OBAMA-BIDEN TRANSITION PROJECT

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Health IT: Health Care Transformation Requires Patient-Centric Individual Records

January 2009

Two significant issues with harnessing information technology for better health care remain a challenge and the sought-after transformation of the health care sector may elude us. These issues are the need to (1) create a unique and comprehensive single record in real time for each patient to support clinical decisions, care management, and quality measurement/improvement, and (2) provide a modern communication infrastructure to replace the non-communication that is inherent in the present paper-based/siloed electronic amalgam of records we have currently. These goals are hard to achieve and do not automatically flow from the deployment of electronic records, even when technical interoperability exists.

Quality health care is dependent primarily on having accurate and complete information about each patient at the time of decision or action – by the patient, caregiver, payer or researcher. We must refocus resources to engineer an information system that can create a comprehensive picture of individual patients for all appropriate users from data that may be found in a wide variety of places. It must be a single record, unique to that patient, and the same record every time it is viewed. Once data are pulled from disparate sources into such a real-time structured record, communication among patient and caregivers is created automatically where it did not exist before.

Moreover, that patient record must be more than just data. The data content must be understood by underlying technology. Then the technology can apply evidence-based quality rules, care management protocols, and business or other administrative rules in a manner unique to each patient. Most importantly, the technology can apply the privacy and security policies desired by patients to their individual records. Only then does one have a comprehensive record of each patient and his or her care environment that is of great value to both the patient and all relevant providers of care.

The approach outlined herein – patient-centric individual health records combined with a set of

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capabilities that supports patients, physicians, payers and administrators, and researchers simultaneously – has been deployed in real-world environments. The results in actual use, not as a test or a demonstration or a trial, show that it:

- Is easier, faster, and cheaper to deploy
- Provides a superior foundation for care, and
- Provides a superior foundation for saving money.

This paper goes into more detail on each of these points and why this approach works. It is essential that all health IT investment have this patient-centric focus or we will continue to see little impact from health IT. Later in the paper there is also a discussion of how an infrastructure with this focus will, through potential competition among stakeholders, greatly improve how health IT benefits patients – again, our primary focus.

This approach is not proprietary or unique to a specific product.

The proposed legislation based on this approach has three parts:

- Core requirements for all health IT investment – the essentials that address the flaws in current approaches to promoting health IT investment
- Provision to fund applicants to be custodians, as described in this paper, in an infrastructure that uses patient-centric health records to maximum benefit – to scale up the model for greater value-add
- Some necessary fixes to permit state and federal programs to participate fully

Industry Challenges and the Promise of Health Information Technology

The US health care system is costly, provides poor quality care, and is unsafe. Health information technology's (health IT's) potential is to resolve all three challenges. However, the path has so far eluded national efforts. As the CEO of the Medical Records Institute said, "For 25 years, electronic medical records (EMRs) have been our number one priority on which billions of dollars have been spent, yet virtually no one uses them. Perhaps we are doing the wrong thing". Why are conventional EMRs the wrong thing? Because <u>the root cause of the three fundamental challenges above is reliance on an archaic communication infrastructure. Conventional electronic medical records do not solve this problem</u>.

What is really needed is a communication infrastructure or platform that allows *every physician* or other provider involved in the care of a patient *and the patient himself or herself* to make ideal care management decisions from a cost, quality, and safety perspective. Ideal management decisions can only be made if every caregiver in the care delivery process has all of the relevant information (synthesized and understood) about the patient at the time of their interaction. This does not happen even with the most sophisticated EHRs except in special circumstances such as an integrated delivery system where all the patient's caregivers are part of the health delivery system. Even then, quality improvement incentive programs and other innovations are slow to be incorporated.

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Ideal care management decisions also require caregivers to *communicate with each other* efficiently, effectively, and immediately. Most importantly, the patient must be included in these communications with all of their caregivers – often half a dozen physicians, pharmacists, and health coaches for a mostly "well" patient and far more for one with a chronic disease.

Current Federal activities do *not* create the needed communication platform that supports physicians and patients working together. The majority of health IT systems only provide a comprehensive patient record for as long as the patient gets care in a single provider's office, within a health system, or when services are paid by the same plan, depending on who invested in the system. EMRs do not connect to the hundreds or thousands of individual data sources in a particular region in order for the necessary complete patient record to be generated. Currently, most sophisticated EHR products remain siloed even in integrated delivery systems, because they cannot "talk" to each other.

The current Federal approach to this problem is called "interoperability". It assumes all EMRs will plug into a regional network known as a Health Information Exchange. When a patient presents for care, the EMR will ask the Health Information Exchange where all the records are on the patient in question. The RHIO or exchange will deliver this information to the EMR asking for it and display it to the end user.

Even if gathered from multiple sources, this solution is still at best only a collection of data of all types; no real picture of the patient and his/her care environment – including status relative to best care practices – is created. In other words, the new system still does not transform the data into useful information or operate to provide the additional information necessary to secure the maximum value from that data. Even more worrisome, generally each time the exchange delivers this information it can be different as source systems are variously available or not. As a result, patients stand a real risk of getting sub-standard care because of data variability introduced as part of this proposed solution.

Finally, this model of interoperability results in real-time communication among patients and caregivers only after significant investment of resources and time by each stakeholder.

In contrast, a comprehensive patient-centric record like that described below provides a platform for the communication and range of operations on which the transformation of the health care delivery systems depends.

Characteristics of Transformational Health IT

We recommend that this new approach be used for all health IT investments, with a focus on building a comprehensive, patient centric record and the communication platform that enables the record to be shared when needed. This communication infrastructure must then be surrounded with functionality that is required for the transformational value that is anticipated.

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The new system must have the following characteristics:

Patients

Health IT must engage and influence patient behavior – The greatest health care challenges involve chronic diseases and their complications. These diseases are largely the consequences of or can be mitigated by changes in behavior. Therefore, highly effective health IT must support patients in managing their diseases or preventing disease occurrence. These systems must also support patients' interactions with their care team so that patients can effectively carry out the proper management strategies and interventions during the 99+% of the time they are not interacting with their care team members.

Physicians

Health IT must engage and influence physicians – Physicians are primarily responsible for the quality, efficiency and safety of care that patients receive. Yet studies repeatedly show that evidence-based interventions that improve patient outcomes are grossly under-used. Further, there is excessive use of outmoded or disproven therapies and far too many outright errors (provision of care proven to be harmful). Properly designed health IT systems can solve these challenges.

The first step is creating a comprehensive patient record that is used by every physician and other caregiver involved with the patient – and it needs to be the same one used by the patient (although each kind of user will clearly use and interact with it differently). This comprehensive patient record must be synthesized from varied clinical and administrative data sources operating in hospitals, labs, physician offices and health plans.

Such a record creates immediate value because it creates for every patient the communication among patients and caregivers that is currently missing. Most patients are cared for by a number of physicians who frequently do not know what other providers are doing for the patient. A comprehensive record shared among the care team improves quality and efficiency simply by allowing Dr. A to know what Dr. B is doing. Systems being deployed today, however, do not fully deliver on this critical value. In addition to being incomplete, the data are not understood, just "reposited"…so these solutions become data presenters only. With this approach we must hope that repeated human effort performed without error causes the right thing is manually viewed by the right person at the right time. This is not adequate.

The data must all be transformed into a shared understanding, not just a shared repository, to be of real use. The key step is to create a unique level of data *understanding* for each patient, procedure, drug, lab, and benefit plan. By understanding the data and how all the benefit and quality rules apply, the information system supports the clinician in his or her interaction with the patient. Key information is available in real time to discuss with the patient and to support care decisions.

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Payers and Administrators

Health IT must improve current industry payment and administrative challenges – Today, health plans attempt to influence utilization, quality, and cost through a variety of mechanisms largely based on their control of payment for services. These payment mechanisms have been recognized to reward poor quality (fee for service) or to put in place excessive administrative barriers for care that is appropriate and needed (managed care).

Proposed solutions such as Pay for Quality or Pay for Performance may align incentives more appropriately but are limited by their overhead and reliance on claim data. A successful health IT deployment must provide the foundation to support multiple payment mechanisms that reward physicians and other providers based on quality of care, efficiency of care delivery, and quality of the patient outcome. The common understanding of individuals' health information and consistent application of metrics and payment rules becomes key to efficacy.

This must be coupled with a movement of quality monitoring from *post hoc* to real-time. Telling physicians a year later what they might have done for a patient is not useful.

Researchers

Health IT must provide for a foundation upon which research can be conducted – Although pharmaceutical firms spend $800 million or more in bringing a drug to market, their primary goal is to get product to market and so their focus is to prove the efficacy of their product. Relatively little is known about drug performance in real world settings (as opposed to the highly controlled nature of a clinical trial). How drugs perform for patients with multiple diseases or receiving multiple therapies is poorly known and understood. Comparisons of new treatments versus established ones (Comparative Effectiveness) or the safety profile of drugs newly introduced to the market also is poorly studied. Health IT can not only reduce the cost of bringing a new drug to market but can also improve drug safety and appropriateness of use through new, low cost, yet highly effective electronic data sets. These data sets can fill the current holes in our research knowledge base and address current safety issues. The infrastructure must deliver these key elements.

The data architecture ontologizes, models, and transforms data as received which means that virtually all data in the IHR is completely *understood*, enabling a rules engine to apply clinical and business rules at a patient specific level on a real-time basis. A system that is architected to provide an *understanding* of the data allows the use of new and important cost and quality tools.

The Individual Health Record (IHR) – Transformational Health IT

Most of the characteristics of Transformational Health IT are embodied in a new record concept called the

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Individual Health Record (IHR). The IHR is a comprehensive patient health record with a view for patients (a "PHR"), a view for use by doctors (an "EHR"), integrated e-prescribing, and an integrated data model/ontology. In the IHR, the data architecture ontologizes, models, and transforms data as received, which means that virtually all data in the IHR is completely *understood*, enabling a rules engine to apply clinical and business rules at a patient-specific level on a real-time basis. A system that is architected to provide an *understanding* of the data allows the use of new and important cost and quality tools.

Because it understands the data, the IHR, in real-time as care is being delivered applies quality rules derived from the evidence base and business (payment) rules derived from health plans. **These rules allow money-saving benefit plans to be administered without the headaches physicians typically have** when benefit plans become more restrictive. Efficiency gains are immediately realized by avoidance of duplicate and conflicting therapies. These duplications amount to anywhere from 3%-5% (radiology) to 10% or more (labs) of all tests ordered.

This comprehensive patient record can then also **operate with clinical rules derived from clinical research**. These rules are commonly known as clinical decision support. They are designed to apply the knowledge derived from clinical research to each patient uniquely. By doing this, physician decisions are grounded in research and are as effective as they can possibly be. Further, because algorithms can be developed in a few weeks or months, the delay in moving clinical research advances into common clinical practice can be reduced from the up to 17 year delay seen today to something far shorter.

Although a number of architectural approaches could be selected for the IHR, one essential must be the ability to start with any kind of data and then to add additional data elements and content to each patient's record as additional sources become available. For example, claim data can be provided by health plans that have already aggregated this information and then clinical data added. Or health systems can provide clinical information to be supplemented later by claims data. (Importantly, a unique feature of the data transformation (to make the data "understood") that can be performed by an IHR approach is that **claims data is made maximally useful for clinical care**, removing many of the oft-expressed "claims data is not useful" barriers.) Combining, for example, Blue Cross/Blue Shield claims data with Medicare/Medicaid data available from intermediaries, a rapid path to constructing a useful base record on over 2/3 of all Americans is possible. This type of deployment flexibility allows large scale programs with quick value realization to be launched.

Another distinctive IHR feature is its orientation. This is a record **meant to improve care of patients first and foremost**. That means that it does not contain, nor does it need to contain, all of the data on a patient (much of which is gathered to run organizations rather than to provide patient care). The IHR is designed to create the best possible record from the data sources it can get. It is not primarily designed to "provide for the needs of a large physician office" like an EMR but rather to "provide for the clinical data needs important for each patient" irrespective of the venue of care. As such, it makes a compelling platform for the introduction of clinical rules that help patients.

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What Can Be Done To Transform Health Care through Health IT

In order to realize the benefits of health IT and allow applications like the IHR to become commonplace, several important steps could be taken by the Federal government to accelerate its deployment and realize its benefits.

The Federal government should create a program for electronic records designed to support *each patient's individual health environment*. This program should complement existing components of the health care system (plans, hospitals, providers…) but provide a service that no one entity is charged with today…creating, storing, and providing the components of a patient's records that are currently scattered among the many caregivers a patient might have. This new role is Health Care Custodian. Support of this custodial role includes a new and effective electronic communication infrastructure and a master patient record for patient-centric health and wellness.

Custodians will be charged with providing an infrastructure for sharing, managing and coordinating care and wellness with characteristics that ensure the maximum transparency, efficacy, and efficiency of health and wellness delivery. They will be required to be HIPAA compliant. In fact, security, privacy, and confidentiality assurance is at the very core of Health Care Custodianship.

The New Role: Health Care Custodian

The Health Care Custodian is the organization designated by patients to hold and manage their clinical data. This organization is similar to choosing a bank to house your financial accounts or a retirement custodian to managing your retirement funds. The Health Care Custodian is responsible for gathering the clinical information on an individual's health, keeping it private and secure, and providing it both to the individual and to physicians or other care givers that the individual designates.

Health Care Custodians will become an important relationship for each patient. They will vary in what types of organizations they are. A health care custodian could be a RHIO, a hospital, a health plan or some other sponsoring entity in the health care industry. Because health care is by its very nature local, it is expected that Health Care Custodians will be granular, focused on cities, regions or at the maximum extent states. Custodians will be charged with providing an infrastructure for sharing, managing and coordinating care and wellness with characteristics (listed below) that ensure the maximum transparency, efficacy, and efficiency of health and wellness delivery. They will be required to be HIPAA compliant. In fact, security, privacy, and confidentiality assurance is at the very core of Health Care Custodianship.

It is expected that hospitals, health plans, financial custodians, technology companies and others will all find reason to become Health Care Custodians. In fact, it can be anticipated that Health Care Custodians would expand their services over time to compete with one another, just as banks and retirement custodians compete for deposits based on a variety of programs

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(discounts, bundled services, quality of service, cost of service, etc.). Services such as disease management (more effective with the IHR due to data sharing and understanding), outcomes research (information on the best therapy for each specific individual), quality profiling (information on physician performance) and the like could all be offered by Health Care Custodians to increase their market share. A hospital might join with a technology company to offer virtual patient visits or other capabilities to woo potential patients and highlight the value of their custodial services.

The Health Care Custodial Infrastructure (HCCI) – An Important Federal Role in Improving Both Health and the Economy

The build-out of the necessary Health Care Custodian infrastructure will transform health and wellness care in ways that will make an extraordinary difference in improving the efficacy, efficiency, access, and quality of care delivery. This in itself will have immediate effects on the competitiveness of the economy.

In addition to this second order effect, the infrastructure to support Health Care Custodianship needs to be put into place. The Federal Government can get the double benefit of promoting substantial technologic and organizational investment (building both people and technology infrastructures) and improving health by launching a program by which entities apply for funding to be Health Care Custodians. The funding will be to procure the necessary human and technology infrastructures (the Health Care Custodial Infrastructure or HCCI) and to ensure that the infrastructure that is developed is sustainable and capable of meeting the following base criteria:

- The HCCI must utilize a single record for the individual and all providers and payers involved in his or her care. The record must be available in seconds irrespective of who is requesting it and must not change based on the passage of time other than the addition of new information. Expressed another way, if information has ever been available to be seen by a user, it must always be available to be seen. (Some systems give a different "look" to the user each time depending on what systems might be operating at that time. This creates situations in which critical information which may have been acted upon no longer exists; clearly this is a major hazard.) Important information to a provider or individual should appear without the user having to "request" such information.

- The HCCI must be able to easily receive relevant information from virtually any source and to use it effectively in the ways set forth below. Such sources must include, but are not limited to, direct physician entry, direct patient entry, real-time data feeds and batch uploads. To rapidly provide leverage from IT monies already invested, the HCCI must be designed to maximally leverage existing health plan, hospital, and physician office information management infrastructures such as existing: provider portals, intra-plan connectivity and private networks, privacy and security measures, transactional systems, and data warehouses. This will save a major share of development costs while

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leveraging the hundreds of thousands of organizations and offices already gathering important information for their own operational purposes.

- There can be no requirement that records must begin with any particular kind of information, be it claim, result, encounter, etc. This would inappropriately skew the baseline custodian to some particular kind of organization. Rather, the record must be supported and available irrespective of the kinds of data received and the order of data receipt. The best possible record must be built from all information received up to any point in time.

- The HCCI must receive all such information, extract what is important for the continuing care of each individual, and transform that information to a single model and a single understanding of what it means. An ontology designed and demonstrated to perform this transformation is presumed to be a critical component of any such data transformation. Part of the transformation must be the consolidation of all transactions concerning a single event (e.g., the bill, the claim, the order, the result, the report, the EOB, etc.) into a single record for review. This prevents the confusion that inevitably arises when the same event is represented many different ways in the record and it is up to each user to figure out which events are actually redundant.

- Every health transaction has administrative, financial, and clinical components. The HCCI must use an integrated clinical/administrative/financial model so that all such components are seen as parts of the same process.

- The HCCI must be HIPAA compliant and must leave the ultimate control of all information in the hands of the individual. In addition, since multiple sources are feeding the HCCI, the HCCI must be designed so that each contributor can only see the information it has contributed unless otherwise authorized by the individual. Every access to any information by anyone must be recorded, including what has been seen by whom. All data taken in, irrespective of necessary transformations, must be traceable to its source. Sealed envelopes and "break this glass in emergency" protection concepts must be incorporated to provide for emergency medical care.

- Security/privacy/confidentiality are not only baseline characteristics of the HCCI, but augmentations to such functions are likely to competitively differentiate one Health Care Custodian from another. Thus, the HCCI must simultaneously support many security policies and models, as long as they are all HIPAA compliant and, in the final determination, subject to control of the Individual. The necessity for individual users to have to change their security will be a function of the goodness-of-fit of the Health Care Custodian's security policies.

- The HCCI deployment model must be based on the fact that health care is delivered locally and respect the variation in business relationships, clinical relationships, structural organization, and local population needs. The HCCI should be able to be held and maintained by the Health Care Custodian or the Health Care Custodian's technical designee without mixing data from other HCCIs on the same physical environment. This

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dramatically simplifies the security/privacy/confidentiality envelope of the solution, significantly minimizing the effects of a possible breach.

- In keeping with the regional deployment model, while large, national organizations will certainly compete as Health Care Custodians, since health care is local, it is vital that local health delivery systems be involved as part of effective deployments. In many cases, state-wide or national organizations will contribute information for a locality that will be used, with regional providers, to create the HCCI.

- Billing and claims data is ubiquitous and therefore a key data source for any HCCI. This data is already electronic, already aggregated, and frequently made available today by health plans to their members as a PHR or to physicians as a claims based summary of the patient. The HCCI must be capable of transforming such information into useful clinical information, subject to the transformation constraints set forth above. Medicaid and Medicare claim data must be included for the Health Care Custodian to maximally benefit a region, so the legislative / regulatory changes to allow Health Care Custodians to easily receive and use Medicare and Medicaid data (an impediment to almost all current health record efforts) must be a part of this bill. CMS must be directed to make sure that Medicare and Medicaid programs make timely claim data available for treatment purposes through current intermediaries via ANSI HL-7 and X12 standards as set forth below.

- While standards are not a necessary predicate to operating an HCCI (and history has shown that this effort should *not* wait for standards) they are helpful to making the interchange of information easier to effect. Therefore, as part of the HCCI initiative, the legislation should provide that all clinical data sources that receive or deliver information to entities contracted with CMS become HL-7 compliant by a date certain, and also that such entities deliver their information easily and electronically in HL-7 formats to appropriate HCCIs as requested by such HCCIs. (Without having the clinical data sources embracing data standards, the pace of Health IT deployments will be slowed and the value realization delayed. Mandating these standards will create some economic boost as well through spending for updating and modernizing various information sources.)

- Access to the HCCI by patients and providers must require nothing more than a computer running an industry-standard browser of recent vintage. Interactions with the HCCI should be portlet or Web Service driven, and conform to JSR 168/268 and/or WSRP standards so that they are maximally useful.

- Multilingual access for a broad number of languages must be supported. The same information must be displayed irrespective of language translation; the HCCI should check the language of the user and preferentially communicate in that language. English should be displayed where no translation is available.

- The HCCI must be fault tolerant at a high level; 98% uptime is a reasonable level to set.

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- The HCCI must include e-prescribing as a fundamental deliverable; e-prescribing must function as part of the total HCCI incorporating relevant clinical and financial information into the prescribing process. Stand-alone e-prescribing siloed within the HCCI does not meet this requirement.

- The HCCI must provide for individualized connection of each person's record to relevant content appropriate for the person looking at that record.

- The HCCI must not only allow for secure use of Health IT with appropriate privacy protections but must also provide the characteristics of a transformational health IT solution as described earlier in this paper. The operational framework must include clear processes for value realization. Value realization must be recognized by the payer community (employers, health plans, governmental entities, pharmaceutical firms, etc.).

- Part of this initiative should be the requirement that the technology enable clinical data from the HCCI to be made available under appropriate circumstances to researchers, P4P programs, drug companies, and academic medical centers... for ongoing research in both real world and clinical trial uses.

- Current CMS financial incentives for E-prescribing and PQRI will be continued as part of this initiative and will assist in its adoption, as both functions will be easier to realize with the HCCI.