



FUNDING HEALTH INFORMATION TECHNOLOGY – REQUIREMENTS FOR EFFECTIVE SYSTEMS

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Funding Programs – Requirements for All Health IT Spending

As part of a comprehensive initiative to promote improved health care quality and safety that incorporates the effective use of information technology, federal funding/financial incentives programs must incorporate the following requirements regarding the technology and its use. The technology must have as its primary purpose support of the patient’s whole health care environment through a single, comprehensive patient record.

Instead of siloed systems that are designed to support hospital or physician office practices and that frequently do not include data from outside sources, we must engineer systems to produce individual health records that provide a comprehensive view in real-time of each individual patient and that include data from all relevant sources (according to the patient’s direction). Additional capabilities that “understand” that record and that can apply quality rules, business rules, and other analyses in real-time while care is being delivered or managed should also be required.

This individual health record (IHR) is more than a PHR, or an EHR, or eRx, or clinical decision support. It includes all of those capabilities and more.

The following requirements can be for loan, grant, or incentive programs such as pay-for-use or pay-for-performance.

Proposed Language:

Section ____ . REQUIREMENT FOR INDIVIDUAL HEALTH RECORD CAPABILITY –

Under a process that shall be determined by the Secretary, eligible applicants for [funding/incentive program] shall demonstrate that the qualified technology to be acquired with such funds has (or will be an integral part of a larger system that has) the following characteristics –

- (1) Security and privacy protections and policies are incorporated, including the ability to manage consent according to patient/consumer rights, transparency about collection and use of data, and role-based access to data. Such protections must include (irrespective of the health care entity status of the data holder):
 - a. HIPAA compliance
 - b. Auditable records of who looked at the information, when, and what they saw



- c. Other requirements of Federal and state law
 - d. Other applicable community and industry standards
- (2) Compliance with national standards that have been recognized by HHS, such as HL7
 - (3) Electronic prescribing
 - (4) An ability to receive and incorporate data from multiple external sources in real time and in batch
 - (5) Relevant data from all available sources (e.g., hospital, clinician office, laboratory, health plan, pharmacy, imaging) is used to create a comprehensive, single patient record based on a single model and a single data understanding (ontology) that gives a complete view of the patient to the patient and to each authorized health care user at the point of care and on which analyses, clinical decision support and other tools can operate effectively in real time to support evidence-based care, prevention, and quality improvement activities
 - (6) A single, comprehensive, real-time patient-centric health record accessible to the patient and all members of the patient's care team when and where needed
 - (7) Health data persist in the record to provide a consistent, longitudinal view of the patient and his/her care whenever viewed (i.e., data once seen is always there)

In addition, preference shall be given to applications for technology projects with the following characteristics –

- (1) Multilingual capabilities inherent
- (2) Leverages existing/legacy systems and technology investment
- (3) Consistent with MITA
- (4) Aids in meeting Medicare and state program requirements
- (5) Health Care Custodial capability to aid patients and consumers with managing their health data by providing an infrastructure for sharing and managing data and coordinating care and wellness as set forth below
- (6) Provides for the real time application of clinical rules derived from the evidence base (clinical research...) and business rules derived from health plans, governmental programs or other state/federal program requirements to influence care delivery as it is occurring
- (7) Research support capability

“Eligible applicants” shall be two or more unrelated entities with a binding agreement to procure and deploy a single, common electronic patient record for use in diagnosis and treatment according to the requirements in ___ above.

“Patient-centric” shall mean data are collected from all available sources on the basis that they relate to the patient, in order to create a single record that is accessible to all users of the record.



Each user shall have appropriate role-based access to data in the record, including data from other caregivers as determined by the patient. Patients must have access to all of their data and the technology must support interactions with a patient's care team and any agreed-upon prevention and care management strategies.

“Qualified technology” shall mean hardware, software, license, right, intellectual property, equipment, or other information, transmission and communication technology (including new versions, upgrades, and connectivity) designed or provided primarily for the electronic creation, maintenance, protection, exchange or viewing of health data or information.

Funding Programs – Health Care Custodians

A Health Care Custodian (HCC) is an organization designated by a patient to hold and manage the patient's clinical data. HCCs operate within a Health Care Custodian Infrastructure (HCCI) designed primarily to support each patient's individual health environment. The HCCI complements existing components of the industry's current information system. The HCCI's technical backbone is called the IHR or Individual Health Record. It is needed in order to provide a service that no entity is charged with today: creating, storing, and providing access to the components of a patient's health record that may be scattered among any number of the patient's caregivers. The requirements of the IHR provisions (above) are integral to this model and provide essential baseline functionality for achieving maximum benefit for patients, the industry, and the economy from the HCCI. The IHR is the technological backbone of the custodial system; the Health Care Custodian paradigm includes governance, organizational structure, operations and management structure that provides value added services, additional privacy and security protections, and maximizes the benefits of IHRs. There may be any number of Health Care Custodians competing in a region over time; it will be up to patients to select which best meet their service, privacy, and other needs.

Proposed Language:

Section _____. HEALTH CARE CUSTODIANS – Under a process that shall be determined by the Secretary, eligible entities may apply for funds to be Health Care Custodians (HCCs) as provided in this section. HCCs are entities or organizations designated by patients to hold and manage their clinical data. An HCC 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 and other caregivers as the individual designates, in a manner meeting the requirements of [IHR section] and this section.

The Secretary shall establish a process to approve and fund HCCs that may be designated by patients to hold and manage their clinical data, and shall assure that each HCC:



- (A) uses a single patient-centric record for the individual and all providers and payors involved in the individual's care; information important for the continuing care of the individual appears each time the record is accessed and must be available in seconds;
- (B) is able and committed to receive relevant information easily from virtually any source (such as direct physician entry, direct patient entry, real-time data feeds and batch uploads, existing health plan, provider and physician office management systems' provider portals, private networks transactional systems, and privacy and security measures) and use it effectively in the HCCI;
- (C) uses an ontology designed and demonstrated to transform patient information to a single model and a single understanding of what it means, including the ability to consolidate all transactions concerning a single event into a single record for review and analysis;
- (D) uses an integrated clinical/administrative/financial model so that all such components are seen as part of the same process;
- (E) is HIPAA-compliant and includes at least one HIPAA covered entity and has the ability to give ultimate control of information to the individual, so that viewers of the record see nothing they have not contributed unless the patient gives permission; ensures that data include source information; and is capable of managing emergency/break-the-glass protections concepts
- (F) is capable of transforming billing and claims data, including those from Medicare and Medicaid, into useful clinical information [timely Medicare and Medicaid data MUST be included via ANSI HL-7 standards or great value is foregone];
- (G) content (health care content) appropriate to the individual is selected by the technology based on that individual's health, health care, and health management statuses. [For instance, instead of randomly typing "leukemia" into WebMD and seeing what comes out, the right information on the patient's own leukemia (there are dozens of different leukemias, with widely different life expectancies, etc.) is delivered.]
- (H) is capable of managing financial incentives for federal, state and private market programs; and
- (I) [any conflict of interest or independent entity rules]

In implementing this section, the Secretary shall take into account that the IHR concept and HCCs are essential to an organizational and technology infrastructure – Health Care Custodial Infrastructure (HCCI) – that has the following characteristics:

- (A) respects variations in local/regional health care practice, relationships and markets that are not inconsistent with evidence-based care, and includes the ability to maintain separate data storage for entities on the same physical environment, in order to enhance security and privacy;
- (B) is capable of supporting multiple privacy and security models that exceed HIPAA compliance as well as patient-control requirements, in order to enable competition among HCCs on the basis of enhanced privacy and security protections;
- (C) facilitates local delivery systems' involvement in the HCCI;
- (D) is portlet or web-service driven and conforms to JS 168/268 and/or WSRP standards;



- (E) is multilingual and the data displayed do not vary by language differences; HCCI confirms preferred language of the user;
- (F) is fault tolerant to a high level (e.g., 98% uptime);
- (G) has e-prescribing that is integral to and integrated into the HCCI;
- (H) must include clear processes for value realization; and
- (I) is capable of interfacing with researchers for appropriate use of clinical data

The Secretary shall also provide that all clinical data sources that receive or deliver information to entities contracted with CMS become HL-7 compliant by [date 18 months after enactment], and all such entities are capable of delivering such data quickly, easily and electronically in HL-7 formats to appropriate HCCI participants.

In order to receive funding under this section, eligible entities must submit a plan to the Secretary for operation as a HCC consistently with the requirements of this section and [IHR section].

“Patient-centric” shall mean data are collected from all available sources on the basis that they relate to the patient, in order to create a single record that is accessible to all users of the record. Each user shall have appropriate role-based access to data in the record, including data from other caregivers as determined by the patient. Patients must have access to all of their data and the technology must support interactions with a patient’s care team and any agreed-upon prevention and care management strategies.

“Eligible entity” means a public or private health care provider, health plan, federal or state health program, or other sponsoring entity with demonstrated ability to meet the requirements of this section.

Medicare and Medicaid

Certain actions at the federal level will accelerate deployment and realization of the benefits of this more effective health information technology. The following will greatly increase the number of patients for whom data will be available in a *single* information system to caregivers at the point of care, which will greatly increase the value of these systems to both patients and clinicians. Moreover, these will allow publicly-funded programs (state and Federal) to leverage others’ investment in technology and participate in and benefit from the cost savings possible through these investments.

- mandate all clinical data sources in use by CMS contractors become HL-7 compliant
- direct CMS to make timely claims data available for treatment purposes through current Medicare intermediaries



- clarify Medicaid reimbursement criteria to allow enhanced reimbursement for information systems designed to improve beneficiary care quality and safety, including use for diagnosis and treatment

Proposed Language [from S 2662, with changes]:

Medicare

Sec. _____. The Secretary shall use and release Medicare data (including beneficiary data, subject to ___, below) for quality improvement, performance measurement, public reporting, and diagnosis- and treatment-related purposes. In implementing this provision, the Secretary shall determine the manner (including the use of Medicare contractors) and circumstances under which it is appropriate to release such data.

Sec. _____. In implementing this [section], the Secretary shall ensure that individually-identifiable beneficiary health information is protected (in accordance with the regulations adopted under section 264(c) of HIPAA and such other laws and regulations as may apply). [NOTE for legislative counsel: Determine whether this reference incorporates some specific provision that will bar use of identifiable Medicare data in real time for treatment and diagnosis in the same manner as PHI for non-Medicare beneficiaries is used in electronic information systems. If so, we need to modify such provision. Extensive conversations with CMS and HHS staff have been unsuccessful in securing a reference to a specific provision that creates such a bar, though CMS and HHS staff have consistently maintained that Medicare individually-identifiable beneficiary health information is not permitted to be so used outside the research demonstration paradigm, and that only after it has aged too long.]

Medicaid

For Medicaid, legislative language is not needed. Rulemaking should be sufficient. *See* 42 U.S.C. 1396b. The implementing regulation, 42 CFR Part 433.111, could be modified to clarify the appropriate authority:

(b) ``Mechanized claims processing and information retrieval system" or ``system" means the system of software and hardware used to process Medicaid claims from providers of medical care and services for the medical care and services furnished to recipients under the medical assistance program ~~and to~~ to retrieve and produce service utilization and management information required by the Medicaid single State agency and Federal Government for program administration and audit purposes; and other mechanized information retrieval systems [and related tools such as portals], including those for clinical information, as the Secretary determines are likely to provide more efficient, economical, and effective administration of the program.