SECTION I – PHR Tool – Required Elements

1. Functionality

At a minimum, the on-line, web-based PHR tool will capture, maintain and display data reflecting the beneficiary's current medical state and history and provide the ability to manage the beneficiary's health information over time. Information may include procedures, diagnoses, surgeries, conditions, and visits to providers whether office, outpatient, or inpatient, as well as other types of health related information referred to in this Solicitation.

1.1. Compile and Manage Beneficiary Information from Medicare Claims History

1.1.1. Receive and display Medicare enrollment, claims, and eligibility data provided by NAS for the initial population of PHR information for the beneficiary.

1.1.2. Receive and display basic demographic, eligibility, and enrollment information including name, date of birth, address, phone number, Medicare health insurance claim number (HICN)

1.1.3. Receive and display pre-populated information from Medicare claims data which could include the available medical service information and related dates including office visits, procedures, diagnoses, hospitalizations, admission and discharge dates, procedures (including surgeries), diagnoses, and laboratory tests (claim information, not test results)

1.1.4. Receive and display the date the diagnosis or service was rendered.

1.1.5. Refresh PHR data a minimum of once a week with new claims information, as it is available, and on a schedule agreed upon with NAS

1.1.6. Receive and display up to two years history if available

1.2. Compile and Manage Information Entered by the Beneficiary

1.2.1. Allow the beneficiary or authorized representative to enter information manually that has not been pre-populated by the PHR tool

1.2.2. Provide the ability to manage information about the beneficiary's social history This may include education, marital status, care giver resources at home, living arrangements, habits such as smoking, recreational drugs and alcohol, sports, hazardous exposure to asbestos, radiation or other chemicals, other health related habits, and other risk factors

1.2.3. Provide the ability to edit or correct the information, and annotate the date that any changes were made

1.2.4. Provide the ability to capture and manage beneficiary entered contact information including name, address, e-mail address, phone numbers, and relationship about an individual or individuals whom the beneficiary considers next of kin or emergency contacts.

1.2.5. Provide the ability to capture and manage information entered by the beneficiary or other authorized users including information not captured in current claims data or information supplementing a limited Medicare claims history

1.2.6. Provide the ability to capture and maintain information entered by the beneficiary or other authorized users about prescription and over-the-counter medications, including brand and generic name, fill and refill dates, vitamins, and supplements

1.2.7. Provide the ability to capture and manage name of the Pharmacy and the Pharmacy phone number entered by the beneficiary

1.2.8. Provide the ability to and maintain the beneficiary's list of known allergens and adverse reactions to medications, animals, insects and other substances; as well as related family history; genetic information

1.2.9. Provide the ability to capture provider information including provider name, address, phone numbers, and specialty

1.2.10. Allow for both structured and unstructured data

1.2.11. Explicitly label data entered by the beneficiary or other authorized user such that it is differentiated from data obtained from claims data or other external sources.

1.3. Authorizations for third parties

1.3.1. Allow the beneficiary to designate authorized providers, family members, or caregivers to view all or part of the record

1.3.2. Ability to track changes that are made to the PHR record by user

1.4. Views of the Personal Health Record

1.4.1. Provide the ability for the beneficiary to maintain an accurate and current view of his or her health habits and risks

1.4.2. Provide the ability to manually sort and/or order lists of information by different criteria

1.4.3. Provide the ability to create customized views of information and summarized information based on sort and filter controls for chronology, reverse chronology, date or date range, condition, provider and care setting or other parameters

1.4.4. Provide the ability to create reports or views of all data based on searching on standard or custom index tags

1.5. Print Capabilities

1.5.1. Provide the ability for the beneficiary and other authorized users to create printable report(s) about their health conditions, medication lists, diagnoses and procedures

1.6. Convert Medical Codes and Terminology

1.6.1. Convert medical codes, clinical data, and standard terminology (such as ICD-9, CPT, HCPCS) into "plain language" that is, common everyday words appropriate for the beneficiary except for necessary technical terms

1.7. Health Education Information or Links to Trusted Sites

1.7.1. Provide access to on-line patient education information or links to familiar and "trusted sites" such as the American Heart Association, American Cancer Society and similar organizations

1.7.2. Provide access to educational information that can be used by the beneficiary to understand his or her condition(s)

1.8. Standard Terminologies

1.8.1. Use standard terminologies to ensure data correctness and to enable semantic interoperability

1.8.1.1 For codes used to identify diagnoses, use The International Classification of Diseases, 9th Revision, Clinical Modifications (ICD-9 CM)

1.8.1.2 For codes used to identify medical services and procedures, use the Current Procedural Terminology (CPT) Fourth Edition (CPT-4)

SECTION II – Highly Recommended Elements

2. Other Features and Content

2.1. Medication/Allergy Information

2.1.1. Ability to import medication data from other sources such as pharmacy benefit managers, pharmacies, Part D plans, or companies that manage pharmaceutical transactions such as RxHub.

2.1.2. Provide drop down lists for fields that will be entered by the individual for certain information, including medications and allergies. Other drop down lists may be provided as well.

2.1.3. Provide the capability for a list of common terms to appear when a beneficiary or authorized user is entering data so that a term can be selected and populated automatically.

2.1.4. Provide the capability for the dose and frequency of medications to be selected and populated automatically

2.1.5. Provide the ability to look up medications to understand uses, contraindications, and side effects.

2.2. Standards

2.2.1. Use standards recognized by HHS Secretary as of January, 2008 relating to providing data to moving data in and out of PHRs (http://hitsp.org/)

- Consumer Empowerment Interoperability Specification (HITSP V2.1 2007 IS03)
- Summary Documents Using CCD Component (HITSP V2.1 2007 C32)
- Patient Demographics Query Transaction (HITSP V2.0 2007 T23)
- Manage Sharing of Documents Transaction Package (HITSP V2.2 2007 TP13)
- Patient ID Cross-Referencing Transaction Package (HITSP V2.0 2007 TP22)
- IHE IT Infrastructure Technical Framework
- Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 3.0
- Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 3.0
- Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0
- Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 XCA Supplement
- Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 4.0 - Registry Stored Query Transaction for XDS Profile Supplement
- International Organization for Standardization (ISO) Electronic business eXtensible Markup Language (ebXML), Technical Specification # 15000 -- Part 4: Registry services specification (ebRS), May, 2004
- Health Care Provider Taxonomy
- CDC Race and Ethnicity Code Sets
- Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity
- Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)
- HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), Release 1.0, April 01, 2007

- American Society for Testing and Materials (ASTM) Standard Specification for Coded Values Used in the Electronic Health Record: # E1633-02

2.3. PHR to PHR Transfer

2.3.1. The beneficiary can transfer the PHR account information to another PHR

2.3.2. The beneficiary can transfer the PHR information to another type of electronic record or file

Section III – PHR Tool – Other Potential Differentiators

3. Other Features

3.1. Authorizations and Consents

3.1.1. Allow the beneficiary to manage documents related to authorizations and consents such as those provided or needed by emergency rooms, providers and other health care organizations to perform services or provide information to others.

3.1.2. Provide the ability to indicate that the beneficiary has granted, withheld or withdrawn completed consent and authorization documents

3.1.3. Provide the ability to view or download the forms on-line

3.1.4. Provide the ability display electronic copies of authorization and/or consent documents associated with a specific clinical activity such as treatment or surgery

3.2. Communication with Providers

3.2.1. Provide the capability to allow for email or other electronic communication with providers through an email connection in the PHR tool.

3.2.2. Provide the ability to send email to providers or other caregivers with a link to information in the PHR tool

3.3. Communication with Medical Devices

3.3.1. Provide the ability to capture and view monitoring device data. Examples include a pedometer recording walking activity, sleep apnea monitor, pill dispensing device that prompts and records medication compliance.

3.4. Family History

3.4.1. Provide the ability to receive and display the beneficiary’s family health history.

3.4.2. Provide the ability to capture major illnesses and cause of death of primary family members (e.g., cancer, smoker, diabetes, high blood pressure, heart conditions)

3.4.3. Provide the ability to enter past medical history information about primary family members such as mother, father, aunt, uncle and grand parents

3.5. Graphic Displays of Clinical Information

3.5.1. Provide for views of clinical information in graphs and charts

3.5.2. Provide the ability to create graphs or charts of clinical information such as laboratory results over time, blood pressure, glucose monitoring.

3.6. Health Risk Assessment On-Line Tool

3.6.1. Provide assessment tool to assess an individual's health status based on self-entered responses to a series of health related questions that will highlight current or potential health and social issues for the beneficiary

3.7. Import data from External Clinical Sources

3.7.1. Allow and manage information captured from outside clinical sources, which may include lab results, radiographic images, EKG, or scanned documents that are captured, annotated and stored as coded and structured documents or unstructured documents

3.7.2. Provide the ability to capture externally sourced clinical documentation as structured content

3.7.3. Provide the ability to capture provider sourced original electronic documents

3.7.4. Provide the ability to search, sort and view the information

3.7.5. Capture provider information such as name, phone number, and specialty from claims or other external sources.

3.7.6. Provide the ability to capture medications data from provider systems, pharmacy benefit management systems or other sources.

3.7.7. Capture timing, route of administration and dose of all medications on the list

3.8. Laboratory Information

3.8.1. Manage results of diagnostic tests

3.8.2. Provide the ability to self-enter laboratory information

3.8.3. Provide the ability to import lab result data from external sources in accordance with jurisdictional laws

3.8.4. Provide the ability to filter results by test type and date

3.8.5. Display normal and abnormal ranges as reported by the source of the data

3.8.6. Display numerical results in graphic form and allow comparison of results

3.9. Personal Observations

3.9.1. The beneficiary can record his or her own health observations (symptoms, vital signs, physical observations, home lab studies such as blood sugars)

3.9.2. Capture self-measured and externally sourced vital signs (blood pressure, heart rate, temperature, severity of pain)

3.10. Dental Services

3.10.1. Allow for self-entry of dental services or past dental health issues.

3.11. Refill Notification

3.11.1. Ability to inform the beneficiary that it may be time to request a prescription refill from a provider

3.11.2. Ability to request a prescription refill electronically

3.12. Delete Self-entered Data

3.12.1. The ability for the beneficiary or authorized user to delete data that has been entered only by them.

3.13. Ability to Change Font Size

3.13.1. The ability for a user to easily change the font size of text on the screen.

3.14. Session Time Out

3.14.1. Provide a means by which the on-line PHR tool would log the user out after a period of non-use (for example15 to 30 minutes of non use)

3.14.2. Notify the user that the session will be timed out if no action is taken within 5 minutes.

3.15. Customized Views

3.15.1. Provide the ability to save customized views for more rapid display of information by the account holder

3.16. Annotate Claims Data

3.16.1. The ability to enter commentary about claims data

3.16.2. The ability to create an entry that disputes claims information and provides the ability to include a rationale.

3.17. Preventive Health Reminders

3.17.1. The on-line PHR tool will send preventive health reminders, based on claims data.

Section IV – PHR Vendor Requirements

4. PHR Privacy and Security Safeguards

4.1. Privacy Policies

4.1.1. Provide PHR vendor Privacy Policy on its Web site

4.2. Data Use Agreement

4.2.1. Meet the requirements outlined in this document and enter into a Data Use Agreement with CMS. A sample Data Use Agreement is provided in Attachment B – Data Use Agreement.

4.2.2. The policies, standards and procedures that pertain to the Data Use Agreement must be executed prior to the disclosure of data from CMS' System of Records to ensure that the disclosure will comply with the requirements of the Privacy Act, the Privacy Rule, and CMS data release policies.

4.2.3. The Data Use Agreement must be completed prior to the release of, or access to, specified data files containing protected health information and individual identifiers.

4.2.4. The Data Use Agreement requires all data recipients to agree to: "establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III--Security of Federal Automated Information Systems (http://www.whitehouse.gov/omb/circulars/a130/a130.html), which sets forth guidelines for security plans for automated information systems in Federal agencies."

4.2.5. Because of the large volume of personal identifiable information to be provided by CMS and risk of unauthorized access to these data, the Data Use Agreement shall further require that, as part of its compliance with Section 7, the PHR Vendor shall provide an assurance that its security controls will conform to the Minimum Security Controls for Moderate-Impact Systems described in Appendix D and Appendix F of NIST Special Publication 800-53, Recommended Information Security Controls for Federal Information Systems. The PHR vendor will agree in the Data Use Agreement to have its compliance with these controls independently tested. Any findings identified as a result of the testing must be corrected before data is provided by NAS according to the terms of this agreement. The PHR vendor will provide NAS with an attestation of its compliance. Additionally, the PHR vendor must agree to annually test its security controls, including its contingency plan, to ensure ongoing compliance.

4.2.6. The PHR vendor will agree to maintain documentation to support its compliance with the NIST requirements along with the results of all testing and corrective actions for vulnerabilities identified in the testing. Required documentation includes but is not limited to a systems security plan describing all procedures to address the NIST 800-53 controls, information security risk assessment, and contingency plan.

4.3. Access to Medicare claims and Eligibility Data

4.3.1. Provide to registered Medicare beneficiaries an operational on-line PHR tool that accesses, stores, and manages protected health information provided by CMS

4.3.2. Require the beneficiaries to register to use the on-line PHR tool, and request that their claims history data be transferred from NAS to the on-line PHR tool.

4.3.3. To identify and authenticate the beneficiary requesting an account with the on-line PHR tool vendor, at a minimum, the following three functions will be performed before Medicare data can be viewed: Beneficiary Registration, Beneficiary Authorization, Beneficiary Login

4.3.3.1. Beneficiary Registration: The PHR tool vendor will require Medicare beneficiaries to register to use the PHR tool through the PHR vendor’s website and require registering beneficiaries to read and accept an Online Services/Web Confidentiality Agreement. The beneficiary authorization process will be triggered when the beneficiary registration is routed to NAS with all required data elements:

- Medicare Health Insurance Claim Number, listed on Medicare card (includes letters and numbers)
- Last Name
- Date of Birth in the format of mm/dd/yyyy
- Gender
- Zip Code
- Email address (required)

4.3.4.2 Beneficiary Authorization: NAS will obtain authorization from the beneficiary to move their data to the PHR vendor's tool . NAS will send a response to the PHR tool vendor that includes eligibility information.

4.3.4.3 Beneficiary Login: The PHR tool vendor will provide this functionality only to valid registered beneficiaries and other users authorized by beneficiaries. The PHR tool vendor will identify and authenticate registered beneficiaries or authorized users against the on-line PHR tool prior to permitting further use of the tool.

4.4. Data Disposition/Destruction

4.4.1. Prior to the conclusion of this project, alternatives must be considered for each participating beneficiary's PHR. If beneficiaries choose to discontinue using their PHR, each participating vendor must remove the CMS-provided data from its on-line PHR tool and provide CMS with an attestation that all protected health information received from CMS has been destroyed.

4.4.2. Alternately the PHR tool vendor may choose to continue to offer the on-line PHR tool to the beneficiary but without the data refresh from CMS. Beneficiaries may also be offered a copy of their CMS data in a format to be determined.

5. Beneficiary Education, Outreach, and Customer Service

5.1. Outreach

5.1.1. The PHR tool vendor will collaborate with the CMS Office of External Affairs in performing outreach. Collaboration may include, but is not limited to, attendance at community based events and the provision of information needed to address frequently asked questions.

5.1.2. Develop and execute a beneficiary outreach and education program to build awareness of and adoption by eligible beneficiaries about the on-line PHR tool, provide information about how to use the on-line PHR tool, and respond to questions or problems about access to, or use of the on-line PHR tool. The target audience for outreach should include both beneficiaries and their caregivers.

5.2. Help Desk Support and Customer Service

5.2.1. Provide Help desk support and customer service for the duration of the pilot.

5.2.2. Provide a 1-800 number during regular business hours for Mountain Time and/or provide on-line customer service to assist beneficiaries in using the PHR tool or resolving technical problems (5 days per week; 9 a.m. to 5:00 p.m. MST). Multiple language capabilities are not required but language capability in multiple languages, especially Spanish, is desirable. The PHR vendor may use existing PHR tool personnel.

5.2.3 Provide customer service support via e-mail

6. Reporting

Submit to NAS regular reports of utilization, education and outreach activities, and service.

6.1. Beneficiary Utilization reports (monthly)

6.1.1. Submit to NAS monthly beneficiary utilization reports containing:

- Number of unique new users;
- Cumulative number of registered users;
- Cumulative number of registered users by age (under 65; 65-74; 75-84; 84 and above;
- Cumulative number of registered users by sex (female/male) if available;
- Cumulative number of registered users who have designated authorized representatives such as other family members or care givers;
- Counts of the number of times per month registered users have accessed the PHR tool (for all beneficiaries and for those beneficiaries using the PHR tool at least twice in past month).

6.2. Outreach Reports (quarterly)

6.2.1. Provide to NAS a schedule of outreach campaign activities with objectives and description of targeted populations (characteristics of targeted population, number of items mailed, etc.). Activities can include all forms of outreach and advertising to include, but not limited to, community based, media based, and e-communication strategies. If outreach includes events, the PHR vendor will report the number of individuals invited and the number who actually attended.

6.2.2. Provide to NAS copies of all materials distributed to beneficiaries each quarter. Materials include those distributed at events, through e-communications, and other forms of advertising. Materials shared are not to be limited to print materials only.

6.3. Customer Service Reports (monthly)

6.3.1. Provide to NAS the number of inbound inquiries to PHR vendor provided 1-800 number and on-line customer service, if offered;

6.3.2. Provide to NAS a high level summary of types of inquiries (access, passwords, how to give access to family member or provider etc).

6.3.3. Provide to NAS the number of complaints each month as well as a summary of the types of complaints received to the extent possible.

7. Participation in PHR Project Evaluation

7.1.1. Participate in the evaluation of this PHR pilot to be conducted by an independent third party vendor.

7.1.2. Make available to the evaluation contractor its key staff with subject matter expertise about the PHR tool functions, security and outreach activities.

7.1.3. Provide screen shots of the PHR tool as requested.

7.1.4. Provide NAS with one “dummy” account for purposes of validating functionality and compliance.

Note: These requirements were developed in part by using the PHR-System Functional Model, Release 1 DSTU May 2008 developed under the guidance of the HL7 EHR Technical Committee and the PHR-S work group. The HL7®Standard, ©2008 Health Level Seven®, Inc. All Rights Reserved. The work group chairs and HL7 headquarters were notified that this draft standard would be referenced in this work.