

## Background and Rationale for Recommendations 2.0 and 2.1:

Each breakthrough Workgroup has identified policy issues which must be addressed in order to establish public trust and lead to the successful adoption and subsequent implementation of the breakthrough.

### a. The need to establish Trust

The consumer empowerment group, in particular, has recognized that its work brings 300 million new users into the national health information network, raising numerous questions about privacy, data security, consumer control, and trust. Survey data and early user experience confirm that Americans see their personal health information as highly sensitive and will demand that strong policies be in place to assure its proper management, sharing, and use. Without addressing these concerns upfront, and without promoting trust in the system through general conformance to legitimate policies and practices, users will refuse to adopt and use the network suggested, undermining the mission of AHIC.

We recognize that important interoperability work is already underway, both in the private sector and with public support. Yet personal health records, RHIOs, and national data networks are proliferating without a common policy structure. These policy questions will be with us for many years to come, and a durable framework will be needed – and will evolve – to give efforts in this field a stable environment in which to operate.

### b. The need to develop a common framework of policies and practices that provides for Trust

The first responsibility assumed by the AHIC in its charter (9/13/05) is “protection of health information through appropriate privacy and security practices.” Exposure of personal health information across electronic networks demands broad adherence to uniform, well-understood policies and practices. Without such uniform behavior, key data suppliers (such as doctors or pharmacies) and many data users (such as patients and providers) may believe that a “weak link” could lead to misuse of personal data, patient safety errors, identity theft, or job and insurance discrimination.

There are many dimensions of a comprehensive privacy and security framework, and even the first three breakthroughs and use cases will tax general understanding of current practice and law. Given how little experience we have with nationwide exchange of health information, the process of developing a robust policy structure, and enforcing new policies, will require extensive collaboration among many stakeholders, review by legal, security, and privacy experts, and iterative field experience. Practice will teach us much about policy – but we can ill afford high-risk experiments during our “practice” period.

### c. The need for a legitimate policymaking authority

The process of identifying, specifying and enforcing these policies will require sufficient authority and influence with both the general public and the health and IT sector participants to overcome existing unease and resistance. **We recommend that HHS support the development of an**

**independent, sustainable privacy and security advisory body.** Such an authority should adhere to several principles:

- A bounded and well-defined mission;
- Strong strategic direction from public interest leadership;
- Strong participation by all affected stakeholders on recommending standards and policies that support the strategic goals;
- Minimizes barriers to entry for health IT interoperability and application solutions;
- Builds upon existing standards and policy work and works closely with existing SDOs and other organizations;
- Minimizes impact on economic performance and user rights (such as privacy and security);
- Equal representation of key interest groups, including consumers and patients;
- Accountability to affected stakeholders, including effective independent review procedures;
- Openness and transparency, including procedural and financial transparency;
- Support for long-term evolution and innovation.

d. The need to address the policy issues in the interim

The numerous interoperability and consumer empowerment activities already in the field need some level of interim policy direction during the next 18 months, while a more durable process and authority is put in place. Each workgroup has surfaced issues that should be addressed before technical work is begun, and which should be evaluated through a broad collaboration that includes policy and technical experts as well as representatives of all affected stakeholders. No existing body meets all of the desired criteria.

**We recommend that AHIC create and charge an ad hoc policy workgroup comprised of representatives from each existing workgroup to develop a process to address the pressing policy questions identified by each of the three breakthrough workgroups.** Such a process should attempt to fulfill the above criteria to the degree feasible. The process should:

- Be open, public, and transparent
- Include both technical and policy expertise
- Include members from each AHIC workgroup
- Include representatives of all affected stakeholders
- Be limited to a finite set of policy tasks and a predetermined schedule (to avoid “scope creep”)
- Be supported with adequate staffing or consulting resources to give issues proper research and attention
- Seek consensus recommendations that are considered workable by all stakeholders