

## **Introduction**

[Massachusetts Health Data Consortium](#) (MHDC) welcomes the opportunity to respond to the RFI put forward by the Office of the National Coordinator for Health Information Technology. Founded in 1978 by the state's major public and private health companies, MHDC's mission is to "lead the development of a comprehensive data system to address the health information needs of the Commonwealth for the purpose of improving health care and health." The development of a National Health Information Network is consistent with MHDC's core mission (albeit on a national versus statewide level).

Massachusetts, long recognized as a world class center of medical excellence, is also recognized for its innovative use of state-of-the-art healthcare IT. Leading healthcare organizations along with the MHDC through its collaborative MA-SHARE initiative have successfully deployed the following representative projects in the Commonwealth:

### **CLINICAL DATA EXCHANGE**

#### ***Collaborative Community Efforts to Reduce Adverse Drug Events in Emergency Departments***

[Massachusetts SHARE, LLC](#) (Simplifying Healthcare Among Regional Entities) the RHIO for Massachusetts. The sole "member" of MA-SHARE is the community board of directors of Massachusetts Health Data Consortium (MHDC). MA-SHARE seeks to promote the inter-organizational exchange of healthcare data among the various participants in the healthcare system (patients, providers, payers) using information technology, standards and administrative simplification, in order to make accurate clinical health information available wherever needed in an efficient, cost-effective and safe manner.

[MedsInfo-ED](#), a MA-SHARE project, required unparalleled cooperation among health plans and their pharmacy benefit managers (PBMs), hospitals, government agencies and technology companies to provide dispensed drug history derived from prescription claims to emergency department clinicians. This project represents the first time Medicaid information was made available to support patient care initiatives.

### **CPOE**

#### ***Serious Medical Errors Reduced Significantly by Installing Computerized Physician Order Entry***

[Brigham and Women's Hospital](#) is among the first in the country to pioneer the development and use of CPOE, advancing patient safety.

### **E-PRESCRIBING**

#### ***Two Groundbreaking Initiatives Wire Massachusetts Physicians for ePrescribing***

[Tufts Health Plan](#) and [Blue Cross Blue Shield of Massachusetts](#) teamed with [ZixCorp](#) to launch [eRx Collaborative](#), a groundbreaking \$3 million initiative to accelerate e-prescribing in Massachusetts, advance patient safety and reduce healthcare spending.

[Massachusetts Medical Society](#) is the first state medical society to endorse an **electronic prescription program** for its members with the signing of an agreement with [DrFirst](#).

#### **PHYSICIAN PATIENT CONNECTIVITY**

##### ***IDN Portals Provide Secure Channel for Patients to Communicate with their Physicians***

[CareGroup](#)'s [PatientSite](#) and [Partners](#)' [Patient Gateway](#) provide secure online-communication between patients and providers, allowing patients to view their clinical records, request appointments, referrals and prescription renewals, and ask providers non-urgent questions.

[CareGroup](#) and [Blue Cross Blue Shield of Massachusetts](#) have licensed [RelayHealth](#)'s webVisits that enables charging and reimbursement for patient **eVisits**.

#### **SECURE E-MAIL**

##### ***Secure Email Initiative Enables Healthcare Stakeholders to Exchange Patient Information Securely and Efficiently***

The [Open Group and Massachusetts Health Data Consortium](#) (MHDC) launched **S/MIME Gateway Certification**, a certification program which guarantees the interoperability of e-mail products that encrypt e-mail at the organization boundary to ensure the privacy and security of information carried by e-mail across public networks for HIPAA compliance.

#### **RECENTLY FUNDED INITIATIVES**

##### ***Clinical Data Exchange***

[SAFE Health Info](#) (Secure Architecture for Exchanging Health Information), a clinical data exchange covering central Massachusetts, will be created [Fallon Clinic](#), a 240-doctor multispecialty group practice; [Fallon Community Health Plan](#); and [UMass Memorial Health Care](#) -- all in Worcester, Mass. The participants initially will exchange medication lists, information on allergies, diagnoses, immunization status, test results and text-based reports such as discharge summaries, operative notes and radiology reports.

##### ***Electronic Health Records***

The [Massachusetts eHealth Collaborative](#) (MAeHC) is a newly launched, non-profit entity backed by 34 key Massachusetts stakeholders seeking to create a state-wide health information network to improve the quality, safety, and affordability of health care. [Blue Cross Blue Shield of Massachusetts](#) pledged \$50 million to help fund the first three EHR pilot communities.

## **ONCHIT RFI Response**

MHDC will focus its response to the ONCHIT RFI on several key questions that underscore the communitywide collaborative efforts it is currently undertaking through its MA-SHARE initiatives.

- 1. The primary impetus for considering a NHIN is to achieve interoperability of health information technologies used in the mainstream delivery of health care in America. Please provide your working definition of a NHIN as completely as possible, particularly as it pertains to the information contained in or used by electronic health records. Please include key barriers to this interoperability that exist or are envisioned, and key enablers that exist or are envisioned. This description will allow reviewers of your submission to better interpret your responses to subsequent questions in this RFI regarding interoperability.**

### *Lessons Learned*

Through MA-SHARE's groundbreaking work on MedsInfo-ED, an early stage clinical data exchange project, we have cataloged "lessons learned" that will need to be addressed on the regional, and in some cases at the national level, for the National Health Information Network to be successful.

1. CDE requires considerable resource commitments from stakeholders
2. Strategic alignment among stakeholders is required
3. Patient identification is difficult - but not impossible
4. Clinical data standards are needed ASAP
5. Contracting for data access and distribution rights is time consuming
6. Privacy and security issues are on the "critical path"
7. Not everyone interprets HIPAA Electronic Data Standards the same way
8. State privacy laws and regulations can be more stringent than HIPAA--imposing workflow modifications
9. Stakeholder policies and procedures can impede CDE (e.g. Employers' PBM carve-outs complicate access to prescription data).
10. Data limitations (e.g. timeliness, retention) impact on CDE
11. Technology issues require consensus on scalability and interoperability.
12. Sustainable business case for regional CDE starts with local stakeholders.
13. Senior-level management team with project management and consensus-building experience is essential.
14. Start with an "easily" explained application (e.g. electronic Rx history) derived from an existing quality improvement/ patient safety community



activity ( e.g. JCAHO's Reconciling Medications) as a time limited pilot project with enthusiastic stakeholder/ participants — as the “dry-run” for broader CDE.

*Key Barriers Observed in our MA-SHARE Projects*

- Lack of funding for capital investments in information technology
- Slow widespread adoption of EHRs, CPOEs and other clinical systems capable of local clinical data exchange intra- and inter-enterprise
- Inadequate provider IT investment, especially by physician practices
- Broadband connectivity is not ubiquitous (but it is expanding) in all regions or used by all stakeholders, again especially in physician offices
- Incomplete access to data (e.g., Medicare will need to allow its data to be shared data electronically)
- No clear cut business case established – who will pay and who will get paid?
- Competitive nature of healthcare stakeholders, and especially vendors, needs to be overcome to create a collaborative working relationship among the participants in either the RHIO or NHIN.
- Competing vendors' market objectives and business models must be balanced with community-wide goals for clinical connectivity. Delays will be inevitable if organizations are reluctant or hesitant to collaborate. Such a delay in our region's CDE initiative occurred for a number of reasons, including:
  - the CDE project requires changes in the vendor-collaborators' business standard practices
  - the project is not perceived as having value for some of the collaborating vendors
  - or the project was seen as a competitive threat.

*Key Enablers for our RHIO in Massachusetts*

- Programs, grants, initiatives like pay-for-performance to encourage the adoption of EMRs, CPOEs and ePrescribing systems
- Federal mandates to electronically transmit standards-based prescriptions (new and renewal) to pharmacies, as well as formulary checking with health plans and medication history and issuing an e-prescribing NPRM based on the NCVHS recommendations.



3. **What aspects of a NHIN could be national in scope (i.e., centralized commonality or controlled at the national level), versus those that are local or regional in scope (i.e., decentralized commonality or controlled at the regional level)? Please describe the roles of entities at those levels. (Note: “national” and “regional” are not meant to imply federal or local governments in this context.)**

*For our Regional Health Information Organization — MA-SHARE*

- *Think nationally, act locally.* While Federal officials are trying to reach consensus on a national health information network, our community’s RHIO has focused on reaching consensus on prototype clinical data exchange projects in Massachusetts starting with MedsInfo ED, a patient safety initiative that makes dispensed prescription history available to emergency department clinicians. MedsInfo-ED is live and is transmitting real-time data from health plans and PBMs to emergency departments.
- Patient identification and verification in the ED is difficult since it is outside of an existing PCP/Patient relationship; RHIOs are better positioned to perform the sensitive patient identification and verification functions across settings.
- Given that most healthcare delivery is local, the primary clinical data exchange will occur locally within the RHIO. That said, RHIOs will need to be able to “connect” to other RHIOs to access clinical data for patients receiving care away from home (e.g., “Snowbirds” wintering in more temperate climates, college students, travelers, in addition to healthcare organizations with border state facilities).
- The local RHIO will establish the community MPI with pointers to where a patient received care. Patients/providers will have the option to not publish a pointer to their medical records at a certain location. E.g., it may be acceptable to show that the patient was an inpatient at Massachusetts General Hospital for cardiac care, but may not be acceptable to show that the patient received mental health counseling at a psychiatric hospital.
- The local RHIO will prioritize which data sets (e.g., dispensed drug history, lab results, etc.) are brought online first, according to local demand.
- A template for contracting is needed for community-wide permitted data disclosures; and the community’s IT intellectual property resulting from collaboration. Contracting took more time than planned for in our MedsInfo-ED pilot.
- The local RHIO establishes the “chains of trust” relationships between the RHIO and stakeholders. Contracting for data access and distribution rights between the stakeholders will be the purview of the RHIO.
- The local RHIO will establish the community’s baseline standards for security and privacy practices. However, these local standards needs to be rationalized



somehow at the national level with an acceptable standards “floor”; otherwise it may be possible for some RHIOs to isolate their data and prohibit access because their privacy and security requirements are more stringent than any other RHIO or the national guidelines.

*National*

The following must occur at the National level – and in some cases be promulgated by the Federal government.

- Clinical data standards are needed ASAP and a neutral, non-partisan organization like a RHIO is well suited to be the regional enforcer of those national standards. ePrescribing has been a good process to start with to learn which data standards are needed for CDE.
- Standards and transaction mandates occur at the national level. Standards need to be promulgated for e-prescribing including the prescription message, formulary information and dispensed drug history.
- There are no standards for data source timeliness. For example, in Massachusetts, MedsInfo ED clinical data exchange pilot data sources make medication claims history available for active subscribers anywhere from 24-hours to 3-months after the prescription was dispensed.
- Similarly, there is no standard for how long data sources maintain medication history available for active subscribers. In this pilot, we discovered a variation from 6 months to 24 months. (by Massachusetts law, hospitals must maintain records for 30 years.)
- For terminated health plan subscribers, there is no standard for data retention for CDE. There is uncertainty over who must seek the subscriber’s permission for data access — the new health plan only or both former and new data source
- Technical vendors still have different interpretations of what comprises a HIPAA eligibility transaction (x12n 270/271). Further clarification of transaction standards need to be issued.
  - What data fields are required to be returned for CDE?
  - What additional data fields are situational?



**7. What privacy and security considerations, including compliance with relevant rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), are implicated by the NHIN, and how could they be addressed?**

- Privacy and security issue resolution is achievable. However, reaching consensus among regional stakeholders regarding reasonable and appropriate local practices is critical. Formation of Privacy and Security Workgroups that are empowered to perform the final review and sign off of local privacy and security should happen early in the development of the RHIO.
- Privacy and Security requirements interpretation may vary based on covered entity type, size and organizational resource availability, requiring managing acceptable compromises when working collaboratively with regional stakeholders.
- Varying interpretations of HIPAA data transaction rules among stakeholders can impede progress. For example in Massachusetts, privacy interpretations caused health plans and their respective PBMs to “withhold” inactive (i.e., terminated) health plan member information from the database of claims/clinical information available to the MedsInfo Pilot, the Commonwealth’s first CDE project that makes available prescription data to ED clinicians. Pilot hospitals explored “incidental” disclosure HIPAA interpretation to address the issue, but this argument would not be readily considered by PBMs or health plans. Consequently, when a patient switched health plans, the prescription data associated with the first health plan and its PBM could no longer be accessed by the MedsInfo ED application.
- Federal preemption of certain state disclosure laws and regulations may be needed. We have filed a bill with the Massachusetts legislature to obviate the need for a second patient consent (in addition to the consent obtained at point of service) to disclose health plans’ dispensed drug history for the treatment of HIV, substance abuse and mental health. Also in Massachusetts, the Fair Information Practice Act (FIPA) is stricter than HIPAA’s privacy regulations. FIPA requires that hospitals notify certain classes of patients (State employees and Medicaid members) that their PHI was accessed while in the ED if they were unconscious and/or unable to grant access. This requirement resulted in additional workflows for these patients, creating a burden on already resource-strapped healthcare organizations, and the risk of the hospital being out of compliance with FIPA despite its best intentions to protect the patient from an adverse drug event.
- The design of the community’s master patient index should accommodate patients and clinicians who may want to request restrictions for access and distribution of clinical data.





- Business associate agreements between organizations will need to be specified in as much detail as possible in advance of both vendor selection and contracting.
- If contracting is done between the RHIO/NHIN and the stakeholder, then it may not be necessary between and among the individual stakeholders connected to the RHIO/NHIN
- Adequate testing environments and processes to conduct regression, end-to-end and application testing must be addressed in the privacy and security agreements. Test data sets to verify interoperability between disparate systems would be extremely helpful.





**12. How could community and regional health information exchange projects be affected by the development and implementation of a NHIN? What issues might arise and how could they be addressed?**

- To reach Dr. Brailer's goal of "informed clinical practice", RHIOs will need help from ONCHIT/NHIN to encourage competing organizations with clinical data (laboratory and x-ray vendors) to collaborate and develop strategies to engage RHIOs (see RxHub and SureScripts as models).
- Medicare and the Veterans' Administration (VA) with help from ONCHIT/NHIN must participate and contract with each RHIO for CDE. (E.g. most VA patients are treated in multiple public and private settings. Their medication history is needed by all of their prescribing physicians.)
- Health plans (commercial, Medicare and Medicaid) and their agents (PBMs) are new players in CDE. A strategic alignment is needed among employers, health plans and providers on data policies. National entities (e.g., Cigna, Aetna, United) participating in the NHIN would also be encouraged by the ONCHIT to participate in a RHIO even though they may not have significant market presence in a particular region of the country.
- The NHIN could extend the clinical data available to RHIOs by pointing to where data would be found in other RHIOs. The NHIN in effect could be a master RHIO index. RHIOs would be able to access the NHIN to locate patient record/pointers to patient records in other RHIOs across the nation.



**24. How could success be measured in achieving an interoperable health information infrastructure for the public sector, private sector and health care community or region?**

- Local RHIOs are established, contracts are in place, and clinical data are exchanged in support of payment, treatment and operations.
- Clinical data are available seamlessly at point of care regardless of where prior care was rendered (provided patient or provider did not opt out of CDE).
- High percentage of institutions have installed EHRs, CPOEs and make use of CDE across enterprises within the RHIO and then out to the NHIN.
- One hundred percent of all claims and eligibility transactions are transmitted by providers using HIPAA standard electronic transactions.
- High percentage of all prescriptions are transmitted electronically by providers directly to pharmacy computers.
- High percentage of local RHIO initiatives raise money from stakeholders in their region.
- E-prescribing national standards promulgated.
- State Medicaid agencies participate in or help initiate RHIOs across the United States.
- CMS regional offices participate in and/or help initiate RHIOs across the United States.
- Veterans Administration offices participate in and/or help initiate RHIOs across the United States.
- A resource center is established by the NHIN, that is used effectively and with satisfaction by RHIOs.
- Care management goals are met across all enterprises in the region (via health information technology.) especially for patients with chronic illnesses.
- High percentage of stakeholders can install internally-developed or third party applications with relative ease as a result of the vendor-neutral CDE engine.
- The local RHIOs and NHIN are easily accessible by using a simple web browser; this capability will address the wide variation in its deployment across the different stakeholders.
- Increased consumer satisfaction with healthcare “customer service”. Patients will no longer be asked to provide the same information or have duplicate services rendered at multiple sites across the RHIO and ultimately NHIN.