

U.S. Department of Health and Human Services

Office of the National Coordinator for Health Information Technology



Remote Monitoring

Draft Detailed Use Case

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1.0 Preface

Use cases developed for the American Health Information Community (AHIC) are based on the priorities expressed by the AHIC, which include needs expressed by the AHIC Workgroups. These high-level use cases focus on the needs of many individuals, organizations, and systems rather than the development of a specific software system. The use cases describe involved stakeholders, information flows, issues, and system needs that apply to the multiple participants in these arenas.

The use cases strive to provide enough detail and context for standards harmonization, certification considerations, architecture specifications and detailed policy discussions to advance the national health information technology (HIT) agenda. These high-level use cases focus, to a significant degree, on the exchange of information between organizations and systems rather than the internal activities of a particular organization or system.

During the January 2007 AHIC meeting, nine priority areas (representing over 200 identified AHIC and AHIC workgroup detailed issues and needs) were discussed and considered. Three of these areas (Consumer Access to Clinical Information, Medication Management, and Quality) were selected for use case development and the final 2007 Detailed Use Cases were published in June, 2007.

The remaining six priority areas from the January 2007 AHIC meeting (Remote Monitoring, Patient-Provider Secure Messaging, Personalized Healthcare, Consultations & Transfers of Care, Public Health Case Reporting, and Immunizations & Response Management) are now being developed into the 2008 Use Cases which will be processed in the national HIT agenda activities in 2008.

The 2008 Use Cases are being developed by the Office of the National Coordinator for Health Information Technology (ONC) with opportunities for review and feedback by interested stakeholders within both the private and public sectors. To facilitate this process, the use cases are being developed in two stages:

- The **Prototype Use Cases** describe the candidate workflows for the use case at a high level, and facilitate initial discussion with stakeholders; and
- The **Detailed Use Cases** document all of the events and actions within the use case at a detailed level.

This document is the Draft Detailed Use Case. Feedback received on the Prototype Use Case has been considered and incorporated where applicable into this document.



This Draft Detailed Use Case is divided into the following sections:

- Section 2.0, Introduction and Scope, describes the priority needs identified by one or more AHIC workgroups and includes draft decisions made regarding the scope of the use case.
- Section 3.0, Use Case Stakeholders, describes individuals and organizations that participate in activities related to the use case and its components.
- Section 4.0, Issues and Obstacles, describes issues or obstacles which may need to be resolved in order to achieve the capabilities described in the use case.
- Section 5.0, Use Case Perspectives, describes how the use case combines similar roles (or actors) to describe their common needs and activities. The roles are intended to describe functional roles rather than organizations or physical entities.
- Section 6.0, Use Case Scenarios, describes how various perspectives interact and exchange information within the context of a workflow. Use case scenarios provide a context for understanding information needs and are not meant to be prescriptive.
- Section 7.0 provides a greater level of detail for each scenario and includes information flows. Specific events and actions for each perspective and scenario are presented and discussed. These are also not intended to be prescriptive.
- Section 8.0, Information Exchange, describes the role of information exchange in the use case at a high level.
- Section 9.0, Dataset Considerations, identifies specific information opportunities relevant to this use case that may support future standardization and harmonization activities.
- Appendix A, the Glossary, provides draft descriptions of key concepts and terms contained in the draft detailed use case.

Following receipt of feedback from interested stakeholders, ONC will develop a final detailed use case.



2.0 Introduction and Scope

In January 2007, the AHIC approved a recommendation to develop a use case addressing remote monitoring. The ability for a clinician to monitor patient information captured remotely, such as physiological, diagnostic, medication tracking, and activities of daily living (ADL) measurements, may be a key enabler for the management of chronic health problems and initial management of new conditions. Remote monitoring may also be a component of maintaining wellness for the aging population. Measurement devices designed for use by the patient or a patient caregiver can communicate measurements to a clinician's electronic health record (EHR) and/or the patient's personal health record (PHR). The Remote Monitoring Detailed Use Case will focus on the communication of interoperable remote monitoring information from applications or devices to the EHR and the PHR.

In specific terms:

- Patients and clinicians may benefit from the ability for the patient to gather and communicate remote monitoring information electronically from measurement devices in a home or other non-clinical setting to a clinician's EHR system and/or to the patient's PHR. Remote monitoring could include, but is not limited to, communication of: physiologic measurements (e.g., weight, blood pressure, heart rate and rhythm, pulse oximetry, glucose, etc.), diagnostic measurements (e.g., transthoracic impedance, etc.) medication tracking device information (e.g., medication pumps, infusion devices, electronic pillboxes, etc.), and activities of daily living measurements (e.g., ADL biosensors, pedometers, sleep actigraphy, etc.).
- Interoperable, user-friendly technologies are needed to enable the flow of information to EHRs and PHRs utilized by clinicians, care coordinators, patients, and family caregivers responsible for their care.

One of the goals of the AHIC is establishing a pathway, based on common data standards, to facilitate the incorporation of interoperable, clinically useful remote monitoring information into EHRs and PHRs to support clinical decision-making and management of patients with chronic conditions. This use case addresses areas for many stakeholders who are active in the development and implementation of EHRs, PHRs, and other remote monitoring tools including those engaged in activities related to standards, interoperability, harmonization, architecture, policy development, and certification.

There are a variety of mechanisms by which the remote monitoring information can be communicated to the EHR or PHR. The most common mechanism is via an information exchange capability provided by a device data intermediary. The device data intermediary serves as the direct interface to extract and store remote monitoring information from the device. The information exchange may provide a mechanism for clinicians and care coordinators (such as case managers, physician office support personnel, clinical call



centers, etc.) to access and review remote monitoring information and determine the information to be communicated to the clinician's EHR, or just a mechanism to access data from many individual devices, and transmit them to different EHRs and PHRs. Remote monitoring information may also be communicated to an EHR or PHR via other health information exchange capabilities or health data banks. Lastly, a remote monitoring device may connect directly to an EHR or PHR via a direct device interface, although this method is less prevalent in the market today. The Remote Monitoring Detailed Use Case will focus on the information needs to communicate information to the EHR or PHR specifically, not the communication from the device itself to an information intermediary.

The demands for remote monitoring information at times support needs for care coordinators or other clinical support personnel who can monitor trends in data. Care coordination can include a variety of tasks; some may be more clinical in nature and support the clinician, while others may be more patient-oriented, and provided by caregivers, call centers, and health plan case managers. "Care coordinators" that serve in this role and are likely to need access to detailed measurements, while clinicians preferences may range from access to comprehensive raw data to a summarized dataset, which may include comments and interpretations provided by the care coordinator. Clinicians may also serve as the care coordinator and perform the functions described in this use case in both the clinician and care coordinator roles.

Decision support capabilities may exist within the device itself, information intermediary or exchange, EHR, or PHR. Decision support may be as simple as threshold testing that accesses remote monitoring data and generates alert information. The design of decision support rules that may utilize remote monitoring information are not within the scope of this use case. However, rules may be set and alert information may be communicated as part of the communication of information to the EHR or PHR.

This use case assumes the developing presence of electronic systems such as EHRs, PHRs, information intermediaries, and other local or Web-based solutions supporting patients and clinicians, while recognizing the issues and obstacles associated with these assumptions.



3.0 Use Case Stakeholders

Figure 3-1. Remote Monitoring Use Case Stakeholders Table

Stakeholder	Contextual Description
Care Coordinators	Individuals who support clinicians in the management of health and disease conditions. These can include case managers and others.
Clinical Support Staff	Individuals who support the workflow of clinicians.
Clinicians	Healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, and other credentialed personnel involved in treating patients.
Consumers	Members of the public that include patients as well as caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient receiving or potentially receiving healthcare services.
Decision Support Tool Providers	Organizations that provide tools to aid in the understanding and treatment of health and disease conditions. These tools encompass a wide range of capabilities that may be useful and available to patients, consumers, clinicians, and other health professionals.
Device Data Intermediary Providers	Organizations that provide a direct device interface to obtain, store, and/or view measurement data from remote devices.
Electronic Health Record Service Providers	Organizations which assist in providing EHR capabilities to consumers. These capabilities may include providing services using information which is gathered/stored from a separate organization. Organizations that provide these capabilities may include: vendors, healthcare providers, health data banks, healthcare payors, etc.
Geographic Health Information Exchange/Regional Health Information Organizations	A multi-stakeholder entity, which may be a free-standing organization (i.e., hospital, healthcare system, partnership organization, etc.) that supports health information exchange and enables the movement of health-related data within state, local, territorial, or jurisdictional participant groups. Activities supporting health information exchanges may also be provided by entities that are separate from geographic health information exchanges/Regional Health Information Organizations including integrated delivery networks, health record banks, and others.



Stakeholder	Contextual Description
Health Record Banks	Entities/mechanisms for holding an individual's lifetime health records. This information may be personally controlled and may reside in various settings such as hospitals, doctor's offices, clinics, etc.
Health Researchers	Organizations or individuals who use health information to conduct research.
Healthcare Entities	Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health programs, school health programs, dental clinics, psychology clinics, care delivery organizations, pharmacies, and other healthcare facilities.
Healthcare Payors	Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations. As part of this role, they provide information on eligibility and coverage for individual consumers, as well as claims-based information on consumer medication history. Case management or disease management may also be supported.
Medical Device Manufacturers/Suppliers	Organizations that design, build, sell, or support the use of medical devices by consumers to support their health needs with coordinated assistance from clinical and other health support personnel.
Patient	Members of the public who receive healthcare services. For hospice providers, the patient and family are considered a single unit of care. Synonyms used by various health care fields include client, resident, customer, patient and family unit, consumer and health care consumer.
Personal Health Record Service Providers	Organizations which assist in providing PHR capabilities to consumers. Organizations that provide these capabilities may include: vendors, healthcare providers, health data banks, healthcare payors, referral management providers, etc.



4.0 Issues and Obstacles

Realizing the full benefits of HIT is dependent on overcoming a number of issues and obstacles in today's environment. Inherent is the premise that some of these issues and obstacles will be cross-cutting and therefore shown in all use cases, while others are unique to this specific use case.

Issues and Obstacles which are applicable across use cases appear below in problem and consequence form:

- **Confidentiality, privacy, and security:**
 - Consumers may require privacy controls for personal health information that govern how patient data is accessed, viewed, and communicated. Privacy controls and the means of restricting data access, which are available for paper-based records, are not currently available for electronic records.
 - Without permissions and controls, consumer participation in the act of electronic health information exchange may be limited.
 - There are regulations concerning the storage, transmission, or destruction of electronic health information. These regulations are inconsistent across federal, state, and local jurisdictions.
 - Without consistent standards, the viewing, accessing, or transmitting of electronic health information may be inhibited.
- **Information integrity, interoperability, and exchange:**
 - Incomplete, inaccurate, or proprietarily-formatted information prevents efficient exchange or utilization of electronic health information.
 - Without data standards that promote compatibility and interoperability, longitudinal patient medical records may be incomplete or of questionable integrity.
- **EHR and HIT adoption:**
 - The processes identified in the use cases rely upon successful integration of EHRs into clinical activities. Because this integration may not align with current workflow and may require additional upfront costs, it may not be widely pursued or implemented.



- Low adoption of HIT, particularly within rural areas and long-term care settings, may create disparate service levels and may adversely affect healthcare for these populations.
- **Lack of business model and infrastructure:**
 - Financial incentives are not currently sufficient to promote the business practices necessary for sustainable HIT.
 - If sufficient reimbursement policies and other financial incentives are not established, HIT adoption may be difficult or unsustainable.
 - Activities involving health information exchange will require additional technical infrastructure, functionality, and robustness, beyond what is currently available.
 - Unless the requisite infrastructure for health information exchange capabilities is established, improved upon, and sustained, these capabilities may have limited success and provide few benefits.
- **Clinical Decision Support:**
 - The capabilities, requirements, and standards needed for consistent development and implementation of Clinical Decision Support have not been identified.
 - The utility and benefits of Clinical Decision Support cannot be fully realized without the development of workflows and standards demonstrating benefits for consumers, patients, and providers.

In addition to the cross-cutting issues and obstacles described above, several other issues or obstacles exist that are specific to this use case.

- **Confidentiality, privacy, and security:**
 - Along with allowing consumers to control who can access their personally controlled health information, the consumer needs to be able to control the specific information that can be accessed. This control is not widely implemented today.
 - Patients may be reluctant to make remote monitoring information accessible to clinicians and care coordinators unless they have adequate assurance that their concerns about confidentiality, privacy and security have been addressed. Patients will want confidentiality,



access control and information describing who has had access to their information.

- Remote monitoring information could be utilized by EHRs and other applications for secondary uses such as research and device safety and recall needs. The use of information for secondary use must be adequately controlled and managed. Standards for these secondary uses do not exist.
 - Without consistent standards, secondary uses of remote monitoring information may be limited and patient privacy could be compromised.
- **Lack of business model and infrastructure:**
 - The development of a clear business case for cost-savings or quality improvement has not been established, as a number of pilot tests are currently being conducted in the market to evaluate the impact of remote monitoring on improved health outcomes and costs.
 - If a business case or quality improvement impacts are not established, remote monitoring adoption may be difficult or unsustainable.
 - All payor programs do not currently reimburse for the purchase, operation, and maintenance of remote monitoring devices for clinician-ordered remote monitoring. Some payors have setup payor-based disease management programs that provide remote monitoring devices and care managers. Health care clinicians may not be reimbursed for time spent with (and expertise provided to) patients to support the remote monitoring of their conditions outside of the office setting.
 - If reimbursement policies and other financial incentives are not established, remote monitoring adoption may be difficult or unsustainable.
- **Data validation, verification, and reliability**
 - As remote monitoring takes place without direct supervision, there is a greater potential risk for self-diagnosis or improper response to monitoring data.
 - Information types generated by remote monitoring devices must be adequately understood by all parties involved in their use including patients, patient surrogates, clinicians, and care coordinators.
 - Mechanisms do not currently exist to ensure that the information transmitted is reliable, accurate, and representative of the appropriate patient. Providing



adequate safeguards to protect the data during information exchange activities is another dimension of this need.

- Clinicians may be reluctant to access remote monitoring information unless they have adequate assurance that the data is valid, accurate, and reliable.
- There should be mechanisms for a clinician and/or care coordinator to determine the source of the data (e.g. device-generated vs. patient-entered data).
 - Clinicians may have preferences regarding acceptance or review of device-generated information due to potential reliability issues associated with patient-entered data.
- Clinicians will want remote monitoring information to be for the right patient, right device, right date/time, and the right/accurate measurement. The device, patient, and provider's identity should be registered and verified before remote monitoring information is acted upon.
 - Without mechanisms to ensure that remote monitoring information is accurate and contains minimal device, calibration, and transmission errors, market adoption of remote monitoring by clinicians may be limited.
- **Remote monitoring data standardization**
 - Currently, a standardized nomenclature for describing devices and data has not been established.
 - Data outputs from devices must also be standardized so widespread use of devices and their data streams is possible with minimal customization of supporting systems.
 - Standards development efforts are needed to develop uniform mechanisms to communicate remote monitoring information. Remote monitoring information from various manufacturers and exchanges need to utilize interoperable data, including the same units of measure to prevent inaccurate or conflicting clinical results.
 - Without standardization of remote monitoring information such as units of measure, adoption of remote monitoring may be segmented among technology providers (brands) and thus overall adoption may be limited.



- Remote monitoring information may need to adhere to medical device reporting requirements requiring the ability of the device and information intermediaries to communicate device identification information to the provider/caregiver for complete disclosure.
 - Without standardization of device identification, the ability to adhere to medical device reporting requirements may be limited.
- Although EHRs and PHRs may be available, a standardized interface for remote monitoring technology is not.
 - A standardized remote monitoring interface with determinations regarding the detail, structure, and quantity of patient information to be stored may not exist with EHRs and PHRs, limiting widespread adoption.
- **Patient/Consumer Education and Support**
 - Patients and family caregivers may require assistance and education in learning how to utilize and calibrate the device to obtain accurate measurements. Assistance or support may also be required subsequent to initial setup at other times during the remote monitoring.
 - Without adequate education and support, remote monitoring information received by clinicians and care coordinators may not be accurate and quality of care may be impacted.
 - Patients, family caregivers, and patient surrogates may require assistance in the registration and setup process to determine the appropriate authentication and authorization controls, identify the authorized recipients of monitoring data, and configuring device connectivity.
 - Inadequate training or assistance may prevent the transmission of remote monitoring information to EHRs and PHRs and limit widespread use and adoption.
- **Medical practice and state laws**
 - Wide-spread remote monitoring may require analysis and change to existing laws and regulations related to treating/monitoring patients and use of remote assessment information despite the clinician's physical location and scope of practice.
 - Medical practice may be inhibited by additional administrative burden and legal concerns regarding clinician responsibility for remote



monitoring information that may be contained within an EHR and use of consumer vs. regulated medical devices.

- **Legal medical record**

- Regulatory and process considerations regarding whether remote monitoring information should be included as part of the legal medical record need to be considered.
 - Without clarity about the scope of the legal medical record, particularly as it relates to remote monitoring data, clinical interpretation, or summary analysis, adoption of remote monitoring by clinicians may be limited.
- Information included in a medical record could include a vetting or attestation step, where a medical professional reviews and accepts the data as part of the record.
 - Clinicians may want to receive notification and choose whether to accept remote monitoring information, especially when it may not be ordered by the clinician (e.g. initiated by the patient, initiated by payor disease management programs, etc.).
- Without the ability for clinicians to specify the desired scope of remote monitoring information, clinicians may be overwhelmed by the amount of non-pertinent information received, or question the reliability of limited information.
 - Unless clinicians have the ability to designate the amount of remote monitoring information that can be accepted into an EHR, such as the ability accept all remote monitoring information or only summary information that has been reviewed or analyzed by a care coordinator, adoption may be limited.



5.0 Use Case Perspectives

The Remote Monitoring Draft Detailed Use Case focuses on the exchange of physiological and other test measurements between patient's monitoring devices and their clinicians (and the clinicians' supporting systems). The use case will describe remote monitoring from three perspectives. The perspectives are representative of roles and functions, rather than organizations or physical locations. Each perspective is described below:

- **Clinician**

The clinician perspective includes physicians, nurses, nurse practitioners, physician assistants, and other clinical personnel who clinically evaluate the remote measurements in the EHR and determine appropriate clinical interventions if needed to manage patient care. Clinicians may also serve as the care coordinator and perform the roles and functions described in this use case in both the clinician and care coordinator perspectives.

- **Care Coordinator**

The care coordinator perspective includes clinically-trained individuals who monitor the information received from the patient's device(s). Care coordinators assist the patient and/or clinician in managing remote monitoring information and could include clinicians, nurses, caregivers, case managers, home health resources, and payor case managers. The care coordinator may help patients understand their conditions, assist with device training, remind patients to take their measurements, and assist patients in following their care plans and treatment regimens. A care coordinator may intervene if measurements indicate that there has been a change in the patient's health status, or if the measurements fall outside of a predetermined range. The care coordinator may also inform the patient's clinician if measurements indicate a potential health issue. Finally, the care coordinator may help determine the need for an immediate face-to-face visit or urgent/emergency care. The care coordinator may determine the relevant information that needs to be communicated to the clinician to determine appropriate clinical interventions. The care coordinator may be the same individual as the clinician responsible for care and management of the patient and could perform the roles and functions described in both the clinician and care coordinator perspectives.

- **Patient**

The patient perspective is comprised of the patient, family caregivers, patient surrogates, advocates, and other parties who may be acting for, or in support of, a patient, who could use a remote monitoring device to gather measurements. These measurements are then communicated to the appropriate clinician's EHR via an information intermediary which could be provided by a device manufacturer or other



entity based upon authorization of the patient. The patient measurements may be taken in various non-clinical settings such as at home, at work, at school, while traveling, or assisted living facilities.

These perspectives are the focus of the events detailed in the scenarios described in Section 6.0.



6.0 Use Case Scenarios

The Remote Monitoring Draft Detailed Use Case focuses upon the exchange of remote monitoring devices used to gather and communicate measurements from the patient's location to the appropriate care coordinators and/or clinicians.

Remote Monitoring

The patient or caregiver prepares the device for use and communication. This may involve registering the device with the manufacturer and/or setting up the communications capabilities of the device. The patient or caregiver uses the remote monitoring device to gather patient measurements. Measurements could be communicated each time the device gathers the data or the accumulated measurements could be communicated periodically (e.g., daily). Measurements could be communicated to an information exchange, such as a device intermediary, to the patient's PHR, or to an EHR directly. The mechanisms to obtain device connectivity and communicate data from the device itself can vary greatly based upon clinical goals and objectives, device types, communication protocols, and manufacturer design. Therefore, direct device connectivity between the information intermediary and the device is not a focus of this use case.

With appropriate safeguards for patient privacy and security, a care coordinator may review the measurement information received via a portal provided by an information intermediary, such as a device data intermediary provided by the device manufacturer or a third party, or within the EHR. Care coordinators may interact directly with the patient or caregivers to verify the information received and gather additional information about the patient's situation.

If a clinician review, analysis, or intervention is needed, remote monitoring information and any additional information about the patient's situation is communicated to the clinician's EHR. The clinician reviews the remote monitoring information received and determines if a patient evaluation or change in treatment plan is necessary. Upon completion of the patient evaluation and modified treatment plan, the appropriate information may be communicated to the care coordinator and the patient's PHR.



7.0 Remote Monitoring

Figure 7-1. Remote Monitoring

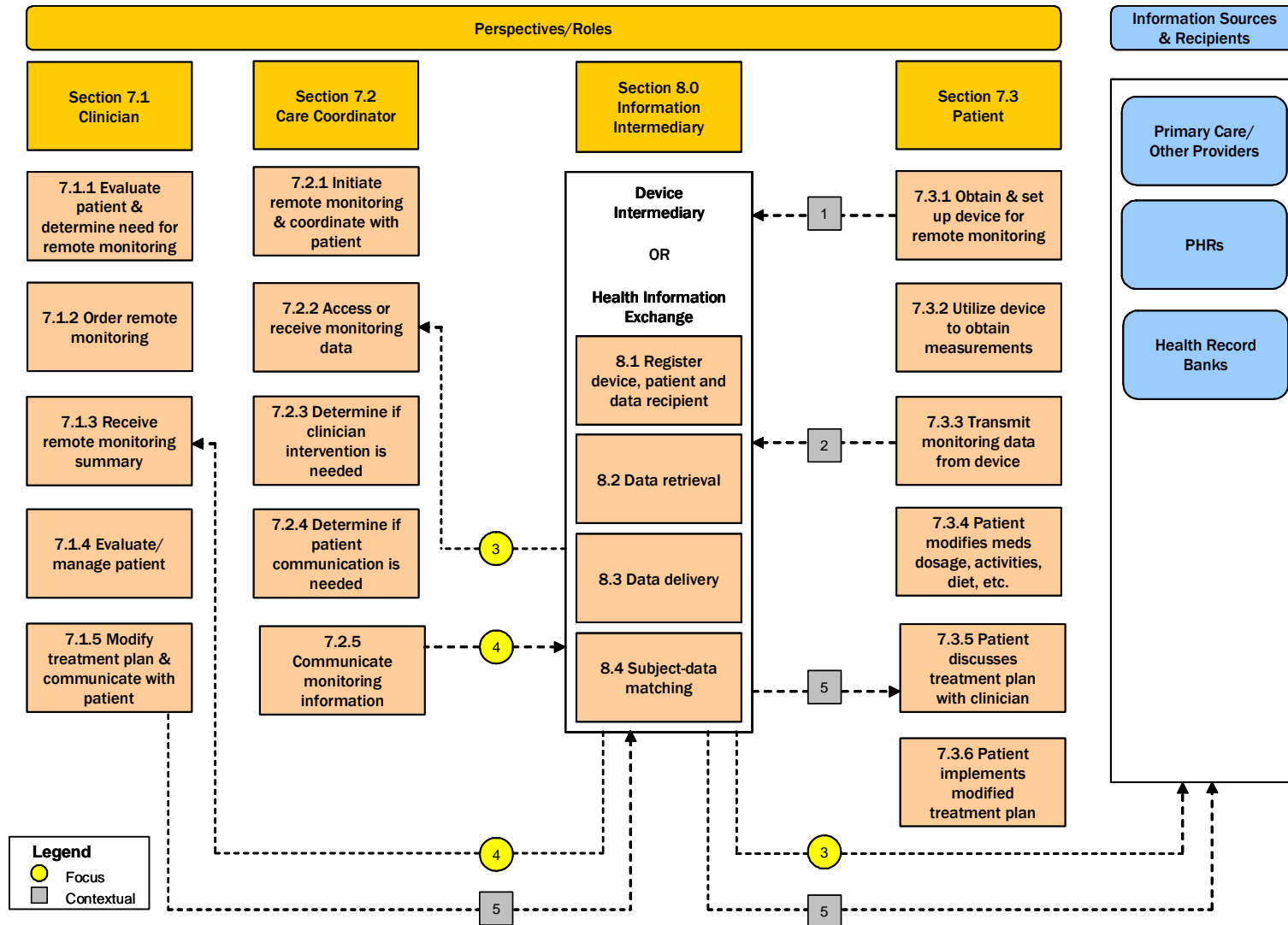




Figure 7-2. Remote Monitoring Scenario Flows

- 1 Patient and device registration information.
- 2 Remote monitoring data originating from device to device manufacturer interface.
- 3 Remote monitoring data is communicated to electronic patient records.
- 4 Monitoring summary information is communicated to the clinician.
- 5 Clinician modifications in treatment plan is communicated to the patient and other recipients.



Figure 7-3. Remote Monitoring, Clinician Perspective

Code	Description	Comments
7.1.1	Event: Evaluate patient and determine need for remote monitoring	
7.1.1.1	Action: Evaluate patient and order tests as appropriate.	The patient is seen by the clinician for a wellness visit, new problem, or follow-up visit for existing condition(s). The clinician may order tests and enact a care plan as appropriate. The care plan may include the prescribing of medications and providing recommendations to the patient for managing their disease or wellness plan (e.g., diet, activity, etc).
7.1.1.2	Action: Evaluate patient and recommend remote monitoring.	The clinician recommends remote monitoring and discusses the process with the patient or family caregiver.
7.1.1.2a	Alternative Action: Receive notice of patient enrollment in remote monitoring or disease management program.	Remote monitoring may be initiated by disease management programs. The disease management program notifies the clinician that the patient has been enrolled in a disease/remote monitoring program.
7.1.1.2b	Alternative Action: Receive notice of patient self-initiated remote monitoring.	The patient may acquire a remote monitoring device with the ability to send the data to a health record bank, device data intermediary, or other methods of information exchange. This may provide a mechanism to send remote monitoring data to clinician EHRs.
7.1.2	Event: Order remote monitoring	
7.1.2.1	Action: Clinician orders remote monitoring.	The clinician orders remote monitoring for the patient. This may involve notification to a care coordinator within the clinician's office or another care coordinator to initiate the remote monitoring process with the patient or patient's caregiver.
7.1.2.1a	Alternative Action: Clinician receives notification of a patient request to send remote monitoring information to the clinician's EHR.	The clinician may choose to accept or deny receipt of patient-initiated remote monitoring data depending upon whether the clinician or clinician office may be responsible for reviewing and monitoring the information.



Code	Description	Comments
7.1.2.2	Action: Clinician performs setup required to accept patient remote monitoring information within the clinician's EHR.	The clinician or support staff establishes required authentication and authorization to receive patient monitoring information within the clinician's EHR. This process may also be accomplished by the care coordinator on the clinician's behalf.
7.1.3	Event: Receive remote monitoring summary	
7.1.3.1	Action: Remote monitoring information is communicated to the clinician's EHR.	Remote monitoring information is received in the clinician's EHR. The clinician may be notified of receipt of remote monitoring information based upon the design or configuration of the clinician's EHR.



Code	Description	Comments
7.1.3.2	<p>Action: Clinician reviews remote monitoring information within the EHR.</p>	<p>The remote monitoring information may be formatted and displayed in the clinician's EHR to facilitate review and interpretation. The information communicated to the clinician's EHR may include all measurements communicated by the patient's device or it may be an excerpted set of measurements identified for clinician review by a care coordinator. If the remote monitoring information was reviewed by a care coordinator, the information received in the EHR may contain assessment information such as a summary of the care coordinator's findings/recommendations, summary of interaction with patient, or specific items for the clinician to consider, etc.</p> <p>The remote monitoring information communicated to the EHR includes data that may or may not be utilized by the decision support to alert the clinician. Alert information may be generated by the device, data intermediary or information exchange and may be communicated to the clinician's EHR.</p> <p>The clinician is able to determine the source of the measurement data (e.g. direct device generated or patient entered), the date/time of the measurement, any patient-entered supporting data.</p> <p>Clinicians can benefit in receiving remote monitoring information from a disparate set of sources and device manufacturers to facilitate review of remote device measurements within an EHR.</p>
7.1.4	<p>Event: Evaluate/manage patient</p>	
7.1.4.1	<p>Action: The clinician may recommend patient follow-up based upon remote information received.</p>	<p>The clinician may recommend that the patient schedule a follow-up office visit, seek urgent/emergency care, or have a discussion regarding the patient's adherence to the recommended care plan (e.g. medications, diet, activity, etc.)</p>



Code	Description	Comments
7.1.4.2	Action: The clinician evaluates the patient.	The clinician evaluates the patient and may order tests, etc. if appropriate.
7.1.5	Event: Modify treatment plan and communicate with patient	
7.1.5.1	Action: The clinician modifies the patient's treatment plan if required.	The clinician may need to modify the patient's care plan based upon remote monitoring information received and evaluation of the patient.
7.1.5.2	Action: The clinician communicates a change in care plan to the patient and other information recipients.	The clinician may update the patient's care plan including modification of medications, etc. The modified care plan and recommendations may be electronically accessed by the patient as described in Consumer Empowerment: Consumer Access to Clinical Information Use Case. The modified care plan information may also need to be communicated to other providers or care coordinators that are managing the patient.

Figure 7-4. Remote Monitoring, Care Coordinator Perspective

Code	Description	Comments
7.2.1	Event: Initiate remote monitoring and coordinate with patient	
7.2.1.1	Action: Initiate remote monitoring for the patient.	The care coordinator may be a clinician support staff member, patient caregiver, or care manager as part of a payor or disease management program. The care coordinator may receive a notification from the patient's clinician to initiate remote monitoring or may initiate remote monitoring as part of a disease management program.
7.2.1.2	Action: Coordinate with patient to setup remote monitoring.	The care coordinator may contact the patient to coordinate acquisition, setup, and any necessary training for the remote monitoring device.



Code	Description	Comments
7.2.1.3	Action: Setup remote monitoring information recipients.	<p>The care coordinator may coordinate with the patient to register the device to communicate measurements to a device data intermediary or information exchange and also set up authorized recipients of remote monitoring information.</p> <p>In some instances, the device may be able to communicate measurements to the clinician's EHR directly. Device registration may still need to occur to setup the recipients of the monitoring information.</p>
7.2.2	Event: Access or receive monitoring information	
7.2.2.1	Action: The care coordinator reviews a patient's remote monitoring information via information intermediary.	A care coordinator may access data via a data intermediary or information exchange to review patient remote monitoring information. The data intermediary may be a device manufacturer portal, other 3rd party application, or health information exchange provided for review of remote monitoring information. The care coordinator must possess the necessary user privileges and authorizations to access patient data. The access and view of remote monitoring data contained within the information intermediary is not a focus of this use case.
7.2.2.1a	Alternative Action: The care coordinator will receive remote monitoring information within an EHR.	A care coordinator will review remote monitoring information within the EHR.
7.2.3	Event: Determine if clinician intervention is needed	
7.2.3.1	Action: The care coordinator may contact a clinician if needed.	A care coordinator may discuss patient care details with the clinician or determine that the patient should seek urgent or emergency care. The care coordinator may have access to decision support alerts that were generated by the device, information intermediary, or EHR based upon the patient measurement data.
7.2.4	Event: Determine if patient communication is needed	



Code	Description	Comments
7.2.4.1	Action: The care coordinator may communicate with the patient to verify remote monitoring information received or discuss care management details.	A care coordinator may contact the patient to validate the measurement data reviewed prior to acting upon any measurements that are a cause for concern. The care coordinator may also contact the patient to determine whether the patient is following the recommended care plan and provide supplemental assistance. The care coordinator may remind the patient to take their measurements, determine additional remote monitoring training needs, validate/manage medication compliance, and follow-up on general chronic care management or wellness items.
7.2.5	Event: Communicate monitoring information	
7.2.5.1	Action: Care coordinator documents summary of clinician and/or patient interaction.	The care coordinator may document a summary of clinician and patient interactions in the EHR or within the information intermediary (e.g., device data intermediary portal, etc.).
7.2.5.2	Action: Care coordinator communicates remote monitoring information and assessment information to the clinician.	The care coordinator may direct the communication of remote monitoring information to the clinician or this may be an automated function. The care coordinator may send all available measurement data, or select a subset to be communicated to the clinician's EHR. Included with the measurement data communicated to the clinician's EHR may be assessment information or recommendations the care coordinator provides the clinician.
7.2.5.2a	Alternative Action: Care coordinator reviews remote monitoring information within the EHR and notifies the clinician.	If the care coordinator has already received the remote monitoring information within the EHR, the care coordinator may need to notify the clinician that follow-up is needed. This may be performed within the EHR or accomplished via other mechanisms such as secure messaging or a phone call.

Figure 7-5. Remote Monitoring, Patient Perspective

Code	Description	Comments
7.3.1	Event: Obtain and set up device for remote monitoring	



Code	Description	Comments
7.3.1.1	Action: Patient obtains remote monitoring device.	A patient may be instructed to begin remote monitoring by a clinician, through a disease management program, or through a self-initiated chronic care or wellness management program. The device may be provided to the patient, or the patient may need to obtain their device on their own.
7.3.1.2	Action: Patient completes education on device use.	The patient may complete self-directed training via instructions or online education, or the patient may receive training from a care coordinator or training program on device use and calibration.
7.3.1.3	Action: Patient sets up the device to communicate measurement information to clinicians and/or care coordinators.	<p>The patient registers the device with an information intermediary to communicate measurement data to the appropriate recipients such as clinicians and care coordinators. The patient may need to establish an identification code, password, and other security measures to enable communication of measurement data. The patient may provide authorization to clinicians and care coordinators to access and/or receive measurement data via the information intermediary or device interface.</p> <p>The device interfaces that collect and transmit measurement information to the information intermediary may include patient identification, device identification, and measurement details that may be needed by clinicians and care coordinators.</p>
7.3.2	Event: Utilize device to obtain measurements	
7.3.2.1	Action: Patient utilizes the device to obtain measurements as directed by his/her clinician or care coordinator.	The patient utilizes the device to obtain measurements as directed. Some devices (e.g. implanted devices, wearable patient monitors, etc.) may not require a patient to actively take a measurement, as they are setup to take passive measurements at predetermined intervals or times.
7.3.3	Event: Transmit monitoring data from device	



Code	Description	Comments
7.3.3.1	Action: Patient measurements are communicated to the information intermediary.	<p>Patient measurements may be communicated to the information intermediary upon patient initiation or may occur passively without patient intervention based upon device. Some devices may provide the ability for patients to provide manual input as part of the measurement, either via the device directly or via a patient-focused application.</p> <p>The patient may access measurement information on the device directly, via a patient-focused application associated with the device. A patient may also receive and view remote monitoring information within the PHR via an information intermediary.</p>
7.3.4	Event: Patient modifies meds, dosage, activities, diet, etc.	
7.3.4.1	Action: Patient self-manages chronic disease or wellness care based upon measurement values.	The patient may modify medication dosage (per clinician instructions), activities, diet, etc. based upon device measurement information and the care plan specified by the clinician.
7.3.4.2	Action: The patient may be contacted by a coordinator to review or modify care management activities.	The patient may be contacted by a care coordinator to verify measurement data or discuss modification of care management such as medication dosage (per clinician instructions), activities, diet, etc. The patient may be instructed to seek urgent/emergency care if appropriate, or schedule a follow-up appointment with a clinician responsible for his/her care.
7.3.5	Event: Patient discusses treatment plan with clinician	
7.3.5.1	Action: Patient discusses treatment or management with their clinician.	The patient is evaluated by their clinician and is provided with an updated care plan.
7.3.5.2	Action: Patient receives modified treatment plan information from a personal clinician.	The patient may electronically access updated treatment plan information may be electronically accessed through the PHR as described in the Consumer Empowerment: Consumer Access to Clinical Information Use Case.



Code	Description	Comments
7.3.6	Event: Patient implements modified treatment plan	
7.3.6.1	Action: Patient implements modified treatment plan and continues remote monitoring participation as directed.	<p>The patient implements the modified treatment plan. Remote monitoring may continue as directed by the patient's clinician and/or care coordinators.</p> <p>The patient may continue to access measurement information on the device directly, via a patient-focused application associated with the device, or via a PHR.</p>



8.0 Information Exchange

This section highlights selected information exchange capabilities which enable the scenarios described in this use case. These functional capabilities may be provided fully or partially by a variety of organizations including data intermediaries, free-standing or geographic health information exchanges (e.g. RHIOs), integrated care delivery networks, provider organizations, health record banks, public health networks, specialty networks, and others supporting these capabilities.

Figure 8-1. Remote Monitoring Information Exchange Capabilities

Code	Capability	Comments
8.1	Register device, patient and data recipient	Capability to maintain information describing the remote monitoring device, the patient being monitored and the individuals who will be reviewing the monitoring data. For example, this may include registering the device with the manufacturer or data intermediary and performing other functions to uniquely identify the individual being monitored.
8.2	Data retrieval – including data lookup, retrieval and data location registries	Capability to locate and retrieve requested data subject to consumer access decisions and local policies. The remote monitoring data is received via the information exchange and associated with the appropriate patient and data recipients. A clinician, care manager, or patient may access remote monitoring and clinical information directly via the information exchange using a portal if available.
8.3	Data delivery – including secure data delivery, confirmation of delivery to EHRs, personally controlled health records, other systems and networks	Capability to securely deliver data to the intended recipient, confirm delivery, including the ability to route data based on message content if required. For example following the care coordinator's evaluation of the remote monitoring data via the information exchange, monitoring information may be delivered to the appropriate clinician's EHR or patient's personally controlled health record.



Code	Capability	Comments
8.4	Subject-data matching	Capability to match available data to the appropriate person during retrieval or routing. For example, when the clinician requests additional clinical information for a specific person, the systems involved in the information exchange confirm that the data available for retrieval match the person of interest to the clinician.

While not described in this section, other capabilities which support information exchange include data integrity and non-repudiation checking; subject and user identity arbitration with like identities during information exchanges; access logging and error handling for data access and exchange; consumer review of disclosure and access logs; and routing consumer requests to correct data.

Device Data Intermediary: These entities provide a direct device interface to obtain, store, and/or view measurement data collected from remote patient devices. In this role, they can be both a conduit for communicating information to EHRs and PHRs and a source of information that can be directly accessed by patients, family caregivers, care coordinators, and clinicians via an access-controlled user interface (e.g. web-based portal, etc.). This stakeholder group includes device manufacturers and other third party entities that have developed device interfaces and associated applications for this purpose.

Health information exchange (HIE): For the purpose of this use case, the functional capability to exchange health information between networks in order to exchange the health information of individuals or populations. These functional capabilities may be provided fully or partially by a variety of organizations including free-standing or geographic health information exchanges (e.g. RHIOs), integrated care delivery networks, provider organizations, health record banks, public health networks, specialty networks, and others supporting these capabilities.

Specialty Network: may provide all, or a portion of the capabilities needed to accomplish the activities involved in the exchange of health information. Specialty networks may focus on the exchange of specific types of health information, may focus on specific patient populations, may focus on the capabilities needed to support specific types of healthcare activities, or may perform a combination of information exchange activities and other services.

Point-to-Point Exchange: A direct link or communication connection with defined endpoints.



9.0 Remote Monitoring Dataset Considerations

To date, there is no established “data set” of elements associated with communication of remote monitoring information to EHRs and PHRs. Remote monitoring information communicated to EHRs and PHRs could include raw data, selections of raw data, alert information, and summary assessments.

For the purposes of addressing the scenarios in this use case, the following information categories may be considered:

- Identification/Remote Monitoring Registration Data
 - Patient ID
 - Provider ID
 - Device ID (Device Type, Brand, Serial Number)
 - Other Identifying Information – Case Manager
 - Other Identifying Information – Device Manufacturer or Intermediary
- Physiological Measurement Data Types and Devices
 - Blood Glucose
 - Blood Pressure
 - Brain Activity (Ambulatory EEG)
 - Cholesterol
 - Esophageal pH
 - Heart Rate
 - Heart Rhythm (AECG, Holter Monitor, Cardiac Implants)
 - ICD Monitoring (Intercardiac Pressure, Intrathoracic Fluid, EGM Waveforms)
 - Lung Function (FEV1, FVC, PEV)
 - Oxygen Saturation
 - Respiration Rhythm



- Temperature
- Weight
- Medication Management and Administration Data and Device Types:
 - Electronic Pillbox – Patient Alerts and Medication Administration Tracking
 - Medication Pumps – Medication Administration
 - Medication Infusion Devices – Medication Administration
- Activities of Daily Living Data and Device Types:
 - ADL Biosensors and Detection Devices
 - Emergency Alerting, GPS
 - Fall Detection
 - Pedometer (Steps Moved)
 - Sleep Actigraphy
- Measurement Metadata – Device-Generated:
 - Device Identification Information
 - Patient Identification Data
 - Date/Time of Measurement
 - Data Source (Device-generated vs. Patient-entered)
 - Measurement Characteristics (Raw vs. Summary Data)
 - Measurement Scale/Units
 - Device Calibration/Programming Data
 - Error Details:
 - Device Malfunction
 - Device not Functioning within Specifications
 - User Error During Measurement



- Measurement Cancelled by Patient (Stopped measurement process or marked measurement as invalid)
- Patient-Entered Metadata:
 - Measurement-Instance Specific Details (e.g., patient-entered accompanying the measurement such as stress level, position, etc.)
 - Measurement Error Details
- EHR and PHR Alerts and Notices
 - Normal Range
 - Normal Range for Patient
 - Alert (Low Value, High Value, Change in Trend)
- Care Coordinator Assessment Information
 - Care Coordinator Reason for Referral/Summary (Care Coordinator Determines Clinician Attention Required)
 - Care Management Program Notification (Patient Has Opted to Participate in Health Plan Care Management Program)
 - Care Manager to Clinician Summary (Summary of Recommendations, Patient Status)



Appendix A: Glossary

These items are included to clarify the intent of this use case. They should not be interpreted as approved terms or definitions but considered as contextual descriptions.

AHIC: American Health Information Community; a federal advisory body chartered in 2005, serving to make recommendations to the Secretary of the U.S. Department of Health and Human Services regarding the development and adoption of health information technology.

Care Coordinators: People who support clinicians in the management of health and disease conditions. These can include case managers and others.

Clinical Support Staff: Individuals who support the workflow of clinicians.

Clinicians: Healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, and other credentialed personnel involved in treating patients.

CMS: Centers for Medicare & Medicaid Services; a federal agency within the Department of Health and Human Services that administers Medicare, Medicaid and the State Children's Health Insurance Program.

Consumers: Members of the public that include patients as well as caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient receiving healthcare services.

Decision Support Tool Providers: Organizations that provide tools to aid in the understanding and treatment of health and disease conditions. These tools encompass a wide range of capabilities that may be useful and available to patients, consumers, clinicians, and other health professionals.

Department of Health and Human Services (HHS): Department of Health and Human Services; the United States federal agency responsible for protecting the health of the nation and providing essential human services with the assistance of its operating divisions that include: Administration for Children and Families (ACF), Administration on Aging (AOA), Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Services (IHS), National Institutes of Health (NIH), Program Support Center (PSC), and Substance Abuse and Mental Health Services Administration (SAMHSA).

Device Data Intermediary Providers: Organizations that provide a direct device interface to obtain, store, and/or view measurement data from remote devices.



Electronic Health Record (EHR): The electronic health record is a longitudinal electronic record of patient health information generated in one or more encounters in any care delivery setting. This information may include patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory information, and radiology reports.

Electronic Health Record (EHR) Service Providers: Organizations which assist in providing EHR capabilities to consumers. These capabilities may include providing services using information which is gathered/stored from a separate organization. Organizations that provide these capabilities may include: vendors, healthcare providers, health data banks, healthcare payors, etc.

FDA: Food and Drug Administration; a federal agency within the Department of Health and Human Services responsible for the safety regulation of foods, dietary supplements, vaccines, drugs, medical devices, veterinary products, biological medical products, blood products and cosmetics.

Geographic Health Information Exchange (HIE)/Regional Health Information Organizations: A multi-stakeholder entity, which may be a free-standing organization (i.e., hospital, healthcare system, partnership organization, etc.) that supports health information exchange and enables the movement of health-related data within state, local, territorial, or jurisdictional participant groups. Activities supporting health information exchanges may also be provided by entities that are separate from geographic health information exchanges/Regional Health Information Organizations including integrated delivery networks, health record banks, and others.

Health Record Banks: Entities/mechanisms for holding an individual's lifetime health records. This information may be personally controlled and may reside in various settings such as hospitals, doctor's offices, clinics, etc.

Health Researchers: Organizations or individuals who use health information to conduct research.

Healthcare Entities: Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health programs, school health programs, dental clinics, psychology clinics, care delivery organizations, pharmacies, home health agencies, hospice care providers, and other healthcare facilities.

Healthcare Payors: Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations. As part of this role, they provide information on eligibility and coverage for individual consumers, as well as claims-based information on



consumer medication history. Case management or disease management may also be supported.

HITSP: The American National Standards Institute (ANSI) Healthcare Information Technology Standards Panel; a body created in 2005 in an effort to promote interoperability and harmonization of healthcare information technology through standards that would serve as a cooperative partnership between the public and private sectors.

Medical Device Manufacturers/Suppliers: Organizations that design, build, sell, or support the use of medical devices by consumers to support their health needs with coordinated assistance from clinical and other health support personnel.

ONC: Office of the National Coordinator for Health Information Technology; serves as the Secretary's principal advisor on the development, application, and use of health information technology in an effort to improve the quality, safety and efficiency of the nations health through the development of an interoperable harmonized health information infrastructure.

Patients: Members of the public who receive healthcare services. For hospice providers, the patient and family are considered a single unit of care. Synonyms used by various health care fields include client, resident, customer, patient and family unit, consumer and health care consumer.

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

Personal Health Record (PHR) Service Providers: Organizations which assist in providing PHR capabilities to consumers. Organizations that provide these capabilities may include: vendors, healthcare providers, health data banks, healthcare payors, referral management providers, etc.