Supporting Statement for ARRA Section 3013 State Health Information Exchange Cooperative Agreement Program: State Plans Expedited Clearance Request

A.   Justification

1. Circumstances Making the Collection of Information Necessary

Office of National Coordinator for Health Information Technology (ONC) is requesting expedited processing procedures for this application by the Office of Management and Budget to assure that ARRA funds are used timely and effectively. In a flurry of ONC requests for clearance in the fall, the request for clearance for this activity was not correctly filed. ONC re-submitted the request for clearance in March; however that was also not correctly filed. ONC resubmitted the information collection request in June and was published in the *Federal Register* on July 2nd. To date, ONC has 42 respondents and recognizes that a violation has occurred. Clearance is needed to prevent additional violation and to continue data collection.

The purpose of this program, as authorized by Section 3013 of the American Recovery and Reinvestment Act of 2009 (Attachment 1: Authorizing Legislation), Title XIII - Health Information Technology, Subtitle B—Incentives for the Use of Health Information Technology, Section 3013, State Grants to Promote Health Information Technology, is to provide grants to states and Qualified State Designated Entities (QSDE) for planning and implementation of interoperable health information technology. Section 3013 requires States or QSDEs to submit and receive approval of a "state plan" in order to qualify for implementation funding. To carry out the intent of the Act, the State Plan is defined as consisting of two deliverables: a Strategic Plan and an Operational Plan. Both the Strategic and Operational Plans, hereby referred to as the State Plan, must be approved by the National Coordinator for Health Information Technology. This information collection request is for the collection and annual updates of the State Plans. Continuing this data collection activity is critical to ensuring that states can progress on State Plans to expand health information exchange capacity in order to support the meaningful use incentives through the Centers for Medicare and Medicaid Services (CMS) (Medicare and Medicaid Electronic Health Record Incentive Program 42 CFR Parts 412, 413, 422, and 495).

For purposes of this supporting statement, "state" includes the District of Columbia and the U.S. territories – Puerto Rico, U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.

2. Purpose and Use of Information Collection

Guidance on content to be included in the State Plan is given through the Funding Opportunity Announcement (Attachment 2) and the Program Information Notice (Attachment 3: ONC-HIE-PIN-001), which provided focused direction on State Plan requirements and prioritized focus areas for 2011. The issuance of PINs is ONC's process for issuing guidance and clarification on program requirements.   States and QSDEs have been awarded 10 percent, or one million dollars (whatever is less), of their total grant award to complete development of

the State Plans. This limit was determined because the authorizing legislation for this program emphasized funding states for implementation of health information exchange capacity. Upon ONC approval of the State Plans, the States and QSDEs are given access to their full grant award and enter the implementation stage of the program. Timely progress on the collection, review, and approval of the State Plans is critical to implementation of health information exchange capacity within the states. This capacity is vital for providers to achieve the meaningful use requirements through CMS.

Attachment 4 includes the cooperative agreement general requirements issued as part of a revised Notice of Grant Award once the State Plan is approved. The requirements are developed based on the State Plan content areas in the FOA (Attachment 2).   Additional state-specific requirements for the cooperative agreement implementation period may be included depending on the State's unique strategy for enabling health information exchange as described in the State Plan and environmental landscape in the states.

States and QSDEs will be required to submit annual update to the State Plans reflecting updates in legal, policy, or technical infrastructure changes, as well as expanded content on sustainability and business planning for the HIE services fostered through the cooperative agreement, evaluation of the project, and alignment with other Federal programs authorized in HITECH. ONC will issue future PINs to provide additional guidance to States and QSDEs on the annual updates to Plan content areas needed. Annual updates to the plan are required one-year from the approval date of the State Plan. Upon receipt of the updated State Plan, ONC will review the additional and updated content. An updated Notice of Award will be issued reflecting updated cooperative agreement general requirements based on the individual State progress on the strategy discussed in the State Plan, as well as based on the health information exchange functionality required for providers to obtain the meaningful use incentives per CMS (Medicare and Medicaid Electronic Health Record Incentive Program 42 CFR Parts 412, 413, 422, and 495). Without the annual updates to the State Plan, ONC's ability to monitor the activities and progress to program goals under the cooperative agreements would be compromised.

Per the FOA and ONC-HIE-PIN-001 (Attachments 2 and 3), the Strategic and Operational Plans shall describe activities the state or SDE will complete to enable or implement HIE services that will allow for eligible providers to achieve success. Specific actions and roles of various stakeholders in the development and implementation of HIE services must be discussed in the State Plan. Consensus building of stakeholders may take significant time and resources but is important to ensure a successful strategy. The State Plan must address the following five domains: governance, finance, technical infrastructure, business and technical operations, and legal/policy. The State Plan must be grounded in a detailed environmental scan that identifies the strengths and gaps in HIE capabilities, focusing on the meaningful use criteria which require health information exchange capabilities. The following capabilities have been identified as priorities for the ONC State HIE program for 2011: e-prescribing, receipt of structured lab results, and sharing of patient care summaries across unaffiliated organizations.

ONC program and grants staff will use project management timelines and milestones provided in the State Plans to monitor progress to expand health information capacity within the

states. The development and provision of technical assistance on state, regional and national levels will be based on the State Plans' content. ONC intents to use the State Plans' content to highlight best practices, identify areas in need of technical assistance, and document progress to program goals. ONC intends to leverage the information collected through the State Plans to inform ONC policy development and other activities, such as responding to requests for information on specific state activities or the program from the National Coordinator, other agencies, Congress, and outside interest groups (as appropriate).

3. Use of Improved Information Technology and Burden Reduction

All documents will be submitted electronically. ONC staff will analyze the data electronically and communicate with the applicants and recipients using email.

4. Efforts to Identify Duplication and Use of Similar Information

Since this is a new program that was created through the Recovery Act, the information that will be collect has never been collected before by the Federal government. This program is one of several initiatives funded through the Recovery Act in support of the Medicare and Medicaid Electronic Health Record Incentive Program (42 CFR Parts 412, 413, 422, and 495). As such, ONC is working internally between ONC programs and with CMS to ensure data collection are not duplicative, particularly around the CMS collection of the Medicaid HIT Plans. To ensure both Plans are consistent and aligned, staff from CMS are reviewing the State Plans and staff from ONC are reviewing the Medicaid HIT Plans.

5. Impact on Small Businesses or Other Small Entities

No impact on small business.

6. Consequences of Collecting the Information Less Frequent Collection

The collection of the State Plan is a one-time submission; while some States and QSDEs have submitted early, the State Plans are due August 31, 2010 and September 27, 2010, depending on the State's cooperative agreement award date. Review and approval of the State Plan by the National Coordinator for Health Information Technology is an iterative process between ONC and the State/QSDE to review, update and approve State Plans that are aligned with the goals of the State HIE program , build upon resources within the State, and address gaps in HIE capabilities in the states. The National Coordinator for Health Information Technology has approved State Plans on a rolling basis in order to move States and QSDEs into the implementation phase efficiently. To date, seven State Plans have been approved: New Mexico, Utah, Maryland, Delaware, California, South Carolina and Tennessee. Once approved, a revised Notice of Grant Award (NGA) is issued with the updated implementation requirements for the cooperative agreement (Attachment 4).

Updates to the State Plan will be collected annually and are due one year from receipt of the revised Notice of Grant Award.

Collecting the data less frequently would not allow ONC to effectively monitor progress across the project period, which ends in February and March, 2014. These are Recovery Act funds and it is ONC's responsibility to ensure the funds are used timely and effectively.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
This data collection request fully complies with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice/Outside Consultation
Due to the emergency nature, this request is for the ongoing data collection that is occurring in order to continue the program required by the Recovery Act.

A 60-day Federal Register Notice was published in the *Federal Register* on July 2, 2010, vol. 75, No. 127; pp 38524-38525 (see Attachment 5: Federal Register Notice). There were no public comments.

ONC sought consultation with numerous agencies in developing the State Plan requirements within the Funding Opportunity Announcement. Consultation included the content, the frequency of collection, the clarity of instructions in the FOA and subsequent program guidance, the data elements to be included, and the time, resources, and expense necessary to develop the State Plan. In addition, consultation was received through the HITCH implementation workgroups that advised ONC and the Secretary on the implementation of the State HIE Grant program as designated in the American Recovery and Reinvestment Act of 2009, Title XIII - Health Information Technology, Subtitle B—Incentives for the Use of Health Information Technology, Section 3013, State Grants to Promote Health Information Technology. These offices and agencies include:
- Centers for Medicare and Medicaid Services*
- Agency for Healthcare Research and Quality*
- Office of Civil Rights
- Office of the General Counsel
- Health Resources and Services Administration*
- Indian Health Service
- Centers for Disease Control and Prevention*
- Food and Drug Administration
- Assistant Secretary for Planning and Evaluation
- Federal Communications Commission
- Department of Veterans Affairs*

ONC also analyzed published State Plans and consulted with the State agencies implementing these plans during the summer of 2009.

The ONC State HIE program continues to have regular HIE coordination calls with partner agencies (starred above in the list) during which the State Plan collection and review process is discussed. Additional consultation with CMS is discussed in section 4 of this document.

9. Explanation of any Payment/Gift to Respondents
No payments or gifts of any kind are provided to the respondents.

10. Assurance of Confidentiality Provided to Respondents
No personal information will be collected other than general contact information. All

grant information will be kept confidential as possible.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature collected in the Progress Report. No patient- or client-level identifying data are reported. Identification of the grantees as recipients of ONC funding is a matter of public record.

12. Estimates of Annualized Burden Hours (Total Hours & Wages)

The estimate of average annualized hour burden for respondents is shown in Table 1. As Table 1 shows, a total of 56 respondents will submit the State Plans. Each respondent will submit 4 responses—the initial State Plan Submission and three annual updates. The initial State Plan development will take approximately 10,024 hours on-average to complete and approximately 10 percent of the State HIE cooperative agreement funds are dedicated to that development. Table 1 represents the annualized burden hours for the State Plan submission and subsequent annual updates. Per the direction of the HHS Paperwork Reduction Act Officer, the State Plan submission annualized burden hours of 10,024 is divided by three in the table to represent the annualized burden hours; however, the full State Plan submission is a one time data collection in the first year of the program. The annualized burden hours include the strategic planning process and the development of the operational detail. It also includes donated hours from volunteers serving on planning committees in each of the domain areas in the FOA (Attachment 2), which is a significant inkind resources utilized in all states. The burden hours are estimated for a state without any of this planning in place; many states were much further in the planning process and the burden hours are much less. The annual updates will take approximately 500 hours on-average to complete. This includes the recipient's time to update the State Plan, as well as donated hours from volunteers serving on the committees and oversight boards for health information exchange in the State. As the State develops its own State Plan and there is not a form to complete, the burden statement is included on the instructions from the FOA included in Attachment 2: Detailed Guidance for Strategic and Operational Plans.

Table 1. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
State government or Qualified State Designated Entity	State Plans (Strategic and Operational)	56	1	3,341.3	**187,112.8**
State government or Qualified State Designated Entity	Subsequent updates to the State Plan	56	1	500	**28,000**
Total					**215,114.6**

The estimate of annualized cost to respondents for the hour burdens for collection of information and identifying and using appropriate wage rate categories from the Bureau of Labor Statistics. ONC estimates that expertise from program managers, program assistants and technical consultants will be necessary to complete the State Plan and subsequent annual updates. Table 2 demonstrates the estimated total burden costs for recipients to complete state plans. Per the direction of the HHS Paperwork Reduction Act Officer, the hourly wage rates of the staff necessary to complete the State Plan and annual updates was averaged. The $52.00 hourly wage rate was determined by averaging the estimated time burden from program managers ($35.00), program assistants ($20.00) and technical consultants ($85.00) burden hours. The hourly wage rate for the program manager and program assistant averages are taken from the Bureau of Labor Statistics; the technical consultation hourly wage rate is based on current contract support at ONC. The estimated annualized burden costs for the 56 respondents to complete the State Plan is $9,729,865.6; the estimated annualized burden costs for the 56 respondents to complete the annual update to the State Plan is $1,456,000.

Table 2: Estimated Annualized Burden Costs for 56 Recipients to Complete State Plans (Strategic and Operational components) and Annual Updates to State Plan

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State government or Qualified State Designated Entity	State Plans (Strategic and Operational)	187,112.8	$52.00	$9,729,865.6
State government or Qualified State Designated Entity	Subsequent updates to the State Plan	28,000	$52.00	$1,456,000
Total		**215,112.8**		**$11,185,865.6**

13. Estimates of other Total Annual Cost Burden to Respondents or Record Keepers/Capital Costs

ONC does not anticipate additional recordkeeping/capital costs related to this effort.

14. Annualized Cost to Federal Government

ONC estimates an annual investment of approximately $300,000 for the first year of

State Plan data collection for the review and analysis of the State Plans by Federal staff and contractors. ONC estimates that subsequent annual updates to the State Plans will require an ONC estimate of $75,000 per year.

15. Explanation for Program Changes or Adjustments
This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule
Data collection has begun (see section 1 of this document). States and QSDEs are currently in the process of submitting State Plans for review and approval by the National Coordinator for Health Information Technology. Upon receipt of the State Plan, ONC staff review the plans against the requirements in the FOA (Attachment 2) and ONC-HIE-PIN-001 guidance (Attachment 3). Attachment 6 includes internal ONC tools used to review the State Plans. ONC recognizes the Recovery Act provided a one-time investment to facilitate state efforts. State Plans are reviewed critically to ensure the proposed strategies are reasonable and achievable with the funding level and timeframes imposed by the legislation. The State Plans must target facilitating health information exchange services that enable providers to have options to meet meaningful use information exchange requirements. ONC employs a range of technical assistance tools to support States and QSDEs in finalizing State Plans that meet the requirements, and States and QSDEs may be referred to technical assistance at any point in the process. Cooperative agreement budgets for the implementation stage are also reviewed as part of this process to ensure the strategies in the State Plan are reflected in the allocation of funding in the budget. CMS staff also review the State Plans and provide feedback on alignment with the Medicaid-funding HIT efforts.

Feedback on the State Plan is communicated both in writing and through conference calls to the State/QSDE, and the State/QSDE revises to provide clarification and update missing content in the State Plans. The National Coordinator is the authority for approving the State Plans, and upon the approval, a revised Notice of Grant award is issued to the State providing access to the full cooperative agreement award. After the approval of the State Plan, States and QSDEs will submit annual updates due one year from receipt of the revised NGA, pending OMB approval.

To support transparency encouraged in the Recovery Act, State Plans will be made available for review on the ONC website. States will have the opportunity to remove any proprietary information before posting publicly. Many States have already posted their plans on State websites.

17. Reason(s) Display of OMB Expiration Date is Inappropriate
As the State develops its own State Plan and there is not a form to complete, the burden statement and expiration date is not included on the guidance documents for the State Plan: FOA or the ONC-HIE-PIN-001 (Attachments 2 and 3). ONC is open to OMB direction on the location of the burden statement and expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions
There are no exceptions to the certification.

Attachments

Attachment 1: Authorizing Legislation

Attachment 2: Funding Opportunity Announcement

Attachment 3: ONC-HIE-PIN-001

Attachment 4: General Implementation Requirements for Cooperative Agreement

Attachment 5: Federal Register Notice

Attachment 6: Internal ONC Tools for State Plan Review

Attachment 1

See *Attachment 1: Authorizing Legislation: HITECH*

Due to the length of the American Recovery and Reinvestment Act of 2009, a hyperlink is included below. Please see Title XIII - Health Information Technology, Subtitle B—Incentives for the Use of Health Information Technology, Section 3013, State Grants to Promote Health Information Technology.

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1enr.pdf

Attachment 2

The full Funding Opportunity Announcement can be found here: Funding Opportunity Announcement: State Health Information Exchange Cooperative Agreement Program [MS Word doc - 845 KB]

The FOA Appendix **Detailed Guidance for Strategic and Operational Plans** is cut and pasted in the next five pages of this document.

Detailed Guidance for Strategic and Operational Plans

Detailed Guidance for the Strategic Plan
The strategic planning process includes the development of the initial Strategic Plan and ongoing updates. There are distinct and/or concurrent planning activities for each domain that need to be coordinated and planned. The Strategic Plan may address the evolution of capabilities supporting HIE, as well as progress in the five domains of HIE activity, the role of partners and stakeholders, and high-level project descriptions for planning, implementation, and evaluation.

The following criteria in General Topic Guidance and Domain Requirements must be included in the Strategic and Operational plans unless noted as otherwise.

General Topic Guidance

- **Environmental Scan** – The Strategic Plan must include an environmental scan of HIE readiness which may include broad adoption of HIT but must include HIE adoption across health care providers within the state and potentially external to the state, as relevant. The environmental scan must include an assessment of current HIE capacities that could be expanded or leveraged, HIT resources that could be used, the relevant collaborative opportunities that already exist, the human capital that is available and other information that indicates the readiness of HIE implementation statewide.
- **HIE Development and Adoption** – The Strategic plan must address vision, goals, objectives and strategies associated with HIE capacity development and use among all health care providers in the state, to include meeting HIE meaningful use criteria to be established by the Secretary through the rulemaking process. The Strategic Plan must also address continuous improvement in realizing appropriate and secure HIE across health care providers for care coordination and improvements to quality and efficiency of health care. Strategic Plans should also address HIE between health care providers, public health, and those offering services for patient engagement and data access.
- **HIT Adoption** *(encouraged but not required)*–
    o HIT adoption may also be included in the Strategic Plan. Although it is beyond the scope of this program to fund HIT adoption initiatives described in a State Strategic Plan, it does not preclude other HITECH ACT programs or state funded initiatives to advance HIT adoption in a state.
    o While many states have already addressed HIT adoption in their existing Health IT State Plans, it is not a requirement. However, the inclusion of Health IT adoption in the Strategic Plan is valuable and provides for a more comprehensive approach for planning how to achieve connectivity across the state.
- **Medicaid Coordination** – The Strategic Plan must describe the interdependencies and integration of efforts between the state's Medicaid HIT Plan and the statewide HIE development efforts. The description should include the state's HIE related requirements for meaningful use to be established by the Secretary through the rulemaking process and the mechanisms in which the state will measure provider participation in HIE.
- **Coordination of Medicare and Federally Funded, State Based Programs** – Strategic Plan shall describe the coordination activities with Medicare and relevant federally-funded, state programs (see program guidance). These programs include:

- o Epidemiology and Laboratory Capacity Cooperative Agreement Program (CDC)
- o Assistance for Integrating the Long-Term Care Population into State Grants to Promote Health IT
- o Implementation (CMS/ASPE)
- o HIV Care Grant Program Part B States/Territories Formula and Supplemental Awards/AIDS Drug Assistance Program Formula and Supplemental Awards (HRSA)
- o Maternal and Child Health State Systems Development Initiative programs (HRSA)
- o State Offices of Rural Health Policy (HRSA)
- o State Offices of Primary Care (HRSA)
- o State Mental Health Data Infrastructure Grants for Quality Improvement (SAMHSA)
- o State Medicaid/CHIP Programs
- o IHS and tribal activity
- o Emergency Medical Services for Children Program (HRSA)
- **Participation with federal care delivery organizations** *(encouraged but not required)*– When applicable, the Strategic Plan should include a description of the extent to which the various federal care delivery organizations, including but not limited to the VA, DoD, and IHS, will be participating in state activities related to HIE.
- **Coordination of Other ARRA Programs** – Because other ARRA funding will be available to the state that can help advance HIE, the Strategic Plan must describe, when applicable, coordination mechanisms with other relevant ARRA programs including Regional Centers, workforce development initiatives, and broadband mapping and access. As these programs are developed, ONC will provide program guidance to facilitate state specific coordination across Regional Centers, workforce development and broadband programs. For planning purposes, applicants should specify how entities or collaboratives planning to be Regional Centers will provide technical assistance to health care providers in their states, how trained professionals from workforce development programs will be utilized to support statewide HIE, and how plans to expand access to broadband will inform State Strategic and Operational Plans overtime. This program coordination will be the subject of future guidance, and plans may need to be modified as other programs are clarified

Domain Requirements
- **Governance**
- o **Collaborative Governance Model –** The Strategic Plan must describe the multi-disciplinary, multi-stakeholder governance entity including a description of the membership, decision-making authority, and governance model. States are encouraged to consider how their state governance models will align with emerging nationwide HIE governance.
- o **State Government HIT Coordinator** – The Strategic Plan shall identify the state Government HIT Coordinator. The plan shall also describe how the state coordinator will interact with the federally funded state health programs and also the HIE activities within the state.
- o **Accountability and Transparency –** To ensure that HIE is pursued in the public's interest, the Strategic Plan shall address how the state is going to address HIE accountability and transparency.

- **Finance**
- o **Sustainability –** In order to ensure the financial sustainability of the project beyond the ARRA funding, the Strategic Plan shall include a business plan that enables for the financial sustainability, by the end of the project period of HIE governance and operations.

- **Technical Infrastructure**

o **Interoperability -** The plan must indicate whether the HIE services will include participation in the NHIN. The plan shall include the appropriate HHS adopted standards and certifications for health information exchange, especially planning and accounting for meaningful use criteria to be established by the Secretary through the rulemaking process .

o **Technical Architecture/Approach** *(encouraged but not required)*– Because the state or SDE may or may not implement HIE, the Strategic Plan may include an outline of the data and technical architectures and describe the approach to be used, including the HIE services to be offered as appropriate for the state's HIE capacity development.

• **Business and Technical Operations**

o **Implementation –** To address how the state plans will develop HIE capacity, the Strategic Plan must include a strategy that specifies how the state intends to meet meaningful use HIE requirements established by the Secretary, leverage existing state and regional HIE capacity and leverage statewide shared services and directories. The implementation strategy described in the Strategic Plan shall describe the incremental approach for HIE services to reach all geographies and providers across the state. The implementation strategy shall identify if and when the state HIE infrastructure will participate in the NHIN.

• **Legal/policy**

o **Privacy and Security**– The Strategic Plan shall address privacy and security issues related to health information exchange within the state, and between states. The plan shall give special attention to federal and state laws and regulations and adherence to the privacy principles articulated in the HHS Privacy and Security Framework, and any related guidance.

o **State Laws** – The Strategic Plan shall address any plans to analyze and/or modify state laws, as well as communications and negotiations with other states to enable exchange.

o **Policies and Procedures** – The Strategic Plan shall also address the development of policies and procedures necessary to enable and foster information exchange within the state and interstate.

o **Trust Agreements** –The Strategic Plan shall discuss the use of existing or the development of new trust agreements among parties to the information exchange that enable the secure flow of information. Trust agreements include but are not limited to data sharing agreements, data use agreements and reciprocal support agreements.

o **Oversight of Information Exchange and Enforcement** - The Strategic Plan shall address how the state will address issues of noncompliance with federal and state laws and policies applicable to HIE.

Detailed Guidance for the Operational Plan

Prior to entering into funded implementation activities, a state must submit and receive approval of the Operational Plan. The Operational Plan shall include details on how the Strategic Plan will be carried forward and executed to enable statewide HIE. It must also include a project schedule describing the tasks and sub-tasks that need to be completed in order to enable the statewide HIE. The implementation description shall identify issues, risks, and interdependencies within the overall project. In addition, the Operational Plan must include the following general topics and domains. The requirements for the initial Operational Plan are outlined below.

General Topic Requirements

Coordinate with ARRA Programs – The Operational Plan must describe specific points of coordination and interdependencies with other relevant ARRA programs including Regional Centers, workforce

development initiatives, and broadband mapping and access. As these programs are developed, ONC will provide program guidance to facilitate state specific coordination across Regional Centers, workforce development and broadband programs. For planning purposes, applicants concurrently applying as HIE recipients and Regional Center recipients should specify how they will provide technical assistance to health care providers in their states with estimates of geographic and provider coverage. In addition, project resource planning should take into account how and when trained professionals from workforce development programs will be utilized to support statewide HIE, and how and when broadband will be available to health care providers across the state according to the availability of up to date broadband maps and funded efforts to expand access.

Coordinate with Other States – In order to share lessons learned and encourage scalable solutions between states, the Operational Plan shall describe multi-state coordination activities including the sharing of plans between states.

Domain Requirements

- **Governance**
o **Governance and Policy Structures –** The Operational Plan must describe the ongoing development of the governance and policy structures.

- **Finance**
o **Cost Estimates and Staffing Plans** – The Operational Plan must provide a detailed cost estimate for the implementation of the Strategic Plan for the time period covered by the Operational Plan. It must also include a detailed schedule describing the tasks and sub-tasks that need to be completed in order to enable statewide HIE along with resources, dependencies, and specific timeframes. The implementation description shall specify proposed resolution and mitigation methods for identified issues and risks within the overall project. Additionally, recipients shall provide staffing plans including project managers and other key roles required to ensure the project's success.
o **Controls and Reporting** – The Operational Plan must describe activities to implement financial policies, procedures and controls to maintain compliance with generally accepted accounting principles (GAAP) and all relevant OMB circulars. The organization will serve as a single point of contact to submit progress and spending reports periodically to ONC.
- **Technical Infrastructure**
o **Standards and Certifications** –The Operational Plan shall describe efforts to become consistent with HHS adopted interoperability standards and any certification requirements, for projects that are just starting; demonstrated compliance, or plans toward becoming consistent with HHS adopted interoperability standards and certifications if applicable, for those projects that are already implemented or under implementation.
o **Technical Architecture** – The Operational Plan must describe how the technical architecture will accommodate the requirements to ensure statewide availability of HIE among healthcare providers, public health and those offering service for patient engagement and data access. The technical architecture must include plans for the protection of health data. This needs to reflect the business and clinical requirements determined via the multi-stakeholder planning process. If a state plans to exchange information with federal health care providers including but not limited to VA, DoD, IHS, their plans must specify how the architecture will align with NHIN core services and specifications.
o **Technology Deployment** – The Operational Plan must describe the technical solutions that will be used to develop HIE capacity within the state and particularly the solutions that will

enable meaningful use criteria established by the Secretary for 2011, and indicate efforts for nationwide health information exchange. If a state plans to participate in the Nationwide Health Information Network (NHIN), their plans must specify how they will be complaint with HHS adopted standards and implementation specifications. (For up-to-date publicly available information on meaningful use, see: http://healthit.hhs.gov/meaningfuluse).

- **Business and Technical operations**
o **Current HIE Capacities** – The Operational Plan must describe how the state will leverage current HIE capacities, if applicable, such as current operational health information organizations (HIOs), including those providing services to areas in multiple states.
o **State-Level Shared Services** and Repositories – The Operational Plan must address whether the state will leverage state-level shared services and repositories including how HIOs and other data exchange mechanisms can leverage existing services and data repositories, both public or private. Shared services for states to consider include (but are not limited to): Security Service, Patient Locator Service, Data/Document Locator Service, and Terminology Service. These technical services may be developed over time and according to standards and certification criteria adopted by HHS in effort to develop capacity for nationwide HIE.
o **Standard operating procedures for HIE** *(encouraged but not required)*– The Operational Plan should include an explanation of how standard operating procedures and processes for HIE services will be developed and implemented.

- **Legal/policy**
o **Establish Requirements** – The Operational Plan shall describe how statewide health information exchange will comply with all applicable federal and state legal and policy requirements. This plan needs to include developing, evolving, and implementing the policy requirements to enable appropriate and secure health information exchange through the mechanisms of exchange consistent with the state Strategic Plan. The Operational Plan should specify the interdependence with the governance and oversight mechanisms to ensure compliance with these policies.
o **Privacy and Security Harmonization** – The Operational Plan must describe plans for privacy and security harmonization and compliance statewide and also coordination activities to establish consistency on an interstate basis.
Federal Requirements – To the extent that states anticipate exchanging health information with federal care delivery organizations, such as the VA, DoD, Indian Health Service, etc. the Operational Plan must consider the various federal requirements for the utilization and protection.

The full Program Information Notice ONC-HIE-PIN-001 can be found here: Program Information Notice: Requirements and Recommendations for the State Health Information Exchange Cooperative Agreement Program [PDF - 209 KB]

The ONC-HIE-PIN-001 Attachment **Guidance on State Strategic and Operational Plans (State Plans)** is cut and pasted below:

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 http://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:
    - o Health care provider directories
    - o Health plan directories
    - o 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: o Master Patient Index
    - o Patient locator services
    - o 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

Attachment 4
General Implementation Requirements for Cooperative Agreement

California is included as the example.

California Implementation Requirements
The following are requirements that State HIE Grant Recipients are to meet. The required documentation described within each requirement must be submitted to and reviewed by ONC program staff for approval. Further guidance will be provided on the reporting of requirement fulfillment.
These requirements reflect the actions/accomplishments expected of recipients to comply with the Terms and Conditions of the Notice of Award for states that have received ONC approval of their Strategic and Operational Plans. Each requirement is mapped to a category outlined in the State HIE Cooperative Agreement Program Funding Opportunity Announcement.

Requirements *Red Indicates Restriction*	FOA Reference:	Date
Planning		
Strategic and Operational Plans endorsed by Stakeholders		60 days from date of Strategic and Operational Plans approval notification (i.e., 60 days from date of this revised notice of grant award)
Previously approved Strategic and Operational Plans reviewed annually and any necessary updates submitted to ONC		2/8/2011 2/8/2012 2/8/2013
Updated Strategic and Operational Plans approved by ONC		8/12/2011 8/12/2012 8/12/2013
Governance		
Stakeholder collaboration demonstrated and documented, e.g. participation in meetings	*Governance Structure - Establish a governance structure that achieves broad-based stakeholder collaboration with transparency, buy-in and trust. (p.12)*	Ongoing requirement
Medicaid agency has designated governance role, and the representative's participation adapts as necessary to ongoing state HIE needs	*Medicaid and Public Health Alignment - Coordinate and align efforts to meet Medicaid and public health requirements for HIE & meaningful use criteria. (p.13)*	Ongoing requirement
HIT Coordinator has designated governance role, and his/her participation adapts as necessary to ongoing state HIE needs	*State Government HIT Coordinator – The state government has appointed a State Government HIT Coordinator who is a state official and will coordinate state government participation in HIE. (p. 23)*	Ongoing requirement
State or SDE maintains and adheres to established policies and procedures.	*Oversight and Accountability – Establish oversight and accountability mechanisms to protect the public interest. (p.12)*	Ongoing requirement
State or SDE maintains oversight for HIE services, and is responsible for ensuring that HIE is operating effectively and within the appropriate regulatory environment		Ongoing requirement
Organization meetings posted and open to the		Ongoing requirement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-XX. The time required to complete this information collection is estimated to average 215,114.6 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer

public Requirements *Red Indicates Restriction*	FOA Reference:	Date
Governance model aligned with NHIN governance (as applicable)	*Alignment with National HIE Governance – Account for the flexibility needed to align with emerging nationwide HIE governance. (p.12)*	Ongoing requirement
State/SDE representatives in NHIN activities identified		Ongoing requirement

Finance		
Establish financial policies and implement procedures to monitor spending and provide appropriate financial controls.	*Fiduciary Oversight - Develop capacity to effectively manage funding necessary to implement the state's Strategic and Operational Plans.*	Ongoing requirement
As part of annual updates to the strategic and operational plans/as a separate report, must develop a business plan that includes a sustainability plan capable of supporting HIE governance and operations beyond the ARRA funding	*Sustainability Plan - Develop a path to sustainability including a business plan with feasible public/private financing mechanisms for ongoing information exchange. (p.52)*	2/8/2011 2/8/2012 2/8/2013
Sustainability plan endorsed by stakeholders		2/8/2011 2/8/2012 2/8/2013
As part of annual updates to the strategic and operational plans, the recipient must report on the status of plans to use state purchasing power to enhance the demand for care coordination and information exchange.	*Business Plan – Develop a path to sustainability including public/private financing mechanisms (p/12).*	2/8/2011 2/8/2012 2/8/2013
Technical Infrastructure		
Implement statewide technical infrastructure as described in state's ONC approved plan	*Technical Infrastructure - Develop or facilitate the creation of a statewide technical infrastructure that supports statewide HIE. HIE Services include: Electronic eligibility and claims transactions; Electronic prescribing and refill requests; Electronic clinical laboratory ordering and results delivery; Electronic public health reporting (i.e. immunizations, notifiable laboratory results); Quality reporting; Prescription fill status and/or med fill history; Clinical summary exchange for care coordination and patient engagement.*	Ongoing requirement, with specific targets as identified in approved Strategic and Operational Plans
Statewide technical infrastructure integrates with state-specific Medicaid management information systems		Ongoing requirement, with specific targets as identified in approved Strategic and Operational Plans
Statewide technical infrastructure integrates with regional HIEs using NHIN standards		Ongoing requirement, with specific targets as identified in approved Strategic and Operational Plans
Statewide technical infrastructure captures clinical requirements of healthcare providers of low income, longterm care and underserved populations		Ongoing requirement, with specific targets as identified in approved Strategic and Operational Plans
Shared services offerings determined and developed consistent with state's ONC approved plan	*Shared Services – Develop or facilitate the creation and use of shared directories and technical services, as applicable for the state's approach for statewide HIE. (p.55)*	Ongoing requirement, with specific targets as identified in approved Strategic and Operational Plans
State technical infrastructure aligns with HHS adopted interoperability standards	*Interoperability and Certification – Technical infrastructure leverages the appropriate HHS*	Ongoing requirement, with specific targets as

Finance

		identified in approved Strategic and Operational Plans
Plan for maintaining alignment with NHIN core services and specifications established and on track - applies to inter-HIO exchange (intra-state and inter-state)	*adopted standards and certifications for health information exchange.* *Federal Healthcare Provider Exchange Architecture – Technical architecture aligns with NHIN core services and specifications.*	Ongoing requirement, with specific targets as identified in approved Strategic and Operational Plans
As part of annual updates to the strategic and operational plans, the recipient must report on the status of plans to create web-enabled state level directories, supporting standards-based directory queries, including health care provider directories, health plan directories, and licensed clinical laboratories.		Ongoing requirement, with specific targets as identified in approved Strategic and Operational Plans
As part of annual updates to the strategic and operational plans, the recipient must report on the status of demonstrations of provider and patient authentication services.		2/8/2011 2/8/2012 2/8/2013

Business and Technical Operations

Alignment between State Medicaid HIT Plan (SMHP) and statewide HIE plan. The recipient must also confirm that the State Medicaid Director (SMD) supports the Medicaid content in the HIE Strategic and Operational Plans as a required sign-off. In order to demonstrate coordination and alignment, the recipient must provide ONC with a letter of support from the State Medicaid Director.	*Medicaid and Public Health Alignment - Coordinate and align efforts to meet Medicaid and public health requirements for HIE & meaningful use criteria. (p.13)*	Ongoing requirement with initial confirmation 60 days from date of Strategic and Operational Plans approval notification (i.e., 60 days from date of this revised notice of grant award)
Alignment between public health requirements and statewide HIE plan. The recipient must also confirm that the State Public Health Administrator approves the content in the HIE Strategic and Operational Plans as a required sign-off.		Ongoing requirement with initial confirmation 60 days from date of Strategic and Operational Plans approval notification (i.e., 60 days from date of this revised notice of grant award)
Collaboration with relevant Federally qualified health centers (FQHC) or health center controlled networks (HCCN) to support the statewide HIE plan.	*Alignment with ARRA – Statewide HIE efforts are aligned with other federal programs. (p.30, 52, 54)*	Ongoing requirement with initial confirmation 60 days from date of Strategic and Operational Plans approval notification (i.e., 60 days from date of this revised notice of grant award)
Collaboration with relevant Regional Extension Centers (Regional Centers) to support the statewide HIE plan.		Ongoing requirement with initial confirmation 60 days from date of Strategic and Operational Plans

Business and Technical Operations		
		approval notification (i.e., 60 days from date of this revised notice of grant award)
Project management protocols implemented and, as necessary, reviewed and updated	*Monitoring Capacity - Monitor and plan for remediation of the actual performance of HIE throughout the state. (p.13)*	Ongoing requirement
State or State Designated Entity is monitoring and reporting on all required program evaluation metrics		Ongoing requirement with reporting due according to schedule outlined in the original notice of award and additional ONC guidance
All staff positions filled consistent with state's ONC approved plan	*Staffing – Establish and maintain adequate staff to effectively operate statewide HIE functions. (p.54)*	Ongoing requirement with initial confirmation 60 days from date of Strategic and Operational Plans approval notification (i.e., 60 days from date of this revised notice of grant award)
Communications strategy implemented to effectively communicate with stakeholders and the health community.	*Communications – Effectively communicate with key stakeholders and the health community. (p.37)*	Ongoing requirement

Legal/Policy		
Privacy policies are updated as needed to reflect new flow and uses of protected health information and any new obligations of patients	*Harmonization – Identify and harmonize legal and policy requirements that enable appropriate HIE. (p.13)*	Ongoing requirement
Statewide Policy Framework established and submitted to ONC	*Statewide Policy Framework – Establish a statewide policy framework that allows incremental development of HIE policies over time. (p.13)*	Ongoing requirement, with specific targets as identified in approved Strategic and Operational Plans
Statewide Policy Framework endorsed by stakeholders		Ongoing requirement, with specific targets as identified in approved Strategic and Operational Plans
Privacy policies, procedures and trust agreements allow incremental/adaptable development of HIE policies over time		Ongoing requirement
Enforcement mechanisms have been implemented and are actively maintained that ensure appropriate safeguards are in place and adherence to legal and policy requirements	*Enforcement – Implement enforcement mechanisms that ensure appropriate safeguards are in place and adherence to legal and policy requirements. (p.13)*	Ongoing requirement, with specific targets as identified in approved Strategic and Operational Plans
As part of annual updates to the strategic and operational plans/as a separate report, on the implementation and evaluation of policies and legal agreements related to HIE submitted to ONC	*Implementation and Evaluation – Policies and legal agreements are implemented and evaluated as a part of annual program evaluation. (p.13)*	2/8/2011 2/8/2012 2/8/2013
Within three months of ONC approval of the	*State Roles – States are to use their authority,*	11/12/2010

Business and Technical Operations		
State Plan, the recipient must begin executing their plan to remove regulatory and policy barriers identified in the analysis conducted as part of the State Plan and also use regulatory authority to advance standards compliance and trading partner participation in HIE.	*programs and resources to remove barriers and create enables for HIE. (p.8)*	
Outcomes and Performance Measures		
Establish performance benchmarks for HIE enabled state level technical services, following future ONC provided program guidance.	*Outcomes and Performance Measures – Monitor and maintain a targeted degree of participation in HIE enabled state level technical services. (p.31)*	Ongoing requirement, with delivery dates to be established through future ONC guidance
Recipient submits a report to ONC on statewide HIE alignment with other federal programs.	*Alignment with ARRA – Statewide HIE efforts are aligned with other federal programs. (p.30, 52, 54)*	2/8/2011 2/8/2012 2/8/2013
For each year of award, the recipient participates in the nationwide HIE program evaluation.		Ongoing requirement
Training and Technical Assistance		
Recipients are required to participate in NHIN Governance Training. Further guidance will be provided by ONC.		Ongoing requirement
Recipients are required to review updates to the statewide HIE toolkit modules as new guidance is announced. Further guidance will be provided by ONC.		Ongoing requirement

Attachment 5

See PDF file: *Federal Register Notice 2010-16164*

Attachment 6

Internal Tools for State Plan Review

Included in this attachment are two State Plan review tools utilized by ONC staff internally to review and analyze the State Plans submitted for approval by the National Coordinator. These tools were developed from the FOA and the Program Information Notice. These tools are updated as gaps in review are identified or as the internal process is modified to ensure efficient processing of the State Plan reviews.

There are two tools included in this attachment:
- *High Level State Plan Review*: utilized in the first 2 weeks of State Plan receipt to summarize the high level strategy taken by the state and the responsiveness of the State Plan to the 2011 priorities clarified in the Program Information Notice (ONC-HIE-PIN-001 in Attachment 3 of this document).
- *Detailed Strategic and Operational Plan Review*: utilized after the *High Level State Plan Review* to guide Federal staff and contractors in the full analysis of the State Plan.

High Level State Plan Review

High Level (3-day) Plan Summary for State: XXXXXX
Reviewer:

1. Summary of State Strategy

2. Baseline and Gaps Identified?
% pharmacies accepting electronic prescribing and refill requests

% clinical laboratories sending results electronically, and using standards

% health plans supporting electronic eligibility and claims transactions

% health departments receiving immunizations, syndromic surveillance, and notifiable laboratory results electronically

3. Strategy Addresses Gaps? Gives Providers MU Options for 2011?

Does state's strategy address the gaps the state identified, enabling eligible providers in the state to have at least one viable option for the three key HIE requirements in 2011?

      i. delivery of structured lab results

      ii. e-prescribing

      iii. sharing patient care summaries across <u>unaffiliated </u>organizations.

4. Budget Supports the Strategies?

Do the budget allocations reflect the strategies that the State has described in the State Plan? Are the Contractual and Other categories of expenditures clear and detailed? Is there sufficient staff time dedicated to the oversight and management of vendors and subrecipients?

Detailed Strategic and Operational Plan Review

Strategic and Operational Plan Review

1. High level review

    a. Do the plans establish baseline status and clear gaps (geographic, provider type) for:

        i. % pharmacies accepting electronic prescribing and refill requests

        ii. % clinical laboratories sending results electronically

        iii. % health plans supporting electronic eligibility and claims transactions

        iv. % health departments receiving immunizations, syndromic surveillance, and notifiable laboratory results

    b. Does the state's strategy address the gaps the state identified, enabling every eligible provider in the state to have at least one viable option for the three key HIE requirements in 2011

        i. delivery of structured lab results

        ii. e-prescribing

        iii. sharing patient care summaries across <u>unaffiliated </u>organizations.

    c. Are the state's strategies and plans clear and operationally feasible, building on existing exchange activities in the state?

        Potential strategies include:

       i. 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.

       ii. 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.

       iii. 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.

    d. Are the strategies backed up with robust timelines, clear outline of deliverables and clear project management plans?

    e. Does the budget support the state's strategies and plans?

2. **Strategic Plan Review**

    f. Environmental Scan
       i. Does it 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.

       ii. Does it identify specific gaps by geography or type of provider in the following areas
          1. % pharmacies accepting electronic prescribing and refill requests
          2. % clinical laboratories sending results electronically
          3. % health plans supporting electronic eligibility and claims transactions
          4. % health departments receiving immunizations, syndromic surveillance, and notifiable laboratory results

    g. HIE development and adoption (MU attainment)

       i. Does the state's strategy address the gaps the state identified, enabling every eligible provider in the state to have at least one viable option for the three key HIE requirements in 2011
          1. E-prescribing
          2. Receipt of structured lab results
          3. Sharing patient care summaries across unaffiliated organizations

       ii. Does the plan establish a strategy and immediate next steps to address the following over the course of the project:
          1. Building capacity of public health systems to accept electronic reporting of immunizations, notifiable diseases and syndromic surveillance reporting from providers.

  2. Enabling clinical quality reporting to Medicaid and Medicare.

 h. Medicaid coordination
  i. Does the plan reflect the following Medicaid coordination structures and 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.

 i. Coordination of Medicare and other federally funded state programs
  i. Does the plan reflect coordination with other federally funded state programs? These might include:
   1. Medicare coordination (e.g. DOQ-IT, Care Management Performance Demonstration, Chartered Value Exchange Program, and the EHR Pilot Program)
   2. CDC coordination (e.g. Epidemiology and Laboratory Capacity Cooperative Agreement Program)
   3. CMS/ASPE coordination (e.g. Assistance for Integrating the Long-Term Care Population into State Grants to Promote Health IT Implementation)
   4. HRSA coordination (e.g. Maternal and Child Health State Systems Development Initiative, State Offices of Rural Health Policy, State Offices of Primary Care, Emergency Medical Services for Children Program, HIV Care Grant Program Part B States/Territories Formula and Supplemental Awards/AIDS Drug Assistance Program Formula and Supplemental Awards
   5. SAMHSA coordination (e.g. State Mental Health Data Infrastructure Grants for Quality Improvement)
   6. Indian Health Service coordination

 j. Governance (see below for required elements)
 k. Finance (see below for required elements)
 l. Technical Infrastructure (see below for required elements)
 m. Business and technical operations (see below for required elements)
 n. Legal/Policy (see below for required elements)

3. **Operational Plan Review**

 o. Project Schedule and Management Plan

i. **Does the plan include a robust project management plan outlining timelines and clear deliverables?**
   1. Include a robust project management plan with specific project timelines that clearly illustrate when tasks and milestones will be completed and a staffing plan
   2. Identify resources and interdependencies for all the activities
   3. Include a clear outline of project management approach including the project plan tasks that are managed by vendors
   4. Identify potential barriers and risks including approaches to mitigate them. . 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.

p. **Strategies to Achieve Meaningful Use**

   i. **Does the plan 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 for**
      1. e-prescribing,
      2. receipt of structured labs
      3. sharing care summaries: across unaffiliated providers

   ii. **For each of the three areas, does the plan:**
      1. Outline a clear and viable strategy to ensure that all eligible providers in the state have at least one viable option in 2011.
      2. Include a project timeline that clearly illustrates when tasks and milestones will be completed (see above)
      3. Provide an estimate of all the funding required, including all federal funding and state funding, used to enable stage one meaningful use requirements.
      4. Indicate the role both in funding and coordination of the state Medicaid agency in achieving the state strategy.
      5. Identify desired technical support and coordination from ONC to support the state strategy.

q. **Coordination with ARRA programs**

   i. **Does the plan identify how SDE and HIT coordinator will work with RECs, Beacon, workforce, Broadband and Medicaid programs to develop and implement an aligned strategy to support providers in achieving meaningful use**

r. **Coordination with other States**

   i. **Does the state plan include a description of multi-state coordination activities**

s. **Governance**

      i. Does the plan include approach for a transparent multi-stakeholder process?
          1. Convening 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.

      ii. Does the plan describe ongoing mechanisms and structures for governance?

t. Finance

      i. Does the budget reflect and support the strategies and timelines outlined in the plans?

      ii. Does it include a detailed cost estimate for the implementation of the Strategic/Operational Plans?

      iii. Does the plan include a description of financial policies, procedures and controls that are in place to maintain compliance with generally accepted accounting principles (GAAP) and relevant OMB circulars?

      iv. Does the plan describe the initial approach to sustainability based on the model pursued, with a primary focus on sustaining information sharing efforts?

u. Technical infrastructure

      i. Are the plans and strategies consistent with national standards, NHIN specifications, federal policies and guidelines?
          1. Describes process or mechanism to ensure adoption and use of standards adopted or approved by the Department of Health and Human Services (HHS)
          2. Explains 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.
          3. Outlines the HHS adopted standards and certification requirements that the state or SDE has implemented

      ii. Does the plan describe the technical approach to facilitate data exchange services within the state?
          1. Facilitating Services (facilitating the statewide coverage of HIE services using a variety of exchange methods)
             a. Describe the approach, how it supports meaningful use.
          2. Directly Offering Services (including shared directories or provider authentication services)
             a. Provide either the detailed specifications or describe the process by which the detailed specifications will be developed.
          3. Participation in development, testing and implementation of standards and services offered by NHIN

     v. Business and technical operations

          i. Does the plan leverage current HIE Capacity?
             1. Describes how the state will leverage existing state and regional HIE capacity

          ii. Does the plan leverage or propose development of state level shared services?
             1. Describes how (whether) the state will leverage or develop state-level shared services and repositories. Shared services might include:
                a. Directories (provider, plans, labs)
                b. Identity assurance and authentication
                c. MPI

    w. Legal/Policy

          i. Does the plan describe how HIE will comply with applicable federal and state legal and policy requirements?

          ii. Does the plan develop and fully describe the state's privacy and security framework ?
             1. 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.
             2. The framework must address all the principles outlined in the HHS HIT Privacy and Security Framework, including:

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