

Implementing a Risk-based Regulatory Framework for EHR

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Abstract

Electronic Health Record (EHR) products are free to enter the US market without earning market authorization. The government runs a voluntary certification process through accredited third parties for manufacturers wanting to avail of incentives created to improve the meaningful use of EHR. The current lack of regulation and the voluntary certification mechanism for electronic health records is heavily criticized by end-users as deficient in rigor resulting in the proliferation of substandard products with poor usability creating high impact system-wide problems. Most important among these is the concern that faulty EHRs lead to patient harm and potential breach of privacy and thus needed a more comprehensive regulatory oversight. Second, but equally alarming is the wide dissatisfaction of its primary end-users. Physician groups are outraged and have expressed strong dissatisfaction with the poor usability of available EHRs which significantly increases the feeling of moral injury, the risk of errors, alert fatigue, and frustrations resulting in wide-scale clinician burnout. The Harvard Global Health Institutes estimated that clinician burnout related to the adoption of EHR is as high as 78%, calling it a public health crisis. A key development that warrants consideration is the emergence of AI/ML-enabled EHR with wireless devices and sensors that significantly increases its functionalities and power. Despite the massive effort and investment in health information systems and technology, and many years of widespread availability, and government incentives the full promised benefits of EHRs are far from fruition. This paper considers and analyzes the effect of these developments and challenges to encourage discussion on how to best move forward and shape a risk-based regulatory framework for EHR.

Keywords: HITECH Act, 2009, Meaningful Use, Interoperability, ONC, Regulation, EHR

Regulatory History

In a national survey, the New England Journal of Medicine documented that in 2008 only 9% of hospitals and 42% of doctors' offices uses "basic" electronic medical records (EHR) in the US.¹⁴ The designs of EHR, its functionalities, and its use are designed by the needs of the end-user with only documentation storage in mind most of the time. Its primary purpose was to eliminate errors in medical practice brought about by poor penmanship. It was unregulated and serves only as a computerized version of the paper documentation. A push to standardize the format of EHR was realized with the passage of the HITECH act of 2009. The Health Information Technology and Clinical Health Act (HITECH Act, 2009) was enacted with the goal of facilitating the adoption of Electronic Health Records with functionalities that improve healthcare quality, safety, and efficiency, patient participation in their care, which promote public and population health, improve care coordination, privacy, and security otherwise known as "meaningful-use" compliant EHR through monetary incentives.¹¹ It also established the Office of National Coordinator for Health Information Technology (ONC) as the lead agency to develop regulatory policies and regulations relating to EHR. ONC has since developed a third-party certification system to evaluate conformity with the meaningful use requirement of the HITECH Act. The certification process is voluntary and non-certified EHR continues to be in circulation in the market. Since its inception, however, various organizations and medical societies have elevated their concerns about the current lack of full regulation and the state of certification of EHR. These concerns stem from verified reports of patient harm, test methods that do not lead to the development of desired functionalities, poorly designed clinical document architecture, substandard user interface passing certification, and lastly, poor oversight of accredited certification bodies.¹³ Congress revisited the regulation of EHR in 2014 and through the FDA Safety Innovation Act and asked the FDA to develop a risk-based regulatory framework for EHR in tandem with the ONC and FCC to encourage innovation, protect patient safety, and avoid regulatory duplication.²⁵ Another key legislation that is hoped to improve these problems was passed in

2016. Congress passed the 21st Century Cures Act to streamline pharmaceutical and medical device regulatory processes to speed up their market availability. The Act also added “Interoperability” requirements for participants of the ONC certification. Participants not able to meet these requirements will have their certification revoked with a corresponding downward payment adjustment in their CMS claims.²⁴

Problems with EHR Products

The ease of entering the market and the lack of full market review of EHR products prior to launch have resulted in the availability of substandard, faulty products that put patients, clinicians, and hospital systems alike in harm’s way. This problem is not exclusive to non-certified EHR alone as evidenced by multiple instances of legal cases against certified EHR as well. In 2015, thirty-one medical societies have written the National Coordinator of NTC to express their concerns that EHR developers are targeting functions that meet government incentive requirements rather than improving functions vital to risk reduction and patient safety including– usability, privacy protection, deployable in the dynamic clinical setting, interoperability, and inability to report due to contractual limitations¹³

1. Usability

In 2019 Dr. Edward Melnick conducted a system usability study et.al. to measure the usability of currently available EHR formats using a standardized metric the System Usability Scale (SUS).¹⁶ Usability is defined as the ease of use of a product by a group of users with effectiveness, efficiency, and satisfaction in doing a contextual function. The usability of the presently marketed EHR was consistently graded F by clinicians with a mean SUS of 45.¹⁶ To put this in perspective the use of the Google search engine has a SUS of 93. Because of poor usability, clinicians are now at maximum, spending 2 hours documenting per 1 hour of direct patient care. The time burden of EHR documentation has also been

correlated with a strong dose relationship to clinician burnout. In addition, per a RAND completed study, other features of current EHR that result in poor usability are: 1. The system is designed to make billing easier but not to make clinical workflow move more efficiently. 2. Data entry while providing patient care is a significant distraction three. A 24-hour alert system increases the clinician's responsibility to respond resulting in alert overload and fatigue.¹⁶

2. Security, Privacy, and Patient Access to EHR

Another key area of concern is the absence of free-flowing user authentication that complicates electronic prescription workflow and allows for unauthorized access to the patient record. Current EHR has not provided the utility needed to support the needs of most users - taking them outside of the current workflow to write prescriptions and orders increasing the complexities of the process. There were also widespread breaches that have resulted in massive patient identity theft. Lax security processes and failure to audit activity trails allow entries to be altered or deleted resulting in allegations of fraud and wrongdoing. This problem together with information blocking or the practice of increasing the complexity of the burden of accessing and exchanging health information creates the perfect situation for legal allegations of negligence and personal injury as in the case of *Kristina Tot v. eClinicalWorks LLC*, Case No. 1:17-cv-08938. The case is a class-action lawsuit brought by Kristina Tot alleging failure to detect fatal illness and delay in treatment due to faulty EHR, on behalf of the estate of her father.²⁶ Tot claims that eClinicalWorks medical records failed to produce an accurate medical history on progress notes. This lack of medical history prevented his father's doctors to ascertain when his cancer symptoms first appeared and rendered those records unreliable for physicians and patients to use to base their treatment decisions. She also asserted that eClinicalWorks software regularly displays erroneous patient information, occasionally displaying patient information from different patients. On

further record inspections, she claimed that their audit logs do not accurately record users' actions and as a result records were altered, deleted and previous records became unavailable. The case is asking for \$999 million worth of damages from eClinicalWorks.²⁶

3. Poor Exception handling

Another flaw common to current EHR is its inability to manage wrong keyed information or exception handling. Because the work environment in the medical space is dynamic, EHR should be able to detect or identify integration errors or errors that originate from the connection between two functions. It is noteworthy to say that EHR vendors have highlighted the various capabilities of their product yet are unable to fix alpha/numeric entry mismatches, text exceeding character limits, or time of day that exceeds 24 hours, all of which are frequently used and unavoidable in medical documentation.¹⁴

4. Not Build to Be Interoperable

The ability for medical information to be exchanged in a meaningful manner from a sending system to a receiving system is the promise of interoperability. It is important in the transition of care to ensure that health records can follow the patient from one level of care to the next. Delay of information can result in an error and patient harm, and rework for clinicians. Researchers have noted that the primary reason for the lack of interoperability is more cultural than technical, as perverse as it may be, it has been documented that market share protection by EHR manufacturers and providers is the leading reason for the absence of robust document exchange.¹

5. Reporting Not Allowed

Most EHR vendors have inserted legal clauses of "Hold Harmless" when providing services and selling to end-user.¹⁴ A hold harmless clause is a clear legal statement indicating that an individual or enterprise will not be held liable in any way for the risk, danger, injury, or damages caused to the other party.¹² The result is there is no sense of shared accountability for product performance. Liability is shifted primarily to the user through the "Learned Intermediary" doctrine that states that a manufacturer of a product has

fulfilled its duty of care when it provides all the necessary information to a "learned intermediary" who then interacts with the consumer of a product. This discourages sharing/reporting of patient safety risks by end-users.¹⁴ It also put a gag on end-users to share their experiences with a particular vendor or EHR products to colleagues and in public.

Problem with Current Regulatory Policy

1. Hands off Regulatory Policy

In absence of a systematic regulation, full review, or market authorization mechanisms, the market for EHR is a mixture of everything, both certified and non-certified products are allowed. Because of this heterogeneity, and lack of assurance of safety and effectiveness verified through rigorous testing, the use of these products poses risks to clinicians, patients, and the public. The various medical societies have voiced their strong criticism of the current certification process with a strong emphasis on the misalignment of end-to-end testing focused on hitting requirements for incentives not on usability, interoperability, and safety or risk management at the expense of physician's needs and patient's safety.¹⁴

2. Lack of Oversight of Third-Party Testing and Certifying Bodies

One other pressing assessment by the American Medical Association was the apparent lack of oversight of Authorized testing and certification bodies (ATCB) by ONC for ensuring the rigor and robustness of testing procedures and standards to:

- a. Secure and protect information contained in EHR as highlighted by the Office of Inspector General (OIG) and evidenced by the failure of manufacturers to address common security issues.
- b. Guarantee that the product will perform as expected even in dynamic clinical settings to minimize error, poor documentation, mismatches, unreliable transmission, lost information, and patient risk.

- c. Will be able to manage exceptions, integration errors, and abnormal events and capable of identifying safety-related issues in fast-paced settings.
- d. Ensure that the EHR demonstrates a vendor's user-centered design (UCD) process to improve user-friendliness.
- e. Ensure scenario-based testing to identify workflow bottlenecks.
- f. Standardized the consolidated clinical document architecture (C-CDA) to avoid system mismatches to smooth out the transition of care from one facility to another³

3. Lack of Transparency

Vendors and manufacturers of EHR are successful in keeping their business private through a combination of legal strategies – “Hold Harmless” clause when signing contracts with physician groups and hospitals, “Trade Secret” for individual clinicians effectively creating a barrier for reporting of problems, potential risk, the potential for harm undercutting product surveillance.¹⁴

Other Developments:

1. Development of Wireless EHR devices

Wireless EHR devices are devices that can be interoperable with the EHR of the patient. These devices can transmit medical information remotely and directly to the EHR and are used for diagnosis, treatment, or prevention of disease. Examples are Abbott's i-STAT – which transmits diagnostic test results in real-time to the EHR, and Welldoc's Diabetes Manager connects directly to Allscripts EHR to manage diabetes remotely.² These plug-and-play sensors are FDA-regulated medical devices. Taking these developments deeper requires us to reconsider the vital role of the integrator (EHR) in the management of the patient as it directly participates in the diagnosis, cure, mitigation, treatment, and prevention of the human medical condition passing the definition of a medical device as stated in 21 USC 321 SEC 201 of the Food, Drug and Cosmetic Act.¹⁴

2. Rising Fraud and Legal liabilities

In a study done by The Doctors Company (TDC), a medical malpractice insurer, EHR-related lawsuits are on the uptick. Civil cases have risen from a low of seven per year in 2010 these claims grew to 22.5 cases per year in 2017 and 2018. 216 of these claims closed from 2010 to 2018. ⁶

Federal prosecutions are also up as evidenced by the following cases:

Company	Year	Charge	Amount of Settlements
1. Athena	2021	False Claim Act	\$ 18.25 M ⁷
2. KPDP	2020	False Claim Act	\$ 1.7 M ⁵
3. Practice Fusion	2021	Kick-back	\$ 263 M ⁹
4. Greenway	2019	False Claim Act	\$57 Million ⁸

Conclusion:

The current state of product safety of EHR is not acceptable, patient safety and healthcare quality are seriously compromised by its flawed designs and deficient functionality. The inability of current testing and certifying organizations to uphold rigorous, high standard assessments has led to products that cause end-user dissatisfaction and widespread clinician burnout, and more importantly, patient harm, the scale of which is just starting to unravel in the nation's court system. Moreover, the involvement of major manufacturers and vendors in fraud and anti-kickback cases is eroding physician, patient, and public trust. Further, the lack of a comprehensive regulation has led to variability in product quality, accuracy, precision, reliability, and safety of EHR products now available in the market. This is not compatible with our goal of developing a national health IT system that is interoperable from device to device, facility to facility, and provider to provider. Finally, the ONC may be too young as an agency and should benefit from FDA's competencies in exercising regulatory powers to ensure products entering

the market are safe for the indicated uses they are made for and effective in doing the things that their manufacturer claimed they can perform. The FDA through FDASIA has been enabled to develop regulations together with ONC and FCC to ensure the public safety of EHR. A combination of multi-agency government oversight and leadership is desperately needed to address the glaring deficiencies and unintended consequences of EHR adoption. Policy uncertainty and compliance uncertainty can stifle innovation, so the FDA needs to clearly state its intent and must show strong leadership, and develop a comprehensive, flexible, risk-based regulatory framework for EHR.

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