APPENDIX A

State-Led Examples of Exchange in the U.S.

State	Consent Model and Related Data Sharing Information
DE	**Type of Consent Model:** Combination of *No Consent* (results delivery) and *Opt-Out* (query function) for the Delaware Health Information Exchange (DHIN). The DHIN has two functions: 1. Results delivery function—all patient laboratory data, radiology reports, and hospital admissions, discharge, and transfer data (ADT data) is uploaded into the system. • There is no patient consent component to this function, so all laboratory, radiology, and ADT data captured on a patient after May 2007 is automatically included in the system. 2. Query function—allows providers to query the system to obtain specific data on a patient. • Patients may choose to opt out of the query function, which effectively blocks all providers from accessing the patient's data in the system. To date, no patients in the state of Delaware have chosen to opt out of the query function, meaning that the entire population of Delaware is currently in the exchange. There is no form of granular consent for DHIN, meaning that patients are either all in or all out. **Type of Information Exchanged:** DHIN began distributing clinical laboratory test results, radiology reports, and admission face sheets (containing admission, discharge, and transfer data) from hospitals and laboratories statewide in May 2007. In January 2010, DHIN expects to add PACS data to the system, which would allow a provider to view a patient's radiology images (x-rays, etc.) through a link in radiology reports. In the near future, DHIN expects to include a patient's 90-day medication history of prescriptions filled. **Obtaining Data and / or Consent:** At the point of care, a provider must educate a patient on DHIN and the *opt-out* procedure. DHIN offers providers talking points, sample privacy language and confidentiality forms to help providers educate patients. Patients can also visit the DHIN website for more information. If a patient chooses to opt out of DHIN, he / she must have a form signed by a provider or notary public (to validate the patient's identity) and return the form to DHIN. This action automatically blocks the data of certain high profile government officials (*e.g.*, Joe Biden) from queries. **Patient Rights and / or Durability of Consent:** Patients may opt out of the exchange at any time. If a person decides to opt out, his / her data remains in the system (and is continually collected by the results delivery function) but providers are blocked from

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	viewing the data. There are no requirements for how often (if at all) consent is to be discussed / revisited (only applicable if the patient has exercised his / her right to opt out). Theoretically, a provider could discuss consent once (if at all) with a patient, and then never again. **Other Related Details:** More than half the providers in Delaware (60%) now use DHIN. Over 85% of lab transactions in the state go through the system, and more than 80% of hospitalizations are reported in it. DHIN contains a relatively sophisticated security system. Providers are only able to access records of current patients, and must "break glass" (list reason for viewing a patient's records and establish a time frame for viewing data) to obtain data on a patient they have not yet treated. Providers can also set the security so that only certain staff members can access the system. DHIN routinely conducts audits to ensure that the system is being used correctly, and revokes privileges of providers who misuse DHIN. A patient has the right to obtain an audit report from DHIN of providers who have accessed their records.
IN	**Type of Consent Model:** *No Consent* required for the Indiana Health Information Exchange (IHIE). (Federally funded substance abuse treatment programs do not provide data to the HIO.) Participating hospitals describe uses of the data in their privacy policies and a provider must suppress the data if a patient requests that his / her information not be shared. **Type of Information Exchanged:** Types of data eligible for exchange include: labs, pathology, radiology, electrocardiogram reports, ER info, hospital encounter info, transcriptions, medication history, discharge summaries, allergies / immunization, tumor registry, ambulatory appointment data, claims processing, and prescription data (dispensing evaluation). In 1994, with funding from the National Institutes of Health and the National Library of Medicine, Regenstrief Institute Medical Informatics extended the Regsenstrief Medical Record System (RMRS) to the Indiana Network for Patient Care (INPC), a city-wide clinical informatics network. Five INPC hospital systems in Indianapolis (Community Hospitals Indianapolis, St. Vincent Hospitals and Health Services, St. Francis Hospital and Health Centers, Clarian Health, and Wishard Health Services) operate a total of 11 different hospital facilities and more than 100 geographically-distributed clinics and day surgery facilities. Collectively, these systems admit 165,878 patients, and serve more than 390,000 emergency room visits and 2.7 million clinic visits per year. All INPC participants now deliver registration records, all laboratory tests, and all UB92 records (diagnosis, length of stay, and procedure codes) for hospital admissions and emergency room visits to separate electronic medical record vaults in a central INPC server located at Wishard Hospital. The computer system standardizes all clinical data as it arrives

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	at the INPC vault, laboratory test results are mapped to a set of common test codes (LOINC) with standard units of measure, and patients with multiple medical record numbers are linked. Each institution has the same file structure and shares the same term dictionary which contains the codes, names (and other attributes) for tests, drugs, coded answers, etc. When a patient is seen in any of the 11 emergency rooms operated by the consortium hospitals, and the patient consents, the information from all of these institutions about one patient can be presented as one virtual medical record. **Obtaining Data and / or Consent:** Data is only used for purposes allowed under HIPAA. **Patient Rights and / or Durability of Consent:** Data is only used for purposes allowed under HIPAA. **Other Related Details:** To gain access to the exchange, providers must be authenticated to the system. Types of HIE services offered in Indiana include: 1. A clinical messaging service that delivers test results from labs to the doctor's office; 2. A patient look-up service; and 3. A quality metrics and reporting service, where the data are used for quality purposes A patient's data is maintained in separate "vaults" or clinical data repositories by the institution until one of the allowed uses is triggered. Then, the patient's data are merged virtually. The triggers are highly specific and tightly controlled.
MD	**Type of Consent Model:** *Opt-Out* (though it functions as an *opt-in*) for the Chesapeake Regional Information System for Our Patients (CRISP; http://www.crisphealth.org/). By default, all patients will be notified about the existence of CRISP and will be in the exchange unless they opt out of exchange participation. Even if patients opt out, a certain amount of basic patient demographic information will still technically reside in the exchange, but in a separate data repository used for the master patient index. Other basics include: 1. No "break the glass" provisions to obtain information for a non-participant (an individual who has opted out) will be permitted, and CRISP does not recommend granular control for exclusion by data type or provider organization; 2. Hospitals and other providers will be permitted to allow patients greater control over which of their records are published to the exchange; and 3. Health record banks (HRB) and personal health records (PHRs) will be an exception to the all-in or all-out principle. A patient will have the option of excluding himself / herself from the exchange for every other purpose, while still allowing information to flow from an HRB to a healthcare provider. This feature of the HIE is designed for patients desiring more granularity than an all-out option. **Type of Information Exchanged:** Two pilot efforts are currently operational: One in Baltimore involves the exchange of medication history between a few hospitals.

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	The other is in Montgomery County and involves the exchange of certain clinical data (not full CCR) between a few hospitals. The state has mapped out 20 use cases and will build up capacity to eventually roll out each one statewide. The purpose for data exchange is treatment, but there are secondary uses of the data—including biosurveillance and public health. **Obtaining Data and / or Consent:** Patients will be able to opt out of the exchange, becoming a non-participant, by calling a toll-free phone number and requesting to be excluded. Patients may enroll via phone or direct contact with a provider (*e.g.*, use of a form), and can also choose to participate at the point of care. HRBs and PHRs are exceptions to the all-in or all-out principle. By using an HRB, a patient has the option of excluding himself or herself from the exchange for every other purpose, while still allowing information to flow from an HRB to a healthcare provider. A policy board will determine the approach for a number of issues that have yet to be decided, including whether to have one consent form that would cover all (or most) use cases, or multiple forms tailored to the type of electronic exchange service. **Patient Rights and / or Durability of Consent:** Patients may revoke their participation in the exchange at any time. If they do so, the existing data in the exchange will remain, but will be sequestered from further circulation unless required by law. Patients are also able to alter their status in either direction (*i.e.*, participate after previously opting out).
MA	**Type of Consent Model:** *Opt-In* for the Massachusetts e-Health Collaborative (MAeHC). Three pilot projects under MAeHC formally ended in December 2008, but MAeHC is maintaining relationships with all participating providers through 2010, in order to allow ongoing collection of performance and evaluation data. In addition, MAeHC gives providers access to a community repository of clinical summaries. The goal of the pilot project was to study and demonstrate the effectiveness and practicality of implementing EHRs in community settings. As of November 2008, the patient *opt-in* rate exceeded 90%. MAeHC is one of four major HIOs in MA. The other three are the MA Health Data Consortium (MHDC), the New England Healthcare Electronic Data Interchange Network (NEHEN), and MA Simplifying Healthcare Among Regional Entities (MA-SHARE). MA-SHARE is a major regional collaborative involving payers, providers, patients, and employees in the state. MA-SHARE seeks to do the following: 1. Promote the inter-organizational exchange of healthcare data using information technology, standards, and administrative simplification, in order to make accurate clinical health information available wherever needed in an efficient, cost-effective, and safe manner;

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	2. Facilitate and incubate new projects exploring healthcare data connectivity in order to develop, pilot, and demonstrate new healthcare information technologies across communities and enterprises; and 3. Design technology solutions that assemble, organize and distribute a variety of up-to-date clinical information to a broad range of clinical settings; all accomplished in a secure, confidential manner. **Type of Information Exchanged:** Data exchanged in the three MAeHC pilots include: problems, procedures, allergies, medications, demographics, smoking status, diagnosis, lab results, and radiology reports. The MA-SHARE program contains a record locator service, medication histories in emergency departments, e-prescription integration, and clinical messaging services. As part of the MA-SHARE Push Pilot, discharge documents created by Beth Israel Deaconess Medical Center, Children's Hospital Boston, and emergency department systems were routed over the new infrastructure to physicians and practices who have volunteered to participate in the pilot. **Obtaining Data and / or Consent:** A patient is given the option to participate in the MAeHC when he / she visits a clinical entity for care, where he / she may opt in all clinical data from each entity. The patient chooses which entity's records to make available to the network, and pre-defined data are then sent to the central server. Data are retrieved by the physician, who views the data prior to or during the patient visit. In the *opt-in* model, a signed patient consent form is required for that patient's clinical data to be uploaded from his / her physician's office EHR to the exchange's community database.
NY	**Type of Consent Model:** *Opt-In* (NY refers to it as an "affirmative consent model"). Consent is considered to be all or nothing, meaning that any data contributed to the exchange could be made available (*i.e.*, no ability to segment by data type). Examples of NY RHIOs include: Long Island Patient Information Exchange (LIPIX), HealtheLink (Buffalo), and Southern Tier Health Link (Binghamton) PCIP. **Type of Information Exchanged:** State-level policies are broad so as to allow for variation by region / HIO. As such, the type of data included in a given exchange varies from one to another. **Obtaining Data and / or Consent:** There are two approaches, depending on the RHIO: 1. The provider organization obtains consent at the point of service. For example, the Brooklyn Health Information Exchange uses a "provider by provider" consent process rather than a universal consent process for enrollment; and 2. The RHIO obtains consent through a RHIO multi-provider consent form, which can be accessed either at the point of service or online via the RHIO website.

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	Patient Rights and / or Durability of Consent: Patients have the ability to revoke their participation in the exchange at any time. If they do so, the existing data in the exchange will remain, but will be sequestered from further circulation unless required by law. **Other Related Details:** The Primary Care Information Project, governed by the NYC Health Department, contains extensive privacy safeguards. These safeguards include the ability of a patient and doctor to see who has gained access to the records, and to lock certain data behind a firewall so it can be seen only by the PCIP. According to the February 17, 2009 Appendix of the Public Governance Models Report, there are 9 state-designated RHIOs in New York.
RI	**Type of Consent Model:** *Opt-In (Double)*. Consent for exchange participation is all or nothing, so there is no granularity of choice with respect to the types of data that can flow through the exchange. Once a patient has enrolled in the exchange, there are three options for his / her participation: 1. All providers involved in care are permitted to access information (akin to HIPAA); 2. Only certain (selected by the patient) provider organizations (no segmentation at the individual provider level) are authorized to access information; and 3. The default setting, in which providers have temporary access to information only in an emergency or unanticipated event. **Type of Information Exchanged:** RI is still in test mode, so no data are currently being exchanged, but the near-term plans are for laboratory and medication history exchange. Eventually, the hope is to exchange other types of data, including radiology reports and discharge summary reports. For the near future, the exchange will be used only to support treatment, including care coordination. An advisory council will determine which, if any, additional purposes should be added. **Obtaining Data and / or Consent:** The RI Quality Institute (RIQI) has been training staff in participating provider and other organizations (including ambulatory and inpatient care settings, employers, community-based organizations, and long-term care facilities) how to walk patients through the consent process. To enroll, a patient completes an enrollment and authorization form for the exchange. Patients can also enroll directly through the Current Care RI website, but will need to call a hotline to indicate their provider preferences if they select participation option 2 (described above). To help offset the cost of administration, RI DHHS is paying a one-time, $3 authentication fee for every participant enrolled. **Patient Rights and / or Durability of Consent:** Patients have the ability to revoke their participation in the exchange at any time. If they do so, the existing data in the exchange

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	will remain, but will be sequestered from further circulation unless required by law. For participants selecting the default option (described above as the third option), information can only be accessed for up to 72 hours. **Other Related Details:** All provider organizations submitting data to the exchange will need to determine if the patient in question is currently participating in the RI exchange. Due to provider reluctance to perform this function, the state is supporting development of a technology solution that will reside (for now) with each contributing provider site. This interface will look up participation status for patients before any information is shared outside of the firewall.
WA	**Type of Consent Model:** *Opt-In* for four HRB pilot programs. Three pilot program locations are state-funded: Bellingham, Wenatchee, and Spokane. The pilot in Tacoma is federally-funded (Madigan Army Medical Center in Fort Lewis, funded by the Department of Defense). HRBs implement a consumer-centric model. The consumer-centric model has instilled some uncertainty among providers, who are concerned that patients would change or misuse their health information in the HRB. **Type of Information Exchanged:** Prescription data, allergies, laboratory results, immunization records. Laboratory results, x-rays, and medication data are currently in the repository. **Obtaining Data and / or Consent:** Patients give consent for the HRB by creating their own personalized account and then, using the HRB model, patients authorize the release of their information to specific providers. Copies of a patient's health information are transferred into a patient's HRB account like a deposit. Patients who choose to participate use web-based tools like Microsoft HealthVault and Google Health to store their personal health information in one location. The Google software does not provide the same level of granularity as Microsoft. With Microsoft, patients can choose what type of information providers can see, and can choose which providers are allowed to view the information. Currently, patients do not have the ability to input or alter their health information in the bank. They can only view the information on the screen and print it out to share with providers in hard-copy form. **Patient Rights and / or Durability of Consent:** There is no time limit. A patient may disenroll from the HRB at any point. If a patient decides to disenroll, the HRB offers a window of time (30 – 90 days) during which the patient can change his / her mind and re-enroll without losing valuable HRB data. Because the HRB model is consumer-centric, the holders of data are released from HIPAA issues (the HRB is obligated under ARRA to release a patient's health information to him /

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	her). HRBs also contain an audit function, which allows patients to find out when their records are accessed. **Other Related Details:** The Washington State Heath Care Authority plans to publish an interim progress report on the pilot projects in the near future.
VA & TN	**Type of Consent Model:** Similar to IN, state laws in VA and TN do not require affirmative consent from patients to share their general clinical information electronically for treatment purposes (or other purposes expressly permitted under the law). CareSpark is a non-profit regional health information exchange operating in a 34-county area of East Tennessee and Southwest Virginia. At present, five provider entities participate in the exchange: 1. Two ambulatory primary care practices; 2. One hospital system; 3. One payer; and 4. One public health agency. As of mid-November 2009, there were 310,000 patients in the master patient index. Only a subset of this population has data in the actual exchange because not all have had a clinical encounter subsequent to receiving notice / opting-in. The Carespark board of directors wanted to ensure that community members whose data were to flow through the exchange would be well-educated about the process. As such, the board established an *opt-out with notice* policy, meaning that no data are collected for exchange until the patient is at least minimally educated about the exchange. In addition, the board allowed individual provider organizations to adopt an *opt-in* protocol, meaning that providers who choose to do so can require affirmative consent. Currently, the information in the exchange is to be used for treatment only, but participants understand that the goal is to be able to expand to public health, and eventually to other approved research applications. Although not yet determined, the organization is leaning toward having a blanket statement for consent on how information can be used for research purposes, but with a supplemental patient consent form for specific studies that would require IRB approval. **Type of Information Exchanged:** At present, Carespark is only exchanging general clinical information, which expressly excludes any type of information deemed sensitive under either state's laws. This issue is currently under consideration, however, so the board may change this policy in the future. They do their best to ensure that sensitive information is not shared by: 1. Restricting the participation of facilities that primarily serve patients with sensitive conditions; and 2. Asserting that the provider is the one responsible for filtering data, and not allowing such information to enter the exchange.

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	Obtaining Data and / or Consent: Carespark has adopted a provider-centric approach to patient education and, where applicable, consent. Based on some early research with patients in the community, they learned that most stakeholders thought it would be best for the provider to directly educate the patient. Carespark has an employee who trains provider organizations, and also supplies them with written and other educational materials that can be used during the notification process. Most of the provider organizations use a paper form (either for notice or for consent) when they first interface with the patient about the exchange. To manage consent more broadly, they have built a custom software solution called Master Patient Option Preference (MPOP). For every patient, a provider can enter a medical record number into the system to see whether that person is has opted out (in which case any clinical info found in the system should not be exchanged), or has either been notified or opted in. **Patient Rights and / or Durability of Consent:** The issue of durability of consent is left to the provider's discretion. If a patient participates and then later decides to opt out, his / her information remains in the exchange, but will not flow.