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**HIT Policy Committee
Adoption/Certification Workgroup
Response from Gay M. Johannes
Cerner Corporation, Kansas City, Mo.
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My name is Gay Johannes, and I am Vice President and Chief Quality Officer at Cerner Corporation, in Kansas City, Mo., where I have been an associate for 26 years. I have spent the majority of my career working on the design and development of *Cerner*[®] solutions. For the last six years, I have led the quality assurance and operations functions of the company.

Cerner and I would like to thank the HIT Policy Committee for the opportunity to testify on patient-safety issues related to the use of electronic health records.

Cerner is transforming health care by reducing error, variance and waste for providers and consumers around the world. *Cerner* solutions optimize processes for health care organizations ranging in size from single-doctor practices, to health systems, to entire countries, for the pharmaceutical and medical device industries, and for the health care commerce system. Cerner began with the development of an information system that optimized processes in the hospital laboratory. Since its founding in 1979, Cerner has expanded the application of health information systems across the entire health care delivery continuum. Today, Cerner's HIT solutions assist clinicians in many areas of care, including surgery, pharmacy, women's health, intensive care, PACS and blood banks.

These solutions are licensed by more than 8,500 facilities around the world, including approximately 2,300 hospitals; 3,400 physician practices covering more than 30,000 physicians; 600 ambulatory facilities, such as laboratories, ambulatory clinics, cardiac facilities, radiology clinics and surgery centers; 700 home-health facilities; and 1,500 retail pharmacies. As such, Cerner provides HIT solutions to nearly one-third of the domestic health care market.

While HIT is transforming the processes of health care, it has not replaced the skilled clinicians who deliver care to the American public. HIT systems collect, record and manage information that is relevant to the diagnosis and treatment of disease. HIT makes that information readily available to the clinician in a form that aids clinical decision making. Ultimately, however, the clinician diagnoses and treats patients based on his or her assessment of the available information in accordance with the medical standard of care. The HIT industry neither intends nor desires to practice medicine. We simply create tools that help clinicians make better care decisions for patients.

In the early stages of HIT system development, Cerner and other HIT companies designed solutions that collected and stored clinically significant data. These systems made information available upon demand, but they did not provide recommendations on medical assessments or proactively push alerts or decision



support to the caregiver. Largely speaking, these systems automated paper processes. As HIT systems expand and become “smart” technology, a new level of opportunity for inadvertent risk and complexities will be introduced into the care process. As the complexity and attendant risk of these solutions grow, enhanced safety measures will be warranted.

Cerner is uniquely positioned to comment on the safety issues facing the HIT industry and the efforts by government to date to address those issues. The U.S. Food and Drug Administration (FDA) actively regulates some *Cerner* solutions as medical devices. As a result, these solutions are subject to the regulations imposed by the FDA under the Food, Drug and Cosmetics Act. These regulations govern the design and development of medical devices, the pre-market clearance of such devices and the post-market surveillance concerning the safety of such devices.

Other *Cerner* solutions are not actively regulated by the FDA and are not subject to these regulatory obligations. Over the last decade, however, Cerner has voluntarily implemented post-market surveillance processes in accordance with FDA standards and has publicly disclosed issues that might impact the public safety by reporting through the FDA’s MedWatch program. These reports are part of the public record. Similarly, Cerner voluntarily complies with the FDA’s Good Manufacturing Practice regulations in the design and development of its unregulated solutions. In addition, Cerner has adopted Quality System Requirements for its development processes across all *Cerner* solutions to meet the more stringent FDA requirements for regulated medical devices.

Cerner is one of the few HIT suppliers in the United States that voluntarily reports safety related incidents for non-FDA regulated solutions to the FDA’s MedWatch program. Cerner is not required to do this. We believe it’s the right thing to do. Such disclosures provide much-needed transparency into the success and challenges of these systems. This transparency is especially important at a time when the federal government—and the American public—are investing heavily in HIT. Cerner believes there will be increasing HIT regulation both here and overseas. This new regulation is not exclusively tied to safety concerns, but rather to the expectation that government should be involved in making health care better and more transparent. Cerner’s participation in MedWatch is just one example of how the company is participating proactively, rather than reactively, in health care reform.

Since 2008, Cerner and Cerner clients have identified 25 incidents of potential patient care issues that warranted the filing of medical device reports to the FDA’s MedWatch program. None of these incidents resulted in serious injury. Overall, these potential incidents of harm represent a small portion of the total number of patient and provider interactions with Cerner systems. More than 30,000 HIT professionals and 2.5 million health care professionals use *Cerner* solutions every day, and *Cerner* solutions play a role in the care of 60 to 70 million patients annually. Additionally, during the same time period, Cerner’s patient safety rules fired more than 100 million times. Taken together, these facts underscore our position that the benefits of HIT far outweigh the risks.



Cerner appreciates the financial and resource commitment the federal government has made to HIT and supports of the work that your committee is doing to create a health care system that is streamlined, coordinated, accurate, predictive, proactive and affordable. Your committee may want to explore the idea of incorporating patient safety-related criteria into the certification requirements for the “meaningful use” of electronic health records, essentially tying the receipt of economic stimulus funding to patient safety. This market-based approach would lessen the need for direct government regulation of HIT suppliers while addressing the important issue of patient safety.

Cerner believes that the design and development of HIT solutions in accordance with Good Manufacturing Practices, the implementation of quality systems, and the use of post-market surveillance and transparency are viable ways to mitigate potential safety risks. Cerner does not believe, however, that all HIT solutions should be classified as medical devices that require pre-market clearance or approval by the FDA. Such a broad classification would be excessive for the level of risk posed by most HIT systems. In sum, we believe the level of risk HIT solutions pose to patient safety should dictate the level of government regulation.

1. What experience have you had with EHR-associated patient safety risks?

Cerner tracks issues with its software solutions as part of its customer support and post-market surveillance activities. The company reviews, categorizes and escalates issues according to their risk to patient safety. As mentioned above, Cerner voluntarily reports issues to FDA’s MedWatch program, even for software solutions that are not actively regulated medical devices. Cerner analyzes, categorizes and reports these issues in accordance with 21 CFR Part 803 Subpart E.

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General types of issues

Cerner has categorized the most common EHR issues that can pose risks to patient safety. This listing is based on the types of software issues that Cerner’s clients have reported and on industry research and intelligence.

Data-integrity issues

- Incorrect updates in the EHR or data not saving as expected

- Record overlay or merging issues leading to incomplete or incorrect information contained in the EHR
- Data retrieval errors
- Truncated text on screens or reports
- Updates not saved as expected

User errors

- Data-entry errors
- Ignored warnings
- Use of system in an unsupported or unintended manner
- Users unfamiliar with the software system or unaware of available features

Design/build/workflow issues

- System configuration and design errors leading to misuse of functionality
- Customizable parameters not configured to mesh with site workflow/care protocols
- Lack of proper planning and design prior to implementation

System-interface issues

- Lack of communication between disparate systems
- Data discrepancies between disparate systems
- Data configuration and terminology differences between disparate systems

Unplanned system downtime

- System not available
- System slow or unresponsive
- Updates lagging or not available when needed

Reducing errors, variance

Research into the challenges facing the health care industry as a whole has delineated two broad patient safety concerns: preventable medical errors and unintended variance. HIT gives clinicians powerful tools to address these issues.

A 1999 watershed study by the Institute of Medicine estimated that preventable medical errors account for up to 100,000 unnecessary deaths in U.S. hospitals each year.¹ Cerner has found that health care organizations can successfully use information technology to help them address this alarming number of preventable medical errors. For example, one Cerner client, a hospital, used the company's Computerized Physician Order Entry (CPOE) system to reduce overall medication errors by 23 percent, harmful medication errors by 42 percent and pharmacy transcription errors by 98.3 percent.

¹ Institute of Medicine, Committee on Quality of Health Care in America. *To Err is Human: Building a Safer Health System*. Kohn LT, Corrigan JM, Donaldson, MS, eds. Washington, D.C: National Academy Press, 1999.

HIT also can help clinicians ensure that medical decisions are based on evidence, not anecdotal memory, which is an important step toward eliminating a second core problem in healthcare—unintended variance. Another study, which quantified this phenomenon, found that Americans receive recommended health care services only half of the time.² Cerner's experience shows us that HIT can help mitigate these sorts of challenges. After implementing a Cerner HIT system, another client decreased severity adjusted mortality by approximately 26 percent (since 2005) and instances of hospital-acquired pressure ulcers by approximately 36 percent (since 2006). Additionally, with the help of an HIT system, this client surpassed Joint Commission clinical performance standards for acute myocardial infarction, heart failure and community-acquired pneumonia.

2. How have you identified those risks?

Cerner has a system in place to track, catalogue and maintain complaints and/or concerns regarding Cerner's HIT solutions.

Cerner offers clients four primary entry points to request support services for *Cerner* solutions: Cerner.com, the Client Care Contact Center, Solution Works and the Immediate Response Center. Support services include Cerner's efforts to assist its clients in operating Cerner clinical solutions and to respond to questions, concerns, complaints and other communications from its clients. To the extent that these client communications reflect dissatisfaction with the quality, reliability, safety, effectiveness or performance of a *Cerner* solution, Cerner maintains an internal system to track and document the communication, Cerner's response and the resolution of the communication. The company also uses this system to track communications from its associates who relate to the quality, reliability, safety, effectiveness or performance of *Cerner* solutions.

Cerner logs communications concerning the performance or operation of *Cerner* solutions as "Service Records." Cerner has adopted processes to ensure the appropriate level of review for Service Records that require escalation as a result of the nature, frequency or severity of the situation reported through the Service Record. Cerner's Client Impact Review Board assesses issues for impact across the Cerner client base for the involved solution and determines appropriate communication methods to proactively inform clients of an issue and corrective actions to be taken. The company tracks communications directed to senior executive leaders through a separate corporate process to ensure timely response and resolution.

Cerner evaluates all Service Records to determine whether they qualify under the Cerner Quality System as "Complaints." The company defines complaints as any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a *Cerner* solution or service after it has been released for distribution. Cerner also can identify and log issues prior to the general release of code.

² McGlynn E, Asch S, Adams J, Keesey J, Hicks J, DeCristofaro A, and Kerr E, "The Quality of Health Care Delivered to Adults in the United States," *The New England Journal of Medicine*, Vol. 348, No. 26, June 26, 2003.



Complaints include but are not limited to events that result or may result in adverse patient or donor care, a significant financial burden, or substantial downtime for a Cerner client. Adverse patient events are those that result or may result in serious injury or death to a patient or donor, and any serious event which is not necessarily life-threatening, but in which patient or donor care is compromised. Service Records that satisfy this definition of “Complaint,” together with Cerner’s ensuing investigation and response are documented through Cerner’s internal complaint-handling system. Cerner categorized complaints further as complaints, hazards, incidents or accidents.

Cerner associates with clinical, technical and functional knowledge evaluate a complaint’s impact on patient care and to the Cerner client base. Those associates investigate the complaint to determine, among other things, the root cause of the event underlying the complaint, the hazard that event may present to Cerner clients and their patients, the severity of that hazard and the probability that the event may recur. As part of this evaluation, solution experts also ensure that Cerner publishes the appropriate client notification to alert the client base of the issue, and to communicate any available workaround and the expected availability of the resolution.

Cerner’s Regulatory Affairs Group and solution experts also review complaints to determine whether the criteria have been met for filing of a Medical Device Report (MDR) with the FDA. Cerner files complaints that meet medical device reporting criteria (21 CFR Part 803 Subpart E) with the FDA, and, if necessary, the company files a follow-up report once it has released a correction to the issue to the client base. Complaint files remain open, and Cerner’s Regulatory Affairs Group monitors them until the company has implemented corrective and preventive actions to address the issue.

Regulatory compliance specialists coordinate and document the complaint handling process, prior to MDR evaluation. First, these specialists log and maintain in a database information concerning activities to 1) assess the event underlying the complaint; 2) identify its root cause; 3) determine whether an FDA MDR is required; 4) prepare the MDR; and 5) notify the Cerner client base. Second, the specialists place artifacts of the process, including, but not limited to, the Service Request, the MDR, and Client Flash Communications (the Cerner process for immediate client notification) in a paper file for each event giving rise to a complaint. The specialists also include a copy of the final report from the database in the file. The company maintains these files as part of the Device Master Record for the applicable *Cerner* solution, and it makes their contents available to internal auditors, FDA inspectors and ISO auditors.

3. What steps have you taken to prevent harm or to mitigate the safety risks?

Cerner has an excellent safety record in no small part because the company has standardized its design and development process and because it uses a collaborative approach for creating high quality software solutions. Cerner has incorporated this process under Cerner’s Quality Management System. Cerner has devised the procedures and required artifacts within the process to demonstrate and maintain compliance with applicable regulations and standards, such as the FDA’s Quality System Regulation/Good Manufacturing Practice, 21 CFR Part 820 Medical Devices, ISO 9001:2008 Quality Management



Systems and ISO 13485:2003 Medical Devices. Cerner applies its Quality Management System to both HIT solutions that are actively regulated by the FDA and those that are not.

Included within the design and development process are steps for establishing and managing functional requirements, performing solution safety hazard analysis, executing solution technical design, implementing the design, verifying and validating processes. These steps ensure that *Cerner* solutions meet design requirements and reasonably mitigate safety hazards by deploying the software into releases, prioritizing and managing projects, and controlling change throughout the software lifecycle. Through these processes, the company identifies, addresses and reports defects in accordance with 21 CFR Part 803 Medical Device Reporting. This standardized design and development process also helps Cerner approve and prioritize enhancements for inclusion into a solution. A detail of the process follows:

Through Cerner's internal development process, Cerner reviews and approves the design, development, and distribution of the company's solutions. Cerner created its design and development process in compliance with the Quality System Regulation, 21 CFR Part 820 Medical Devices; Good Manufacturing Practice (CGMP).

The company created its internal processes using these quality system regulations and associated guidance documents as input. Cerner reviews these procedures whenever the FDA changes its regulations. The following sections provide a high-level summary of how Cerner's internal development process relates to 21 CFR Part 820. Only applicable sections are included.

Quality System Requirements

Cerner has created a design and development process that complies with the company's quality management system. The Cerner Quality System (CQS), in turn, contains corporate policies written to maintain compliance to 21 CFR Part 820 and to ISO 9001:2008 and ISO 13485:2003. Cerner reviews any applicable policies within the Cerner Quality System as a part of the change control process. Cerner's internal audit group audits the design and development process along with those associates performing the process for compliance. Third-party auditors, including the FDA, Cerner's Notified Body and clients, also perform rigorous reviews of Cerner's design and development process.

Importantly, clinicians with experience in the area or specialty addressed by a Cerner solution write the functional requirements for the solution. Clients who are health care providers also actively participate in the development of solutions, from initial concepting to the testing and marketing of solutions. As a result, the design of *Cerner* HIT solutions consider and address typical health care work flows and clinician concerns. In short, *Cerner* solutions are designed for health care professionals by health care professionals. This approach reduces the risk that the solutions omit information of clinical significance or include unwanted information; which, in turn, reduces the risk to the patient receiving care.

Design Controls

The controlled design and development processes for *Cerner* solutions include a series of design controls that help Cerner ensure associates meet design requirements. Because software is the primary product,

Cerner bases design input on the definition of software requirements. Cerner and its development partners formally review these requirements to ensure they address the intended use of the software, including the needs of the health care professionals. Design outputs include technical designs and software code for the solution. Cerner also formally reviews design output to ensure the output meets the defined input.

Additionally, the company uses multiple types of verification and validation throughout the process to ensure the developed software meets both its defined requirements and the needs of the end users. These include a requirements review, technical review (generally code and design), test case review, unit testing, functional testing, deployment (product) testing, installation testing, performance testing and regression testing. Change control procedures are in place to manage any modifications to the inputs or outputs throughout the development process, and Cerner maintains design input and output records as part of the design history for the solution.

Document Controls

All procedures are controlled documents and follow the corporate policy for review, approval, distribution and changes.

Identification and Traceability

Cerner has procedures to identify and trace records of development to the solution, which it maintains as part of the device history. Any change to the solution can be reviewed against all development records for that change.

Acceptance Activities

There are procedures for acceptance, including a transfer to production signature with evaluation of exit criteria. The solution's executive along with subject matter experts from each functional area (design, development, validation) must sign the form. The solution executive has the authority to stop the release of the solution for any quality concerns. These procedures ensure that Cerner completes critical aspects of the development process as required by the regulations and standards prior to distribution.

Nonconforming Products

The transfer to production evaluation and signature process also includes a risk assessment for any known issues identified prior to release. By signing the transfer to production form, subject matter experts assume responsibility for the risk assessment and acknowledge that they believe the risk is low enough to release the solution. Potentially critical issues have an additional layer of review by Cerner's Regulatory Affairs group, which is managed by Cerner's Chief Quality Officer. Cerner must fix issues that fail to meet standards for release prior to distribution, or Cerner may stop the distribution to allow time for correction and review.

Corrective and Preventive actions

Design and development procedures include root cause analysis and test case effectiveness procedures. Cerner uses these procedures to analyze failure points within the process and identify improvement

actions. Process users must also comply with the corporate corrective and preventive action policies as defined by the Cerner Quality System.

Labeling and Packaging Control

There are procedures for creating, reviewing, approving and distributing all labeling content. Subject matter experts must review and approve all labeling content. The review includes a signature acknowledging the subject matter expert believes the labeling content is complete and correct.

Records

Procedures include instructions for the creation and storage of records in compliance with the Cerner Quality System, including the device master record and design history file. The Cerner Quality System includes policies for record retention. For most records, the retention period lasts the life of the solution plus five years.

Validation

Cerner certifies solutions based on the functional requirements of the solution. The company ensures that all functionality through the mapping of test plans to requirements. Cerner maintains the ability to trace test plans as part of the project artifacts. In addition, Cerner reviews and includes, as part of test plans, past critical defects in areas of change.

The types of testing that Cerner employs includes: a) engineering functional testing; b) validation testing, which is performed by a group separate from programmers; and c) regression/ongoing testing, which Cerner performs when expanding features to ensure that these new capabilities do not impact existing functionality.

Implementation

Cerner has a structured implementation strategy that it uses in working with clients to maximize the value they receive from its solutions. This modular methodology draws upon proven practices from a host of past client experiences. With it, a team can deliver the intended outcomes of a project with discipline, predictability and efficiency. Key components of this implementation approach include a) a framework that is benefits-focused and event-based; b) recommended approaches for both workflow and the solution itself; and c) online content that is presented in the context of project and role, and that offers access to recent learning from other projects.

End-User Training

Cerner believes it is important to thoroughly train the clinicians who use its solutions. A successful implementation of Cerner clinical solutions depends on the technical abilities of the client's IT project team and adoption of those solutions by the client's end-user clinicians. Cerner addresses the learning needs of both these client teams. Ultimately, however, the level and amount of training delivered to the IT project teams and the end-user clinicians is a decision made by the client.

4. What approaches would you recommend to prevent or mitigate harm associated with the use of EHRs?

Cerner suggests that approaches to mitigate the risk to the public should not be uniform across all HIT solutions and functionalities. Rather, mitigation requirements should vary as a function of the degree of risk that different types of functionality present to the public. HIT functionality that collects, records, stores and reports health information poses very little risk and, thus, warrants little regulation. As HIT systems evolve from primarily administrative record keeping functions to partnering in care delivery, delivering evidenced-based medical information and providing support for clinical decisions, the complexity and risk to the public will increase such that more aggressive prevention and mitigation activities are warranted and expected.

Cerner has found that incorporating some of the requirements imposed on medical device manufacturers into the processes by which it designs and develops more advanced HIT solutions has helped the company reduce patient safety risks. In particular, good manufacturing practices and quality system requirements can be helpful in providing quality assurance and quality control that reduces the potential safety risk of advanced HIT solutions. However, Cerner believes that such requirements can impede the pace of HIT innovation and delay benefits that come from HIT if they are applied in an inappropriate fashion. Regulators particularly will impede innovation if they impose pre-market clearance or approval standards on HIT for functions that do not represent appropriately high risks to patient care.

As the EMR industry has matured, more healthcare processes are now automated, and the reach of automation has moved from simple administrative billing to more clinical activities, decision support and even condition-specific features and capabilities. These more complex systems and capabilities require the orchestration of software, configuration, processes and training. As such, Cerner believes regulation also will need to be innovative as the information provided by EMRs becomes richer, more contextual and more capable of providing clinical decision support. Many Cerner clients achieve innovations through a combination of assets (software, decision support, content, clinical evidence, workflows and training). Those innovations occurred locally and are not automatically applicable to all Cerner clients. A regulatory approach that does not allow for clinicians to apply new approaches in the field will slow the development of possible HIT benefits on outcomes.

The policy challenge, then, comes in determining when the complexity of HIT solutions and functionality is great enough to create a risk to the public that warrants the mandatory inclusion of these elements into the design and development process. Making that determination of when enhanced prevention and mitigation processes are warranted is a matter of policy. However, Cerner believes that ongoing post-market surveillance activities for HIT can and should inform those policy decisions. Reporting events that constitute material risk to patient safety through the FDA MedWatch program not only serves to inform the end-user health care providers of risks associated with HIT. It also can serve to alert policy makers to systemic issues arising in connection with emerging HIT functionalities that might warrant the imposition



of mandatory good manufacturing practices or quality system requirements on the design and development of HIT.

Regardless of where policy makers draw the line on imposing enhanced mitigation and prevention requirements on HIT, they must support a level playing field across the HIT market. For that reason, whatever standards regulators establish, they must be clear and consistently applied across all HIT developers and classes of HIT functionality.

5. What are the benefits and concerns about making those risks and/or adverse events publically known?

There is an intuitive concern that public disclosure of adverse events will generate an overreaction by the public and unfounded fears about the safety of HIT. Cerner, however, has enjoyed great success in the marketplace during the decade in which it has publicly reported events that have the potential for material adverse impact on patient safety. Our experience has been that end-user health care providers have accepted these events as part of the ordinary course of the health care industry. They have used this information appropriately in evaluating the risk that *Cerner* solutions may pose to their patients against the benefits and safety enhancements that will be derived from the use of Cerner's HIT solutions. Moreover, the relatively small number of adverse events should serve to allay public concerns about the relative benefits of HIT and the low risk HIT poses to the public. For all of these reasons, Cerner believes that public reporting of events that pose material risks to the public is, overall, a positive. We would encourage other HIT vendors to adopt a similar practice of voluntarily reporting events that pose material risk.

Cerner, however, emphasizes that regulators must create a materiality standard to trigger a report of an adverse event. The very nature of HIT development and implementation regularly and frequently includes code issues, which through an extension to the logical extreme, could result in negative impacts on public safety. To report these ordinary course defects would almost certainly lead to over-reporting of HIT events and an unwarranted concern about the risks of HIT. Cerner submits that application of the materiality standards imposed on medical device manufacturers for the submission of Medical Device Reports to MedWatch strikes an appropriate balance in determining the threshold for reporting adverse events. Cerner also submits that these standards should be applied across all HIT developers so as to preserve a level playing field in the market.

Conclusion

We hope that you and your staff find this information to be of assistance. Please feel free to contact us if you have any additional questions or concerns, or if Cerner may be of further assistance. Thank you for this opportunity to speak about the many ways in which HIT is transforming and improving the quality of care delivered to the American public. Cerner would also like to express its appreciation for your hard work in seeking out reasonable and cogent standards for all of us to follow as we reboot America's health care system.