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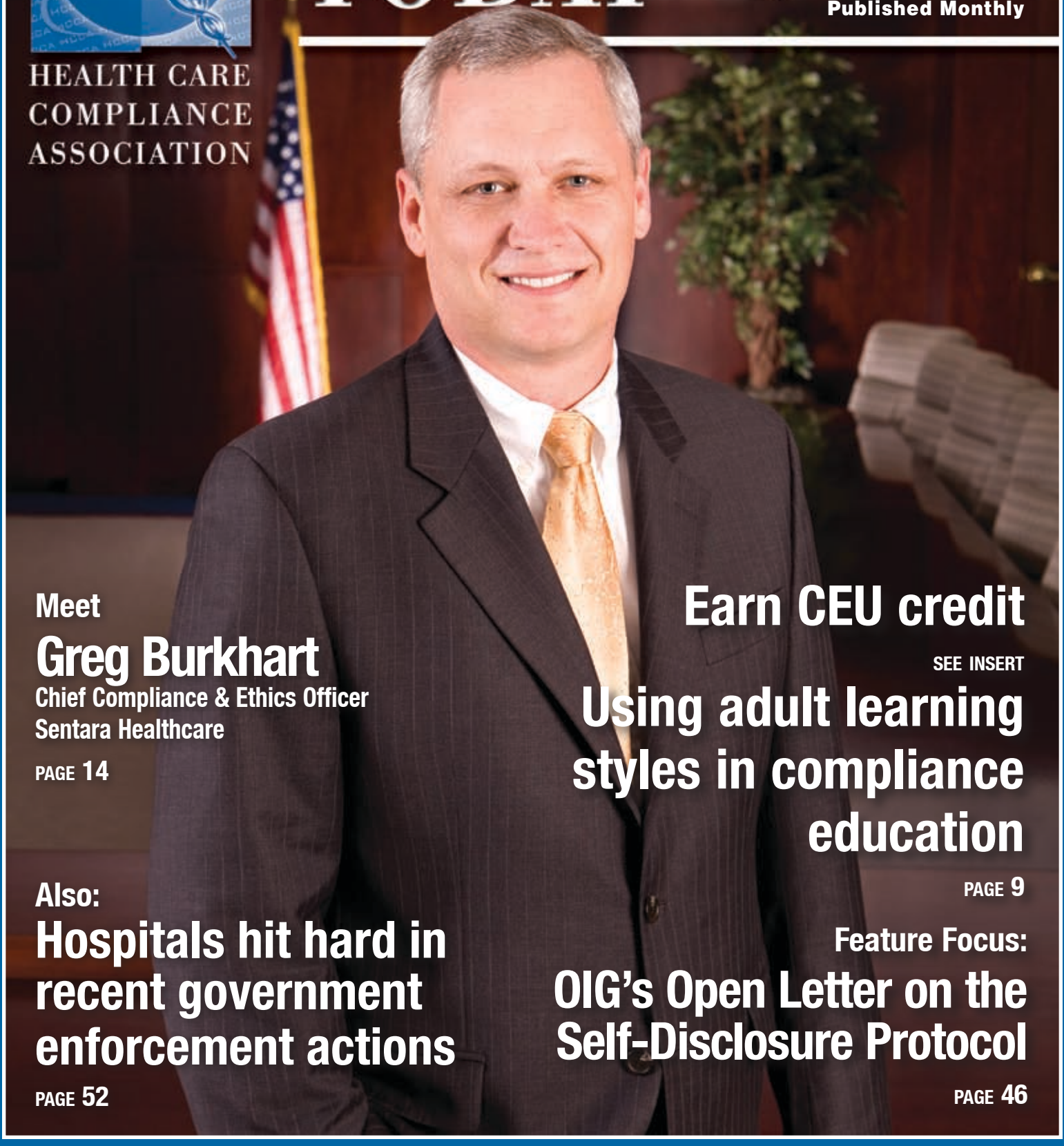

Meet
Greg Burkhart
Chief Compliance & Ethics Officer
Sentara Healthcare
PAGE 14

Earn CEU credit
SEE INSERT

Using adult learning styles in compliance education
PAGE 9

Also:
Hospitals hit hard in recent government enforcement actions
PAGE 52

Feature Focus:
OIG's Open Letter on the Self-Disclosure Protocol
PAGE 46

Patient safety organizations: New protections for quality data

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On February 12, 2008, the Department of Health and Human Services (HHS) Agency for Healthcare Research and Quality (AHRQ) and the Office of Civil Rights (OCR) issued proposed regulations[1] that implement the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act).[2] Read together, the Patient Safety Act and the proposed regulations establish a framework for hospitals, doctors, and other health care providers to voluntarily report information related to patient safety and quality of care. This information, referred to in the Patient Safety Act as "patient safety work product," would be transmitted to newly formed entities called Patient Safety Organizations (PSOs) on a privileged and confidential basis. No federal funding is in place for any part of this new reporting framework.

The Patient Safety Act was, in part, enacted in response to the Institute of Medicine's (IOM) 1999 landmark report "To Err is Human."[3] This report found that at least 44,000 people, and potentially as many as 98,000 people, die in U.S. hospitals each year as a result of preventable medical errors. One of IOM's main conclusions was that the majority of medical errors are not the result of individuals' recklessness. Instead, most errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them. The IOM recommended that, in order to lower the rate of medical errors, the health care system had to make it harder to do something wrong and easier to do something right. Patient safety experts have long argued that improvements to the system can only be developed after reviewing and analyzing the aggregation of significant numbers of individual events in order to identify underlying patterns.

The problem to date, however, is that this kind of large volume of data is not available for analysis. Providers are often reluctant to participate in quality review activities for fear of liability, professional sanctions, or injury to their reputations. Traditional state-based legal protections, typically known as peer review protections, are limited in scope and they do not exist in all states. Furthermore, they typically only apply to hospitals and not to other kinds of health care providers. And most importantly, no system is in place for this kind of data to be shared outside an individual hospital, therefore making it prohibitive for researchers to collect, track, and study patient safety data and develop recommendations for improvement.

The Patient Safety Act and the proposed implementing regulations are an effort to address the barriers to patient safety and health care quality improvement activities. The proposed rules attempt to set forth strong federal confidentiality and privilege protections that will be available in all states and extend to all health care providers. It is yet to be seen if the final regulations will accomplish these goals. Much of the Patient Safety Act's success will depend upon the providers' trust in the federal protections and their willingness to voluntarily self-report their most sensitive and vulnerable information to a third party, a PSO, which is subject to government review and oversight.

Below is a broad overview of the Patient Safety Act and the proposed regulations. The comment period on the proposed rules ended April 14, 2008. AHRQ has publicly stated that the final regulations will be issued "expeditiously."[4]

The Patient Safety Act

Under the Patient Safety Act, PSOs must certify to HHS that they have expertise in patient safety and the ability to provide confidential, expert advice to health care providers in the analysis of patient safety events. A PSO can be a public or private entity, or a component of such an entity.[5] The intent of the statute is that health care providers will report patient safety work product on a confidential and privileged basis to a PSO, which in return will eventually report the information to a central database developed by the federal government. This will allow the aggregation of large volumes of data to be analyzed and studied for purposes of developing improvements in health care safety and quality.

Basic statutory requirements for PSOs

An entity that wants to become a PSO must submit an "initial certification" to the HHS Secretary stating that the entity has policies

Continued on page 22

 ...continued from page 21

and procedures in place to perform each of the patient safety activities described in the statute. The criteria are as follows:

- The mission and primary activity of the entity are to conduct activities that are to improve patient safety and the quality of health care delivery.
- The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals.
- The entity, within each 24-month period that begins after the date of the initial listing . . . has bona fide contracts, each for a reasonable period of time, with more than one provider[6] for the purpose of receiving and reviewing patient safety work product. ("Provider" means individuals or entities licensed or authorized under state law to provide health care services, including hospitals, nursing facilities, physician offices, physicians, social workers, pharmacists, etc.)
- The entity is not, and is not a component of, a health insurance issuer.
- The entity shall fully disclose:
  - any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity;
  - if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity;
  - to the extent practical and appropriate, that the entity collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers; and
  - that it utilizes patient safety work product for the purpose of providing direct feedback to providers.[7]

Components of other organizations

Under the statute, if the entity seeking to be a PSO is a component of another organization, then the PSO must, in addition to the above criteria, maintain patient safety work product separately from the rest of the organization, and must have appropriate data security measures in place to protect the confidentiality of the information. The PSO may not disclose patient safety work product to the rest of the organization.

Benefits of PSO status

Patient safety work product is provided privilege and confidentiality protections when reported to a PSO. Patient safety work product is defined as any data, reports, records memoranda, analyses (such as root cause analyses) or written or oral statements which are assembled or developed for and are reported to a PSO.[8] Patient safety work product also includes information developed by a PSO for the conduct of "patient safety activities" and which could result in improved patient safety, health care quality, or health care outcomes.[9] Patient safety activities include:

- Efforts to improve patient safety and the quality of health care delivery.
- Collection and analysis of patient safety work product.
- Development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.
- Using patient safety work product to encourage a culture of safety and providing feedback and assistance to effectively minimize patient risk.
- Maintaining procedures to preserve confidentiality with respect to patient safety work product.
- Providing appropriate security measures with respect to patient safety work product.
- Using qualified staff.
- Activities related to the operation of a patient safety evaluation system and providing feedback to participants in a patient safety evaluation system.[10]

Patient safety work product also includes information which identifies or constitutes the deliberations or analysis of, or identifies the fact of reporting pursuant to, a PSO's or a provider's "patient safety evaluation system."[11] The law will not, however, prevent access to all data related to adverse events. Patient safety work product does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.[12] Also, if data is collected or exists separately from a patient safety evaluation system, it will not be considered patient safety work product.[13] Therefore, forms used to report adverse incidents to state regulatory agencies will not be protected.

There are exceptions, however, to the privilege and confidentiality protections. For example, patient safety work product may be disclosed for use in a criminal proceeding, with certain restrictions.[14] It may also be disclosed if authorized by each provider identified in the work product.[15]

Proposed regulations

The proposed rules would add a new Part 3 to Title 42 of the Code of Federal Regulations. The proposed rules address (1) the establishment and operations of PSOs; and (2) privilege and confidentiality protections for patient safety work product and enforcement of the confidentiality provisions. AHRQ will handle PSO certification, and OCR will enforce information protections. Under the proposed rules, HHS may impose a civil money penalty of up to $10,000 for confidentiality breaches.[16]

The Secretary of HHS may request informa-

tion or conduct announced or unannounced reviews or site visits to PSOs to assess compliance.[17] The Secretary will be allowed to inspect and/or be given or sent copies of any PSO records the Secretary deems necessary, including patient safety work product.[18]

Confidentiality and Security

With certain exceptions, patient safety work product is privileged and confidential.[19] In many cases, the protection continues even when patient safety work product is disclosed.[20] The proposed rules specify that it will not be subject to discovery or to a federal, state, or local subpoena, whether in civil or criminal court, or in an administrative disciplinary proceeding against a provider.[21] Patient safety work product, under the proposed rules, would also not be admissible in such proceedings, nor could it be admitted in a professional disciplinary proceeding.[22] The proposed rules contain certain limited exceptions. For example, non-identifiable patient safety work product may be disclosed.[23] The information may also be disclosed under certain circumstances in criminal proceedings when it contains evidence of a criminal act.[24] And it may be disclosed if all providers identified in the work product authorize the disclosure.[25]

PSOs can share patient safety work product with other PSOs, and providers may also share this information with other providers, if the direct identifiers of any providers and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, workforce or household members are removed. The direct identifiers include:

- Names
- Postal address information, other than town or city, state, and zip code
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers or taxpayer identification numbers
- Provider or practitioner credentialing or DEA numbers
- National provider identification number
- Certificate/license numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers
- Full face photographic images, and
- Removal of all direct identifiers listed in the HIPAA privacy rules.[26]

The proposed rules contain detailed security requirements for patient safety work product. Unlike the provisions governing both internal use and external disclosure of protected health information (PHI) found in the HIPAA privacy rules, the proposed rules would not regulate the use of patient safety work product within a PSO. But a PSO's security framework is required to contain four elements:

- security management
- separation of systems
- security monitoring and control, and
- system assessment.[27]

Remaining open questions

Comments on the proposed rules were due April 14, 2008. The AHRQ apparently understood that there were additional details that needed to be worked out when they issued the proposed rule, because on their Web site they listed 47 questions[28] for which they sought public comment. Although the scope of the privilege and confidentiality protections that the government grants to patient safety work product is yet to be seen, it will be even more interesting to see if these protections alone motivate providers to incur the cost of complying with the rules and to initiate voluntary disclosures of sensitive data. The regulations arguably will provide some level of legal protections to such sensitive information, which will be the reason some providers will participate. Ideally, providers will also participate for more altruistic purposes such as becoming part of a process that may improve patient care and reduce medical errors. ■

1 73 Fed. Reg. 8113 (February 12, 2008).
2 Pub. L. 109-41, amending the Public Health Services Act (42 U.S.C. 299 et seq.) by inserting new sections 921 through 926, 42 U.S.C. 299b-21 through 299b-26.
3 Institute of Medicine, "To Err is Human: Building a Safer Health System", 1999. Available online at http://www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf. Accessed May 1, 2008.
4 Dr. Carolyn Clancy, Director of AHRQ, in a teleconference February 29, 2008. See also http://www.ahrq.gov/news/press/pr2008/psopr.htm.
5 42 U.S.C. §299b-21(4).
6 See 42 U.S.C. §299b-21(8).
7 42 U.S.C. §299b-24(b)(1).
8 42 U.S.C. §299b-21(7)(A).
9 Id.
10 Id. at (5); see also id. at (6) (defining a "patient safety evaluation system" as "the collection, management, or analysis of information for reporting to or by a patient safety organization").
11 Id. at (7)(A).
12 Id. at (7)(B).
13 Id.
14 42 U.S.C. §299b-22(c)(1)(A).
15 Id. at (c)(1)(C).
16 See Proposed Rule 42 C.F.R. §3.404.
17 See Proposed Rule 42 C.F.R. §3.110.
18 Id.
19 See Proposed Rule 42 C.F.R. §3.206.
20 See Proposed Rule 42 C.F.R. §3.208.
21 See Proposed Rule 42 C.F.R. §3.204.
22 Id.
23 Id.
24 See Proposed Rule 42 C.F.R. §3.206.
25 Id.
26 See Proposed Rule 42 C.F.R. §3.206.
27 See Proposed Rule 42 C.F.R. §3.106.
28 Available at www.pso.ahrq.gov/rulemaking/nprm.htm (Accessed April 8, 2008).