

PROFESSION

Better patient safety is goal of confidential EHR error reports

■ Federal officials will encourage voluntary reporting to help detect and prevent EHR-related adverse events while limiting physician liability.

By KEVIN B. O'REILLY ([HTTP://WWW.AMEDNEWS.COM/APPS/PBCS.DLL/PERSONALIA?ID=KOREILLY](http://www.amednews.com/apps/pbcs.dll/personalia?id=koreilly)) amednews staff — Posted July 24, 2013

The Dept. of Health and Human Services' Office of the National Coordinator for Health Information Technology in July finalized a plan that aims to improve patient safety by enabling confidential reporting of IT-related adverse events.

“When implemented and used properly, health IT is an important tool in finding and avoiding medical errors and protecting patients,” said Farzad Mostashari, MD, the national coordinator for health IT. “This plan will help us make sure that these new technologies are used to make health care safer.”

The ONC says it will use its leverage as a certifying body for electronic health records technology to ensure that EHRs make it easy to report patient safety events and hazards using the common reporting formats developed by the Agency for Healthcare Research and Quality. The plan calls for physicians, hospitals, vendors and others to report adverse events or so-called near misses involving IT to federally designated Patient Safety Organizations using those common formats. That will allow for aggregation and analysis to better understand common problems, how frequently they occur and how to fix them, ONC officials said. Under federal law, de-identified reports to PSOs cannot be made discoverable for medical liability purposes.

As part of the plan, the Centers for Medicare & Medicaid Services will encourage hospitals to use the standard IT-incident reporting forms and will train its surveyors to spot unsafe practices linked to health IT. Meanwhile, AHRQ will standardize reporting forms designed for use in the ambulatory care setting. When the ONC unveiled an earlier version of its plan for public comment in December 2012, the need for more action on EHRs' effect in physician offices drew comment from the American Medical Association.

“There has been limited research on the impact of EHR use on patient safety in the ambulatory setting,” AMA Executive Vice President and CEO James L. Madara, MD, wrote in a Feb. 1 letter to the ONC ([link](#)). “Physicians are concerned about potential liability from EHR system design and software flaws as well as lack of interoperability among EHR systems that could result in incomplete or missing information, which may lead to errors in patient diagnosis and treatment.”

In the letter, Dr. Madara voiced the AMA's support for use of confidential IT-related, adverse-event reporting to PSOs and addressing patient safety as part of the EHR certification process.

The need to quantify harm

The ONC plan comes in response to a November 2011 Institute of Medicine report that called for an independent federal body to investigate patient deaths and other harm caused by flawed health IT. The report documented cases where EHRs have hurt patients, but said there is not enough evidence to say how often such problems occur ([link](#)). A December 2012 report from the Pennsylvania Patient Safety Authority found that voluntary reports of IT-related safety incidents doubled from 2010 to 2011, but noted that less than 1% actually resulted in patient harm ([link](#)).

In a webinar held to detail the ONC plan, HHS officials said the first step to improvement is gathering more information about the scope of the problem.

“We want to increase the quality and the quantity of data that we have about health IT safety, and from that data, improve the knowledge we have about what’s happening out there in the real world,” said Jacob Reider, MD, the ONC’s chief medical officer.

The ONC also announced that it has signed the Joint Commission to a one-year contract to help communicate IT safety priority areas. Officials at the hospital-accrediting body will scour the commission’s sentinel-event reporting database, along with other sources, for cases of serious patient harm related to EHRs and other IT systems. They will then evaluate and explain the sources of problems in 10 cases, said Margaret VanAmringe, the commission’s vice president for public policy and government relations.

“We want to do a more in-depth, IT-related analysis of 10 events,” she said. “That will help support the root-cause analysis approach we’ve been doing for years. It’s similar to what the [National Transportation Safety Board] does. We roll up our sleeves and look into cases where things went wrong.”

AHRQ is developing a common-reporting format for IT safety incidents in the ambulatory setting. That work probably will not be completed until the end of 2014 or early 2015, said Bill Munier, MD, director of the agency’s Center for Quality Improvement and Patient Safety. The complete ONC plan is available at the agency’s website ([link](#)).

In its 2011 report, the IOM said that if the rate of IT-related safety incidents grows worse over time, the Food and Drug Administration should “exercise all available authority to regulate” EHRs, health information exchanges and personal health records. Such regulation may happen regardless of any progress made in preventing IT-linked adverse events.

That is because the Food and Drug Administration Safety and Innovation Act, signed into law in July 2012, requires HHS to develop a “risk-based regulatory framework for health IT, including medical mobile applications, that promotes innovation, protects patient safety and avoids regulatory duplication.” The deadline for the framework is January 2014, and an advisory panel of physician, technology and medical informatics experts is meeting regularly to develop the plan. More information about this panel — the Health IT Policy Committee — is available at the ONC website ([link](#)).

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ADDITIONAL INFORMATION

Hospitals given guidance on safer health IT

It is not solely EHR vendors’ responsibility to ensure that health information technology systems are deployed safely, said a Dept. of Health and Human Services plan finalized in July. To help prevent EHR-related adverse events, hospitals and other health care organizations should:

- Establish a strong executive and clinical leadership commitment to patient safety as a major priority.
- Engage EHR developers in shared responsibility for the safety and safe use of health IT.
- Address, with EHR developers, shared responsibility for the safety of system interfaces and configuration.
- Select systems that will connect data from clinical and other related health IT as well as support clinical and administrative work flows.
- Create and sustain an approach for managing clinical content and change requests.
- Design mechanisms and metrics to promptly identify, escalate and remediate health IT-related patient safety issues.
- Provide user training and periodically assess user competence.

Source: “Health Information Technology Patient Safety Action & Surveillance Plan,” Office of the National Coordinator for Health Information Technology, July 2 ([link](#))

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