Hayes, Yolanda K. (CMS/OSORA)

From: Jones, Martique S. (CMS/OSORA)
Sent: Wednesday, October 18, 2006 2:18 PM
To: Johnson, Sharon B. (CMS/OSORA); Hayes, Yolanda K. (CMS/OSORA)
Subject: FW: Public Submission

Martique S. Jones
Director,
Division of Regulation Development-B
OSORA/RDG
Centers for Medicare & Medicaid Services
410-786-4674
Martique.Jones@cms.hhs.gov
>-----Original Message-----
>From: Whitcraft, Rosie [mailto:rosie.whitcraft@fda.hhs.gov]
>Sent: Wednesday, October 18, 2006 1:45 PM
>To: Braxton, Shawn L. (CMS/OSORA)
>Cc: Jones, Martique S. (CMS/OSORA)
>Subject: FW: Public Submission
>
>
>
>-----Original Message-----
>From: no-reply@erulemaking.net [mailto:no-reply@erulemaking.net]
>Sent: Wednesday, October 18, 2006 9:31 AM
>To: OC AIMS Support
>Subject: Public Submission
>
>Please Do Not Reply This Email.
>
>Public Comments on Medicare Program; Medicare Part D Data:========
>
>Title: Medicare Program; Medicare Part D Data FR Document Number:
>06-08750 Legacy Document ID:
>RIN: <greek-i>
>Publish Date: 10/18/2006 00:00:00
>Submitter Info:
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>
>First Name: barb
>Last Name: sachau
>Category: Consumer Group - CG001
>Mailing Address: 15 elm st
>City: florham park
>Country: United States
>State or Province: NJ
>Postal Code: 07932
>Organization Name: self
>
>Comment Info: ================
>
>General Comment:re page 61445 dhs center medicare program 42 cfr part
>423 rin 0938-ao58 i wanted to recount to you the overcharging for drugs
>that is going on in pharmacies. i had to go to drug fair to get a
>prescription filled for cephalexin. the man behind counter said it
>would cost $20.00 for 1/2 the prescription. i have no insurance. when
>he came out with half the prescription he charged me over $26.00 for 15
>pills of 500 mg. when i went on internet, the pills are offered for
>39 cents a
>pill. i think that is price gouging. i do not think that should be
>going on for health care in america. this is a generic.

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OCT 30 2006

MEDICAL TECHNOLOGY

World Health Organization
Collaborating Center for Health Technology Assessment

October 27, 2006

Centers for Medicare & Medicaid
Services, Department of Health and
Human Services, Attention: CMS–4119–P
P.O. Box 8017, Baltimore, MD 21244–8017.

Dear Sir:

First, I would like to thank CMS for asking for input related to Medicare Part D Data and for the opportunity to comment. I certainly believe that there is an important role to be played by CMS in collecting and promulgating information about the effectiveness of pharmaceuticals and that such efforts can help make the health care system more efficient overall as well as helping individual patients receive the best possible care at the lowest possible cost.

Medicare Part D Data will be very useful in capturing data on drug use among large populations. Such data sets enable the analysis of patient histories and outcomes over extended periods by accumulating claims for services, which should include dosage amounts and diagnoses and procedure information.

If implemented, this effort should lead to development of clinically and scientifically robust policy that will ensure appropriate pharmacotherapy usage and improve the quality of care of Medicare beneficiaries.

Sincerely,

Dennis J. Cotter
President

MEDICAL TECHNOLOGY AND PRACTICE PATTERNS INSTITUTE
4733 Bethesda Avenue • Suite 510 • Bethesda, Maryland • 20814 • 301.652.4005 • fax: 301.652.8335 • e-mail: inquiry@mtppi.org

MEDICAL COLLEGE OF WISCONSIN

Office of Planning and Government Affairs

November 6, 2006

To Whom It May Concern:

RE: CMS-4119-P, particularly Section C "Sharing Data with Entities Outside of CMS"

We would like to commend CMS on its initiative to propose regulations that would allow release of Part D data to academic researchers. We support the proposed rules cited above in the strongest possible terms. It is in CMS and its beneficiaries' best interest to allow full access to Part D eligibility, enrollment, and claims data to academic researchers to enable analyses examining access, cost, quality, and health outcomes.

The effectiveness of the Medicare drug program will depend on how the program is implemented in the field. Understanding the causes and consequences of variation in prescription drug use among Medicare beneficiaries and the impact of such a large systemic shock on existing treatment patterns and outcomes is of great policy interest. From a clinical perspective, the value of disseminating information about prescription drug claims under Part D is even greater. Questions related to intensity and quality of physician prescribing behavior, innovation and adherence to evidence-based pharmacotherapies (and its variation among beneficiaries with different health conditions, membership in different racial-ethnic groups, or place of residence), efficiency (the extension to which unproven or unnecessarily costly pharmacotherapies are avoided) and the relationship between alternative prescription drug treatments and outcomes are of paramount importance to improve the health and well-being of Medicare beneficiaries.

Providing entities outside of CMS access to these data will multiply the rate at which such information can be used to improve the health and healthcare of Medicare beneficiaries and of the American public more generally.

Sincerely,

T. Michael Bolger, J.D.
President & CEO

Michael J. Dunn, M.D.
Dean & Executive Vice President

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DEC - 1 2006 4

THE URBAN INSTITUTE 2100 M STREET, N.W. WASHINGTON D.C. 20037

ROBERT D. REISCHAUER
PRESIDENT

Direct Dial: 202-261-5400
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E-mail: rreischa@ui.urban.org

November 27, 2006

Leslie Norwalk, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Re: CMS-4119-P "Medicare Part D Data"

Dear Ms. Norwalk:

The Urban Institute, a non-profit, non-partisan social science research organization founded in 1968, welcomes the opportunity to comment on a proposed rule, CMS-4119-P, issued on October 18, 2006 by the Centers for Medicare and Medicaid Services (CMS). The proposed rule would allow the Department of Health and Human Services and CMS to use Part D data to evaluate the Medicare prescription drug program. The original Part D regulations cite a statutory section in the Medicare Modernization Act that states these data cannot be used for research—even though under other sections of the statute, these data can be used for research and other purposes.

Under the proposed rule, CMS also specifies that other federal agencies and external research entities would be allowed to use the prescription drug data, under the same safeguards and privacy protections that currently exist when external entities use Medicare's other data. CMS has made the correct decision by using the rulemaking process to resolve this statutory ambiguity, and the Urban Institute applauds the agency for its commitment to ensuring access to these data for government and external research.

Purpose of CMS Collecting Information

The change represented by the introduction of a Medicare prescription drug benefit through Part D is perhaps the greatest change since the Medicare program's inception in 1965. Being able to explore how Part D functions on its own and in relation to other parts of the Medicare program is essential to guiding future policy choices. For example, if it appears that the additional Medicare spending associated with Part D is partially or fully offset by lower Medicare spending on inpatient hospital care or physician services, then there may be a strong argument for maintaining real (inflation-adjusted) Part D funding at current levels. Further, without access to Part D data for research and other purposes, Medicare will limit its ability to monitor expenditures for the new program, to study the impact of the program on public health, and to respond to Congressional requests for information. In addition, it would be difficult to design, implement and evaluate demonstration projects that could be used to test new approaches to delivering prescription drug benefits.

Sharing Data with Entities Outside of CMS

We commend CMS for recognizing the public health benefits of Part D data beyond the administration of the Medicare program, and in seeking to ensure access to Part D data to external research entities. As does CMS, external entities foresee tremendous value in research that explores the impact of prescription drug coverage on the Medicare population. While drug utilization data from commercial companies are available, they are extremely fragmented and their ability to be explored in conjunction with other health service utilization data are limited.

However, the opportunity to combine utilization data from Medicare's existing claims databases with drug utilization data resulting from the implementation of Medicare Part D creates a vast frontier for potential advances in pharmacological, clinical, and other health-related research. The growing prevalence of chronic conditions in America, coupled with the growing role of pharmaceuticals in the management of disease, make the ability to access and combine these types of data a critical component of the toolkit that clinicians, researchers, and policymakers rely on to improve the clinical practice, the health care delivery system, and ultimately the health and economic well-being of individuals.

Through this proposed rule, CMS wisely has taken steps to resolve the statutory ambiguity regarding use of Medicare Part D data. Through its discussion of numerous operational and research activities in which access to these data are fundamentally important, CMS has exhibited both solid logic as the administrator of the Medicare program and forward thinking as a public agency aiming to ensure access to data that, through their use, can benefit the health and security of the nation.

Sincerely,

Robert D. Reischauer
President

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DEC - 4 2006

RTI INTERNATIONAL

3040 Cornwallis Road ▪ PO Box 12194 ▪ Research Triangle Park, NC 27709-2194 ▪ USA
Telephone 919 541-6000 ▪ Fax 919 541-5985 ▪ www.rti.org

Lee R. Mobley, Ph.D.
Senior Economist and Research Fellow
Division for Public Health and Environment
RTI International (Research Triangle Institute)
email lmobley@rti.org
phone 919-541-7195

November 29, 2006

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (DHHS)
Attention: CMS-4119-P Medicare Program: Medicare Part D Data
P.O. Box 8017
Baltimore, Maryland 21244-8017

Re: Comments on Centers for Medicare and Medicaid Services Proposed Rule

To Whom It May Concern:

In response to CMS's Federal Register notice regarding use of Medicare Part D data, I am writing to express support for the proposed rule. The proposal by the Secretary to allow the use of Medicare Part D data for purposes beyond limited payment purposes is reasonable and clearly in the public's interest.

The Secretary's proposal allows for the use of these data, with appropriate review and protections. As the proposed rule notes, CMS is currently responsible for a wide range of program monitoring and evaluation tasks related to the Medicare program. Historically, these CMS functions have been critical in informing policy makers – in Congress and elsewhere – of both successes and necessary changes to Medicare. As Medicare expands to include the new Part D prescription drug program, ongoing program monitoring and evaluation will be important in understanding how Part D is working, and not working, for Medicare beneficiaries.

The proposed rule also includes provisions for the use of these data by other government agencies and external researchers. These additional provisions for Part D data use should be allowed. While many Medicare related monitoring and evaluation studies are conducted by CMS or CMS funded contractors, additional valuable research related to the Medicare program is also conducted by other DHHS agencies, congressional entities, and non-government researchers. In an atmosphere of budget restrictions, it is not feasible for CMS or the federal government to fund every relevant and important analyses of Medicare Part D. Therefore, the Part D data, under the proper protections, should be made available to researchers beyond CMS. Fortunately, CMS already has well established protocols for the review of external research proposals and

protection of data privacy. These established protocols could be extended to cover the new Medicare Part D data.

As one of CMS's primary research contractors, RTI is currently conducting CMS sponsored work related to Medicare Part D. We can confirm that without the proposed use of Medicare Part D data, these essential monitoring and evaluation functions will not be possible. There are no substitutes available for the Medicare Part D prescription drug data. It is impossible to imagine how restrictions on these data, leading to an inability to effectively monitor and evaluate Medicare Part D would be in the public interest, particularly since use of these data will cause no additional burden on Medicare Part D providers.

Sincerely,

Lee R. Mobley
Senior Economist and Research Fellow
Division for Public Health and Environment
RTI International

MEDPAC Medicare Payment Advisory Commission

601 New Jersey Avenue, NW • Suite 9000
Washington, DC 20001
202-220-3700 • Fax: 202-220-3759
www.medpac.gov

Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

December 1, 2006

Leslie V. Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4119-P
P.O. Box 8017
Baltimore, MD 21244-8017

Re: CMS-4119-P

Dear Ms. Norwalk:

The Medicare Payment Advisory Commission is pleased to submit these comments on the Centers for Medicare & Medicaid Services' proposed rule to allow the Secretary to use the claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and public health functions. We appreciate your staff's ongoing efforts to administer and improve the Medicare program, particularly given the agency's competing demands.

The proposed rule enumerates the various purposes for which the claims information can be used, including reporting to the Congress on the performance of the Part D drug program itself and conducting evaluations of many initiatives intended to improve the quality and reduce the cost of the program. To reduce burden on Part D drug plans and Medicare Advantage plans, the rule would use the existing data stream that goes to CMS rather than requiring these plans to submit the data twice. At the same time, the rule recognizes the need to safeguard the data in accordance with provisions of the law. The rule also would allow CMS to share the information it collects with outside entities, including other government agencies. The preamble to the regulation indicates that these would include Congressional support agencies.

Congressional support agencies are charged with reporting to the Congress about the impact of Medicare payment policies on cost, quality, and access. Data on Part D are necessary for analyzing program performance and making policy recommendations. In its June 2005 Report to the Congress, the Commission recommended that the Secretary have a process in place for timely delivery of Part D data to congressional support agencies to enable them to report to the Congress on the drug benefit's impact on cost, quality, and access.

The Commission commends CMS for its steps to make the data available for evaluation, research, and analysis. These data will prove invaluable; without it, entities would be unable to conduct important activities, such as post-surveillance monitoring of the efficacy of particular drugs, developing performance measures for drug plans, and analyzing the effects of the program on the spending and delivery of health care. The Commission urges CMS to finalize this rulemaking and make the data available as quickly as possible.

MedPAC appreciates the opportunity to comment on this rulemaking. If you have any questions, please feel free to contact Mark Miller, the Commission's Executive Director at (202) 220-3700.

Sincerely,

Glenn M. Hackbarth
Chairman

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RTI INTERNATIONAL

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DEC 12 2006

December 7, 2006

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (DHHS)
Attention: CMS-4119-P Medicare Program: Medicare Part D Data
P.O. Box 8017
Baltimore, Maryland 21244-8017

Re: Comments on Centers for Medicare and Medicaid Services Proposed Rule

To Whom It May Concern:

I am writing to express support for CMS's Federal Register notice regarding use of Medicare Part D data. The proposal by the Secretary to allow the use of Medicare Part D data for purposes beyond payment purposes is reasonable and in the public's interest.

The proposal allows for the use of Medicare Part D data with appropriate review and protections. CMS is responsible for program monitoring and evaluation related to the Medicare program. These CMS functions are critical to informing policy makers of program successes and recommended changes. Access to Part D data will be necessary to understanding how Part D is working, and not working, for Medicare beneficiaries.

The proposed rule also includes provisions for the use of these data by other government agencies and external researchers. While, many Medicare related monitoring and evaluation studies are conducted by CMS or CMS funded contractors, additional research is also conducted by other DHHS agencies, congressional entities, and non-government researchers. It is not feasible for CMS or the federal government to fund every relevant and important analyses of Medicare Part D given budget restrictions. Therefore, the Part D data, under the proper protections, should be made available to researchers beyond CMS. CMS already has well established protocols for the review of external research proposals and protection of data privacy and these could be extended to cover the new Medicare Part D data.

The use of the Medicare Part D data is in the public interest. Access to these data, under the proper protections, will allow CMS, contractors, and other researchers to effectively monitor and evaluate Medicare Part D.

Sincerely,

Melissa A. Morley, Ph.D.
Research Associate

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

DEC 15 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4119-P
Mail Stop CS-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

In Reply Refer To: 12

Subject: Comment on Proposed Rule **CMS-4119-P**

We concur with CMS' assertion, expressed in this notice, that the sharing of Medicare Part D claims data with entities outside of CMS for the purpose of research is in the interest of public health and we strongly support this rule change. We wish to comment particularly on Proposed § 423.505(f)(5), **Sharing Data with Entities Outside of CMS.**

The value of Part D claims data to the multiple kinds of studies mentioned (e.g., clinical effectiveness, appropriateness of services, cost effectiveness) and others cannot be underestimated. The information gained from these studies will contribute to our understanding of the causes and distribution of disease, the contribution of medical care and pharmaceuticals to health, the causes of racial/ethnic and socioeconomic disparities in health outcomes, individual, health provider, and institutional behavior related to the use of drugs and healthcare decision making, and other factors relevant to health. Results of studies using Part D claims data will provide information to health policymakers that has never before been available.

Of particular interest to VA research, the availability of Medicare Part D claims data fill major gaps in information about veterans' health, health care behavior, and health care costs and about the impacts of Medicare and VHA policy changes. Over 4.7 million veterans who are eligible to receive health care from the VA are enrolled in Medicare. VA pharmacy data is a rich source of information on the use and cost of medications among veterans who use the VHA but are not able to provide information about pharmaceuticals obtained outside of the VA. Despite this limitation, researchers have used VHA pharmacy data, often linked with VA clinical and administrative data, to answer questions related to the prevalence of specific conditions, patterns of medication adherence and its effect on health care utilization, the prevalence of overprescribing and its association with injury, the impact of medical comorbidities on the quality of pharmacotherapy for a chronic illness, and others. Linked VA and Medicare databases have been used in epidemiological, cost-effectiveness, and health care quality studies. The addition of information on medications obtained by veterans outside the VA will provide a more complete picture of health care

behavior and medical treatment among users of VHA care. Results of veteran's studies using Part D claims data will also provide valuable information to policymakers regarding the impact of dual eligibility on Medicare and VHA costs, health outcomes, and healthcare disparities.

The VA and CMS have had a Memorandum of Understanding for the sharing of Medicare data for many years. Through this mechanism, 70 VA researchers have been afforded the opportunity to use Medicare data in 95 research studies. We strongly support making CMS Part D claims available to VA researchers under the same terms that have long been in place for other Medicare data.

Sincerely yours,

Joel Kupersmith, MD
Chief Research and Development Officer

December 15, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-4119-P, Mail Stop C4-26-05
7500 Security Boulevard, Baltimore, MD 21244-1850

Via: http://www.cms.hhs.gov/eRulemaking

The National Committee on Vital and Health Statistics (NCVHS) is charged to advise the Department on health data, statistics and national health information policy. The Committee also has been called upon by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to develop uniform standards to enable electronic prescribing in ambulatory care. In these capacities, we would like to express support of the Department's efforts to make best possible use of Medicare Part D data for research, analysis, reporting and public health, as detailed in the Centers for Medicare and Medicaid Services (CMS) proposed rule (71 FR 61445-55, October 18, 2006).

NCVHS especially commends the attention of the proposed rule to the following public needs:

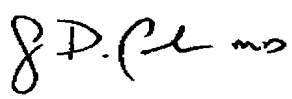
- the internal requirements of the Medicare program not simply to administer the benefit efficiently, but to track, monitor, and test the use of funds over time to measure their efficacy;
- the potential advancement in public health and scientific programs through the creation of essential research resources;
- the reinforcement of existing national databases from Medicare Parts A and B and the Chronic Condition Warehouse, as well as from the health surveys conducted by other federal agencies and from disease registries such as SEER;
- broad access across agencies through exact record linkage of health and other vital data, which, in turn, can help set the standards for future inter-agency sharing of other, valuable data resources;
- the facilitation of studies and evaluations, both observational and designed—some of which would otherwise be infeasible or unaffordable—to enhance disease surveillance and the identification of rare complications.

In all or almost all these examples, we believe it to be fairly certain that the opportunities and economies extend well beyond the Medicare program, thus requiring collaboration between CMS and other agencies, as well as private researchers.

The proposed rule is broadly consistent with NCVHS' view that public benefits can be enhanced though the sharing of data both across government agencies and with responsible and qualified research organizations. The proposed rule also recognizes the essential need for appropriate levels of protection of individual beneficiary privacy though the restriction of data releases to the minimum elements necessary for the conduct of the study and subject to the existing mechanisms for data use agreements. At the individual level, the rule also reflects the increased demand of the public for access to its own records for such purposes as the creation of personal (typically electronic) health records.

In sum, the NCVHS wishes to reinforce that substantial public benefit can be derived through efforts to make the best use—including sharing of claims information and ancillary data—of information collected under Medicare Part D program. NCVHS recommends that the Department issue as expeditiously as possible a final rule that is fully supportive of the goals and the mechanisms to pursue them specified in the draft rule.

Sincerely,



Simon Cohn, M.D., M.P.H.
Chairman, National Committee on Vital
and Health Statistics

Cc: HHS Data Council Co-chairs
Director, Centers for Medicare and Medicaid Services (CMS)

Duke Clinical Research Institute
DUKE UNIVERSITY MEDICAL CENTER

December 8, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4119-P
P. O. Box 8017
Baltimore, MD 21244-8017

RE: File code CMS-4119-P

We appreciate the opportunity to review and comment on the proposed rule regarding access to and use of Medicare Part D claims data. Over the last few years, researchers at the Duke Clinical Research Institute (DCRI) have built a large repository of Medicare claims data that includes the 5% sample from 1991-2004 and all inpatient claims for beneficiaries diagnosed with heart failure from 1999-2004. We have worked closely with the Research Data Assistance Consortium (ResDAC) to secure the necessary data use agreements, and now have research programs funded by the National Institute on Aging, the National Heart, Lung, and Blood Institute, and private organizations.

We take the security of these data very seriously. The Medicare claims data are housed in an Oracle-based warehouse on the DCRI network. Access to the data files in this warehouse is limited to two analysts, one statistician, and two PhD-level researchers. The DCRI Network Infrastructure serves as the principal means of safeguarding this information. Points of internal access to DCRI databases are monitored and maintained by a firewall and router. All users are authenticated, authorized, and accounted on the DCRI domain. The domain is password protected. All passwords are changed every 90 days, and meet characteristics of "strong" passwords. No raw data can be downloaded to a PC or hard drive at any time. In addition, only key-card access is permitted within the DCRI.

In addition to network-based security safeguards, we have operating procedures that further protect the privacy of these data. First, analytical projects begin only with the approval of the Duke Institutional Review Board and an executed data use agreement with CMS. Second, identifiable data elements that are typically irrelevant for research purposes (e.g., patient names and street addresses) are not stored in the Oracle warehouse. Finally, analysis files include encrypted patient identifiers and the minimum amount of protected health information required for a given analysis.

As researchers entrusted with these data, we have an obligation to answer important public health questions in a rigorous, scientific manner. To that end, we assemble multi-disciplinary teams for each project that include clinicians, statisticians, and researchers who are experienced in claims data analyses. This team approach, combined with privacy safeguards in a secure environment, ensures that the benefits of analyzing identifiable data far outweigh the risks to patient confidentiality

In addition to our experience with Medicare claims data, DCRI researchers have considerable experience working directly with prescription claims data and

P.O. Box 17969 • Durham, NC 27715 • express mail and deliveries: 2400 Pratt Street, Room 0311 Terrace Level, Durham, NC 27705

Duke Clinical Research Institute
DUKE UNIVERSITY MEDICAL CENTER

pharmaceutical benefits management (PBM) organizations. Prescription claims data provide empirical evidence of how drugs are used in clinical practice. An analysis of the prescription claims of more than 750,000 elderly Americans suggests that 1 in 5 fills a prescription for a drug deemed to be harmful in clinical practice. (Curtis LH et al., Inappropriate prescribing for elderly Americans in a large outpatient population. Arch Intern Med. 2004;164:1621-1625) In addition, prescription claims data may yield critical signals regarding drug safety. Adverse events, too rare to detect in clinical trials, may become detectable in a database of several million patients. (Reed SD et al, How changes in drug-safety regulations affect the way drug and biotech companies invest in innovation. Health Affairs 2006;25:1309–1317.) Moreover, these databases are especially important in the elderly who—because of age, multiple comorbidities, or concomitant medications—are often excluded from clinical trials. (Lee PY et al. Representation of elderly persons and women in published randomized trials of acute coronary syndromes. JAMA. 2001;286(6):708-13.) Prescription claims data bases, therefore, provide the only means by which to document patterns of prescription drug use and to analyze the safety and effectiveness of those drugs in an elderly population.

Our comments on the proposed rule, therefore, reflect our experience working with Medicare and prescription claims data, and our first-hand understanding of the strengths and limitations of those data.

General Comments

We support the proposed rule regarding access to claims information collected for the Medicare Part D benefit (42 CFR 423; File Code CMS-4119-P). As written, the rule articulates well the urgent need to use Part D claims data for research, evaluation, oversight, and public health purposes. The proposal adequately balances the privacy concerns of Medicare beneficiaries with the need to use the information to protect and improve their health. We believe that the safeguards currently in place regarding the use of Medicare claims data will adequately protect the confidential, private health information of Medicare beneficiaries.

Specific Comments

"Purpose of CMS Collecting Information"

The proposed rule lists four illustrative purposes for which Medicare Part D data are needed: (1) Reporting to Congress on the program, (2) Conducting evaluations, (3) Making legislative proposals, and (4) Conducting demonstration projects. We urge that the list be expanded to include analyzing the intended and unintended consequences of prescription medications under actual conditions of use.

Part D claims data will provide valuable information regarding how prescription medications are actually used in clinical practice. Clinical trials, upon which FDA approvals are based, often exclude patients aged 75 years and older and patients with multiple comorbid conditions. We urgently need information regarding the effectiveness and safety of drugs in these vulnerable populations, all of which are well represented in Medicare.

Duke Clinical Research Institute
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Language describing the importance of using the Part D for this purpose is contained in the proposed rule but only under the section entitled, "Sharing Data with Entities Outside of CMS." We understand that the language, as currently placed, justifies the significance of these data to external researchers and to other federal agencies with complementary public health missions. CMS also has a responsibility to protect the health of its beneficiaries, even though other agencies and external researchers may operationalize that purpose. It is important that the rule reflect the scope of CMS's responsibility, and acknowledge that this limited data access mechanism is the only real means to accomplish this mission.

"Sharing Data with Entities Outside of CMS"
We strongly support the proposal to "make available Medicare Part D claims data linked to other Medicare claims files to external researchers on the same terms as other Medicare Parts A and B data are released today, with appropriate protections for beneficiary confidentiality." The linkage of Part D data with other Medicare claims data will enable researchers to address many critical questions regarding drug safety, effectiveness in real-world settings, the consequences of various cost-sharing arrangements, and the use of and outcomes associated with evidence-based care in the elderly.

In addition, we strongly support the use of existing data use agreement protocols to safeguard against the potential misuse of the data. Given the professional and ethical codes of conduct that guide academic research, the peer review process, and the requirements of data centers under the data use agreements, we believe that existing terms provide sufficient protection. Under current data use agreement protocols, the penalties of misuse are justifiably harsh. They should remain so. To expand the regulatory limitations for external researchers would add unnecessary burden likely limit the available pool of researchers for this important work and the types of analyses that can be performed to improve the health of Medicare beneficiaries.

One example of such an analysis concerns the use of drug-eluting stents (DES). On December 7 and 8, 2006, the Food and Drug Administration held hearings to assess the safety of DES after several reports suggested a higher-than expected complication rate for these new devices. An analysis of data from the Duke Databank for Cardiovascular Diseases, conducted by DCRI researchers, found that the safety of these devices is dependent upon the duration of administration of clopidogrel. (Eisenstein EL et al., Clopidogrel use and long-term clinical outcomes after drug-eluting stent implantation. JAMA. 2006 Dec 5; [Epub ahead of print]) Given how frequently DES are implanted in Medicare beneficiaries, there is an urgent need to validate our findings in that population. Further, if survival is dependent upon taking clopidogrel for an extended period of time, we need to understand fully the barriers that may limit access to the medication among Medicare beneficiaries.

"Beneficiary Access to Part D Data"
We strongly support the use of Part D claims data to develop a personalized beneficiary medication history, accessible by Medicare beneficiaries. At the individual level, a personalized medication history could also have enormous effects on the safety, quality

Duke Clinical Research Institute
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and convenience of healthcare delivery. It could provide ready access to medication information in an emergency situation; it could allow for a highly coordinated delivery of care in chronic conditions like diabetes; it would remove the need to recreate a medication history for new medical care providers.

Most importantly, a personalized medication history could provide the springboard for a personalized health record (PHR). For example, in the first phase the medication history might be augmented with data regarding chronic conditions, family history, and known drug allergies. While claims data could be used to identify chronic conditions, family history and drug allergies could be reported directly by Medicare beneficiaries. Over time, the PHR would become the source of critical data for health care providers.

Again, thank for you for the opportunity to comment on the proposed rule regarding access to Part D claims. We support the rule and believe that it adequately balances privacy concerns with the need to use all available information to protect and improve the health of Medicare beneficiaries.

Sincerely,

R. Harrington MD

Robert A. Harrington, MD, F.A.C.C.
Professor of Medicine
Duke University Medical Center
Director, Duke Clinical Research Institute

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Centers for Medicare and Medicaid

Response for Information on CMS' Role in Personal Health Records

Response from:

Health Record Network (HRN)
2400 Pratt Street
Room 0311, Terrace Level
Durham, NC 27705
www.healthrecord.org

HEALTH RECORD NETWORK

America's Network for Record Health

Contacts: Dr. Kevin Schulman
Director, Center for Clinical and Genetic Economics
Duke University Medical Center
Director, Health Sector Management Program
The Fuqua School of Business
kevin.schulman@duke.edu
919-668-8101

Introduction to HRN Response:

The Health Record Network was initially created and launched as a collaborative program between Duke University – Fuqua School of Business and the Duke Medical Center. Recently it has been incorporated as an independent not-for-profit organization. The intent of HRN is to create consumer market demand for automated health information and to provide a nationally available online portal for consumers to initiate the creation of their individual health records. As such, HRN is intended to complement the efforts of NHII to create a national health information infrastructure.

While generally following the questions raised in the NHII RFI, the HRN response primarily seeks to provide a broad perspective of what HRN is and why it is necessary to achieve the goals of healthcare information automation and individual health records for all Americans. In addition, the HRN response will address some of the more specific questions raised in the RFI such as: how HRN integrates to the overall NHIN architecture, how it will be managed, how it may be initially funded and the impact HRN could have on the delivery of care.

HRN Perspective and Observation:

The lack of information automation in the US Healthcare system has frustrated the best and brightest minds in healthcare and beyond for years if not decades. This frustration extends from the consumer of healthcare that has come to expect information automation based on the advanced state of information management they encounter everyday in almost every other industry, to the physician that can't locate records and key information on the patients he or she is treating, to the researchers that are forced to use primitive methods of data collection to validate hypotheses and identify disease patterns, to an almost endless array of individuals and organizations that are handicapped because health information is not easily, readily available. The costs are staggering – from hard dollars driven by needless duplication of procedures to softer dollars associated with medication errors, lost worker productivity, and in the most extreme cases – loss of life.

Information technology (IT) has solved the issues of cost, quality and efficiency in virtually every other industry. The vision of what IT could bring to healthcare is readily evident and has been discussed at length. Agreement on this is universal - from the President, to both Houses of Congress, to both major political parties, to hospitals, physicians, payors, the business community at large, and even the health consumer. This recognition extends far beyond the US market. Even publicly run health systems like those of the UK and Canada have already committed billions to creating the IT infrastructure within their health systems.

The only challenge is how to move an industry representing almost one fifth of US GDP, with 13 million employees and potentially almost 300,000,000 consumers from a decentralized, fragmented, paper based world, to an integrated, automated, networked world where information follows the consumer, information-based tools can aid in

decision making and patient safety, and population health data can be mined to improve the quality and outcome of care for all.

Given these statistics, the task of creating a National Health Information Network may seem almost beyond comprehension. The vision is in place; however every effort to realize the vision seems to end up at a tactical level that will not allow significant forward progress to gain momentum toward the ultimate goal. It is a classic situation of losing sight of the forest for the trees. Over the past year, as the need for electronic automated health information has become the topic du jour, HRN has had the opportunity to present and participate in the discussions with a number of the local health information infrastructure projects and programs. Each and every one of these discussions includes the most well-intentioned individuals driven by a common commitment to improve healthcare quality and outcomes in their community. Each of these organizations and the individuals that comprise the efforts are to be commended for their dedication and passion. Unfortunately, there is an all too-consistent pattern with these efforts. While starting with a grand vision, they invariably stumble on the trivia – "this doctor doesn't support IT, this doctor is concerned that automation of health information will de-value the resale value of their practice, 80% of our physicians have stated they have no plans to automate. This hospital won't allow access to their information. These vendors won't interoperate. This vendor can't interoperate between their own systems of different generations, let alone other vendors. This business is concerned that its employees will be suspect of any effort by the employer to encourage employee participation in electronic health systems. This hospital administrator does not believe there is any return on IT investment and therefore won't allocate the necessary funding to deploying the infrastructure. Even if they did believe in IT, margins and funds are so low, they don't have the dollars to invest"

And so it goes – more money lost, more inefficiency, more lives lost due to error, and more time goes by without a fix. Already it has been nine months since President Bush issued a proclamation that within 10 years every American that wants an electronic health record will have one. Almost 10% of the time allocated to achieving this goal has elapsed – does anyone feel that true momentum at a national level has shifted to make this statement a reality?

The "Internet" analogy

While at times it seems like the obstacles to automating the nation's healthcare system are simply insurmountable, in fact, HRN believes the vision is quite attainable; however we believe that while the efforts to date – focusing on standards and localized pilots are necessary, they should be augmented with a parallel effort designed to mobilize natural market forces of change.

An analogy exists in considering the current state of the Internet, and the evolutionary process involved in reaching this state. In our Internet analogy, imagine full understanding of how the Internet exists today, but having that vision in 1990. In this

analogy, rather than the orderly, (or chaotic – depending on your perspective), evolution of features/functionality available in today's Internet, a relatively small group of IT industry professionals sought out to create the 2005 Internet in 1990. They would have been faced with a world where the penetration of personal computers in the home was very low, and in the business world was comparatively low. They would have operated in an environment where Internet access was largely via modem at speeds in the low four digits. People still shopped in stores and used the public library for research, sent letters and faxes to each other as a means communication, and on and on. In this scenario, our clandestine team of IT professionals would have set out to define what they needed to accomplish to launch Internet 2005, (in 1990). The work list would have included a few challenges such as:

1. We need to lower the price points of personal computers
2. We need to rewire the nation with highspeed/high bandwidth cable
3. We need to develop fiber optics as a low cost alternative to make more bandwidth available
4. We need to create financing models that will incent carriers to put more bandwidth in place – to the home and to provide greater capacity to support Internet servers across the country
5. We need to create standards of interoperability that will allow disparate email systems to communicate
6. We need to create a new transaction model that allows online commerce to flourish – for now – just call it "Paypal"
7. We need to beef up the transportation industry to accommodate a surge in demand for shipping that will come as people shop online; we'll probably even need to pass legislation to authorize tandem tractor trailers on our nation's highway system because of all the new shipping traffic
8. We need to develop some third world countries as resources for writing code and developing software – there just won't be enough people in the US to do this
9. We need to retool our education system so that we turn out more information technology trained people to support this demand
10. We need to automate inventory management systems – because online transactions will be automated and will require real-time inventory data
11. We need to free up capital to encourage new businesses to develop products, services and new business models
12. Finally – for goodness sake -- don't let anyone know about this until its ready!

Did the Internet evolve this way? Certainly not. It is simply impossible to anticipate every need, every implication and every cause and effect that occurs as something as massive and pervasive as the Internet evolved. Yet every one of these actions did occur and conspire, not by design, but by market force to create an environment that allowed the evolution of the Internet to develop as we know it today.

Taken as a whole, these tasks would have led to the conclusion that "Internet 2005" could simply not be created. While we obviously know the outcome of the Internet evolution,

as a nation we currently seem to be attempting this exact track in our quest to automate our nation's healthcare system. For as vast as the healthcare industry is, the core of people and organizations focusing on healthcare automation is relatively small. Yet this group is attempting to resolve every issue of deployment, standards, interoperability, new product design and new business model creation before the "product" is even introduced. History has repeatedly demonstrated – markets do not behave in this manner. Moreover, the current approach to the creation of an NHIN is fundamentally a "push-strategy" – again, an approach that is not conducive to the basic laws of a free market economy.

Perhaps the most intriguing analogy between the evolution of the Internet and push to automate healthcare lies in the area of financing. Since the "Internet" was not a product or service owned by one individual or one company, there were significant concerns regarding how investments would be made to sustain and grow the infrastructure. As demand for the Internet increased exponentially, there was a growing chorus of opinion that the Internet would ultimately collapse under its own success. Specifically, there were no financial incentives for carriers to invest in Internet infrastructure expansion. However, given the market success of the Internet – two interesting and offsetting phenomena occurred. 1. Technological innovations dramatically lowered transport costs – thereby reducing the absolute funding requirements to expand the Internet capacity, and 2. Carriers found that the Internet could effectively become a loss leader. Their investments in Internet infrastructure could be more than recouped by the sale of other retail services such as online access, and the creation of new business models such as Internet Service Providers, (ISPs).

The other relevant financial analogy between the Internet and healthcare is the potential revolutionizing impact of new markets. As an example, the concept of ASP, or application service providers evolved during the Internet era. During this period many businesses recognized that it was more efficient for them to focus their energies on their core business activities and not invest time and resources trying to manage activities like information technology. Many of these companies opted to entirely outsource functions like IT. Others found that it was much more cost effective to simply outsource the "application". In Healthcare, where funding is a very significant concern, it should be anticipated that these types of solutions – outsourcing and ASPs will emerge in creative ways to address the unique needs of the health industry. As an example, while individual physicians may struggle to see how they can afford to deploy automated clinical systems within their practice, a market of 700,000 physicians "demanding record automation" would emerge as a very desirable market for an entrepreneur with a new concept of cost effectively servicing this market.

Market Dynamics – the HRN Point of View – A complementary parallel path to NHIN

Start simply, start quickly, start nationally – unleash the natural forces of market demand to evolve the fully integrated, automated national health information network.

Just as our Internet analogy, the market never begins at the end. Rather, natural market dynamics occur when the market at-large values an innovation or new product or service. The evolution from that initial level of market acceptance is generally unpredictable. Market demand ultimately drives the product or service in many unanticipated directions as the market matures and demands improvements and advancements in features and functionality. New entrants enter the market addressing needs for lower price points, greater functionality and even, radically new business models.

So how do we apply these basic market forces to the US healthcare system? At the broadest level, HRN operates with one core assumption and several operating tenants:

- HRN Core Assumption: health information, at the individual level, belongs to the individual consumer and is non-competitive. (I.e., don't compete on the information; compete on what can be done with the information).
- HRN Operating Tenets:
  1. Create national market demand within the consumer market for automated health information. This will be accomplished through targeted offers to a segmented market – focusing initially on perceived early adopters - parents with young children, chronically ill, etc. But ultimately engaging consumers universally. "Productize" offers that will be valued by the consumer and provide utility to the consumer.
  2. Establish a nationally-branded online health utility. This is perhaps the most important key of HRN - you can't create demand and not address it. Likewise, if there is no ubiquitous offer - market demand will be diffused and no momentum for change will be unleashed throughout the industry. The ultimate goal of HRN is to create universal availability. Every physician's office, every hospital, every clinic – every point of healthcare will eventually display the HRN logo. In this way – it becomes part of the culture of the US health system. Consumers will come to know it and expect it, physicians will recognize it and subsequently invest the time to understand it and utilize it.
  3. Provide a free service to all consumers where their health information is used in their own care.
  4. Capture the value of the overall national network and the data in the network as the means to cover operating costs of the network. (It is a non-profit, but it is intended to be financially self-sufficient).
  5. HRN will be an overlay network - where some consumer information will be stored in the network, the bulk of the clinical data will reside out in the health systems. HRN will contain pointers from the consumer record back to the various sources of information that exist for an individual consumer. Only information that is relevant to the consumer in managing their health needs to be actively available in their HRN record. The balance can be more efficiently stored

throughout the points of care that comprise an individual's full health history.

6. HRN will be a safe, secure environment that protects the privacy of all consumer information. The consumer will have control access rights to either view information or edit/add information. In this way, HRN will dramatically increase the control consumers have over their health information.

The balance of the HRN response to the NHIN RFI will address many of the questions raised in the RFI, as well as provide an architectural perspective on how HRN will initially be configured, operate and evolve to align with the natural evolution of the market for automated health information. The fundamental key to design must always be – ***flexibility***. While we can pontificate how future iterations of the NHIN may evolve, following the core tenets of HRN, we understand market forces will ultimately dictate this evolution. (One simple example – the discussion of "RHIO's". In some scenario's these may be essential to the ultimate evolution of a national network, in others they may be impediments and in yet others they may be complementary but not essential.) So any design must be flexible in concept to accommodate the unforeseen twists and turns that may occur as the NHIN begins to emerge and more importantly – begins to be utilized.

What is HRN?

- A national utility. As previously stated, the underlying assumption of HRN is that "individual consumer health information is non-competitive" – it belongs to the consumer. Therefore, HRN provides the portal for consumers to initiate the creation of their health record and manage read/write privileges. As a utility, HRN will also address basic consumer functions like online help, call center support, technical support, etc. In the current efforts of LHIIs and RHIO's – while there is ample discussion of themes like consumer focused/patient centric, there seems to be a missing element of execution – who/what actually "services" the consumer? If consumers are to be an active part of their own information-based health management, then there will be obvious issues of consumers needing technical support, having questions about why information has not yet been imported into their record, etc. The support requirements are extensive and have largely been ignored to date.

  When considering possible solutions to the need of servicing health consumers, we find a unique challenge exists as a barrier in the healthcare industry. Specifically, "consumer affinities". What "natural affinities" exist between a health consumer and their health providers? Most health consumers have a primary care provider, a dentist, perhaps one or two specialists – dermatologist, ophthalmologist, allergist, etc. Where is the natural affinity? Who has the responsibility to develop and manage the consumer's health record? Consumers generally do not see an affinity relationship between themselves and a hospital. Their relationship may be "that's my local hospital", but beyond that, they are

much more likely to choose a facility based on their specific care requirements at a point in time. Beyond providers – the health consumer may be a member of a specific health plan or employer. While these represent affinity groups – they are transient in nature – subject to frequent change as an employee changes employers or an employer changes health plans. Likewise, perhaps the consumer is a member of AARP, or a chronic illness group – while these relationships may be longer term – there is no extension beyond the individual and the organization. A member of a diabetes group that uses a health record system provided by that group – can they bring other family members into their diabetes record keeping system? Would that be allowed, and if so, would the features and functionality be optimized for a non-diabetic? The fundamental barrier is who/where does a consumer look to, to manage their health information. At this time, there is no overarching organization that provides this function

HRN – the national utility, resolves these challenges by focusing on enabling the population – whether supporting consumers in their efforts to start the process of health record keeping, or physicians that seek to interface with the network, HRN would have a business mission to service these constituents.

- A "starting point". Rather than a "build it over the next ten years and assume they will come" proposition, HRN's concept is to start nationwide at a basic level – consumer-provided information. This functionality can be built quickly and relatively inexpensively – it represents a "starting point". By starting at this basic level, we can begin to engage early adopters very quickly. Additionally, there are data elements that are readily available that can be linked to the consumer record early on, and will begin to create the path to an automated personal health record. (We will address a possible evolution track toward greater information automation later in our response.)

- A brand. The inverse of the affinity group is demonstrated in how healthcare is delivered, or "consumed". While much of healthcare is local, 14% of our society moves each year and almost 20% of privately insured consumers change their health plan each year. Additionally, a much larger preponderance of the population travels and vacations. Unfortunately, none of us knows exactly when or where we will require healthcare services. If health information networks evolve on a localized basis, or around an affinity group, the healthcare providers are then presented with an almost impossible burden to determine where and whether a patient has documented health information. Imagine the absolute chaos of an unconscious patient showing up at an ER. "Check his pockets to see if he has a health record USB key, or perhaps a smart card. He looks "sick". Check the disease registries to see if he has a health record with any of them. His license says he lives in Indiana. Don't they have a pretty advanced automated record system out there?" This situation is quite real – and quite possible given the current direction of health automation evolution. It is fragmented – consumers don't know where to turn and providers cannot possibly know which of the myriad of alternatives exist, are viable and worth understanding and interfacing

with. This fragmentation also diffuses any possible level of market momentum as we are still in an early stage early adopter market. Given this, the limited demand that may exist is spread among the many varieties of PHR alternatives and therefore has no impact on the industry. So HRN is a brand – a nationally recognized symbol of safe, secure automated health information. The objective – every physician's office, every clinic, every hospital, every point of care will ultimately display the HRN logo – representing their participation in the network. The HRN brand ultimately becomes a component of the US healthcare culture. ER personnel, clinical personnel and consumers no longer have to struggle to consider which record system is best, which one is most accessible – one source – simple and efficient. Individual health information is not competitive.

- A community of portals. While HRN is a consumer-focused initiative, it is anticipated that ultimately it will evolve as a diverse community of portals. The consumer portal will provide the web-based, personal health record to all registered users. But it will be more than just a personal medical record - it will be a series of tools, guides, and health content that will enable the consumer to proactively manage their health. Some of these features will be provided by HRN, others will be provided in association with various third parties.

  Beyond the consumer portal, other portals are envisioned that will address the specific needs of various audiences. For example, physicians would have their own portal where they could review and update their patients' medical record. This would require a substantially different interface. They would not be interested in all of the features and functions of the consumer. Rather, they would be interested in having easy direct access to all of their patients that participate in HRN – (where the patient has given them access), for features like authorizing prescription renewals, certifying vaccinations, etc. Billing interfaces – for the physician and their staff to be able to immediately submit claims via the HRN physician portal. (Note – this functionality could either be provided directly by HRN or as a module through existing sources.) Likewise, additional targeted portals may be necessary for organizations like health insurers – where they would view de-identified member-wide data.

- An overlay network. Interoperability is a key aspect of HRN and the need to connect to other sources of data is central to the long-term viability of the network. Along with the portals, HRN will contain an integration infrastructure to provide all the connectivity to the private and public sources of health data. Known as the Health Exchange Engine, it will provide the set of common intercommunication tools needed to interoperate with current and emerging technologies and standards. For example, the Health Exchange Engine will provide connectivity to payor organizations using the HIPAA transaction set or to a health system or government agency using HL7. As the standards evolve over time, so will the Health Exchange Engine.

- A self-funding, non-profit structure. HRN is structured as an independent not-for-profit. However, while not-for-profit, we believe the concept can ultimately be financially self-funding. As a critical mass of membership is developed, the value of the network and the value of de-identified health information will generate adequate revenues to sustain the operation of HRN. Therefore, the goal of HRN is to always provide a free service to the consumer where their individual health information is used in the delivery of care to them; and mine the value of the network and the aggregated de-identified data to sustain operations.

- A market enabler. While HRN would represent the "umbrella brand", it would be an open community where both fee-based, value-added services and other not-for-profits could exist and would be encouraged to exist. As an example, in earlier discussion we referenced the chronically ill markets. Diabetes support organizations may choose to offer enhanced services – as a member of the umbrella HRN brand – to the unique needs of this population. In this case it is a win/win proposition. The needs of the consumer can be better served by an organization specifically focused on them, yet they do not exist as a "splinter" group outside of the national community.

  Additionally, many of the challenges currently being addressed relative to the creation of the NHIN would likely be resolved with robust market demand. In our free market economy, market demand is the ultimate driver of innovation. So while interoperability issues stifle deployment today, and financial challenges prohibit deployment – robust demand could have a stimulating affect. Imagine the health IT vendor that prefers to pursue their proprietary architecture in a market where consumers are saying, "I really prefer to be treated by physicians at hospitals that utilize automated health information". We need look no further than the legendary history of "Betamax vs. VHS" to understand the impact of a "better" format, vs. a market standard format.

  A national goal. "America's Network for Record Health". Ultimately, the goal of HRN is to directly engage the consumer in the management of their individual health. To this end, our tagline is specifically designed for future use. As HRN develops its market presence and awareness, we will launch a campaign to execute our tagline – "America's network for record health". The concept behind the tagline is that by leveraging online/automated health information, we can strive as a nation to achieve record levels of health for all citizens. This can be accomplished if every consumer uses their own health information in collaboration with their clinical care team to manage to optimal health – getting appropriate tests, screenings, vaccinations, asking the right questions, etc.

  Record Health also means patient safety - lowering medical errors by reducing drug-to-drug interactions, reducing service duplication (and lowering costs) by centralized and accessible patient records, and tracking implanted devices so that, in the unfortunate instance where such devices need to be recalled, there is a method to track them.

Also, at a population level, using de-identified data to more effectively develop new therapies, spot drug/drug interactions, identify new disease trends, etc. This is a natural campaign that could see the participation of many businesses, associations, consumer groups, etc. – *this is cultural change.*

How would HRN operate and be managed?

- Board of Directors – HRN would be governed by an independent Board of Directors. The objective of the Board of Directors would be to serve as the Network *regulator*, prescribing and enforcing standards and protocols to ensure individual privacy and Network security, and fair and non-discriminatory access to aggregated data (*e.g.*, codes of conduct for Network operators and users, pricing structures). It is those Network users (individual consumers, public and private users of aggregated data) that will comprise the principal constituency of the Board and to whom Directors will owe a fiduciary responsibility.

  The intended cross-section of Board expertise would include representatives from medical academics, health care economists, network security expertise, ethicists, consumer and public policy persona of unquestioned integrity and popular renown; they will help immeasurably to achieve the initial goals of HRN while simultaneously providing the foundation upon which to ultimately achieve financial self-sufficiency. The HRN Board is already being developed, current members (while not identified by name), have already been recruited and include:

  - A nationally recognized health economist and federal health policy expert, has been involved with setting the national health agenda for many years. An active member of The Institute of Medicine and serves on several boards
  - A nationally recognized bio-ethicist, has authored or edited twenty-five books and over 500 papers in peer-reviewed journals of medicine, science, philosophy, bioethics and health policy.
  - A practicing child, adolescent, and adult psychiatrist and faculty member at an internationally renown Academic Medical Center.
  - A founding member of the Academy of Radiology Research (ARR) and was ARR president when the bill to establish the National Institute of Biomedical Imaging and Bioengineering was introduced in the Senate..
  - **Kevin Schulman, MD** - Dr. Schulman is a (co-founder of HRN) and a Professor of Medicine at the Duke University School of Medicine, Vice Chair of the Department of Medicine for Business Affairs, and serves as Director of the Center for Clinical and Genetic Economics (CCGE) at the Duke Clinical Research Institute (DCRI). Dr. Schulman also serves as the Director of the Health Sector Management Program, Director of the Center for the Study of Health Management, and Professor of Business Administration at the Fuqua School of Business, Duke University

To help assure Board sensitivity to the needs and concerns of Network users, an Advisory Committee of Network Users will be established comprised of representatives of, among others, consumer advocacy groups, corporate sponsors, providers of health care products and services, payors and health care officials from both state and federal government. In addition to educating the staff and Board of HRN as to the needs and concerns of user communities, the Advisory Committee would offer a platform for the exchange of views among representatives of often divergent constituencies, thereby facilitating a better understanding of competing concerns and even serving as a catalyst for cooperative movement.

- Ombudsman - Soon after commencement of HRN operations, an Office of the Ombudsman would be established that would operate independent of the Network management. It would provide an avenue for the receipt, investigation and resolution of consumer concerns about privacy or confidentiality or provider concerns about neutrality. Going forward, the Ombudsman function would help the Board in its development of privacy protocols while, again, adding to consumer confidence.

- Publicly vetted rules of operation – An important element of defining the rules of operation for HRN would be extensive public involvement in the development process. It is the intent of HRN to conduct regular public sessions designed to collect market input on the key issues related to the operation of HRN. Including, but not limited to privacy issues, security, data access and usage (where de-identified data can be used and not used), and services that may be offered within the network.

How would HRN be funded?

There are two distinct funding requirements to launch HRN. The first, the initial startup and the second, ongoing support once the network is fully operational and achieves a critical mass of members. It is anticipated that the start-up period for HRN would be approximately 3 – 5 years. During this period, operations would require outside investment to reach the point of critical mass membership where the value of the network and the data sources would be adequate to sustain ongoing operations.

Startup

A recent Commonwealth Foundation study polled the CEO's of the top US businesses. The results report that universally – the cost of healthcare was cited as the number one or two issue facing their businesses. The follow up question – "What do you think is the solution?" -- was met with a uniform response of "No idea how it will be resolved". This sentiment reflects the fact that the national health care crisis has become a factor that is impacting the financial performance of our nation's businesses. Therefore, a long-term fix (not a cost-shifting

approach), but a fix to alleviate the cost of care while improving the quality of care, is truly in the best interest of all businesses. Information technology is well known and understood in the business world. Virtually every industry has seen revolutionary change as a result of IT. While the applications vary, the results are consistent – where IT is applied – costs are reduced, efficiency is improved and most importantly quality is dramatically improved.

The HRN proposition is then grounded in two very fundamental business principals: 1. IT automation reduces cost and improves quality and efficiency, and 2. market demand drives market behavior. On this basis, one approach – (which is currently being pursued), is that businesses on a voluntary basis could participate in funding the creation of HRN and driving the awareness and demand for HRN. Spread across a broad cross-section of US businesses, the financial investment in the form of a "voluntary contribution" to HRN to create a robust consumer market for information-based health products could be, individually, quite insignificant. Additionally, if businesses choose to participate in HRN, they could also be quite effective in driving the national dialogue regarding individual participation in health management through information. This would provide the additional benefit of helping to drive cultural change throughout the healthcare industry. Since the Federal government is also the payer for care of about half the US population, it would be important for the government to also play a sponsoring role in HRN. This government participation would also have the side benefit of signaling to the business community that HRN was in fact an element of the national plan to move toward automation of the health care industry.

Ongoing Operation

Once HRN is operational and begins to accumulate registered members, its broader value to the community of healthcare becomes apparent. Aggregated/de-identified data can be used for a multitude of purposes – from research to clinical studies to disease tracking to bio-terrorism monitoring. The revenues from the sale of this data and access to the network would be used to attain the HRN not-for-profit goal of providing free service to all consumers and their care team where their health information is used in the delivery of healthcare services. Additionally, in keeping with the HRN assumption that "individual health information is not competitive", HRN would essentially be a wholesaler of the information. Based on the criteria defined and publicly vetted by the HRN Board of Directors, aggregated/de-identified data would be made available to any sources that meet the criteria. These sources could then add value to the raw data, for example, through aggregation and analysis efforts, and make it available at a retail level to their target markets. In this manner, competitive markets can exist and develop around the use of the information source.

How could HRN impact the delivery of care?

Perhaps the greatest challenge or barrier to the development of a health information network is understanding and valuing the utility of it as it emerges through various stages

of evolution. If it were introduced on a flash cut basis – just universally available instantly, the utility would be there. However, the cultural change necessary for the market to embrace it would not have occurred and therefore the very real risk would be that no one would use it.

HRN envisions an evolution where consumers start the process of creating personal health records. Obviously, the only participants at this stage would be the early adopters that see the utility in creating a historical account of their health – family health history, medication lists, allergies, clinical care team. However, over time, as automated data sources link into the record, the consumer's HRN record becomes a tool for the consumer to use in conjunction with their physicians to manage their health. HRN will be interactive – so alerts for medications, need to refill prescriptions, need to maintain diet/exercise programs, need to schedule periodic tests and physicians' visits can all be triggered through HRN. So the long term goal is to create a cultural environment where consumers are active participants in the management of their care, and they have the tools to achieve this – information and information management services. As consumers become active, there will be a natural "cause/effect" reaction that encourages physician and provider participation.

How would HRN impact the IT market at large/what role should the IT industry play in creating the health IT market?

As a $1.7 trillion information-intensive industry, the healthcare industry should be spending close to 10%, (assuming it matched the relative level of investment in IT seen in other industries), of this total spend on information technology, or $170 billion per year. Obviously, this is an incentive for the IT industry to cultivate the health IT market. Unfortunately, healthcare is not an easy industry in which to sell IT. Information Technology is still viewed with skepticism and has not driven the necessary process change within the healthcare culture to enjoy broad adoption. HRN has talked with some of the top IT organizations in the US economy. One example of the experience as recounted from perhaps the largest software vendor in the world is as follows: "We felt like we had really achieved something significant. We had just completed our second pilot application. Unfortunately, after 18 months of work, we realized that what we accomplished was nothing more than two successful pilots. They were not replicable anywhere." This type of result is far too common and represents the fragmented nature of our current approach to automating information within healthcare.

While every IT vendor has organized their sales efforts and has forecast their quarterly sales targets for health industry sales, they have uniformly failed to allocate adequate investment to actually "create the Health IT market".

It is universally accepted that healthcare in the US is in national crisis. Further, it is widely accepted that information technology can provide long term improvements in healthcare by lowering cost of care and improving quality and outcomes. Unfortunately, "injecting" IT into the healthcare system is not as easy as selling more servers and more

software next month. A slightly longer term horizon must be tolerated by the IT community.

HRN proposes the establishment of an IT consortium of competitive and complementary IT vendors that could effectively leverage their investment dollars in the creation of the Health IT market. This "ITVAHI", (information technology vendors for the automation of health information), could pool resources to advance the concept and market awareness of the national health utility – HRN, as well as leverage their technical capabilities to refine and/or develop products and services necessary to automate the health industry. This coalition could have a limited life of 3 – 5 years with a mission to drive the revolution of US healthcare around information technology. This approach would benefit all individual health consumers, the nation as a whole and obviously open a competitive market for all participants.

How would competition exist within the HRN framework?

The core operating assumption of HRN is that individual health information is non-competitive. It is the property of the individual health consumer. Therefore, while we believe that HRN is truly a utility and as such, non-competitive, we believe the existence of the network will create an environment in which competition can thrive. This competition can exist at many levels. Several examples:

- One of the nation's largest payer organizations responded to the HRN concept by preemptively stating our operating assumption – "Don't compete on the information. We'll compete on what we do with the information to add value".
- One of the nation's largest employers responded to HRN by stating that, "Since the health information within HRN is the property of the individual, we as the employer would be in a better position to negotiate optimal health plans in a competitive environment because the burden on the employee would be minimized if we made a change in health plans.
- Providers could retool their business models and create new revenue sources by offering proactive health management services. Offering – with consumer consent services that perform a complete diagnostic of health status – via HRN record, then assemble a "10 year health plan". A comprehensive service including diet recommendations, exercise, medication, testing schedules and ongoing monitoring. The offer could be "to drive your physical age 10 years below your chronological age".
- Competition could also flourish on the use of aggregated/de-identified data. Specialized firms could emerge that could access the HRN data source and focus on specific disease categories, reporting new trends, evaluating new treatments, recommending new areas of research.
- Competitive personal health record vendors could exist within the HRN umbrella. The features and functions for tracking a diabetes patient vs. a heart patient vs. a healthy individual that wants to optimize their health –

all have different needs and specialized services and vendors could emerge to cater to these unique needs.

In short, the mere existence of this network creates an unparalleled market. Essentially, an "Internet" of healthcare. Just as we could not foresee all of the business derivatives that emerged from the Internet – (online travel, online banking, shopping, online auction services, etc.), the possibilities for using a network like HRN are only constrained by our current imagination.

What is HRN relative to NHIN?

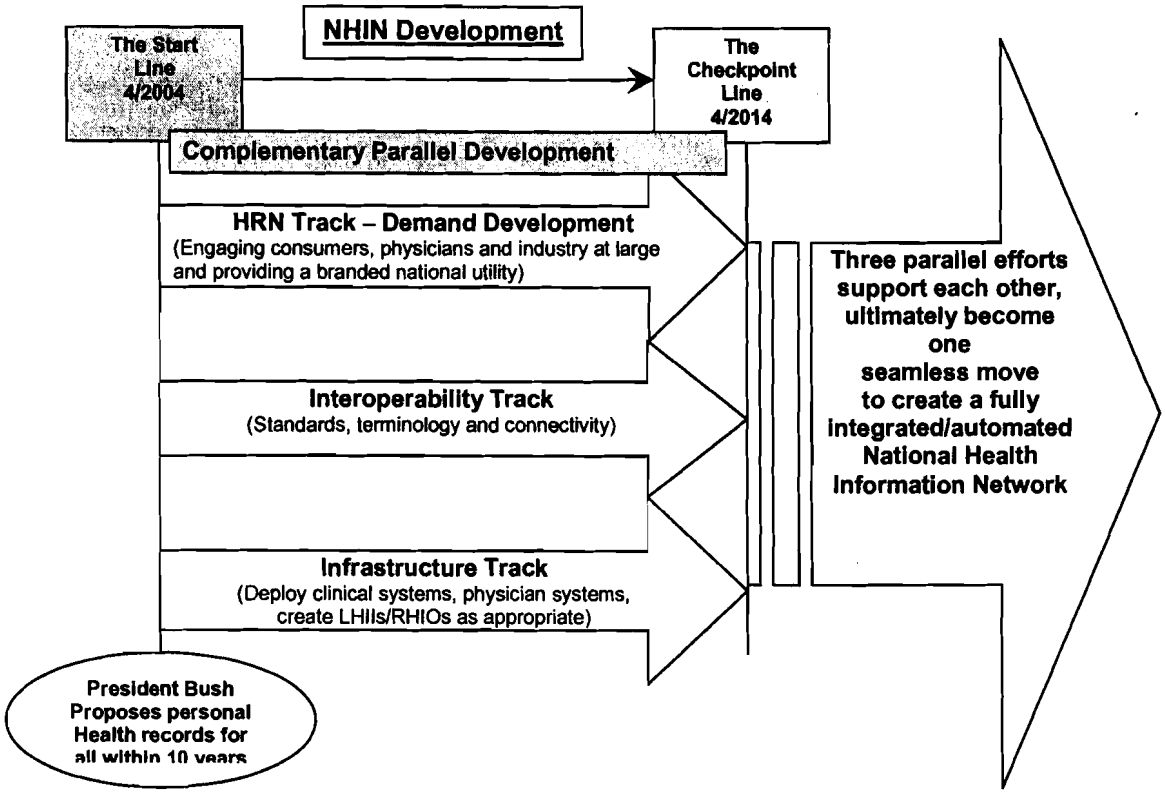
The perspective of HRN is that NHIN represents "everything". From the automation of the individual physician's office, to the automation of hospital systems, electronic prescribing, automated lab data, imaging data, -- in short, the goals of NHIN will be accomplished when every US citizen that wants an individual electronic health record has one. Further, this individual record can be utilized by any and every point of care across the country – anytime/anywhere access, as authorized by the individual health consumer.

In this scenario, HRN represents the utility overlay. HRN supports the users' needs and interfaces with either the individual points of care, or if aggregated networks such as LHIIs or RHIOs do emerge, HRN would interface with them. HRN is not NHIN, nor is it a replacement. It is a complementary component of building the fully integrated/automated national health information system.

How do we start HRN?

The launch of HRN is already well-underway. The initial HRN program was announced in March, 2004. Since that time, interest in the concept of leveraging consumers and creating market demand for health information automation has gained increased attention across the industry, and the nation at-large.

At this point, it is important to note that HRN is not a replacement or single strategy. It is a complement to what must be a multi-pronged approach to driving change in Healthcare. We see this multi-track approach as follows:



The three paths envisioned include:

- The HRN – demand development track, (the focus of this RFI)
- The Interoperability Track – (largely underway through the efforts of various organizations such as HL7, CCR and others)
- The Infrastructure Track – (this track is also underway in varying degrees through the various LHII and RHIO pilots as well as more targeted deployment of systems in hospitals, clinics across the country.)

The opportunity is to link these parallel efforts and to create complementary forces of demand that drive resolution of issues and barriers that heretofore have acted to stifle significant movement of the health industry toward information based automation.

Pilots – Several HRN pilots are already in advanced stages of planning. The intent of these pilots is to gather additional information regarding the market for automated health information. Specifically, issues such as: who are the early adopters, what features/functions are in the greatest demand, what is the most efficient means of communicating with the early adopter markets, and what are the right messages to communicate. This information will be assembled as the broad strategy for a nationwide launch of HRN is prepared.

- Wyoming – statewide market-creation pilot. The state legislature and the Governor have approved a statewide pilot program designed to create consumer

market demand and interest in creating and maintaining online personal health records.

- Duke Heart Center pilot – This pilot will provide HRN records for patients referred to the Duke Heart Center from surrounding hospitals. Additionally, it will provide HRN records for a local population that maintains dual residence in the Durham area and Florida. In addition to the consumer provided information provided in HRN, linkages will be made with clinical data and imaging records that are developed for each pilot participant. The impact of the HRN record will be to provide anywhere/anytime access to patients and their care team at Duke and at their secondary care centers. The intent of this pilot is to create a working demonstration site of the benefits of automated health information.
- Breast Cancer pilot – negotiations are underway for an HRN pilot with a major academic medical center to evaluate the impact on and demand for automated health records within this population segment.

Building HRN

The Personal Health Record

The personal health record is instrumental in getting the consumer to become more involved with managing their healthcare. HRN will provide all consumers access to a portal - a free and secure web-based personal health record that can be used to track, manage, and monitor their own, their family's, and elderly relative's health information. HRN will be more than just a place to store one's private medical information. It will contain a set of tools that will guide and assist them in managing their own health. From quality of life assessments to automated prescription refills to managing chronic conditions, HRN will help Americans better manage their own health and live healthier lives.

HRN will also support the differing needs of America's population. We recognize that people are in different stages of their lives and have needs. HRN's personal health record will be standard enough to support the standard personal health record requirements, but will also contain specific programs targeted at key audiences. At this point, three major products are envisioned:

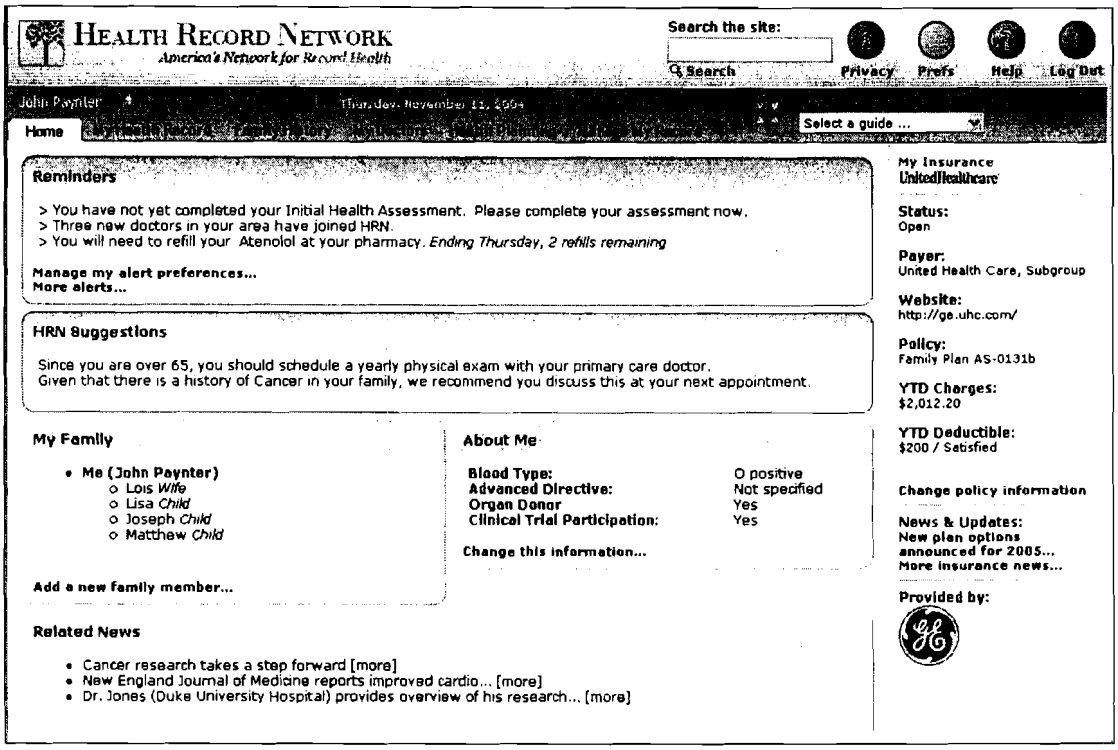
- **Infant Care** – This product is geared toward families with young children. As a newborn enters the world, their parents would be given the opportunity to create a personal health record for their child. This record would then track all metrics for a young child and monitor all the immunization requirements. It will remind the family when inoculations are due, document when they are complete, and produce forms necessary to demonstrate that a child is current with their immunizations, and provide this information to the CDC. Additionally, links can be established to share this information to organizations to which this information needs to be reported, e.g., schools and camps. Through HRN's relationship with outside content providers, it will provide the mother with useful information to help them answer any questions they have.

- **Chronic Care** – This product is geared toward consumers with chronic conditions such as diabetes, asthma, cancer or congestive heart failure. HRN will provide specific features to monitor and measure key medical values associated with these conditions. Additionally, working with third parties, HRN will help the patient monitor their chronic condition by interfacing with portable self-monitoring medical devices that upload this data to the personal health record.

- **Elder Care** – This product is geared towards consumers who would like to manage the care of their parents or another elderly relative. A major challenge facing the elderly population is making sure they are taking their medications and following any established protocols. Through HRN, authorized family members can monitor the progress of their family members without the need to be in the same location.

Below is an early rendition of what the consumer portal could look like.

Health Record Network
View of the Consumer Portal



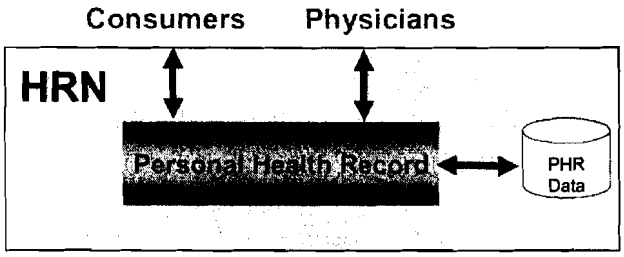
Regardless of how much HRN helps the consumer, it doesn't replace the physician. Instead, it will make the consumers' interaction with the physician more productive. Consumers will be able to print out their medical information using HRN's report manager and present it at any point of care. This will alleviate the constant headache of always filling out the same questions over and over again. And with the consumer's authorization, physicians will be granted access to their personal health record and will be able to review and update the information directly using the HRN Physician portal. Moreover, a consumer will also have the control to determine what the physician actually sees. There may be some information that the consumer doesn't want to share with all doctors – this control is imperative to maintain patient privacy. (However, to protect the physician – flags would alert both the consumer of the associated risks of withholding health information from their physician, and an alert to the physician if their patient has chosen to suppress information. In this way, the physician can choose whether to counsel the patient on providing the information, or simply decline to treat the patient.) All outside access will be logged and any information that was added or changed will be written to an audit trail for full review by the consumer.

A separate Physician portal is needed because the view the physician needs of the data is different than that of a consumer. Physicians will access their portal and will be able to view a list of all of their patients that have granted them access to HRN. Using a key that had been provided to them, the physician will be able to log on and review the

consumer's information in a manner that is customized for them. This portal will also allow the physician to update key information directly into the personal health record – as long as they are authorized. All information entered by a physician will be logged and electronically signed so that the consumer knows where it came from. Information that has been entered by the physician and electronically signed will not be able to be changed by the consumer – it becomes part of their record. However, it can be suppressed so that others cannot see it. The physician's interaction can be passive or active. In other words, the physician can simply use the record as a source for information, or they can contribute information to it. It is anticipated that as the interfaces are built between HRN and the clinical systems, the physician input will be on an automated basis and will occur as the physician enters data in their own electronic record system.

The diagram below depicts the consumer and physician access to the personal health record. The database represented in the diagram will be secure and all access will go beyond HIPAA's security requirements.

Health Record Network
The Personal Health Record



A preliminary list of HRN's features and functions is provided below:

Consumer Portal

- **Notifications & reminders** – receive reminders for items such as doctors appointment, prescription refills and immunizations due;
- **Suggested actions** – prompts that suggest and recommend actions you should take to realize a healthier life;
- **Personalized news feeds** – customized new feeds based on your preference;
- **Family health history** – a complete picture of a your family's health history through graphical view;
- **Manage personal information** – information about you that is central in managing your health;
- **Manage health information** – tools to manage all aspects of your health including items such as doctors appointment, allergies, problem and medication lists, procedures and therapies;
- **Encounters** – track all visits to doctors offices;

- **Lab Results** – a centralized repository for all your test results; allows you to graph and examine trends of those results over time;
- **Medical images** – store and view still or move digital images;
- **Implanted medical devices** – maintain a list of any medical device that has been implanted within your body;
- **Tracking** – tracking and graph your vital statistics, lab values, and exercise results;
- **Doctors list** – maintain a list of all your doctors – primary or specialists;
- **Assessments** – take quality of life and risk assessment to determine your health profile;
- **Drug Interaction** – check to see if any medication you are taking is in conflict with another;
- **Device interfaces** – directly retrieve medical values from portable devices to help monitor chronic conditions such as diabetes, hypertension, or asthma.
- **Security & privacy** – maintain controls on who can view your account and view who has accessed or updated your account;
- **Report Management** - generate reports such as your health history or a wallet-sized emergency card;

The physician portal will provide authorized doctors with access to the approved medical information listed above, but in a format that is conducive to a physician's perspective. It will also provide these extra features:

Physician Portal

- **Patient lists** – view a list of patients who have provided authorization;
- **Record review** – review the medical record and record any changes or additions the medical information;
- **Electronic signatures** – digitally sign any updates made to the personal health record;

The Overlay Network

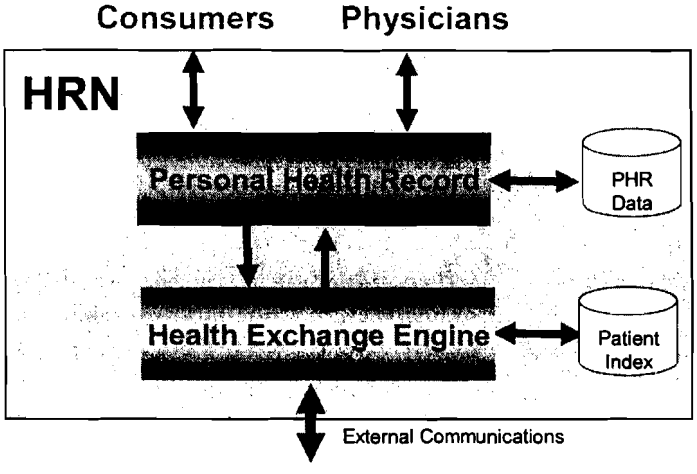
While HRN's premise is grounded in the fact that focusing first on the consumer is the best way to meet Presidents Bush's vision of interoperable electronic health records within 10 years, connectivity between all the healthcare stakeholders will be instrumental in order to realize this vision. This connectivity is not just limited to clinicians, but to all parties that are involved in the diagnosis, delivery, and payment of healthcare – physicians, hospitals, commercial payors, clinical researchers, pharmaceutical companies, and the government (state and federal).

The HRN model, with its concept as an overlay network, supports this vision. Moreover, it provides a step-by-step approach to develop this interoperability in a manner that allows the consumer to begin to realize the benefits from day one. It is also consistent with and leverages all the other activities that are already underway across the country including the creation of the regional health information organizations, stand-alone health

system networks (for example, the Geisinger Health System and Inland Northwest Health Services), and other specialty networks (for example, SureScripts and RxHub).

A central requirement for building the overlay network and providing the interoperability required is a robust set of middleware software that can handle the communications between HRN and any external organization's data formats. This is accomplished through HRN's Health Exchange Engine, as depicted below. The purpose of this engine is to provide the technical infrastructure to process all incoming and outgoing transactions between the multitudes of organizations with which HRN interacts.

Health Record Network
The Health Exchange Engine



Initially, the Health Exchange Engine will support physical interoperability. That is, a physical connection between entities where data can freely flow between them. This level of interoperability will exist where the data formats are known and mature standards are in place. After physical interoperability, HRN will move to support semantic interoperability. That is, the standards that allow data on one machine to be represented in an unambiguous format so that it retain its meaning ("semantics") between the source machine and target machines. There has been progress in this area through some of NLM's and HL7's efforts, and the expectation is that many vendors will begin to embrace the technologies that provide this level of support.

From the technical perspective, the Health Exchange Engine can be thought of as an enterprise application integration (EAI) engine and will be "constructed in the model of an event-driven, enterprise service bus" and will provide the following services:

- **Content-based routing and filtering** – provide the ability to route content between sources, and filter that content based on a set of predefined rules;
- **Data transformation** – provide the ability to transform data from one format to another – a critical need given the different formats established across the country;

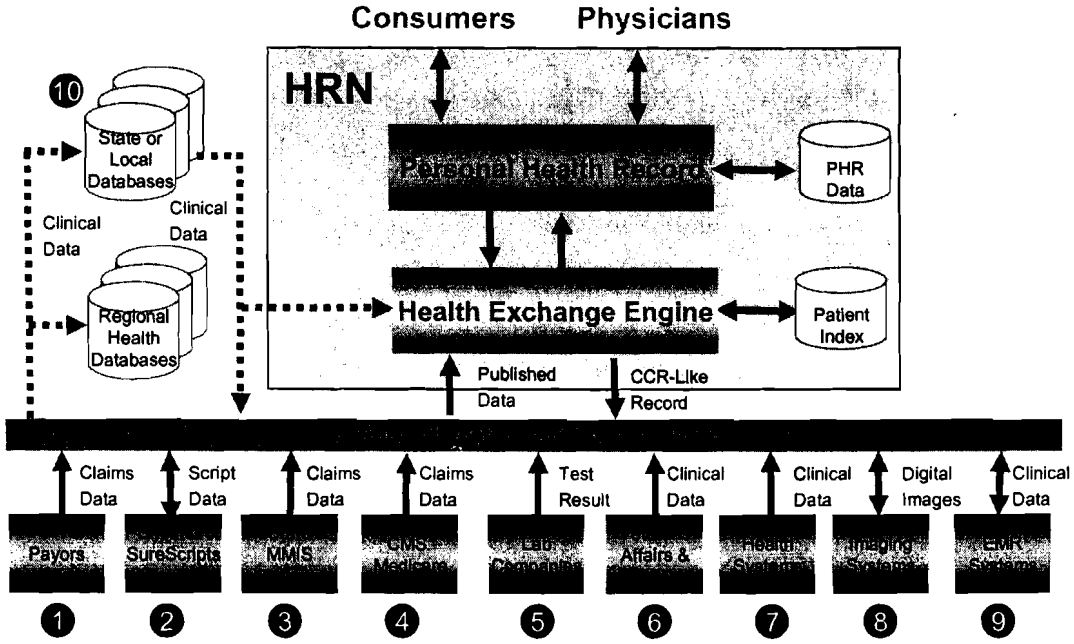
- **Support for standard interfaces** – provides support for standard interfaces including X12 and HL7;
- **Error processing** – provide error processing in the event errors are encountered during the processing of a transaction;
- **Security Processing** – provide the ability to authorize and authenticate transactions;
- **Transaction logging** – log all transactions to provide a detailed audit trail and a mechanism for non-repudiation; and
- **Terminology standardization** – the ability to map concepts, descriptions and relationships between the multiple healthcare vocabularies (for example, SNOMED-CT, ICD-9, LOINC),

The Health Exchange engine will support the multiple modes of processing including synchronous, asynchronous, and batch and will also support the existing and growing list of input and output channels including: standard web (HTTP, HTTPS), web services (SOAP, XML, UDDI), email (SMTP), file transfer (FTP), mobile (WAP, WML), and voice (vXML).

Central to the Health Exchange Engine is the master patient index, MPI. It is widely recognized that one of the greatest challenges in health IT interoperability is identification of an individual. And while a national or universal standard patient identifier would facilitate this interoperability, the reality is that it raises too many privacy concerns and would be a major obstacle to overcome. However, in order to locate and individuals data outside of the personal health record, HRN will construct an internal MPI that will be used to link an individual with all their other healthcare accounts – whether that is for a hospital, physician, laboratory, etc. The MPI will be maintained by HRN and will conform to any emerging standards that are being considered such as the Object Management Group's current MPI effort. .

With the Personal Health Record and Health Exchange Engine in place, the construction of the overlay network can begin. The diagram below depicts the step-by-step approach HRN will employ to interoperate with the rest of the healthcare industry. In its entirety, this model will support the interoperability to all stakeholders required to deliver care to a consumer. However, we recognize the inherent complexity and existing barriers with trying to build this connectivity from the onset. Therefore, coupled with the HRN philosophy that market forces will drive innovation in healthcare IT (i.e., the "Pull" model), we have laid out a step-by-step approach for accomplishing this integration. This integration process would start with the data sources that are most readily available for interface and gradually evolve to include those that require significantly more work/investment to create – such as individual clinical systems. It must be noted that this diagram is meant to be conceptual. While it only depicts one personal health record (PHR), one set of PHR data, and one Health Exchange Engine, the physical implementation will consist of many of these instances – perhaps region by region. This will be worked out as the HRN implementations begin across the country.

Health Record Network
Conceptual Interoperability Model



The first step will be to integrate the payors' claims data into HRN. While the claims data does not contain any clinical information, it presents itself with the most efficient way to provide some benefit to the consumer and physician. Using the diagnosis and procedure codes and blending them with the medical history already in the PHR, users of the data will be able to get a picture of the health of the individual. A consumer can then append any other related information to the claims data – such as outcomes or results of a test.

The second step is to integrate all the prescription data for a consumer by leveraging the existing networks already in place for this type of data including SureScripts and RxHub. HRN will be able to read all prescriptions that have been written for an individual and will also be able to send out requests for refills. This data will supplement any other medication data that the consumer might be taking – such as over-the-counter or herbal. This will present a complete picture to any authorized physician.

The third and fourth steps are to integrate the claims data from government agencies – state and federal. Just as with the payors, the claims data from the State Medicaid systems and the Federal Medicare system presents a way to enhance the personal health record for the elderly and impoverished. Additionally, we expect that the use of the Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) data will facilitate the implementation of federal Medicaid requirements.

The fifth step is to bring in the laboratory test results for all consumers. Until some organization develops the equivalent of a SureScripts for the laboratory market, HRN's plan is to integrate directly with the major vendors (LabCorp, Quest Diagnostics, etc).

The sixth step is to integrate actual clinical data with two of the Federal government's most advanced efforts – Veterans Affairs and The Department of Defense. In both of these instances, the benefits of a "closed" health care system have allowed the Federal government to rapidly forge ahead with an advanced electronic health record system for their respective populations. In the VA, through the ongoing development of VistA, there is a great opportunity to build the bridges to integrate all of their clinical data. This is also true with DoD's TRICARE system. Moreover, given the closed nature of these systems, it is easier to attain the semantic interoperability that is essential for moving clinical data from one source to another.

The seventh step is to integrate with the major health systems' electronic health records or clinical information system capturing inpatient and (to a lesser extent) ambulatory data Because of the complexity inherent with managing the HIT of a large health system, there are fewer vendors in this space. Therefore, there are fewer barriers from an integration standpoint and achieving semantic interoperability is facilitated.

Given the innovations and efficiencies with capturing digital images, many radiology departments have moved towards this technology and away from film for all types of radiology needs. Moreover, with the advent of newer equipment such as Cardiac MR's, more and more organizations will take advantage of this new technology to be able to better diagnose a patient. As a result, the eighth step is to integrate with imaging systems (both PACS and web-based) to provide consumers with their digital images. However, given the size of some of the moving images and the bandwidth considerations, many of these images will reside in their current location and HRN will "locate" these and take the consumer to where they are stored.

The ninth step, and perhaps the most difficult, is to integrate with all the various ambulatory electronic medical record systems supporting physician practices that exist across the country. However, given the size range of physician practices coupled with the large number of vendors in this space, this level of integration presents a real challenge and one of the most extensive barriers to the implementation of the NHIN. However, at this point in the evolution of HRN, with numerous automated data feeds already integrated into HRN, it is anticipated that the market pressure to achieve integration at the medical record system level will be pervasive. Essentially, the market will be maturing and will demand greater automation and integration. This "market lever" can be used as a tool to resolve outstanding issues and barriers to electronic medical record system adoption at the provider level.

Finally, the tenth is the integration with all the regional health information organizations and other state efforts that are underway around the country. While this is labeled step 10, this optional integration can occur at any time and can theoretically take place first. The RHIO's are building their own MPIs and are receiving clinical data from sources

within their own region. And while the RHIO's can also share data between any of the entities within their own region, it presents a great source of clinical data for HRN. Furthermore, as the RHIO's move toward semantic interoperability, it greatly facilitates the integration with HRN. However, even without semantic interoperability, it does provide a single source of accumulated clinical data.

This step also demonstrates the inherent flexibility of HRN. If RHIOs continue to develop as a component of the NHIN, HRN can simply interface with them as a point of aggregation. If alternatively, RHIOs do not flourish, HRN can continue to evolve with a direct interface to the broad community of providers across the nation.

But the Health industry really isn't a "free market", so how can HRN succeed?

That is correct. The health industry has not been a free market and the financial relationship between a consumer decision to "purchase" health services and the actual "payment' for those services is both unusual and complex.

However, a variety of forces are conspiring to fundamentally change this dynamic. These include:

- An overall aging population, with a particular concentration of baby boomers that will be entering peak health consumption years. This market segment has been responsible for driving revolution throughout every phase of their lives - from basic standards of living, to travel patterns to financial interactions. It is highly unlikely that this market segment will casually enter the morass of the US health care system and simply pick up a pencil and paper and begin to quietly co-exist in this environment.
- Cost shifting – as the costs of healthcare is increasingly transferred to the individual consumer, their participation in decisions regarding their health care and the decisions they make that affect their overall health will become more significant. As consumers have more control of health dollars, they will require tools that can more effectively allow them to make decisions about health care.

Perhaps the most important factor in the probable evolution of the consumer as a driver of change in healthcare will be a fundamental reexamination of "health care" itself. Specifically, the traditional model of healthcare is a reactive model – get sick and we'll heal you. In this world, the forces of demand are regulated by "sick people", whom inherently make uneconomic decisions about their care.

Going forward, as consumers are asked to pay more for care and as baby boomers age, an increasing focus will develop and an increasing value will be placed on *preventive care.* This trend has already manifested itself in the burgeoning herbal therapy market, vitamin supplement market, elective surgery market and most recently the evolution of diagnostic services such as "virtual body scans". In all of these cases, the consumer is voluntarily taking discretionary dollars and directing them to proactive means of staying and looking

younger and being healthier. The barrier to achieving a quantum shift in these behaviors is information. Until individual personal health information is in the hands of consumers, it will be difficult for them to make this shift from treatment to prevention. Once this information is made available, it will likely set in motion a dramatic shift in the delivery of healthcare services across the US, and this will ultimately result in significant cost savings in healthcare that is the key to the financial health of future generations.

Conclusion – What NHIN support is required to move HRN forward?

Perhaps the most intriguing aspect of HRN is the ability to move the program forward rapidly in the national market. Providing a national portal for consumers to initiate the creation of their own personal health record is a minimal effort compared to equipping every physician's office, hospital and clinic across the country with the necessary IT infrastructure. Moreover, by moving forward on a national "consumer focused" basis, the opportunity to dramatically change the dialogue around healthcare from "it's hopelessly broken" to an environment where individual consumers and the media begin talking about "information automated healthcare" could provide a significant boost to all the ongoing efforts to define standards, fund pilots, fund general deployment, etc. If we are ever to fulfill the goal stated by President Bush, at some point, the average health consumer must begin talking about automated health records, and must begin the process of creating them.

Based on numerous discussions within the Health industry, the business community and with consumer representatives as well, HRN proposes the following steps:

1. Concept vetting – does the HRN model make sense?

   The HRN startup strategy assumes participation of the business community from both a financial and a communications perspective. While we have received a positive response from every business we've contacted regarding HRN, and even regarding their participation in creating HRN, most choose to remain on the sidelines until they see a signal at the federal level that HRN is consistent with the NHIN agenda.

   We suggest that NHIN convene a forum to present the concepts of HRN to an appropriate cross section of industry, government, business and consumers to determine if HRN is a viable and attractive approach for creating a consumer market for automated health information. Such a forum would be a clear signal to the market that this utility is a complementary element of the NHIN strategy.

2. Integration into NHIN piloting activities.

   While HRN has obtained legislative approval to pilot HRN statewide in Wyoming, and is in discussions with the Rhode Island Quality Institute regarding a pilot in Rhode Island – it would be helpful to encourage other pilot programs that are considering a consumer dimension to engage in dialogue with HRN.