



## New competition for TJC: DNV Healthcare granted deeming authority from CMS

*How a competitive accreditation marketplace could affect health care*

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Is it the end of an era for The Joint Commission? Following on the heels of Congress' move to require the organization to reapply for deeming authority for the first time, DNV Healthcare on Sept. 26 was granted deeming authority from the Centers for Medicare & Medicaid Services (CMS). It is the first organization to gain deeming authority in more than 30 years. Just how big is this news, and how much will it affect health care, hospitals, and you?

"It's a big issue. We haven't had an alternative to The Joint Commission and the American Osteopathic Association in my lifetime," says **Sue Dill Calloway**, RN, MSN, JD, director of hospital patient safety at OHIC Insurance Co./The Doctors Company in Columbus, OH.

As far as bringing competition to a market that has seen one major player, **Nancy Foster**, vice president for quality and patient safety for the American Hospital Association, says: "At the AHA we recognize that having a choice of accrediting organizations could be good for patients and for hospitals. Both The Joint Commission and DNV Healthcare will work with hospitals to reach their goal of quality improvement — they'll just take different paths to get there. We look forward to learning more about DNV Healthcare's approach and how well it works to help hospitals achieve better quality."

### What is DNV?

Houston-based DNV Healthcare, a subsidiary of the Norwegian company Det Norske Veritas, first applied for deeming authority in December 2007 and learned in early March from CMS that its application was complete. CMS then had 210 days to either approve or reject DNV's application.

Of the application process, President **Yehuda Dror**, says, "the barriers to entry I would say are quite high, justifiably so, because you cannot come to CMS with a program that shows what you will do. You have to come in with a program that shows what you have done." You have to prove to CMS that you are "committed" and "are in it for the long haul," he says.

In the three years the company worked toward achieving deeming authority, it accredited 27 hospitals using its National Integrated Accreditation for Healthcare Organizations (NIAHO) program. Those hospitals, Dror says, are a testimony to the strength of its program as they

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“went through our accreditation process without gaining any favors or benefits from CMS.” They also gave DNV the experience it could bank on in applying with CMS.

## The ISO difference

“The major difference [between DNV and The Joint Commission] is that in our program we

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### Editorial Questions

For questions or comments, call **Jill Robbins** at (404) 262-5557.

have taken the Conditions of Participation from CMS and we have married it to ISO 9000,” Dror says.

“We like this standard,” he adds, “not just from the certification point, but from the fact that is what I would call one of the better attempts to standardize common sense, as oxymoronic as it may sound.”

ISO 9000 is an internationally recognized family of standards for quality management originally used in the manufacturing, aerospace, agriculture, banking, and steel industries among others.

With the rise in popularity of quality and process management systems such as Six Sigma, Lean, and others used in industries including aviation and manufacturing, how does ISO measure up? And is this the way quality and safety should be moving?

The Joint Commission has “essentially become a monopoly in the last half of the last century and it was very focused on health care,” says **Martin Merry**, MD, CM, adjunct associate clinical professor of health management and policy at the University of New Hampshire and partner, Dynamic Health Systems. “It really was relatively slow to incorporate, in my opinion, some of the quality systems such as manufacturing.”

He says many hospitals he sees across the country already have been looking for alternatives to Joint Commission accreditation, often opting instead to go through state certifying organizations, and a number of hospitals, though it previously didn't give them deemed status, have been ISO certified.

“In fact, here in my home state of New Hampshire, many hospitals have opted out of The Joint Commission. They don't even worry about The Joint Commission. They've made the judgment, whether for better or for worse, that The Joint Commission was not offering them adequate value for the expense that these surveys cost,” says Merry, who serves on the advisory board of TUV, which was acquired by DNV in 2007.

In talking with hospitals that have ISO certification, he says, “they found quite great value in working with the ISO standards, and it gives them what most of them reported as a much greater depth of understanding of quality management standards than the very broad Joint Commission standards.”

He acknowledges that ISO doesn't focus as broadly on health care as The Joint Commission, focusing instead on “true quality management support systems” for companies that he says are serious about quality and process improvement.

"I've often said, tongue in cheek, that The Joint Commission standards can be a mile wide but not that deep, while ISO is relatively narrow," he says.

But he sees a sea change in health care. "Health care has been kind of cloistered; it's not been a part of the real world. It has a preindustrial-based culture, and The Joint Commission classically represents that culture," he says. If he were an investor, he says he would hedge his bet with ISO, but for his clients and audiences he recommends that they compare the accreditation programs side by side and that they look "very seriously" at what ISO has to offer in terms of quality and process development.

And though he welcomes a competitive field, he sees a potential threat. "The trouble with the whole compliance industry," he says, "is that it can be gamed." People find out what surveyors are looking for and try to give them just that. Corporations such as General Motors tended to require their suppliers to get ISO certification, but it was never compulsory and appealed "to those who really wanted to do something in quality." Merry says. Now that DNV is an accrediting organization, he says, it, too, could fall into the gaming trap.

### **More frequent surveys**

"Every two or three years, everyone scrambles around [in preparation for a Joint Commission survey]. They put everything in the corridor," Merry says.

But The Joint Commission, he adds, has been aware of that problem and has improved processes with new survey methods, tracking systems, and surprise visits.

With DNV, surveys still will be unannounced, but more frequent, and surveyors will all be cross trained in ISO methodology. "It's a shame with an audit that takes place every three years," Dror says. "It makes it a show. Our system is different. We want it to be a way of life, and in order to assure it is, we do it once a year."

He says hospitals won't need to prepare and spend overtime and hire more personnel in preparation for their audits. The method DNV uses, he says, is more about system creation and improving that system in a less prescriptive way than The Joint Commission. Hospitals' responsibility is to "meet the objectives in whichever way they do" and if there's a problem, he says, you change it.

**Robert Wachter**, MD, professor and associate chairman of the department of medicine at the University of California, San Francisco, doesn't

think the move to DNV will be an automatic one. "At this point," he says, "the name recognition of The Joint Commission remains pretty powerful."

**Peter Angood**, MD, vice president and chief patient safety officer for The Joint Commission, which must reapply for deeming authority in two years, says, "We've been very successful in the marketplace and have been for over 50 years. So the fact that there is a new competitor in the hospital marketplace is fine by us.

"But we have a long-standing legacy of excellence. We've got over 80% of the hospitals accredited by us, and in sum total, we do well over 10,000 more types of health care facilities in an accreditation program. And in so many ways we are the gold star of accreditation in America."

He says The Joint Commission is evaluating DNV standards "but it looks like they're more or less focused on the CMS standards and haven't gone much beyond it."

As far as its stake in the industry, he says, The Joint Commission "will respond as a competitive organization and we expect to have success as we have for over 50 years."

However, Joint Commission and ISO certification are not necessarily exclusive of one another. **Mickey Christensen**, president of TQM Systems, a quality management consulting company, suggests dual certification. "I don't promote ISO 9001 [part of the ISO 9000 series] in lieu of The Joint Commission or the American Osteopathic Association or something like that because ISO 9001 doesn't have the clinical aspect The Joint Commission does.

"I think the two complement themselves very well," he says, but adds that he sees gaps in The Joint Commission standards and CMS CoPs in terms of looking at quality management systems.

"I don't want this to come out sounding negative, just stating the facts. If the IOM report ["To Err is Human: Building a Safer Health System"] is correct, and I have no way of knowing for sure whether it is or isn't, that we kill up to roughly 98,000 people a year due to medical errors, and 80% of the hospitals are accredited by The Joint Commission, then there's gaps in there somewhere," he says.

Many clients, he adds, think The Joint Commission has included things that aren't value-added and doesn't address issues related to, for example, dealing with ancillary support (i.e., housekeeping, dietary functions, maintenance, purchasing) and running an efficient business.

Exactly how it will play out remains to be seen,

but Dror says he has gotten many calls since Sept. 26 about DNV's program. Dill, too, reports fielding a lot of questions about the new accrediting body from her clients.

"There's a buzz in the field. There's someone new. They want to test us out," Dror says.

"We'll see. Time will tell." ■

## New Sentinel Event Alert addresses blood thinners

*Anticoagulants once again hit center stage*

**A**nticoagulants, or blood thinners, have taken the mainstream media by storm with salacious tales of medical errors and tragic stories of babies' deaths. While you are dealing with the phase-in period on National Patient Safety Goal 3E, another call for alarm has been sounded on anticoagulant use and management.

The Joint Commission's new Sentinel Event Alert urges greater attention to be paid to this high-risk set of medications. (*For the complete sentinel event information, including suggestions, visit [http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea\\_41.htm](http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_41.htm).*)

Also, in preparation for implementation by Jan. 1, 2009, The Joint Commission says hospitals should now have completed pilot testing on strategies for managing blood thinner use in conjunction with NPSG 3E. "As hospitals are struggling to come into compliance, we know a lot of them are actually behind," says **Sue Dill**

### Resources

- Purdue University PharmaTAP Anticoagulant Toolkit: <http://www.purdue.edu/dp/rche/pharmatap/resource.php>.
- University of Washington Medical Center Anticoagulation Services: <http://uwmcacc.org/>. This site includes several patient education handouts in five languages.
- Surgeon General's Call to Action 2008 on preventing deep vein thrombosis and pulmonary embolism: <http://www.surgeongeneral.gov/topics/deepvein/call-toaction/call-to-action-on-dvt-2008.pdf>.
- Pennsylvania Safety Authority toolkit: <http://www.psa.state.pa.us/psa/cwp/view.asp?a=1293&q=446932#9>.

**Calloway**, RN, MSN, JD, director of hospital patient safety at OHIC Insurance Co./The Doctors Company in Columbus, OH. "We've heard a lot of hospitals say that there's just no way they can meet that deadline."

Recommendations in the newest Sentinel Event Alert include:

- Assess the risks of using anticoagulants.
- Use best practices or evidence-based guidelines regarding anticoagulants.
- Establish standard dose limits on anticoagulants and require that a doctor confirm any exceptions.
- Clearly label syringes and other containers used for anticoagulants.
- Clarify all anticoagulant dosing for pediatric patients, who are at higher risk because these drugs are formulated and packaged for adults.

### Why now?

"The Joint Commission has had medication management standards in place for a long time," says **Frank Federico**, RpH, content director, Institute for Healthcare Improvement. "The fact that we're highlighting the anticoagulants, as they have with the National Patient Safety Goals, is just because it's not happening. We're not seeing improvements."

The problems that are occurring are numerous and multidimensional. But telling staff to just work harder, to be more vigilant, to pay more attention is not the answer, says Federico. And **Mark Chassin**, MD, MPP, MPH, president of The Joint Commission, agrees.

"It is important that we stop relying on the idea that if only everyone in the medication delivery process tried harder that doctors, nurses, pharmacists, and other caregivers could eliminate every single error by just trying harder," he said in a press conference on the new alert.

### Where errors are occurring

In general, Chassin said, this set of drugs is challenging because the difference between a harmful dose and an appropriate one is so narrow. **Peter Angood**, MD, vice president and chief patient safety officer at The Joint Commission, said compliance is hampered by these persistent problems: the storage of the medication, the legibility of written orders, and the transcription of the orders.

"The cases show that errors occur at every stage the medication is processed — from ordering, to transcribing or documenting, dispensing, adminis-

tering, and monitoring. And they happen in almost every unit in the hospital,” said **Diane Cousins**, R<sub>p</sub>H, vice president, Center for the Advancement of Patient Safety, United States Pharmacopeia.

Some of the most frequent errors occur in admissions, she added, including:

- failure to administer a single dose but also failure to initiate a course of therapy when it’s ordered;
- failure to resume therapy (for example, after surgery).

Among the top 10 most frequent causes for harm, she listed:

- poor communications;
- knowledge deficits among health care personnel;
- inadequate or absent monitoring;
- inaccurate computer entry, including computerized physician order entry;
- performance deficits, in which trained personnel still make errors because of distractions, workload increases, and inexperienced staff.

### ***So what can we do about it?***

Federico says all health care professionals should look at the errors occurring across the United States and ask themselves, “Could this happen here?” Process evaluation and improvement are essential.

The second thing he stresses is taking a system approach. “Although education and training are necessary, they are not sufficient,” he says, especially in lieu of sound system development.

Chassin said health care organizations should take a look at other companies in other industries and reliable systems that “anticipate, look for, track the small errors that people make every day before they result in harm.” The first step, he said, should be undertaking an in-depth assessment to evaluate “how these processes fail.”

Angood added that patients, before receiving anticoagulant therapy, should be screened for the “appropriateness” of receiving the medication and for any possible contraindications or adverse drug reactions.

He also emphasized that hospitals should standardize the way blood thinners are “prescribed, delivered to the bedside, and administered,” strengthen communication about lab values, and determine dose limits when dosing is out of the “usual and expected” range. This last point, he said, should always be a checkpoint. “Unless there’s a specific physician order that says, ‘Yes, that’s an OK dose,’ those drugs should not be administered.”

Cousins recommended all caregivers in the hospital setting “understand what the proper dosing is and stay up to date on proper dosing regimens. They should be aware of what those products look like and the various strengths that are available.”

Federico suggests minimizing look-alike, sound-alike medications and emphasizes the importance of monitoring the patient. Some facilities, he says, use clinical pharmacists in the monitoring role because they can “monitor lab values, monitor patients, and make appropriate adjustments.”

He also stresses identifying and managing high-risk patients: the frail and elderly and infants. It’s a much different discussion with these patients than dealing with a healthy “normal” patient. Federico says two questions must be asked. First, can the patient comply with the regimen? Second, what’s the risk of putting this patient, for example, on warfarin vs. not putting the patient on warfarin?

“Those are the kinds of issues that I think are the next step in the evolution toward a safer system,” Federico says.

Another central element to anticoagulation management: education while patients are in the hospital and upon discharge. “There are some studies out there that report that self-managed anticoagulation is probably better than some of the other methods out there, Federico says. So an engaged patient who knows what to look for and when to call for help is probably a much better-cared-for patient.”

Lastly, he emphasizes that anticoagulants are effective drugs and save many lives. “So the message we want to send out is we don’t want to create so much fear that people won’t use them. What we want to do is develop systems so people use them safely.”

*(Editor’s note: Revisit the guidelines for National Patient Safety Goal 3E for new notations and clarifications.) ■*

## **The technology factor: Is it our friend or our foe?**

*New study highlights errors with bar coding*

**W**hile The Joint Commission is asking health care facilities to use computerized physician order entry and bar coding technology as an adjunct to arm themselves in managing high-risk

medications including anticoagulants, a recent study highlights the errors implicit in this kind of information technology support.

**Peter Angood**, MD, vice president and chief patient safety officer for The Joint Commission, points out that while technology is helpful, it is not a panacea. "The expectation is that technology will solve the problem," he says. "And it does not."

A first-of-its kind study tackles the problems inherent in IT systems often praised and recommended as first-line defense against medication errors. The study examining flaws in barcode medication administration (BCMA) systems was published in the July / August issue of the *Journal of the American Medical Information Association*.

Led by **Ross Koppel**, PhD, lecturer/adjunct professor in the department of sociology at the University of Pennsylvania, researchers looked at five hospitals in the Midwest and on the East Coast and found 15 types of workarounds in

which clinicians overrode the BCMA system to compensate for difficulties in the system.

One of the major findings, Koppel says, is "contrary to what is ordinarily discussed in the literature." In the study, he says, about 11% of medication bar codes were unreadable because they were:

- torn, smudged, ripped, sodden, or covered by another label;
- the scanner was outside of the Wi-Fi range for that patient's room.

In other instances, clinicians couldn't use the BCMA system because they were perhaps near the MRI machine or in an X-ray room.

Koppel says the team also found 4% to 5% of patient IDs were unreadable. Some of the reasons include:

- they were from another floor in the hospital;
- patients with dementia had torn them off;
- children ripped them off;
- there was no room for IDs on premature

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babies with tubing, so they were attached to the crib or the incubator, and Koppel points out these IDs might not be moved when the infant is moved;

- they were covered by sterile gauze dressings;
- they were removed so clinicians could perform clinical procedures, such as taking blood.

“So the usual claim that the bar codes worked 99 point something percent turns out not to be true,” Koppel says. So that clinicians could do their jobs, he says, the research team found “tens of thousands of situations” where extra copies of bar codes were made and found on places like door jambs, taped on places like refrigerators or scanning machines, or worn as bangles on nurses’ arms that already held all their other patients’ IDs.

But Koppel stresses that these instances are not a result of clinicians who are lazy, uncaring, or stupid. It’s that systems don’t support the reality of processes that need to occur in health care settings, he says.

“No one has thought about the process in its entirety,” Koppel says and he gives this example: A nurse has a 94-year-old patient and needs to access a refrigerator two floors down. Instead of wheeling the infirm patient down two floors and a long hospital corridor, the nurse decides to just make an extra copy of the bar code to scan.

### ***What is the answer?***

“I don’t think anyone is bright enough to predict problems [that can occur with BCMA] a priori,” Koppel says, suggesting instead continuous observation of BCMA use and coordinated multidisciplinary discussion.

“Ultimately, it comes down to the quality people, who have to simply not accept vendor claims that nothing can be done or local IT claims that it’s not their fault and somebody has to take responsibility for this,” he says. In working with vendors, the hospital must have the last word and the final decision. Vendors, he says, can only do their part in fixing the problems but must be directed to priorities by the hospital team.

### ***The future of IT in health care***

“Koppel’s study is a very important part of a larger literature that’s emerged in the last three to five years on the consequences of information technology,” says **Robert Wachter**, professor and

associate chairman of the department of medicine at the University of California, San Francisco, and blog author.

“Whenever there’s a glitch with a new technology, people always get very wistful and romantic about how good things were before we had it,” however unjustified that may be, he says. But in this instance what we had before IT development wasn’t working either, he adds.

Early systems are always laden with things to learn, Wachter says, and “no one has done studies like Koppel’s study to observe what isn’t working and fix it.”

Though we’re “clearly not” there yet with IT and he applauds Koppel’s study, Wachter says, if you take it “the wrong way” and decide to “stop the IT train” than you’re just not getting it.

He recently wrote an article about The Joint Commission performance measure on door-to-antibiotic time for pneumonia patients in the emergency department. “It was a mistake,” he says, resulting in some patients receiving antibiotics who didn’t need them. It was subsequently modified from four to six hours. “Naysayers look at that and say, ‘See. We weren’t ready for transparency,’” he says. “But you wouldn’t get to the place we need to get unless you started somewhere and recognize there’s going to be glitches... We have to be smart enough to learn from the experience.”

That is what he says progress looks like, learning from errors to improve processes to get to where you want to be.

“If I was buying a bar code system, I would do it with [Koppel’s article] in hand and ask the vendor: How do you know these things aren’t going to happen? What are the steps that you’ve taken to ensure they won’t happen?” ■

## **Wristband standardization: Why we aren’t there yet**

*AHA issues quality advisory on wristband colors*

**I**n September, the American Hospital Association issued a quality advisory on implementing standardized colors for patient alert wristbands, citing a near miss when a nurse mistakenly placed a wrong-colored bracelet on a patient, confusing the color codes of the two hospitals for which she worked.

The dangers in confusion about wristbands are well noted, and the AHA is encouraging the adoption of three consensus colors on a nationwide basis — red for allergy, yellow for fall risk, and purple for do not resuscitate — while emphasizing that the final word on all patients' care is the medical record.

"This is really an issue I like to give state hospital associations credit for," says **Beth Feldpush**, AHA's senior associate director for policy. "They've been really engaged for several years with this. Now over 25 state hospital associations have adopted a voluntary initiative for these three consensus colors."

She says "it made sense" for the AHA to encourage all U.S. hospitals to adopt the three consensus colors while emphasizing that hospitals have to choose "what makes sense to them" in implementation — for example, using what they have before purchasing new bands.

State laws, however, can conflict. Ohio's law reads that the DNR wristbands be clear with the DNR logo. But **Tiffany Himmelreich**, of the Ohio Hospital Association, says state legislators and the Department of Health are currently looking to revise the DNR wristband guidelines.

"The hope is, going into the future, Ohio can join in with this national standard," she says.

The reasons nationwide standardization has not yet taken hold are multidimensional and represent a larger truth about the health care system, says **Robert Wachter**, MD, professor and associate chairman of the department of medicine at the University of California, San Francisco.

"There's sort of a macro issue and a micro issue," he says.

The larger issue is that "you've got to get a lot of different stakeholders to sit down and agree on something."

The micro issue?

"We didn't even start thinking this way until four or five years ago. It wasn't seen as odd or unusual that every hospital in the country would have its own way of doing it — it's a metaphor for a larger problem in health care," Wachter says.

He cites the aviation industry and the strict standardization there. Get on any 747, he says, and it will look the same as any other 747 you've been on. "People will speak in the same language with standard terms and that creates a huge amount of predictability and safety," he says, something you don't see in hospitals because

facilities and physicians like to do things in their own ways.

"The reason I find the wristband issue interesting is not that it's the most important thing in the universe — it's not — but it's a nice metaphor for this larger issue of the importance of standardization, and it's something we really haven't thought about much in health care."

Wachter favors nationwide use of standard colors. He points to The Joint Commission's list of high-risk abbreviations. "When The Joint Commission came out and said, 'Here's a list of high-risk abbreviations that are dangerous. We want you to purge them from the lexicon of medicine,' they didn't allow every state to come up with a different list. And that's actually eased implementation tremendously," he says.

"The same thing should be true for something like wristbands."

Though he favors standardized wristband colors, **Peter Angood**, MD, vice president and chief patient safety officer for The Joint Commission, says wristband use is not without risk. "The color coding could be put into place wrong, there can be loss of bracelets, there can be branding of the patients by what kind of color they have, there can be lack of understanding of why they have those bracelets on, [patients] can remove them or take them off.

"A reliance on what seems like a simple solution is not without risk," he says. "In general, we support appropriate use of bracelets, but they are not a replacement for good, solid patient identification and the strong processes of patient care."

*(Editor's note: To view the AHA advisory, go to <http://www.aha.org/aha/advisory/2008/080904-quality-adv.pdf>.) ■*

## 'Mandatory or not,' errors are going unreported

*Ambiguity big reason for underreporting*

A story that ran in the Sept. 12 issue of the *Philadelphia Inquirer* — "Hospitals' mistakes are going unreported" — might have shocked readers with its description of unreported errors in New Jersey and Pennsylvania despite the states' mandatory reporting requirements. But it came as no surprise to those in the health care or regulatory industry.

“For me it’s not a surprise,” says **Debora Simmons**, RN, MSN, CCRN, CCNS, formerly senior clinical quality improvement analyst for the Institute of Healthcare Excellence at M.D. Anderson Cancer Center in Houston.

**William Hyman**, PhD, professor of biomedical engineering at Texas A&M University, agrees. “Mandatory or not,” errors are going unreported, he says, despite the fact that 26 states now have state reporting requirements.

### ***Deterrents to reporting***

The reasons for under- or unreporting are plenty and, according to the experts *Hospital Peer Review* spoke with, the most common is simply not understanding what should be reported. A “really important piece” of encouraging disclosure is “making sure everyone is clear on what needs reporting,” says **Diane Rydrych**, MA, assistant director of the division of health policy at the Minnesota Department of Health.

Though the law might seem black and white, she says, “there are lot of gray areas, and we have to do a lot of work on definition and making it clear to people what’s reportable and what’s not. There’s a lot of confusion.”

Minnesota requires health care facilities to report on any of the 28 National Quality Forum (NQF) serious adverse events. Seems clear enough, but Rydrych points out there are multi-

ple nuances within this. For instance, with an object left in a patient after surgery. At what point the surgery ends is one of the definitional areas she says needs clarification. Or what about instances in which the object is intentionally left in because to get it out would put the patient at greater risk than leaving it be?

She prefers a nonpunitive approach to encourage reporting and says that in Minnesota, reporting requirements resulted from a “collaborative” effort with hospitals at the table, specifically the Minnesota Alliance for Patient Safety, which was founded by the Department of Health, hospital associations, and medical associations.

“They worked together with other stakeholders to get the law passed in Minnesota so it didn’t have that adversarial or punitive tone from the beginning,” she says. “I think that that has really helped in Minnesota with compliance.”

Others do see merit in stronger enforcement. “I think there’s an inherent flaw in asking hospitals to report with no meaningful enforcement... They’re clearly not doing it,” Hyman says.

“People don’t like the big stick approach, but I think the only way you’re going to get it is serious enforcement,” he adds. He questions if states are doing enough with the information. “What’s the level of analysis? What’s the response from the state? What are they making publicly available? And is it of use to anybody?”

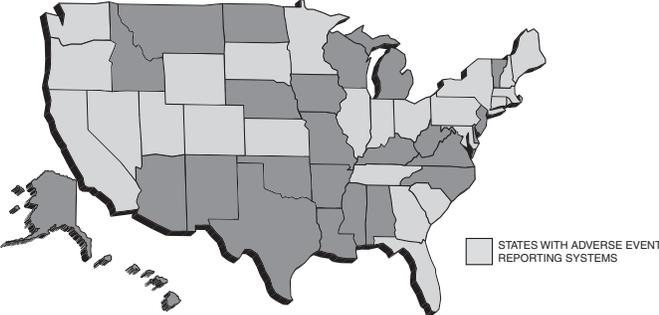
Simmons says it all comes down to human nature. “It’s not our human nature to want to say you made a mistake in any circumstance, even if it’s nonpunitive, even if I feel like I’m not going to get any repercussions from it. We don’t like saying we made mistakes, especially if you’re a highly esteemed professional,” she says.

Rydrych doesn’t believe the majority are knowingly not reporting and says it comes back to a lack of understanding. “Someone can make what they feel is a legitimate decision that it’s not a reportable event and that’s where we have to make sure we’re educating them on what their responsibilities are. It’s hard for me to imagine people are deliberately not reporting things they know are reportable,” she says. “Maybe it’s naive, but I really don’t believe that’s going on in any widespread fashion.”

### ***Trying to make it work***

**Robert Wachter**, MD, professor and associate chairman of the department of medicine at the University of California, San Francisco, thinks

## States with mandatory reporting requirements



The 26 states highlighted here and the District of Columbia have adopted adverse event reporting rules and statutes. For more information or to view state-specific policies and legislation, go to <http://www.pstoolbox.org/index.cfm> and click “26 states” where it is underlined.

Source: National Academy for State Health Policy.

linking reporting to the NQF serious adverse event list is the way to go to promote compliance, citing California, Minnesota, and Indiana practices.

"I've never been a fan of Pennsylvania's reporting initiative that basically said report everything and has generated, at last count, 600,000 or 700,000 reports. I think that's silly. That's way too much data," he says.

The NQF list provides "a nice start of a manageable number of pretty serious things," he says. When California began requiring that facilities report on those events, "it really transformed our internal processes," he says.

"I'm convinced that maneuver markedly improved safety, but it didn't do it because the state is doing anything so spectacular with regard to reports," he says. "It did it because we now know when one of those things happened, we had to create an internal process to learn about it, analyze it quickly, come out with an action plan, see that to fruition, and share the results of what we learned." It's a much more systematic approach, he adds.

### **Double checking**

In Minnesota, Rydrych says getting reporting facilities on board to help sort out definitional issues has helped compliance. The state also requires all professional boards, such as boards of medical practices and boards of nursing, to report any event they've heard of as a sort of "cross check."

The Department of Health reviews death records monthly to see if any events show up. "That's only a partial cross check," she says, "because not all of the events are associated with death." One problematic area, she sees, is linking one hospital-associated event with problems at other facilities or nursing homes. For instance, if a patient falls in one facility but later dies in another, no good mechanism exists to check that, so death records in those cases have helped. But she thinks the recent law change to include not only death but serious disabilities that stem from falls will help.

Her advice for quality and safety managers is to view reporting as "an opportunity to learn and an opportunity to learn how you can improve your system."

"If you have a reporting system in place, figuring out what really specifically you do have to report and what you don't have to report, getting

## **CNE questions**

17. According to **Diane Cousins**, RpH, vice president, Center for the Advancement of Patient Safety, United States Pharmacopeia, most errors with anticoagulant medications occur after discharge.
  - A. True
  - B. False
  
18. Which of the following are reasons for unreadable bar codes, according to **Ross Koppel**?
  - A. They're torn.
  - B. They're wet.
  - C. They're ripped.
  - D. all of the above
  
19. The American Hospital Association is endorsing which of the following colors for wristband use?
  - A. red
  - B. yellow
  - C. clear
  - D. A and B
  
20. Health care facilities in Minnesota are required to report near-misses.
  - A. True
  - B. False

**Answer Key: 17. B; 18. D; 19. D; 20. B**

## **CNE instructions**

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 the **December** issue, you must complete the evaluation form provided in that issue and return it in the reply envelope provided to receive a credit letter. ■

those grey areas sorted out, is really important.”

When you're not sure if you should report something, she suggests calling your department of health or hospital association. When health care facilities call her with a questionable case, she'll discuss it with them and if needed she'll refer to the hospital association and discuss it further with them. In more challenging cases, the event goes before a larger group, comprised of mostly the larger urban hospitals, for further review.

“I think an outsider would be really surprised” by the amount of work that goes into these discussions, she says. “It's ultimately the department of health that decides,” she adds, but says she gets a lot of feedback from outside experts.

She acknowledges the difficulties in 100% compliance with any mandatory reporting efforts. “It's not perfect,” she says. “I talk a lot with other states that have similar laws, and the underreporting question is something that everyone struggles with.”

### **AHRQ efforts to centralize reporting**

The Agency for Healthcare Research and Quality (AHRQ) is responsible for administering the provisions of the Patient Safety and Quality Improvement Act of 2005, which authorized the creation of patient safety organizations (PSOs) to collect voluntary reporting data from health care facilities to counteract the two big impediments to reporting: confidentiality and isolated data with no ability to aggregate and compare. The Department of Health and Human Services issued interim guidance in early October to implement the act and to allow organizations to apply to act as a PSO. Final guidance is expected at the end of the year.

“It's exactly where we needed to go,” Simmons says of the PSO initiative. “The fact that it's taken us 10 years to get there is really sad.”

Hyman sees one issue with the PSO roll out:

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duplication. If you're in state that requires reporting and if you also decided to report to a PSO, you're reporting to many agencies — the state, the PSO, the FDA, your risk management committee, The Joint Commission, CMS, etc. — and often you're reporting similar things to more than one place, he says. If only there was one online checklist, he adds wistfully and only half joking.

*(Editor's note: For more information about AHRQ's PSO roll out, go to [www.pso.ahrq.gov/](http://www.pso.ahrq.gov/).)* ■

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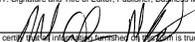
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