

Clinician's Guide to Reporting Health Information Technology Related Patient Safety Concerns

This guide describes best practices for reporting patient safety concerns related to health information technology (Health IT). It includes information on the Electronic Health Records Association's Code of Conduct that sets expectations for electronic health record (EHR) vendor performance. The guide also contains information about how to report patient safety concerns to a federally certified patient safety organization (PSO) or other organization that supports health care quality. PSOs can serve as a venue for discussion of patient safety concerns among clinicians. More information about patient safety organizations is available here: <http://www.pso.ahrq.gov/>.

Reporting to Patient Safety Organizations

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) authorized the creation of PSOs. The Patient Safety Act encourages patient safety reporting by offering protections from legal discovery if the report is submitted to a federally certified PSO.

The federal Agency for Healthcare Research and Quality (AHRQ) has developed definitions and reporting formats that can be used by health care providers to report patient safety events. Reporting is not limited to patient safety-related adverse incidents. Close calls, in which the patient was not harmed, or unsafe conditions that increase the probability of a patient safety event, can be reported to a PSO.

All PSOs work to improve patient safety; however there are differences in their areas of expertise. You should consider the types of analysis and services a PSO offers when selecting a PSO. For example, if you are looking for a PSO that offers services related to EHRs, you should ensure that the PSO you are considering offers such services. AHRQ provides a geographic directory of PSOs on their website, (<http://www.pso.ahrq.gov/listing/geolist.htm>). PSOs can operate nationwide as well as in particular geographic areas.

Reporting to a PSO enables you to share information that might improve patient safety through increased general knowledge. It will not provide an immediate resolution of software issues or enable you to avoid discovery of patient records related to litigation. Only the report to the PSO is protected from legal discovery.

Reporting to Electronic Health Record Vendors

You should familiarize yourself with your EHR vendor's reporting process. Most EHR vendors have specified processes for reporting problems, with some specific steps if patient safety is potentially involved. Some EHR vendors enable electronic reporting of adverse events through their software.

Think about your objectives: do you simply want to report the problem, do you want to validate your understanding of the issue with the EHR vendor or are you seeking a software enhancement? All defects in EHR software should be reported to the EHR vendor through their support system so that the defect can be corrected even if the incident has also been reported to a PSO. Reports to the vendor are not protected under the PSO legislation so only pertinent facts related to the incident and actions that triggered the incident need to be reported. Contributing factors (i.e., lack of training, poor communications) can be excluded from the vendor report and limited to the PSO report.

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You should educate staff about your own reporting procedures, as well as the PSO and Vendor reporting processes. Some organizations will have first or second level internal support while smaller organizations will have an identified contact person to report defects. If you suspect the software to be a contributor to an unsafe condition or patient harm, be certain to indicate this prominently in the report and include enough information so that the vendor can understand the issue. Protected Health Information (HIPAA PHI) should not be included in the initial report as your vendor will want to limit PHI to secured or encrypted communication channels. Most EHR vendors will have a formal patient safety process for those reported issues it validates as potentially contributing to patient harm, and which are reviewed by clinical leadership at the vendor. If confirmed, the vendor should notify you and all affected users, and identify appropriate remediation, mitigation, or fixes. You should understand the vendor process for handling these incidents.

You should also inquire as to whether your vendor is affiliated with a PSO. If they are, it may be in your interest to also report to the same PSO as that ensures that appropriate expert analysis of the health IT component of the incident under the Patient Safety Act protections.

Many EHR vendors support user groups of customers, where you can learn from other users' experiences.

Remember that, unlike reporting to PSOs, reports to EHR vendors and user group discussions are not protected from legal discovery.

If your EHR is Meaningful Use certified by the Office of the National Coordinator for Health Information Technology (ONC), the ONC-authorized testing body which certified the EHR is responsible surveillance of certified EHR technology.

Reporting to Hospitals

Patient safety concerns related to hospital IT systems should be reported according to the hospital's internal policies and procedures. You may also wish to inquire about the hospital's Patient Safety reporting practices and opportunities to participate in this process.

A resource to understand best practices to address electronic health record safety in health care organizations is the Safer Guide series developed by the ONC. The Safer Guides enable an organizational self-assessment through a series of checklists that address foundational requirements, infrastructure and clinical processes. Each guide provides recommended practices, a rationale for the recommended practice, and suggested actions to support the recommended practice.

The ONC Safer Guides (<http://www.healthit.gov/policy-researchers-implementers/safer>) can provide an excellent reference material on patient safety concerns a clinician may have.

Reporting to Other Organizations

If you wish to provide information to third parties to enable comparison of your EHR to another product, or to support research on quality or safety, you should make sure exclude or de-identify any patient data and review the non-disclosure and confidentiality provisions in your EHR vendor contract. There may be restrictions on the release of screen shots and software documentation. This topic should be also part of your legal review prior to engagement of the vendor.

Electronic Health Records Association Code of Conduct

The EHR Association, a trade association of software developers, issued an EHR Developer Code of Conduct in June of 2013. The Code of Conduct addresses topics of patient safety, interoperability and data portability, clinical and billing documentation, privacy and security, and patient engagement. The Code of Conduct is not limited to EHR Association members, so clinicians may ask any EHR vendor whether they have adopted the Code of Conduct. EHR Association members are listed on their website at <http://www.himssehra.org/ASP/members.asp>.

Below are excerpts from the EHR Developer Code of Conduct principles related to patient safety and clinical documentation.

EHR Association Code of Conduct Principles Related to Patient Safety and Clinical Documentation

Patient Safety

- **We are committed to product design, development, and deployment in support of patient safety.** We will utilize such approaches as quality management systems (QMS) and user-centered design methodologies, and use recognized standards and guidelines.
- **We will participate with one or more Patient Safety Organizations (PSOs) (and/or other recognized bodies) in reporting, review, and analyses of health IT-related patient safety events.** The exact nature, extent, and timing of our participation will depend on the outcome of current industry and policy discussions; such factors as legislative, regulatory changes, or agency guidance; the availability of the appropriate recognized organizations; development of standardized definitions for safety events; and other implementation factors. This work will require close collaboration with our customers.
- **We will share best practices with our customers for safe deployment, implementation, maintenance, and use of our products.**
- **We will notify our customers should we identify or become aware of a software issue that could materially affect patient safety, and offer solutions.**
- **We recognize the value of our customers' participation in discussions about patient safety. We will not contractually limit our customers from discussing patient safety issues in appropriate venues.** In applying this policy, we will maintain fair and reasonable intellectual property protections.

Clinical and Billing Documentation

- We will make available to our customers information about our products' approaches to clinical documentation, coding, and quality measurement, examples of which include the coding guidelines referenced, conformity with applicable regulatory and documentation standards, or the source of a quality measure.

Role of Florida Agency for Health Care Administration

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The Agency for Health Care Administration (Agency) promotes the adoption and meaningful use of EHRs through the Medicaid EHR incentive program. The Agency has developed this guide as part of its health IT safety program. The goal of the safety program is to promote the safe and effective use of EHRs and health IT. More information about the Florida Medicaid EHR incentive program is available at: <http://ahca.myflorida.com/medicaid/ehr/>.

Other resources include the following:

EHR Contracts: Key Contract Terms for Users to Understand

http://www.healthit.gov/sites/default/files/ehr_contracting_terms_final_508_compliant.pdf

How to Identify and Address Unsafe Conditions Associated with Health IT

http://www.healthit.gov/sites/default/files/How_to_Identify_and_Address_Unsafe_Conditions_Associated_with_Health_IT.pdf

ONC Patient Safety Action and Surveillance Plan

<http://www.healthit.gov/policy-researchers-implementers/health-it-and-patient-safety>