

**Summary of Responses to an Industry RFI
Regarding a Role for CMS with
Personal Health Records**

Table of Contents

<i>EXECUTIVE SUMMARY</i>	4
<i>1. INTRODUCTION</i>	7
<i>2. CMS ROLE WITH PHRs</i>	9
What PHR functionalities are important for CMS beneficiaries to have available to them?	9
Should CMS provide some PHR type services directly, and if so which ones? For example, CMS currently enables a beneficiary to find out if he or she is eligible for expert-recommended screening tests that are covered by Medicare.....	10
Should CMS identify vendors who can provide appropriate PHRs to our beneficiaries and promote their use by beneficiaries through sharing of CMS data, links to them, communication to beneficiaries about their capabilities, etc?	11
Should CMS make data available to many PHR vendors? If so, should CMS require vendors to be “certified” at some level to ensure that the vendor PHR provides the proper privacy and security safeguards for protecting beneficiary data? If so, how? If not, why not?	11
Should CMS regulate data content for PHRs targeted towards Medicare beneficiaries?	12
<i>3. TECHNOLOGY AND STANDARDS</i>	13
What technologies are available to transmit information to PHRs from other record systems? Are there some technologies used more than others?	13
What data and communication standards exist for the exchange and storage of PHR data among providers, individuals, and PHR vendors?.....	14
What technologies and standards should be supported by CMS?	14
<i>4. DATA CONTENT</i>	15
What pieces of information housed by CMS could be used to populate a PHR?.....	15
How often should the information be updated?	16
What information, beyond claims data and clinical and functional assessment data, should CMS provide to populate a PHR?	16
Should CMS provide “processed” beneficiary data, or should PHR services use claims information as it is received from the provider?	17
<i>5. MARKETING & TRAINING</i>	17
Is the market ready for increased use of PHRs? If not, how can CMS encourage growth of the market?.....	17
What efforts should be undertaken to inform CMS beneficiaries about the benefits of PHRs?.....	19
How can CMS encourage the appropriate use of PHRs by beneficiaries?	19
How can beneficiaries be trained on the use and maintenance of PHRs?	20

Who can CMS best partner with to better publicize PHRs?	21
6. PRIVACY & SECURITY OF INFORMATION.....	22
What methods are currently being used to obtain and track authorization from individuals to use their information to create or populate PHRs?	22
What types of authentication is used to allow an individual to access a PHR? To modify a PHR?	23
How can we assure beneficiaries that their information is adequately protected?	23
What privacy practices do vendors now put in place to protect the information?	24
What security technologies do vendors currently use to protect PHR information?	24
Do the HIPAA privacy and security regulations (45 CFR Part 164) provide a basis for designing the privacy and security aspects for PHRs?	25
7. OTHER ISSUES MENTIONED REGARDING PERSONAL HEALTH RECORDS.....	26
APPENDIX A.....	27
List of Respondents to RFI.....	27
APPENDIX B.....	29
European Union Safe Harbor Framework Principles	29
APPENDIX C.....	31
RFI Published in Fedbizopps	31

EXECUTIVE SUMMARY

Over the past several years there has been a major push by the American public to become more actively involved in their health care. The growth of the Internet, web technologies, and other electronic tools are allowing the public to become more informed and actively engaged in their health care than was possible in the past. The Medicare population has lagged somewhat behind the general public but that is rapidly changing as both beneficiaries and their families are beginning to use the new technologies to get information about conditions and track medication history.

Personal health record systems (PHRs), while still in the early stages of evolution, are poised to grow rapidly over the next several years. At the Centers for Medicare and Medicaid Services (CMS) we need to ensure that our policies and operations support our beneficiaries' use of PHRs. We are currently trying to determine what the agency's role or roles should be to best provide the proper level of support. It is also important to ensure that CMS' efforts are coordinated with other HHS PHR activities, especially those promoted by the Office of the National Coordinator and the American Health Information Community.

On August 16, 2005, CMS published a Request for Information (RFI) to obtain public feedback on our role regarding PHRs. Fifty-one organizations responded, including small and large vendors, health plans, provider organizations, and trade associations. We asked for information in five general areas - CMS's role with PHRs, Technology and Standards, PHR Data Content, Marketing and Training, and Privacy and Security of Information.

A key point made by many respondents was the lack of an industry agreed upon definition of a PHR, and the boundaries between a PHR and an Electronic Health Record (EHR). Consensus on this point will be needed to enable the industry to move forward in implementation. The following summarizes the major feedback from the respondents:

CMS's role with PHRs

Most respondents were very clear that CMS's role should be limited to that of providing data to outside PHR vendors. The majority of respondents agreed that it was a good idea for CMS to identify and promote the use of vendors who can provide appropriate PHRs, as it would further encourage their use.

Respondents indicated that enabling beneficiaries to understand and manage their health care should lead to improved quality and efficiencies in their care. This would be increasingly important as more and more individuals move to consumer-directed health care models (higher deductible health plans, health savings accounts, etc.). The issue of patient control was paramount – that it is critical for beneficiaries (or other authorized parties) to control the input and output of the PHR.

Technology and Standards

Respondents urged CMS to use open standards, and collaborate with industry groups on the development of consensus standards for the exchange and storage of PHR data. There are numerous possibilities for data and communication standards for PHRs, but no set of consensus standards.

PHR Data Content

While claims information is considered necessary for populating PHRs, additional information is necessary to fully realize all of the benefits of a PHR. CMS should consider providing additional demographic, program benefit, and quality information on as timely a basis as possible. Whatever information CMS provides, the ultimate presentation of that information needs to be understandable to the end user of the information; i.e., the beneficiary.

Marketing and Training

Respondents felt that consumer education is a key factor in driving the demand for PHRs, education that addresses both the benefits and risks of the technology so that individuals can make informed choices. It was suggested that outreach efforts should target both providers and beneficiaries. This could be provided directly by CMS or through partnerships. Incentives to beneficiaries and providers for the use of PHRs would also encourage use. Pilot tests and segmented roll outs would allow CMS to demonstrate the values to smaller groups of beneficiaries. The results of these smaller tests could be used to fine tune marketing and training packages to better encourage participation and use throughout the Medicare program.

Privacy & Security of Information

Respondents felt that CMS should assure Medicare beneficiaries that their information will be safe if they use a PHR. They recommended CMS support high standards for certification of PHR vendors, that any participating entity would need to sign an agreement of compliance, and that CMS should monitor ongoing compliance with privacy and security standards for every entity that receives CMS information. Such agreements of compliance would need to include provisions that entities meet HIPAA privacy and security standards, data is used appropriately, and that audit trails are maintained and are available for inspection.

The remainder of this document provides more detail on the responses for each of the above areas. It is important to note this document is a summary of responses and does not necessarily reflect CMS positions or future plans. CMS is using information gathered from the RFI and other sources to develop a PHR action plan. The action plan will focus on ways that CMS can help promote the growth of PHRs and ensure that our beneficiary needs are supported. The plan will lay out activities that CMS will be doing over the next

several years. Questions on this document should be directed to Mr. Stanley Nachimson at 410-786-6153 or stanley.nachimson@cms.hhs.gov.

1. INTRODUCTION

CMS is the largest purchaser of health care in the United States, and as such has a significant interest in the health and well being of its Medicare beneficiaries. In addition, CMS has one of the largest stores of health data in the country, with robust claims history for all of its Medicare beneficiaries. With the addition of the prescription drug benefit in 2006, CMS will have claims information on virtually all types of services that Medicare beneficiaries receive. CMS also has extensive claims history data on Medicaid beneficiaries.

Because of our position, CMS is looking for ways to make its information more available and more useful to our beneficiary population. One area we are investigating is personal health records (PHR). In particular, CMS would like to determine what role(s) the agency should play in this area – in what ways would Medicare claims data be useful in the creation, maintenance and use of personal health records for our beneficiary population.

While CMS is currently testing a Medicare Beneficiary Portal, the intent of that portal is limited to providing only Medicare information that CMS stores or collects, such as claim information or benefit information. It is not intended as a complete personal health history for an individual.

There are significant technical and policy issues involved in this determining the appropriate role for CMS. As there is already private sector activity in this area, CMS would like to assess how to leverage that activity to further PHRs, and their use, for Medicare beneficiaries. On August 16, CMS published a Request for Information (RFI) regarding our role regarding Personal Health Records. Our purpose was to assist us in determining how we should proceed on participating with existing PHRs, or fostering the development of PHRs which focus on the needs of the Medicare population.

This document is a summary of the information received in response to the RFI. Note that these are the views of the respondents, not necessarily the views of CMS. We intend to use this information to assist us in developing our strategy for CMS's participation in fostering the development of PHRs for the Medicare population.

While not specifically asked, the issue of what is a PHR is a critical issue expressed by several responders. There is not yet an industry consensus definition of what a PHR is, and the boundaries between the EHR and the PHR. This will be critical to CMS to determine some set of boundaries, so that we can determine who we will provide data to, who beneficiaries can use as PHR vendors, and the costs and benefits of a PHR. One of the respondents provided some suggested attributes of a PHR, which include:

1. Each person controls his or her own PHR.
2. PHRs contain information from one's entire lifetime.
3. PHRs contain information from all health care providers.

4. PHRs are accessible from any place at any time.
5. PHRs are private and secure.
6. PHRs are “transparent.” Individuals can see who entered each piece of data, where it was transferred from, and who has viewed it.
7. PHRs permit easy exchange of information with other health information systems and health professionals.

The RFI was intended to reach a wide audience to provide feedback to CMS. We were pleased with the response. There were 51 responses to the RFI from small and large vendors, health plans, provider organizations, and trade associations. Appendix A contains a list of the respondents.

We asked for information in 5 general areas - CMS’s role with PHRs, Technology and Standards, PHR Data Content, Marketing and Training, and Privacy and Security of Information. What follows is the summary of responses to the questions in the RFI for each area, along with some additional issues which were identified.

2. CMS ROLE WITH PHRs

Question 1

What PHR functionalities are important for CMS beneficiaries to have available to them?

This question provoked a wide range of responses. While several suggested that CMS convene focus groups to make this determination, and others suggested that CMS either work with standard developing organizations (SDOs) to develop standards for a PHR, or develop a reference model for the PHR, there were many suggestions for PHR functionalities beyond the storage of information. These were summarized nicely by one respondent that stated a PHR is a “tool for beneficiaries to help them manage their health care.” Respondents indicated that enabling beneficiaries to understand and manage their health care should lead to improved quality and efficiencies in their care. This would be increasingly important as more and more individuals move to consumer-directed health care models (higher deductible health plans, health savings accounts, etc.).

Along these lines, respondents provided a wide variety of PHR functionalities that are important for CMS beneficiaries. Most respondents suggested the following:

- Health history, as current as possible
- Medication listing
- Health plan membership
- Health plan coverage information
- Health plan benefit availability
- Preventive care reminders
- Links to trusted medical information based on health history
- Allergies/Immunizations

A smaller number of respondents suggested the inclusion of:

- Provider availability
- Provider/quality performance indicators
- Medical alerts
- Medical decision aids

And one or two suggested the inclusion of financial information such as:

- Sources of payment (HSA, health plan, etc)
- Status of deductibles
- Claim payment status

It seems clear that the respondents believe there is a need for a robust PHR for CMS beneficiaries that will enable them to take a much more active role in their health care activities. The view that a PHR is simply a storehouse of clinical information was rejected.

Along with the functionalities for the PHR as a whole, there was much discussion of the input and output capabilities for PHRs. The issue of patient control was paramount – that it is critical for beneficiaries (or other authorized parties) to control the input and output of the PHR. Several respondents mentioned the need for emergency access to the information, which was also discussed in the responses regarding privacy and security. While it would be necessary for individuals to have the capability to input and edit information, many respondents stressed the need for the PHR to have the ability to accept information from health plans, pharmacy vendors, and providers. They stressed the need for interoperability (for PHRs and EHRs, between PHRs, etc.) and the need for standards. Several respondents mentioned that most information in a PHR should be updated electronically from provider or health plan information, not rely on a beneficiary to continually update the information.

As will be discussed in the next section, standards are looked at as a key to PHR success. Respondents stressed the need for CMS to participate in the standards process to define PHRs and data exchanges, and for CMS to support industry standards. They felt the need for CMS to define and empower the PHR market, as the agency is looked upon as a major force in the industry. With CMS supporting these efforts, more vendors would participate, and other health plans would follow the CMS lead.

Question 2

Should CMS provide some PHR type services directly, and if so which ones? For example, CMS currently enables a beneficiary to find out if he or she is eligible for expert-recommended screening tests that are covered by Medicare.

Most respondents were very clear that CMS's role should be limited to that of providing data to outside PHR vendors. CMS should not be a direct provider of PHR services, as these should be private sector activities, and CMS does not have the expertise to perform these services. The general consensus was that PHR vendors are already operating in the industry and have established a number of products. Beneficiaries should have the choice of those products, and CMS should simply provide the data to populate PHRs. One respondent suggested that CMS contract with some outside entities to be data wholesalers, to retain some control over data distribution and quality.

Some respondents did see a limited role for CMS to provide some PHR services directly, generally administrative information that CMS already is providing on a routine basis such as eligibility or claim status. Some respondents mentioned the Medicare Beneficiary Portal that CMS has made available, but suggested that even that information be available from CMS for download to a PHR. Other suggested information that CMS should provide directly included demographics, treatment options, quality of care indicators, drug and formulary information, notification of overdue tests, and crossover information. However, the greater involvement for CMS was in the provision of data, and the standardization of that data.

Question 3

Should CMS identify vendors who can provide appropriate PHRs to our beneficiaries and promote their use by beneficiaries through sharing of CMS data, links to them, communication to beneficiaries about their capabilities, etc?

The majority of respondents agreed that it was a good idea for CMS to identify and promote the use of vendors who can provide appropriate PHRs, as it would further encourage their use. They argued that this would be beneficial because it would:

- Identify those who meet standards to encourage use of standards
- Identify and catalogue PHR vendors who have some unique capabilities
- Identify qualified vendors to establish public trust
- Identify especially PHRs linked to EHRs, as this is an important function for a PHR to have
- Identify and provide a consumer selection tool to beneficiaries to assist them in their selection of PHRs
- Raise the market bar to encourage more robust and complete PHRs

The minority of respondents who opposed vendor identification had some specific reasons for their point of view. They preferred that CMS take a more limited role for several reasons, including:

- CMS should not assume any risk for identification
- CMS should focus only on establishing standards, not identifying vendors who may or may not meet those standards.
- CMS should control access to PHRs through the Medicare.gov portal, only allowing access to certain vendors.
- CMS should not set any limits or have any lists of vendors, as this could stifle innovation.

Question 4

Should CMS make data available to many PHR vendors? If so, should CMS require vendors to be “certified” at some level to ensure that the vendor PHR provides the proper privacy and security safeguards for protecting beneficiary data? If so, how? If not, why not?

Most respondents did agree on the need for some method of approval or certification, as this could provide further assurance of data security and privacy, and make beneficiaries more comfortable in signing up and using PHRs. Those respondents that recommended certification did not provide much guidance as to how the vendors were to be certified. Many placed the responsibility on CMS; others suggested using the same organizations that certify EHRs to provide some consistency in the certification process.

The answers to this question were tied somewhat to the responses to the previous question. Since many of the respondents suggested that CMS publicize only those vendors who were certified, they also recommended that CMS only provide data to certified vendors. Many respondents suggested limiting data to those vendors that met

industry standards, or were approved by CMS. This would encourage vendors to meet standards, assuring greater privacy and security of information. One respondent argued for a select few suppliers that could demonstrate interoperability, standards adherence, and security.

There were respondents who did not see the need for any limitation on the provision of CMS data to vendors. They felt that CMS was obligated to provide data to any vendor who could accept it and was approved by a beneficiary to receive it. Others felt that it would be a boost to the industry, and encourage the growth of PHRs, if CMS agreed to make data available to almost any vendor.

Question 5

Should CMS regulate data content for PHRs targeted towards Medicare beneficiaries?

There was not a clear direction on the answer to this question. Respondents were split almost evenly as to whether CMS should regulate the data content for PHRs. Many felt that CMS should leave the data decisions to a variety of entities, ranging from the market (i.e. those vendors with the best data content would be most popular), to the beneficiaries themselves, stating that a personal health record should be just that – personal. Others felt that CMS should participate in the standards development for data content, but leave the final decision to the standards organizations, and enforce those decisions through certification. Some felt that as long as standards for data exchange with CMS, interoperability, privacy, and security were developed and followed, the data content need not be controlled by CMS.

There were about as many respondents who felt that CMS should regulate the data content of PHRs. They felt it was CMS's responsibility to determine and approve data content. Concerns were raised that if there was no regulation, PHRs could contain advertising information and marketing information which could make beneficiaries uncomfortable. They stressed the need for the data content being applicable to support the creation of standardized EHRs and its use as part of the National Health Information Network. Several suggested that CMS create a minimum data set for PHRs, to set a baseline standard for vendors. The vendors could build PHRs beyond the minimum, but all PHRs would need to contain at least the minimum data set.

3. TECHNOLOGY AND STANDARDS

Question 1

What technologies are available to transmit information to PHRs from other record systems? Are there some technologies used more than others?

Responders provided a wide range of answers to this question, indicating the early stages that this industry is in. While most respondents indicated some sort of a web based solutions, there were also calls for other types of technologies. Many mentioned USB drives as a portable technology. There were frequent reminders of the need to allow manual entry by individuals, the capacity for scanning technology, and the means for direct downloads to home based PC systems. Web services were the predominant communication method discussed by the respondents. They provided a range of technologies to be used. HTTP, FTP, SOAP, XML, WSDL, UDDI were all frequently mentioned. These technologies were advocated as they are standards supported, can be made secure, and are in use in other industries. There were suggestions that APIs and .NET toolkits be developed provided for vendors to use to achieve further standardization in the industry.

One respondent proposed the use of mobile telephone devices to deliver information like laboratory results and reminders of appointments and necessary medical services. With the increasing use of mobile phones, this could provide a way to quickly notify beneficiaries (or their representatives) of important medical events. Another respondent touted the establishment of a Medicare smart card as potential holder of data for a PHR, suggesting that CMS issue these to all Medicare beneficiaries as an ID card. Another responder insisted that a central database accessible only through the web is the only viable model, that individuals' storing data or any type of distributed system is not a workable solution as it would encounter significant problems with interoperability. Several current military initiatives were mentioned as potential models for PHRs – TACMEDcs which uses an RFID chip, and Composite Health Care System II. There was a general recognition that open standards must be agreed upon by the industry and supported by CMS.

One initiative mentioned was “Integrating the Healthcare Enterprise (IHE)”. IHE is a multi-year, global initiative that creates the framework for passing vital health information data seamlessly – from application to application, system to system, and setting to setting – across multiple healthcare enterprises. This initiative involves developing integration profiles which allow different systems to talk to each other through the use of standards. This was offered as a model to use in having disparate provider and health plan systems integrate with PHR systems.

Many respondents mentioned the need that any method must be secure, and advocated the use of Virtual Private Networks (VPNs) for the transmission of data, rather than through a less secure public Internet connection.

There was very little discussion of the second part of this question. No technologies were advocated as being used more than others, although the web services were discussed the most as having the potential for use.

Question 2

What data and communication standards exist for the exchange and storage of PHR data among providers, individuals, and PHR vendors?

There was a wide variety of responses to this question, indicating again that there are numerous possibilities for data and communication standards for PHRs, but no set of consensus standards. HL7 was mentioned most often in the responses, specifically its Clinical Document Architecture (CDA), but other relatively well known standards such as DICOM (for images), NCPDP (for pharmacy transactions), X12 (for administrative transactions), IEEE (for device transmission), and ASTM's Continuity of Care Record (CCR) were also prominently mentioned in the responses. These standards were mentioned as possibilities because they are relatively mature and well-known, and maintained by recognized organizations. The VHA Healthcare Information Model was mentioned as a UML messaging based model compliant with HL7 and XML.

These standards are generally used for data structure and content. Coding standards mentioned included SNOMED, LOINC, ICD, and CPT, and RxNorm. These coding standards are generally well known and are in the widest use in the industry for coding of medical procedures, diagnoses, and laboratory tests. In addition, the Federal Government has supported SNOMED thru the purchase of a license for nationwide use.

Question 3

What technologies and standards should be supported by CMS?

Many respondents repeated their answers from the previous question, without narrowing the list of technologies and standards. However, those that did provide some direction to CMS urged the use of open standards and collaboration with industry groups. There was also a call for CMS to develop use cases to facilitate PHR adoption. There was a strong bias towards ASTM's CCR as the standard for the personal health record, with somewhat less of a mention of the HL7 CDA approach. Note: recently, HL7 and ASTM have agreed to cooperate with HL7 creating a CDA document to use the CCR.

Other specific suggestions included:

- SOAP based technology encrypted by SSL and/or VPN
- A web-based approach using published metadata formats (ebXML, SOAP, CCR).
- XML over HTTPS
- The HL7- Object Management Groups "Health Services Specification Project"

These approaches were suggested because of their strong focus on standards and that each could be made secure.

There was also a suggestion that CMS stay away from technology standards and focus only on functional standards. This would allow vendors to use the technology they felt most appropriate, and allow for innovation and the use of new technologies as they are developed.

4. DATA CONTENT

Question 1

What pieces of information housed by CMS could be used to populate a PHR?

Several respondents indicated that CMS should simply make all of its data available, allowing vendors to determine what to present and what not to present in a PHR. There were also detailed responses that provided specific suggestions for CMS data. Some respondents were not ready to provide specifics, and suggested that CMS conduct surveys of beneficiaries to determine data needs, or work with their organizations to determine the data to be provided.

The data to be provided is based on the suggested functions of a PHR, as was discussed in the previous section on PHR functionalities. The basic function is to serve as a storehouse of beneficiary health information. All respondents recognized that information on Medicare claims was a necessary for populating PHRs, although not all respondents felt that all of the information on the claim was necessary to provide. Some respondents focused on procedure and diagnosis codes, with suggestions to provide interpretation of those codes, rather than just the code itself. The upcoming drug benefit can provide medication data which would prove valuable to beneficiaries in a PHR. Several respondents indicated that the HIPAA designated record set was the appropriate information to provide outside the agency. This is the data that would be most appropriate for a PHR that served as a record of a beneficiary's medical or health history.

As was stated in Section 2, many respondents believed that the PHR should do much more than simply keep a record of medical history. To fully realize the additional functions of a PHR, much more information would need to be provided. The additional information beyond the claim information would include:

- Demographic information (age, etc.)
- Benefit information – what benefits Medicare provides.
- Third party insurance information, so both the individual and provider would know financial responsibility
- Immunization history
- Nursing home and home health functional assessments required to be submitted to CMS
- Health maintenance reminders, to allow beneficiaries to better manage their health.
- Consents for medical procedures, DNR, etc.

- Lists of physicians seen, to provide a contact list
- Laboratory test results
- Special needs information
- Physician plans of care for home health
- Home health and nursing home admissions
- Financial status (deductible, etc.)

Question 2

How often should the information be updated?

Many respondents answered this question with the ideal update – on a real time basis, as soon as a beneficiary accesses the health care system. Others requested that CMS make the data available as soon as it is received.

There were also suggestions for daily, weekly, or monthly updates, depending on the information. Medicare eligibility and benefits do not change often, so that update need not be done frequently. However, items like laboratory results should be updated frequently. There was a consistent message that updates need to be done as soon as possible to keep a PHR relevant and allow individuals to have an up to date record of their health and medical history.

There was considerable support for automatic updating of PHRs so that beneficiaries would not be responsible for the update process. What CMS could provide is the continuous or periodic data stream to vendors that would allow the update process to occur automatically, at an interval determined by the vendor or the individual.

Question 3

What information, beyond claims data and clinical and functional assessment data, should CMS provide to populate a PHR?

Most of the responses here repeated what was said in question 1, where much information above and beyond the claims and functional data was requested. Some additional information suggested included drug interactions and medication safety warnings, health risk assessments, links to health information networks, cost comparisons, over/under utilization indicators.

A few respondents suggested that CMS subscribe to health information networks and provide the subscriptions to beneficiaries as part of the PHR. This would provide valuable information on preventive health care, recent medical developments, and other items to beneficiaries at no cost to them. This would be another incentive for beneficiaries to use PHRs and allow them to better manage their health care.

Question 4

Should CMS provide “processed” beneficiary data, or should PHR services use claims information as it is received from the provider?

By processed data, we were referring to data summaries, data translations from codes to more textual data, and some “cleaning” of the data where anomalies may occur. Responses greatly varied for this question, with no clear consensus emerging. Some respondents want CMS to provide standardized data and a data dictionary, so that there is a basic understanding of the data and information provided. Others wanted CMS to do some basic cleaning of the data, especially when there are claims adjustments and other actions taken. This would provide a consistent set of information. Care needs to be taken that the meaning of the information is not changed. The procedures used to process the data must be communicated to and understood by the PHR system vendors, and the vendor processes for coding and presenting the data must be understood by CMS before a decision of which data to be used is made.

The middle ground was taken by a number of respondents, saying that CMS should provide both raw and processed data. This would enable vendors to see what changes CMS made, and determine for themselves what the best set of information to display would be.

There were other respondents who did not want any processing of the data to be done. Some felt that CMS would be usurping part of their responsibilities. Others felt the need to look at the data for themselves and make decisions as to the quality of the data and what should be presented in a PHR.

What seemed very important to a number of responders was that the information provided needed to be understandable to the ultimate user of the information, the beneficiary. Whether processed or unprocessed, some translation needs to be done before information like clinical codes would be presented to individuals. Those respondents advocating unprocessed data would place that responsibility on the PHR vendors. Others felt that CMS should do some of the explaining. What is important is the ultimate presentation – that the beneficiary understands the information, trust the information, and feel that the PHR has value.

5. MARKETING & TRAINING

Question 1

Is the market ready for increased use of PHRs? If not, how can CMS encourage growth of the market?

There was general agreement by respondents that the market is, if not ready today, at least is in the early stages of being ready to open up. There are several factors that are at work in opening up the possibilities. First, the Presidential initiatives led by Dr. Brailer to increase the use of health IT have raised the interest of many in the industry in the

possibilities of PHRs. Secondly, the trend toward more consumer-directed health care has made individuals aware of the need to understand their health activities and the options open to them. The increased use of the Internet by patients for research into medical procedures, prescription ordering, and group discussions indicates that patients are willing to use online tools to help them with their health care.

Respondents provided evidence of consumer surveys showing willingness of even the current Medicare population to use PHRs, with increasing interest in the population which will be entering the Medicare program in the next several years. One survey found that one-third of people over 65 with at least one chronic condition were interested in some sort of personal health record tool. Another survey found that the interest in PHRs in the age 46-65 group was double that of the over 65 group. This provides an opportunity for the future adoption of PHRs in the group of Medicare beneficiaries entering the program in the next two decades. The expectation was stated that initial adoption will be slow, but should increase as more people who are used to using technology enter the Medicare program.

One respondent indicated that there is even now a proliferation of PHR vendors, and the market should be entering a consolidation phase. CMS could encourage appropriate consolidation by offering its data and seeing what vendors could take advantage of the offer.

Given that the market is in the early stages of opening up, respondents provided many steps that CMS should take to encourage the growth of the market, especially among Medicare beneficiaries. The simple fact that CMS, as the largest payer of healthcare in the United States, is taking any steps to encourage use of PHRs will likely cause a ripple effect that should spread across the industry as other segments pick up the cause. However, there are specific steps that CMS could take to encourage market growth.

Consumer education is a key factor in driving the demand for PHRs, education that addresses both the benefits and risks of the technology so that individuals can make informed choices. It was suggested that both providers and beneficiaries receive training. CMS has several avenues to provide direct education – the Medicare handbook, thru its contractors, thru Medicare Advantage plans, and there are many avenues available for partnerships. These will be discussed more fully in the next questions.

Several respondents suggested incentives for the use of PHRs, primarily to the providers who make them available for their patients. Another suggested that CMS pay any subscription fees for beneficiaries who use PHRs, even so far as to make it a Medicare benefit. A certification process should make beneficiaries more comfortable that a PHR vendor is providing proper services and protecting their information.

There were several suggestions regarding the segmenting of the market. Respondents looked to CMS to direct the marketing at first to the segments of the market more likely to adopt PHRs (younger or more technologically advanced beneficiaries) or those beneficiaries with chronic conditions because the PHRs could help them or their

caregivers more effectively manage their health care. Marketing PHRs to these segments should show increased effectiveness, and can provide evidence of the benefit of the technology. Another respondent suggested that PHRs be test marketed through a QIO to determine the best strategies for promotion, as the QIOs have had experience in marketing advances in health care and have a wide network of contacts.

Question 2

What efforts should be undertaken to inform CMS beneficiaries about the benefits of PHRs?

Respondents agreed that an overall informational campaign needs to be undertaken by CMS to inform beneficiaries about PHRs. A national campaign, headed by the Secretary of HHS or the administrator touting the values of PHRs and how CMS will be using them would send a strong message. Public Service Announcements, publication in the Medicare handbook, direct letter or brochures, grants to vendors for educational documents touting PHRs, partnering with AARP and other advocacy groups, a PHR web site, focus sessions with doctors and beneficiaries, a multiple level campaign – what is a PHR, how should it be used, who are the vendors, etc. All of these need to be directed at both beneficiaries and providers so that they are aware of PHRs. Part of the initial welcome to Medicare package could include an introduction to PHRs.

More importantly, respondents emphasized that whatever efforts are undertaken, they must emphasize the value of a PHR. Beneficiaries will not flock to use a PHR just because it is there, they must be assured that it is valuable for them to take the time and effort to use the PHR. Research was suggested to understand what a PHR should and would provide for Medicare beneficiaries, and the results of that used to craft a message. Pilot project could be undertaken with a specific message targeted at a small set of data (e.g. explaining the benefits of a medication list and sharing it with your doctor). CMS could also start out by requiring providers to make available to beneficiaries a small set of data, and having beneficiaries provide that to their other providers at every visit.

Question 3

How can CMS encourage the appropriate use of PHRs by beneficiaries?

Along with the educational component, many respondents emphasized that CMS needs to take more proactive steps to encourage the use of PHRs so that beneficiaries understand their value. The first step is the establishment and communication of a clear vision for what a PHR is and how it can provide value to a beneficiary. Specific value such as faster treatment thru providers, quicker receipt of laboratory results, improved claims handling must be included to drive the message home. The message needs to be clearly conveyed that the PHR is not just a static record, but a tool to significantly improve health.

Respondents mentioned that beneficiaries should be encouraged to use them through a series of incentives which could include a “Club Medicare” membership for those who have used a PHR, incentives for completing PHRs for those with certain conditions, incentives for maintaining preventive services and health indicators within targeted

ranges. Several respondents suggested the promotion be done through Medicare contractors who already have significant ties to Medicare beneficiaries. CMS could also consider promoting these “preferred” vendors thru financial incentives to beneficiaries.

Monitoring and measuring PHR use can foster continued adoption and appropriate use. Again, rewards for appropriate use and health improvement can be considered.

Pilot tests and segmented roll outs would also allow CMS to demonstrate the values to smaller groups of beneficiaries. The results of these smaller tests could be used to fine tune marketing and training packages to better encourage participation and use throughout the Medicare program.

Question 4

How can beneficiaries be trained on the use and maintenance of PHRs?

Most respondents recognized the need for beneficiary training on the use of PHRs to assure their continued and appropriate use. There were suggestions to work with web based organizations such as Ebay or Amazon.com to understand how they trained their users. It was also suggested that the VA’s experience with the MyHealthyVet program would be valuable. Respondents agreed that the PHR should be as user-friendly as possible, which should reduce the need for educational and training material.

There were mixed responses on exactly the role that CMS should take in the training process. While most suggested there would be some role for CMS, the respondents varied as to how big a role the agency should play. The majority talked about the things that CMS could do, with several suggesting private-public partnerships.

A significant minority of respondents indicated that the primary responsibility for training of beneficiaries lies with the vendors of the product. The wide variety of possible PHR offerings would make it difficult for CMS to do more than provide generic training on the use and value of PHRs. In addition, different people will need different types of training, so vendors will need to make these types available.

Suggestions for what CMS should do included developing a simulated PHR on the medicare.gov portal to provide information on use, have dedicated email or customer support people to answer questions on PHRs, send out DVDs or USB drives with training information, or developing Public Service Announcements. Another suggestion was for CMS to partner with AARP, community colleges, and senior centers to create PHR training programs, as these organizations have had success in the past in training seniors on computer and internet use.

A suggested technique would be for CMS to support the phasing in of PHR functions by providing the data for those functions, with training offered on those functions. Once beneficiaries became comfortable with a set of functions, the next set could be rolled out for training. This would avoid overwhelming beneficiaries with too much information.

Again, the suggestion for pilot projects and targeted efforts was made here, for the same reasons as above – the opportunity to learn what works and what doesn't work, and to improve educational efforts.

Question 5

Who can CMS best partner with to better publicize PHRs?

A wide range of organizations was suggested for CMS to partner with, indicating the difficulty of reaching out to all Medicare beneficiaries, and the cost and effort involved in the program. Suggestions for partners included:

- Provider groups, to get their cooperation and as a trusted source of information for patients
- Health plan groups, as entities that will benefit from the use of PHRs, and that may provide PHRs to their members.
- Senior advocacy organizations, like AARP, as direct contacts to seniors
- Vendor groups, as they will need to provide the most education and will probably be doing the majority of the marketing.
- Government agencies involved in homeland security and health monitoring – CDC, FEMA.
- Pharmaceutical manufacturers, who would promote online medication profiles and provide drug information.
- Medical, dental, and nursing schools, to train their students on PHRs.
- Web search sites, to ensure that web searches link appropriately to PHRs
- Industry groups such as HIMSS and AHIMA who have advocated the use of PHRs and are involved in standardization efforts.
- Local community organizations such as Lions Club or Kiwanis which could provide free community service training on PHRs.
- Companies such as Apple for co-marketing (PHRs on your IPOD!)
- QIOs, in testing strategies for promotion and in researching the health effects of PHRs. QIOs have developed a network of community partners.
- Banks, in their role as storehouses of financial information.

Most respondents supported a major nationwide effort to market PHRs, train beneficiaries, publicize their benefits, and explain their use. Respondents felt that many organizations would be ready, willing and able to participate, especially if CMS or the Department led the effort.

6. PRIVACY & SECURITY OF INFORMATION

Question 1

What methods are currently being used to obtain and track authorization from individuals to use their information to create or populate PHRs?

In this context, authorization means the granting of permission to an entity to view, add, or edit PHR information. The overall consensus of the respondents was that the individual should be the one to own and control the population, management, and distribution of data in a PHR. Under that assumption authorization is necessary for outside entities to provide data for input directly into the PHR, or for outside entities to view or receive data from the PHR. Any data input or viewed by the individual (or authorized representative) need not be subject to any authorization.

Respondents noted that the methods of authorization will differ depending on the sponsor of the PHR. For independent sponsors that an individual chooses to use as their PHR vendor, paper forms or online forms are used to provide authorization to collect medical records and claims on behalf of the beneficiary. Patients may receive information directly and enter it in, or the information may be sent right to the PHR vendor.

For payer supported PHRs, a broad authorization for the PHR is generally included with the PHR vendor and the health insurer. Steps are then taken to ensure that member agrees to participate in the PHR. When the patient agrees, a User Agreement is signed and a logon process is initiated. Another model allows the user to opt in or out at either the payer's website or the vendor's website. An audit trail is generally kept with the user's designation.

For provider sponsored PHRs, authorizations are collected during the patient registration process at the PHR site. Privacy policies and terms of agreement are available at the site and the user must actively accept them. Other possibilities for authorization are at patient registration at the provider, where forms can be signed and held as part of the medical record.

Several respondents indicated that paper forms and filing systems are often used for authorization. Communication regarding logins and passwords are sent via postal mail for use by individuals to access systems.

Authorization processes are necessary for different situations when PHR is added, edited, or viewed. There is the ongoing feed from health plans and providers into the PHR. There is the need to provide for occasional access by other providers and entities to view the PHR. Several respondents mentioned the need for an emergency authorization process, giving providers the ability to access the PHR in an emergency. Authorization processes must be in place to handle all of these situations. These processes must be clear and easy for beneficiaries to use, to assure the smooth flow of information.

Question 2

What types of authentication is used to allow an individual to access a PHR? To modify a PHR?

Authentication is the identification of an entity to a system so that the system can provide the appropriate access. The most common method of authentication in use today is the username and password combination. Some vendors provide guidance on how to create a “good” password. Some vendors require additional information like the zip code and date of birth.

Many respondents suggested that higher levels of security should be implemented for CMS beneficiaries so that beneficiaries are assured and feel comfortable that their information is secure. The use of physical tokens as an additional level was suggested, with others suggesting the use of biometrics. The cost of these was mentioned as an issue to be dealt with, however further logistical details were not provided. There were suggestions the a Medicare smart card be created, which could assume the functions of an ID card, a physical token, and a storage medium for key pieces of information.

A number of the PHR vendors provide an emergency access card that contains information allowing ER personnel access in emergency situations. This typically contains a user id and password to allow viewing of information.

There were further discussions of role based access. That is, functions that a user could perform (e.g. viewing, adding, editing, deleting information) and the types of information a user could access will differ depending on who the user of the system is. A beneficiary might have complete control and access, while an individual provider may only be able to view a certain section of the information, or be only able to add, not edit, data. The PHR systems must the capability of enforcing this. This could restrict both the function that a user can perform (data views, editing, update, etc.) and the range of data that a user has access to. This would make users more comfortable in allowing access to a wider range of entities, and place more authority and control with the owner of the PHR.

Question 3

How can we assure beneficiaries that their information is adequately protected?

Respondents recognized that assuring beneficiaries of information protection is a key step in encouraging their use of this technology. As CMS will not be creating and maintaining the PHRs, the key responsibility for protection lies with the vendors of the PHRs. However, CMS must be able to assure Medicare beneficiaries that their information will be safe if they use a PHR.

There were general consensus recommendations that CMS needs to support high standards for certification of PHR vendors that any participating entity would need to sign an agreement of compliance, and that CMS should monitor ongoing compliance with privacy and security standards for every entity that receives CMS information. Such agreements of compliance would need to include items that entities meet HIPAA privacy

and security standards, data is used appropriately, audit trails are maintained and are available for inspection.

CMS also needs to ensure that its data feeds meet HIPAA requirements for access controls, audit controls, integrity, authentication, and transmission security.

Other techniques that were mentioned by various respondents that vendors should consider including are intrusion protection, using virtual private networks, business continuity, disaster recovery and continual high levels of security. As smaller providers participate in data feeds, they will need to pay greater attention to network security.

While these protections are put in place, respondents emphasized that CMS must ensure efforts be undertaken to assure beneficiaries of protection. People may not use PHRs because of fears of security breaches, many of which are highly publicized. Beneficiary education will be critical, providing guidance on not only what vendors are doing to protect security, but also what individuals must do to protect security. A balance here needs to be struck - too much security education will frighten beneficiaries, not enough will leave them vulnerable. One suggestion was for CMS to publish or maintain a list of security best practices so that beneficiaries can determine for themselves if a PHR system is adequately protecting their information.

Question 4

What privacy practices do vendors now put in place to protect the information?

There was not a lot of privacy information included in these responses. Much of the responses dealt with security protections which will be discussed in the next question.

The relevant responses indicated that the PHR privacy policies may be governed by the health plan that has sponsored the PHR. Other vendors abide by the principles set forth in the Safe Harbor framework defined by the European Union (<http://www.export.gov/safeharbor/>). This is a European “adequacy” standard for privacy protection. These principles are detailed in Appendix B.

In general privacy policies are disclosed in legal documents, disclaimers, and warning.

HIPAA privacy protections provide the basis for most of the privacy programs in place.

Question 5

What security technologies do vendors currently use to protect PHR information?

A wide range of general security measures was mentioned by respondents. For controlling access, these included role-based access controls, encrypting passwords, encrypting individual session, and monitoring user id activity and web access.

For protection of data in transit, many vendors encrypt the data so that it cannot be easily viewed if intercepted. Cryptographic functions can also be used to verify the message

was not altered during transmission. The use of Virtual Private Networks is also common so that data is not being sent over “open” Internet connections.

To protect against hackers accessing their systems, technical controls including intrusion detection systems and auditing systems are used. Firewalls between protected systems and untrusted networks are used prohibit unauthorized access.

Physical security measures include pass cards, biometric identification, protection from fire, and other hazards. Business continuity and disaster recovery plans are prominent.

It should be noted that the responses to this question often followed the HIPAA Security Rule framework for administrative, physical, and technical safeguards.

Question 6

Do the HIPAA privacy and security regulations (45 CFR Part 164) provide a basis for designing the privacy and security aspects for PHRs?

The general consensus from respondents to this question was the regulations provide a strong foundation for the design of privacy and security aspects for PHRs, and in fact may provide a national floor of protections. However, while applying them in the PHR industry, certain areas may need to be emphasized, and guidance provided by HHS in other areas. First, as vendors may not be covered entities, some respondents suggested guidance be provided that the vendors follow all requirements of the privacy and security regulations (not just sign a business associate agreement). In fact, some suggested that all of the entities involved in the PHR (user, source, vendor, etc) be subject to HIPAA privacy and security standards (although it would be difficult to enforce them on individual users). Vendors and hosts have acquired a better knowledge of privacy and information security through HIPAA, and they should use that knowledge and apply it to their operations.

Specific security rules on encryption, authentication, incident response, and access controls should be part of a PHR design. Privacy rules regarding minimum necessary disclosures, accounting, and patient rights to access data should also be included.

Several respondents suggested that specific guidance be provided for encrypting data transmissions. It was suggested that 256 bit protection using Triple DES or other open encryption method should be used as an initial standard for encrypting data transmissions, perhaps with the concurrence of the National Institute for Standards and Technology.

7. OTHER ISSUES MENTIONED REGARDING PERSONAL HEALTH RECORDS

Some respondents provided comments on issues beyond those specifically mentioned in the RFI. We provide a brief discussion of these:

A. CMS Implementation Approach

There was considerable discussion about whether CMS should provide data feeds for all beneficiaries, or should look for specific groups of beneficiaries (by medical condition, age or other demographic) to pilot test or roll out PHRs. Targeted rollouts or pilot tests were suggested in many responses. For example, CMS could work with vendors in a particular geographic area and roll out PHRs for Medicare beneficiaries in that area. This would allow the industry to test and measure the acceptance, cost, and benefits of PHRs. Another suggestion was to identify beneficiaries with certain chronic conditions (diabetes, hypertension) and roll out PHRs just for them. By focusing on smaller groups of beneficiaries at first, CMS can fine tune the process and the message regarding PHRs, making them more valuable for future beneficiaries.

B. Interoperability of PHRs and EHRs

This issue was mentioned briefly as a desirable characteristic of PHRs, but was not widely discussed. While there is still no clear industry consensus on the definitions and functions of these, in general PHRs are beneficiary owned and controlled, while EHRs are provider owned and controlled and focus primarily on clinical information. EHRs and PHRs will share many pieces of information, so the development of these should be done in tandem. They should be using the same sets of standards for information so that this information can freely pass between them. The respondents believed that these two initiatives should not be developed independent of each other.

APPENDIX A

List of Respondents to RFI

ABC Virtual
ACS Government Healthcare Solutions
The American Health Information Management Association (AHIMA)
America's Health Insurance Plans (AHIP)
Allina Hospitals and Clinics
Argosy Omnimedia, Inc.
Blue Cross Blue Shield Association (BCBSA)
Blue Cross and Blue Shield of Alabama
Booz Allen Hamilton
CapTech Ventures, Inc.
Center for Health Information and Decision Systems (CHIDS) at the Robert H. Smith School of Business, University of Maryland
Center for Health Transformation
Center for Information Therapy
CentrifyHealth
Cerner Corporation
CGI-AMS Inc.
CheckUp Software
CodeRyte, Inc.
Cogon-Nokia
Connecting for Health Steering Group and the Personal Health Technology Council
Diamond Cluster International North America, Inc.
Department of Defense
EDS
eHealthTrust
Emdeon
ES Enterprises, Incorporated
First Coast Service Options, Inc.
HealthTrio, Inc
Harris Corporation
Health Record Network
HealthRight, Inc.
Healthwise
HIMSS
InterComponentWare
Kaiser Permanente
Lockheed Martin Service, Inc.
Medem/Ihealth
Medical Banking Project
Medical Data Consolidation and Management Corporation
Multimed Solutions
NoMoreClipboard.com

Noridian Administrative Services, LLC
Northrop Grumman Information Technology, Inc.
Oracle Corporation
ORC Macro
QMed, Inc.
RelayHealth Corporation
University of Pittsburgh Medical Center
Universal Medical Card, Inc.
West Virginia Medical Institute

APPENDIX B

European Union Safe Harbor Framework Principles

Notice: Organizations must notify individuals about the purposes for which they collect and use information about them. They must provide information about how individuals can contact the organization with any inquiries or complaints, the types of third parties to which it discloses the information and the choices and means the organization offers for limiting its use and disclosure.

Choice: Organizations must give individuals the opportunity to choose (opt out) whether their personal information will be disclosed to a third party or used for a purpose incompatible with the purpose for which it was originally collected or subsequently authorized by the individual. For sensitive information, affirmative or explicit (opt in) choice must be given if the information is to be disclosed to a third party or used for a purpose other than its original purpose or the purpose authorized subsequently by the individual.

Onward Transfer (Transfers to Third Parties): To disclose information to a third party, organizations must apply the notice and choice principles. Where an organization wishes to transfer information to a third party that is acting as an agent(1), it may do so if it makes sure that the third party subscribes to the safe harbor principles or is subject to the Directive or another adequacy finding. As an alternative, the organization can enter into a written agreement with such third party requiring that the third party provide at least the same level of privacy protection as is required by the relevant principles.

Access: Individuals must have access to personal information about them that an organization holds and be able to correct, amend, or delete that information where it is inaccurate, except where the burden or expense of providing access would be disproportionate to the risks to the individual's privacy in the case in question, or where the rights of persons other than the individual would be violated.

Security: Organizations must take reasonable precautions to protect personal information from loss, misuse and unauthorized access, disclosure, alteration and destruction.

Data integrity: Personal information must be relevant for the purposes for which it is to be used. An organization should take reasonable steps to ensure that data is reliable for its intended use, accurate, complete, and current.

Enforcement: In order to ensure compliance with the safe harbor principles, there must be (a) readily available and affordable independent recourse mechanisms so that each individual's complaints and disputes can be investigated and resolved and damages awarded where the applicable law or private sector initiatives so provide; (b) procedures

for verifying that the commitments companies make to adhere to the safe harbor principles have been implemented; and (c) obligations to remedy problems arising out of a failure to comply with the principles. Sanctions must be sufficiently rigorous to ensure compliance by the organization. Organizations that fail to provide annual self certification letters will no longer appear in the list of participants and safe harbor benefits will no longer be assured.

APPENDIX C

RFI Published in Fedbizopps

REQUEST FOR INFORMATION CENTERS FOR MEDICARE & MEDICAID SERVICES' ROLE IN PERSONAL HEALTH RECORDS

Background of Personal Health Records

Personal health records (PHRs) are an emerging technology to enable people to electronically manage their health information and that of others for whom they are authorized. PHRs allow an individual to store and manage important information about his or her current health status, and their medical history. PHRs are available in several formats today, such as stand-alone software applications installed on a personal computer, or a website hosted by a private company, provider or insurance agency. They may be populated by Electronic Health Record systems (EHRs) managed by provider organizations. Using a PHR can allow an individual to be more involved in his or her own care and health management. Therefore, PHRs have the potential not only to improve personal and family health but also to support national objectives for health care quality, safety, efficiency and ultimately, health outcomes.

There are currently many models of personal health records. Two broad types of PHRs are evolving in the private and public sectors, distinguished primarily by their relationship to EHRs. One is a patient-facing extension of clinician-controlled EHRs; the other is not routinely linked to the patient's EHRs.

Some large health care organizations are developing models in the first category. These PHRs give enrollees a view of their EHRs along with other functionalities that facilitate administrative tasks (e.g., appointments and medication refills), health and disease self-management (e.g., exercise or blood pressure records), communication with physicians, and access to health information resources.

Free-standing PHR products are offered by several dozen companies. In general, there is greater variety among these products, which typically are made available to consumers through a third-party sponsor such as a health plan, employer, or disease management program. By definition, the PHRs in this group do not derive from EHRs, although some are designed to link to users' EHRs through voluntary participation by their health care providers.

No uniform understanding yet exists about what threshold a personal e-health tool must cross to be called a PHR, or about the boundary between the PHR and the many functions it enables. Another source of confusion is the lack of a clear dividing line between the EHR and the PHR. Opinions also vary as to whether the PHR consists only of the health record—an index or document—or encompasses a set of interactive functions and activities. These functions can help consumers and family caregivers manage health

across a continuum that includes staying healthy, managing illness and handling transitions such as the end of life. We are including all of these models in the definition of PHR for this document.

The government agencies that are beginning to explore uses of PHR technology are moving into a terrain in which there is already considerable private sector activity. Government programs serve millions of people; many with special health needs, chronic conditions and who are users of multiple services. Questions about the federal role with PHRs therefore, have become increasingly relevant and concrete. The evolving public, private and joint activities can either complement each other for the good of the nation's health care consumers, or they can add to the fragmentation of the health system.

The President provided the highest-level rationale and context for a federal involvement in PHRs when he announced, in April 2004, an ambitious goal of assuring that most Americans have electronic health records within the next 10 years.. In addition, there is broad acceptance the principles of patient-centered care, greater consumer control and empowerment, improved chronic care management and fuller translation of knowledge into practice with respect to both public health and health care. PHRs are a means toward these important policy goals.

CMS Interest

CMS is the largest purchaser of health care in the United States, and as such has a significant interest in the health and well being of its Medicare beneficiaries. In addition, CMS has one of the largest stores of health data in the country, with robust claims history for all of its Medicare beneficiaries. With the addition of the prescription drug benefit in 2006, CMS will have claims information on virtually all types of services that Medicare beneficiaries receive. CMS also has extensive claims history data on Medicaid beneficiaries.

Because of our position, CMS is looking for ways to make its information more available and more useful to our beneficiary population. One area we are investigating is personal health records. In particular, CMS would like to determine what role(s) the agency should play in this area – in what ways would Medicare claims data be useful in the creation, maintenance and use of personal health records for our beneficiary population.

While CMS is currently testing a Medicare Beneficiary Portal, the intent of that portal is limited to providing only Medicare information that CMS stores or collects, such as claim information or benefit information. It is not intended as a complete personal health history for an individual.

There are significant technical and policy issues involved in this determination. As there is already private sector activity in this area, CMS would like to assess how to leverage that activity to further PHRs, and their use, for Medicare beneficiaries. To this end, we are publishing this Request for Information (RFI) to determine how we should proceed

on participating with existing PHRs, or fostering the development of PHRs which focus on the needs of the Medicare population.

Issues and Questions

Our request for information covers several areas. We realize that the answers to some of these questions may be interdependent. We suggest that responders review the entire list of issues and questions before preparing their responses.

1. CMS Role with PHRs

One issue that needs to be determined is the role that CMS will play with PHRs. While we do not believe that CMS should build or house a comprehensive beneficiary PHR system, what other roles could CMS assume? We are interested in answers to the following questions:

- A. What PHR functionalities are important for CMS beneficiaries to have available to them?
- B. Should CMS provide some PHR type services directly, and if so which ones? For example, CMS currently enables a beneficiary to find out if he or she is eligible for expert-recommended screening tests that are covered by Medicare
- C. Should CMS identify vendors who can provide appropriate PHRs to our beneficiaries and promote their use by beneficiaries through sharing of CMS data, links to them, communication to beneficiaries about their capabilities, etc?
- D. Should CMS make data available to many PHR vendors? If so, should CMS require vendors to be “certified” at some level to ensure that the vendor PHR provides the proper privacy and security safeguards for protecting beneficiary data? If so, how? If not, why not?
- E. Should CMS regulate data content for PHRs targeted towards Medicare beneficiaries?

2. Technology and Standards

There are a variety of technologies in use for PHRs today. Some PHRs are stored and accessed on websites, some are stored on disks or drives on an individual computer. Still others are housed on a provider’s system.

Whatever technology is chosen, CMS is interested in promoting a standards based approach to PHRs. It is critical that CMS be able to interface with a wide variety of PHR (and Electronic Health Record – EHR) systems. Communication and transmission standards are essential to meeting this need.

We are interested in answers to the following questions:

- A. What technologies are available to transmit information to PHRs from other record systems? Are there some technologies used more than others?
- B. What data and communication standards exist for the exchange and storage of PHR data among providers, individuals, and PHR vendors?
- C. What technologies and standards should be supported by CMS?

3. Data Content

CMS collects a wide variety of data on our Medicare beneficiaries. For example, 100% of Medicare fee-for-service claims information is collected and stored.. CMS will also be collecting 100% of claims paid for drugs under the new Medicare Part D benefit. CMS maintains clinical and functional assessment data for patients in nursing homes and inpatient rehabilitation facilities, as well as for those served by home health agencies. With such a vast storehouse of data, we need to determine the subset of information to be included in a PHR. Therefore, we are interested in answers to the following questions:

- A. What pieces of information housed by CMS could be used to populate a PHR?
- B. How often should the information be updated?
- C. What information, beyond claims data and clinical and functional assessment data, should CMS provide to populate a PHR?
- D. Should CMS provide “processed” beneficiary data, or should PHR services use claims information as it is received from the provider?

4. Marketing and Training

The use of PHRs is not yet widespread in this country for a variety of reasons – lack of awareness, cost, inconsistent content etc. However, we believe that using PHRs can provide health and wellness benefits to our beneficiaries. Therefore, it would be imperative to inform beneficiaries of the availability of PHRs, and how best to use them. We are interested in answers to the following questions:

- A. Is the market ready for increase use of PHRs? If not, how can CMS encourage growth of the market?
- B. What efforts should be undertaken to inform CMS beneficiaries about the benefits of PHRs?
- C. How can CMS encourage the appropriate use of PHRs by beneficiaries?
- D. How can beneficiaries be trained on the use and maintenance of PHRs?
- E. Who can CMS best partner with to better publicize PHRs?

5. Privacy and Security of Information

With the recent events regarding identity theft or inadvertent release of credit card and other financial information, interest in protecting the privacy and security of all personal information has risen. With the sensitive nature of individual health information, and

increasing reliance on electronic storage and transmission of such data, it is even more critical to ensure the protection of this information. Fear of inadvertent disclosure may very well discourage individuals from creating and using PHRs.

In addition to these concerns, Federal and State regulations regarding the privacy and security of health information may apply to some PHRs. Depending on the circumstances, the HIPAA regulations regarding the privacy and security of individual health information may apply – if for example, the PHR is managed and maintained by a covered entity or by a business associate of a covered entity. The Federal Privacy Act, and other state and federal rules may also place restrictions on access to information.

Permission, or authorization to share information, may also be needed from individuals to populate the PHR with medical data. The processes for securing authorization to share data with a PHR, and tracking the directions of the beneficiaries, with respect to such data sharing, and other related tasks, will be a complex administrative function.

Privacy and security of health information is a primary concern for CMS. We are interested in answers to the following questions:

- A. What methods are currently being used to obtain and track authorization from individuals to use their information to create or populate PHRs?
- B. What type of authentication is used to allow an individual to access a PHR? To modify a PHR?
- C. How can we assure beneficiaries that their information is adequately protected?
- D. What privacy protections do vendors now put in place to protect the information?
- E. What security technologies do vendors currently use to protect PHR information?
- F. Do the HIPAA privacy and security regulations (45 CFR Part 164) provide a basis for designing the privacy and security aspects for PHRs?

Specific Directions

• **Response package:** The entire RFI response package should not exceed 25 pages. Due to limited reviewing resources, CMS appreciates brevity whenever possible.

- **Text font and point size:** Times New Roman 12-point
- **Margins:** One-inch margins and full-line height/spacing (required)

• **Graphics:**

- Font recommended is Arial Narrow
- Font size should be no smaller than Arial Narrow 8 point.

- **Subsections:**

The responses should be organized according to the sections identified in the “Issues and Questions” section of the RFI. We realize that some of the answers may be related, however we ask that Responders provide separate answers to each of the questions.

- **Contact Information**

At the end of each response, we ask that the Responder provide contact information, including company name, address, city, state, zip code, and the phone number and e-mail address of the primary contact. CMS does not plan to notify each contact with an acknowledgement that it has received the RFI response.

Proprietary information: CMS recommends that you do not provide proprietary information since CMS will consider all comments and may incorporate them in any future requirements. In the event you do submit proprietary information, Potential Responders should identify any proprietary information in their RFI responses. Proprietary materials will neither be distributed to nor discussed with any other potential Responder.

- **Questions:**

Should be directed to Stanley Nachimson, stanley.nachimson@cms.hhs.gov; 410-786-6153

- **Delivery format and media:** The preferred delivery format is Adobe PDF.

- **Means of delivery:** Delivery shall be made electronically by e-mail.

- **Delivery due date:** The RFI responses *to Questions for Industry* are requested by e-mail to Stanley Nachimson, Stanley.Nachimson@cms.hhs.gov, by close of business August 31, 2005.

