclosure of records *shall be evidenced by a signed authorization* from the consumer or his or her legally authorized representative.	
HealthStart Maternity Care	**N.J.A.C. 10:52-3.11(a),(c)** (a) HealthStart maternity care providers shall have policies which protect patient confidentiality, provide for informed consent and document… services in accordance with the Department of Health and Senior Services' "HealthStart Comprehensive Maternity Care Services Program Guidelines." (c) Each record shall be confidential….	
	N.J.A.C. 10:52-3.15(a),(c) (a) HealthStart pediatric care providers shall have policies which protect patient confidentiality, provide for informed consent and document comprehensive care services. (c) Each record shall be confidential….	
	N.J.A.C. 10:54-6.12 (a) HealthStart Maternity Medical Care providers shall have policies which protect patient confidentiality, provide for informed consent and document… services in accordance with the Department of Health and Senior Services' "HealthStart Comprehensive Maternity Care Services Program Guidelines." (c) Each record must be confidential….	

[i] Who is an authorized person for federal law purposes? May lab results go into an HIE without patient consent?

42 CFR 493.1241(a)

"Authorized person means an individual authorized under State law to order tests or receive test results, or both."

42 CFR 493.1291

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry…to final report destination, in a timely manner.

(f) Test results must be released only to authorized persons and, if applicable, *the individual responsible for using the test results* and the laboratory that initially requested the test.

(i) If a laboratory refers patient specimens for testing—

(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test.

CMS Interpretive Guidelines 493.1291(a)

To ensure the accurate, timely, confidential, and easily understood reporting of patient test results to the authorized person, their agent (if applicable) and others who are identified as responsible for using the test results on the requisition, a laboratory may contract with another entity to assist in the delivery of patient reports in a manner that complies with all applicable laws, including the CLIA regulatory and statutory requirements.

CMS Interpretive Guidelines FAQs

Test results must be released to the authorized person, or if applicable, their agent. Test results must also be released to any additional individuals/entities designated on the test requisition. These entities are understood to be "responsible for using" the test results.
An authorized person *may contract with an EHR vendor or HIE to serve as their agent. That agent, as noted below, could then receive test reports from laboratories on behalf of that authorized person.* To do so, authorized persons *might* designate these persons/entities as the final report destination on the test requisition. Based on that requisition, the laboratory would then be able to send the test results to the identified HER vendors or HIEs.

Who is an authorized person for NJ purposes? May lab results go into an HIE without patient consent?

N.J.S.A. 45:9-42.27

"Person" means any individual, partnership, limited partnership, corporation or other legal entity.

N.J.S.A. 45:9-42.34

Where feasible such rules and regulations shall equal or exceed minimum standards for laboratory certification contained in Federal rules and regulations promulgated pursuant to [CLIA] of 1967.

N.J.S.A. 45:9-42.38

The department and any officers or employees thereof in the performance of any duty imposed by this act shall have the power and authority to enter at any time and inspect any clinical laboratory for the purpose of studying and evaluating the operation, supervision, records, and procedures of such facilities and to determine their effect upon the health and safety of the people of the State.

N.J.S.A 45:9-42.42
No person shall:
(c) Accept specimens for tests from and make reports to persons who are not legally qualified or authorized to submit specimens to clinical laboratories and to receive such reports, but this shall not prohibit the referral of specimens from one licensed clinical laboratory to another similarly licensed under the laws of the state in which it is located, providing the report indicates clearly the clinical laboratory performing the test and the name of the director of such clinical laboratory.
N.J.A.C. 8:44-2.7
(g) The laboratory shall examine specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations and *shall report only to those authorized by law* to receive such results.
(1) If **a patient is sent to the laboratory, a written request for the desired laboratory procedures must be obtained from a person authorized by law to use findings of laboratory examination.**
(2) If only a specimen is sent, it must be accompanied by a written request.
(i) The original or true duplicate of the laboratory report *shall be sent promptly to the licensed physician or other authorized person who requested the test*….
(3) The results of laboratory tests or procedures or transcripts thereof *shall be sent to the licensed physician, dentist or other person authorized by law to use the findings of laboratory examinations*. *The patient may request a copy of such reports….*
(6) If the laboratory refers specimens to another laboratory, the physician ordering an examination shall receive the original reference laboratory report or a true duplicate of that report. The reference laboratory must report its findings on report forms of the reference laboratory. *If the physician so requests, the referring laboratory may authorized the testing laboratory to report directly to the physician or other authorized person who requested the test, in which even the testing laboratory must send a duplicate of the report to the referring laboratory.*