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Addressing Liability and Clinical Decision Support: A Federal Government Role

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ADDRESSING LIABILITY AND CLINICAL DECISION SUPPORT: A FEDERAL GOVERNMENT ROLE

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I. INTRODUCTION

Health information technology ("HIT") has the power to improve the delivery of health care and bring needed information to the health care provider at the point of care. This includes information about the patient from disparate sources. Clinical decision support ("CDS") facilitates the use of this patient information, combined with medical knowledge, to support decision making by healthcare providers with the aim of improved quality of care and patient safety. The consequences of effective CDS are far-reaching: where does the computer's advice become an essential component of clinical decision-making? How do we maintain confidence that the guidance offered by the computer is aligned with best practices? When is it acceptable for the clinician to ignore the advice of a CDS intervention? Liability concerns are a backdrop to many of these questions.

The article by Susan Ridgely and Michael Greenberg, *Too Many Alerts, Too Much Liability: Sorting Through the Malpractice Implications of Drug-Drug Interaction Clinical Decision Support*,[1] was part of the *Advancing Clinical Decision Support* initiative sponsored by the Office of the National Coordinator for Health Information Technology ("ONC") at the U.S. Department of Health and Human Services ("HHS"). The initiative focused in part on the issue of "alert fatigue"–in which excessive numbers of alerts may result in health care providers ignoring or turning off important CDS functionality.[2] The Ridgely and Greenberg article explores liability concerns raised by alert fatigue for electronic health record ("EHR") developers and users.[3] They have advanced the issues related to liability and drug-drug

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1. M. Susan Ridgely & Michael D. Greenberg, *Too Many Alerts, Too Much Liability: Sorting Through the Malpractice Implications of Drug-Drug Interactions Clinical Decision Support,* 5 ST. LOUIS U. J. HEALTH L. & POL'Y 257, 257, 259 (2012).

2. *Id.* at 259.

3. *Id.*

interactions ("DDI"), and they have identified potential solutions.[4] ONC funded this work; however, the authors' statements and views do not represent the policies or positions of ONC.

This response explores the role of the federal government, the proposals made by Ridgely and Greenberg, and a proposed way of thinking about liability and clinical decision support from the federal government perspective.

II. FEDERAL GOVERNMENT ROLE

The healthcare industry has been slow to adopt information technology, including electronic health records ("EHRs"), as compared to other industries, despite the call for adoption to improve health care quality.[5] As a result, the federal government stepped in to promote adoption and "meaningful use"[6] of HIT under the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") through Medicare and Medicaid incentive programs.[7] Beginning in 2011, eligible professionals and hospitals that achieve meaningful use of "certified EHR technology"[8] and complete an attestation process receive payments.[9] These programs are led by the Centers for Medicare & Medicaid Services ("CMS") in close collaboration with the ONC.[10] ONC adopts standards and criteria for EHR technology.[11]

CDS has been the subject of greater interest as HHS has moved to promote EHR adoption. Among the requirements for the technology is to "implement automated, electronic CDS rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements

4. *See id.* at 278.

5. *See* COMM. ON PATIENT SAFETY & HEALTH INFO. TECH., INST. OF MED., HEALTH IT AND PATIENT SAFETY: BUILDING SAFER SYSTEMS FOR BETTER CARE, 1-2 to 1-5 (2011) [hereinafter HEALTH IT AND PATIENT SAFETY], *available at* http://www.nap.edu/openbook.php?record_id=13269&page=13.

6. 42 C.F.R. §§ 495.4, .6, .8 (2010); *see also CMS EHR Meaningful Use Overview*, CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/EHRIncentivePrograms/30_Meaningful_Use.asp (last visited Mar. 23, 2012).

7. The Health Information Technology for Economic and Clinical Health (HITECH) Act comprises Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act (ARRA) of 2009, Pub. L. No. 111-5, 123 Stat. 115 (to be codified in scattered sections of 42 U.S.C.). Particularly relevant are HITECH Act §§ 4001-4101, 4103, 4201, 123 Stat. at 467, 470, 487.

8. 45 C.F.R. § 170.102.

9. 42 C.F.R. Parts 412, 413, 422 et al., Medicare and Medicaid Programs. Electronic Health Record Incentive Program Final Rule.

10. Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. 44,314, 44,316 (July 28, 2010) (codified at 42 C.F.R. §§ 412, 413, 422, 495).

11. 45 C.F.R. § 170 subparts B and C (2011).

included in: problem lists; medication lists; demographics; and laboratory test results."[12] For a provider or hospital to receive incentive payments, they must use certified EHR technology that includes this functionality and "implement one clinical decision support rule."[13] There also are requirements related to computerized provider order entry ("CPOE") for medication orders and for drug-drug and drug-allergy interaction checks.[14] These elements are critical to the objectives of the programs as the focus is not only on adoption but also on meaningful use of HIT. Many of the benefits of the technology are only achieved when there is intelligence built in to inform decisions and when health care providers use this intelligence to improve health care delivery and patient outcomes. "If implemented correctly, alerts can improve patient safety."[15] Therefore, effective CDS is an important component of EHRs and critical to effectuate meaningful use.[16] Medication-related CDS that includes a DDI list is an important tool to reduce adverse drug events.

In general, the federal government has an important, but limited, role in influencing the market, and acts when there is a legitimate public purpose and authority for doing so. The federal government has intervened for the following reasons, among others: (1) market forces are not producing an outcome that is of widespread public benefit; (2) a market failure is allowing persistent inefficiencies; (3) it is more efficient for the government than the private sector to act to address a public need; or (4) it is necessary to protect the public. While in some cases it is appropriate for the government to step in to address these types of concerns, it is prudent to limit such intervention to no more than that which is necessary to address the problem. Many efforts currently underway involve leveraging public-private partnerships to develop the appropriate balance between government and the private sector.[17]

In the case of CDS and liability, there seem to be appropriate roles that the federal government may take because of its interest in consumer protection and a failure of the market to address this concern. As Ridgely and Greenberg point out, the research shows that adoption of CDS, including clinical alerts, appears to reduce the rates of adverse drug

12. 45 C.F.R. § 170.304(e) and § 170.306(c) (2011).

13. 42 C.F.R. § 495.6(d)(11)(ii), (f)(10)(ii) (2010).

14. 45 C.F.R. § 170.302(a) (2011).

15. HEALTH IT AND PATIENT SAFETY, *supra* note 5, at 2-10.

16. *Id.* at 2-9.

17. *See, e.g.*, *Public Private Partnership Tools*, FEMA, http://www.fema.gov/private sector/ppp_tools.shtm (last visited Jan. 17, 2012) (encouraging public private partnerships); *see Partnership Provides Health IT Training and Electronic Health Records,* THE OFF. OF MINORITY HEALTH, http://minorityhealth.hhs.gov/templates/content.aspx?lvl=1&lvlID=46&ID =9241(last visited Feb. 2, 2012).

events.[18] They also argue that concerns about liability and CDS may result in risk avoidance behaviors of various players.[19] If the CDS is designed in a way that causes users to ignore interventions because they are too often irrelevant and unhelpful, then there are two unintended consequences. First, patients who could have been helped by information provided through this technology are not helped, and medical errors that could have been avoided are not avoided. ONC has an interest in alert fatigue because of its interest in using HIT to improve healthcare outcomes. Second, as Ridgely and Greenberg describe, health care providers who ignore interventions may be faced with a new source of liability risk if it can be shown that the interventions could have prevented injuries.[20] This is important to ONC because the fear of increased liability–even if unfounded–has been raised as a concern by health care providers[21] and may impact adoption of EHRs. Ridgely and Greenberg researched a specific kind of CDS (alerts) in a specific domain (drug-drug interactions).[22] It is not clear, however, that their findings generalize to all types of CDS. Osheroff and colleagues define ten types of CDS.[23] Ridgely and Greenberg's focus on just one of these types of CDS intervention, without consideration of the others, limits their analysis and their conclusions.

In the case of DDI alerts and liability, the market has not developed a solution for the liability risk. This failure impedes quality and safety improvements in health care. Ridgely and Greenberg note that "the HIT vendor market has not produced a solution to over-inclusive DDI warnings,

18. Ridgely & Greenberg, *supra* note 1, at 261.

19. *Id.* at 262.

20. *Id.* at 268.

21. *American Health Information Community (AHIC)*, U.S. DEP'T OF HEALTH & HUMAN SERVICES, http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&cached=true&objID=1199&PageID=15512 (last visited Mar. 27, 2012); *Electronic Health Records Workgroup*, U.S. DEP'T OF HEALTH & HUMAN SERVICES, http://healthit.hhs.gov/portal/ server.pt/community/ahic_workgroups/1201/electronic_health_records/15527 (last visited January 29, 2012); *AHIC Workgroups*, U.S. DEP'T OF HEALTH & HUMAN SERVICES, http://healthit.hhs.gov/portal/server.pt/community/ahic_workgroups/1201/home/15523; *see also* U.S. DEP'T OF HEALTH & HUMAN SERVS., THE COMMUNITY: AMERICAN HEALTH INFORMATION COMMUNITY 14, 23 (2008).

22. Ridgely & Greenberg, *supra* note 1, at 257.

23. JEROME A. OSHEROFF ET AL., IMPROVING OUTCOMES AND CLINICAL DECISION SUPPORT: AN IMPLEMENTER'S GUIDE (2011). CDS during data-entry tasks (Smart Documentation Forms, Order Sets, Care Plans and Protocols, Parameter Guidance, Critiques and Warnings – "Immediate Alerts"), CDS during data-review tasks (Relevant Data Summaries (Single-patient), Multi-patient Monitors, Predictive and Retrospective Analytics), CDS during assessment and understanding tasks (Filtered Reference Information and Knowledge Resources, Expert Workup and Management Advisors), CDS not triggered by a user task (Event-driven Alerts (Data-triggered) and Reminders (Time-triggered)).

or to the well-documented problem of physician alert fatigue."[24] They assert that vendors and presumably content developers are "creating CDS systems that generate massively over-inclusive automated warnings" and then using contract terms to shift liability for the use of the EHR to the users without regard for the possible vendor contribution to alert fatigue.[25] Indemnification clauses, disclaimers, and limitations on damages that reduce the vendor's liability for alert fatigue are common EHR contract terms. The authors suggest, but do not fully explore, how these contract terms may reduce the need for the EHR vendors to find solutions for the problem of alert fatigue by relieving them of liability for their own poor design or poor content. This point deserves additional policy consideration. The policy problem raised by concerns of liability for CDS is not the potential for liability itself but that the fear of liability will negatively impact design, clinical content, EHR adoption, and EHR implementation.

In *Health IT and Patient Safety: Building Safer Systems for Better Care*, commissioned by ONC, the Institute of Medicine ("IOM") highlights broader safety risks and asserts that HHS should work with a variety of stakeholders to mitigate the risks and make HIT-enabled care safer. [26] In this report, IOM provided a set of recommendations, which HHS is currently evaluating as it develops a safety plan.[27] The issue of alert fatigue and the potential impact on patient safety may appropriately be considered in this plan.

III. PROPOSED STRATEGIES AND CHALLENGES

Given the primacy of health care quality and patient safety, the goal should be to figure out how to improve the likelihood that the most important CDS interventions are viewed and considered by clinicians. There are a number of players that are potentially liable if there is a problem with CDS or if it is not viewed or used: software designers, the providers of the medical knowledge used by the system, and the end users, i.e., the health care providers. Each of these players is likely to make decisions to minimize its risk of liability. However, actions based on risk avoidance do not necessarily result in the best and safest care for the patient.

The first strategy proposed by Ridgely and Greenberg is the creation of a standard for the content of a particular form of alert—the creation of a DDI list.[28] Three of the other strategies involve mechanisms to endorse this list through various policies.[29] The second recommendation is for regulation of

24. Ridgely & Greenberg, *supra* note 1, at 259.
25. *Id.* at 262.
26. *See* HEALTH IT AND PATIENT SAFETY, *supra* note 5, at S-2, 6-3 to 6-5.
27. *Id.* at 6-11 to 6-13.
28. Ridgely & Greenberg, *supra* note 1, at 279.
29. *Id.* at 286, 289-90.

CDS tools by the Food and Drug Administration ("FDA").[30] This would be oversight of both the content and design of CDS.

I agree with the authors that consensus on a clinically significant DDI list could help address problems of liability. However, I also agree with the authors that achieving and maintaining such a consensus would likely be challenging.[31] It would be very challenging to develop and maintain standard content for CDS, and DDI specifically, as medical knowledge changes rapidly. In the case of the creation and maintenance of a DDI list, it is likely that the creation is best done by experts in the field, not the federal government. As they state, it requires finding a willing group of organizations to take on such an effort and to develop a system for updating the list over time.[32] They note that this would likely require government involvement and funding, which may be challenging in the current economic environment. [33] This is only exacerbated by the fact that it would be difficult to obtain consensus on a common DDI list, and creating and maintaining such a list would likely be time consuming and expensive. In addition, the emergence of personalized medicine means that there will be increasing complexity of information regarding drug interactions in relation to genetic profiles further complicating the creation of a DDI list.[34]

The second approach, FDA oversight of CDS as a device, may address concerns of liability, but raises other challenges. The IOM report highlights that the safety and improvements in care that can be delivered through HIT require considerations of the socio-technical system in which the EHR operates.[35] This includes considering not just the technology, but also the people, processes, organizations, and external environments.[36] For example, even if the technology has the right information in it, the way it is implemented, or the processes for use can impact its effectiveness. Therefore, regulating the technology may address the liability issue up to a point, but may not necessarily solve the safety and effectiveness problem. In addition, in a market that is emerging and changing rapidly, such as HIT, there have been concerns raised about the appropriate balance of government oversight and market innovation.[37] Regulation may add complexity and delays in updating and maintaining products as knowledge changes. The IOM considered the role of FDA oversight of HIT from a

30. *Id.* at 281.

31. *Id.*

32. *Id.*

33. Ridgely & Greenberg, *supra* note 1, at 281.

34. Wolfgang Sadée & Zunyan Dai, *Pharmacogenetics/Genomics and Personalized Medicine*, 14 HUM. MOLECULAR GENETICS 207, 207, 210 (2005).

35. *See* HEALTH IT AND PATIENT SAFETY, *supra* note 5, at 3-2 to 3-4.

36. *Id.* at 3-3 to 3-4.

37. *Id.* at 6-12.

safety perspective.[38] They were concerned that the "FDA framework is oriented toward conventional, out-of-the-box, turnkey devices" and that such oversight may stifle innovation.[39] They specifically recommended that the FDA not regulate at this time, but recommended re-evaluating this position if other mechanisms for safety prove ineffective.[40] Given the IOM's recommendations, it is unlikely that the FDA will, in the short run, actively regulate CDS as a medical device using its existing authority. However, software developers may be well advised, from a liability perspective, to consider certain FDA guidance and regulations, including human factors guidance, and pending guidance from ONC regarding quality management best practices, as reflecting a developed federal standard.

IV. NEW STRATEGIES TO CONSIDER AND THE FEDERAL GOVERNMENT'S ROLE

Ridgely and Greenberg provide evidence of a problem, whereby fears of liability result in DDI alerts (and arguably CDS) that may not support providers in delivering the best care to patients, and therefore, of a need for solutions to address the problem.[41] There is also a valid basis for the federal government to take steps to address this problem in order to support improved clinical care and meaningful use of EHR. It is best for the government action to be limited to that which is necessary to address the failure or need that exists. There may be opportunities for federal government involvement to support the solution that is less heavy-handed, with fewer potential unintended consequences. These approaches include focusing on user-centered design and collaborating with public and private stakeholders to understand and address concerns and actions that are counter to safety goals.

First, it would be valuable to consider some creative solutions to the problem of DDI alert fatigue, which results from conservative, risk-averse behavior on the part of the relevant players. Human computer interaction research, i.e., human factors research and user-centered design, could provide helpful lessons for DDI alerts and CDS more broadly. The National Institute for Standards and Technology ("NIST") has released an EHR Usability Protocol ("EUP") identifying alert fatigue as a usability problem.[42] The IOM recommended that HHS specify the "quality management

38. *Id.* at S-9.

39. *Id.* at S-10.

40. HEALTH IT AND PATIENT SAFETY, *supra* note 5, at S-10.

41. Ridgely & Greenberg, *supra* note 1, at 262.

42. NAT'L INST. OF STANDARDS & TECH., U.S. DEP'T OF COMMERCE, NISTIR 7804, TECHNICAL EVALUATION, TESTING AND VALIDATION OF THE USABILITY OF ELECTRONIC HEALTH RECORDS (2012), *available at* http://www.nist.gov/healthcare/usability/upload/EUP_WERB_Version_2_23_12-Final-2.pdf.

principles" that HIT vendors must adopt, with a particular focus on human factors, safety culture, and usability."[43] There may be opportunities to design systems that provide the most relevant support to health care providers without over-inclusive alerts. Ridgely and Greenberg consider the DDI alerting challenges, which is only one aspect of the expansive domain that CDS encompasses.[44] For example, while CDS can involve "pop-up" alerts or messages, it may also be instantiated as the prioritization of various selections to make the preferred choice more prevalent, or pre-selecting drugs or procedures in an order set that are most consistent with guidelines.[45] Effective CDS involves using design to affect provider decision-making that improves care and outcomes. The federal government can play a role in promoting user-centered design that focuses on areas of patient safety, particularly with respect to CDS. This may result in effective CDS that does not lead to alert fatigue.

Second, we should consider directly addressing the problems of liability, or fear of liability. It would be valuable to look at the issues of contracting to determine if there are ways to align liability risks with the party most able to mitigate the risks. It would also be valuable to determine if there are ways of setting guidelines to establish a reasonable process for developing CDS in order to minimize the risks to those assuming them. An effective way for determining a solution to this complex problem with a variety of stakeholders with different incentives is to bring together the stakeholders–including the clinical knowledge providers, the EHR vendors, the health care providers and systems, malpractice insurers, and other liability insurers–to develop approaches and options that would work together to manage risk for all while focusing on improving patient safety and outcomes. The best solutions may only emerge when all of the relevant players work together to identify solutions and the entities that are best suited to implement those solutions. The federal government may play a valuable role in bringing a focus to this issue, helping to convene stakeholders, and collaborating with stakeholders to develop solutions or to set mutually agreed to guidelines.

V. CONCLUSION

Ridgely and Greenberg have done a great service in describing the liability risks borne by physicians, hospitals, other health care organizations, and EHR software vendors and clinical knowledge providers as well as the

43. HEALTH IT AND PATIENT SAFETY, *supra* note 5, at 6-19.

44. *See generally* Ridgely & Greenberg, *supra* note 1.

45. Adam Wright et al., *Development and Evaluation of a Comprehensive Clinical Decision Support Taxonomy: Comparison of Front-End Tools in Commercial and Internally Developed Electronic Health Record Systems*, 18 J. AM. MED. INFORMATICS ASS'N 232, 237, 239 (2011).

impact on DDI lists and CDS. Their determination that there is very little actual liability related to drug-drug interaction software should reduce defensiveness and encourage a dialogue about solutions to the problem of alert fatigue. Patient safety and the reduction of medical errors should be the focus of concern. It is critical that we create a culture of safety that promotes actions that support patient safety. ONC looks forward to fostering and participating in that dialogue.