Program Information Notice

Document Number: ONC-HIE-PIN-001

Date: July 6th, 2010

Document Title: Requirements and Recommendations for the State Health Information Exchange Cooperative Agreement Program

TO: State Health Information Exchange Cooperative Agreement Program Award Recipients

As stated in the State Health Information Exchange Cooperative Agreement Program Funding Opportunity Announcement (FOA), the Office of the National Coordinator for Health Information Technology (ONC) may offer program guidance to provide assistance and direction to states and State Designated Entities (SDEs) that receive awards under the program. The purpose of this Program Information Notice (PIN) is to clarify the FOA with respect to state and SDE responsibilities under the program, recommended roles for the State HIT Coordinators, and elements of the state strategic and operational plans.

If you have any questions or require further assistance, please contact your project officer or the State Health Information Exchange Cooperative Agreement Program at statehiegrants@hhs.gov.

Sincerely,

David Blumenthal
National Coordinator

Attachment

Introduction

This PIN provides direction to state level efforts under the State Health Information Exchange Cooperative Agreement Program (State HIE Program). Specifically, this PIN clarifies the State Health Information Exchange Cooperative Agreement Program Funding Opportunity Announcement, EP-HIT-09-001, CFDA 93.719, with respect to state/SDE[1] responsibilities under the program, recommended roles for the HIT Coordinators, and elements of the state strategic and operational plans. Success of this program is dependent on a strong and productive collaboration between states/SDEs and ONC.

The HITECH Act authorized the award of funds to states/SDEs to facilitate and expand health information exchange (HIE) among organizations. These resources, which should be viewed as a one-time investment, can provide a critical impetus to facilitate state HIE efforts including those meeting HIE meaningful use requirements, but substantial challenges face ONC and states/SDEs in developing the robust exchange infrastructure that we all seek. The amount of funding and timeline will in many cases make it challenging for states to implement and operate comprehensive statewide health information exchange services. States, therefore, should carefully consider the advantages and disadvantages of using limited HITECH funds -- without substantial other sources of support and/or a strong existing infrastructure -- to immediately deploy a robust, fully developed statewide exchange. Similarly, the alternative of deploying a series of local pilots of exchange, while useful for the long-term, may not enable the levels of exchange necessary to meet the requirements for meaningful use, especially as these requirements become more demanding in later stages. Furthermore, ONC is concerned that HIE sustainability models that rely on mandated provider or hospital participation in specific HIE services offered by the state or SDE might inappropriately limit provider choices in the full array of information exchange alternatives, thereby threatening the ability of providers to achieve meaningful use, particularly where state-designated services are still limited or nonfunctional.

While states have the responsibility to determine HIE strategies that may be accomplished through a variety of approaches, ONC will work with states to be creative and resourceful, identifying ways to use these critical but scarce resources to fill gaps in a thoughtful and reality-based way while leveraging existing information exchange activities and engaging trading partners to encourage and sustain health information sharing. We encourage states to focus on targeted actions to ensure that all eligible providers have options to meet meaningful use information exchange requirements.

A common set of principles shapes ONC's work in health information exchange including the state HIE program:

- Support privacy and security
- Focus on desired outcomes, especially meaningful use of EHRs.
- Support HIE services and adoption for all relevant stakeholder organizations, including providers in small practices, across a broad range of uses and scenarios
- Be operationally feasible and achievable, building on what is already working
- Remain vigilant and adapt to emerging trends and developments
- Foster innovation

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[1] References to states and SDEs throughout this PIN are used interchangeably unless inconsistent with the context or otherwise indicated.

Please note that the terms "shall" and "should" are used in very specific ways in this document. "Shall" equals a mandatory action while "should" equals a recommended course of action within the State HIE Program.

Key Deliverables and Objectives for State HIE in 2011

The immediate priority of the State HIE Program is to ensure that all eligible providers within every state have at least one option available to them to meet the HIE requirements of meaningful use in 2011. The Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that sets forth proposed Stage 1 criteria for meaningful use to include objectives and associated measures for the exchange of health information. 75 Fed. Reg. 1844 (Jan. 13, 2010). References to meaningful use requirements in this PIN are based on the proposed rule. In the event that the proposed rule is finalized and/or additional rules or guidance are issued related to meaningful use, ONC may update this PIN or issue further guidance as appropriate. Therefore, in support of this program priority related to meaningful use in 2011, states and SDEs shall outline in their State Strategic and Operational Plans (state plans) a concrete and operationally feasible plan to address and enable these three HIE capabilities in the next year[2]:

1. E-prescribing
2. Receipt of structured lab results
3. Sharing patient care summaries across unaffiliated organizations

State and SDE Responsibilities under the State HIE Program in 2011

States and SDEs are given discretion to determine how best to enable these HIE capabilities in their health care delivery and market environments and how to ensure that options will be available to satisfy the increasingly robust exchange requirements for meaningful use. However, consistent with the description of program requirements in the FOA, states and SDEs shall fulfill the following six responsibilities for continued funding as part of their participation in the State HIE Program. Specifically, states and SDEs shall use their authority, programs, and resources to:

1. **Initiate a transparent multi-stakeholder process**—Convene a representative group of relevant stakeholders, including consumers, to set clear goals for state HIE efforts and assess how those efforts can link to and support care delivery and payment reforms. Additionally, states and SDEs shall analyze and fully understand the health information exchange currently taking place within the state, complete a gap analysis, and determine how the state or SDE needs to address these gaps to ensure options are available to eligible providers in the state who seek to meet the Stage 1 meaningful use requirements for HIE, with a focus on delivery of structured lab results, e-prescribing, and sharing patient care summaries across unaffiliated organizations.

2. **Monitor and track meaningful use HIE capabilities in the state**-Set the baseline, monitor, and report on the following measures as required by the State HIE Program, which will be finalized in additional program guidance:
    - % health plans supporting electronic eligibility and claims transactions
    - % pharmacies accepting electronic prescribing and refill requests

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[2] Administrative transactions with health plans and Medicaid, and public health reporting will be the subject of future operational plans

- % clinical laboratories sending results electronically
- % health departments electronically receiving immunizations, syndromic surveillance, and notifiable laboratory results

3. **Assure trust of information sharing**—Ensure the state has a privacy and security framework for state health information exchange efforts that is consistent with and clearly addresses the elements of the HHS HIT Privacy and Security Framework found at http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848088_0_0_18/NationwidePS_Framework-5.pdf.

4. **Set Strategy to Meet Gaps in HIE Capabilities for Meaningful Use**—Develop and implement a strategy and work plan to address the gaps in HIE capabilities as identified in the environmental scan with a focus on delivery of structured lab results, e-prescribing and sharing patient care summaries across unaffiliated organizations.

   Gap-filling strategies might include:

   - Policy, purchasing and regulatory actions, such as requiring e-prescribing or electronic sharing of lab results in state or Medicaid contracts with pharmacies and clinical labs.

   - Core services to reduce the cost and complexity of exchange including authoritative provider and plan directories and authentication services that would support both simplified and comprehensive interoperability.

   - Targeted infrastructure for gap areas such as shared services for small labs or pharmacies, or to serve rural providers, which could utilize both simplified and comprehensive interoperability solutions.

   In filling these gaps, the state is not required to directly provide or construct technology infrastructure or services. A key role for states can be to provide leadership and direction to public and private stakeholders. States may also use policy and purchasing levers to extend and enhance existing HIE activities in the state so as to encourage key trading partners such as pharmacies and clinical laboratories to participate in electronic service delivery and to enable providers to meet meaningful use requirements.

   States shall also establish a strategy and immediate next steps to address the following over the course of the project:

   - Building capacity of public health systems to accept electronic reporting of immunizations, notifiable diseases and syndromic surveillance reporting from providers.

   - Enabling clinical quality reporting to Medicaid and Medicare.

5. **Ensure consistency with national policies and standards—S**tates and SDEs shall ensure that any HIE services that are funded through this program are consistent with national standards, NHIN specifications, federal policies and guidelines, and are based on technologies that are adaptable and flexible for future requirements, including exchange of information across state boundaries.

6. **Align with Medicaid and public health programs—S**tates and SDEs shall coordinate with Medicaid and public health programs to establish an integrated approach including having both programs represented in the state's governance structure and processes.

Federal Government Participation

As stated in the FOA, the ONC will work with states to advance interoperability and health information exchange through a variety of activities, including:

- Collaborate with states and SDEs to promote, monitor and share efficient, scalable and sustainable mechanisms for HIE within and across states.
- Help to coordinate and share information regarding federal health IT investments and programs across agencies (e.g., CDC, CMS, HRSA, AHRQ, ONC and non-HHS federal agencies).
- Conduct a national program evaluation and offer technical assistance for state-level evaluations.
- Adopt standards and certification criteria to enable interoperability and HIE.
- Provide technical assistance to states and SDEs.
- Coordinate information sharing across states.
- Advance standards-based HIE through Nationwide Health Information Network (NHIN) standards, services and policies.

Expected Roles for HIT Coordinator

ONC requires each state to have an HIT Coordinator who will provide HIT leadership and coordination across the federally funded state programs including supporting the efforts of the State Medicaid Directors (SMDs) in developing the state's Medicaid EHR incentive program. We expect the Coordinator to fulfill two main roles while realizing that states have flexibility in how these roles are fulfilled:

- The HIT Coordinator should develop and advocate for HIT policy to achieve statewide goals. The Coordinator will need to focus and prioritize activities to make rapid progress to help state providers meet stage 1 meaningful use requirements. Key activities may include:
    - Collaborate with state health policy makers in establishing HIT strategies for reaching shared health care goals.
    - Leverage state purchasing power such as establishing requirements for entities reimbursed by the state to participate in e-prescribing, electronic labs results delivery or electronically sharing care summaries across transitions in care.
    - Address legal or policy issues to ensure the information may be shared securely and with appropriate privacy protections.
    - Lead efforts to enable interstate HIE, such as harmonizing privacy policies and consent laws with neighboring states where appropriate.
- The HIT Coordinator should coordinate HIT efforts with Medicaid, public health and other federally funded state programs. Examples of the Coordinator fulfilling this role include:
    - Advance operationally viable strategies that accelerate the success of the EHR incentive program in meeting shared meaningful use goals.
    - Ensure state program participation in planning and implementation activities including, but not limited to Medicaid, behavioral health, public health, departments of aging.
    - Ensure that State Medicaid HIT Plans and State HIE plans are coordinated.

- Leverage various state program resources such as immunizations registries, public health surveillance systems, and CMS/Medicaid funding to ensure resources are being maximized (e.g., ARRA authorized Medicaid 90/10 match leverage to support HIE activities).
- Assure integration of other relevant state programs into the state's HIT governance structure.
- Identify, track and convene the various federal HIT grantees for cross-program coordination and to leverage program resources. Examples: RECs, Beacon Communities, Community Colleges involved in HIT workforce efforts, HRSA HIT adoption projects, federally supported broadband programs, CHIPRA HIT grantees.

Conclusion

Based on the above program guidance including state/SDE responsibilities and HIT Coordinator roles, and also based on issues that have arisen in the first wave of state plans that have been submitted to ONC, the following attachment contains additional guidance on developing state strategic and operational plans for a successful program. Additional resources to assist in the development of state plans, including a new chart showing requirements of the FOA and this PIN, can be found at www.statehieresources.org.

Attachment

Guidance on State Strategic and Operational Plans (State Plans)

In an effort to support the success of states and SDEs participating in the State Health Information Exchange Cooperative Agreement Program, ONC has compiled this planning guidance to highlight and clarify an important subset of plan requirements. Detailed guidance on state plans, including a chart with requirements for plan content, can be found at www.statehieresources.org.

Environmental Scan

Within the strategic plan, the environmental scan shall include an overview of the current HIE activities within the state including the penetration of electronic lab delivery, e-prescribing networks and other existing HIE solutions. The environmental scan should include the following measures or similar measures to determine the health information exchange taking place with these important data trading partners :

- % pharmacies accepting electronic prescribing and refill requests
- % clinical laboratories sending results electronically
- % health plans supporting electronic eligibility and claims transactions
- % health departments receiving immunizations, syndromic surveillance, and notifiable laboratory results

Strategy to Meet Meaningful Use

Strategic plans shall describe the state's overall strategy for supporting Stage 1 meaningful use including how to fill gaps identified in the environmental scan. Specifically, states and SDEs shall describe how they will invest federal dollars and associated matching funds to enable eligible providers to have at least one option for each of these Stage 1 meaningful use requirements in 2011:

1. E-prescribing
2. Receipt of structured lab results
3. Sharing patient care summaries across unaffiliated organizations

As part of the Strategic Plans, states and SDEs should also describe a strategy and plan to address the other required information sharing capabilities specified in the FOA over the course of the project, including, but not limited to:

- Building capacity of public health systems to accept electronic reporting of immunizations, notifiable diseases and syndromic surveillance reporting from providers;
- Enabling electronic meaningful use and clinical quality reporting to Medicaid and Medicare.

Coordination with Medicaid

Because of the importance of the Medicaid program in setting state level HIT policy, states and SDEs are required to describe their coordination with Medicaid in their Strategic Plans. The following activities

are either required or highly encouraged and the activities adopted shall be reflected in the state HIE plan.

Required Activities:

1. The state's governance structure shall provide representation of the state Medicaid program.
2. The grantee shall coordinate provider outreach and communications with the state Medicaid program.
3. The grantee and the state Medicaid program shall identify common business or health care outcome priorities.
4. The grantee, in collaboration with the Medicaid program, shall leverage, participate in and support all Beacon Communities, Regional Extension Centers and ONC funded workforce projects in its jurisdiction.
5. The grantee shall align efforts with the state Medicaid agency to meet Medicaid requirements for meaningful use.

Encouraged Activities:

6. The state's HIE program is encouraged to obtain a letter of support from the Medicaid Director. If a letter of support is not provided, ONC will inquire as to why one was not provided and the lack of a letter may impact the approval of a state plan, depending on circumstances.
7. Conduct joint needs assessments.
8. Conduct joint environmental scans.
9. Collaborate with the Medicaid program and the ONC-supported Regional Extension Centers to provide technical assistance to providers outside of the federal grant for Regional Extension Centers' scopes of work.
10. Leverage public help desk/call center contracts and services between the State HIE Program, Medicaid and the REC.
11. Conduct joint assessment and alignment of privacy policies at the statewide level and in the Medicaid program.
12. Leverage existing Medicaid IT infrastructure when developing the health information exchange technical architecture.
13. Determine whether to integrate systems to accomplish objectives such as making Medicaid claims and encounters available to the health information exchange and information from non-Medicaid providers available to the Medicaid program.
14. Determine which specific shared services and technical services will be offered or used by Medicaid.
15. Determine which operational responsibilities the Medicaid program will have, if any.
16. Use Medicaid HIT incentives to encourage provider participation in the health information exchange.
17. Collaborate during the creation of payment incentives, including Pay for Performance under Medicaid, to encourage participation by additional provider types (e.g. pharmacies, providers ineligible for incentives).

HIE Sustainability Plans

ONC recognizes the importance and challenges of developing a sustainable health information exchange capability. It is essential, therefore, that for the initial submittal of the Strategic Plan, that states and SDEs shall describe initial thoughts for sustaining HIE activities during and after the cooperative

agreement period. It is important to consider how to achieve sustainability based on the model being pursued and to incorporate any work that has been done to test the market acceptance of revenue models. The primary focus of sustainability should be on sustaining information sharing efforts, and not necessarily the persistence of government-sponsored health information exchange entities. ONC anticipates that annual updates to the state plans will provide further developed approaches and activities for long-term HIE sustainability.

Facilitating Services - If the state HIE effort is facilitating the statewide coverage of HIE services using a variety of exchange methods, the state plan shall describe preliminary plans for how sustainability of the HIE market in the state may be enhanced by state or SDE actions including any state policy or regulation. Specific plans for sustainability of any directories or authentication services offered at the state level by the grantee must be addressed during the course of the four-year program.

Directly Offering Services - If the state HIE effort is directly providing the services, the state plans shall provide preliminary but realistic ideas on who will pay for the services and under what mechanisms (e.g., per transaction fees, subscription models, payers receiving a percentage allocation based on their covered base) The state plan should also consider how program sustainability can be supported by state policy or regulation including payment reforms to incentivize demand for information sharing or contracting requirements to ensure participation of key partners such as labs and pharmacies.

Executing Strategy for Supporting Meaningful Use

Operational plans shall describe how the state will execute the state's overall strategy for supporting Stage 1 meaningful use including how to fill gaps identified in the environmental scan. Specifically, states and SDEs shall describe how they will invest federal dollars and associated matching funds to enable eligible providers to have at least one option for each of these Stage 1 meaningful use requirements in 2011:

1. E-prescribing
2. Receipt of structured lab results
3. Sharing patient care summaries across unaffiliated organizations

For each of these areas, the Operational Plans shall:

- Outline a clear and viable strategy to ensure that all eligible providers in the state have at least one viable option in 2011;
- Include a project timeline that clearly illustrates when tasks and milestones will be completed;
- Provide an estimate of all the funding required, including all federal funding and state funding, used to enable stage one meaningful use requirements;
- Indicate the role both in funding and coordination of the state Medicaid agency in achieving the state strategy;
- Identify potential barriers and risks including approaches to mitigate them; and,
- Identify desired technical support and coordination from ONC to support the state strategy.

Project Management Plans

State Operational Plans shall include a robust project management plan with specific timelines, milestones, resources and interdependencies for all the activities in the state's HIE project. States and

SDEs shall explain their project management approach including the project plan tasks that are managed by vendors in order for ONC to judge the comprehensiveness and the feasibility of the plans. State plans should also describe the change management and issue escalation processes that will be used to keep projects on schedule and within budget.

Risk Assessment

Managing risk is an important element of successfully building HIE capacity to support meaningful use. Within their Operational Plans, States and SDEs shall identify known and potential risks and describe their risk mitigation strategies. Risks should be prioritized using risk severity and probability. Examples of risks that may be included are: changes in the HIE marketplace, evolving EHR and HIE standards, lack of participation of large stakeholders including Medicaid, breach of personal health information.

HIE Architecture and Standards

Within the operational plans, States and SDEs shall describe the technical approach taken to facilitate data exchange services within the state based on the model being pursued.

Facilitating Services - If the state HIE effort is facilitating the statewide coverage of HIE services using a variety of exchange methods, the state plans shall describe the approach of obtaining statewide coverage of HIE services to meet meaningful use requirements and also the processes or mechanisms by which the state or SDE will ensure that the HIE services comply with national standards.

Directly Offering Services - If the state HIE effort is directly providing or provisioning services (including shared directories or provider authentication services) the state plans shall provide either the detailed specifications or describe the process by which the detailed specifications will be developed. For those plans that don't have a detailed architecture, the updated Notice of Award for implementation will have a requirement to provide the detailed plans at a later date.

When developing strategies for their state plans, states may be eligible to participate in the development, testing and implementation of various standards and services including those offered by the NHIN:

- Authoritative directories that are web-enabled and support standards-based queries, including:
  - Health care provider directories
  - Health plan directories
  - Directories of licensed clinical laboratories
- Identity Assurance and Authentication Services: These services should meet relevant state and federal privacy and security requirements and be appropriate to the exchange approach selected. They should include: 1) ability to ensure the provider receiving the record is authorized and is who they claim to be and, 2) ensure the provider sending the information is an authorized recipient of the information.
- Secure Routing
- NHIN Direct specifications to enable simplified interoperability between two known endpoints
- NHIN Exchange services for robust information exchange, such as:
  - Master Patient Index
  - Patient locator services

- Document lookup and retrieval

The use of standards to support HIE enabling technology is a critical aspect of this program and needs to be part of a longer-term framework to support interoperability. Due to the evolving nature of health information technology, standards, requirements related to meaningful use, and standards adoption, there should be an explicit mechanism specified in state plans that ensures adoption and use of standards adopted or approved by the Department of Health and Human Services (HHS) as well as the appropriate engagement with ONC in the ongoing development and use of the NHIN specifications and national standards to support meaningful use. The plans should also explain how the states will encourage any vendors or service providers to follow national standards, address system modularity, data portability, re-use of interfaces, and vendor transition provisions.

Privacy and Security

Within the Operational Plans, States and SDEs shall develop and fully describe their privacy and security framework including the specific policies, accountability strategies, architectures and technology choices to protect information. The state privacy and security framework shall be consistent with applicable federal law and policies. To assist the states, ONC will provide guidance on security and privacy policies and programs in the near future. The state plan shall contain a description of the analysis of relevant federal and state laws as related to HIE and the plans for addressing any issues that have been identified. If an analysis hasn't been done, the state or the SDE shall provide a description of the process and the timeline for completion. Furthermore, states should describe the methods used to ensure privacy and security programs are accomplished in a transparent fashion. If a complete framework is not available, the state or the SDE shall describe the process they will use to fully develop such a framework. The framework must address all the principles outlined in the HHS HIT Privacy and Security Framework, including:

- Disclosure Limitation
- Individual Access
- Correction
- Openness and Transparency
- Individual Choice
- Collection and Use
- Data Quality and Integrity
- Safeguards
- Accountability