Healthcare Risk Management™

June 2011: Vol. 33, No. 6
Pages 61-72

IN THIS ISSUE

Financial Disclosure: Author **Greg Freeman**, Executive Editor **Joy Daughtery Dickinson**, and Nurse Planner **Maureen Archambault** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Grena Porto**, contributing author, and **Radha V.Bachman**, guest columnist, have no relationships to disclose..

AHC Media

ACO rule provides detail but creates regulatory burden for providers

Concern about funding schemes running afoul of fraud, tax laws

The much anticipated proposed rule on accountable care organizations (ACOs) has healthcare providers studying their markets and trying to determine whether this brave new world of managed care will benefit them or just pose more risks than they are willing to take. For risk managers in particular, there are serious concerns about how ACO participation might set up the provider for charges of fraud and abuse.

On March 31, 2011, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule to implement Section 3022 of the Patient Protection and Affordable Care Act (ACA), which requires the secretary of the Department of Health and Human Services (HHS) to establish a Medicare Shared Savings Program (SSP). Under the proposed rule, eligible providers, hospitals, and suppliers that participate in the SSP by creating or joining ACOs can continue to receive traditional Medicare fee-for-service payments under Medicare Parts A and B and be eligible for additional payments based upon specified quality and savings requirements.

On the same day, CMS and the Office of Inspector General (OIG) jointly issued a proposed rule describing the waiver of application of various fraud and abuse laws with respect to ACOs. Also the Federal Trade Commission (FTC) and the Department of Justice (DOJ) jointly issued a proposed policy concerning the application of antitrust laws to ACOs; and the Internal Revenue Service (IRS) issued a notice concerning tax-exempt entity participation in the SSP.

The release of the ACO rules should command the attention of risk managers, says **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, LHRM, a patient safety and risk management consultant with The Kicklighter Group in Tamarac, FL, and a past president of the American Society

Solutions for patient ID errors coming next month

Watch for the July issue of *Healthcare Risk Management* in which we will address one of the simplest but most dangerous errors that can threaten patient safety: misidentifying specimens. There are new ideas for this old problem, and we will show you how to implement solutions in your own facilities. Don't miss this special focus in Healthcare Risk Management!

for Healthcare Risk Management (ASHRM) in Chicago. Whether the ACO concept brings the promised benefits or not, the change in relationships among the hospital, physician, and other players will open up many risk and compliance concerns, she says. "As risk managers we need to learn all we can about ACOs and watch the new regulations closely so we can be ahead of, or at least at the beginning of, the learning curve," Kicklighter says. "We have to be positioned so that we can assist management in our organizations to address any risk issues that may arise as the ACOs are more broadly implemented and activated."

The nearly 500 pages of proposed rules make it clear that CMS is committed to the ACO concept, despite the mixed record of outcomes from pilot programs around the country, says **Anil Kottoor**, president of MedHOK Healthcare Policy Practice, a healthcare consulting firm in Tampa, FL. "CMS and HHS have painted a very solid picture of what they want to see in what we consider one of the most far-reaching Medicare reorganizations since managed care was introduced. Agency leadership seems to see ACOs as an alternative to full-fledged managed care, one that can take a huge bite out of existing Medicare costs and future trend if done right," Kottoor says. "CMS also makes it clear that not every organization that fancies itself an ACO will be accepted, a retreat from previous pilot initiatives that almost seemed doomed to failure before they were even launched."

On the equally important tenets of cost-effectiveness and quality, Kottoor says CMS makes clear that enrollment will be through a passive system. Medicare beneficiaries attached to primary care physicians in an ACO will be deemed enrolled after the physician notifies the beneficiary that he/she is a participant and that clinical and other information will be used to help improve care and save dollars. A retrospective look at all beneficiaries' use of services and costs will be taken to arrive at a benchmark and determine whether an ACO has saved Medicare money. "One problem area we immediately see is that a beneficiary can opt out of participation entirely, but also could opt out of just data sharing," Kottoor says. "Since data sharing will be crucial to monitoring costs and quality, we don't see how a partial opt-out makes sense."

Must take downside risk

The new rule proposes two shared-savings mod-

EXECUTIVE SUMMARY:

The proposed rule on accountable care organizations (ACOs) included some surprises and cause for concern. Providers might be at risk of fraud and abuse charges, as well as tax law violations, if the ACO is not carefully structured.

- Providers need to act now to start considering whether to participate in an ACO.
- The funding and governance provisions of the rule pose the most compliance risks.
- A special waiver addresses some compliance concerns about savings distribution.

Healthcare Risk Management® (ISSN 1081-6534), including HRM Legal Review & Commentary™, is published monthly by AHC Media, a division of Thompson Media Group LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304.

POSTMASTER: Send address changes to Healthcare Risk Management®, P.O. Box 105109, Atlanta, GA 30348.

SUBSCRIBER INFORMATION

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $499. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. For approximately 15 CE nursing contact hours, $545. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. Back issues, when available, are $87 each. (GST registration number R128870672.)

AHC Media is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity has been approved for 15 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider #14749, for 15 Contact Hours.

This activity is valid 24 months from the date of publication.

Healthcare Risk Management® is intended for risk managers, health system administrators, and health care legal counsel.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Editor: **Greg Freeman**, (770) 998-8455.
Executive Editor: **Joy Daughtery Dickinson** (229) 551-9195 (joy.dickinson@ahcmedia.com).
Production Editor: **Kristen Ramsey**.

Editorial Questions
For questions or comments, call Greg Freeman, (770) 998-8455.

els, in part to broaden the universe, but also to show CMS means business, Kottoor says.

In the first, an ACO can elect to take on a smaller share of upside savings but assume no risk until its third year. In the second model, an organization willing to take on upside gains and downside risk can qualify for a higher proportion of shared savings from the start. Medicare will continue to pay individual providers and hospitals as it does under fee-for-service (FFS).

"Given the poor outcomes in the FFS system, CMS is taking a very aggressive approach on quality. Even if an ACO achieves cost savings, over time no payment will be made unless quality metrics are met," Kottoor says.

The rules establish quality performance measures and a methodology for linking quality and financial performance, Kottoor notes. They also require the ACO to have in place procedures and processes to promote evidence-based medicine and beneficiary engagement. "The quality measures outlined are among the most rigorous we have seen, and may end up being judged as more expansive than even the Medicare Advantage Star rating system," Kottoor says.

The quality measures touch upon four main areas: outcomes from the Healthcare Effectiveness Data and Information Set (HEDIS), Consumer Assessment of Healthcare Providers and Systems (CAHPS) satisfaction, clinical/disease management infrastructure, and hospital-based quality interventions and after care. "In this last area, the ACO is held responsible for poor hospital outcomes, so ACOs, physicians, and hospitals will have to work together to monitor hospital stays and aftercare," Kottoor says. "Interestingly, some of these hospital-type measures tie to the other FFS reforms in PPACA that force hospitals to ensure better clinical monitoring and outcomes lest they lose revenue in numerous areas."

There were a few surprises in the rule, says **Robert D. Belfort**, JD, a partner with the law firm of Manatt in New York City, including the requirement that providers move to a two-sided risk model by the third year. CMS appears to have decided that incorporating a downside risk within the first period was important to changing provider behavior, Belfort says.

"That requires that every organization considering an ACO be prepared to take some downside risk and have the reserves and solvency necessary to sustain potential losses," he says.

Belfort also notes that the rule requires primary care physicians to be exclusive to one ACO. He expects that requirement will be a major driver for quick action by providers. Although some providers will want to wait until the ACO program is further along before jumping in, there is now the risk that waiting will mean there are not enough primary care providers who have not yet committed. "Most providers I've talked to are not jumping for joy with this rule. There are a lot of burdensome requirements, and the quality reporting is very demanding," Belfort says. "There are very demanding rules about governance and representation of all participants, and concern about how to give governance rights to physicians without running afoul of the tax exemption and fraud and abuse laws."

The biggest challenge regarding compliance issues in ACOs involves the funding and investment side, Belfort says. The recently announced waiver covers the shared savings distribution to participating providers, but Belfort says there is no similar waiver for investments made to capitalize the ACO. "The challenge comes when the doctors and the hospital want to go in on this joint venture, but the doctors don't have the capital to match what the hospital can do," Belfort says. "The venture has to be structured in such a way that the government can't come in and say the hospital is essentially subsidizing the doctors in violation of the fraud and abuse laws or the tax exemption laws."

Think now about benefits, risks

Belfort advises providers to waste no time in considering the potential pros and cons of an ACO arrangement, particularly because delaying will create problems with finding primary care providers in some markets.

"There is a need for some strategic planning and financial analysis, which I sense a lot of organizations are not doing right now," he says.

The retroactive attribution and assignment of beneficiaries surprised **C. Frederick Geilfuss II**, JD, a partner with the law firm of Foley & Lardner in Milwaukee. That change makes it more difficult to maximize care management and the use of protocols, because the patient is free to receive services and get second opinions from non-ACO participants, Geilfuss says. He also was concerned by some of the regulatory risks posed by the rule.

"There are new risks that will arise. There are a variety of provisions where officers of the ACO will have to certify on their performance, and they have to make a request for payment as

well," Geilfuss says. "My read would be that the False Claims Act and other compliance provisions would relate to those certifications. You have to be truthful, but mistakes can be made so there would be compliance risks related to all of those certifications."

SOURCES

For more information, contact:

• **Robert D. Belfort**, JD, Partner, Manatt, New York City. Telephone: (212) 830-7270. E-mail: Rbelfort@manatt.com.
• **C. Frederick Geilfuss II**, JD, Partner, Foley & Lardner, Milwaukee. Telephone: (414) 297-5650. E-mail: Fgeilfuss@foley.com.
• **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, LHRM, The Kicklighter Group, Tamarac, FL. Telephone: (954) 294-8821. E-mail: lkicklighter@kickrisk.net.
• **Anil Kottoor**, President, MedHOK Healthcare Policy Practice, Tampa, FL. Telephone: (888) 963-3465. E-mail: akottoor@medhok.com. ■

Proposed rule specifies ACO quality standards

The proposed rule for accountable care organizations (ACOs) from the Department of Health and Human Services (HHS) specifies how teams of doctors, hospitals, and other healthcare providers and suppliers will work together to coordinate and improve care for patients.

The rule specifies that to share in savings, ACOs must meet quality standards in five key areas:

- patient/caregiver care experiences;
- care coordination;
- patient safety;
- preventive health;
- at-risk population/frail elderly health.

The proposed rule also includes strong protections to ensure patients don't have their care choices limited by an ACO.

If ACOs save money by getting beneficiaries the right care at the right time — for example, by improving access to primary care so that patients can avoid a trip to the emergency department — the ACO can share in those savings with Medicare. ACOs that don't meet quality standards cannot share in program savings, and over time, those who don't generate savings can be held accountable.

The new program will be established on Jan. 1, 2012. Before the rule is finalized, CMS will review all comments from the public and might make changes to its proposals based on those comments.

HHS Secretary Kathleen Sebelius also announced that the agency will hold a series of open-door forums and listening sessions during the comment period to help the public understand what the Centers for Medicare & Medicaid Services (CMS), the agency administering the ACO program, is proposing to do and to ensure that the public understands how to participate in the formal comment process.

By focusing on the needs of patients and linking payment rewards to outcomes, this delivery system reform will help improve the health of individuals and communities while saving as much as $960 million over three years for the Medicare program, Sebelius said in a press conference.

CMS has worked closely with other federal agencies, including the Department of Health and Human Services Office of Inspector General (OIG), the Department of Justice (DOJ), the Federal Trade Commission (FTC), and Internal Revenue Service (IRS) to ensure that providers and suppliers have the clear and practical guidance they need to form ACOs without running afoul of the fraud and abuse, antitrust, and tax laws, Sebelius said. Concurrently with the publication of the proposed rule, the following documents have been issued: a joint CMS and OIG notice and solicitation of public comments on potential waivers of certain fraud and abuse laws in connection with the Medicare Shared Savings Program; a joint FTC and DOJ proposed antitrust policy statement; and an IRS notice requesting comments regarding the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals, participating in the Medicare Shared Savings Program. The proposed rule and joint CMS/OIG notice are posted at http://www.regulations.gov/#!documentDetail;D=CMS-2010-0259-0425. A fact sheet is available at www.HealthCare.gov/news/factsheets/accountablecare03312011a.html. The Proposed Antitrust Policy Statement is posted at www.ftc.gov/opp/aco. The IRS Guidance and Solicitation of Comments are posted at http://www.irs.gov/pub/irs-drop/n-11-20.pdf. ■

OB program aims to cut claims, improve safety

The nation's largest Catholic and nonprofit healthcare system is launching a demonstration project to determine best methods to reduce or eliminate birth complications and at the same

seeking to avoid obstetrics claims through a renewed emphasis on transparency and full disclosure.

Ascension Health, based in St. Louis, MO, has begun the Excellence in Obstetrics program within the obstetrical care units at five Ascension Health facilities. The project is made possible through a $2.9 million grant that Ascension Health received from the Agency for Healthcare Research and Quality (AHRQ) under its Patient Safety and Medical Liability initiative.

The AHRQ initiative seeks to foster better doctor-patient communication, and ensure patients are fairly and quickly compensated in a fair and timely manner for medical injuries, thus reducing the incidence of lawsuits and liability premiums. The initiative also seeks to reduce the incidence of frivolous lawsuits and liability premiums. *(See the story on p. 66 for more about the key concepts of the AHRQ initiative.)*

The Excellence in Obstetrics project is designed to determine whether and how birth complications can be reduced or eliminated altogether, says **Christine K. McKoy**, JD, vice president of risk management at Ascension Health. It also will evaluate medical liability models that put patient safety first and foster better communication between doctors and their patients. The project initially will focus on improving patient safety and outcomes related to obstetrical deliveries, with the long-term goal of spreading concepts and key lessons to other high-risk areas, including emergency departments and operating rooms, McKoy says. The goal is to evaluate 40,000 obstetrics patients representing uniquely diverse geographies and ethnicities.

The model being studied is based on a pilot program of team training, situation analysis, and simulation exercises that have been developed as part of a bundle with measurable outcomes, says **Ann Hendrich**, RN, PhD (c), FAAN, vice president of clinical excellence operations for Ascension Health. One example is a new method for responding as a clinical team to changes in electronic fetal monitoring, and evaluation of how cases of shoulder dystocia are handled.

"We believe the Excellence in Obstetrics demonstration project will help save the lives of mothers and their babies by improving safety in the birthing process," Hendrich says.

The project also will evaluate a medical liability response model based on full disclosure, transparency, and early resolution, McKoy says. The model also calls for an immediate root cause analysis when unpredictable events happen. "We want to see, when we do a uniform approach to communicating with patients, if that has an impact on their response," McKoy says. "Do they still file a claim or suit? Or when the incident is without error, can we explain to the family what happened and potentially reduce any frivolous suits?"

The five Ascension Health Ministries that will participate in the study are: Sacred Heart Hospital on the Emerald Coast (Miramar Beach, FL), St. Vincent's Birmingham (Birmingham, AL.), St. John Hospital and Medical Center (Detroit), Columbia St. Mary's (Milwaukee), and Saint Agnes Hospital (Baltimore). The sites were chosen in part because they treat patients from a wide variety of social and economic backgrounds. The patient education materials are available in 11 languages, including Arabic, Farsi, Vietnamese, Burmese, and Hmong. "The business case for patient safety has not been adequately established in health care," Hendrich says. "We anticipate that the Excellence in Obstetrics project will offer successful models of practice, and we intend to translate the anticipated success of this program to other hospitals and clinical practice areas across Ascension Health and, ultimately, to other healthcare facilities across the U.S."

The program began in January 2011. While it is too early for any results to be available, the initial response from physicians, nurses, and patients has been extremely positive, McKoy says. More than 1,000 health care professionals have been trained in electronic fetal monitoring, simulation, managing shoulder dystocia, disclosure, and cause analysis. The sites also have begun consenting patients, and more than 80% of those approached have agreed to participate in the study.

At each participating facility, the lead obstetrician acts as the principal investigator, supported by the lead nurse, risk manager, and a project manager. The sites provide education and training to all clinicians working with the OB unit, going beyond the standard competency training, McKoy says. For example, electronic fetal monitoring is a seven-module course for physicians and nurses, offered online. The shoulder dystocia training is provided in the same way, and the participants also are trained in crisis response and teamwork using simulations. Ascension Health provided all of the sites with a high-tech mannequin and new video equipment for the training.

All of the clinicians go through a three-hour course on communication and disclosure, and some leaders take additional training, McKoy says.

EXECUTIVE SUMMARY:

A patient safety program at Ascension Health is focused on improving obstetrical (OB) outcomes. The program includes a component specifically intended to reduce malpractice claims and liability.

- The program will be carried out at five hospitals.
- Improving communications among caregivers will be a top priority.
- Lessons learned from the OB effort will be used in other specialties.

(See story below for more about a special team that responds after adverse events.)

Ascension Health expects to see significant patient safety improvements from the Excellence in Obstetrics program, but there are no specific thresholds for success.

"If we implement a comprehensive approach to reporting, investigating, and communicating events, we will see a reduction in frequency and severity. The question is how much and how soon," McKoy says. "Obstetrical claims have a longer lag time than most claims typically do, and they're fairly rare events, even though they can be quite large claims. We're looking at our past data to benchmark our past experience, and we hypothesize that we will see significant results in the coming years."

SOURCES

For more information, contact:

Ann Hendrich, RN, FAAN, Vice President of Clinical Excellence Operations, Ascension Health, St. Louis, MO. Telephone: (314) 733-8207. E-mail: Ann.hendrich@ascensionhealth.org.

Christine K. McKoy, JD, vice president of risk management, Ascension Health, St. Louis, MO. Telephone: (314) 733-8702. E-mail: Christine.mckoy@ascensionhealth.org. ■

Team investigates OB adverse events

The medical liability response model being implemented in the OB units of five Ascension Health hospitals model emphasizes the need for clinicians to report all events that could result in a lawsuit.

Encouraging clinicians to report the event is crucial to providing a quick and effective response from a specially trained team, says **Christine K. McKoy**, JD, the system's vice president of risk management.

"We like to think that nurses and physicians will report these incidents to risk management every time, but we know that doesn't always happen," McKoy says. "Our caregivers know that there are certain triggering events that we absolutely want to know about. They don't mean that any error was involved necessarily, but they are unanticipated outcomes that we need to immediately look at and respond to them. The patient is going to want to know what happened, and it is our obligation to inform them."

When risk management learns of a triggering event such as shoulder dystocia resulting in a brachial plexus injury or APGAR scores below 3 at 5 minutes, the "OBERT" team responds. OBERT stands for Obstetrical Event Response Team, headed by the lead physician and including the lead nurse and representatives from risk management and quality. Others, such as a pediatrician or chaplain, might be included in some situations.

"We're training them in root cause analysis and improving the way they investigate events after they occur," McKoy says. "They learn to be situation managers. They can help coach and prepare their clinicians when they need to communicate with families after an adverse event."

The OBERT team begins the investigation immediately and starts planning for communicating with the family. Ascension Health uses the term "coordinated communication" to describe its approach. "We're trying to get away from the word 'disclosure,'" McKoy says. "When we started training physicians on a more standardized approach to communication, we found that 'disclosure' has a negative connotation to it. They're fearful of it. It sounds to them like they're admitting guilt or taking the blame for what happened, and that's not always the case." ■

Key to OB safety effort: high-reliability concepts

Ascension Health, the nonprofit health system based in St. Louis, MO, already had made progress in reducing injuries to newborns and the associated management of risk exposures before launching the Excellence in Obstetrics program, says **Christine K. McKoy**, JD, the system's vice president of risk management.

The improvements were made through proactive strategies including more open commu-

nication with patients and families, she says. Nonetheless, Ascension leaders realized that an opportunity existed to learn more about ways to reduce injury and death for newborns and to share the knowledge of successful models with other healthcare providers, McKoy says. That led Ascension Health to choose obstetrics as the focus of its initial demonstration project in linking patient safety to medical malpractice reform using what the Agency for Healthcare Research and Quality (AHRQ) calls "high-reliability concepts." According to AHRQ, high-reliability organizations (HROs) are characterized by five defining elements of high-reliability:

- **A preoccupation with failure** — tracking small failures and near misses with a focus on predicting and eliminating catastrophes;
- **A reluctance to simplify** — an awareness that in a complex environment, a simplistic solution may not acknowledge the full range of opportunity for error or look deeply enough into the complex interactions and processes;
- **Sensitivity to operations** — recognizing that in an environment of frequent change, situational awareness is critical to recognize and address anomalies and potential errors;
- **Resilience** — the capability to quickly contain errors. It requires effective teamwork to adapt and respond quickly when setbacks occur;
- **Deference to expertise** — de-emphasizing hierarchy to get to the person most knowledgeable of the issue.

McKoy explains that because patient safety and medical liability are inextricably linked, Ascension Health's project is based on the concept that instituting the culture and procedures inherent in an HRO not only will improve patient safety, but also will reduce medical liability. ■

Lawsuit shows new risk from competitors

A lawsuit involving two rival health systems, with one alleging that the other overcharged Medicare by at least $280 million, might portend more such situations in which a competitor throws a healthcare provider to the auditor wolves.

Tenet Healthcare Corp. in Dallas recently accused Community Health Systems (CHS) in Franklin, TN, of overcharging Medicare at least $280 million in a lawsuit intended to block the unsolicited bid from CHS. After the lawsuit was filed, CHS announced that it had withdrawn its offer to acquire all of the outstanding shares of common stock of Tenet and also had withdrawn its nominees for election to Tenet's Board of Directors.

Tenet had rejected an unsolicited bid from CHS in December 2010. When CHS persisted in attempts to take over the company, Tenet filed the lawsuit in U.S. District Court in Dallas accusing the company of using "liberal" criteria to decide whether to admit a patient or treat the person less expensively on an outpatient basis. CHS could be "subject to liability and damages of well over $1 billion" for improper Medicare admission practices from 2006 and 2009, Tenet alleged in the suit. Soon after the lawsuit was filed, CHS shares dropped 36%, raising questions about the company's ability to raise the cash for its proposed $7.3 billion takeover of Tenet.

The Tenet lawsuit says CHS' rate of keeping patients on an observational basis was less than one-half of Tenet's rate of 12.06% or of the national average of 12.60%. Data developed by consultants hired by Tenet showed CHS' outpatient rate was 5.11%, according to the lawsuit.

"We filed this complaint because our due diligence revealed that Community Health has been systematically overbilling Medicare and likely other payers by causing patients to be admitted to its hospitals when industry practice is to treat them in outpatient observation status," Tenet said in a statement provided to *Healthcare Risk Management*. "We believe this unsustainable strategy has resulted in Community Health overstating its inpatient admissions, revenues and profits and has created substantial financial and legal liability. We are seeking to provide Tenet stockholders with the information they need to make an informed decision by asking the court to compel Community

EXECUTIVE SUMMARY

An unusual lawsuit against a health system is drawing attention to a new area of risk for providers: charges of fraud from a competitor. The lawsuit was brought by Tenet Healthcare Corp. against Community Health Systems.

- The lawsuit was filed in an attempt to thwart a takeover bid.
- Tenet alleges that the other health system overcharged Medicare.
- Legal experts say more of this type of lawsuit might be coming.

Health to correct its false and misleading statements and omissions."

Suit can lead to federal scrutiny

Tenet seeks to compel CHS to disclose how it admits patients to hospitals for "financial rather than clinical purposes," according to the lawsuit. By exposing the supposed compliance issue, Tenet seeks to tell its shareholders that CHS is not as profitable as it claims to be, thereby discouraging them from approving the takeover, explains **Douglas B. Swill**, JD, a partner with the law firm of Drinker Biddle in Chicago and chair of the firm's Health Law Practice Group.

Regardless of how the takeover bid turns out, the charges might open CHS, the second-largest publicly traded U.S. hospital operator, to federal scrutiny, Swill says.

"This is quite remarkable because we already see a lot of enforcement and compliance activity at the federal level, and with whistleblowers, and this a new development where you have a party to a transaction that has access to the other party's data through due diligence," Swill says. "Tenet was using information about the status of CHS' patients and concluded that it was maximizing reimbursement by taking what should be observation patients and converting them to admissions. That has the effect of increasing reimbursement by about $7,000 per patient with Medicare alone."

CHS released a statement calling Tenet's allegations "baseless." The company also stated that investment bankers had reaffirmed their confidence in financing the transaction. "Its actions today prove that Tenet has adopted a 'scorched earth' defense without regard for the best interests of shareholders," the company statement said. "These self-serving allegations are an attempt by Tenet's management and board to continue their entrenchment strategy and to distract Tenet shareholders from CHS' pending offer."

Unheard of in healthcare industry

The lawsuit also claims that one year after CHS acquired another hospital system in 2007, that system had a 52% drop in its observation rate. Swill says that change, if accurate, is "stunning."

Such lawsuits, challenging a corporation that is attempting a takeover, are not uncommon in other industries but are unheard of in healthcare, says **Sheryl R. Skolnick**, PhD, senior vice president of CRT Capital Group in Stamford, CT. Skolnick is an analyst for Wall Street and has studied Tenet for the past 20 years. In addition, she says, the fraud component of this lawsuit is unusual for any industry. "We see suits involving company secrets and unfair competition, but we rarely see lawsuits in which the request disclosure is essentially, 'Why don't you fess up that you've been committing fraud?'" Skolnick says. "It's not a step that I think Tenet would have taken lightly."

The Tenet lawsuit might have far reaching implications for all healthcare providers, Swill says. It might signal that corporate leaders are more willing to play hard ball when it comes to unwanted bids, even if that means alerting regulators and auditors to the questionable practices of a competitor. "This case puts what otherwise might be a whistleblower-type lawsuit, or a government investigation, into a new arena of risk arising from a corporate transaction," he says. "We're seeing lots of corporate transactions now, and they have to include disclosures to comply with the Securities and Exchange Commission rules. That means competitors have access to data that may lead them to make charges like this to either discourage the takeover or to obtain further information."

[For more information about the lawsuit, see the April 15, 2011, issue of Healthcare Risk Management Alert. *To sign up for this free weekly ezine, contact customer service at (800) 688-2421 or customerservice@achmedia.com.]*

SOURCES

- **Sheryl R. Skolnick**, PhD, Senior Vice President, CRT Capital Group, Stamford, CT. Telephone: (203) 569-4359. E-mail: Skolnick@crtllc.com.
- **Douglas B. Swill**, JD, Partner, Drinker Biddle, Chicago. Telephone: (312) 569-1270. E-mail: Douglas.swill@dbr.com. ■

Corporate suits make RMs more valuable

The potential for more corporate lawsuits such as the one involving Tenet Healthcare Corp. and Community Health Systems should highlight the value of the risk manager (RM) in any healthcare organization, says **Sheryl R. Skolnick**, PhD, senior vice president of CRT Capital Group in Stamford, CT, who has studied Tenet for Wall Street.

This kind of case shows important the job of a risk manager is to the organization," she says.

"For hospital management, the lesson is that if your risk manager says you shouldn't be doing something the way you're doing it, somebody should sit up and listen. Because somebody, someplace out there is going to be watching you, and it's not going to be just the very busy Office of Inspector General or the very busy fiscal intermediary."

The Tenet lawsuit has broken the ice on such provider-to-provider challenges, Skolnick says. What was previously unheard of in the healthcare arena might become more common now because Tenet has removed the taboo of making charges that might bring regulators and auditors down on a competitor, she says.

The move toward computerized physician order entry (CPOE) will only increase the risk, Skolnick says. CPOE will promote the standardization of care, and that change means that healthcare providers must ensure the system is directing clinicians properly.

"It becomes incumbent upon the risk manager to ensure that those evidence-based protocols are updated with robustness, meaning you are really 100% sure at any time that you are using the right protocols," Skolnick says. "You should be doing that today, of course, but the automation of the process makes it that much easier for the regulators and investigators to look over your shoulder and ask why you didn't update."

Suit shows good compliance needed

The lawsuit involving Tenet Healthcare Corp. and Community Health Systems could open up a whole new area of risk for health care providers, says **Douglas B. Swill**, JD, a partner with the law firm of Drinker Biddle in Chicago and chair of the firm's Health Law Practice Group.

Once such a lawsuit is filed, the Department of Justice is likely to investigate, along with the fraud units of Blue Cross and Blue Shield, state Medicaid offices, and other groups that might have overpaid for services,

"We haven't really seen this type of situation before, in which a compliance issue comes out during the disclosure process of a merger bid," he says. "There have been claims of misrepresentation and litigation, but this is different because it is raising a very significant compliance issue."

The situation reinforces the need for a solid compliance program, Swill says. He recommends that all providers investigate their observation and admission rates now, because the Tenet lawsuit might bring more focus on that issue from regulators and auditors.

Risk managers also should be closely involved with the preparations for any corporate transactions, Swill says. "If you're about to engage in a strategic transaction — an affiliation, a merger, or a sale — you need to ensure that your house is in order by undertaking the due diligence before you start handing over information to the other side," Swill says. "A lot of times hospitals won't do that. They don't have their own documents reviewed by counsel before transmitting them to the other side, only to find out that the other side's counsel or consultants have found compliance issues."

Sheryl R. Skolnick, PhD, senior vice president of CRT Capital Group in Stamford, CT, who has studied Tenet for Wall Street, points out that hospital utilization data is far more available now than in the past, which allows competitors, analysts, consultants, and anyone else to analyze a hospital's information in search of potential fraud.

"Once that cost data is reported, your actions are going to be scrutinized by people who may not understand the rigors and the necessity of coding a certain way or treating a patient a certain way," she says. "The level of scrutiny has changed dramatically in the last 20 years, and especially in the last five or six. This means that the need for documentation, your evidence of why you made these decisions the way you did, is more important than ever." ■

Professional group targets patient safety

Patient safety professionals are moving toward more prominence and stature in the health care community with the recent launch of the first professional organization devoted to their work.

The American Society of Professionals in Patient Safety (ASPPS), based at the National Patient Safety Foundation (NPSF) in Boston, officially launched recently as the first and only individual membership program for the patient safety field. The announcement was made by **Diane C. Pinakiewicz**, president of ASPPS and NPSF.

Established to advance patient safety as a unique and vital health care discipline, the ASPPS was created to build an engaged, focused community of individuals committed to accelerating the delivery of safe patient care, Pinakiewicz says. The

ASPPS made its debut with 175 inaugural members.

"Ensuring patient safety has never been a more important priority for our healthcare system," says Pinakiewicz. "For too long, the patient safety field has lacked needed cohesion and lines of communication. Today, we are taking the next step toward establishing the consistency in safety practices and tools that will help healthcare professionals keep patients safe."

The ASPPS also announced plans to establish a certification program designed to elevate the patient safety profession through patient safety competencies. Using criteria determined through clinical research and review of best practices, the certification for professionals in patient safety (CPPS) will enable healthcare professionals to implement strategies to reduce medical errors. Taken together with membership in the ASPPS, this certification program will provide a level of professional development for patient safety practitioners that has not previously existed, Pinakiewicz says.

The CPPS certification program is expected to begin in January 2012, she says.

"The ASPPS and the CPPS certification will bring a level of professionalism to the work," Pinakiewicz says. "It also will bring some standardization to the competencies so that when someone is certified, we can feel comfortable there are certain things they know and know how to do."

Membership in the ASPPS is open to professionals whose primary responsibility is patient safety, including risk managers. Others who could be eligible include medical students, providers, quality leaders, and patient safety advocates. "The need for a patient safety professional organization began to emerge as we saw risk management evolve from a reactive effort to a more proactive discipline to improve patient safety," Pinakiewicz says. "The ASPPS was established in recognition of the fact that patient safety is a discipline that has competencies associated with it, that people have a strong commitment to, and that people need a structure to organize around."

More information about the ASPPS is available at http://www.npsf.org/hp/ASPPS.php.

SOURCE

• **Diane C. Pinakiewicz**, President, American Society of Professionals in Patient Safety, Boston. Telephone: (617) 391-9900. E-mail: Dpinakiewicz@npsf.org. ■

Survey: Social media seeing more restrictions

More employers are restricting the use of social media and disciplining workers for violations, according to the results of a recent survey.

To find out what effect the social media explosion is having in the workplace and how companies are responding to its use, the Society of Corporate Compliance and Ethics (SCCE) in Minneapolis, MN, and its affiliated Health Care Compliance Association (HCCA) fielded a survey among compliance and ethics professionals. This is the second survey SCCE and HCCA conducted on business' response to social media; the first survey was conducted in 2009. The research was designed to track how business has responded to the explosion of social media usage.

Healthcare providers, in particular, have been faced with difficult situations involving employees who posted patient information on social networking sites such as Facebook. *(See "Facebook, other social sites continue posing problems" Healthcare Risk Management, October 2010, p. 10.)* Hospitals and others in the healthcare field will always be at the front lines of this difficult issue because the requirements for privacy, and the implications for noncompliance, are so serious for them, says **Roy Snell**, CHC, CCEP, CEO of HCCA and a former Mayo Clinic administrator, consultant, and compliance officer.

Survey respondents reported that discipline of employees for their activities on Facebook, Twitter, and LinkedIn is on the rise. According to the survey results, 42% of respondents reported that their organization has had to discipline an employee for behavior on these sites. That number is up significantly from 24% reported in 2009. "Yet, while headlines tell of employee firings for Facebook or Twitter rants or privacy violations, only about one-third of survey respondents report that their organizations have adopted policies specifically addressing the use of social media sites outside of work," Snell says.

The data reveals an increase from 10% in 2009 to 31% in 2011 of respondents who report that their employer has specific policies for social media use when away from work.

Companies often set site-specific policies for workplace access to social media, Snell says. Forty-seven percent reported that anyone may access

LinkedIn, while lower numbers are reported for Facebook and Twitter — 32% and 31% respectively — and 35% of respondents companies allow no access to those two sites at work.

Snell points out that for-profit companies are more likely than non-profits to allow access to LinkedIn. Health care companies (40%) were far less likely to allow access than industry as a whole (77%).

In 2009, passive systems for monitoring social media policies — acting when appraised of an issue — was used by 32% of respondents. Yet, despite the exponential growth of social media use, the availability of monitoring solutions, and the increase in company policies that restrict its use, passive systems are now relied upon by 48% of respondents. "Business has clearly awoken to the risks and opportunities posed by social media. The increase in business usage of social media sites has been accompanied by increased efforts, at least on paper, to control employee activity inside and outside of work," Snell says. "However, reliance on informal monitoring methods and lack of clear owners of monitoring suggest that many companies have a long way to go in ensuring that their policies are followed. At the same time we must be very careful not to stifle one of the most effective business tools we have: social media."

SOURCE

For more information, contact:

Roy Snell, CHC, CCEP, CEO, Health Care Compliance Association, Minneapolis, MN. Telephone: (952) 933-8009. E-mail: roy.snell@corporatecompliance.org. Web: www.hcca-info.org. ■

Nurse kills herself after medical error

The fatal overdose of an infant last year at Seattle Children's hospital has resulted in another death: The nurse at fault committed suicide.

Kimberly Hiatt, 50, a critical care nurse who had worked at Children's for 27 years, took her own life recently, the family confirmed in an interview with The Seattle Times newspaper. *(For the full story, go to http://seattletimes.nwsource.com/html/localnews/2014830569_nurse21m.html.)* After Hiatt's death, the state's Nursing Commission closed its investigation of her actions in the Sept. 19, 2010, death of Kaia Zautner. The critically ill infant died in part from complications from an overdose of calcium chloride, and Hiatt had been identified as the nurse who made the math error and administered the overdose.

The hospital put Hiatt on administrative leave and dismissed her soon after, according to information provided by the hospital. After a state investigation, she agreed to pay a fine and to undergo a four-year probationary period during which she would be supervised at any future nursing job when she gave medication, according to Hiatt's mother, Sharon Crum of Issaquah, WA.

Hiatt and the hospital settled with the Zautner family, but nondisclosure agreements prevent the parties from discussing the terms. An investigation by state facilities licensing officials into this death and two unrelated cases at Children's concluded that the hospital had "effective, adequate systems to prevent patient harm," according to the hospital.

In the months since the adverse event, Hiatt had been fighting to keep her nursing license, family members said. She had recently passed an advanced cardiac life-support certification exam to qualify for a job as a helicopter transport nurse, but she was having difficulty finding another nursing job. ■

CNE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- describe the legal, clinical, financial and managerial issues pertinent to risk management;
- explain the impact of risk management issues on patients, physicians, nurses, legal counsel and management;
- identify solutions to risk management problems in health care for hospital personnel to use in overcoming the challenges they encounter in daily practice. ■

COMING IN FUTURE MONTHS

- Joint venture agreements and anti-kickback risk
- Falls: New solutions for perennial problem
- Tips for working well with compliance officers
- The biggest problems found in RAC audits

CNE QUESTIONS

Nurses participate in this continuing education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this semester's activity with this issue, you must complete the evaluation form provided and return it in the reply envelope provided in this issue in order to receive a letter of credit. When your evaluation is received, a credit letter will be mailed to you.

20. What does the proposed rule on accountable care organizations (ACOs) say about primary care physicians?
    A. They must be exclusive to one ACO.
    B. They may participate in more than one ACO.
    C. They may not participate in ACOs.
    D. They are required to participate in at least one ACO.

21. According to Robert D. Belfort, JD, a partner with the law firm of Manatt in New York City, what is the biggest challenge regarding compliance issues in ACOs?
    A. The funding and investment of the ACO
    B. Distribution of shared savings
    C. Documentation of savings achieved

22. In the Excellence in Obstetrics program at Ascension Health, what is one strategy intended to lower the risk of malpractice lawsuits?
    A. Earlier admission
    B. Early resolution after an adverse event
    C. Involving fewer team members per patient

23. Why does Ascension Health avoid using the term "disclosure" when encouraging better communication with patients and family?
    A. It has a legal meaning that is not always appropriate.
    B. It has a negative connotation with some clinicians, suggesting an admission of guilt.
    C. Many patients and family do not understand the term.

24. What is the basic allegation in the lawsuit filed by Tenet Healthcare Corp. against Community Health Systems?
    A. Tenet says the company's surgical infection rate is higher than it claimed in disclosure documents.
    B. Tenet claims that the company's staffing ratios are artificially inflated.
    C. Tenet says the company illegally interfered with a previous takeover attempt by Tenet.
    D. Tenet accuses the company of using "liberal" criteria to decide whether to admit a patient or treat the person less expensively on an outpatient basis.

ANSWERS: 20. A 21. A 22. B 23. B 24. D

Healthcare Risk Management's
Legal Review & Commentary™
A Monthly Supplement

Incorrect calculation of medication dose leads to baby's permanent disability, $19.2M verdict

By **Radha V. Bachman**, Esq.
Buchanan Ingersoll & Rooney
Tampa, FL

Grena Porto, RN, ARM, CPHRM
QRS Healthcare Consulting
Hockessin, DE

News: A woman gave birth to a baby at 24 weeks gestation. Physicians at the hospital ordered that the baby receive parenteral nutrition (PN). The amount to be administered to the child was documented in the child's birth as being calculated according to "standard protocol." For 11 days, the hospital administered the PN solution intravenously without incident. On the 13th day, the dose administered to the child was incorrect and resulted in an overdose. As a result, the child suffered catastrophic injuries, and the child's parents sued. The jury returned a verdict in favor of the plaintiff in the amount of $19.2 million.

Background: At 24 weeks gestation, a baby was born prematurely weighing 685 g. The child was immediately admitted to the hospital's Neonatal Intensive Care Unit with a diagnosis of low birth weight, respiratory distress syndrome, and possible sepsis. A day after birth, a physician order was received stating that the child should receive neonatal parenteral nutrition (PN) via a central venous line. The order sheet identified specific amounts of amino acids, carbohydrates, additives, and fat emulsion components to be included in the PN solution. The order sheet further stated that the vitamins and trace elements to be included in the PN solution were to be calculated by the hospital pharmacy in accordance with "standard protocol." Standard protocol was to be determined using the baby's body weight. For 11 days, the physician orders for the PN solution were updated daily, and the child received the intravenous PN solution without complication. Thirteen days after birth, an updated physician order sheet for the PN solution incorrectly listed the baby's weight as 720 *kilograms*. On the child's 15th day of life, the amount of vitamins and trace elements in the PN solution were improperly calculated. As a result, the child received an overdose of cysteine, zinc, copper, manganese, chromium, and selenium. The overdose caused the child to develop severe metabolic acidosis and suffer a severe cardiac and respiratory decompensation that required cardiopulmonary resuscitation and an exchange transfusion. Ultimately, the child developed an intraventricular hemorrhage and suffers from permanent injuries.

The child's parents sued the hospital on behalf of the minor and alleged that the hospital was negligent in the treatment of their daughter. Counsel for the plaintiff's argued that immediately following the overdose, the child suffered metabolic acidosis, decreasing pH levels, and cardiac arrest. In contrast to the 13 days prior that she had been receiving PN, on this day the child suffered a brain hemorrhage and other severe injuries.

The hospital conceded that the dosage was wrong but contended that the injuries suffered by the child were not a result of the mistake but rather the child's extreme prematurity. They also contended that based on placental pathology, a severe infection was passed from the mother to the baby in utero. Following delivery, the child's white

blood count remained elevated despite antibiotics. Due to lack of growth of the child's head, she was diagnosed as microcephalic.

The child is 3 years old, is confined to a wheelchair, and is required to wear diapers. She is extremely developmentally delayed and requires around-the-clock care.

Plaintiff's counsel submitted a life plan totaling about $5 million. The jury found the defendant negligent and awarded the plaintiffs $19.2 million in total damages.

What this means to you: This tragic case perfectly illustrates the importance of a well-designed medication administration process that incorporates redundant checks and "failsafes" to prevent patient harm. Medication administration is a high risk process that is complex and, therefore, prone to failure. To extract lessons learned from this devastating case, we must first study how the system failed to protect this neonate.

First, the physician made a clearly erroneous entry regarding the baby's weight. He probably intended to write 720 grams, but instead wrote "kilograms," which would have meant that this neonate weighed about 1,584 pounds. It is possible that this mistake was prompted by the common practice of prescribing PN medications in terms of micrograms per kilogram of body weight, or mcg/kg. Thus, with the term "kg" already in mind, the physician inadvertently entered "kg" instead of "g" for the baby's weight.

Even this gross error in documenting the baby's weight should not have led to patient harm, however, if appropriate checks and balances were present and functioned properly. For example, upon reviewing this order, the nurse should have noted the use of "kilograms" rather than "grams" to describe the baby's weights, and this should have set off mental alarm bells. Yet, that apparently did not happen. Why? It is possible that the nurse committed the same mental "slip" as the physician when reviewing the order. It is also possible that the nurse was rushed or distracted when reviewing the order, or that he or she was interrupted when checking the order and thus failed to notice the mistake.

Furthermore, it is possible that none of these factors came into play as the nurse reviewed the order, and that instead "confirmation bias" played a role. Confirmation bias is a common failure of human cognition that causes us to look at something and see what we expect to see. Thus, in this scenario, it is possible that the nurse looked at this order expecting to see grams rather than kilograms and thought he or she saw exactly that.

We also must examine why the system of checks and balances in the pharmacy dispensing process failed. Upon receipt of this order in the pharmacy, it would normally be reviewed by a pharmacist and possibly entered into a computer system with automatic compounding software, which then would calculate the appropriate dose based on patient weight. Any questions or concerns about an order would normally be brought to the attention of the ordering physicians, and these would have to be addressed to the satisfaction of the pharmacist before he or she would approve the order for dispensing.

Why didn't this occur in this scenario? Again, we are left to speculate about what happened. Is it possible that the reviewing and dispensing pharmacist and/or pharmacy technician failed to appreciate the use of kilograms rather than grams? If automated compounding software was used, why did it generate no alert for this excessive dose? Furthermore, why did the pharmacy technician or pharmacist preparing the PN fail to notice that properly preparing the PN required multiple vials of highly toxic substances, a phenomenon that usually points to a dosing error in a pediatric patient? Were they excessively busy, understaffed, or just plain tired? Or, did this hospital pharmacy use larger vials that "masked" the excessiveness of the dose? Did everyone involved have appropriate training in the handling of PN and, just as importantly, in how to correctly perform an independent double check?

Although there are many unanswered questions in this scenario that prevent us from drawing definitive conclusions about what might have occurred, we can still extract some lessons learned by looking at similar errors. The Institute for Safe Medication Practices (ISMP) web site contains a detailed account of a similar error that may be useful for this purpose *(ISMP Medication Safety Alert, Sept. 6, 2007. Web: ismp.org)*. In that case, PN was ordered for a baby born at 26 weeks gestation. The order included the addition of zinc to the PN, the dose of which was expressed in mcg/100 mL. However, the automatic compounding software required the order to be entered in terms of mcg/kg dose. The pharmacist had to manually convert the mcg/mL dose into mcg/kg, and in so doing, she accidentally wrote "mg" instead of "mcg." The PN bag then was checked by another pharmacist, who likewise failed to appreciate the conversion of "mg" to "mcg" by the original phar-

macist, perhaps to due confirmation bias.

In addition, the 1,000-fold dose required the pharmacy technician who prepared the PN to use multiple vials of zinc — many more than normally would be used — yet this did not raise concerns in the mind of the technician and was not identified as a possible error until a change-of-shift review of the work. Thus, although the pharmacy technician viewed the dispensing process as unusual enough to mention to the oncoming technician at the end of the shift, he or she did not raise any concerns to the pharmacist at the time of dispensing. The result of this cascade of errors resulted in a 1,000-fold overdose, which led to the baby's death.

More recently, ISMP reported another case of a PN error involving a newborn *(ISMP Medication Safety Alert, April 21, 2011)*. In that case, an infant had been born prematurely but thriving at 6 weeks was receiving PN. The physician prescribed a total of 14.7 mEq of sodium chloride and 982 mg of calcium in the infant's PN. The order was faxed to the pharmacy after midnight, at which time a pharmacy technician made an error when entering the order into automated compounder software. The technician accidentally entered the prescribed dose of calcium ("982" mg) into the mEq field for sodium. The technician then prepared the PN, which contained a total of 982 mEq of sodium, using an automated IV compounder. The technician affixed the printed label to the PN, which showed the erroneous sodium content. Unfortunately, the error was not detected when a pharmacist checked the final product. Furthermore, a different label that listed the sodium content as 14.7 mEq, the originally prescribed amount, was applied directly over the label produced by the compounder software that had listed the actual amount of sodium (982 mEq) in the solution. Thus, the nurse who eventually started administration of the PN solution was unable to detect the error. A few hours after the PN was started, routine lab studies showed that the infant's sodium level was abnormally high. The infant's physician assumed the study results were inaccurate and asked for the lab test to be redone. This lab test was never accomplished before the infant experienced a cardiac arrest and died.

Even without benefit of all of the facts in the original case mentioned above, we still can apply the systems solutions identified by ISMP:

• Standardize the prescribing methods.

Standardize the method of ordering PN solutions (and other routinely compounded solutions) for neonates, pediatric patients, and adults, so that each prescribed ingredient matches the dosing templates used for entering the orders into the computer system and automated compounder. Use preprinted forms or standard order sets that list typical ingredients and prompt the correct dosing method. On the rare occasions that calculations are necessary, require two clinicians to calculate the dose independently and compare their answers for verification.

• Prescribe and transmit PN orders during the day.

Policies that require prescribers to order PN daily during the day shift should be established and enforced to maximize the safety with which these solutions are prepared and dispensed. Pharmacy staff should be aware of patients who are receiving PN and check if orders have not been received by the established time.

• Allow manual-only additions of low-volume ingredients.

For PN ingredients that typically require very small volumes, require staff to prepare, check, and inject those ingredients manually. Do not allow a trace element such as zinc to be loaded on a compounder for automated preparation.

• Build, test, and heed automated warnings.

Install, test, and maximize automated dose-limit warnings in the pharmacy computer system and automated compounders, particularly for high-alert medications such as PN and its ingredients. Baxa, an automated compounder vendor with a large share of the hospital market, allows users to add soft warnings and hard stops if a dose limit is breached when entering an order. The company's more recent compounder software has "catastrophic" limits that stop the process completely when 100-fold or 1,000-fold overdoses caused by decimal point errors or mcg to mg selection errors occur.

However, DO NOT rely solely on the catastrophic dosing limits established by software vendors. Vendor-established dose limits, such as the Baxa Only Warning Limits, still will allow a potentially fatal dose to be entered into the software without issuing a warning. Organizations need to define more restrictive weight-based dosing limits applicable to their patient populations. These warnings should function as a hard stop without the ability to proceed until the dose has been reviewed via a peer review process.

Organizations also should print all alerts encountered during the order entry process so the person checking the order entry also can view and respond to the alerts. Reinforce the importance of

reacting to the alerts with all staff. Print all alerts encountered during the order entry process so the person checking the order entry can also view and respond to the alerts. Reinforce the importance of reading and reacting to the alerts with all staff.

• Heighten the suspicion of an error.

Continually emphasize that the following should trigger a full review of the patient's medications and treatment plan to ensure an error has not occurred:

— the need to use more than a few dosage containers (whether it be tablets, capsules, vials, ampuls, etc.) to prepare or administer a single dose of any medication;

— unexpected differences in the appearance of medications or solutions;

— other unusual circumstances regarding a medication or solution;

— unexpected patient response to a medication.

Technicians who compound products should be required to stop the process if they encounter situations which they need to add an electrolyte or mineral in large doses or in large volumes to complete a single preparation. A full review of the work label and order by a pharmacist should be required before proceeding. Nurses who work in pediatric and neonatal units should question products that are dispensed in larger quantities than typically supplied for children or neonates. Create a culture that encourages all staff, despite their level of experience or education, to speak up about unusual conditions.

• Carry out effective redundancies.

Several verification processes should occur in the pharmacy:

— before order entry into the automated compounding software to verify that the PN order is appropriate for the patient (e.g., based on weight, height, disease state, and lab values);

— after initial order entry into the automated compounding software to match it to the verified order;

— before injecting any additives that must be added manually;

— once the PN has been compounded.

Verification of manual additives should include inspection of the actual vials and filled syringes prior to admixture. The "pullback" method is not recommended. Final verification of the compounded PN should include review of the original order, product label, and work label, as well as comparison of the expected weight/specific gravity with the actual weight/specific gravity. If different than expected or off by 3% or more, the product should be prepared again. If PN compounding is outsourced, a pharmacist should verify the appropriateness of the order before sending it to the pharmacy and verify that the product received matches the verified prescriber order. Before administering PN, nurses also should independently compare the label on the solution with the physician's order.

• Label products and use critical thinking skills.

Produce product labels and associated work labels used by pharmacy staff to compound solutions that include the actual dose/strength of the base solution and each additive, not just the volume amounts needed to prepare the products. Encourage technicians who compound products to focus not only on the volumes needed to prepare the solution but also on the *dose* of the additives and the *concentration* of the solutions. Apply easy-to-read labels that print from the compounder order entry system to compounded products to ensure the label lists the actual contents. The label format should follow the prescriber's order.

• Provide education and validate competency.

Establish a formal training process for pharmacy staff who are required to enter PN orders into the pharmacy computer, compound the solutions, or check the products after preparation. Designate and train specific staff members to function as preceptors and provide one-on-one supervision until trainees are comfortable providing the service and have demonstrated the skills and knowledge necessary to function independently. Training should focus on dose and dose concentration, not just the volume of additives, when preparing the solutions.

If compounding services are provided for neonatal and pediatric patients, include age-specific training emphasizing weight-based dosing, and validate the competency of all staff who serve the pediatric population. Develop learning modules and competency validation tools to expose trainees to a broad spectrum of responsibilities that they might not encounter during their on-the-job orientation. Plan adequate staffing with trained practitioners to cover vacations, illnesses, and other causes of planned and unplanned absences. Establish guidelines for closer supervision of work if emergency coverage with an inexperienced staff member is necessary.

REFERENCE

Florida Circuit Court, Twentieth Judicial Circuit, Lee County, Case No. 09-CA-003963. ■

Healthcare Risk Management™

HRM060111TM

PLEASE NOTE: If your correct name and address do not appear below, please complete the section at right.

Please make label address corrections here or PRINT address information to receive credit letter.

Account # _____

Name: _____

Company: _____

Address: _____

_____

City: _____

State: _____

Zip _____

Fax: _____

Phone: _____

E-mail: _____

CNE Evaluation

Please take a moment to answer the following questions to let us know your thoughts on the CNE program. Fill in the appropriate space and return this page in the envelope provided. **You must return this evaluation to receive your credit letter.** Thank you.

CORRECT ● **INCORRECT** ◌ ✓ ✗ ⊘

1. If you are claiming nursing contact hours, please indicate your highest credential: ◌ RN ◌ NP ◌ Other _____

	Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree	Agree	Strongly Agree
After participating in this program, I am able to:						
2. Describe legal, clinical, financial, and managerial issues pertinent to risk management.	◌	◌	◌	◌	◌	◌
3. Explain the impact of risk management on patients, physicians, nurses, legal counsel and management.	◌	◌	◌	◌	◌	◌
4. Identify solutions to risk management problems in health care for hospital personnel to use in overcoming the challenges they encounter in daily practice.	◌	◌	◌	◌	◌	◌
5. The test questions were clear and appropriate.	◌	◌	◌	◌	◌	◌
6. I am satisfied with customer service for the CNE program.	◌	◌	◌	◌	◌	◌
9. I detected no commercial bias in this activity.	◌	◌	◌	◌	◌	◌
10. This activity reaffirmed my clinical practice.	◌	◌	◌	◌	◌	◌
11. This activity has changed my clinical practice.	◌	◌	◌	◌	◌	◌

If so, how? _____

12. How many minutes do you estimate it took you to complete this entire semester (6 issues) activity? Please include time for reading, reviewing, answering the questions, and comparing your answers to the correct ones listed. _____ minutes.

13. Do you have any general comments about the effectiveness of this CNE program?

_____

I have completed the requirements for this activity.

Name (printed) _____ **Signature** _____

Nursing license number ***(required for nurses licensed by the state of California)*** _____