

WASHINGTON STATE CONSUMER-CONTROLLED HEALTH RECORD BANK (HRB) PILOT A "STRAW CONCEPT" DESCRIPTION

B A C K G R O U N D

The Health Information Infrastructure Advisory Board (HIIAB) is currently finalizing the conceptual development of a Health Record Bank (HRB). This work is expected to conclude by early 2008. The HIIAB desires to provide sufficient clarity and definition on the consumer-controlled HRB concept to begin the pilot phase. To that end, this document outlines the Board's current understanding of:

- Key features and functions of a consumer-controlled health record bank.
- Core and optional elements and requirements of a health record bank to be implemented and functioning as pilots.
- Information and clarity needed to begin conversations with interested parties that may want to be pilot sites, solicit their input and encourage commitments.
- Questions that will be answered by the pilots and the experiment.

I. The Problem

Consumers do not have their personal health information available when and where needed. This health information exists mostly on paper, and is scattered among different care locations.

Information sharing mechanisms for consumers and providers are mostly ineffective or non-existent. Current methods for sharing health information are cumbersome, expensive, time-consuming and fallible. As a result, value has not been created for consumers and providers to optimize the use of all available health care information.

There is no trusted entity to promote uniform health information technology standards and policies or to collect health information for consumers and their providers from scattered sources when and where needed.

II. Consequences of the Problem

Multiple studies identify this problem and its consequences. It is known that:

- Medical errors are common – 44,000 to 98,000 preventable deaths/year in hospitals.
- Quality is poor – only 55% of adults receive recommended care (RAND study)
- Health care costs are:
 - Rising in excess of 10% annually;
 - Consuming an ever increasing portion of GDP;
 - Now \$ 2 trillion and growing.
- Consumers have no control of health information:
 - There is no system to allow patients to control access to THEIR information
 - Consumers do not have tools and mechanisms to be more informed and involved in their health and health care decisions

III. An Approach and Strategy to Address the Problem

The Washington State Health Care Authority (HCA) and the HIIAB submitted [a report to the Legislature](#) and the Governor in December 2006. This report included recommendations for a consumer-centric HRB model. The Blue Ribbon Commission [report](#) and subsequent legislation (E2SSB 5930, section 10) directed the HCA and HIIAB to implement the recommendations contained in the report and “roadmap”.

A key deliverable of the roadmap is to develop and implement a consumer-controlled HRB pilot designed to address the problem outlined above. This approach will test an innovative and promising concept with the aid of Washington communities and private entities. The strategy will utilize community pilots as “proof of concept” laboratories for the HRB concept to learn what works and what does not in addressing the problem through a HRB model.

Health care is delivered locally. Community health information infrastructure is also locally developed and supported. Some communities have already developed repositories that contain a subset of consumer’s medical records that can be leveraged to build a system of consumer-controlled HRBs as envisioned by HCA and the HIIAB. Engaging local initiatives to address the problem may expedite consumer and provider engagement and technical development.

IV. The Vision

It is helpful to get a visual “snapshot” of the health record concept. The following vision statement summarizes what the HRB concept is and what it is intended to do. This statement was adopted by the reconstituted HIIAB:

“To build the necessary infrastructure and to pilot a consumer designated and controlled health record bank to enable consumers to use their health information to improve their health and provide a mechanism for health data sharing in the state of Washington.”

V. What is a Consumer-controlled Health Record Bank and What Does It Do?

At its most basic level, the HRB is a means to activate consumers. It is a secure consumer-controlled repository of a defined set of aggregated health care information and it will allow consumers to better navigate the delivery system and manage their health care. Armed with their own health care information, consumers can engage in meaningful conversations with their providers about their own health and healthcare options.

The “bank” is a valuable tool which allows consumers to store, organize, manage and facilitate the sharing of their data with everyone involved in their care. The HRB will have the capability for many different types of applications, including a wide variety of PHRs to allow participating consumers to share their health information at their discretion and for their benefit.

A HRB provides electronic copies or “deposits” of patient data for use by the patient. The original records remain the legal record of the originator. HIIAB envisions a simple application that allows users to read and add to their data, make decisions about who can see which items, and track who has accessed that data. The HRB will also allow “withdrawals” and “queries” of the consumer’s health information to those granted such permissions by the consumer.

The HRB makes health care information accessible to providers and reduces their workloads with patient validated information such as:

- Medication, allergy lists, immunization records.
- Cancer screening tests.
- Past medical, family and social history.
- Office visit print-outs or “views” from the HRB will give providers information they currently spend valuable office resources to obtain.
- Advance directives and other forms (work release, etc).
- Home monitoring devices (glucose, blood pressure, daily weights).
- Review of systems.

Some of the infrastructure required to support HRB information exchange is very similar to the health information infrastructure (HII) needed to support health industry information exchange. It is envisioned that this common HII or “neutral ground” will be shared and become the connection between consumer and provider health information zones. Where outpatient data is not currently electronic, initial HRB accounts will rely on data from other industry sources (PBMs, labs, hospital EMRs, etc.) as well as information essential to efficient care delivery for which consumers themselves are responsible (L&I and FMLA forms, advance directives, data from home monitoring devices, etc.).

The HRB benefits from community data sharing arrangements between provider groups and is meant to complement and accelerate those existing health information exchange activities.

VI. Health Information Zones

The HRB lies in the consumer-controlled zone of health information. A HRB is related to, but separate and distinct from, health information infrastructure (HII) owned and controlled by health industry participants, vendors, the public sector and others. Nothing in the HRB extends consumer control into the health industry zone. Nothing in the HRB modifies or limits the current operation of industry-controlled HII.

For example, consumer data in a provider’s electronic medical record (EMR) remains under the control of the provider. If a copy or version of that consumer’s EMR data is imported to the consumer’s HRB, the version of the data resident in the HRB comes under consumer control. The data resident in the EMR remains under provider control. Likewise, nothing in the EMR extends provider control into the consumer controlled zone.

Once a copy of the consumer’s EMR data is placed in the HRB, consumers may give permission for it to be available to other applications that may reformat or otherwise modify the data to make it more useful to the consumer. Any activity around the copy of the EMR data does not affect the original EMR data which continues to reside under provider control and is stored at its source.

The HIIAB has found it helpful to refer to the diagrams on the next page to better capture a visual image of the relationship of the “industry controlled health information zone” and the “consumer controlled health information zone”. The diagrams show the where health information resides today, and the evolution to the time when HRBs will be in operation.

Figure 1. Health Information Zones — Today

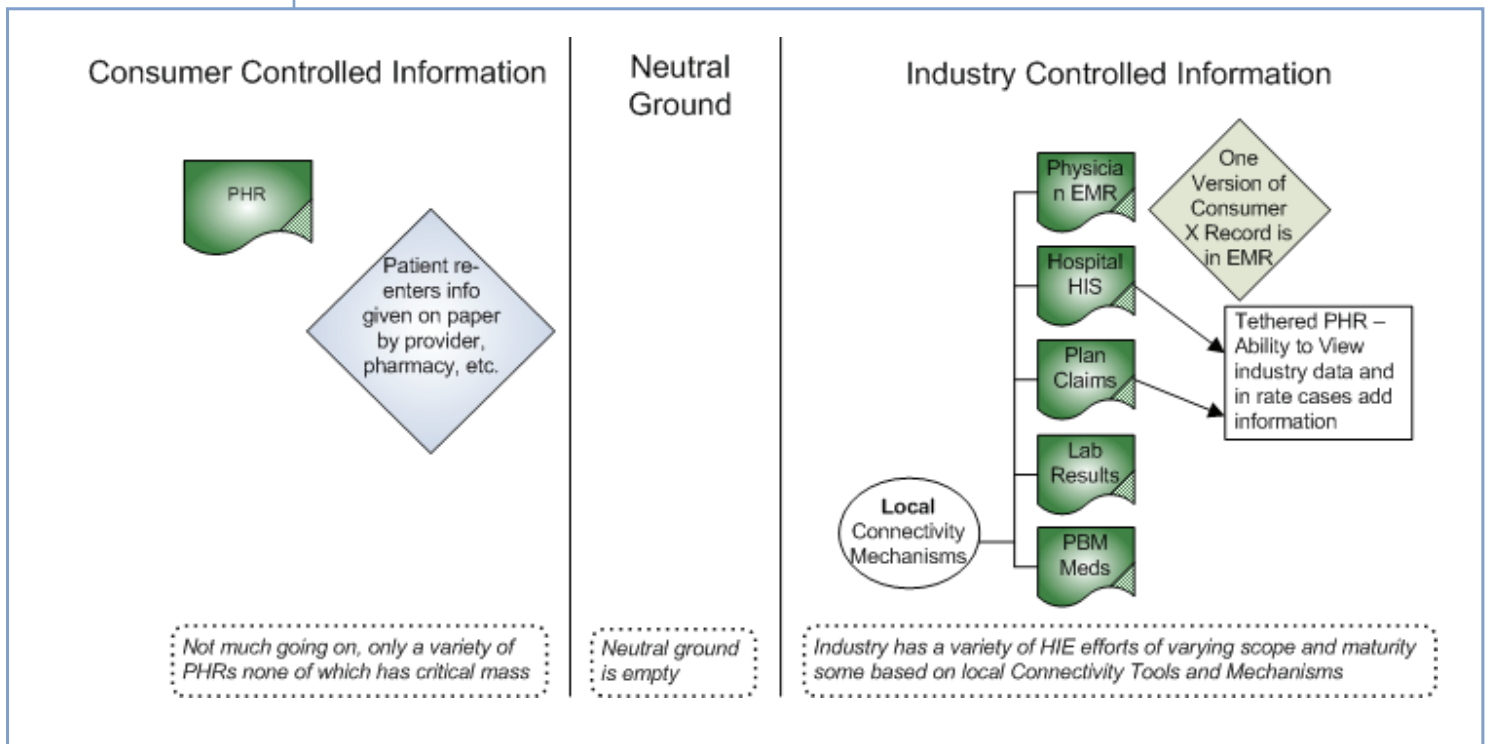
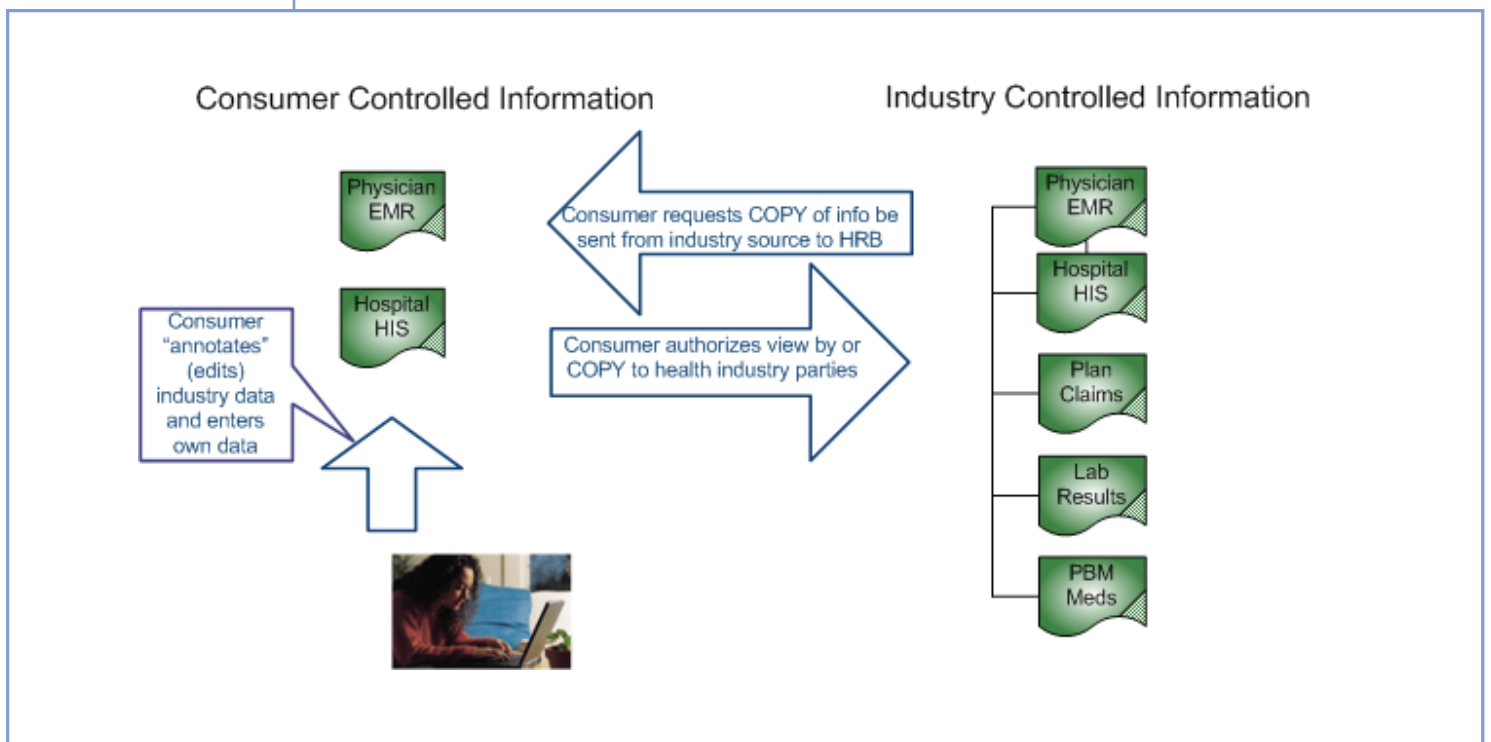


Figure 2. Envisioned Health Information Zones



- In the Health Record Bank model copies of industry data will be sent to the HRB.
- Once in the HRB, all data is controlled by the consumer.
- This does not affect industry control of any data or copies they retain.
- The consumer can grant industry views/copies of HRB data.
- Data provided back to industry systems will have “meta-data” so that source, edits, and caveats are available for audit or other industry system usage

VII. Objective: Proof of Concept

The key objective for this phase of work is a “proof of concept.” The HIIAB intends to set minimum requirements for this experiment, yet ensure basic design principles and policy objectives to effectively prove the concept.

The HIIAB desires to structure the pilots in a way that yields maximum learning and the highest probability of success. Pilot sites will help finalize draft specifications and requirements. Outside of the minimum specifications, pilot participants have flexibility and discretion to implement a HRB that best suits their environments and maximizes consumer and provider adoption and participation.

Success will be evaluated in terms of the value created for consumers and providers, as well as achievement of functionality of the key attributes of a consumer-controlled HRB. Demonstrable and replicable success of minimal functionality may be of greater value than limited success of a more complex and comprehensive initiative.

In the aggregate, the experiment will also address as many policy questions as possible in order to learn what works and does not and contribute to refining the HRB concept.

VIII. Pilot HRB Components

- 1. Consumer controlled.** The individual consumer or their authorized designee will:
 - A. Decide which, if any HRB to join. Participation in HRB is voluntary for consumers.
 - B. Authorize who will be able to access their HRB account and decide what that person can see and do with the account.
 - C. Determine what data is stored in their HRB account
 - D. Have reasonable access to audit reports and a clear process for investigating misuse and appropriate recourse measures
- 2. Data Management Functionality.** For the consumer’s health data resident in the HRB’s the following capabilities must be available (collectively described as “manage”):
 - A. Input from external sources (health industry source, consumer entered, etc.)
 - B. Create consumer generated custom data presentations from internal sources (e.g., computing a new third data presentation element from two existing data elements)
 - C. Store health data
 - D. Source comments and additions to data from the consumer
 - E. Update account with new health data deposits (see edit)
 - F. Restrict access by person, entity, time, and data item (see security)

- G. Remove (see edit)
- H. Read (at minimum must include both a view and print to paper capability)
- I. Export (e.g., send to other data base or application)
- J. Consumers may not change a data item from another source. However they may add comments to it, restrict who can access it, or even delete it.

3. High Value Data Set. Pilot HRBs must provide the functionality to manage a specified number of data items. Where recognized national standards exist, the HRB must use these standards when exchanging data.

- Further surveys and feedback from consumers, providers, advocates, and healthcare industry participants is planned.
- The HIIAB values forward-looking compatibility that leverages national standards and moves towards growing connectivity with consumer applications and industry HII.
- Based on existing research of high-value data sets, informal HIIAB member poll and other stakeholders, the list below are an example of a combination of consumer (*listed in blue*) and industry generated data that might be of highest value to store in a HRB:
 1. Patient demographics
 2. Advance directives
 3. Immunizations
 4. Home monitoring information: Blood pressure, glucose monitoring, daily weights
 5. Forms (FMLA, L & I, Disability forms, etc.)
 6. Family history
 7. Self administered care
 8. Health goals and preferences
 9. Medications
 10. Allergies
 11. Labs (diagnostic tests)
 12. Problem lists – diagnosis (chronic conditions, diabetes, etc)
 13. Images and interpretation reports
 14. Discharge summaries
 15. Care plans

4. Editing: Control vs. Source. Since the consumer owner of the HRB account has control over their copy of the data, metadata to track the source of information and of any edits to that information will be a key to data integrity. This will become especially important when the functionality is in place to move data from the HRB out to industry sources of data. For example, a medication list imported from a PBM may then be modified by the consumer to reflect dose changes, unfilled prescriptions, or prescriptions paid in cash. This real-time list of meds is obviously of use to providers, but must be sourced as coming from the consumer. This “edit” capability will likely be in the form of the following functions:

- Notate and comment on
- Remove/delete
- Hide (see security)

5. **Security.** The HRB must offer the following capability related to security:
 - Physical security of data base must meet industry standards
 - Service availability must be 24/7 with at least 99.9% uptime
 - Data transmission to and from HRB must be encrypted to industry standards
 - All data imported/exported to or from external sources or read from the HRB is matched to the appropriate individual consumer (with mechanisms for deleting and rapidly correcting any errors that may occur)
 - **Authentication:**
 1. Registration data collected for all individuals/entities accessing HRB
 2. Identity verified
 3. Information sharing agreement executed
 4. Digital credential provisioned (single factor is acceptable)
 - **Authorization:** Consumer owner of the HRB account will have the capability to administer (e.g., set, view, maintain and/or modify) access control for all data managed by the HRB at the following levels
 1. Permit data to be input, imported, created or otherwise deposited
 2. Permit data to be viewed, printed or otherwise exported
 3. Grant/restrict access to specific individuals or entities (by name or role)
 4. Grant/restrict access to specific data items for specific individuals or entities
 5. Change any of the above at any time
 - **Audit:** Consumer owner of HRB account will have reasonable access to audit reports containing the following
 1. Unique identity of parties accessing data
 2. Affiliation and role of parties (where available)
 3. Data elements accessed
 4. Manner of access (view, print, export, etc), date/time of access
6. **Activation.** The HRB technology is a means to an end. Consumer engagement and activation is the primary objective. Pilot participants will identify and measure how deployment of the HRB accelerates consumer engagement and activation in their community of users, how they assess these dimensions of activation and how they will identify their target populations and audience. The HIIAB will be able to provide pilot participants with assistance and suggestions if requested.
7. **Enrollment.** The HRB must enroll a determined number of individual consumers.
8. **Disclosure.** The HRB must agree to participate in HIIAB pilot reporting and require HRB staff to make personal appearances to provide progress updates. Nothing in this disclosure section should be interpreted to require the HRB to disclose proprietary intellectual property. Finally, the HRB must fully disclose in clear language all policies, procedures, terms, major risks and fees, if any, to the consumer enrollee prior to enrollment.

HIIAB will work with pilots on key issues

1. *Recruitment.* While the pilot sites are building, HIIAB and HCA will be developing a communications campaign targeted at consumers to assist with the recruitment effort.
2. *Activation.* The HRB is designed to help activate consumers. HIIAB will work with pilot sites to accelerate and measure consumer activation.

3. *Financial Sustainability.* The HIIAB will work with pilot sites on potential financial models.
4. *Technical design.* The HIIAB Technology Committee will have pilot member involvement and participate in HRB specifications and component technical design

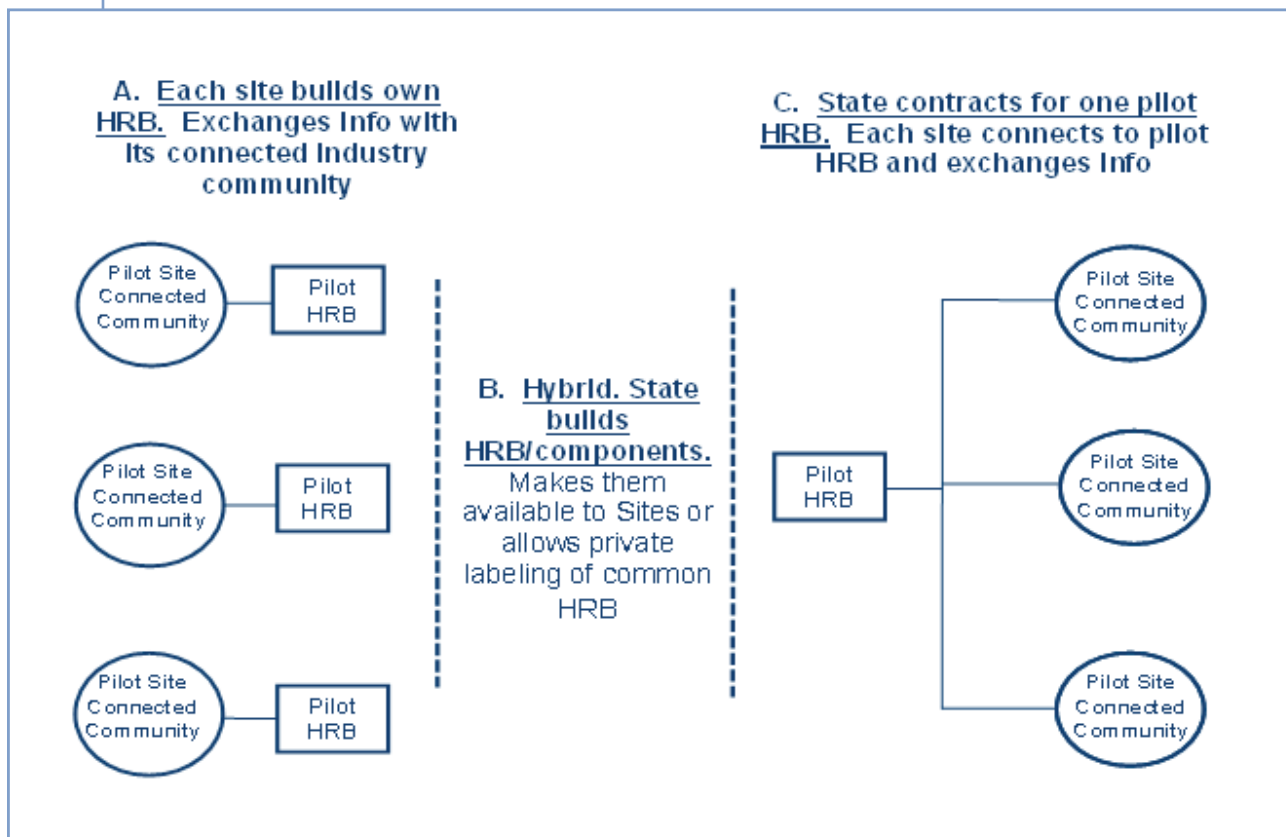
IX. How Best To Deploy the Pilot HRB?

There are several options on how to best deploy this pilot.

1. Each pilot site builds their own HRB and exchange information with its industry community.
2. Washington State builds the core HRB information system and components and makes them available to pilot sites or allows private labeling of a common HRB.
3. Washington State contracts for one pilot HRB and each pilot site connects to the pilot HRB and exchanges information.

The following figure depicts the potential options outlined above:

Figure 3. How Best to Deploy Pilot HRB? Possible Options



X. Beyond Technology—Policy Questions To Be Answered

It is expected that the implementation process will be challenging. Many lessons need to be learned before success is fully achieved. The purpose and focus of these pilots is to test key HRB concepts, determine feasibility and learn to guide next steps. In order to maximize the value of these pilot projects, key concepts to be examined will be clearly delineated and specific outcome measures developed and utilized.

In the aggregate, the HIIAB expects this experiment to help answer these key questions:

1. What needs to be done to get consumers and providers to use a HRB?
2. How much/What data is needed to provide value to the user for a HRB?
3. How can timely data be obtained?
4. What needs to be done to earn the trust of the public?
5. What needs to be done to earn provider trust?
6. What standards/technical mechanisms facilitate HRB development?
7. What types of policy, organizational structure and governance paths are there for HRBs (including financial sustainment)?
8. What impact does a HRB have on health disparities and special populations?
9. What impact does a HRB have on public health reporting and surveillance?
10. What is the role of government with HRBs?

XI. Potential Benefits for Pilot Participants

1. **Funding.** Precise budgets will be determined on number of interested parties. HIIAB initial estimates are that funding will be available for 3-5 pilots each of which could receive grant dollars for 6-12 months.
2. **Recruiting/Outreach.** The HIIAB will be conducting extensive education, communication and outreach to consumers. The HIIAB will work cooperatively with pilot participants to aggressively market pilot HRB offerings to interested consumers.
3. **Publicity.** The HIIAB will share the results of the pilots locally and nationally with the policy, consumer, health industry, and vendor communities.
4. **Participation in Design Process.** Pilot participants will be invited to participate in the design process to refine pilot requirements. In addition, based on knowledge gained in the pilot, participants will have an opportunity to influence the on going development of HRB concept in Washington State.
5. **Community Service.** Pilot participants will be providing a valuable service to their communities, the state, the industry and most importantly health care consumers by helping to pilot and refine the HRB concept.

XII. Taking the Process Forward

The HCA and HIIAB have identified a process to guide its work over this final development and pilot implementation phase. Below is a tentative and proposed timeline.

Dec 07 – Mar 08 Develop draft pilot requirements and specifications

Feb 08 – Apr 08 Review draft specifications with pilots sites and finalize

May 08 – July 08 Solicit/evaluate pilot sites and finalize

July 08 – Dec 08 Pilot selection and build

Jan 09 – Jun 09 Pilot implementation and assessment

XIII. Invitation to Participate

If you are interested in applying for pilot participation and joining the HIIAB Pilot Design Committee please provide your name, organization name, mailing and e-mail address, and phone number to:

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