DEPARTMENT OF HEALTH & HUMAN SERVICES USA

Office of the National Coordinator for Health Information Technology
(ONC)

Consumer Empowerment: Consumer Access to Clinical Information

Prototype Use Case

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1.0 Introduction

1.1 Use Case Description

Enhancing a consumer’s ability to make well informed decisions about their healthcare and healthy lifestyles can be supported by the consumer having access to their health information. Consumers may also want to have the ability to make their information available to their healthcare providers in ways which respects the consumer’s needs for privacy and confidentiality. A secure Personal Health Record (PHR) has the potential to become a key enabler for the consumer to gather and share this information with adequate safeguards.

In March 2006, the Office of the National Coordinator for Health Information Technology (ONC) published a Harmonized Use Case for Consumer Empowerment (Registration and Medication History.) In January 2007, the American Health Information Community (AHIC) approved a recommendation to extend the use case to include consumer access to additional types of clinical information as well as to address aspects related to privacy and access controls. The recommendation included the following AHIC prioritized needs:

- Lab results as needed by the patient: Ability for the consumer to retrieve, store, graph and share numerical laboratory test results;
- Lists of conditions and allergies, including:
    - Health problems: Ability for consumer to retrieve and store lists of current and previous health conditions;
    - Medication allergies: Ability for consumer to retrieve and store lists of current medication allergies; and
    - Allergies: Ability for consumer to retrieve and store lists of current environment, dietary or medical supply allergies.
- Diagnosis codes: Ability for a consumer to retrieve and store a list of diagnosis codes in their PHR with appropriate translations into layperson terms;
- PHR portability: Ability for a consumer to move their information between PHRs;
- Privacy and access control: Ability for a consumer to identify those providers which are permitted to view information in the consumers' PHR, and which of those data they are permitted to view. Ability to communicate the consumer's decisions to other entities which also hold data about the consumer;
- Audit and logging exchange: Ability for a consumer to request, consolidate, and view audit log information from multiple sources to create logical views of access to their information;

- Vocabulary for role-based access control: Ability to describe a consumer's access decisions using information which can be communicated among systems involved in information exchange; and
- Provider lists: Ability to identify and maintain a list of all providers involved in the care of a specific patient. Ability to use the provider list to communicate information about patient to all or selected providers. Ability to forward the list of providers to another provider or entity.

This use case is being developed by ONC to represent these AHIC priorities, with opportunities for review and feedback by interested stakeholders within both the public and private sectors. To facilitate this process, the use case is being developed in two stages:

- The **Prototype Use Case**, which describes the flows of the use case at a high level and facilitates initial discussion with stakeholders; and
- The **Detailed Use Case**, which documents all of the events and actions within the use case at a detailed level.

This document is the Prototype Use Case.

1.2 Scope of the Use Case

This use case describes at a high level specific capabilities that would enable a consumer to access clinical information via their PHR(s). These include:

- Information flows needed to support a consumer's access to clinical information;
- Consumer capabilities for controlling, and controlling access to, their PHR information;
- The roles of the consumer, provider, and health information exchange;
- Needs for a consumer to be able transfer their health information between PHRs (portability); and
- Support roles for health information exchange services and other participating entities which may be sources or recipients.

The use case includes three scenarios which describe highlights of the processes, roles and information exchanges which could enable a consumer's access to clinical information via a PHR. The three scenarios are:

- Consumer views and retrieves clinical information;
- Consumer creates provider lists and establishes provider access permissions; and
- Consumer transfers PHR information between PHRs.

While out of scope for this particular use case, capabilities for a consumer to self-report information about medications and allergies to providers is included in the 2007 Medication Management use case. The ability for a consumer to provide interoperable registration information was addressed by the Harmonized Use Case for Consumer Empowerment (Registration and Medication History).

This use case does not attempt to describe in detail all steps in this process nor all the roles and functions that are present during this complete cycle. Rather, the intent is to focus on the interoperability and information flows that would provide access to additional clinical information in a secure manner while respecting the consumer's need for privacy and security.

This use case assumes the presence of widespread electronic systems such as EHRs, PHRs, etc. while recognizing the issues and obstacles associated with these assumptions. This approach promotes the development of longer-term efforts.

This use case focuses on the exchange of information between organizations and systems rather than the internal activities of a particular organization or system. However, certain internal processes have been included in order to provide a context for the information exchange needs.

2.0 Use Case Stakeholders

Stakeholder	Working Definition
Ancillary Entities	Organizations that perform an auxiliary role in delivering healthcare services. Ancillary entities may include diagnostic services such as laboratories and radiology in either in a hospital or ambulatory environment, which analyze specimens and radiographic images, as ordered by clinicians to assess the health status of patients. Pharmacies, therapies, etc. may also be included.
Consumers	Members of the public who may receive healthcare services and have a PHR which may be used to access and maintain their personal health record. These individuals may include: caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient in the activities of receiving healthcare and/or using a PHR.
Health Care Entities	Organizations, such as hospitals, ambulatory clinics, and physician practices, which manage the delivery of healthcare.
Health Care Registries	A systematic collection of a clearly defined set of health and demographic data for patients and providers with specific health characteristics, held in a database for a predefined purpose.
Health Information Exchanges	Organizations that may provide trust and governance relationships for a network of users and applications. Organizations playing this role may be, but are not limited to, statewide or regional groupings, or geographically diverse integrated delivery networks. Some HIEs may receive networking services from other health information providers.
Payors	Insurers providing for healthcare coverage to their enrolled members.
Personal Health Record Vendors	Organizations which provide specific PHR solutions to consumers such as applications, data repositories, web services, etc.
Pharmacy Benefit Managers	These entities manage pharmacy benefits on behalf of payors, interacting with pharmacies and providers via a pharmacy network intermediary. As part of this role, they can provide information on pharmacy benefits available to an individual consumer and an individual consumer's medication history.
Providers	The healthcare clinicians within healthcare delivery organizations with direct patient interface in the delivery of care, including physicians, nurses, and other clinicians. May have the ability to access and/or incorporate information designated as appropriate by the consumer.

Stakeholder	Working Definition
Public Health Agencies (local/state/federal)	Local, state, and federal government organizations and personnel that exist to help protect and improve the health of their respective constituents.

3.0 Issues and Obstacles

Realizing the full benefits of health information technology capabilities mentioned above is dependent on overcoming a number of issues and obstacles in today's environment. Inherent in this use case is the premise that some of these will be addressed through health information technology standardization and harmonization activities, policy development, health information exchange networks and other related initiatives.

Confidentiality, Privacy, Security, and Data Access

Confidentiality, privacy, and security. Consumers may be reluctant to make information in from their PHR accessible to others unless they have adequate assurance that their concerns about confidentiality, privacy and security have been addressed. There must be ways to ensure that the information transmitted is reliable, accurate, secure, representative of the appropriate consumer, and is transmitted to the appropriate recipients. Providing adequate safeguards to protect the data during information exchange activities is another dimension of this need.

Access controls. Mechanisms for consumers to control who can access their personal health record, and what parts they can access, are key dimensions of confidentiality, privacy and security. Interoperable standards and vocabulary are needed to implement the consumer's access decisions during information exchange activities, as well as, to provide the feedback to consumers about who has accessed their information. Interoperable safeguards for the protection of information during data exchange are also needed. In certain situations, clinicians involved in the care of the consumer may also need to have the capability to "break the glass" in order to gain access to information which has immediate relevance to the clinician's decisions about the care needed during urgent situations.

Audit and logging exchange. The mechanisms needed to review access to a specific consumer's information across multiple organizations, geographic regions, or health information exchanges may not be readily available. The ability to create an integrated view of who has accessed the consumer's information across multiple markets and timeframes may be challenging without standards for access related information and for exchanging this information among networks.

Interoperability and Portability

The ability for the consumer to retrieve, move, or share their health record may be hampered by a lack of harmonized standards and vocabularies for describing and exchanging this information between the consumer's PHR and the various external systems which have, or need, such information. In addition, if a consumer elects to transfer their PHR information to another PHR, these standards and vocabularies may also be needed to accomplish the transfer of the consumer's information without error or omission.

Policies for Consumer-Entered Information

Consumers may need the ability to modify or annotate the health information which they retrieve from external sources. Policies must guide decisions about which data the consumer should be able to modify if retrieved from external sources. Likewise, there may be situations in which the consumer wishes to annotate the received data with additional information which would be relevant to their providers. Providers may need to know how to identify information in a PHR which has been entered by the consumer as compared to information provided by a clinician and when access has been blocked.

Translation of Medication Terminology into Layperson Terms

Information retrieved by consumers from external sources may be described in the medical terminology of clinicians, rather than in terms which the consumer can readily understand. There may be a need for the ability to translate retrieved information into layperson's terms, while still preserving the original form of the medical information. Vocabularies and mechanisms to accomplish this translation may need to be compatible with the interoperable vocabularies and standards required to support information exchange between the consumer's PHR and external sources.

Limited Integration of PHRs with Provider Workflows

In order for a care provider to readily retrieve information available in a consumer's PHR, there may need to be some level of integration with the provider's workflow. Barriers to accomplishing this integration today include the lack of EHR penetration into the provider's care settings, as well as, the lack of available interoperable PHR solutions which could exchange the data electronically. Furthermore, providers must be assured that information received via the PHR and other sources is valid, reliable, and accurate.

State Laws Regarding Laboratory Results

State laws would need to be analyzed and potentially altered in order enable timely access to laboratory test results which require clinician interpretation.

4.0 Use Case Perspectives

The Consumer Access to Clinical Information Use Case focuses on communicating the consumer's health information to support interactions among consumers, providers and others who are involved in the consumer's care. The perspectives portrayed are role-based and functional in nature, and are not indicative of physical location. Within the scope of the use case the following perspectives have been defined:

- ***Consumer***

  The consumer perspective includes those who may receive healthcare services and have a PHR which may be used to access and maintain their personal health information. This perspective also includes: caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient in the activities of receiving healthcare and/or using a PHR.

- ***Provider***

  The health care provider perspective includes physicians, nurses and other clinicians, who may need access to clinical information from external sources including the consumer's PHR.

These perspectives are the focus of the events described in the following scenarios.

5.0 Use Case Scenarios

Three scenarios are included in the use case in order to illustrate the need for specific types of information exchanges among the perspectives.

5.1 Scenario 1: Consumer Retrieves Clinical Information

In this scenario, the consumer views and incorporates their health information available from external sources into their PHR. The consumer may chose to identify their PHR(s) of choice in order to receive information automatically from external sources, or receive notifications that new information is available. The consumer may also wish to annotate or request a change to their information retrieved from external sources.

5.2 Scenario 2: Provider List & Permissions

In this scenario, the consumer creates and/or updates their list of providers and determines the access permissions that should be granted to those providers for information in their PHR. The consumer may view logs of who has had access to their information. The scenario also includes a capability to communicate the consumer's access decisions to health information exchanges to implement while carrying out information exchange functions.

5.3 Scenario 3: Transfer PHR Information

In this scenario, the consumer transfers information in an existing PHR (A) to another PHR (B) including provider lists and provider permissions as designated by the consumer.

5.4 Common Processes

The event descriptions in the sections that follow represent a high-level view of healthcare processes that pertain to this use case. In some instances, an event, or a sequence of events, may occur in more than one process, or more than one use case. For the prototype use cases, these common processes have not been specifically recognized. In the forthcoming detailed use cases some common processes will be detailed with the intent that reusable models can be referenced in these and future use cases. Examples of these common processes could include:

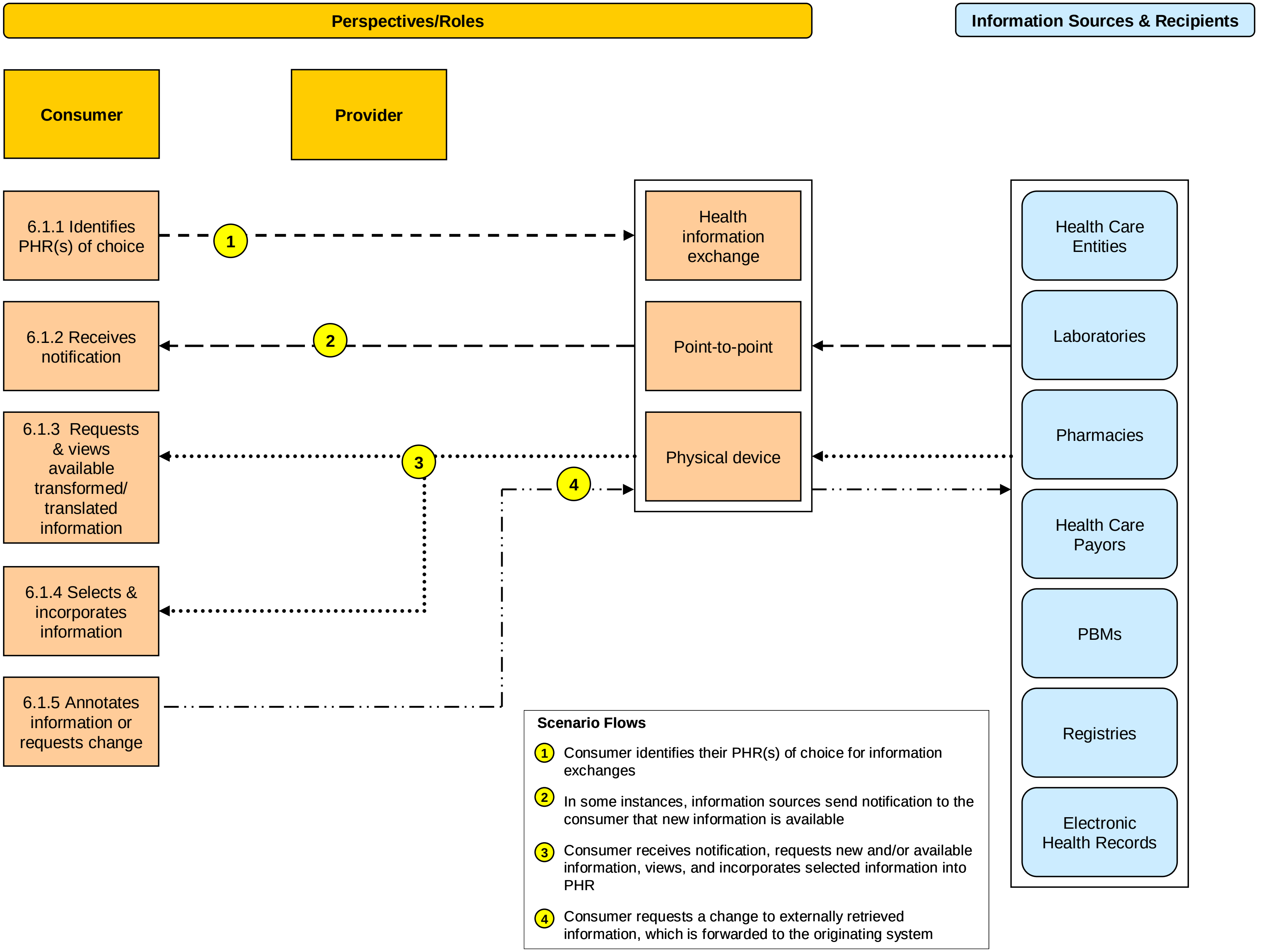
- ***Adjudication of identities***

  Systems involved in exchanging patient-specific information need mechanisms to reconcile person identity between nodes (e.g. between health information service providers).

- ***Create and maintain access control lists***

  Systems involved in information exchange may need a mechanism to provision target systems with information needed to assign access privileges and communicate access control lists to other systems so they can also implement the access controls.

Scenario 1: Consumer Retrieves Clinical Information



Scenario Flows

1. Consumer identifies their PHR(s) of choice for information exchanges
2. In some instances, information sources send notification to the consumer that new information is available
3. Consumer receives notification, requests new and/or available information, views, and incorporates selected information into PHR
4. Consumer requests a change to externally retrieved information, which is forwarded to the originating system

6.0 Scenario 1: Consumer Retrieves Clinical Information

6.1 Consumer Perspective

6.1.1 Identifies PHR(s) of choice

The consumer identifies their PHR(s) of choice in order to inform health information exchanges that this is their preferred location for their personal health record.

Data Exchange: The consumer's PHR(s) of choice are communicated to health information exchanges.

6.1.2 Receives notification

Consumers may find it helpful to receive notifications from external sources that new information is available. Notification may be received via the consumer's PHR or other mechanisms. Consumers may need the option to suspend or stop notification messaging for certain types of messages or situations.

Data Exchange: External information sources send notification to the consumer that new information is available.

6.1.3 Requests and views available transformed/translated information

The consumer requests and views available health information from external sources utilizing their PHR. Information types may include laboratory results, current and previous health problems, diagnosis codes and diagnosis codes translated into layperson terms and medication allergy information.

Data Exchange: Consumer requests and views available information from external sources.

6.1.4 Selects and incorporates information

After viewing the available information, the consumer may select items which they would like to incorporate into their PHR.

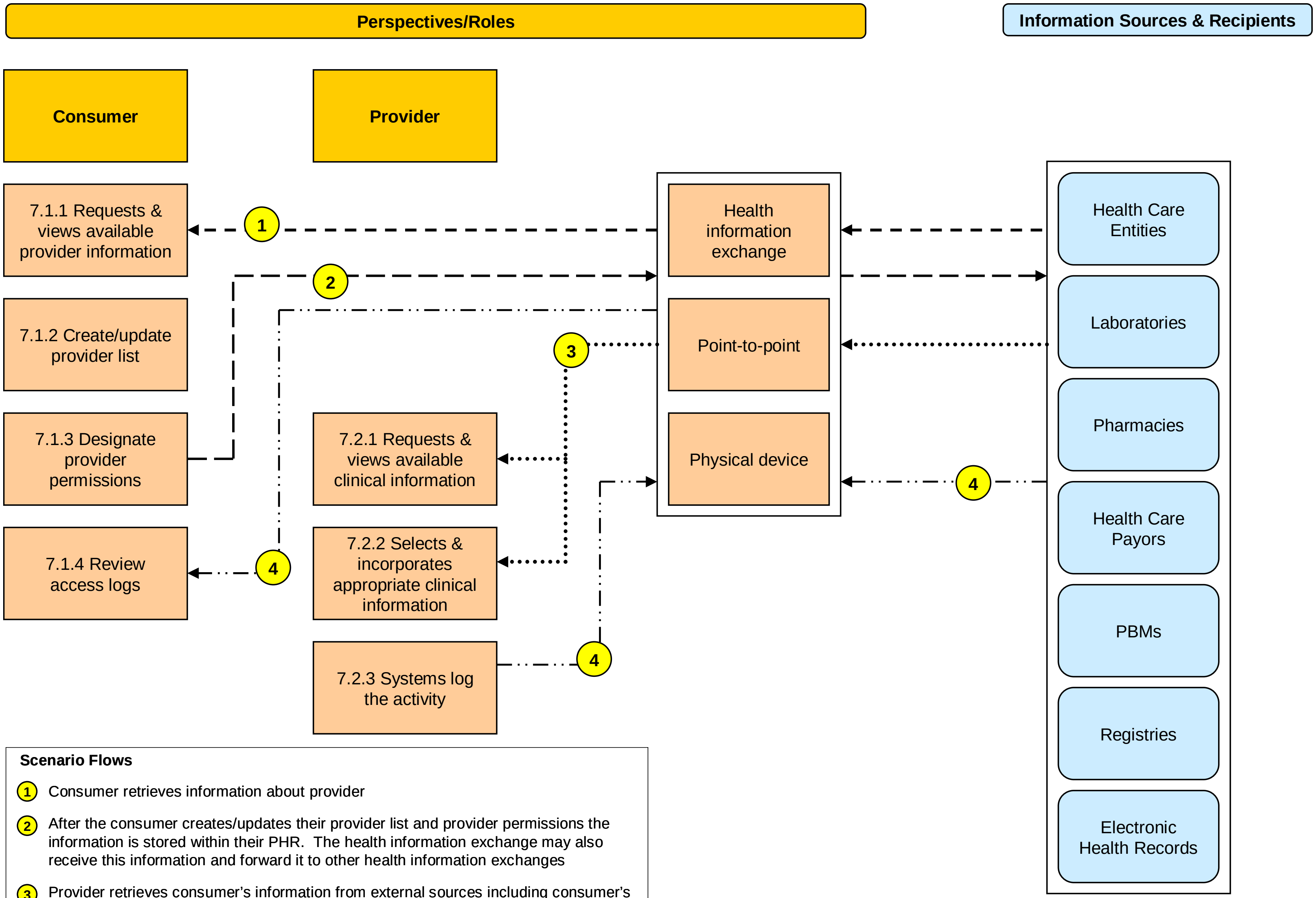
Data Exchange: The selected information is retrieved from external sources and incorporated into the consumer's PHR.

6.1.5 Annotates information or requests change

The consumer may need the capability to annotate the information they have retrieved in order to provide additional clarifying information to providers whom they authorize to retrieve information from their PHR. The consumer may also need the capability to request modifications be made to information retrieved from external sources (e.g. to request corrections to errors or omissions).

Data Exchange: Annotations to retrieved information could be retained in the consumer's PHR and available if the information is subsequently retrieved by their providers. Requests to modify information in external sources could be forwarded from the PHR to the originating external source.

Scenario 2: Provider Lists & Permissions



Perspectives/Roles

Information Sources & Recipients

Consumer

Provider

7.1.1 Requests & views available provider information

7.1.2 Create/update provider list

7.1.3 Designate provider permissions

7.1.4 Review access logs

7.2.1 Requests & views available clinical information

7.2.2 Selects & incorporates appropriate clinical information

7.2.3 Systems log the activity

Health information exchange

Point-to-point

Physical device

Health Care Entities

Laboratories

Pharmacies

Health Care Payors

PBMs

Registries

Electronic Health Records

Scenario Flows

① Consumer retrieves information about provider

② After the consumer creates/updates their provider list and provider permissions the information is stored within their PHR. The health information exchange may also receive this information and forward it to other health information exchanges

③ Provider retrieves consumer's information from external sources including consumer's PHR(s) based on the permissions established by the consumer for that provider

④ Consumer retrieves access logs from PHR, health information exchange and external sources to review who has viewed their information

7.0 Scenario 2: Provider Lists & Permissions

7.1 Consumer Perspective

7.1.1 Consumer requests and views provider information

Using their PHR, the consumer identifies the appropriate provider(s) to add to their provider list. Providers may be individuals or organizations.

Data Exchange: Provider identity information is reconciled with external sources**.**

7.1.2 Creates/updates provider list

The consumer selects the desired provider information and creates/updates their list of providers in their PHR.

Data Exchange: Selected provider information from external sources is stored in the consumer's PHR.

7.1.3 Designates provider permissions

The consumer may wish to designate which information in their PHR can be viewed by which providers. This could be accomplished by assigning roles to providers, by designating access for individual providers, by designating access by type of health information or some other criteria.

Data Exchange: Consumer's decisions about provider permissions are incorporated into the consumer's PHR for implementation when information is requested by authorized providers. These permissions may also be communicated to health information exchanges and other external systems which contain information about the consumer in order to implement the consumer's access decisions during information exchange activities.

7.1.4 Retrieve access logs

The consumer may also need the capability to review access logs which identify who has viewed their health information. The ability to merge or integrate information from multiple logs into a time-sequence or other logical view may also be important for the consumer to fully understand who has accessed their information.

Data Exchange: Access logs from external systems which contain the consumer's information are retrieved for review by the consumer.

7.2 Provider Perspective

7.2.1 Requests and views available clinical information

The provider requests and views available information from the consumer's PHR and external sources based upon access permissions established by the consumer. The information exchanges are logged by the systems involved in this process including the consumer's PHR, health information exchanges and external sources. The provider may need to be aware that some of the consumer's information is not viewable as a result of the consumer's access decisions.

> ***Data Exchange:*** Information is provided from the consumer's PHR based on permissions established by the consumer for that provider.

7.2.2 Selects and incorporates appropriate clinical information

After viewing the available consumer information based upon permissions set by the consumer, the provider may choose to incorporate selected information into the local EHR.

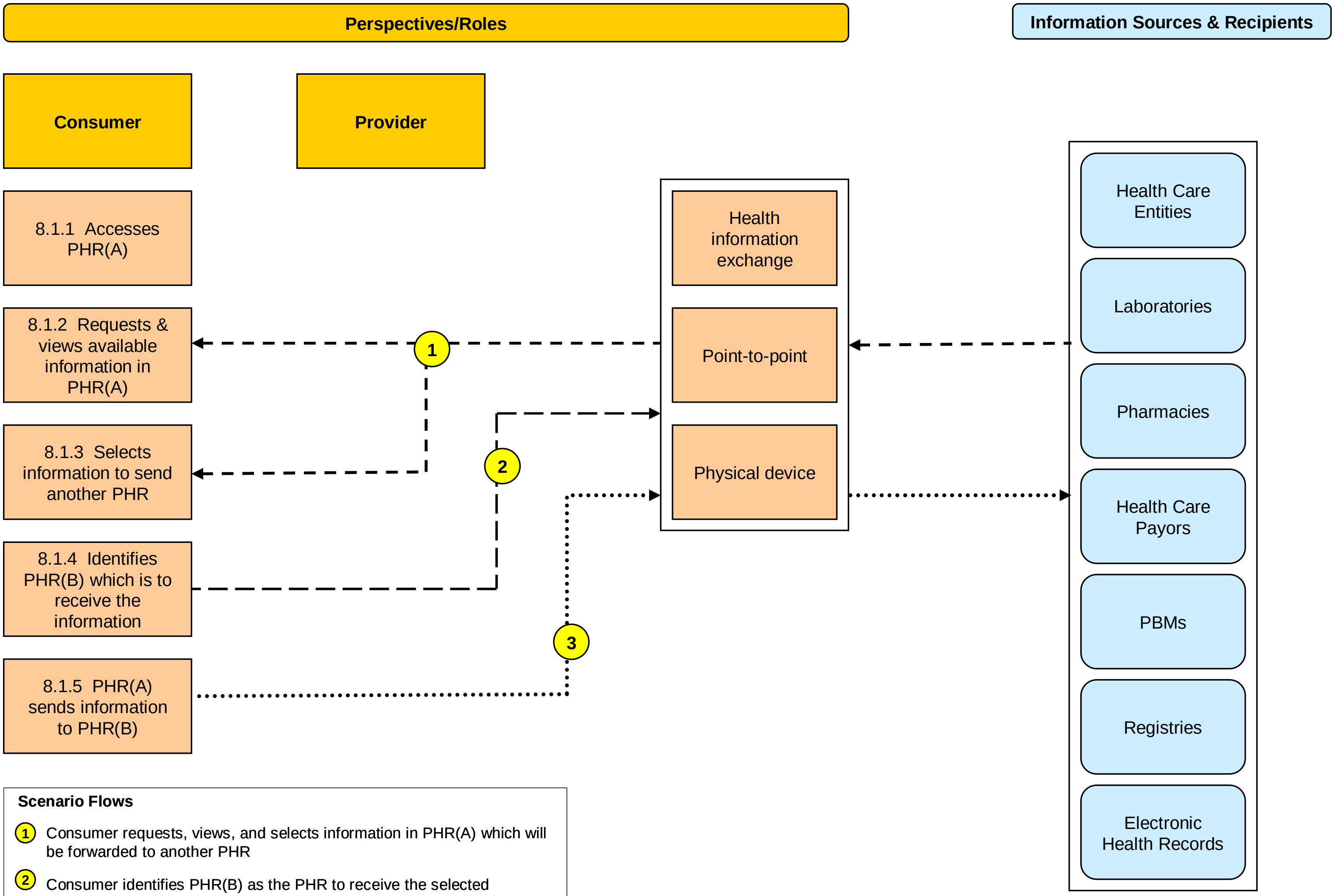
> ***Data Exchange:*** Selected information is retrieve and incorporated into the local EHR.

7.2.3 Systems log the activity

The consumer's PHRs and other systems which provide access to the consumer's information create system logs of the information exchanges. The access logs could be reviewable by the consumer. It may be helpful to combine log information from several systems in order to establish a complete view of who has viewed the consumer's information over a period of time.

> ***Data Exchange:*** Upon consumer request access logs from PHRs, health information exchanges, and external sources are retrieved for review.

Scenario 3: Transfer of PHR Information



Perspectives/Roles

Information Sources & Recipients

Consumer

Provider

8.1.1 Accesses PHR(A)

8.1.2 Requests & views available information in PHR(A)

8.1.3 Selects information to send another PHR

8.1.4 Identifies PHR(B) which is to receive the information

8.1.5 PHR(A) sends information to PHR(B)

Health information exchange

Point-to-point

Physical device

Health Care Entities

Laboratories

Pharmacies

Health Care Payors

PBMs

Registries

Electronic Health Records

Scenario Flows

① Consumer requests, views, and selects information in PHR(A) which will be forwarded to another PHR

② Consumer identifies PHR(B) as the PHR to receive the selected information

③ PHR(A) sends the selected information to PHR(B)

8.0 Scenario 3: Transfer of PHR Information

8.1 Consumer Perspective

8.1.1 Accesses PHR (A)

The consumer accesses an existing PHR (A).

8.1.2 Requests and views available information in PHR (A)

The consumer requests and views their information utilizing the PHR.

Data Exchange: Information available in PHR (A) is provided to the consumer.

8.1.3 Selects information to send another PHR

At some point the consumer decides to move the information in PHR (A) and the consumer selects the information which should be transferred to another PHR (B).

8.1.4 Identifies PHR (B) which is to receive the information

The consumer identifies PHR (B) as the PHR to receive the selected information.

Data Exchange: The electronic address of PHR (B) is identified via health information exchange or other means.

8.1.5 Consumer sends information to PHR (B)

The consumer authorizes PHR (A) to send the selected information to PHR (B). Information may be transmitted as discrete data or summary information data. In addition to clinical and registration information, this may include the provider list and provider permissions as designated by the consumer.

Data Exchange: The selected PHR information is communicated to PHR (B) from PHR (A).

Appendix A: Glossary

AHIC: American Health Information Community.

Ancillary Entities: Organizations that perform an auxiliary role in delivering healthcare services.

Consumer: Members of the public who receive health care services in ambulatory and inpatient environments. This also includes caregivers, patient advocates or surrogates, family members, and other parties who may be acting for, or in support of, a patient.

Data Augmentation: Increasing or supplementing of data usually though manual entry into a system.

Health Information Service Provider: A network service provider that enables or oversees the access to and exchange of health information, in a secure manner, for the purpose of supporting clinician and consumer needs.

Health Information Services (HIS): Services provided by Health Information Networks for information exchange and interoperability.

Health Registries: A health registry is an organized system for the collection, storage, retrieval, analysis, and dissemination of information on individual persons who have either a particular disease, a condition (e.g., a risk factor) that predisposes to the occurrence of a health-related event, or prior exposure to substances (or circumstances) known or suspected to cause adverse health effects.

Healthcare Entities: A collection of organizations that are engaged in or supporting the delivery of healthcare.

Healthcare Information Exchanges: Organizations that may provide trust and governance relationships and information exchange for a network of users and applications. Organizations playing this role may be, but are not limited to, statewide or regional groupings, or geographically diverse networks. Having the role of HIE does not imply that the HIE directly provides networking services.

Information Annotation: Extra information may be associated with the previous information within an EHR/PHR. There may be policies, procedures, regulations, etc. which determine who and what information may be annotated.

Laboratory: A facility that provides controlled conditions in which scientific research, experiments, and measurement may be performed.

Notification Model: A data exchange model where a notification (e-mail, text to PDA, regular mail, etc.) is sent (to a clinician, consumer/patient, network administrator, etc.) alerting participating entities that data is available for retrieval.

Payors: The organization that pays for healthcare claims, may participate as a data or network system of claimed medications, and can act as a provider of PHR services.

Personal Health Record (PHR): A health record that can be created, reviewed, annotated, and maintained by the patient or the care giver for a patient. The personal health record may include any aspect(s) of the health condition, medications, medical problems, allergies, vaccination history, visit history, and other functions such as communications with healthcare providers.

Pharmacy Benefit Managers (PBM): The organization that has delegated authority from the payer to process pharmaceutical claims, intermediary or sub-network to provide data for medication history.

Pharmacy: The organization that dispenses pharmaceuticals to consumers, utilizes data to check for contraindications and allergies, may participate as an intermediary or sub-network provider of data on dispensed medications, or even as a provider of PHR services.

PHR Portability: The ability to transfer PHR data between PHR suppliers such as when consumers change coverage from one health insurer to another health insurer.

Population health: A population health perspective encompasses the ability to assess the health needs of a specific population; implement and evaluate interventions to improve the health of that population; and provide care for individual patients in the context of the culture, health status, and health needs of the populations of which that patient is a member.

Provider: Provider of medical or health services; any person or organization that who furnishes, bills, or is paid for healthcare services.

Registries: A systematic collection of a clearly defined set of health and demographic data for patients with specific health characteristics, held in a central database for a predefined purpose.