

Finding A Cure: The Case for Regulation and Oversight of Electronic Health Record Systems



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EHR systems



- Record systems
- Clinical alerts and reminders
- Decision aids
- Links to medical literature
- Computerized physician order entry
- Data analysis tools (enable searches)
- Interoperability

Support for EHR systems

- Pres. Bush 10 year initiative for NHIN
- Congressional bills
- State initiatives
- 2008 campaign issue



Benefits of EHR systems

- Reduce errors
- Improve patient safety
- Improve preventive care
- Facilitate communication
- Cost savings
- Improve search capabilities and promote evidence-based medicine and clinical practice guidelines



Risks of EHR systems

- Cost & burden of adopting EHR systems
 - Only 24% of physicians & 5% of hospitals had EHR systems in 2005
- Time investment
- Potential for errors
- Privacy and security concerns



Legal issues

- Will use of decision support be a defense?
- Will EHR system vendors always be sued in medical malpractice cases?
- How will failures of complex EHR systems be proven?
- Faithfully recording all medical interventions can facilitate discovery of truth
- EHR systems will allow for electronic searches of medical records

Federal regulation needed

- Oversight is provided solely by CCHIT, an industry-based organization
 - Testing lasts only 1 day; applicants are given testing scenarios; CCHIT criteria don't address reliability, safety, usability
- Federal regulation should:
 - incentivize EHR system adoption
 - establish quality control

Potential regulatory agencies

- FDA
- CMS
- Newly created agency





Role of government

- Funding to encourage adoption of EHR systems: tax credits, grants, etc.
- Establish EHR system approval and monitoring processes
 - EHR System Oversight Committees (SOCs)
 - Field testing of new products for 6 months
 - Ongoing monitoring



EHR system criteria

- Reliability and safety
- Interoperability
- Audit trails
- Security requirements
- Decision support mechanisms





National research database

- De-identified EHRs sent to national database
- Accessible to researchers who apply to regulatory agency
- Allow for review of millions of files and long-term observational studies
- Fill knowledge gaps and promote evidence-based medicine



Article

- Finding A Cure: The Case for Regulation and Oversight of Electronic Health Record Systems
 - Forthcoming in Harvard Journal of Law & Technology
 - http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1122426