

Collaborative ONCHIT RFI Response

This Collaborative Response is submitted by: American Health Information Management Association (AHIMA), American Medical Informatics Association (AMIA), American National Standards Institute-Healthcare Informatics Standards Board (ANSI HISB), Center for Information Technology Leadership (CITL), Connecting for Health (CFH), eHealth Initiative (eHI), HIMSS EHR Vendor Association (EHRVA), Healthcare Information and Management Systems Society (HIMSS), Health Level Seven, Inc. (HL7), Integrating the Healthcare Enterprise (IHE), Internet2, Liberty Alliance, National Alliance for Health Information Technology (NAHIT)

Prologue

In this new century, health care will again be transformed. During the last hundred years, medicine incorporated new science, new approaches to management, and new strategies for professional education. Great 20th century institutions were created: universities, research institutes, pharmaceutical companies, health insurance plans, hospital and clinic networks, government oversight agencies, and public health infrastructures. Extraordinary change and improvement occurred in the lives of many.

And during that remarkable period, even as we realized its benefits, society also discovered the limits of institutional medicine. The more science and applied technology we possessed, the higher our expectations became and the more we were frustrated when these expectations were not met. Practice variations, less-than-optimal outcomes of care, and life-threatening errors persisted despite the explosion of medical knowledge. We learned that the availability of new information does not necessarily improve – and may in fact diminish – the quality of care if practitioners do not have the tools to interpret and apply it effectively. The sophistication and complexity of our health care system introduced new costs, inefficiencies and workforce challenges. A payment system – birthed in the 1930s to pay for hospital services – proved to be inept at rewarding the comprehensive, coordinated, outcomes-oriented and patient-centered care suited to an aging population facing multiple chronic illnesses.

During the last hundred years, the patients changed too. In 1910, 13% of American adults had completed high school; today it's 84%. In today's information-based economy, the median new job requires 13.5 years of education. Prescription drug use has grown dramatically. Today more than 40% of Americans take prescription medicines on a daily basis, and one person in six takes three or more. In daily life, people are responsible for managing their own health. More patients seek out health information on the Web, in libraries, and on TV and try to assimilate it into their own care. The health care system built in the 1950s and 1960s is not the system we need or want for the 21st century.

We need to construct a health information environment that is based on safe, high-quality and efficient modern medical care. We are reminded of one of the remarkable stories from "Achieving Electronic Connectivity in Healthcare: A Preliminary Roadmap from

47 the Nation's Public and Private-Sector Healthcare Leaders" published in July 2004 by
48 Connecting for Health (www.connectingforhealth.org). Dr. J.T. Finnell was able to avert
49 a dangerous medical error common to Emergency Departments across the country, thanks
50 to a connected information environment at the Wishard Memorial Hospital. A patient
51 complaining of crushing chest pain was admitted to the ER but was not able to recount
52 his medical history. Typically a patient with symptoms suggesting a heart attack would
53 have been given a blood thinner. Fortunately, attending physicians were able to access
54 the patient's health records electronically from another institution, learning
55 instantaneously that he had recently been treated for a head injury. Giving the patient a
56 blood thinner would have put him at risk for bleeding in his brain and caused serious
57 injury. With the right information, doctors were able to prescribe the appropriate
58 treatment. The chest pain was relieved and turned out not to be a heart attack. Time,
59 money, and possibly a patient's life were saved.

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61 The urgency and importance of making this transformation to a better use of information
62 and related technologies in the health system is very widely appreciated. Unacceptable
63 rates of avoidable medical errors, as much as \$300 billion in unnecessary expense, and
64 continuing disparities in health care quality constitute a call to action to the health care
65 system and to policymakers. We must act and we must act together now. Dozens of
66 communities and innovative networks across America have begun implementing
67 information exchange solutions – yet they are following no common pathway, no
68 uniform standards, and have established no basis for eventual information exchange
69 among them or with the important national information networks already in existence. A
70 common framework is needed to guide and maximize the value of the enthusiastic efforts
71 already in the field.

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73 This document represents a collaborative – indeed a *consensus* – process among hundreds
74 of the leading contributors to the American health care system. Some of us have worked
75 together for several years under the umbrella of the Connecting for Health initiative.
76 Others have participated actively in professional and industry associations, each of which
77 represents hundreds and thousands of members, and we all chose to come together to
78 seek common ground on this most essential strategy for modernizing and improving our
79 health system. This document is based upon a collaborative effort of organizations that
80 diverge on many issues of policy, business, and philosophy – except their shared belief in
81 the importance of a new national framework for exchanging health information. We
82 represent America's clinical leadership, academic institutions, health insurance plans,
83 consumer and patient leaders, technology vendors, employers, and some of the foremost
84 thinkers on information technology. This submission was crafted during seven weeks of
85 intensive weekly work sessions and conference calls. The Markle Foundation's
86 Connecting for Health leadership and staff organized and carried out the work of drafting
87 the document and integrating the thoughtful input of the collaborative organizations listed
88 below. An expansive, unprecedented network of collaborators generated the input, with
89 specific and concentrated participation by:

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- **The American Health Information Management Association (AHIMA):** the national association of health information management professionals. AHIMA's 50,000 members are

- 93 dedicated to the effective management of personal health information needed to deliver quality
94 healthcare to the public.
- 95 • **The American Medical Informatics Association (AMIA):** AMIA is dedicated to the
96 development and application of medical informatics in support of patient care, teaching, research,
97 and health care administration.
 - 98 • **The American National Standards Institute, Healthcare Informatics Standards Board**
99 **(ANSI HISB):** ANSI HISB provides an open, public forum for the voluntary coordination of
100 healthcare informatics standards among all United States standard-developing organizations.
 - 101 • **The Center for Information Technology Leadership (CITL):** CITL is a non-profit research
102 group based at Partners HealthCare in Boston and supported by HIMSS that assesses the value of
103 clinical information technologies to help provider organizations maximize the value of their IT
104 investments, to help technology firms understand how to improve the value proposition of their
105 healthcare products, and to inform national healthcare IT policy discussions.
 - 106 • **The Connecting for Health Steering Group (CFH):** Connecting for Health...A Public Private
107 Collaborative was conceived and is operated by the Markle Foundation and receives additional
108 support from The Robert Wood Johnson Foundation. The Steering Group includes more than 60
109 diverse stakeholders from the public and private sector, committed to accelerating actions on a
110 national basis to tackle the technical, financial and policy challenges of bringing healthcare into
111 the information age.
 - 112 • **The eHealth Initiative (eHI):** eHI is an independent, non-profit consortium of practicing
113 clinicians, employers and healthcare purchasers, health plans, healthcare information technology
114 vendors, hospitals and other healthcare providers, manufacturers, patient and consumer
115 organizations, and public health agencies, whose mission is to improve the quality, safety and
116 efficiency of healthcare through information and information technology.
 - 117 • **The Healthcare Information and Management Systems Society (HIMSS):** HIMSS is the
118 healthcare industry's membership organization exclusively focused on providing leadership for the
119 optimal use of healthcare information technology and management systems for the betterment of
120 human health.
 - 121 • **Health Level Seven, Inc. (HL7):** HL7's comprehensive suite of ANSI accredited standards for
122 the exchange of demographic and clinical information provides the syntax and semantics for
123 interoperability in a large number of provider organizations in the United States and around the
124 world.
 - 125 • **HIMSS EHR Vendor Association (EHRVA):** Representing more than 25 Electronic Health
126 Record (EHR) vendors with a mission to address national efforts relative to health information
127 interoperability, standards, EHR certification, performance and quality measures, and other
128 evolving government, industry and physician association initiatives and requests (www.ehrva.org).
 - 129 • **Integrating the Healthcare Enterprise (IHE):** (American College of Cardiology, Healthcare
130 Information and Management Systems Society, and Radiological Society of North America): IHE
131 drives standards adoption to address specific clinical needs, by creating a framework and testing
132 vendor implementations for passing vital health information seamlessly - from application to
133 application, system to system and setting to setting - across and between healthcare enterprises
134 (www.ihe.net).
 - 135 • **Internet2:** Internet2 is a consortium being led by over 200 universities working in partnership
136 with industry and government to develop and deploy advanced network applications and
137 technologies, introduce innovations, and expand technological capabilities, accelerating the
138 creation of tomorrow's Internet for a broad spectrum of organizations, including those in the
139 health sciences.
 - 140 • **The Liberty Alliance Project:** Liberty Alliance is a consortium of more than 150 organizations
141 from across the globe, committed to developing open standards for federated network identity that
142 support all current and emerging network devices.
 - 143 • **The National Alliance for Health Information Technology (NAHIT):** The Alliance is a
144 diverse partnership of influential leaders from all healthcare sectors working to achieve
145 measurable improvements in patient safety, quality and efficiency through information
146 technology.
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148 In addition, through targeted sessions, Connecting for Health sought out additional input
149 into the core principles embedded in this document from broad national networks of
150 consumer and patient advocates, groups representing the research community, and health
151 care purchasers and payers. Across the enormous range of this broad group, we
152 discovered an essential consensus:

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154 *We believe that general adoption of a small set of critical tools can permit rapid*
155 *attainment of an interoperable information environment that supports modern*
156 *health care practice.*

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158 *In our view, the NHIN consists of a carefully planned Health Information*
159 *Environment that meets society's requirements through widespread adoption of a*
160 *formal set of technical components, standardized methodologies, and explicit*
161 *policies for use and governance.*

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163 This new Health Information Environment – based on open, consensus-driven and non-
164 proprietary standards, uniform policies that protect privacy, assure security, and support
165 existing trust relationships, and a common technical approach to linking personal health
166 information – can be the springboard to a generation of innovation and improvement in
167 health care and in personal health. Clinical models, self-care and decision-support tools,
168 application and communications software, and even redesigned care practices will
169 emerge within this new environment. Research and innovative approaches to prevention
170 and treatment can be strengthened and the results integrated more rapidly into health care
171 and health-related decision making. The delivery of high quality care can become more
172 likely, less expensive, and timelier – bringing the right skills and knowledge to the right
173 person at the right time. We can put patients and families at the very center of the health
174 care system, supported and surrounded by an information environment that they can use –
175 or allow others to use – to make decisions, monitor health, provide feedback, and support
176 strategic analytic functions that produce measurable improvements in health.

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178 Critical elements of the Health Information Environment are:

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- Facilitates and structures connectivity.
- Builds connectivity on the Internet and other existing networks without “new wires.”
- Provides the capabilities to support near real-time information access when essential for routine and emergency clinical care and also supports ongoing monitoring of disease outbreaks and threats of bioterrorism, research, and quality improvement.
- Leverages existing (and upcoming) open, non-proprietary standards for data content and transmission.
- A national Common Framework supports and guides all participation. The Common Framework consists of the essential technical and policy standards necessary to ensure interoperability, serve the patients whose data it shares, and connect systems of varying technical sophistication.

- 193 • A Standards and Policy Entity (SPE) identifies and recommends standards and
194 policies for the Common Framework, to be used to meet the ongoing
195 requirements for interoperability.
- 196 • Governance is transparent and accountable and includes consumer, patient,
197 and other stakeholder representation at all levels.
- 198 • Connectivity respects and serves patients and is built on the premise of patient
199 control and authorization.
- 200 • Data is decentralized – stays where captured.
- 201 • Connectivity is achieved through a federated structure for policies,
202 procedures, and standards.
- 203 • Patient identification is based on standardized methodologies but without a
204 mandated national unique health identifier.
- 205 • Record Locator Services (RLS), situated in regional or other sub-networks,
206 are new infrastructure components.
- 207 • The “build” of the new information environment happens incrementally,
208 through accretion of sub-networks.
- 209 • A mechanism for validating compliance with the standards of the Common
210 Framework is required for the early phases (there is uncertainty about how
211 long this may be necessary), but the network eventually becomes entirely self-
212 validating.
- 213 • Privacy and security are among the primary design considerations.
- 214 • The Health Information Environment facilitates growth, innovation and
215 competition in private industry.
- 216 • Health IT financing is multi-stakeholder with public and independent funding
217 for the national Standards and Policy Entity; seed grants and funding for
218 Record Locator Services and regional start-ups; incentives built into routine
219 payment and operations at the regional and local level are tied to the use of the
220 Common Framework.
- 221 • The Health Information Environment provides financial value to the entire
222 health enterprise. The value that is generated ultimately funds the financial
223 incentives for performance and stimulates the availability of private capital.
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225 *Challenges ahead*

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227 The collaborators who have come together to develop this response are proud of their
228 progress in identifying consensus strategies for a national health information
229 environment. We have found that we hold far more in common than we ever imagined.
230 And the process of seeking agreement on the fundamentals has also revealed complex
231 problems that deserve continued examination and discussion. We have identified some of
232 these complex problems in an appendix to our response, in addition to a glossary
233 providing our definition of certain key terms.
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235 We applaud ONCHIT’s commitment to dramatic improvements in the use of health
236 information technology. We believe strongly in rapid-cycle times to develop and test
237 both technical and policy mechanisms to drive interoperability. The most critical initial
238 steps to defining the Common Framework will be to identify and implement the essential

239 standards, define policies and technical tools, and evaluate them in the field by listening
240 closely to the experience of its diverse users. The health information environment will be
241 an organic and evolving community of users, technologies, and resources.

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243 In preparing this response to the ONCHIT RFI, we have had the privilege of talking with
244 hundreds of organizations across the entire sweep of U.S. health care. Many of our most
245 active participants have represented associations which themselves include hundreds and
246 thousands of members. It has not been possible, of course, to capture the views or seek
247 the formal endorsement of every individual organization or person. All of our
248 participants, signatories to this submission, agree with the principles outlined here. And
249 some have particular expertise or interest in topics that go beyond the consensus on core
250 principles that is presented in this document. They may provide ONCHIT directly with
251 additional information reflecting their own views.

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253 As ONCHIT continues to evaluate and coordinate national efforts, we will be ready to
254 help in any appropriate way. We represent the widest diversity of our great health care
255 system – patients, professionals, payers, researchers, technologists, regulators – and we
256 want to see our national system fulfill its potential to help every American achieve the
257 best possible health with the available resources. Our approach is above all pragmatic; it
258 is based not on any particular ideology or economic interest, but on our shared sense of
259 what practical actions will bring results. We can work together to achieve the President's
260 vision of an interconnected health information system by 2014.

261 **RESPONSE TO RFI QUESTIONS**

262

263 ***General***

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265 **Question 1. Please provide your working definition of a NHIN as completely as**
266 **possible, particularly as it pertains to the information contained in or used by**
267 **electronic health records. Please include key barriers to this interoperability that**
268 **exist or are envisioned, and key enablers that exist or are envisioned.**

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270 *Our response provides a detailed discussion of the Collaborative's view of NHIN. In our*
271 *view, the NHIN consists of a carefully planned Health Information Environment that*
272 *meets society's requirements through widespread adoption of a formal set of technical*
273 *components, standardized methodologies, and explicit policies for use and governance.*

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275 *The core **functional capabilities** of the Health Information Environment are:*

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- **Extensive Connectivity.** Facilitates and permits the private and secure exchange of necessary health information among authorized clinical care providers, hospitals, labs, pharmacies, payers, and all other parties involved in the delivery and receipt of health care – including the patient and his or her caregiver or designated representative.
- **Just In Time Access.** Provides patients and their authorized health professionals or caregivers access to health information exactly when and how it is needed, in near real-time.
- **Empowers Patients.** Provides patients access to their own health information to enable them to work in partnership with providers to improve the quality and affordability of their health and health care.
- **Enables Decision Support.** Assists patients and professionals in making decisions and avoiding medical and medication errors; facilitates real-time prompts and reminders at the point of care and directly to the patient or caregiver; and enables broader use of evidence-based medicine.
- **Assists in Quality Evaluation.** Allows patients, purchasers, physicians, health systems and others to collect and use scientifically valid information to assess the quality of healthcare and make decisions about where and from whom to seek care. Use of quality information for public reporting should be demonstrated initially on a sub-network scale and should be done according to established guidelines for producing and aggregating measures of quality.
- **Supports Ability to Protect and Maintain the Health of the Public.** Enhances and facilitates the use of patient care data for appropriate public health disease surveillance, outbreak detection, trending, and health protection efforts, and ensures that public health results can be integrated to benefit patient diagnosis, care, and improve personal health decisions.
- **Improves Research for Maintaining Health as well as the Diagnosis, Treatment and Cure of Disease.** Enhances and facilitates the use of authorized patient care data in clinical research and ensures that clinical research results can be integrated to benefit patient care and improve personal

307 health decisions. Provides a broadly enabling research infrastructure that
308 promotes appropriate sharing and reusing of the results of clinical research to
309 inform and improve care and facilitates collaborative research. The Health
310 Information Environment should support use of authorized health and
311 healthcare data collected in the course of routine medical care and from other
312 sources to improve research capabilities, and for data collected in the course
313 of research to improve health and healthcare.

- 314 • **Enables Better Physician and Organizational Performance and**
315 **Benchmarking.** Enhances professionalism and the desire to “do the right
316 thing” by creating the ability for physicians and other clinical care providers
317 and organizations to more easily look at the aggregate processes and outcomes
318 of care and benchmark their performance.

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320 *Technical Overview:*

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322 The Health Information Environment will be a "network of networks," where
323 participants, grouped together through proximity, stakeholder trust and patient
324 care needs, will drive the formation and evolution of sub-networks. As with a
325 Regional Health Information Network (RHIN) or through affinity (as with sites of
326 care operated by organizations such as the VA), the Health Information
327 Environment will support data transmission both within and among these various
328 sub-networks. The Health Information Environment ensures interoperability
329 through open standards, rather than by creation of a new physical network.
330 Existing healthcare IT infrastructure – hardware, software, and network
331 connections – will be able to interoperate in the Health Information Environment
332 if it conforms or is adapted to use the Common Framework. New deployments of
333 hardware and software will likewise be able to interoperate with legacy systems
334 through conformance to the Common Framework. These standards will allow use
335 of the Internet, private networks, and any new network infrastructure for the
336 secure transport of essential health care information and transactions.

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338 *The technical attributes and common requirements of the Health Information*339 *Environment include:*

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- 341 • **A Connected Environment based on Sub-Networks Built on the Internet.**
342 It permits participating sub-networks and their authorized users to access only
343 appropriate information on demand in a private and secure manner. Sub-
344 networks may be determined geographically or be based on other
345 relationships.
- 346 • The Health Information Environment is predicated on a **decentralized and**
347 **federated** model that protects the privacy and security of information and
348 allows accurate and timely access to information.
- 349 • The Health Information Environment is premised on a “**Common**
350 **Framework**” consisting of the technical and policy standards essential to
351 ensure privacy, security and interoperability, serve the patients whose data it
352 shares, and connect systems of varying technical sophistication.

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- The detailed **design principles** of the Health Information Environment are:
 1. **Decentralized.** Data stays where captured: The U.S. healthcare system is fragmented. Many types of institutions are part of the current healthcare network, from giant hospital systems to individual practices, with all manner of specialists, clinics, and agencies in between. The decentralized approach reflects the legal and market realities of healthcare. The Health Information Environment facilitates the transfer of selected information from one end-point system to another (not necessarily the source system), as is required for providing care and supporting informed patient participation in care. The decentralized approach obviates the need for storing identifiable data in a central database, but builds on existing aggregates of data where available or necessary. The infrastructure facilitates information access by authorized end-point systems, or proxies for them, to improve the delivery of patient care and to further other health-related goals. Even though the infrastructure is decentralized, it supports and facilitates authorized aggregation for public health, quality management and other functions.
 2. **Federated.** To maintain the local autonomy of decentralization, a common set of policies, procedures, and standards to facilitate reliable, efficient sharing of health information among authorized users is required. These standards or practices specify when patient information can be shared, which information can be shared, and how the information can be used. That is, the participating members of the health network must belong to and comply with agreements of a federation. Federation, in this view, is a response to the organizational difficulties presented by the fact of decentralization. Formal federation with clear agreements allows participants to access information that has been authorized to share.
 3. **Private and Secure.** All of the activities of the Health Information Environment, including the delivery of care and the conduct of research and public health reporting, must be conducted in an environment of trust, consistent with appropriate requirements for patient privacy, security, confidentiality, integrity, audit and informed consent. All those that generate health information for patients are its stewards. Patients control access, in partnership with their providers.
 4. **Accurate.** Accuracy in identifying both a patient and his or her records with little tolerance for error is an essential element of the Health Information Environment design. The Health Information Environment must also create feedback mechanisms to help organizations to fix or “clean” their data in the event that errors are discovered.
 5. **Reliable.** Assurance of a uniform minimum degree of system service quality (e.g., reliability, dependability, etc.) in addition to backup mechanisms, so that stakeholders can count on the availability of the overall system.
 6. **Fast.** Near real-time information access is crucial, not only for routine clinician and patient needs, but also for particularly time-sensitive

- 398 specialties such as emergency medicine and monitoring of disease
399 outbreak, bioterrorism, or contamination of the food supply.
- 400 7. **Interoperable and built on a Common Framework.** The
401 interoperability of the Health Information Environment is premised on
402 conformance to a Common Framework, which consists of the essential
403 technical and policy requirements to enable the interoperation of standard
404 interfaces and transactions at the local, regional and national level. The
405 technical standards address secure transport over the Internet and other
406 networks, and provide the essential components required for the
407 infrastructure including secure connectivity, reliable authentication and a
408 suite of defined interchange formats for health care data. The policy
409 standards address the privacy, use and access policies for the exchange of
410 health information. The Common Framework also provides a uniform
411 methodology for the identification of users. The modular character of the
412 Common Framework permits rapid attainment of an interoperable
413 information environment using essential requirements but also scales to a
414 more complete structured data interchange for enhanced performance.
415 The suite of interoperability standards will be enhanced over time. The
416 Common Framework is the basis of all subsequent use cases that require
417 specific, uniform interoperable standards to support information exchange.
418 Use cases and accompanying information standards will be specified for
419 each of the myriad of health information exchange requirements and will
420 be supported by detailed implementation guides. The participants in sub-
421 networks will determine which profiles are appropriate to address the
422 requirements established by their stakeholders. The Common Framework,
423 and mechanisms to enforce compliance with it, ensures the creation,
424 interoperability, scalability, efficiency and ongoing evolution of this
425 environment. The Common Framework should be required across all
426 health communities, including the clinical research community, public
427 health, etc. The Common Framework is further described in subsequent
428 sections.
- 429 8. **Designed to Respect and Serve Patients (in addition to the Health
430 System and the Public).** The Health Information Environment is
431 premised on a model of patient authorization and control. Patients must
432 be able to: choose whether or not to participate in sharing personally
433 identifiable information; exercise their rights under HIPAA; control who
434 has access to their records (whether in whole or in part); see who has
435 accessed their information; review, contribute to and amend their records
436 (without unreasonable fees); receive paper or electronic copies of their
437 information; and reliably and securely share all or portions of their records
438 among institutions. Once patient consent has been granted for a certain
439 type of information access, however, information should be able to be
440 accessed freely in a trusted environment.
- 441 9. **Flexible.** The Health Information Environment is flexible in several ways.
442 First, it is heterogeneous with regard to the types of technology and
443 function of the sub-networks and other entities that use it, providing that

444 all of them adhere to the Common Framework. This enables users of
445 varying levels of technical and functional sophistication to use it for a
446 variety of processes. Second, it is flexible in that it facilitates
447 communication among end-point systems at varying levels of
448 sophistication in the structured and coded representation of data and
449 supports the evolution of systems in this regard. For example, while some
450 might use the Health Information Environment to locate records and
451 request them by telephone, others may draw on it to support the full
452 electronic exchange of highly structured data for sophisticated data
453 analysis and decision support. This is necessary because health
454 information will continue to be a mix of unstructured and structured and
455 coded data. The Common Framework provides standards and procedures
456 that allow two systems that support highly coded data to exchange it
457 without loss of data, a system that supports less or little coding to receive
458 information from comparable and from highly structured systems, and a
459 system that supports a high level of coding to receive, file, and make use
460 of lightly coded data when this comes from another system. Lastly, the
461 Health Information Environment is flexible also in that it is able to evolve
462 over time to address the changing needs of users and to increase in scale as
463 the numbers of users and their transactions grow; it supports a reasonable
464 level of variation and innovation in response to local needs.

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466 *What the Health Information Environment is not*

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- 468 • **A “Big Bang” Undertaking.** Although the need for a Health Information
469 Environment would warrant a "moon-shot" type approach to its building,
470 political and practical realities suggest that an incremental approach would
471 gain more support. Given the complexity, diversity and distributed nature of
472 the existing U.S. health system, an incremental approach that builds on and
473 integrates existing networks is more likely to succeed. Therefore, this is not a
474 "big-bang" approach. Furthermore, the standards, validation mechanisms, and
475 governance structures cannot spring into existence at once. The Health
476 Information Environment should be coordinated and built on a plan that
477 recognizes the need for a learning curve. The lessons learned from
478 developing harbinger regional or other sub-networks can prove and improve
479 approaches, leading to accelerated replication and success based on early
480 experience.
- 481 • **A Central Data Repository.** The Health Information Environment is not
482 based upon a national central repository of patient information. Instead, it is a
483 pathway that facilitates, with appropriate authorization, private and secure
484 information identification and access among regional and other sub-networks.
485 Health information resides with the healthcare providers that generate it
486 and/or with patients themselves.
- 487 • **A Significant Financial or Technical Barrier to Connectivity.** The Health
488 Information Environment minimizes any additional financial or technical

- 489 barriers (other than the requirement to comply with the Common Framework)
490 to information sharing for patient care.
- 491 • **Proprietary.** The Health Information Environment is not a proprietary
492 network owned and operated by particular stakeholder groups.
 - 493 • **The Applications that Rely on It.** Healthcare applications or end-point
494 systems (e.g., EHRs) rely on the Health Information Environment and are
495 important extensions of it, but not strictly part of it. Furthermore, the Health
496 Information Environment is not itself an application.

497 *Significant Barriers*

500 **Financial**

- 501 • Health care payment and investment policies that do not stimulate improved
502 information access or healthcare quality.
- 503 • Misalignment of financial burden and ROI among providers, payers, and
504 patients.
- 505 • Inadequate capital for initial investment in infrastructure, systems, and
506 implementation of standards.
- 507 • Financial instability of some technology vendors, particularly EHR vendors.
- 508 • Lack of a robust market for innovation.

509 **Technical**

- 510 • Lack of technical specifications, standards and essential requirements for
511 interoperability that can be validated and will work in all of the sophisticated
512 and unsophisticated environments in healthcare.
- 513 • Lack of experience raising standards for interoperability to a regional or
514 national level.
- 515 • Need for continued progress in developing common nomenclature and
516 vocabulary definitions.
- 517 • Lack of a standard mechanism for patient identification.
- 518 • Lack of user-friendly interface designs and implementation support for
519 clinical and other applications.

520 **Environmental**

- 521 • Complexity, vastness, fragmentation, and sheer volume of health transactions
522 required by the health system.
- 523 • Overlap, competition and fragmentation of existing standards development
524 efforts.
- 525 • Healthcare payment policies and regulations that call for the inconsistent
526 reporting of data or manipulation of data or codes.
- 527 • Inconsistency of laws for information sharing among states—some that may
528 require further policy clarification or action to resolve.

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Educational/Attitudinal

- General lack of public information and understanding about the potential benefits of access to electronic health information for personal health decisions and health care services.
- Public and professional concerns about privacy and security of information.
- Professionals' reluctance to use electronic health records, whether because of potential disruption of workflow, lack of technical and implementation support or other concerns.
- Provider concerns related to liability resulting from the potential availability of additional data for which they may be responsible.
- Lack of research on and understanding of workforce development as it concerns health IT. Areas needing attention include: just-in-time training to help providers and support staff to adapt their work processes; initial and continuing education of health information specialists (e.g., IT specialists, health information management professionals, applied information management professionals); and research on evolving information management practice domains.

Significant Enablers (While the opposite of every “barrier” could be listed as a potential “enabler,” we have chosen to identify only enablers that we believe already exist, to varying degrees.)

Financial

- Increased financial support (from public and/or private sources) for technology adoption, implementation, and training tied to requirements for information standards, patient identification, and interoperability.
- Growing interest on the part of new entrants to the market for IT tools and services as a result of the financial scale of the market.
- Pay for performance, including incentives for information sharing for improved patient care.
- Underserved populations may require financial and other support to ensure that they have access to and can benefit from the Health Information Environment.

Technical

- Developments in information technology sharing tools and process management techniques that enable new decentralized architecture models.
- Growing availability of broad-band access or other connectivity options.
- Digitization of medical technology and research, increasing demand for interoperability of data.

Environmental

- Growing political support in the Administration and Congress (including the creation of ONCHIT).
- Demand (patient, political and financial) for high quality, affordable health care for all.

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- The lessons learned from developing harbinger regional or other sub-networks can prove and improve approaches, leading to accelerated replication and success based on early experience. Large Integrated Delivery Networks, smaller independent providers, and vendor groups have participated in IHE's testing processes and provided opportunities for learning. Additional lessons learned in the United Kingdom, Canada, Australia, and other international venues to revamp infrastructure and promote interoperability should not be overlooked.
 - Agreement on conformance validation mechanisms for interoperability.
 - Agreement on mechanisms for protecting the privacy, security and integrity of health information and the initial Federal floor established by the HIPAA Privacy Rule.
 - Industry consensus on basic administrative, physical and technical framework for protecting health information and security.
 - Industry consensus on the development and adoption of information standards including those that: allow clinical data captured at the point of care; are compatible, easily coordinated, and satisfy diverse user requirements to share and aggregate data; enable systems with varying levels of structured and unstructured data to communicate.
 - Proliferation of regional, state, and local initiatives eager to move rapidly and conform to emerging national protocols and policies. (Note that it is essential to define a Common Framework soon so disparate initiatives do not develop in incompatible ways.)
 - Legal safe harbors with restrictions.

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605 **Educational/Attitudinal**

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- Support for increased patient education to help people understand the value of the network, its privacy and security protections, how to participate in it, and the rights and benefits afforded to them.
 - Professional and industry programs for technology adoption, training and support.
 - Growing patient expectations, interest, and awareness.
 - Payer and employer commitment to IT adoption and health system transformation.
 - HIPAA rules, which have created an emphasis on privacy issues.

617 **Question 2. What type of model could be needed to have a NHIN that: allows**

618 **widely available access to information, enables interoperability, protects personal**

619 **data, allows vendors and other technology partners to be able to use the NHIN in**

620 **the pursuit of their business objectives? Please include considerations such as roles**

621 **of various private- and public- sector entities in your response.**

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623 *The model for the Health Information Environment that will fulfill these requirements*

624 *must:*

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- Create a market for health IT rather than forestalling one.

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- Enhance existing and new sub-networks by interconnecting without overburdening them.
 - Minimize “barriers to entry” in its development.
 - Be built upon existing infrastructure (no “rip and replace” and “no new wires”) including:
 - Internet standards, particularly http, SOAP, and SSL
 - The Internet itself as a means of transport and interconnection
 - Current IT platforms (e.g., labs, rx, EMR)
 - Current master patient index (MPI) systems and technologies
 - Current patient-doctor and patient-organization (e.g. institution or plan) relationships for authentication
 - Current standards identified by the Federal Consolidated Health Informatics Initiative (CHI) including, but not limited to ANSI, ASC X12, NCPDP and HL7 industry standards.

641 *The Health Information Environment will grow incrementally with the creation and*

642 *expansion of sub-networks:*

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- Stakeholder trust and patient care needs will drive the formation and evolution of sub-networks.
 - The Health Information Environment will be developed through a combination of “top-down” (i.e., nationally-defined) policies and standards, and “bottom-up” (i.e., community and market-driven) initiatives.
 - Development of the Health Information Environment MUST be facilitated and supported by:
 - Ensuring that all sub-networks conform to the Common Framework, in order to interconnect with each other in a consistent and uniform manner.
 - Early demonstration of the ability to effectively exchange usable patient information within and among sub-networks.
 - Early establishment of a Reference Implementation Process on a significant scale to reliably and quickly develop the technical and policy requirements for the Common Framework. The first formal version of the Common Framework will be completed after learning from this process and will serve as a basis for others.
 - The accuracy, responsiveness, security, and scalability of the system as demonstrated by the Reference Implementation Process, which will foster broader implementation by vendors, and accelerate deployment in sub-networks. The same cycle will need to be repeated as the Common Framework is extended.
 - The Standards and Policy Entity (SPE), which, when it is established, will take over primary responsibility for the development of the Reference Implementation Process and policies of the Common Framework.
 - Subsequent reference implementations that define the profiles or suites of standards for a complete set of use cases that will also be a primary responsibility of the Standards and Policy Entity (SPE).

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673 *On the specific issue of privacy and data protection and the linking of patient records:*

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- The Health Information Environment requires uniform adherence to a set of policies that are based upon local or sub-network trust relationships, protect privacy and security (at or above applicable federal and state legislation and regulation), minimize the risk of user data misuse, and provide for accountability, transparency and oversight.
- The Health Information Environment is premised on a model of patient authorization and control. Patients must be able to: choose whether or not to participate in information sharing; exercise their rights under HIPAA; control who has access to their records (whether in whole or in part); see who has accessed their information; review, contribute to and amend their records (without unreasonable fees); receive paper or electronic copies of their information; and reliably and securely share all or portions of their records among institutions.
- The Health Information Environment does not require the use of a mandated national unique health identifier.
- However, standardized methodologies are required to identify patients and these methodologies must accommodate any broadly accepted identifier that may emerge to be used as additional sources of likelihood of match. No system will ever rely on a single identifier, as some secondary set of information will be needed to resolve ambiguous matches.
- Any proposed solution for accurately linking patient records must:
 - Support the accurate, timely, private and secure handling and transmission of patient records.
 - Increase the quality of care, the economic sustainability of the healthcare system, and the privacy of patient data.
 - Create value for many different kinds of participants, including (but not limited to) individual healthcare professionals and patients.
- The Health Information Environment is a network of networks, linked only by registries through which information about how to find the sources of authorized records can be found, not any of the actual content of the health records. The registry system knows only where authorized records are, not what is in them.
- To achieve these capabilities, the Health Information Environment requires the addition of one new piece of infrastructure at the sub-network level based on an architecture that separates the function of locating authorized records from the function of transferring them to authorized users. This piece of infrastructure is the Record Locator Service (RLS), described later in this response, and is operated by a multi-stakeholder collaborative at the regional or non-geographic sub-network level and built on the current enterprise use of Master Patient Indices. The Record Locator Service itself is subject to privacy and security requirements, and is based on open standards set by the Standards and Policy Entity.

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- The system supports
 - a. Linking of records via a registry of information about where records are located and sharing among users participating in the system, but it also allows
 - b. Linking without sharing, or sharing pursuant only to higher authorization, as well as
 - c. The ability to choose not to link information in certain sensitive treatment situations determined by users.

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On the specific issue of disclosure and accountability:

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On the specific issue of technical openness and flexibility:

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- The Common Framework does not dictate, recommend or imply specific tools, platforms, products, or vendors. Access to the Record Locator Service and other functions of the environment requires conformance to the Common Framework. Without this, every entity that has to interact with the network would be unable to do so reliably and consistently—multiple and differing approaches to core aspects at the regional level would create undue burden on

764 public and private payers, large delivery organizations, labs, PBMs, pharmacy
765 chains, vendors who supply applications, etc.

- 766 • While the Health Information Environment is built using the existing Internet,
767 it has to anticipate and take advantage of migration to next generation
768 technology, which will include better and different approaches to ensuring
769 privacy and security and performing other functions.
- 770 • The Health Information Environment must have a wide variety of capabilities
771 as articulated in question 1 (e.g. consumer, provider, research, and public
772 health).
- 773 • The Health Information Environment is flexible in several ways. First, it is
774 heterogeneous with regard to the types of technology and function of the sub-
775 networks and other entities that use it, providing that all of them adhere to the
776 Common Framework. This enables users of varying levels of technical and
777 functional sophistication to use it for a variety of processes. Second it is
778 flexible in that it facilitates communication among end-point systems at
779 varying levels of sophistication in the structured and coded representation of
780 data and supports the evolution of systems in this regard. For example, while
781 some might use the Health Information Environment to locate records and
782 request them by telephone, others may draw on it to support the full electronic
783 exchange of highly structured data for sophisticated data analysis and decision
784 support. This is necessary because health information will continue to be a
785 mix of unstructured and structured and coded data. The Common Framework
786 provides standards and procedures that allow two systems that support highly
787 coded data to exchange it without loss of data, a system that supports less or
788 little coding to receive information from comparable and from highly
789 structured systems, and a system that supports a high level of coding to
790 receive, file, and make use of lightly coded data when this comes from
791 another system. Lastly, the Health Information Environment is flexible also
792 in that it is able to evolve over time to address the changing needs of users and
793 to increase in scale as the numbers of users and their transactions grow; it
794 supports a reasonable level of variation and innovation in response to local
795 needs.

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797 ***On the specific issue of interoperability:***

- 798 • The interoperability of the Health Information Environment is premised on
799 conformance to a Common Framework, which consists of the essential
800 technical and policy requirements to enable the interoperation of standard
801 interfaces and transactions at the local, regional and national level.
- 802 • Without this, every entity that has to interact with the network will be unable
803 to do so reliably and consistently—multiple and differing approaches to core
804 aspects at the regional level would create undue burden on patients and
805 providers that cross sub-networks, public and private payers, large delivery
806 organizations, labs, PBMs, pharmacy chains, vendors who supply
807 applications, etc.
- 808 • The technical standards address secure transport over the Internet and other
809 networks, and provide the essential required components for the infrastructure

- 810 including secure connectivity, reliable authentication and a suite of defined
811 interchange formats for health care data.
- 812 • The policy standards address the privacy, security and use and access policies
813 for the exchange of health information.
 - 814 • The Common Framework also provides a uniform methodology for the
815 identification of users.
 - 816 • The modular character of the Common Framework permits rapid attainment
817 of an interoperable information environment using essential requirements but
818 also scales to a more complete structured data interchange for enhanced
819 performance. The suite of interoperability standards will be enhanced over
820 time.
 - 821 • The Common Framework is the basis of all subsequent use cases that require
822 specific, uniform interoperable standards to support information exchange.
823 Use cases and accompanying information standards will be specified for each
824 of the myriad of health information exchange requirements and will be
825 supported by detailed implementation guides.
 - 826 • The participants in sub-networks will determine which profiles are appropriate
827 to address the requirements established by their stakeholders.
 - 828 • The Common Framework, and mechanisms to enforce compliance with it,
829 ensures the creation, interoperability, scalability, efficiency and ongoing
830 evolution of this environment.
 - 831 • This work will necessarily involve choices that eliminate some of the
832 variability in the standards while attaining interoperability.
 - 833 • The Common Framework enables a set of open, non-proprietary interfaces
834 and information transfer protocols to be developed to achieve interoperability.
835 This also permits less standardized records to be accessed reliably and rapidly;
836 it facilitates the best possible interoperability among end-points systems of
837 differing levels of sophistication.
 - 838 • The Common Framework relies upon standards for data content and
839 transmission developed by nationally accredited organizations using an open
840 and consensus-based process. It builds upon existing standards development
841 activity and HIPAA.
 - 842 • The Common Framework should be required across all health communities,
843 including the clinical research community, public health, etc.

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845 ***On the specific issue of enforcing compliance with the Common Framework***

- 846 • The Common Framework, and mechanisms to enforce compliance with it or
847 other applicable standards and policies will be an essential condition of the
848 development of the Health Information Environment. The Common
849 Framework ensures the creation, interoperability, scalability, efficiency and
850 ongoing evolution of this environment. Mechanisms to test and validate
851 compliance may be necessary in several domains, including the “highest” or
852 network environment level, the sub-network level, and the level of end point
853 applications (e.g., EHRs). Validation methodologies should be appropriate to
854 the information exchange, requiring only the elements and protocols essential

- 855 to participation in the Health Information Environment, in a way that
856 encourages innovation and new entrants to the market.
- 857 • An external mechanism for validating compliance with the standards of the
858 Common Framework is required for the early phases, but the network may
859 eventually become entirely self-validating. There is uncertainty about how
860 long the outside compliance validation mechanism may be necessary—until
861 the point at which there is a significant level of stability in the Health
862 Information Environment. From the beginning, self-assessment should be
863 built into the compliance validation mechanism because it helps to assure that
864 programs are on track on a continuous basis, rather than waiting for an outside
865 party to identify significant problems.
 - 866 • Interface and transaction interoperability standards should allow for the
867 appropriate and authorized integration of financial transaction information
868 with related clinical transactional data.
 - 869 • The Health Information Environment is inclusive of participants of varying
870 levels of technical and functional sophistication. Its standards, rules and
871 vocabularies can accommodate a wide variety of participants at any one time
872 and can also be revised over time as user requirements evolve.

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874 *On the specific issue of market incentives and business objectives*

- 875 • Healthcare suffers from a fragmented and stalled market for IT—both for
876 connectivity and IT adoption generally.
- 877 • There is no “network effect” today in healthcare IT.
- 878 • The promulgation of a Common Framework will immediately accelerate the
879 value of adopting IT by creating confidence in the ability of IT systems to
880 reliably enable connectivity. Agreement on conformance validation
881 mechanisms for interoperability will enhance this effect.
- 882 • This approach should catalyze a market by creating a level playing field for
883 market competition. Nevertheless, widespread adoption of interoperable
884 clinical IT will still depend on investment in the key components of the Health
885 Information Environment and the use of incentives that recognize appropriate
886 information use in clinical care.
- 887 • Incentives can include a wide variety of options from fundamental payment
888 reform to eligibility for Federal assistance, eligibility to participate in federal
889 demonstration projects, private-sector pay for performance incentives that
890 require interoperability specified by the Common Framework, and eligibility
891 to receive private IT adoption assistance.
- 892 • Incentives that reward the improved decision-making and quality of care
893 enabled by the Health Information Environment will be more effective at
894 driving participation than incentives tied specifically to IT adoption or
895 network participation.

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900 **Question 3. What aspects of a NHIN could be national in scope vs. local or regional?**
901 **Please describe the roles of entities at those levels.**

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- 903 • The Health Information Environment will take shape incrementally, over time.
904 Its development will include both “top-down” (i.e., nationally-defined) policies
905 and standards, and “bottom-up” (i.e., community and market-driven) initiatives.
- 906 • Both local and national strategies are needed. Most healthcare is local, and a great
907 deal of information access occurs in a patient’s own community. At the same
908 time, many patients receive care, coverage, and benefits across multiple regions;
909 also, the US population is highly mobile, whether moving across state lines from
910 home to work or from winter to summer homes. Many multi-institution networks,
911 that effectively comprise local health information infrastructures, already exist
912 and must be accommodated.
- 913 • In general our proposed model for the Health Information Environment is
914 decentralized and regionally driven. It is desirable to leave to the local systems
915 those things best handled locally, while specifying at a national level those things
916 required as universal in order to allow for interoperability among regional
917 systems. The Common Framework, comprised of the essential security and
918 interoperability standards required to assure secure Internet transmission or
919 patient matching methods, must be national, so that all participating institutions
920 can connect to one another securely and without unworkable variation.

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922 *The various regional and national roles and entities for the Health Information*
923 *Environment are:*

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Regional (or Sub-Network):

- 926 • Each region or sub-network needs an entity (Sub-network Organization) to
927 oversee its health information environment. Regional sub-networks have a
928 public interest responsibility to address the needs of the entire population and
929 all health information providers. Some sub-networks will be geographically
930 based and others will be functional or organizational, crossing geographical
931 boundaries. Some of these enterprise or private sub-networks (e.g., a large
932 health system or research network) may not be subject to the same public
933 interest governance and policy obligations. The responsibilities of the Sub-
934 Network Organizations include:
 - 935 a. Establishing a multi-stakeholder governance structure that includes the
936 representation of patients and consumers and safety net providers. The
937 governance structure should be formalized and address the corporate and
938 tax status of the Sub-Network Organization, its business plan and budget,
939 intellectual property ownership and management, the entity’s statement of
940 purpose and objectives, its decision making model, and its long-term
941 strategic plan. Various types of governance model are acceptable.
 - 942 b. Defining and meeting the particular information access needs of the region
943 or sub-network while addressing the needs of patient populations that
944 cross multiple communities nationwide or are contiguous but cross state
945 lines.

- 946 c. Organizing the creation of “Articles of Federation” and other user
947 agreements. A common set of multi-lateral policies, procedures, and
948 standards to facilitate reliable, efficient sharing of health data among
949 authorized users is required. The participating members of the health
950 network must belong to and comply with agreements of a federation.
951 Formal federation with clear agreements allows participants to access
952 information that they have been authorized to share.
- 953 d. Supervising uniform adoption of information sharing policies or Articles
954 of Federation by participating entities and mechanisms for their
955 enforcement (e.g. sanctions).
- 956 e. Developing policies to address the need for retention and persistence of
957 data.
- 958 f. Addressing conflicts among relevant stakeholders in a timely way.
- 959 g. Building, maintaining and managing the regional Record Locator Services
960 and other sub-network systems and services.
- 961 h. Assuring that sub-network systems and the end-point systems of their
962 members (including the Record Locator Service) adhere to the Common
963 Framework.
- 964 i. Providing support to participants in the federation.
- 965 j. Establishing the financial sustainability models for the entity—
966 responsibilities include:
- 967 a. Working with community payers, purchasers and providers to
968 discuss participation, incentives and appropriate funding models.
- 969 b. Monitoring relevant stakeholder participation regarding
970 conformance with the Common Framework and adoption
971 incentives.
- 972 k. Ensuring that all of the information capabilities that define the Health
973 Information Environment (including public health reporting and
974 surveillance, research and improving health care quality) can be met over
975 time.
- 976
- 977 • In regions where there is low potential for an organizing function, (e.g., rural
978 and underserved), other models of non-geographic sub-networks and Sub-
979 Network Organizations should be established to support these necessary sub-
980 networks. For example, there may be cases, especially in rural areas, where
981 specialized clinical data repositories, or proxies, are shared by the providers in
982 the community. Rural networks that may be meeting the needs of relatively
983 closed provider networks may be best served by shared clinical data
984 repositories that allow acceptable access speeds even when broadband Internet
985 access is limited or less efficient. Any model must include the possibility for
986 such clinical data repositories or proxies to exist as long as they comply with
987 the Common Framework for interacting with other sub-networks as
988 appropriate for patient care or other authorized use. Alternatively, some Sub-
989 Network Organizations can explore potential partnerships with the appropriate
990 State Health Departments, Medical Societies, NGOs, etc.
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Organizational and Business Framework

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Question 4. What type of framework could be needed to develop, set policies and standards for, operate, and adopt a NHIN? Describe the kinds of entities and stakeholders that could compose the framework and address the following components:

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Key Considerations for the Health Information Environment are:

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- A Standards and Policy Entity (SPE) to identify and recommend standards and policies for the “**Common Framework**”- a set of essential technical and policy requirements that enable the interoperation of standard interfaces and transactions at the local, regional and national level (more fully described in the next question).
- Privacy guidelines and policy clarification re: HIPAA, anti-kickback, potentially conflicting state laws and anti-trust laws.
- Performance and accountability metrics
- Experimentation with and creation of financial incentives that require the Common Framework
- Special attention, funding and mechanisms of support for rural and underserved communities
- Enforcement policies for misuse of data
- Coordinated efforts to ensure public understanding of the benefits of health information exchange and patients’ rights in the information exchange environment.

- a. **How could a NHIN be developed? What could be key considerations in constructing a NHIN? What could be a feasible model for accomplishing its construction?**
- b. **How could policies and standards be set for the development, use and operation of a NHIN?**
- c. **How could the adoption and use of the NHIN be accelerated for the mainstream delivery of care?**
- d. **How could the NHIN be operated? What are key considerations in operating a NHIN?**

- An over-arching principle in the development and operation of the Health Information Environment is the importance of serving the public interest: it must above all meet the needs of patients by enabling the provision of high quality care at reasonable costs.
- Consumer and patient advocates, amongst all other stakeholders, must be represented on an equal footing in the governance and advisory structure of all regional and national Health Information Environment authorities, including standard-selection and operational entities. Beyond this requirement, various governance models should be explored to balance stakeholder input while not becoming unduly burdensome.

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- The Health Information Environment, like the Internet that functions as its core, will not be operated by a central entity. However, like the Internet, which has centralized functions such as domain name assignment, the Health Information Environment will require the centralization of some functions, such as those to be carried out by the Standards and Policy Entity described below.

1045 *The Five Critical Key Components of the Health Information Environment are:*

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1. The establishment of the **Standards and Policy Entity (SPE):**
 - a. The SPE is a public-private collaborative entity that identifies and specifies the detailed implementation rules, including business rules, for the standards and policies that make up the Common Framework. It identifies and recommends the technical standards and information policies essential for establishing privacy, security and interoperability. The SPE is responsible for the identification, specification, interpretation, and dissemination of these standards and policies.
 - b. Given the unusually sensitive nature of health information and the complexity of the technical standards and policies needed to guide its use, it is imperative that a single entity – the SPE – be responsible for decisions related to both domains so that they can be closely integrated. While the SPE must be the authority regarding matters in both domains, it may delegate pieces of its work requiring particular expertise to other entities. The SPE’s policy recommendations for use, access, privacy and security of health information are essential for the success of the Health Information Environment. These policies inform users, policy makers and sub-network developers who implement the technical standards recommended by the SPE.
 - c. Without this, every entity that has to interact with the network will be unable to do so reliably and consistently—multiple and differing approaches to core aspects at the regional level would create undue burden on patients and providers that cross sub-networks, public and private payers, large delivery organizations, labs, PBMs, pharmacy chains, vendors who supply applications, etc.
 - d. The SPE must not be disproportionately dependent on any of its stakeholders for its funding and must operate independently.
 - e. The SPE requires public and private support.
 - f. The SPE’s governance and administration must be transparent, accountable, and reflect the participation of all stakeholders, including representatives of the general public who are able to participate on an equal footing. The SPE administration includes a mechanism or formal process that reflects the participation of sub-networks and regional organizations.
 - g. The SPE must protect the public good and ensure that consideration be given to enforcement functions.
 - h. The SPE must be established and funded as soon as possible in order to continue the work of defining the Common Framework under which all the sub-networks will operate. Once the initial set of policies and standards are in

- 1084 place, and with proper incentives, the Health Information Environment will
1085 begin to grow and evolve organically and continually.
- 1086 i. The SPE must strive for maximum cost-effectiveness by building on existing
1087 standards and policy work (no “rip and replace”), establishing legitimate yet
1088 efficient processes and minimizing the negative economic impact of any new
1089 requirements it defines. As a general principle, the SPE should seek existing
1090 solutions and minimal modifications, creating new solutions only as a last
1091 resort. Even so, some change will be required to ensure interoperability across
1092 the boundaries of existing standards. The extent of such change must be
1093 determined using a defined process. To do so effectively requires close and
1094 continuous interaction with standards development organizations (SDOs) and
1095 other potential sources of relevant models for its own work.
- 1096 j. The requirements for interoperability will be specified in a suite of profiles or
1097 use cases defined and detailed by the SPE and premised on the Common
1098 Framework. The use cases will be specified via the selection of candidate
1099 suites or profiles of standards, for which detailed implementation and
1100 technical guides will be made available. The SPE must balance what is
1101 practical to implement with the needs of the nation.
- 1102 k. The SPE may be an existing organization or a new organization modeled after
1103 other quasi-governmental or public-private organizations. Immediate, near-
1104 term efforts need to include an analysis of both the public and private sectors
1105 for viable models. These efforts should be completed in no more than one
1106 year. The analysis of organizational models could be conducted by the
1107 Institute of Medicine (IOM), an agency of the NRC such as the CSTB, a new
1108 specially appointed Commission/Task Force, or other existing entity with the
1109 appropriate stature and credibility.
- 1110 l. The SPE must vigilantly guard against an accretion of duty or scope over
1111 time; its mission must always be to define and maintain the **minimum**
1112 framework necessary for the successful operation of the Health Information
1113 Environment.
- 1114 2. The creation of multi-stakeholder, collaborative, public interest **Sub-Network**
1115 **Organizations** at the regional or the non-geographic “sub-network level” that
1116 facilitate the development, implementation, and application of secure health
1117 information access by establishing and overseeing the sub-networks’ governance and
1118 operation (including the Record Locator Service).
- 1119 3. Financial and non-financial **incentives** to increase HIT adoption by clinicians and
1120 other information suppliers and users and to encourage their connectivity consistent
1121 with the Common Framework. These incentives may include loans, grant funding
1122 and private and public investment through reimbursement changes. Three tiers of
1123 funding and incentives need to be in place to build the Health Information
1124 Environment:
- 1125 a. Providing support for ongoing investment in the Common Framework and
1126 the standards and policies created and maintained by the SPE
- 1127 b. Providing sufficient funding to seed the creation of self-sustaining
1128 regional initiatives consistent with the Common Framework

- 1129 c. Accelerating the adoption of electronic health record systems that adhere
 1130 to the Common Framework, and that promote high quality healthcare
 1131 based on greater access to health information.
- 1132 4. A mechanism for **validating compliance** with the SPE Common Framework and
 1133 standards. Early in the evolution, a separate private sector mechanism that may or
 1134 may not be distinct from the SPE, is needed for validating compliance with the SPE
 1135 Common Framework and standards and policies. Ultimately the network effect may
 1136 create a mechanism for self-enforcing compliance. The method for validation must
 1137 encourage, not deter, new entrants to the health IT market for tools and services to
 1138 encourage competition and innovative business models.
- 1139 5. Special attention must be given to **underserved communities** to ensure that they
 1140 receive additional support and that they are mandatory, early participants in regional
 1141 initiatives and sub-networks. In regions where there is low potential for an organizing
 1142 function, (e.g., rural and underserved), other models of non-geographic sub-networks
 1143 and Sub-Network Organizations should be established to support these necessary sub-
 1144 networks. State Health Departments, medical societies, or other non-government
 1145 organizations may be able to assist in these communities. As with other health policy
 1146 issues that affect underserved populations, government funding may be necessary to
 1147 support this goal. See further elaboration earlier in this draft.

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1150 **Question 5. What kind of financial model could be required to build a NHIN?**
 1151 **Please describe potential sources of initial funding, relative levels of contribution**
 1152 **among sources and the implications of various funding models.**

1153

- 1154 • We have prepared a single response to questions 5 and 6 because there is great
 1155 overlap in the financial model to build the Health Information Environment
 1156 and to operate and sustain it. There are, indeed, requirements in the early
 1157 years that must precede other activities that could be considered a “build”
 1158 period and these will be identified below. However, many of these same
 1159 activities must persist throughout the lifetime of the Health Information
 1160 Environment. Furthermore, “building” the Health Information Environment
 1161 will continue indefinitely and the distinction between “building” and
 1162 “operating and sustaining” the Health Information Environment will blur.

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1164 ***The Health Information Environment is premised on creation of value:***

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- The Health Information Environment development approach must **create value** for all of the stakeholders it connects, including (but not limited to) payers, providers, and consumers. It must build and sustain a robust marketplace for investment and continuous development of the infrastructure.
- The Health Information Environment creates value, and does not incur net, long-term costs for the federal government or other stakeholders.
- The Health Information Environment will create value by returning greater financial savings to U.S. society through use of HIT than the costs incurred through adoption of EHRs, the sub-networks of which they are part, and the support of the environment in which they operate. (See “Accelerating US

- 1175 EHR Adoption: How to Get There From Here, Recommendations Based on
 1176 the 2004 ACMI Retreat” by Blackford Middleton, W. Ed Hammond, Patricia
 1177 F. Brennan, and Gregory F. Cooper., J Am Med Inform Assoc.2005; 12: 13-
 1178 19.)
- 1179 • Full systematic interoperability has been estimated to save \$78 billion per year
 1180 in the United States compared with current manual methods of data recording,
 1181 re-recording and transport. (See "The Value of Health Care Information
 1182 Exchange and Interoperability" by Jan Walker, Eric Pan, Doug Johnston,
 1183 Julia-Adler Milstein, David Bates, and Blackford Middleton at CITL. Health
 1184 Affairs Web Exclusive, January 19, 2005.)

1185
 1186 ***Financial Requirements for the Health Information Environment to be created and***
 1187 ***maintained:***

- 1188 • The Health Information Environment cannot and should not be built and
 1189 funded independently of creating incentives for its use. If it is financed
 1190 without corresponding changes to re-align incentives for its use, providers will
 1191 remain unlikely to use the sub-networks to support patient care, crippling its
 1192 success.
- 1193 • The financial model must result from a combination of sustained public sector
 1194 investment of core functions, seed funding for novel components and must
 1195 also result from significant and sustained commitments of private capital.
- 1196 • The early phase of the Health Information Environment, which could be
 1197 considered the “build” phase, should include financing for the following
 1198 activities:
 - 1199 a. The creation of the SPE and the initial development of the Common
 1200 Framework
 - 1201 b. Seed funding of a critical mass of sub-networks that conform to the
 1202 Common Framework
 - 1203 c. Financial incentives to providers to adopt HIT that conforms to the
 1204 Common Framework and to participate in the sub-networks.

1205
 1206 Each of the components of the “build phase” is elaborated below:

1207 ***a. Funding the SPE:***

- 1208 • The SPE must be established and funded as soon as possible in order to
 1209 continue the work of defining the Common Framework according to
 1210 which all the sub-networks will operate. Once the initial set of standards
 1211 and policies are in place, the Health Information Environment will grow
 1212 and evolve organically and continually.
- 1213 • The SPE will operate indefinitely and continually refine and evolve the
 1214 policies and standards and therefore must also be funded as part of the
 1215 continuing operation of the Health Information Environment.
- 1216 • The SPE must have a secure funding source and be subject to public sector
 1217 oversight to insure continuity of governance of the Health Information
 1218 Environment. Core funding may be provided by DHHS but private sector
 1219 contributions should provide a significant proportion of total support over
 1220 time.

1221 • The SPE may be an existing organization or a new organization modeled
1222 after other quasi-governmental or public-private organizations. Immediate,
1223 near-term efforts need to include an analysis of both the public and private
1224 sectors for viable models. These efforts should be completed in no more
1225 than one year. The analysis of organizational models could be conducted
1226 by the Institute of Medicine (IOM), an agency of the NRC such as the
1227 CSTB, a new specially appointed Commission/Task Force, or other
1228 existing entity with the appropriate stature and credibility.
1229

1230 ***b. Seed Funding of the Sub-networks:***

1231 • As a general principle, the sub-networks must be self-funded and self-
1232 sustaining.

1233 • In order to “prime the pump”, accelerate early growth, and demonstrate
1234 early success of the Health Information Environment, government grants
1235 should be provided as seed funding to a selected group of sub-networks.
1236 This has already begun with the initial AHRQ grants.

1237 • Given the intended national scope of the regional sub-networks,
1238 significantly more capital will be needed for start-up grants than has
1239 recently been made available.

1240 • Recipients of such start-up grants must agree to use the Common
1241 Framework and to create requirements for participants within their
1242 network to do so. They must, in addition, adopt policies that reflect the
1243 public interest including equitable access, participation in governance and
1244 policy making, consumer and professional outreach, and transparency.

1245 • A financing model will need to be developed to provide startup and
1246 operations support for traditionally underserved communities of interest
1247 like those described in question 11.

1248 • To assist with seed-funding of the sub-networks, a range of capital
1249 financing vehicles could be employed, including grant funding, long-term
1250 revolving loan funds and tax credits to investors. Such funds could come
1251 from a wide range of sources, including various public and private sector
1252 funds and vehicles. Government participation in the seeding of these
1253 activities is critical and will accelerate private sector investment. In
1254 addition to direct funding, the Government’s provision of guarantees of
1255 bond issuances or loans can also facilitate private sector investment.

1256 • All healthcare stakeholders that benefit from the sub-network should work
1257 together to assure sustainability and appropriate funding. Costs that could
1258 be covered by the model might include those related to the Record Locator
1259 Service, community governance, and other community-based operational
1260 HIT components.

1261

1262 ***c. Financial Incentives for adoption of interoperable HIT:***

1263 • Financial incentives to providers for the adoption of HIT that conforms to
1264 the Common Framework will be among the factors leading to a critical
1265 mass of participants in the early phase of the Health Information
1266 Environment.

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- Community consortia of public and private payers and purchasers, working in partnership with CMS and other major payers, should share ideas and early findings regarding effective incentive models. Such incentives may reward those clinicians who successfully adopt and use HIT to improve quality performance, and actively participate in the appropriate sub-networks.
 - Incentive arrangements for HIT adoption must recognize that a critical mass of funding must be available to reduce "free ride" potential in which some organizations forgo participation yet reap the benefits.
 - To further reduce "free ride" potential, it will be the responsibility of the Sub-Network Organizations to:
 - Work with community payers, purchasers and providers to discuss participation, incentives and appropriate funding models.
 - Monitor relevant stakeholder participation regarding conformance with the Common Framework and adoption incentives.

1284 **Question 6. What kind of financial model could be required to operate and sustain**
 1285 **a functioning NHIN? Please describe the implications of various financing models.**

Combined response with Question #5, above.
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Question 7. What privacy and security considerations, including compliance with relevant rules of HIPAA, are implicated by the NHIN, and how could they be addressed?

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- All of the capabilities of the Health Information Environment including the delivery of care, the conduct of research, and public health reporting, must be conducted in an environment of trust, consistent with appropriate requirements for patient privacy, security, confidentiality, integrity, audit and informed consent.
 - Participation in the Health Information Environment by providers, patients, or others must be voluntary; no one must be required to share information.
 - The Health Information Environment is premised on a model of patient authorization and control. Patients must be able to: choose whether or not to participate in sharing personally identifiable information; exercise their rights under HIPAA; control who has access to their records (whether in whole or in part); see who has accessed their information; review, contribute to and amend their records (without unreasonable fees); receive paper or electronic copies of their information; and reliably and securely share all or portions of their records among institutions. Once patient consent has been granted for a certain type of information access, however, information should be able to be accessed freely in a trusted environment.

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- Clinical data will be managed by those who have a direct relationship with the patient (patients may also keep their own records of their own information).
 - No mandated national unique health ID is required, but standardized methodologies to identify patients are required.
 - No single repository is intended to hold all of a patient's clinical data (although this does not preclude patients from aggregating their data, either on their own or through the services of a trusted third party such as a personal health record or PHR provider).
 - Authorization and authentication of users takes place at the regional, sub-network or local institution level.
 - Sub-networks will be required to participate in some form of validation process.
 - The Health Information Environment is a network of networks, linked only by registries through which authorized information about how to find the locations of records can be found, not any of the actual content of the health records. Thereby, the registry system knows only where records are, not what is in them.
 - To achieve these capabilities, the Health Information Environment requires the addition of one new piece of infrastructure at the sub-network level based on an architecture that separates the function of locating authorized records from the function of transferring them to authorized users. This piece of infrastructure is the Record Locator Service (RLS) and is operated by a multi-stakeholder collaborative at the regional or non-geographic sub-network level and built on the current enterprise use of Master Patient Indices. The RLS itself is subject to privacy and security requirements, and is based on open standards set by the SPE.
 - The system supports
 - a. Linking of records via a registry of names and record location information, and sharing among users participating in the system, but it also allows
 - b. Linking without sharing, or sharing pursuant only to higher authorization, as well as
 - c. The ability to choose not to link information in certain sensitive treatment situations determined by users.
- By leaving these decisions at the edges (e.g., with patients and the professionals that support them), the architecture supports a range of approaches. It also allows higher levels of approval to be set locally for sharing some records. This obviates the need to have "one size fits all" policies as would be necessary for centrally controlled approaches. The Record Locator Service needs to enable a care professional looking for a specific piece of information (PCP visit or ER record) to find it rapidly. An open design question is how and where in the model this capability can best be accomplished.
- The Privacy and Security Principles (as outlined by Connecting for Health's Linking Workgroup) for the sub-networks and the broader Health Information Environment must address:
 - a. **Confidentiality:** Material existing within the system will only be disclosed to those authorized to have it.
 - b. **Authentication:** The system will require identification for use by all authorized individuals, thus both deflecting unauthorized use and enabling auditing for monitoring of compliance with policy guidelines.

- 1355 c. **Integrity:** Material in the system will be defended against unauthorized
1356 alteration, and all alterations will be logged.
- 1357 d. **Non-repudiation:** Transactions undertaken in the system will be
1358 acknowledged by both parties, and cannot be unilaterally revoked or altered.
- 1359 • The Security Standards (as outlined by Connecting for Health’s Working Group
1360 on Accurately Linking Information for Health Care Quality and Safety in its
1361 report: *Linking Healthcare Information: Proposed Methods for Improving Care
1362 and Protecting Privacy*) must address:
- 1363 a. **Wire Security:** Securing material “on the wire” means making sure that in its
1364 transit from point A to point B it is defended from eavesdropping, copying, or
1365 other interception. In practice, this can mean encrypting all the material
1366 passing over that connection, and ensuring that it is effectively delivered to
1367 the desired recipient.
- 1368 b. **Perimeter Security:** Perimeter security involves requiring some form of
1369 authorization credentials for anyone using the system for any reason, as well
1370 as an auditing program that allows use of the system to be evaluated later.
- 1371 c. **Content Security:** Sometimes a user is both authorized to use the system *and*
1372 a malefactor, as with the hypothetical examples of a file clerk searching for
1373 his girlfriend’s records, or the intern looking at the records of a famous
1374 patient. This type of attack can be limited by restricting what can be done with
1375 the data, even by authorized personnel, and by making sure that physical
1376 access to the equipment does not translate directly to access to its contents.

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1379 **Question 8. How could the framework for a NHIN address public policy objectives**
1380 **for broad participation, responsiveness, open and non-proprietary interoperable**
1381 **infrastructure?**

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1383 *The Five Critical Key Components of the Health Information Environment, when*
1384 *taken together, will address public policy objectives for broad participation,*
1385 *responsiveness and the creation of a non-proprietary interoperable infrastructure. The*
1386 *Five Critical Components are:*

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- 1388 1. The establishment of the **Standards and Policy Entity (SPE)** – (More fully
1389 described under Question 4). The SPE is a public-private collaborative entity
1390 that identifies and recommends the detailed implementation rules for the
1391 standards and policies that make up the Common Framework. The SPE’s
1392 policy recommendations for use, access, privacy and security of health
1393 information are essential for the success of the Health Information
1394 Environment. These policies inform users, policy makers and sub-network
1395 developers who implement the technical standards recommended by the SPE.
1396 The SPE operates and is funded without dependence on any one stakeholder
1397 group. It is transparent, accountable, and reflects the participation of all
1398 stakeholders, including the public. The SPE offers essential guidance – to
1399 encourage an innovative marketplace, regional control, and minimum
1400 redundancy or rework. While actively identifying and responding to new

- 1401 needs and the lessons of experience, the SPE is above all pragmatic, offering
1402 practical tools to address the most pressing priorities.
- 1403 2. The creation of multi-stakeholder, collaborative, public interest **Sub-Network**
1404 **Organizations** at the regional or the non-geographic “sub-network level” that
1405 facilitate the development, implementation, and application of secure health
1406 information access by establishing and overseeing the sub-networks’
1407 governance and operation (including the Record Locator Service).
- 1408 3. Financial and non-financial **incentives** to increase HIT adoption by clinicians
1409 and other information suppliers and users and to encourage their connectivity
1410 consistent with the Common Framework. These incentives may include
1411 loans, grant funding and private and public investment through reimbursement
1412 changes. Three tiers of funding and incentives need to be in place to build the
1413 Health Information Environment:
- 1414 a. Providing support for ongoing investment in the Common Framework and
1415 the standards and policies created and maintained by the SPE
1416 b. Providing sufficient funding to seed the creation of self-sustaining
1417 regional initiatives consistent with the Common Framework.
1418 c. Accelerating the adoption of electronic health record systems that adhere
1419 to the Common Framework, and that promote high quality healthcare
1420 based on greater access to health information.
- 1421 4. A mechanism for **validating compliance** with the SPE Common Framework
1422 and standards. Early in the evolution, a separate private sector mechanism that
1423 may or may not be distinct from the SPE, is needed for validating compliance
1424 with the SPE Common Framework and standards and policies. Ultimately the
1425 network effect may create a mechanism for self-enforcing compliance. The
1426 method for validation must encourage, not deter, new entrants to the health IT
1427 market for tools and services to encourage competition and innovative
1428 business models.
- 1429 5. Special attention must be given to **underserved communities** to ensure that
1430 they receive additional support and that they are mandatory, early participants
1431 in community-based initiatives and sub-networks. As with other health policy
1432 issues that affect underserved populations, government funding may be
1433 necessary to support this goal. See further elaboration under Question 3.
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1436 *Management and Operational Considerations*

1438 **Question 9. How could private sector competition be appropriately addressed** 1439 **and/or encouraged in the construction and implementation of a NHIN?**

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- 1441 • The private sector is best at finding different market niches (clinics, hospitals,
1442 labs) and offering those markets products and services driven by different
1443 competitive strategies (mass production at low cost; high customization and
1444 ongoing services, etc.).
 - 1445 • Historically, the private sector has also advanced national interests when the
1446 goods and services on offer share a small but critical set of standards. The growth

1447 of the railroad industry was helped by standardization of track gauges; prior to
1448 those standards, a train from heading west from New York would have to unload
1449 its passengers and freight at St. Louis in order to change trains running on a
1450 different gauge track. Once the track gauges were standardized, the transport
1451 market for both goods and people became national, and, not coincidentally, entered
1452 a period of rapid growth. At the turn of the last century, a raging fire broke out in
1453 a Baltimore warehouse. When firefighters from neighboring towns arrived to
1454 help, they discovered that their hoses would not fit the Baltimore hydrants. The
1455 catastrophic losses from the fire led to national standards for basic firefighting
1456 equipment.

- 1457 • In the more recent domain of IT networks, the effect of simple standardization
1458 leading to expanding markets for interoperable tools is not only common but
1459 cumulative. The Internet created interoperability between computers made by
1460 different companies, something we take for granted today but which was novel in
1461 1969.
- 1462 • It worked as well as it did because the standards were minimal, creating basic
1463 interoperability but allowing different vendors to sell additional features above the
1464 core interoperability. For instance, once the basic standards of Internet transport
1465 were defined, the invention of e-mail turned the Internet into a communications
1466 channel. And once the basic e-mail headers were defined, any two systems using
1467 standards-compliant e-mail could trade messages, but each of those systems could
1468 have different ways of storing, sorting, and presenting those messages. The basic
1469 standards catalyzed the market, while allowing competition and continuous
1470 improvement for value-added features.
- 1471 • The Web followed the same path, in which a handful of basic standards for
1472 requesting and displaying Web pages led to a proliferation of Web sites— media
1473 outlets, community hubs, commercial centers, and so on. The explosion of
1474 diversity on the Web, expanding to this day, is built on the simple standards for
1475 transport (http) and markup (HTML). Now Web Services, a set of methods for
1476 allowing automated transactions between machines, is repeating the pattern yet
1477 again, with a small set of markup standards such as the Simple Object Access
1478 Protocol (SOAP) that is creating a market for a huge variety of services. And of
1479 course Web Services is built on the Web which is built on the Internet.
- 1480 • Without standards, competition subdivides customers into isolated camps,
1481 preventing the virtuous circle of network effects and returns to scale. When there
1482 is a minimal but essential set of standards, however, competition moves to price,
1483 features, and service, while preserving the interoperability that makes the market
1484 grow for everyone.
- 1485 • In addition to improving outcomes in healthcare, uniform standards are of
1486 paramount importance to the adoption of healthcare IT, because those standards
1487 will give healthcare CIOs and other decision makers confidence in buying
1488 products, and because vendors will have an incentive to offer features and
1489 services above the baseline standards. The Health Information Environment must
1490 be based on such an essential set of standards, developed in partnership with the
1491 industries that will adopt them. The development of these standards must be

1492 hosted by a nationally accredited organization using an open and consensus-based
1493 process.

- 1494 • In order to provide confidence to the eventual buyers and to enable the broadest
1495 possible deployment, these standards must be developed to work in the broadest
1496 range of technological environments, from the very simple to the very complex,
1497 and without making any particular vendor's product or service a requirement for
1498 participation in the Health Information Environment.

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1501 **Question 10. How could the NHIN be established to maintain a health information**
1502 **infrastructure that:**

- 1503 **a. evolves appropriately from private investment;**
- 1504 **b. is non-proprietary and available in the public domain;**
- 1505 **c. achieves country-wide interoperability; and**
- 1506 **d. fosters market innovation**

1507

1508 The Health Information Environment must accommodate a very wide range of
1509 enterprises, ranging from the bedside health care provider to the community
1510 pharmacy, research institute, patient's home, public health agency and health
1511 insurance plan. A number of essential, interdependent elements must be orchestrated
1512 to create a favorable information environment that is sustainable, creates economic
1513 value, and leads to higher quality care:

- 1514 • Facilitates and structures connectivity.
- 1515 • Builds on the Internet and other existing networks without "new wires".
- 1516 • Provides the capabilities to support near real-time information access when
1517 essential for routine and emergency clinical care and also supports ongoing
1518 monitoring of disease outbreaks and threats of bioterrorism, research, and
1519 quality improvement.
- 1520 • Leverages existing (and upcoming) open, non-proprietary standards for data
1521 content and transmission.
- 1522 • A national Common Framework supports and guides all participation. The
1523 Common Framework consists of the technical and policy standards essential
1524 to ensure interoperability, serve the patients whose data it exchanges, and
1525 connect systems of varying technical sophistication.
- 1526 • A Standards and Policy Entity (SPE) identifies and recommends standards and
1527 policies for the Common Framework, to be used to meet the ongoing
1528 requirements for interoperability.
- 1529 • Governance is transparent and accountable and includes consumer, patient,
1530 and other stakeholder representation at all levels.
- 1531 • Connectivity respects and serves patients and is built on the premise of patient
1532 control and authorization.
- 1533 • Data is decentralized – stays where captured.
- 1534 • Connectivity is achieved through a federated structure for policies,
1535 procedures, and standards.
- 1536 • Patient identification is based on standardized methodologies but without a
1537 mandated national unique health identifier.

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- Record Locator Services (RLS), situated in regional or other sub-networks, are new infrastructure components.
 - The “build” of the new information environment happens incrementally, through accretion of sub-networks.
 - A mechanism for validating compliance with the standards of the Common Framework is required for the early phases (there is uncertainty about how long this may be necessary), but the network eventually becomes self-validating.
 - Privacy and security are among the primary design considerations.
 - The Health Information Environment facilitates growth, innovation and competition in private industry.
 - Health IT financing is multi-stakeholder with public and independent funding for the national SPE, seed grants and funding for the RLS and regional start-ups, and the incentives built into routine payment and operations at the regional and local level are tied to the use of the Common Framework.
 - The information environment provides financial value to the entire health enterprise. The value that is generated ultimately funds the financial incentives for performance and stimulates the availability of private capital.

1558 **Question 11. How could a NHIN be established so that it will be utilized in the**

1559 **delivery of care by healthcare providers, regardless of their size and location, and**

1560 **also achieve enough national coverage to ensure that lower income rural and urban**

1561 **areas could be sufficiently served?**

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1563 *On the specific issue of minimizing capital requirements:*

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- It is paramount that the Health Information Environment be developed with as little overhead as possible and without ripping and replacing existing infrastructure.
 - The development of the Health Information Environment must be done as cost-effectively as possible and therefore minimize the opportunity to create unnecessary “tolls” or barriers since the case for health information access already suffers from misaligned incentives.

1572 *On the specific issue of designing with flexibility of users and functionality in mind:*

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- Participation in the Health Information Environment must allow connectivity with a fairly low level of technical sophistication—the provider without an EHR should be able to receive value from the Health Information Environment with only an Internet browser. The approach outlined in this response takes into account three critical elements that create significant flexibility for users and functions:
 - a. First, it is heterogeneous with regard to the types of technology and function of the sub-networks and other entities that use it, providing that all of them adhere to the Common Framework. This enables users of varying levels of technical and functional sophistication to use it for a variety of processes.

- 1584 b. Second it is flexible in that it facilitates communication among end-point
 1585 systems at varying levels of sophistication in the structured and coded
 1586 representation of data and supports the evolution of systems in this regard.
 1587 For example, while some might use the Health Information Environment
 1588 to locate records and request them by telephone, others may draw on it to
 1589 support the full electronic exchange of highly structured data for
 1590 sophisticated data analysis and decision support. This is necessary
 1591 because health information will continue to be a mix of unstructured and
 1592 structured and coded data. The Common Framework provides standards
 1593 and procedures that allows two systems that support highly coded data to
 1594 exchange it without loss of data, a system that supports less or little coding
 1595 to receive information from comparable and from highly structured
 1596 systems, and a system that supports a high level of coding to receive, file,
 1597 and make use of lightly coded data when this comes from another system.
- 1598 c. Lastly, the Health Information Environment is flexible also in that it is
 1599 able to evolve over time to address the changing needs of users and to
 1600 increase in scale as the numbers of users and their transactions grow; it
 1601 supports a reasonable level of variation and innovation in response to local
 1602 needs.

1603
 1604 ***On providers and communities that require special attention:***

- 1605 • Broadband access and alternate connectivity approaches must be contemplated in
 1606 rural and underserved communities.
- 1607 • The use of incentives, grants and loans will drive the development of the Health
 1608 Information Environment—underserved, rural and other communities will require
 1609 a higher level of support, planning and special assistance with the formation of
 1610 Sub-Network Organizations to include safety net providers is paramount.
- 1611 • Specialized support centers or “help desks” familiar with the particular concerns
 1612 of underserved and rural communities should provide support for them. Public
 1613 and/or private financial support should be made available for these centers.
- 1614 • The establishment of a Common Framework has the potential to reduce
 1615 administrative and overhead costs in the healthcare system.

1616
 1617
 1618 **Question 12. How could community and regional health information exchange
 1619 projects be affected by the development and implementation of a NHIN? What
 1620 issues might arise and how could they be addressed?**

- 1621 • Community and regional health information projects could become part of the
 1622 Health Information Environment by adhering to the “Common Framework”—the
 1623 Health Information Environment is built on the success of sub-networks
 1624 regionally or otherwise defined. Immediate action should be taken to identify and
 1625 disseminate the requirements of the Common Framework.
- 1626 • Without this, every entity that has to interact with the network will be unable to
 1627 do so reliably and consistently—multiple and differing approaches to core aspects
 1628 at the regional level would create undue burden on public and private payers,

- 1629 large delivery organizations, labs, PBMs, pharmacy chains, vendors who supply
1630 applications, etc.
- 1631 • However, the complete approach articulated in this response is built upon the
1632 premise that “ripping and replacing” existing infrastructure is not an option and
1633 that creating flexibility in its design was paramount.
 - 1634 • The approach outlined in this response takes into account three critical elements
1635 that create significant flexibility for users and functions:
 - 1636 a. First, it is heterogeneous with regard to the types of technology and
1637 function of the sub-networks and other entities that use it, providing that
1638 all of them adhere to the Common Framework. This enables users of
1639 varying levels of technical and functional sophistication to use it for a
1640 variety of processes.
 - 1641 b. Second it is flexible in that it facilitates communication among end-point
1642 systems at varying levels of sophistication in the structured and coded
1643 representation of data and supports the evolution of systems in this regard.
1644 For example, while some might use the Health Information Environment
1645 to locate records and request them by telephone, others may draw on it to
1646 support the full electronic exchange of highly structured data for
1647 sophisticated data analysis and decision support. This is necessary
1648 because health information will continue to be a mix of unstructured and
1649 structured and coded data. The Common Framework provides standards
1650 and procedures that allows two systems that support highly coded data to
1651 exchange it without loss of data, a system that supports less or little coding
1652 to receive information from comparable and from highly structured
1653 systems, and a system that supports a high level of coding to receive, file,
1654 and make use of lightly coded data when this comes from another system.
 - 1655 c. Lastly, the Health Information Environment is flexible also in that it is
1656 able to evolve over time to address the changing needs of users and to
1657 increase in scale as the numbers of users and their transactions grow; it
1658 supports a reasonable level of variation and innovation in response to local
1659 needs.
 - 1660 • The Health Information Environment could point to and/or develop a sharing
1661 mechanism/resources whereby community and regional health information
1662 exchange projects could share their models and approaches with more fledgling
1663 projects. The newly created Resource Center funded by AHRQ can be leveraged
1664 to fulfill this important function.

1667 **Question 13. What effect could the implementation and broad adoption of a NHIN**
1668 **have on the health information technology market at large? Could the ensuing**
1669 **market opportunities be significant enough to merit the investment in a NHIN by**
1670 **the industry? To what entities could the benefits of these market opportunities**
1671 **accrue, and what implications (if any) does that have for the level of investment**
1672 **and/or role required from those beneficiaries in the establishment and perpetuation**
1673 **of a NHIN?**

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- Markets will be created when the need to access health information for high quality healthcare is aligned with financial incentives that encourage it.
 - Great care should be taken to establish a level playing field in this market by not creating undue barriers to entry or by stifling innovation and competition. The approach outlined here will accomplish these goals.
 - Broad adoption of electronic connectivity will produce market opportunities related to the adaptation and reengineering of workflow.
 - While attempting to create new markets, it is important that the Health Information Environment not be used as a method to selectively steer commercial interests to the point of care in an unrestricted way or in a way that alters the neutrality of the infrastructure.
 - In the long term there are likely to be significant market opportunities including the development of new and nascent products and services such as the PHR, telemedicine/telehealth, “smart” environments that monitor health data, and personalized medicine and genomics.

Standards and Policies to Achieve Interoperability

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Question 14. What kinds of entity or entities could be needed to develop and diffuse interoperability standards and policies? What could be the characteristics of these entities? Do they exist today?

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- Given the unusually sensitive nature of health information and the complexity of the technical standards and policies needed to guide its use, it is imperative that a single entity – the SPE – be responsible for decisions related to both domains so that they can be closely integrated. While the SPE must be the authority regarding matters in both domains, it may delegate pieces of its work requiring particular expertise to other entities.
- Without this, every entity that has to interact with the network will be unable to do so reliably and consistently—multiple and differing approaches to core aspects at the regional level would create undue burden on patients and providers that cross sub-networks, public and private payers, large delivery organizations, labs, PBMs, pharmacy chains, vendors who supply applications, etc.
- We propose the establishment of a **Standards and Policy Entity** (SPE – fully described under Question 4). The SPE is a public-private collaborative entity that identifies and recommends the detailed implementation rules for the standards and policies that make up the Common Framework. The SPE’s policy recommendations for use, access, privacy and security of health information are essential for the success of the Health Information Environment. These policies inform users, policy makers and sub-network developers who implement the technical standards recommended by the SPE. The SPE operates and is funded without dependence on any one stakeholder group. It is transparent, accountable, and reflects the participation of all stakeholders, including the public. The SPE offers the essential guidance – to encourage an innovative marketplace, regional control, and minimum redundancy or rework. While actively identifying and

1719 responding to new needs and the lessons of experience, the SPE is above all
1720 pragmatic, offering practical tools to address the most pressing priorities.

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1723 **Question 15. How should the development and diffusion of technically sound, fully**
1724 **informed interoperability standards and policies be established and managed for a**
1725 **NHIN, initially and on an ongoing basis, that effectively address privacy and**
1726 **security issues and fully comply with HIPAA? How can these standards be**
1727 **protected from proprietary bias so that no vendors or organizations have undue**
1728 **influence or advantage? Examples of such standards and policies include: secure**
1729 **connectivity, mobile authentication, patient identification management and**
1730 **information exchange.**

1731

1732 First, the Common Framework must be defined and specified. Without this, every entity
1733 that has to interact with the network will be unable to do so reliably and consistently—
1734 multiple and differing approaches to core aspects at the regional level would create undue
1735 burden on patients and providers that cross sub-networks, public and private payers, large
1736 delivery organizations, labs, PBMs, pharmacy chains, vendors who supply applications,
1737 etc.

- 1738 • The interoperability of the Health Information Environment is premised on
1739 conformance to a Common Framework, which consists of the essential technical
1740 and policy requirements to enable the interoperation of standard interfaces and
1741 transactions at the local, regional and national level.
- 1742 • The technical standards address secure transport over the Internet and other
1743 networks, and provide the essential required components for the infrastructure
1744 including secure connectivity, reliable authentication and a suite of defined
1745 interchange formats for health care data.
- 1746 • The policy standards address the privacy, use and access policies for the exchange
1747 of health information.
- 1748 • The Common Framework also provides a uniform methodology for the
1749 identification of users.
- 1750 • The modular character of the Common Framework permits rapid attainment of an
1751 interoperable information environment using essential requirements but also
1752 scales to a more complete structured data interchange for enhanced performance.
1753 The suite of interoperability standards will be enhanced over time.
- 1754 • The Common Framework is the basis of all subsequent use cases that require
1755 specific, uniform interoperable standards to support information exchange. Use
1756 cases and accompanying information standards will be specified for each of the
1757 myriad of health information exchange requirements and will be supported by
1758 detailed implementation guides.
- 1759 • The Common Framework should be required across all health communities,
1760 including the clinical research community, public health, etc.
- 1761 • The participants in sub-networks will determine which profiles are appropriate to
1762 address the requirements established by their stakeholders.
- 1763 • The Common Framework, and mechanisms to enforce compliance with it, ensures
1764 the creation, interoperability, scalability, efficiency and ongoing evolution of this

1765 environment. The Common Framework was further described in previous
1766 sections.

1767

1768 Second the SPE must be created to develop, maintain and disseminate the Common
1769 Framework and the suite of profiles for interoperability.

- 1770 • The SPE (fully described under Question 4) is a public-private collaborative
1771 entity that identifies and recommends the detailed implementation rules for the
1772 standards and policies that make up the Common Framework.
- 1773 • The SPE's policy recommendations for use, access, privacy and security of health
1774 information are essential for the success of the Health Information Environment.
1775 These policies inform users, policy makers and sub-network developers who
1776 implement the technical standards recommended by the SPE.
- 1777 • The SPE operates and is funded without dependence on any one stakeholder
1778 group. It is transparent, accountable, and reflects the participation of all
1779 stakeholders, including the public.
- 1780 • The SPE offers the essential guidance – to encourage an innovative marketplace,
1781 regional control, and minimum redundancy or rework.
- 1782 • While actively identifying and responding to new needs and the lessons of
1783 experience, the SPE is above all pragmatic, offering practical tools to address the
1784 most pressing priorities.

1785

1786 Each sub-network should collaborate with the SPE in the identification, interpretation,
1787 and development of standards and policies. Standards development organizations should
1788 participate with the SPE to develop new or modified standards, as requirements become
1789 known. The information technology industry should develop and promote cost-effective
1790 healthcare software and technologies that comply with the Common Framework.

1791 Financial incentives, loan opportunities, and IT procurement requirements, whether
1792 private or public, should be tied to compliance with the Common Framework and the
1793 policies and standards of the SPE.

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1796 **Question 16. How could the efforts to develop and diffuse interoperability standards**
1797 **and policy relate to existing Standards Development Organizations to ensure**
1798 **maximum coordination and participation?**

- 1799 • The work contemplated by the Common Framework is not currently addressed by
1800 any one SDO.
- 1801 • Existing SDOs will need to be responsive to the SPE and cooperative in helping
1802 to close gaps, agree to necessary development cycles and evolving requirements
1803 created by the Health Information Environment.
- 1804 • Existing information standards should be used wherever possible, and
1805 internationally accepted information standards should be favored.

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1811 **Question 17. What type of management and business rules could be required to**
1812 **promote and produce widespread adoption of interoperability standards and the**
1813 **diffusion of such standards into practice?**
1814

1815 Two key components of the Health Information Environment taken together define
1816 the management and business rules that produce this result:

- 1817 1. Management and business rules must adhere to the standards and policies defined
1818 by the SPE.
- 1819 2. They are agreed to and enforced through the Sub-Network Organizations that
1820 oversee the health information environment. Some sub-networks will be
1821 geographically based and others will be functional or organizational, crossing
1822 geographical boundaries. The responsibilities of the Sub-Network Organizations
1823 include:
 - 1824 a. Establishing a multi-stakeholder governance structure that includes the
1825 representation of patients and consumers and safety net providers. The
1826 governance structure should be formalized and address the corporate and
1827 tax status of the Sub-Network Organization, its business plan and budget,
1828 intellectual property ownership and management, the entity's statement of
1829 purpose and objectives, its decision making model, and its long-term
1830 strategic plan. Various types of governance model are acceptable.
 - 1831 b. Defining and meeting the particular information access needs of the region
1832 or sub-network while addressing the needs of patient populations that
1833 cross multiple communities nationwide or are contiguous but cross state
1834 lines.
 - 1835 c. Organizing the creation of "Articles of Federation" and other user
1836 agreements. A common set of multi-lateral policies, procedures, and
1837 standards to facilitate reliable, efficient sharing of health data among
1838 authorized users is required. The participating members of the health
1839 network must belong to and comply with agreements of a federation.
1840 Formal federation with clear agreements allows participants to access
1841 information that they have been authorized to share.
 - 1842 d. Supervising uniform adoption of information sharing policies or Articles
1843 of Federation by participating entities and mechanisms for their
1844 enforcement (e.g. sanctions).
 - 1845 e. Developing policies to address the need for retention and persistence of
1846 data.
 - 1847 f. Addressing conflicts among relevant stakeholders in a timely way.
 - 1848 g. Building, maintaining and managing the regional Record Locator Services
1849 and other sub-network systems and services.
 - 1850 h. Assuring that sub-network systems and the end-point systems of their
1851 members (including the Record Locator Service) adhere to the Common
1852 Framework.
 - 1853 i. Providing support to participants in the federation.
 - 1854 j. Establishing the financial sustainability models for the entity—
1855 responsibilities include:

- 1856 k. Working with community payers, purchasers and providers to discuss
 1857 participation, incentives and appropriate funding models.
 1858 l. Monitoring relevant stakeholder participation regarding conformance with
 1859 the Common Framework and adoption incentives.
 1860 m. Ensuring that all of the information capabilities that define the Health
 1861 Information Environment (including public health reporting and
 1862 surveillance, research and improving health care quality) can be met over
 1863 time.
- 1864 • This approach should catalyze a market by creating a level playing field for
 1865 market competition. Nevertheless, widespread clinical adoption will still depend
 1866 on investment in the key components of the Health Information Environment and
 1867 the re-alignment of incentives to reward and enable appropriate information use in
 1868 clinical care.
 - 1869 • Incentives can include a wide variety of options from fundamental payment
 1870 reform to eligibility for Federal assistance, eligibility to participate in federal
 1871 demonstration projects, private-sector pay for performance incentives that require
 1872 interoperability specified by the Common Framework, and eligibility to receive
 1873 private IT adoption assistance.
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 1875

1876 **Question 18. What roles and relationships should the federal government take in**
 1877 **relation to how interoperability standards and policies are developed, and what**
 1878 **roles and relationships should it refrain from taking?**

- 1879 • The federal government must play a central role in the Health Information
 1880 Environment for it to succeed. That role includes:
 - 1881 ○ Taking a leadership role in creating incentives that are predicated on
 1882 improving quality of care through IT
 - 1883 ○ Investing (with the private sector) in the creation of the SPE and providing
 1884 seed funding to define and disseminate the Common Framework and the
 1885 profiles for interoperability
 - 1886 ○ Medicare and Medicaid should coordinate their incentive structures, and
 1887 should make sure they are compatible with incentives available to regional
 1888 stakeholders.
 1889
 1890

1891 *Financial and/or Regulatory Incentives and Legal Considerations*
 1892

1893 **Question 19. Are financial incentives required to drive the development of a**
 1894 **marketplace for interoperable health information, so that relevant private industry**
 1895 **companies will participate in the development of a broadly available, open and**
 1896 **interoperable NHIN? If so, what types of incentives could gain the maximum benefit**
 1897 **for the least investment? What restrictions or limitation should these incentives**
 1898 **carry to ensure that the public interest is advanced?**

- 1899 • Yes, financial incentives are necessary for the Health Information Environment to
 1900 be used as stated numerous times previously in this response.

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- It would be unwise to establish a permanent payment system tied to IT adoption only; incentives for adoption should be time-limited to encourage rapid acquisition of “Common-Framework-enabled” applications that can connect and share data. Thereafter, funding should be incorporated within other payment methods.
 - Maximum benefit for least investment would result from redesigning current fee-for-service reimbursement to include significant proportion of payment tied to validated health outcomes or evidence-based process measures.

1911 **Question 20. What kind of incentives should be available to regional stakeholders**
 1912 **(e.g. health care providers, physicians, employers that purchase health insurance,**
 1913 **payers) to use a health information exchange architecture based on a NHIN?**

1914 There are a variety of examples that merit further exploration:

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- Pay for Performance incentives for improved outcomes based on validated measures and achieved as a result of health information access (e.g., avoidance of drug interaction by using the Health Information Environment for data access).
 - Fund rapid experimentation with various models of reimbursement.
 - Medicare and Medicaid should coordinate their incentive structures, and should make sure they are compatible with incentives available to regional stakeholders.
 - Provide access to capital through low cost or government-backed revolving loans for EHR purchase.
 - Develop a joint regional or national pool of funds to invest in clinical technology adoption by healthcare providers.
 - Establish a matching grant program.
 - Consider creative structuring to allow early transition from adoption-based to performance-based incentives, e.g., forgiving payments based on physicians meeting performance targets.
 - Allow investment in EHR as a tax credit.
 - (See “Financial, Legal and Organizational Approaches to Achieving Electronic Connectivity in Healthcare” at http://www.connectingforhealth.org/assets/reports/flo_sustain_healthcare_rpt.pdf for greater elaboration.)

1936 **Question 21. Are there statutory or regulatory requirements or prohibitions that**
 1937 **might be perceived as barriers to the formation and operation of a NHIN, or to**
 1938 **support it with critical functions?**

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- Legal safe harbors with restrictions
 - Potential barriers that may be the result of inconsistency of state laws for healthcare information exchange need to be assessed.
 - Healthcare payment policies and regulations that call for the inconsistent reporting of data or manipulation of codes representing healthcare data.
 - Medical malpractice laws that may discourage physicians’ participation because of liability fears

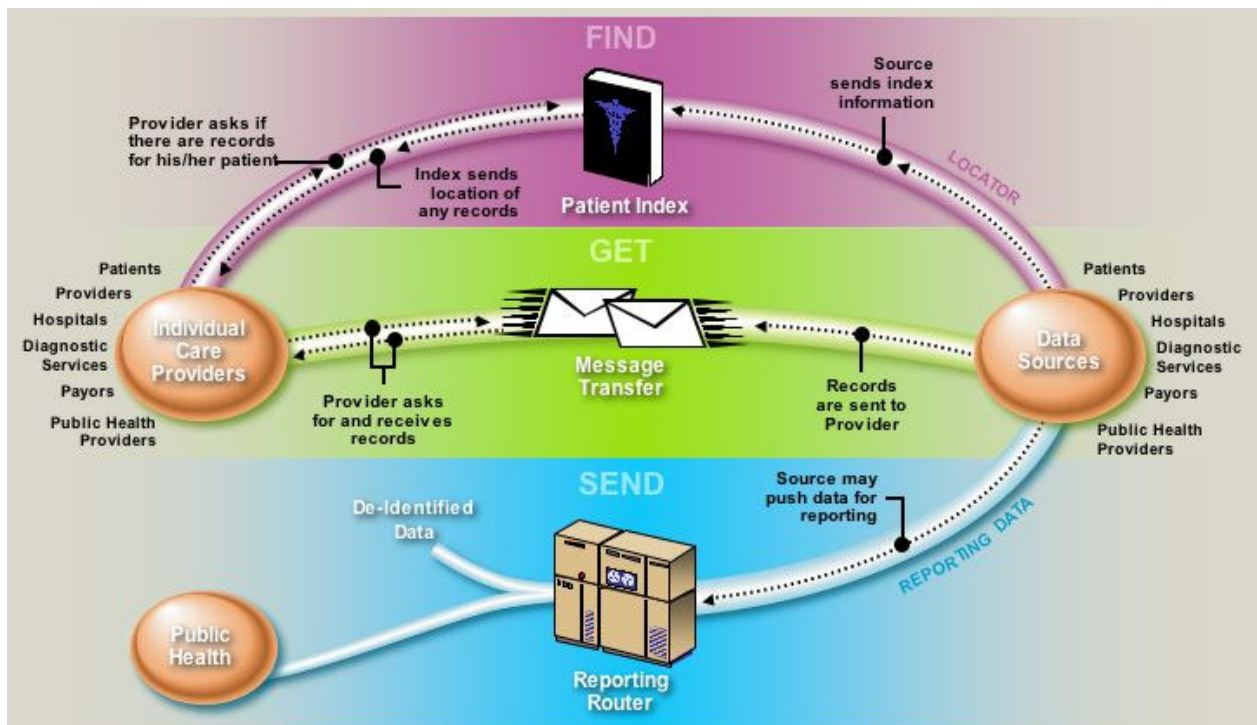
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Question 22. How could proposed organizational mechanisms or approaches address statutory and regulatory requirements (e.g. data privacy and security, antitrust constraints and tax issues)?

- The model proposed here would address issues regarding privacy and security, utilization of existing statutes such as HIPAA, use and access to information, business rules, and utilization of standards established in other domains to protect personal information.

Other

Question 23. Describe the major design principles/elements of a potential technical architecture for a NHIN. This description should be suitable for public discussion.



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About the Health Information Environment

The Health Information Environment develops through the creation and connection of sub-networks that conform to the Common Framework of standards and policies.

- The quickest way to expand the Health Information Environment is by encouraging the parallel creation and connection of multiple sub-networks which all conform to the Common Framework.
- The Common Framework consists of the essential technical and policy requirements to enable the interoperation of standard interfaces and transactions at the local, regional and national level.

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- Utilizing the Common Framework ensures economy of scale and speed of deployment and is essential because it enables the appropriate and necessary participation of national and super-regional entities (e.g., CMS, Kaiser, VA, etc.).

1979 **The Health Information Environment develops incrementally**

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- The Health Information Environment and the Common Framework that supports it should evolve over time and be responsive to new developments and ongoing innovation in technology and policy.

1984 **Healthcare applications are end-point systems connected to a “thin” Health Information Environment**

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- End-point systems include but are not limited to electronic health records, public health reporting systems, and other reporting systems.
 - The Health Information Environment should facilitate the exchange of patient health information between end-point systems, or proxies for them, to improve the delivery of patient care and to further other health-related goals.
 - The vendors or the operators of end-point systems support clinicians at varying levels of technology adoption (including those who do not yet have their own end-point systems) through “light” tools that offer clinicians Web-based information retrieval asymmetrically.
 - A “thin” Health Information Environment builds upon the existing decentralized model and uses available Internet technologies.
 - By utilizing existing Internet technologies, a “thin” Health Information Environment fosters increased competition and innovation by allowing industry efforts to focus on providing evolving healthcare-specific solutions.

2001 *Key to the Diagram*

2002

2003 The Health Information Environment is a circular system; there is no “start” or “end”

2004 point because numerous transactions occur throughout it simultaneously. The following

2005 descriptions are of the elements portrayed in the diagram and the transactions associated

2006 with each of them. It is important to note that **the diagram depicts one sub-network** –

2007 many sub-networks of this type would be linked in an analogous fashion to comprise the

2008 full Health Information Environment. It is also important to highlight that all of the

2009 activities described by the diagram (excluding those of the end-point systems or

2010 applications) take place according to the guidelines set by the **Common Framework**,

2011 which consists of the essential technical and policy requirements to enable the

2012 interoperation of standard interfaces and transactions at the local, regional and national

2013 level.

2014

2015 **Common Framework**

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- 2019
- The **Common Framework** specifies secure Internet based communication methods.
 - Participants in the Health Information Environment are authenticated in a common fashion so that secure communications can occur.

- 2020 • The **Common Framework** specifies information standards to allow unambiguous
2021 communication of clinical data.

2022

2023 **Individual Care Providers**

- 2024 • **Individual Care Providers**, depicted by a circle on the left of the diagram, are
2025 the systems used by individuals or organizations to deliver or track care or health
2026 care operations.
- 2027 • An **Individual Care Provider** system initiates an interaction with the Health
2028 Information Environment. For example, an authorized care professional might ask
2029 the **Patient Index (also referred to as the Record Locator Service)** whether
2030 there are any authorized records available that are necessary for the care of a
2031 patient (see the left side of the arc at the top of the diagram).
- 2032 • An **Individual Care Provider** would use an end-point system or application –
2033 such as an electronic health record or providers’ portal via a thin web based client
2034 – as an interface to the Health Information Environment.

2035

2036 **Patient Index (Record Locator Service)**

- 2037 • The **Patient Index, also referred to as the Record Locator Service**, needs to
2038 enable a care professional looking for a specific piece of information (PCP visit or
2039 ER record) to find it rapidly. An open design question is how and where in the
2040 model this capability can best be accomplished.
- 2041 • The **Patient Index (Record Locator Service)**, is at the top of the diagram. It
2042 contains a directory through which information about how to find the sources of
2043 authorized records can be found, not any of the actual content of the health
2044 records. The registry system knows where authorized records are, not what is in
2045 them.
- 2046 • When an authorized **Individual Care Provider** submits a request to the **Patient**
2047 **Index (Record Locator Service)**, it responds with information about the location
2048 (**Data Sources or Information Sources**) of any authorized and pertinent records
2049 (e.g. records for Jane Doe can be found at Hospital A and Lab B).

2050

2051 **Message Transfer (Information Transfer)**

- 2052 • **Message Transfer, (also described as Information Transfer)**, at the center of
2053 the diagram, is not an object, person, or institution, but an action—it represents
2054 what happens when one authorized part of the Health Information Environment
2055 shares authorized information with another.
- 2056 • The standards and policies associated with the **Common Framework** include
2057 support for **Message Transfer (Information Transfer)**.
- 2058 • **Message Transfer (Information Transfer)** is initiated by a request from an
2059 **Individual Care Provider** directly to a **Data Source (Information Source)**. The
2060 request could be made through a phone call, by paper, or electronically. The
2061 authorized information could be shared by fax, via a secure and standardized
2062 network connection using information standards defined by the **Common**
2063 **Framework**, or via paper.
- 2064 • Requesting a **Message Transfer (Information Transfer)** of an actual record
2065 from a **Data Source (Information Source)** is an action distinct from requesting

- 2066 information from the **Patient Index (Record Locator Service)** about where
 2067 records are located.
- 2068 • When a provider retrieves data from another source to support a clinical decision
 2069 the retrieved copy will usually become a part of the record maintained by the
 2070 receiver.
 - 2071 • **Message Transfer (Information Transfer)** can also support anticipatory
 2072 transfer of authorized patient information, including but not limited to
 2073 distribution of lab results, referral reports, etc.

2074

2075 **Data Sources (Information Sources)**

- 2076 • **Data Sources, (also referred to as Information Sources)**, are the people or
 2077 institutions that store health records. They are end-point systems supporting
 2078 patients, providers, hospitals, diagnostic services, payers, or public health
 2079 providers.
- 2080 • When **Data Sources (Information Sources)** receive authorized requests for
 2081 information from authorized **Individual Care Providers**, they send the
 2082 appropriate records (a process described as **Message Transfer or Information**
 2083 **Transfer**) – much as is done today.
- 2084 • **Data Sources (Information Sources)** use end point systems or applications –
 2085 such as electronic health records – as an interface to the Health Information
 2086 Environment.
- 2087 • **Data Sources (Information Sources)** communicate regularly with the **Patient**
 2088 **Index (Record Locator Service)** to make sure it is up to date about the
 2089 availability of patient data, ideally registering this availability in “real time.”
- 2090 • **Data Sources (Information Sources)** may also communicate with the **Reporting**
 2091 **Router** as appropriate.

2092

2093 **Reporting Router**

- 2094 • **Reporting Router**, at the bottom of the diagram, is an optional piece of
 2095 infrastructure – a particular sub-network may choose whether or not to have one.
- 2096 • The function of the **Reporting Router** is to find authorized identified or de-
 2097 identified data appropriate for uses such as public health, quality improvement or
 2098 research, and send or “push” it to the appropriate recipient (e.g. a public health
 2099 agency, policy making body, research organization, etc).

2100

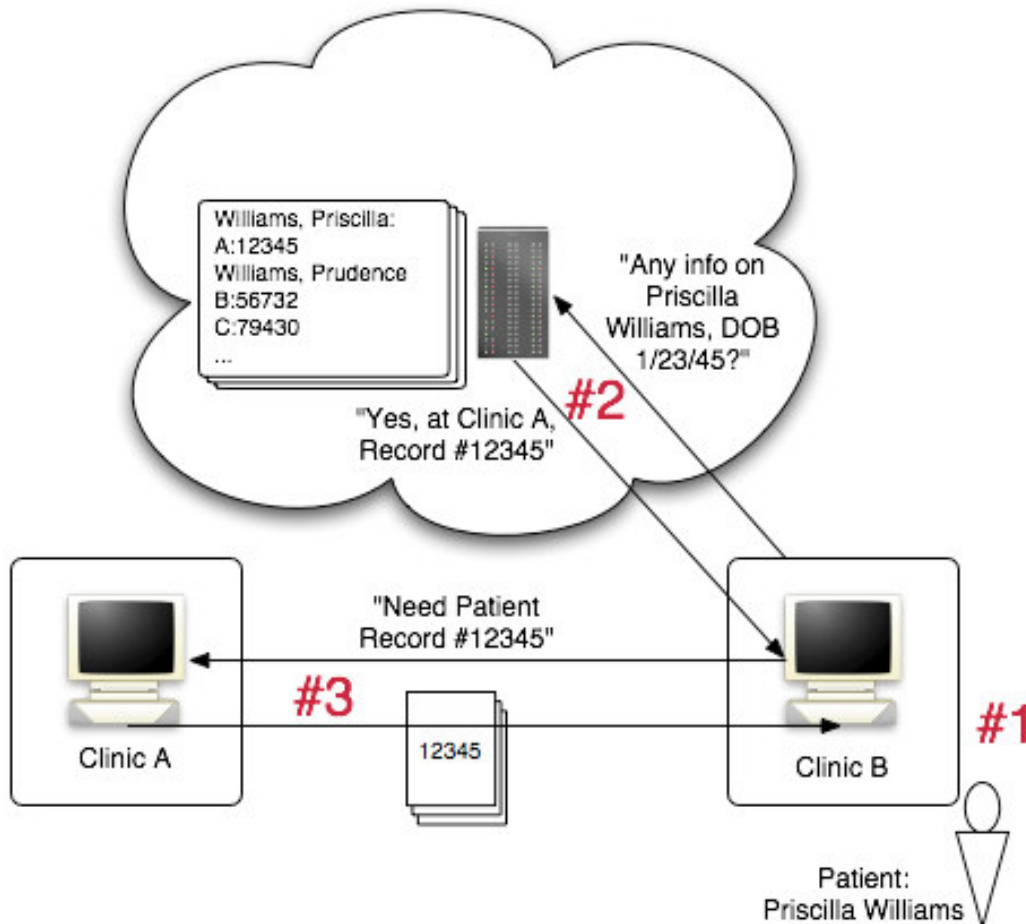
2101 **Public Health**

- 2102 • **Public Health**, at the bottom left of the diagram, is an example of an entity, other
 2103 than an **Individual Care Provider**, that may need access to health information.
- 2104 • **Public Health**, like other users of the system, would access authorized
 2105 information from the Health Information Environment via an end point system or
 2106 application.

2107

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2108 **Example of How the Health Information Environment Works: Priscilla Switches**
 2109 **Doctors**



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2111

2112 Above is an illustration of how linking, identification and transfer of a patient's records
 2113 might happen. A patient, Priscilla Williams, moves and wants her new primary care
 2114 physician at Clinic B, to have the results of her most recent pap smear, currently held at
 2115 Clinic A. If her new physician can't get the results, she will have to take the test again,
 2116 resulting in additional expense, difficulty, and delay.

2117

2118 Clinic A, a participant in the system, has provided the Record Locator Service with an
 2119 authorized, updated list of patients it holds records on. This is a background process,
 2120 where Clinic A communicates directly with the Record Locator Service at regular
 2121 intervals, rather than part of the individual search transaction.

2122

2123 Once the staff of Clinic B has taken Priscilla's identifying details (Transaction #1 above),
2124 they will authenticate themselves to the Record Locator Service (RLS) or to a local
2125 institution to allow for auditing. After they are authenticated, they will make a request for
2126 the location of any of Priscilla's other authorized records.

2127

2128 The request from Clinic B to the RLS will travel over secure transport such as a Secure
2129 Socket Layers (SSL). On receiving it, the RLS will compare Priscilla's information with
2130 their database. There are three possible outcomes here -- the Record Locator Service
2131 finds records with such a high probability match that they can be identified as Priscilla's;
2132 it finds no records that match; or it finds records that might match, and asks Clinic B for
2133 more identifying information. (This third option would require staff allocated to handling
2134 such requests; some system designs may simply treat such ambiguous pairs as non-
2135 matches, to minimize human input, even at the expense of additional false negatives.)

2136

2137 Assuming there is a match, the RLS will return authorized pointers to other institutions
2138 such as Clinic A that hold her records (transaction #2 above). Clinic B will then make a
2139 request for Priscilla's records directly to Clinic A, also via a secure internet connection,
2140 again providing authorization credentials to show that it is allowed to do so (transaction
2141 #3).

2142

2143 Some of the resulting authorized records may be returned from A to B directly over the
2144 Internet, using standardized interfaces for secure transport. The content of the messages
2145 may also be represented in a standardized format, for direct and automatic import into the
2146 new clinic's database, while other records may be sent by secure email, or even simple
2147 fax. Once B has the results of her earlier pap smear (as well as any other records held by
2148 clinic A), the staff of Clinic B can then add them to Priscilla's file.

2149

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2151 **Question 24. How could success be measured in achieving an interoperable health**
2152 **information infrastructure for the public sector, private sector and health care**
2153 **community or region?**

2154 A comprehensive set of metrics should be established and tracked. Examples include:

2155

- 2156 • Ratio of users to potential users of the Health Information Environment
- 2157 • Development and tracking of Healthcare Quality Indicators that derive from data
2158 access capability
- 2159 • Speed with which outbreaks affecting the public's health are identified
- 2160 • Stable and secure coordination of key Health Information Environment functions
- 2161 • Degree of interoperability across regional or other sub-networks
- 2162 • Accountability to affected stakeholders, including effective independent review
2163 procedures
- 2164 • Transparency, including procedural and financial transparency
- 2165 • Financial metrics to evaluate the return on investment for each stakeholder.
- Representation of key interest groups, including the public interest representation

- 2166 • Extent to which views of patients are taken into account in crafting policies and
- 2167 procedures relating to their rights and privacy
- 2168 • Increased security of the root server system
- 2169 • Support for long-term Internet and ICT evolution and innovation.
- 2170 • Satisfaction of consumers with their health care system encounters
- 2171 • Extent to which research and innovative approaches to prevention and treatment,
- 2172 (such as genetic treatment), are strengthened and made more cost-effective.
- 2173 • Speed with which research results are integrated into health care and health-
- 2174 related decision-making.
- 2175
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APPENDIX A: Glossary of Key Terms

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2178 **Common Framework** – The interoperability of the Health Information Environment is
2179 premised on conformance to a Common Framework, which consists of the essential
2180 technical and policy requirements to enable the interoperation of standard interfaces and
2181 transactions at the local, regional and national level. (see Question 1 for full description)

2182

2183 **Health Information Environment** – The NHIN consists of a carefully planned Health
2184 Information Environment that meets society’s requirements through widespread adoption
2185 of a formal set of technical components, standardized methodologies, and explicit
2186 policies for use and governance. The Health Information Environment ensures
2187 interoperability through open standards, rather than by creation of a new physical
2188 network. Existing healthcare IT infrastructure – hardware, software, and network
2189 connections – will be able to interoperate in the Health Information Environment if it
2190 conforms or is adapted to use the Common Framework. New deployments of hardware
2191 and software will likewise be able to interoperate with legacy systems through
2192 conformance to the Common Framework. These standards will allow use of the Internet,
2193 private networks, and any new national network infrastructure for the secure transport of
2194 essential health care data and transactions. The Health Information Environment will be a
2195 "network of networks," where sub-networks of participants grouped together through
2196 proximity, as with a Regional Health Information Network (RHIN) or through affinity (as
2197 with sites of care operated by entities such as the VA) can use the Health Information
2198 Environment’s capability to support both data transmission within and among these
2199 various sub-networks.

2200

2201 **Interoperability** – As used in this filing and as presented in the Health Information
2202 Environment, interoperability has three distinct components, each of which must be
2203 present to enable full participation:

- 2204 a. At the I/T network access level (here meaning the Internet), Interoperability
2205 means the capacity to physically connect a sub-network user to the network for
2206 the purpose of exchanging data over its components with other users.
- 2207 b. At the network authentication level, interoperability consists of the ability of a
2208 connected user to demonstrate appropriate permissions to participate in the instant
2209 transaction over the network, based on demonstrating appropriate
2210 authentication(s) of user and subnet work identity as a privileged party;
- 2211 c. At the application level, interoperability means the capacity of a connected,
2212 authenticated user to access, transmit and/or receive/exchange usable information
2213 with other users. The interoperability standard must support the full spectrum
2214 from uncoded and unstructured data to highly structured and coded semantics.
2215 Therefore, at the application level, there will be a hierarchy of coexisting
2216 interoperability information standards to accommodate the varying needs and
2217 sophistication of the user information exchange.

2218

2219 **Open Standards** – The European Interoperability Framework 1.0 identifies these
2220 “minimal characteristics that a specification and its attendant documents must have in
2221 order to be considered an open standard:

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- The standard is adopted and will be maintained by a not-for-profit organization, and its ongoing development occurs on the basis of an open decision-making procedure available to all interested parties (consensus or majority decision etc.).
 - The standard has been published and the standard specification document is available either freely or at a nominal charge. It must be permissible to all to copy, distribute and use it for no fee or at a nominal fee.
 - The intellectual property – i.e. patents possibly present – of (parts of) the standard is made irrevocably available on a royalty-free basis.
 - There are no constraints on the re-use of the standard.”

2233 **Patient** – The term “patient” as used in this filing is intended to be inclusive of
 2234 “consumer,” “individual,” and “person”. The patient is any person who has a health
 2235 record or receives services from the health system.

2236

2237 **Record Locator Service (RLS)** – The Record Locator Service is the only new piece of
 2238 infrastructure required by the Health Information Environment. The RLS is subject to
 2239 privacy and security requirements, and is based on open standards set by the Standards
 2240 and Policy Entity.

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- The RLS holds information authorized by the patient about where authorized information can be found, but not the actual information the records may contain. It thus enables a separation, for reasons of security, privacy, and the preservation of the autonomy of the participating entities, of the function of locating authorized records from the function of transferring them to authorized users.
 - Release of information from one entity to another is subject to authorization requirements between those parties; in certain sensitive treatment situations patients or providers may choose not to share information.
 - RLSs are operated by multi-stakeholder collaboratives at each sub-network and are built on the current use of Master Patient Indices.
 - The Record Locator Service needs to enable a care professional looking for a specific piece of information (PCP visit or ER record) to find it rapidly. An open design question is how and where in the model this capability can best be accomplished.

2257 **Reference Implementation Process** – The “Reference Implementation” Process is a
 2258 functional demonstration and testing on a significant scale of the Common Framework
 2259 that others can easily understand and replicate. The Reference Implementation Process
 2260 will demonstrate that the Common Framework components, if fully specified, permit
 2261 secure, standards-based data exchange within a community and among communities. It
 2262 will further show that the Common Framework permits a variety of high value
 2263 applications – including those directly serving the patient – to be rapidly and effectively
 2264 implemented. The Reference Implementation Process will produce resource materials for
 2265 use by other sites and sub-networks, and will provide a test-bed for validation of systems
 2266 to be connected to the exchange.

2267

2268 **Sub-Network** – The sub-network, an affiliation of users that share health information
2269 and/or a technical framework, is the essential building block of the Health Information
2270 Environment. Many sub-networks are regionally or geographically based, and some of
2271 these cross state or other jurisdictional boundaries. Others, such as national research
2272 communities, major federal programs, and large commercial enterprises, are organized
2273 around other criteria. Regardless of their organization and geographic span, all sub-
2274 networks must conform to the Common Framework in order to interconnect with each
2275 other and the relevant regional structures in a consistent and uniform manner. This
2276 definition of a sub-network encompasses the notion of a RHIN, and expands it to include
2277 other types of organizational structures.

2278
2279 **User** – Users of the Health Information Environment include but are not limited to
2280 patients and individuals designated by them as their representatives, provider
2281 organizations of all types, payers, disease and case management organizations. All users
2282 must be authorized and authenticated prior to use.
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APPENDIX B: Priority Areas for Continuing Work

Commercialization – While the development of some commercial applications that are integrated into the Health Information Environment is desirable and should be encouraged, it is important to differentiate and constrain those commercial uses that may hamper the ability of providers and patients to gain maximum benefit from access to clinical information, or compromise their trust. The Health Information Environment should not be used as a method to selectively steer commercial interests to the point of care in an unrestricted way or in a way that alters the neutrality of the infrastructure. Which types of commercial activity based on the Health Information Environment should be discouraged? Who should decide and how should this decision be enforced?

Finance – What is the best financial model to support the development and maintenance of the Health Information Environment? How should public and private funds be allocated? How should incentives for use of the environment be structured? What is the best model to support traditionally underserved communities?

Patient Control/Education – What are the implications of patient control of health information? What are the best ways to educate the public about how to use health information and ensure that patient consent to information exchange is meaningful? How should the public understand or engage with the Record Locator Service? What process and / or entities should carry out patient education, and how can multiple efforts best be coordinated?

Reconciliation of Potentially Conflicting State Laws – How do some state laws impede our ability to achieve vital national objectives? How should differences in state laws regarding access to or use of health information be addressed? What are the sources of leadership for reconciling state and federal legislation?

Standards and Policy Entity – The SPE may be an existing organization or a new organization modeled after other quasi-governmental or public-private organizations. Immediate, near-term efforts need to include an analysis of both the public and private sectors for viable models. These efforts should be completed in no more than one year. The analysis of organizational models could be conducted by the Institute of Medicine (IOM), an agency of the NRC such as the CSTB, a new specially appointed Commission/Task Force, or other existing entity with the appropriate stature and credibility.

Validation of Conformance and Interoperability – What processes should be used for validating compliance with the Common Framework? Should the mechanism be persistent? How should compliance be enforced?