Comments of
The Health Record Banking Alliance
In response to
Office of the National Coordinator for Health Information Technology (ONC)'s
Recognized Coordinating Entity's (RCE's)
Request for Comments on its
Draft of July 28, 2021 of the
Qualified Health Information Network (QHIN) Technical Framework

Submitted September 17, 2021 via rce@sequoiaproject.org

The Health Record Banking Alliance (HRBA)[1] offers these comments in response to the Recognized Coordinating Entity's (RCE's) request for feedback on its July 28,2021 draft of the Qualified Health Information Network Technical Framework (QTF Draft).

Introduction and Summary of Comments

The 21st Century Cures Act requires that TEFCA enable network-to-network exchange of health information without disrupting existing trusted exchange networks. The most urgent and efficient way for ONC to effect this mandate is *to replace the still-widespread use of fax machines with a nationwide standard for secure point-to-point exchange of patients' health information*.

Including *patients* in digital point-to-point exchanges between and among existing networks of hospitals, physician offices, pharmacies and others will preserve essential existing health data networks, minimize disruption to their operations, and advance the role of patients in health information exchange. Thus there is no need, and no warrant, to adopt the proposed elaborate contractual QTF protocols to sustain existing Health Information Networks (HINs).

The QTF as proposed also fails to deal with questions of data integrity that are integral to any *trust* framework for health information exchange. HRBA endorses the comments filed by Gary Dickinson, Executive Director of EHR Standards Consulting. Those comments examine in detail a series of fundamental data provenance, quality, and integrity issues, as well as basic structural problems apparent in the proposed QTF that fail to place patients at the center of information flows about them.

A national, digital, health information exchange standard (the Exchange Standard) is essential to meeting the Cures Act's mandates. Assuming ONC implements its Interoperability Rule *to require EHR systems' use of uniform Exchange Standard output and input formats* – not something within the RCE's control – there will be no need for HINs as intermediaries or otherwise in the network architecture for national health

[1] The Health Record Banking Alliance (P.O. Box 6580, Falls Church, Virginia 22040), is recognized as a business league by the Internal Revenue Service under Section 501(c)(6) of the Internal Revenue Code.

information exchange. (Various parties including Health Information Exchanges (HIEs) with sufficient resources may consider becoming or creating Health Record/Health Data Banks (HRBs or HDBs), as discussed in more detail below in text and Appendices A and B.)

The QTF draft also retains use of "broadcast query" (also known as the "scattered model" because it assumes a network's capacity to gather a patient's records that are scattered among multiple providers) as a mode of health data interchange. Broadcast query has been thoroughly discredited, and the QTF should not retain it for any purpose.

Separately – and beyond the RCE's control – ONC's sub-delegation to the RCE of essential governmental regulatory powers risks being found in violation of the private nondelegation doctrine established by judicial precedent. That will be a significant matter for congressional oversight, whether or not it spawns litigation.

These points are addressed in detail below.

The Cures Act Does Not Require Sustaining HINs

Section 4003 of the Cures Act (amending Section 3001(c)(9) of the Public Health Service Act) requires ONC to ensure full network-to-network exchange of health information. It is to do this in part by establishing a trusted exchange framework and common agreement – what has become TEFCA.

How does ONC most efficiently fulfill the Cures Act's requirement "to avoid the disruption of existing exchanges between participants of health information networks"? It does so by replacing point-to-point fax exchanges with trusted digital point-to-point networks that include mechanisms for identity proofing and authorization while avoiding unnecessary complexity and cost. HINs are unnecessary for these purposes. Indeed, inserting HINs between endpoints adds cost and complexity for no purpose and, in the process, multiplies security risks.

Therefore it is apparent that the QTF Draft's proposed technical framework is based on a misreading of the 21st Century Cures Act's guiding policy mandates and mandatory technical specifications. Crucially, inserting HINs in digital health data exchanges is provider-centric, failing to elevate patients' powers to use and control their health information through a data architecture based on Health Record Banks. (See Appendix A for HRBA's 2021 Systems Design Proposal for Interoperable Health Data Exchange Under the Cures Act; see Appendix B for a comparison of use cases between a HRB-based information architecture and an architecture that inserts QHINs into health information exchanges.)

"Broadcast Query" Should Be Dropped From the QTF

The RCE's proposed QTF includes offering "Broadcast Query" as an optional mode of interchange for QHINS. This is so despite the fact that Broadcast Query has been thoroughly discredited, even for local health data interchange, because of its intractable security and privacy issues, among other problems.[2] ONC's own demonstration projects, properly analyzed, also illustrate that Broadcast Query is so inefficient and problem-laden that it cannot be used at scale.[3]

Broadcast query should be put to rest.

TEFCA Must be Centered Around Patients, Not Institutions

The 21st Century Cures Act has a clearly stated "goal of offering patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically." This goal has not and will not be met by the QTF as proposed.

The current QHIN Technical Framework Draft perpetuates the provider-centric model of HIEs and TEFCA. As such, it ignores the central role of patients' individual agency in health care, as mandated by the Cures Act. Individual patient agency is key to maintaining wellness, supporting clinical trials and other healthcare research, and enabling individuals to participate, at their election, in public health initiatives.

Individual agency solves a wide-range of healthcare problems. One-time identity proofing of individuals, combined with identity proofing of providers, could allow an individual the ability to validate and maintain a complete health/wellness record, including information from wearables. Such a record would combine maintaining wellness with a focus on whatever specific problems an individual might have. Opting-in is a key step in the creation of such a record and in providing agency.

Appendix A illustrates how individual agency is effectuated by an information architecture using Health Record/Health Data Banks to place individual patients at the center of health data exchanges about them. Appendix B illustrates how individual agency in an HDB-based architecture is less complex and far more efficient than the exchange mechanisms envisioned by the proposed QTF.

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[2] *See, e.g.,* Robert H. Miller and Bradley S. Miller, *The Santa Barbara County Care Data Exchange: What Happened?*, *Health Affairs* 26, no.5 (2007):w568-w580.

[3] *See generally* W. Rishel, et al. (Gartner, Inc.), *Summary of the NHIN Prototype Architecture Contracts*, Report for the Office of the National Coordinator for Health IT, May 31, 2007(reveals, inadvertently, why health record broadcast query cannot be made to work at scale); *see, e.g.,* Lapsia V, Lamb K, Yasnoff WA: Where should electronic records for patients be stored? *International J Med Informatics* 81(12):821-7, 2012.

Information Quality and Integrity Are Essential to TEFCA, and the Proposed QTF Assures Neither

The Cures Act requires the Secretary of HHS to establish a *Trust* Framework. Data and information quality and integrity are essential to trust in establishing such a framework. Digital health exchange lacking demonstrable data integrity cannot meet the following Cures Act's specifications. They include:

- EHR data exchange *must not* be implemented by ONC in ways that *"are likely to substantially increase the complexity or burden"* of access to, or exchange of, health information. (HITECH new section 3022(a)(2)(B) as added by Cures Act section 4004; emphasis added.) This provision, which necessarily imposes a specific requirement for nationwide standardized exchange, cannot be satisfied by the RCE's proposed QTF.

- EHR data must be exchangeable "*without special effort"* on the part of users. (Patients and physicians are among "users" under the Cures Act.) (HITECH as amended, new §3000(10)(A), as added by Cures Act section 4003(a); emphasis added.)

- EHR data exchange must provide *the patient or an authorized designee* with a *complete copy* of his or her health information from an electronic record *in a computable format*. (HITECH new §3000(10)(B) as added by Cures Act section 4003; emphasis added.)

- EHR systems must be capable of exchanging health data with "clinical-led clinical data registries" that are "designed to collect detailed, standardized data . . . for medical procedures, services, or therapies for particular diseases, conditions or exposures," and that meet data quality standards including "using standardized data elements . . . to verify the completeness and validity of those data." (Cures Act §4005(a),(b).)

- ONC's implementation rule has the goal of "offering patients access to their electronic health information *in a single, longitudinal format that is easy to understand, secure, and may be updated automatically*" and supports patients' ability to add "patient-reported information" electronically as well as patients' access (at each patient's option) for research purposes. (HITECH new section 3009(e)(2)(A) as added by Cures Act section 4006; emphasis added.)

HRBA therefore endorses the comments filed by Gary Dickinson, Executive Director of EHR Standards Consulting, in response to the RCE's request regarding the proposed QTF. We need not repeat those comments here, and instead urge the RCE and

ONC to recognize how those comments expose wide, fundamental flaws in the QTF as proposed.

ONC's Delegation of Governmental Regulatory Authority to the RCE Violates the Private Nondelegation Doctrine and Therefore Undermines TEFCA

The judicially created private nondelegation doctrine applies to, and likely prohibits, ONC's delegation of governmental regulatory powers to the RCE. ONC has through this delegation created a "boundary agency" that exists at, and straddles, the boundary between a federal executive agency and a private organization. Release of the draft QTF now makes clear that ONC contemplates The Sequoia Project's exercising significant legislative and adjudicatory – governmental – powers in administering the QTF as proposed. These powers include administration and enforcement of the Carequality Interoperability Framework as adopted for the QTF. To quote from Sequoia's Executive Summary of the QTF, "the Trusted Exchange Framework and Common Agreement (TEFCA) includes the trust policies and practices and a "Common Agreement*"* that will *establish a governing approach for exchange* among Qualified Health Information Networks (QHINs)." (Emphasis supplied, footnote omitted.)

ONC's delegation of governmental functions to the RCE lacks necessary specific statutory authority in the Cures Act. The Cures Act's provisions offer no "intelligible principle" that a court would recognize to guide ONC in creating an entity such as the RCE. The Act, in this area, only grants ONC, through the Secretary of HHS, authority "directly or with a private entity [to] establish a provider digital contact information index . . . for health professionals and health facilities."[4] This language is insufficient to authorize ONC's wide delegation of governmental functions to a purely private entity, Sequoia, whether or not that delegation is done by a cooperative agreement, as it is with the RCE.

ONC's creation of the RCE, and the delegation of ONC's administrative and governing functions to Sequoia, is a textbook example of a federal agency's insulating itself from accountability for the administration of a federal government program while creating due process issues for program participants and potential participants.

As implementation of the QTF progresses, accompanied by the forthcoming release and eventual implementation of the Common Agreement, ONC and the Secretary of HHS face the possibility that a party or parties may emerge with standing to sue to stop the RCE from continuing to function. Whatever the prospects for such a suit, oversight by cognizant House and Senate committees will likely raise significant questions about whether the Cures Act grants the Secretary any power to create the RCE in the first place, by contract or otherwise.

[4] Cures Act Section 4003(c).

Oversight will also examine ONC's authority to spend federal funds on the RCE. This is a pressing concern, especially in light of the QTF's concentration on soon-to-be superfluous QHIN-to-QHIN health data exchange and the necessary cost, complexity, and security vulnerabilities that the QTF would introduce. All these are impediments to patients' being placed at the center, and in control, of health information exchange about them.

Implementation of the Interoperability Rule by Requiring Exchange Parties to Use Only Uniform Data Exchange Formats is Essential to Meeting Cures Act Requirements

Doubts about the RCE's legitimacy and significant flaws in the QTF as proposed bring ONC's faithful implementation of the Interoperability Rule to the forefront. This is a matter beyond the RCE's capacity to control. The RCE cannot even affect it through a revised QTF. Yet issues raised by the proposed QTF give context to ONC's interpretation and enforcement of the Interoperability Rule. That, more broadly, makes it appropriate here to offer comment on how the Cures Act mandates ONC to conduct health data exchange.

The Cures Act requires ONC to promulgate rules for a national, digital, health data exchange standard. In the introduction to these comments, we referred to this as the "Exchange Standard." It is, we believe, not optional. Rather, Cures Act specifications and policy prescriptions make the Exchange Standard an inevitable requirement of the statute.

ONC's implementation of the Interoperability Rule must among other things meet the Cures Act's "ease of use," "standardized data elements," "complete record," and "computable" criteria. The umbrella "computable" criterion, cited above (specified in HITECH new §3000(10)(B) as added by Cures Act section 4003), is especially significant in this analysis. The known engineering approach to meet this specification is for ONC to mandate that certified EHR systems have the capacities (1) to map health record outputs to the Exchange Standard format and (2), to map received Exchange Standard inputs to the receiving certified EHR system, placing all data elements appropriately in the receiving EHR system. The second criterion is necessary to reduce clinicians' burdens in using EHR systems and to satisfy clinical data reliability concerns. These burden reduction and reliability issues are so serious that they implicate not just ease-of-use but feasibility.

This ONC mandate thus would forbid use of vendor-specific output and input formats for *all* health data exchange under the Interoperability Rule. That prohibition is a precondition to a workable, national health data exchange system under the Rule. Otherwise, all EHR and PHR system vendors would be forced to develop different import logic for every possible sending system, a wholly impractical requirement.

In summary, a uniform national Exchange Standard cannot work unless ONC now explicitly requires that export and import of data and other information exchanged under the Interoperability Rule be done using *a specified, uniform export format interface and a*

specified, uniform import format interface. EHR vendors must engineer export and import interfaces so their systems can utilize the export and import format standards easily and reliably. This is well within EHR vendors' means and capacities. It is an essential enforcement standard if ONC's Implementation Rule is to deliver what Congress demands in the Cures Act.

Conclusion

For the foregoing reasons, the RCE should withdraw the current proposed Qualified Health Information Technical Framework and, under ONC's supervision, develop a revised technical framework. The goal should be to replacing the current fax-based system of health data exchange with an efficient digital, point-to-point information architecture including secure repositories – Health Record or Health Data Banks – so that patients are at the center of information flows about them. Unlike the present QTF proposal, the systems design we urge upon ONC would comport with the policy mandates and design specifications in the 21st Century Cures Act.

A revised QTF must place consumers/patients at the center, and in control, of information flows about them in order, faithfully, to implement the Cures Act.

Respectfully submitted,
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Appendix A
Health Data Bank/Health Record Bank Systems Design Overview

Health Record Banking Alliance

Organizing Health Data Around the Patient Using New
21st Century Cures Act Interoperability Rules
Health Data Bank National Systems Design Overview

A **Health Data Bank** (**HDB**, also called a Health Record Bank) is an **integrated patient information services organization**. As a **trusted agent**, it offers a **secure repository** for each individual to collect and compile their **"interoperable"** digital health information in a **smart Personal Health Record (PHR).** Individuals own and control their Personal Health Records, as in a bank checking account. With these **new information flows**, consumers will:

- **exchange** medical records and other health data in their Personal Health Records conveniently with doctors' offices and hospitals for better, faster care; improve patient safety; and reduce information burden on physicians by supplying an aggregated, lifetime, searchable medical record for easy and immediate reference.
- **control** Personal Health Record access for doctors and hospitals; family, friends, and health coaches; medical researchers; members of the press; and others as they wish.
- **use** their Personal Health Records to help manage their health and healthcare, and to help shop for doctors, hospitals, and health insurance.
- **view** their Personal Health Records on smartphones, tablets, and other computers.

Health Data Banks and Efficiency: Integrating health information around each patient via HDBs is the most efficient way to aggregate and use **"interoperable"** health data under 21st Century Cures Act regulations. It is far more efficient and useful than a collection of "apps."

HRBA's Education and Policy Advocacy: HRBA advocates government policies promoting Health Data Banks as **a major new structural sector in U.S. health care**. This systems design includes a **national regulatory framework for Health Data Banks**.

Health Data Banks and Health Equity: Health Data Banks will promote **health equity** because **everyone can have a Personal Health Record**.

Health Data Banks as Medical Research Clearinghouses: Medical researchers cannot get enough patient data to make fast or sufficient progress. HDBs can be clearinghouses between patients and researchers. Patients can **voluntarily** list themselves with their HDBs to be informed of research projects they are interested in, and to which they want to **contribute or sell their data**. This also is a path to developing **national federated diagnostic and research databases** while respecting **patients' privacy rights** (because patients are in control). Better research will improve treatment for acute, chronic, and orphan diseases.

Health Data Banks, Security, and Patient Matching: Security, credentialing, and patient authentication and efficient matching are systems design features of HDBs.

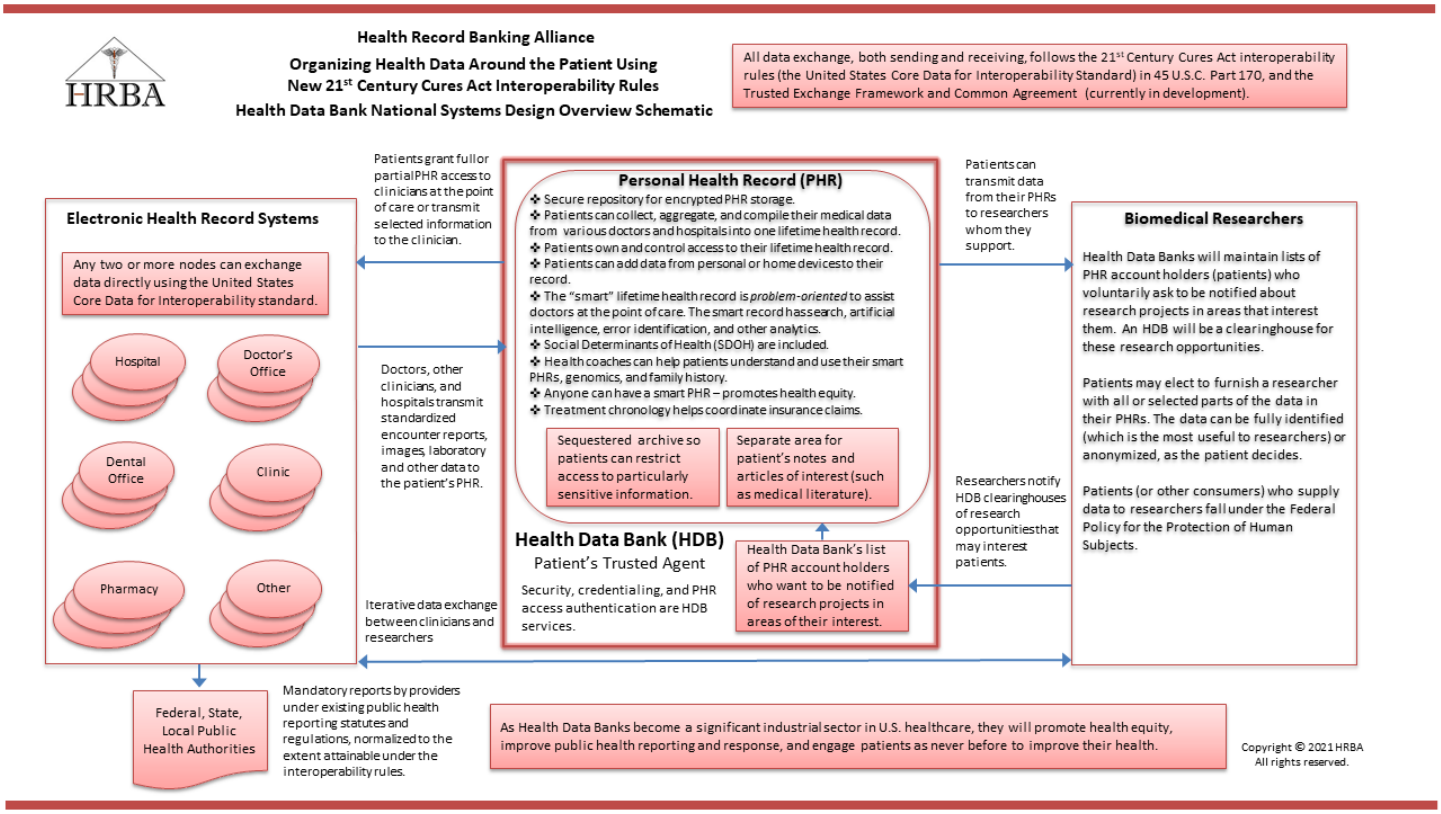
Advanced Features of Smart Personal Health Records: Systems design features such as artificial intelligence (AI) and search capabilities, robust family history, and genomic analytics will deliver **problem-oriented data and analysis** to **mesh** with clinicians' Electronic Health Record (EHR) systems **at the point of care**. Availability of this aggregated **reference record** will reduce burdens on clinicians while improving diagnosis, treatment, and patient outcomes.

The schematic diagram on the following page illustrates this systems design.

Health Data Banks will operate as patient's trusted agents. HDBs will store secure, longitudinal, problem-oriented health records *compiled* by HDB software applications for each patient. Patients will have full, granular control of access to their compiled records. Thus patients can grant secure access to all or specific parts of their records to various persons or entities. Patients can have strong assurance that no unauthorized people or entities can access the records stored in their HDB accounts. Consumers' ownership and control of their *compiled* records is a central, unvarying attribute of HDBs; and preserving patients' trust in the structure, soundness, and fiduciary operation of HDBs is an ongoing, basic requirement of the HDB model. (Providers retain ownership and control of the medical records they create to document their processes with respect to each patient. It is the separate *compilation* of various medical records and other information stored in an HDB account that the patient owns and controls.)

"Problem-Orientation" is a first-order organizing principle for health record compilations. The principle is that each entry in a patient's health record is specifically linked to a stated patient problem, with each problem carefully defined by the patient's demonstrable needs. Absent this organizing principle, compiled records gathered from various providers and other sources (such as wearable devices or patient observations) would be aggregations of fragmentary records, often with inconsistencies and other errors. Such collections of disparate data would not be structured for ease of use by clinicians, researchers, or patients and their caregivers. The world's leading standards-setting organization for health information, HL7, is now examining development of specific standards to achieve problem-oriented records. We believe these standards will provide industry-wide, detailed guidance to EHR and PHR vendors, health care organizations, clinicians, patients, researchers, payers, regulators, and others, all of whom require *computable*, interoperable, navigable, intelligible, easily usable, trustworthy health record *compilations* for *reference* as a Single Source of Truth (SSOT). As transition advances to use of problem oriented PHRs stored in HDB accounts, fragmentation should diminish. Additions will simply be made to increasingly organized compilations.

"SSOT" is used here as a term of art in computer science and information systems design. In a systems architecture premised on SSOT, a *reference database* (such as a problem-oriented PHR in an HDB account) is the central location for all data and information updates pertaining to a patient. A variety of provider databases and other information sources will furnish *computable* updates to the central reference database over time. The reference database will log each update for audit purposes and record the provenance of data or information in each update.



Appendix B

Comparing Cures Act Use Cases: Health Record Banks Versus QHINs

ONC provided a Draft TEFCA 2 User's Guide (https://www.healthit.gov/sites/default/files/page/2019-04/TEFCADraft2UsersGuide.pdf) to describe operation of use cases under the proposed QTF. This appendix compares the QTF architecture and use case functions to that of a patient-centered approach using Health Record Banks. Slides from the original ONC QTF User's Guide which are used in the figures in this appendix have the ONC logo in the top right corner. Supplementary figures provided in this appendix have the HRBA logo in the top right corner.

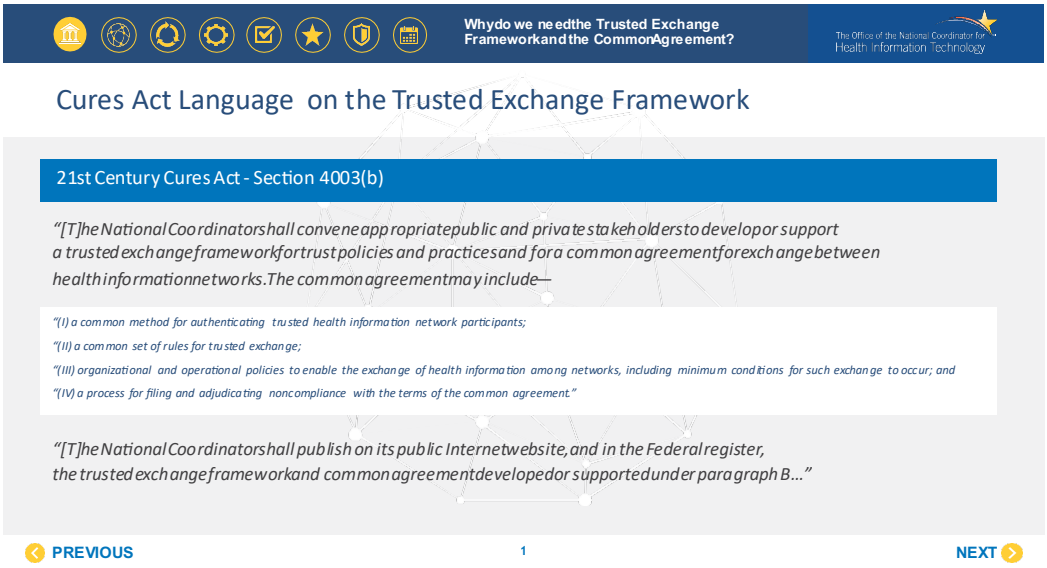


Figure 1- Cures Act Language on the Trusted Exchange Framework

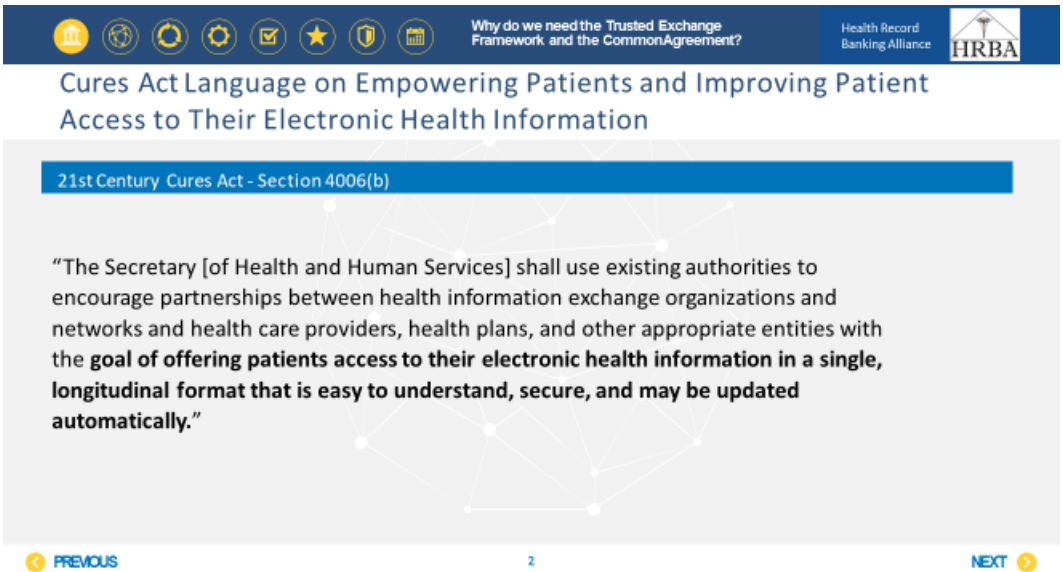


Figure 2 - Cures Act Language on Empowering Patients and Improving Access to Their Electronic Information

The 21st Century Cures act contains two key provisions that impact the design of a Trusted Exchange Framework. The first (Figure 1) tasks the National Coordinator with developing a Trusted Exchange Network and Common Agreement, that is, TEFCA. The second (Figure 2) tasks the Secretary of HHS with "offering patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically." While these requirements are separately described, any framework developed to fulfill the first requirement clearly must support the second. The current QTF does not support (or even directly mention) the second. This Appendix provides an alternative, patient-centered, architecture that directly supports the second requirement. The QTF should be reimagined to support a patient-centered architecture.

The QHIN Technical Framework continues and expands the attempt to organize health information around EHI located and controlled in the EHRs of healthcare providers (Figure 3). While "Individual User Services" are recognized as a use case, the use case is limited to the release of information. There is no indication that the information released will be "easy to understand," "longitudinal," "secure" (after release) or "updated automatically."

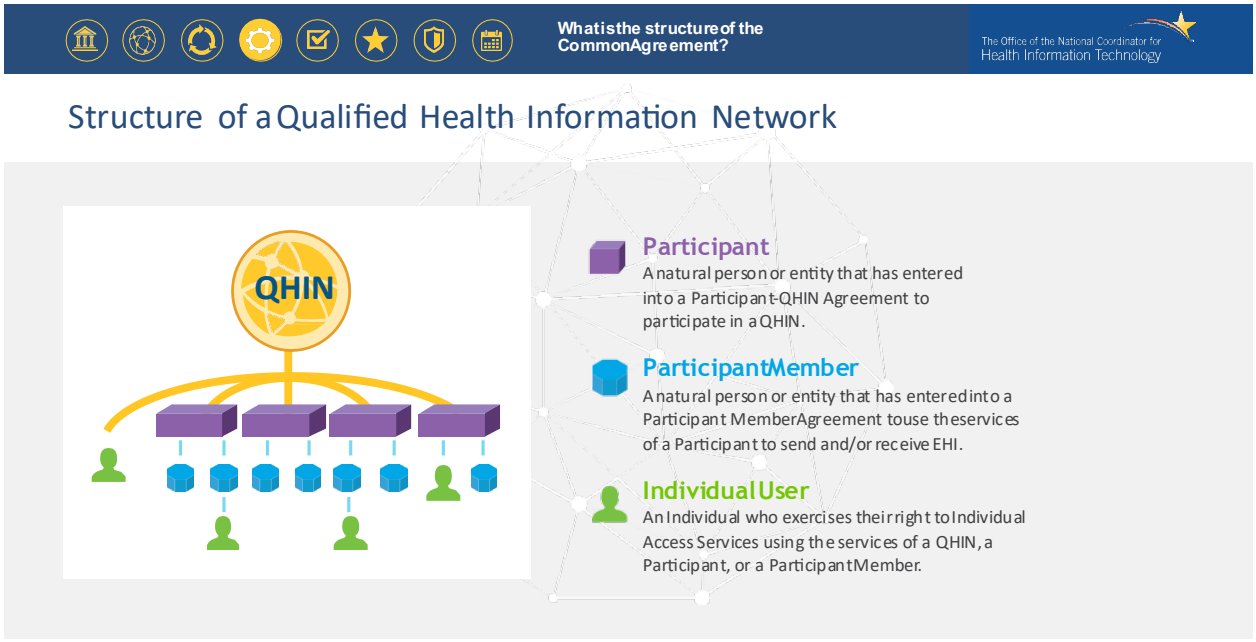


Figure 3 - Structure of a QHIN

An alternative architecture, based on secure repositories of longitudinal patient information which we call Health Record Banks or Health Data Banks (Figure 4), fulfills both goals of the Cures Act listed in Figures 1 and 2.

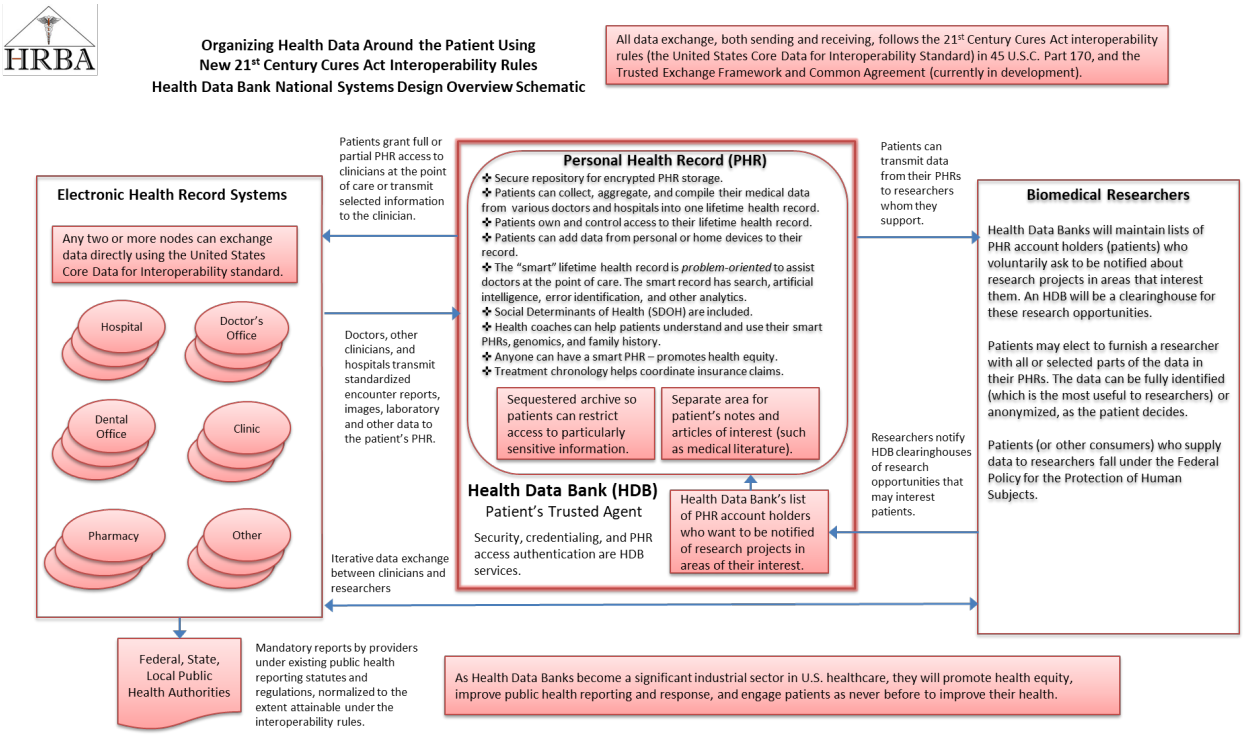


Figure 4- Structure of a Health Record Bank

The remainder of this appendix compares operation of the use cases described in the ONC TEFCA 2 User's Guide in the QTF and HRB models (the HRB Model with text and schematic is also found in Appendix A).

In all cases, for both the QTF and HRB models, patients, providers and other participants are assumed to have been verified by identity proofing to the IAL2 level and authenticated to the AAL2 level. Transactions are also assumed to be digitally signed, with provenance assured via normal methods associated with secure transmission of documents, and there is an appropriate audit trail of information transmissions.

While the HRB model has not been implemented to any degree in the United States, France is in the process of providing secure, longitudinal health records to all of its citizens. All citizens will be notified of the implementation between January and March 2022. Unless they opt out, a "My Health Space" (including a Sharable Health Record (Dossier Médical Partagé (DMP)), will be created for each of them a month after notification. While such a national system might not easily fit the U.S. environment, adding an equivalent feature at a state HIE level, for example, could be a straightforward extension of their capabilities. It would also be an appropriate approach to implementing the Cures Act requirements for patient access to EHI.

Exchange Purpose Example – Benefits Determination

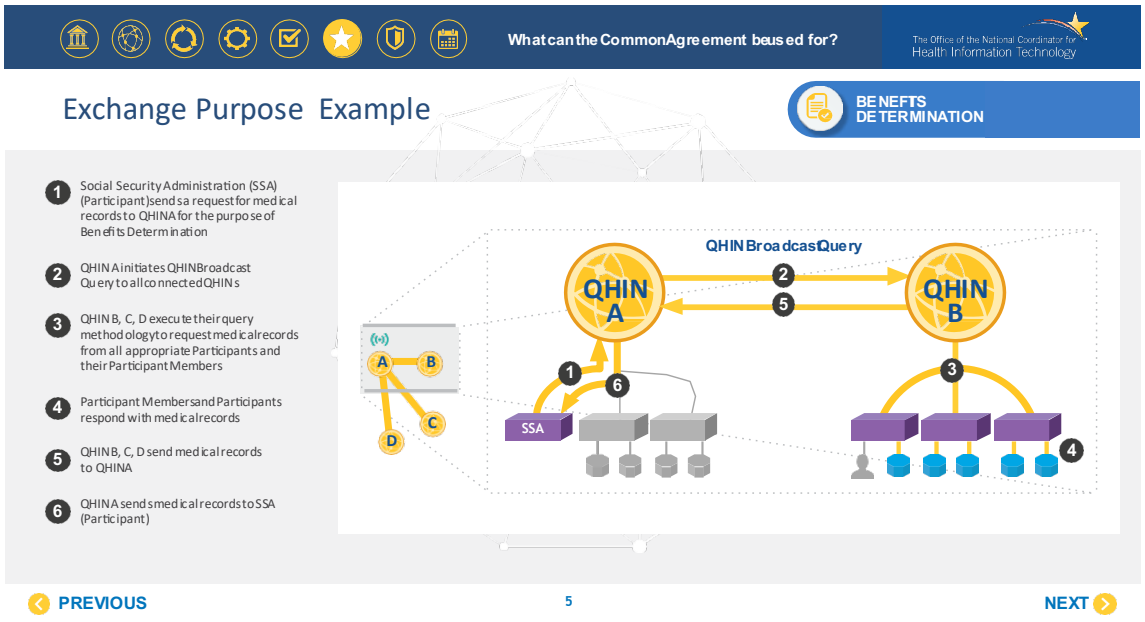


Figure 5- QHIN Implementation of Benefits Determination

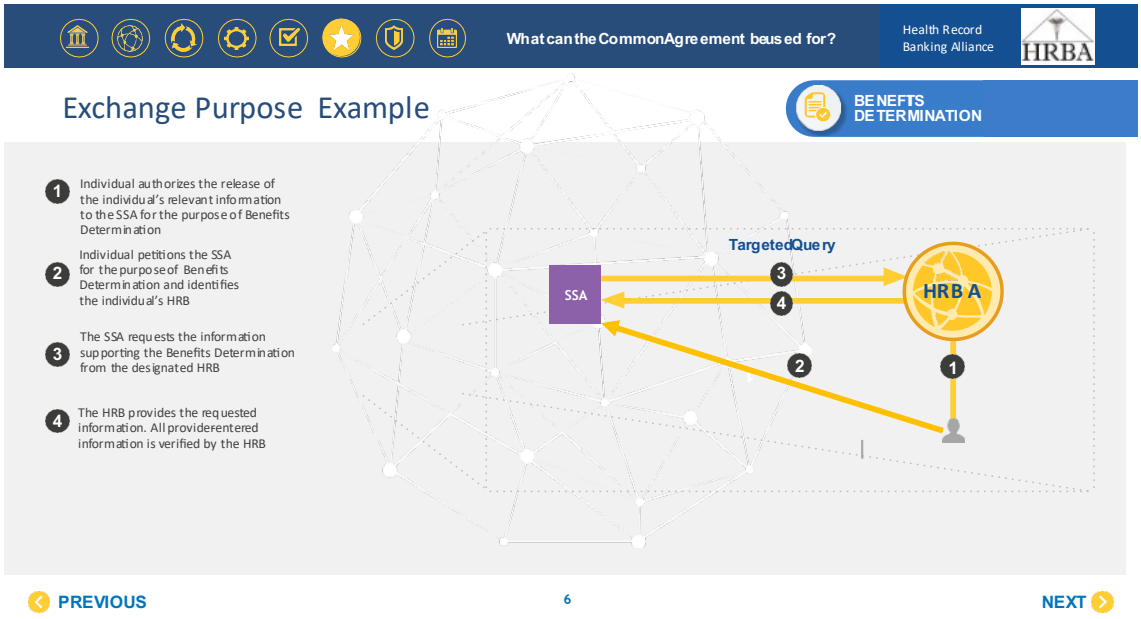


Figure 6 - HRB Implementation of Benefits Determination

The QHIN approach allows a Broadcast Query (now optional in the QTF 2) and does not appear to require benefits applicant approval for a complete transmission of EHI. The results of the (possibly large) number of queries are not likely to be integrated or easily used for the benefit determination.

The simplified HRB approach necessitates only Targeted Queries, involves the individual in both the agency application and the information release, and (assuming a Problem Oriented Health Record in the HRB) release of only the EHI required for the benefit determination.

Exchange Purpose Example – Quality Assessment and Improvement

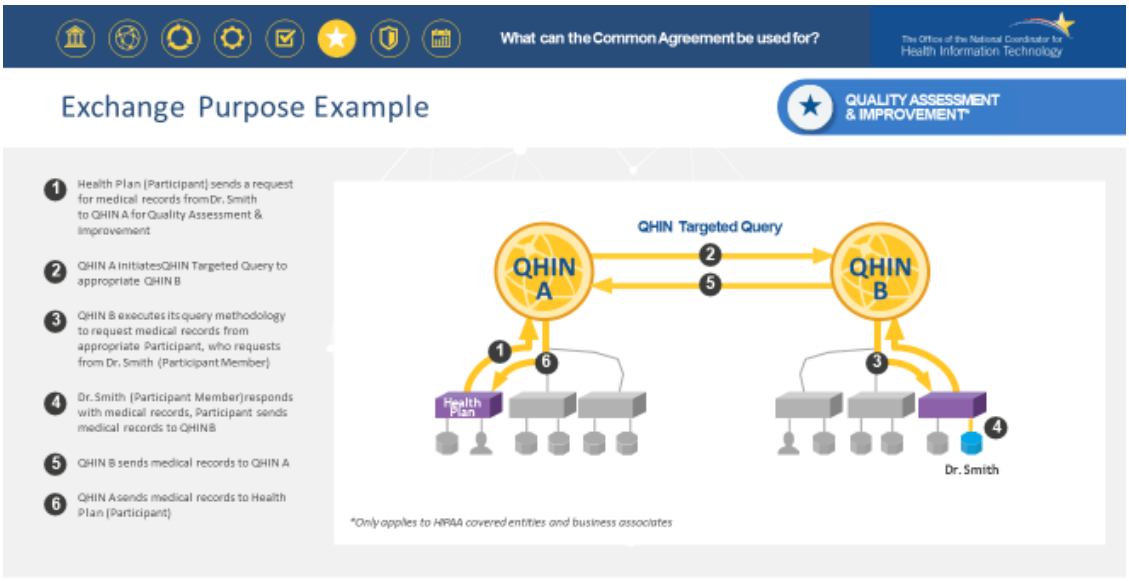


Figure 7 - QHIN Implementation of Quality Assessment and Improvement

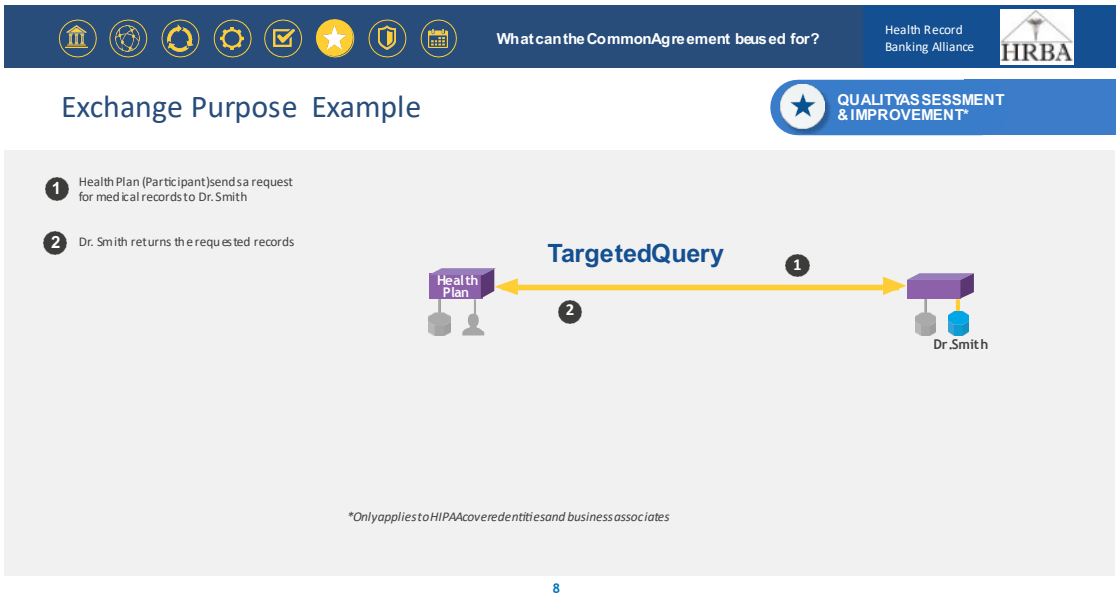


Figure 8 - HRB Implementation of Quality Assessment and Improvement

The QHIN approach requires the involvement of multiple additional participants (QHIN 1 and QHIN 2) in what is in essence an exchange between two parties – the health plan and Dr. Smith.

The HRB approach requires the participation of just the two parties involved in the transaction. There is no need for HRB involvement.

Exchange Purpose Example – Treatment

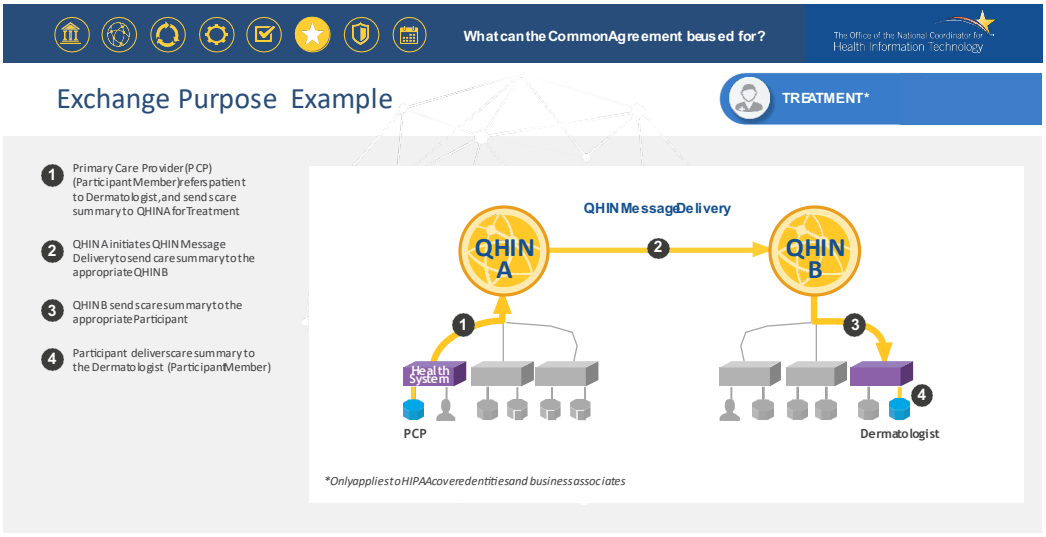


Figure 9- QHIN Implementation of Treatment

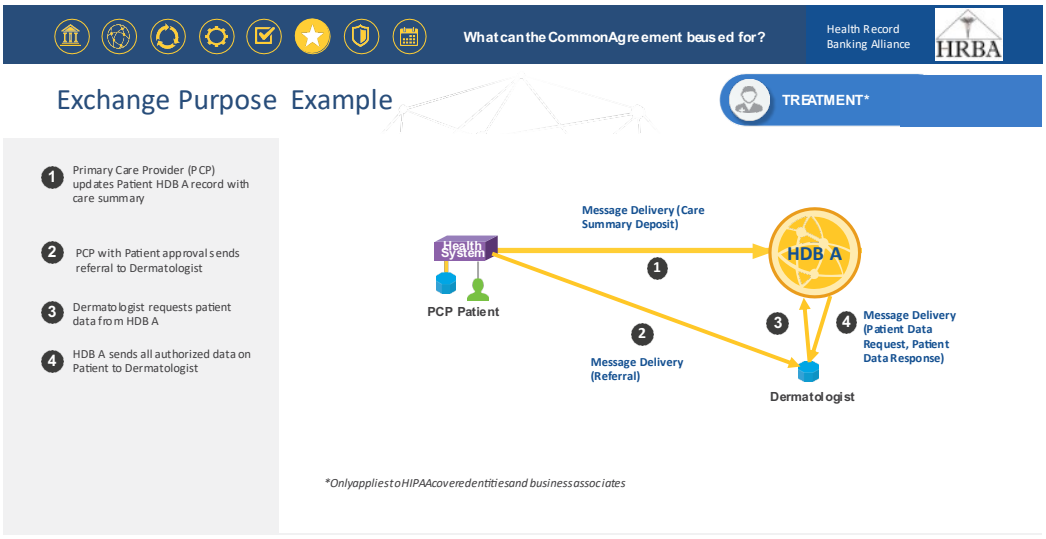


Figure 10 - HRB Implementation of Treatment

The QHIN approach delivers the referral to the Dermatologist via the QHINs. However, no additional EHI relevant to the patient is delivered. Either the patient is left to fill out the necessary forms to provide demographic and other PHI manually once again at the time of visit, or additional queries are required by the Dermatologist.

In the HRB approach, on approval of the referral by the patient, the referral includes the information necessary for the Dermatologist to request and retrieve the patient's demographic and other relevant information from the HRB.

Exchange Purpose Example – Public Health

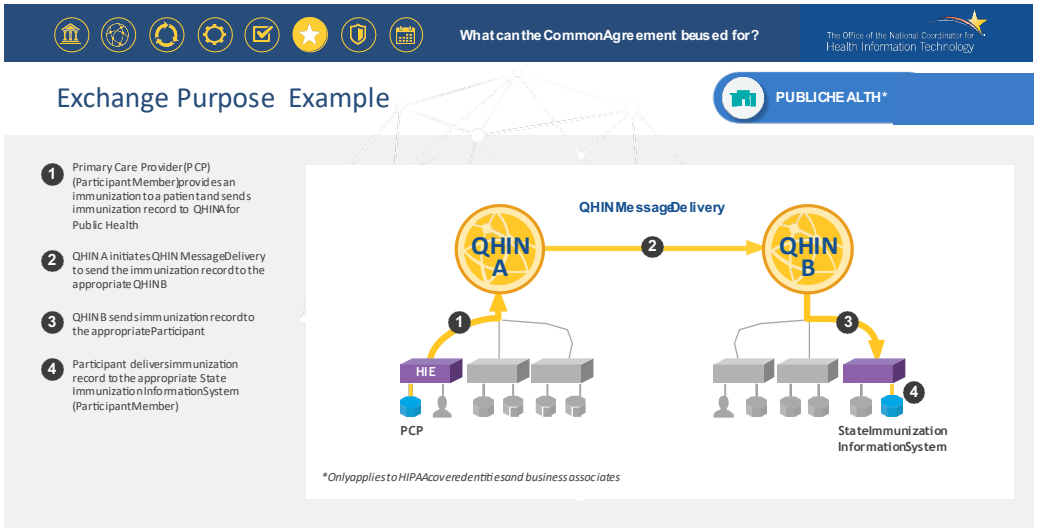


Figure 11 - QHIN Implementation of Public Health

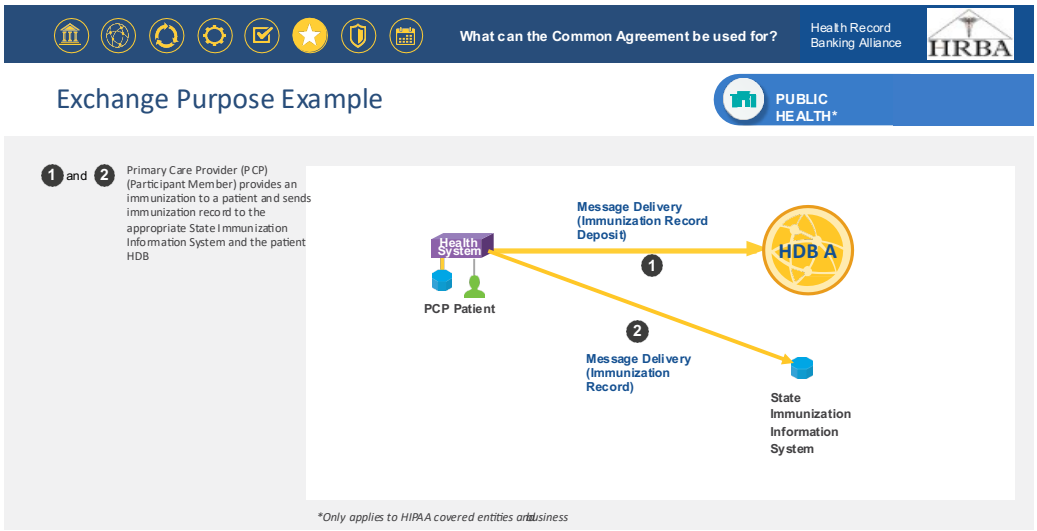


Figure 12- HRB Implementation of Public Health

The QHIN approach delivers the immunization record to the state immunization information registry via the QHINs. The patient must remember where the immunization took place and may not have easy access to a trusted immunization record that can be retrieved and shared.

Under the HDB approach, the provider delivers a normalized immunization record to both the state registry and the individual's HDB account. The HDB is the patient's trusted repository of the information and the immunization information can be retrieved as needed by the individual.

Exchange Purpose Example – Individual Access Service

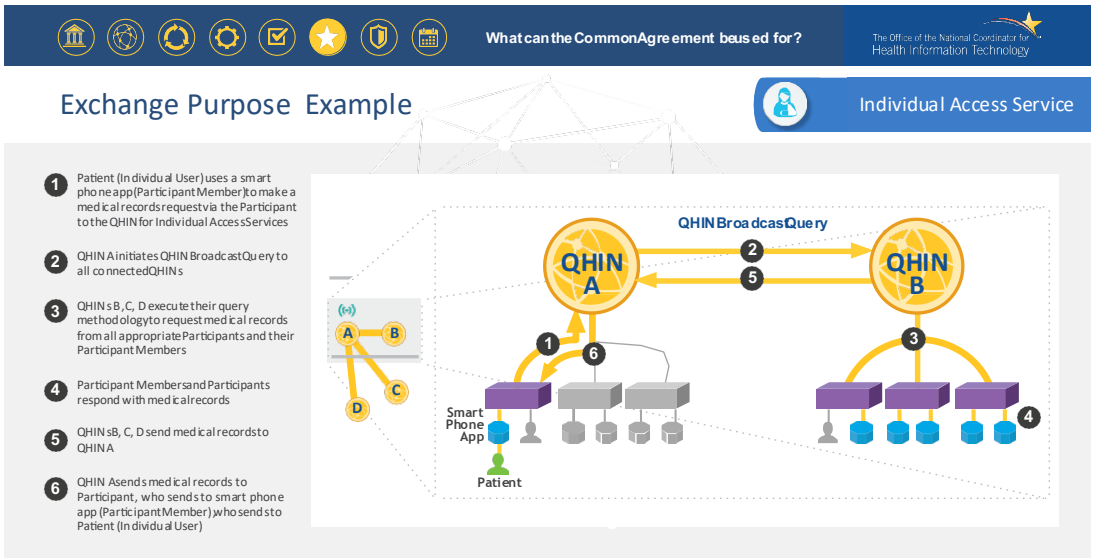


Figure 13 - QHIN Implementation of Individual Access Service

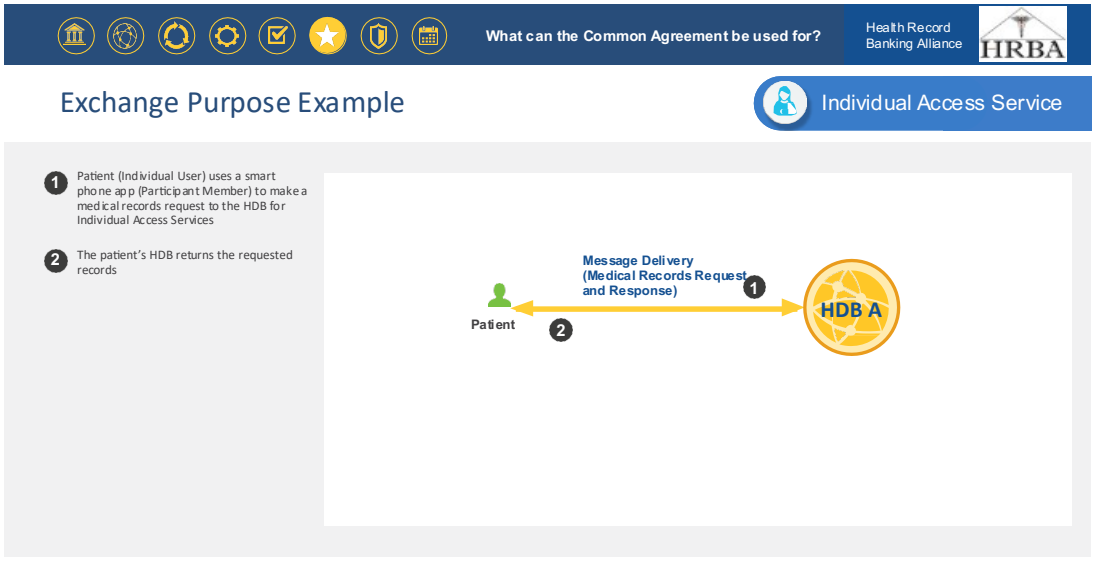


Figure 14 - HRB Implementation of Individual Access Service

The QHINs use a Broadcast Query to retrieve information from all Participants that might have it. The real-time gathering of complete, potentially lifetime, health data is an inefficient way to respond to most individual information requests. Record retention rules and institution failures may limit access to older information.

The HRB will have gathered and retained all of the individual's information and can directly respond to any query authorized by the patient and based on that data.

Exchange Purpose Example – Utilization Review

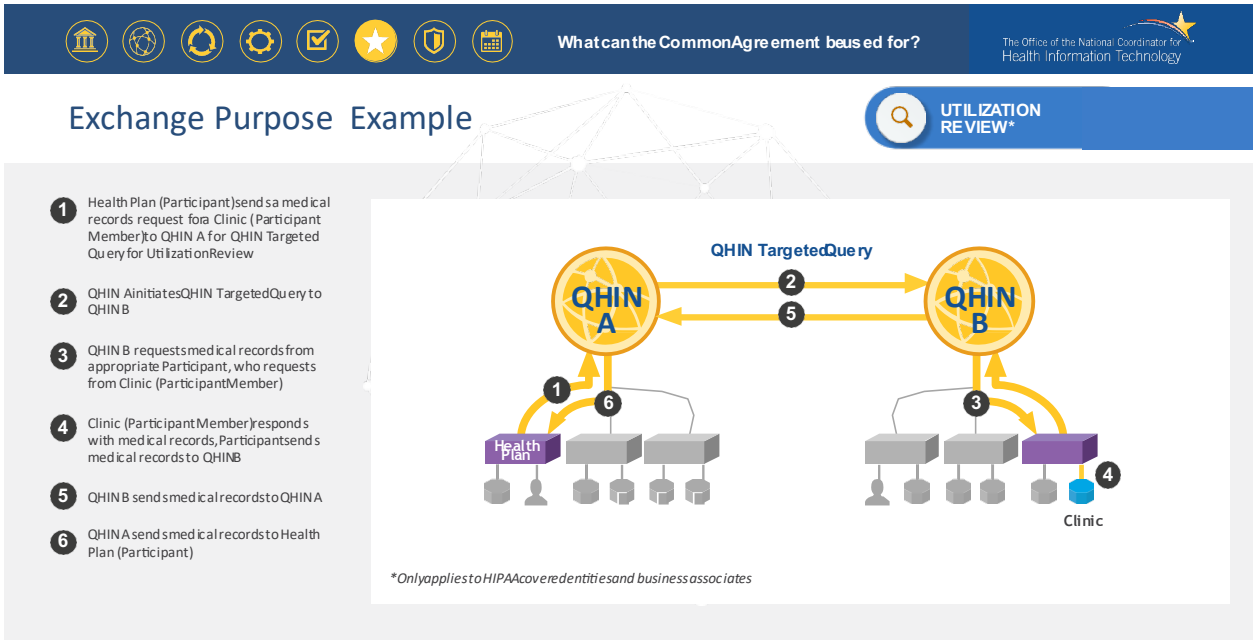


Figure 15 - Implementation of Utilization Review

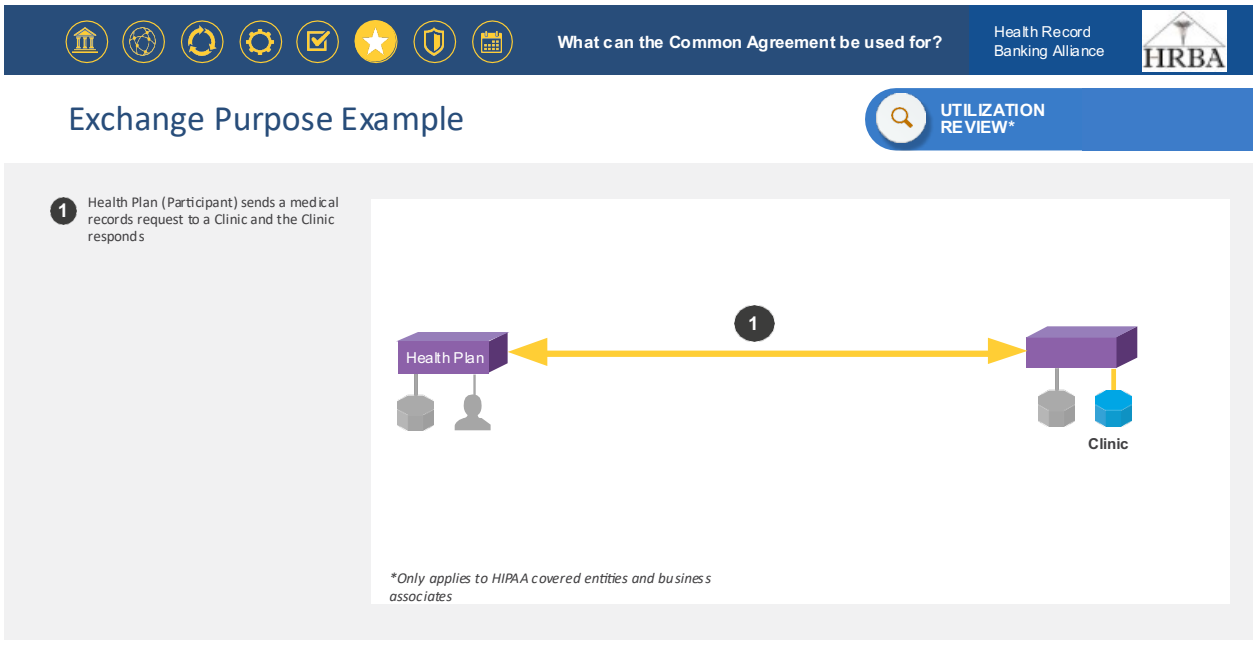


Figure 16 - HRB Implementation of Utilization Review

In the QHIN approach, although only two parties (presumably with a business associate agreement) are involved, the information travels through QHINs.

In the HRB approach, the two parties communicate directly.

Exchange Purpose Example – Business Planning and Development

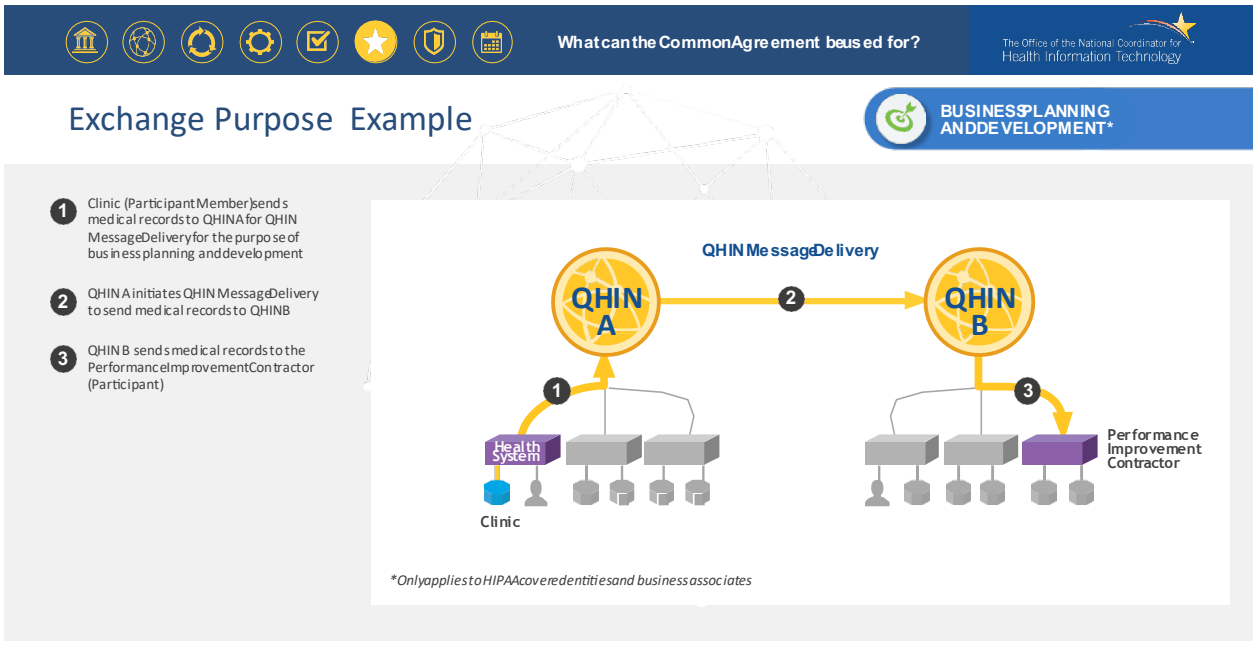


Figure 17 - QHIN Implementation of Business Planning and Development

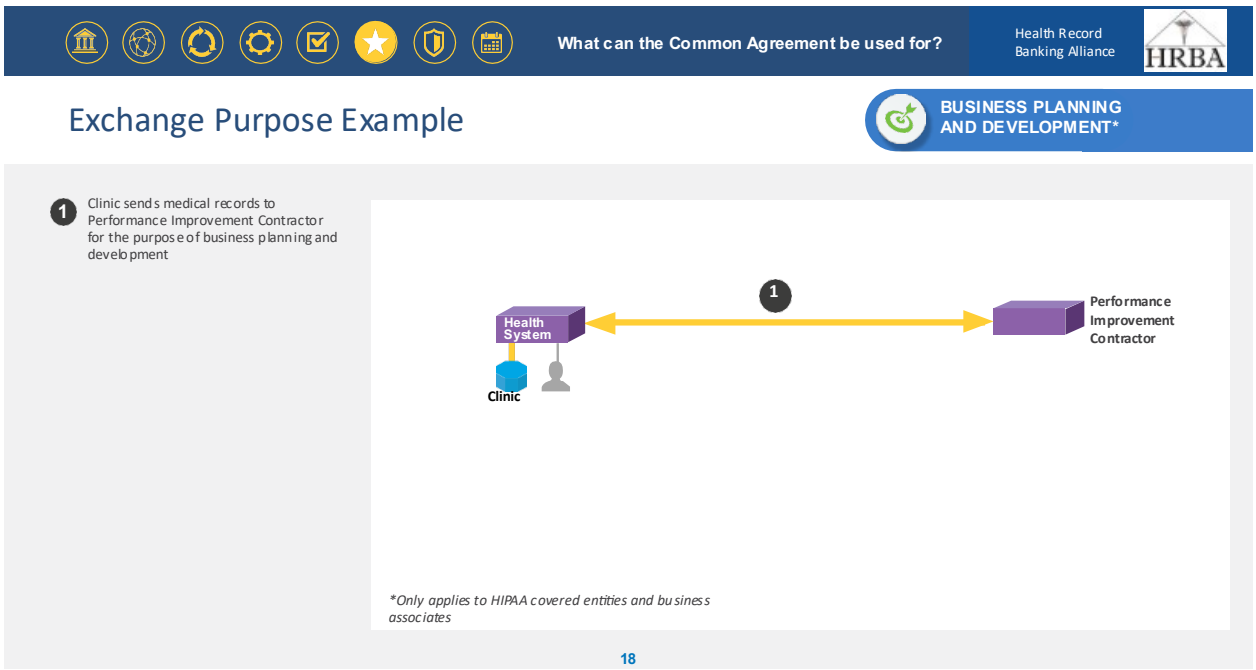
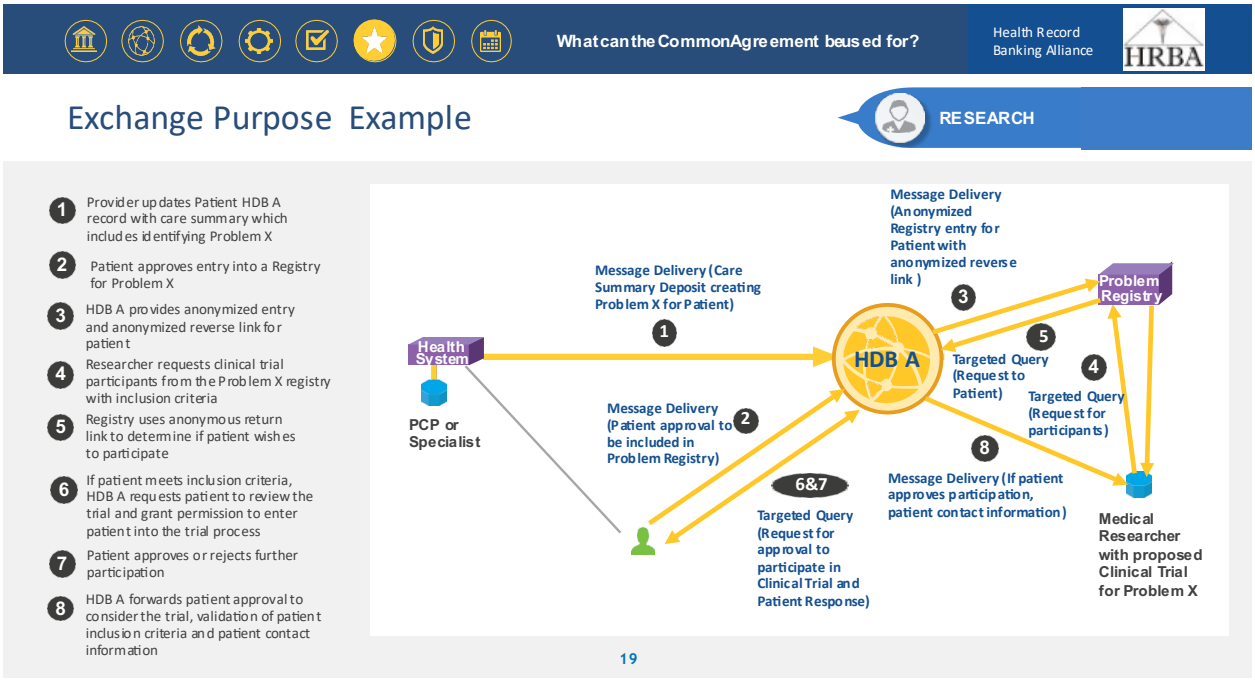


Figure 18 - HRB Implementation of Business Planning and Development

In the QHIN approach, although only two parties (presumably with a business associate agreement) are involved, the information travels through QHINs.

In the HRB approach, the two parties communicate directly.

Exchange Purpose Example – Research



The QTF defers the research use case for future implementation.
The HRB approach assumes a rapid implementation of the research use case, with improved patient involvement over the current approach, in particular for Clinical Trials. Currently, there are a limited number of problem registries (e.g., for cancer) that are completely anonymized. As a result, individuals with a specific problem cannot be directly notified of a clinical trial associated with a problem in which they might be interested or in connection with a trial for which they might be eligible.

In the HRB model, an anonymized reverse channel is provided to the registry. Researchers can request trial participants via the reverse channel, including advising about any restrictions on trial participants. The HRB can notify individuals who have listed themselves with the HRB as being interested in particular areas of research or particular kinds of clinical trials. Individuals can then approve their participation if they wish to participate. Further, and of special importance for advancing research, individuals can furnish their entire or partial *identified* record to the researchers. The can do so on a free or paid basis, depending on particular research projects. Patients' privacy is protected under the Common Rule (The Federal Policy for the Protection of Human Subjects, 45 CFR Part 46). Identified patient records typically are far more valuable to researchers than anonymized records. Having an HRB account therefore allows patients more effective opportunities to support research they care about, and to do so under each

patient's control. Researchers potentially can obtain access to many more identified patient records, and do so more rapidly and at lower cost, than at present. This would be a profound change in the conduct of a significant proportion of medical research.