B. Detailed Guidance for Strategic and Operational Plans

1. 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.

a) 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)*–
    - 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.
    - 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:
    - Epidemiology and Laboratory Capacity Cooperative Agreement Program (CDC)
    - Assistance for Integrating the Long-Term Care Population into State Grants to Promote Health IT
    - Implementation (CMS/ASPE)

- HIV Care Grant Program Part B States/Territories Formula and Supplemental Awards/AIDS Drug Assistance Program Formula and Supplemental Awards (HRSA)
- Maternal and Child Health State Systems Development Initiative programs (HRSA)
- State Offices of Rural Health Policy (HRSA)
- State Offices of Primary Care (HRSA)
- State Mental Health Data Infrastructure Grants for Quality Improvement (SAMHSA)
- State Medicaid/CHIP Programs
- IHS and tribal activity
- 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.

b) Domain Requirements

- **Governance**
  - **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.
  - **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.
  - **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**
  - **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**

- **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 .
- **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**
  - **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**
  - **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.
  - **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.
  - **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.
  - **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.
  - **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.

2. 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.

a) 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.

b) Domain Requirements

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

- **Finance**
  - **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.
  - **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**
  - **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.
  - **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.

- **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**
  - **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.
  - **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.
  - **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**
  - **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.
  - **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 of health data will be accomplished.