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Cost of privacy rules could dwarf Y2K, experts say

One estimate puts the 5-year cost to hospitals at $43 billion, but true cost will go higher

The Y2K computer problem may have cost U.S. hospitals billion of dollars to fix, but many experts now claim hospitals haven't seen anything yet. Looming on the horizon, and largely ignored by mainstream media and many hospital administrators, is a regulatory cost potentially many times larger than the Y2K bug.

The challenge: effectively implementing the provisions contained in the Health Insurance Portability and Accountability Act (HIPAA) of 1996. **Karen Milgate**, senior associate director for policy development at the Chicago-based American Hospital Association, says that although her organization hasn't yet performed a detailed cost analysis of HIPAA, it's apparent that the expense to hospitals could dwarf that of Y2K. Although no one's yet set a price tag for all of HIPAA's provisions, the Chicago-based Blue Cross and Blue Shield Association estimates that the HIPAA-mandated confidentiality regulations proposed by the Department of Health and Human Services will cost the industry $43 billion. Meanwhile, the Health Care Financing Administration (HCFA) has projected the massive industry effort to comply with HIPAA will generate government savings of $1.5 billion from HIPAA over the same time.

HIPAA encompasses three main areas: administrative simplification, security standards, and privacy standards. Administrative simplification includes standardization of transactions, including formats for claims and claims attachments; new, unique provider identifiers; and possible changes

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in CPT code sets. The security standards outline a lengthy list of administrative and technical safeguards that hospitals would have to put in place to ensure the security of information in their systems. The privacy standards — which experts say are likely to generate most of HIPAA's enormous cost — go well beyond the security standards.

"The privacy standards as proposed basically establish rules for every single use and disclosure of information for hospitals," Milgate says. "It's likely to be the most expensive piece, simply because it's so broad. I mean, you're talking about establishing new procedures for how much a physician can say to a nurse, for example. There's another standard that says you can only use or disclose the minimum amount of information necessary to accomplish the purpose for which you're using or disclosing the information, and they specifically state that they want it to apply in individual situations."

Because the privacy rules are so far-reaching, hospitals will likely have to perform an exhaustive and complicated analysis just to determine exactly which rules apply to them, Milgate says. Further complicating the issue is the fact that while HIPAA pre-empts state privacy laws, it does so on a limited basis. "It's a fairly low pre-emption, meaning that a lot of state laws will still apply," she says. "So this really doesn't create standardization across states. What it does is just add another layer of complexity, because you have to take into account the laws in all the states you work in, then throw the federal rules on top and see how they match up."

After figuring out exactly which laws apply specifically to your facility or system, you'll need to decide which of your policies to change regarding disclosure and patient notification and what kinds of authorization forms you need to develop. For example, "there's a requirement that you track your disclosures and that you make that record available to patients," Milgate says. "There are patients' rights in terms of inspecting, copying, and amending those records. That may be new for some hospitals. There's a whole host of new processes and procedures, so you can see why we don't really know how to cost it out yet. But we know it's a lot. It's tremendous."

Gwen Hughes-Wright, RHIA, practice manager at the American Health Information Management Association in Chicago, agrees that the cost of HIPAA will likely vary among hospitals in different states, depending on how stringent their state privacy laws are. "For example, in Washington State, patients have access to their records, and

HIPAA Implementation Timetable

Standard	NPRM[1] Published	Expected Final Rule Publication	Expected Date Compliance Required
Transactions and code sets	5/07/1998	3/2000	5/2002
National provider identifier	5/07/1998	6/2000	12/2002
National employer identifier	6/16/1998	3/2000	5/2002
Security	8/12/1998	5/2000	7/2002
Privacy	11/3/1999	Unknown	Unknown
National health plan identifier	4/2000 (expected)	4/2001	6/2003
Claims attachments	3/2000 (expected)	10/2000	12/2002

[1]Notice of Proposed Rule Making.

Note that standards are required to be implemented within two years of the effective date of the final rule. The effective date is generally 60 days after the final rule's publication.

there are notices posted. The state law has already defined how patients can access records and how to correct things. But in other states, particularly in the South, patients don't yet have that right. So it kind of depends on what regulations you've been operating under as to how big a change this is, and therefore how much you're going to have to spend making that change."

A major concern among HIPAA analysts is the fact that many hospitals haven't even begun to devote resources to the problem. Hughes-Wright says that many facilities focused on Y2K over the past two years to the exclusion of HIPAA. Another reason why HIPAA has been relegated to the back burner at many facilities is that final rules for the various components of the law haven't been published yet. **(See HIPAA timetable, above.)**

"It's always hard for us to say exactly what people need to do when we don't know exactly what the rules are," Milgate says. "We know that some of the proposed rules aren't going to change very much, but the privacy one is relatively new. It came out in November [1999], and it's massive. We're just now talking to our members about what this means for them."

Even without a final rule, however, there are things you can do now to prepare for HIPAA — before the official clock starts running. Indeed, experts say if you haven't started getting ready, you may already be playing catch-up. After the final rule is published, there's likely to be a 60-day grace period before the effective date of the rule. After that, hospitals probably will have no more than two years to achieve full implementation.

If your hospital isn't in compliance when time runs out, penalties can be steep. The civil monetary penalty for violating transaction standards is up to $100 per person per violation, up to $25,000 per person per violation of a single standard for a calendar year. The penalty for knowing misuse of health information can run up to $250,000 and imprisonment for up to 10 years.

Hughes-Wright emphasizes that many of the things included in the proposed rules "are good things to do anyway, like letting patients know what your information practices are. Those sorts of things you can do, and even if the final rule never came out, they would still be good things to do."

Hughes-Wright recommends that someone at the facility work to become a HIPAA expert. "That way, even if not all of the elements pass, you can move forward more quickly," she says. "You should also pick out the things you can do now as opposed to waiting, and decide what things you want to do anyway." She specifically advises that hospitals start taking action on issues such as patient access to records, establishing procedures for correction and amendment of records, and maintaining records of release.

Milgate recommends performing an assessment of where you currently stand with your security and privacy policies. That way, no matter what the final rule says, you'll be able to move more quickly in adapting to the HIPAA requirements.

It's also important to remember that wholesale changes in the HIPAA rules aren't likely, although the AHA remains hopeful that it can force some revision or at least clarification regarding the privacy standards. The proposed rules "probably give the general direction things are going to go," Milgate says. "Like, [the proposed rules] say you have to have a privacy officer. Well, do you have

an individual who is specifically identified with the responsibility for privacy policies? What kind of training do you already do? What kind of access do you give different levels of employees within the hospital? Those are the kinds of things you can already look at."

It's important to note that, technically, the HIPAA provisions apply only to electronic records. But in practical terms, "it's going to be too hard to separate out the information that falls under the law and the information that doesn't," Hughes-Wright says. "So I imagine we're going to find ourselves treating all information the same, whether it's paper or electronic." ■

New ORYX measures mean more work for you

Measures reflect those already used by PROs

At its Feb. 4-5 meeting, the Oakbrook Terrace, IL-based Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) Board of Commissioners approved 25 new core performance measures as part of the organization's troubled ORYX initiative. While the dust hasn't settled yet, some observers are already concerned that the process-level measures will increase the burden on quality managers charged with collecting ORYX data.

The core measures, grouped into the five focus areas the Joint Commission identified last year, include: eight measures under acute myocardial infarction; seven under community-acquired pneumonia; five under heart failure; three under pregnancy and related conditions; and two under surgical procedures and complications. **(See a breakdown of the new core measures, p. 33.)**

"A large number of these measures are the same ones used by the peer review organizations that contract with the Health Care Financing Administration," says **Becky Miller**, director of performance measurement and quality at the Missouri Hospital Association (MHA) in Jefferson City. "On one level, I think that's good, because it means we're not reinventing the wheel with these measures. But these are process-level measures, which means they're a little more difficult to collect."

The MHA and a coalition of other hospital associations have been in talks with the Joint Commission about phasing the new measures in slowly, with some of the easier-to-collect measures phased in first. "I think that would help," Miller says. "But there are a lot of details that aren't entirely ironed out. I do think that we're continuing to have an open dialogue [with the Joint Commission] to discuss these issues. They seem to be responsive, from my perspective."

Even so, Miller is concerned about the number of measures staff might have to collect at one time. "And also the resources that will be required to get medical record-level data. We don't have all the questions answered yet."

Despite that concern, even the strongest critics of the Joint Commission's ORYX initiative have recently tempered their attacks. Only a year ago, 17 hospital associations, including the MHA, sent a fiery letter to the Joint Commission expressing their dissatisfaction with ORYX and threatening to halt participation in the initiative unless the organization listened to their demands and took input from individual hospitals. **(See "Joint Commission Jettisons ORYX Plus in favor of core measures reporting," *Hospital Peer Review*, August 1999, p. 117.)** As a result of that letter, JCAHO president Dennis O'Leary formed a nationwide Core Measurement Implementation Task Force to offer recommendations regarding ORYX measures.

"[The task force] has met periodically and has provided a significant amount of input to the Joint Commission," Miller says. And to its credit, "the Joint Commission seems to have listened to them. I think the group has been able to impact some of the decision making there."

Miller says one of the most positive developments to come out of the state hospital associations' talks with the Joint Commission has been the appointment of five pilot states in which to test new core measurements. "Missouri is one of those pilot states," Miller says. "We're pleased because this will give us a small group to work on these measures before they're taken out across the whole United States."

Hospitals will have until September 2001 to select two of the new measurement sets, after which they won't have to collect any more data on non-core measure requirements. (Until now, hospitals participating in ORYX were required to collect data on up to six non-core measures.)

After September 2001, hospitals will have four months to collect data on a subset of care measures within the two measurement sets they've selected. By Jan. 1, 2003, hospitals must have collected data on all of the core measures in the measurement sets they chose. ■

The Joint Commission's 25 new ORYX measures

Acute Myocardial Infarction (AMI)

• **Smoking Cessation Advice/Counseling** — AMI patients with a history of smoking who are given smoking cessation advice or counseling during hospitalization.

• **Aspirin at Arrival** — AMI patients who are given aspirin within 24 hours of arrival or within 24 hours prior to arrival at the hospital.

• **Reperfusion Therapy: Time from Arrival to Initiation** — Timely reperfusion (opening blocked arteries) of eligible AMI patients; time from arrival to initiation of thrombolysis medication administration or primary percutaneous transluminal coronary angioplasty procedure.

• **Aspirin at Discharge** — AMI patients who are prescribed aspirin at discharge from the hospital.

• **Beta Blocker at Arrival** — AMI patients who receive beta blocker medication within the first 24 hours of arrival to the hospital.

• **LVEF < 40% Prescribed ACEI at Discharge** — AMI patients with low left ventricular ejection fraction (LVEF, an index of how well the heart functions) who are prescribed an angiotensin-converting enzyme inhibitor (ACEI) medication at discharge from the hospital.

• **Beta Blocker at Discharge** — AMI patients who are ideal candidates for beta blocker medication who are given a prescription for beta blockers at discharge.

• **Intrahospital Mortality** — Patients with a primary diagnosis of AMI who expire during hospitalization.

Heart Failure

• **Patients with Atrial Fibrillation Prescribed Warfarin at Discharge** — Heart failure patients with atrial fibrillation (irregular heartbeat) who are given a prescription for oral anticoagulation therapy (warfarin) at discharge from the hospital.

• **Diet/Weight/Medication Management Instructions at Discharge** — Heart failure patients who receive patient education (as documented on their written discharge instructions) regarding all of the following: all discharge medications, weight monitoring, diet, activity level, follow-up appointment, what to do if symptoms worsen.

• **Assessment of Left Ventricular Function** — Heart failure patients not admitted on ACEIs or angiotensin receptor blocking (ARB) agent medications who have LVEF evaluated before or during admission.

• **LVEF < 40% Prescribed ACEI at Discharge** — Patients with low LVEF who are prescribed an ACEI medication at discharge.

• **Smoking Cessation Advice/Counseling** — Heart failure patients with a history of smoking who are given smoking cessation advice or counseling during hospitalization.

Community-Acquired Pneumonia

• **Pneumonia Screen or Pneumococcal Vaccination** — Patients age 65 or older who are screened for or given pneumococcal vaccination during hospitalization.

• **Smoking Cessation Advice/Counseling** — Pneumonia patients with a history of smoking who are given smoking cessation advice or counseling during hospitalization, or advice or counseling is given to pediatric caregiver about effects of second-hand smoke.

• **Oxygenation Assessment** — Patients who receive oxygenation assessment (determine amount of oxygen in blood) within 24 hours of hospital arrival.

• **Blood Cultures** — Of patients who have blood cultures collected, those who have them drawn prior to first dose of antibiotic administration in the hospital.

• **Antibiotic Timing** — Time in hours from initial presentation at hospital to first dose of antibiotics.

• **Empiric Antibiotic Regimen Non-ICU** — For pneumonia patients not admitted to an ICU, the antibiotic given is consistent with current consensus guidelines (e.g., the American Thoracic Society, Infectious Disease Society of America, and the Centers for Disease Control and Prevention).

• **Empiric Antibiotic Regimen ICU** — For pneumonia patients admitted to an ICU, the antibiotic given is consistent with current consensus guidelines (e.g., the American Thoracic Society, Infectious Disease Society of America, and the Centers for Disease Control and Prevention).

Surgical Procedures and Complications

• **Surgical Site Infection Within 30 Days (for selected surgical procedures)** — Patients undergoing selected surgical procedures who develop a surgical site infection within 30 days of the procedure.

• **Timing of Prophylactic Administration of Antibiotic** — Timing of when patients were given prophylactic intravenous antibiotic administration for selected surgical procedures.

Pregnancy and Related Conditions

• **VBAC Rate** — Patients who have had a cesarean section who have a vaginal delivery.

• **Third- or Fourth-Degree Laceration** — Patients who have vaginal deliveries with third- or fourth-degree laceration.

• **Neonatal Mortality** — Infants who expire within 28 days of birth.

Root-cause software: Look before you leap

Ensure software's logic is compatible with yours

Your facility probably doesn't use computer software to handle its root-cause analyses of sentinel events, but odds are good that in the not-too-distant future, the issue won't be whether to use it, but which software package to choose.

Currently, only about 1% of hospitals use a designated software package to handle root-cause analyses, says **Charles Jones**, president of Long View, TX-based Decision Systems, maker of the software program Reason. That's primarily because the leading root-cause analysis software products — some of which have been around for a decade — were developed for use in the areas of engineering, manufacturing, and accident investigation in other industries. Until recently, no one had thought to gear these products specifically to the needs of the health care industry.

"In certain [products], the terminology is so arcane as to be mind-boggling," says **Kenneth A. Hirsch**, MD, PhD, medical manager for inpatient mental health and continuous quality improvement coordinator for mental health services at the Naval Medical Center in San Diego. The problem is that some of the companies that produce root-cause analysis software "don't have people who are able to speak medical risk management or medicine," Hirsch adds. "None of the three leaders developed their products in conjunction with anyone who is medically oriented. That doesn't mean that the processes that underlie [the software] are not good. But it does mean that they do not have a very good understanding of the specific needs of the health care industry. It's very clear when you open it up and you find terms like 'latent causality' and somewhat arcane mathematical terminology, that this isn't something that the OR nurse is going to make sense out of or even want to."

Further, some of the software systems developed for other industries don't generate graphics. "That's a problem, because it means that you then have to use a different program to develop the process flowcharts that the Joint Commission rightly wants to see," Hirsch says.

This state of affairs is already changing, however, as software companies like Decision Systems (Reason), Hopewell, VA-based Reliability Center, (PROACT), and Knoxville, TN-based System Improvements (TapRooT) continue to develop and refine their products for use in the health care industry. **(See partial list of root-cause analysis software packages, p. 35.)** And despite sometimes steep learning curves, there are a number of advantages to taking an automated approach to conducting root-cause analyses, the developers contend.

For example, Jones says, "At the user level, the procedures and the formats that produce accurate data are geared into and imbedded in the software, so that using a software [system] tends to guide and to filter out erroneous information." Jones adds that software can also help in "transferring knowledge" to other staff members. "If you have software in-house, several people can leave your organization, but by using the same software, they'll find that there's continuity in the reporting and in the data, because it's imbedded in the software itself."

Also, root-cause analysis software stores information electronically, allowing for easier access. "And if it's tied into a proper kind of 'lessons learned' system, it provides a wonderful resource for data, so that mistakes made in the past need not be repeated," Jones says.

"Basically, it gives you a standardized process," Hirsch adds. "Anytime you have a standardized process for anything, it means that you then have some organization. You can control the process and make sure that it meets the criteria that you as an organization have established."

Software can guide disparate personnel

Also, in many facilities, no one person has full-time responsibility for conducting root-cause analyses. "You're going to have practitioners, clerical people, security guards, logistical personnel, and others — people with jobs that have nothing to do with a root-cause analysis," says Hirsch. "And while it's possible to conduct a root-cause analysis with an effective team leader and facilitator, "good software will guide the team as a whole in how it should conduct a root-cause analysis. It will tell them what tools to use and when to use them."

The advantage of this, Hirsch says, is that once a facility starts doing root-cause analyses well, it tends to do more and more of them. "The threshold for doing them drops, and the reason is that it's a very value-added process or endeavor."

Even so, it's important to note that there are also potentially serious drawbacks to taking an automated approach to root-cause analysis. First, the logic structure — the set of assumptions and values that underlie an individual software program — might not square with your own ideas (or the Joint Commission's) of how a root-cause analysis should be conducted and what factors should be considered.

"If one is going to judge the value of a software root-cause analysis product, you have to know what the process is that it utilizes," Hirsch stresses. "Some are going to be good, and some are going to be bad. If you happen to buy a software root-cause analysis tool or product that is based on a not-very-good analytic process, the quality of your analysis is going to be poor." Hirsch adds that it's easy to be taken in by a software tool that "looks good and feels good" to use. "But if it doesn't have a good process, it will give the illusion of having led a team through an effective analysis when in fact it has not done so."

The solution, Hirsch says, is to ask this question: If you were to conduct a root-cause analysis manually using the procedure contained in the program, would you be comfortable in the belief that you had achieved a good-quality analysis?

Will JCAHO give a seal of approval?

As root-cause analysis software enters the mainstream in health care, some experts already have begun clamoring for some type of certification program to help establish uniform standards for what the software should include. Inevitably, that discussion has centered primarily on the Oakbrook Terrace, IL-based Joint Commission on Accreditation of Healthcare Organizations, whose sentinel event policies opened the gate for the introduction of such software in the health care industry. Jones acknowledges that his company at one point had engaged in talks with the Joint Commission about some sort of relationship, but he doubts anything will come of it.

That's good news to Hirsch, who recently unveiled his own software package, Root Cause Analyst. He says, "If the Joint Commission were to sign a contract with any software developer, we'd probably sue. They'd be establishing a mandate and then partnering in the development and marketing of a software product designed to meet that mandate, and that smacks of conflict of interest."

A better approach, he says, would be for the Joint Commission to establish criteria by which to evaluate all root-cause analysis software products. "Then all of them could compete, and multiple ones could be endorsed," Hirsch says. "That would be very legitimate, but they should have no pecuniary interest in any of them."

Whether or not your facility chooses to go with root-cause analysis software in the near future, Jones and Hirsch agree that it would do well to build uniformity and standardization of procedures into its root-cause analysis process. "So often, we see people using concepts that are nothing more than somebody's opinion, based on brainstorming or group voting, and while all of those systems have some advantages in employee involvement and things of that nature, they usually provide inconsistent and misdirecting information," Jones says. "In my opinion, the health care industry must not fall into the trap of using processes and approaches that are subjective, because people's lives are on the line."

(Editor's note: Next month, we'll follow up with specific advice on how you can choose the root-cause analysis software product that's right for your institution.) ■

A Partial List of Root-Cause Analysis Software Products

- **PHA-Pro**, marketed by Dyadem International Ltd., Markham, Ontario. Telephone: (905) 940-1600. Web site: www.dyadem.com.
- **PROACT**, marketed by Reliability Center, Hopewell, VA. Telephone: (804) 458-0645. Web site: www.reliability.com.
- **Reason**, marketed by Decision Systems, Longview, TX. Telephone: (903) 236-9973. Web site: www.rootcause.com.
- **TapRooT**, marketed by System Improvements, Inc., Knoxville, TN. Telephone: (423) 539-2139. Web site: www.taproot.com.
- **FaultTree+**, marketed by Item Software Corporation, Hampshire, UK. Telephone: +44 (0) 1489 885085. Web site: www.maintainability.com/safety.html.
- **CARA-FaultTree**, marketed by SINTEF Industrial Management, Trondheim, Norway. Telephone: +47 73 59 27 56. Web site: www.sintef.no/sipaa/prosjekt/cara/cft.html.
- **Root Cause Analyst**, marketed by Medical Risk Management Associates, LLC, San Diego. Telephone: (800) 324-7966. Web site: www.sentinel-event.com.

Joint Commission veers from hard-line approach

Shady Grove retains accreditation after all

Two separate actions taken last month by the Joint Commission on Accreditation of Healthcare Organizations have some JCAHO-watchers wondering if the organization isn't already backing away from its apparent get-tough response to last year's Office of Inspector General (OIG) report.

Until recently, some complained that the Oakbrook Terrace, IL-based Joint Commission had over-reacted to the OIG report and to criticism that the organization had become too friendly with the industry it was set up to oversee. Of particular interest was the organization's decision in December 1999 to revoke the accreditation of Shady Grove Adventist Hospital in Rockville, MD. Following the preliminary non-accreditation ruling, Shady Grove officials argued publicly that the Joint Commission had judged the hospital too harshly, punishing it for relatively minor infractions in order to blunt recent criticism.

Prior to the Shady Grove ruling, 100 hospitals had been hit with preliminary non-accreditation status over the past three years. Of those hospitals, however, 39 ended up receiving "a different accreditation decision," says **Donna Larkin**, a JCAHO spokeswoman. Of the remaining 61, Larkin acknowledges that some had simply dropped out of the accreditation process, while others may have merged with or been acquired by another entity. Even considering those "drop-outs," less than 1% of hospitals received non-accreditation status.

In light of those numbers, many interpreted the Joint Commission's stern handling of Shady Grove as a sign that the gloves had come off. But at a meeting on Feb. 3, the Joint Commission's Accreditation Committee ruled to upgrade Shady Grove to "conditional accreditation" status, meaning that the hospital must pass a random, unannounced survey within 90 days to keep its accreditation status.

Not surprisingly, Shady Grove officials have backed off their earlier criticism of the Joint Commission's motives. "I think as we came together and began to work with the Joint Commission in our appeal, we came away feeling that [JCAHO] worked very hard with us to ensure that we had fair and impartial hearings," says **Robert Jepson**, regional director for communications for Adventist HealthCare in Rockville, MD. "And we feel that was achieved."

Don Nielsen, MD, senior vice president for quality leadership at the American Hospital Association in Chicago, has sympathy for the Joint Commission and the difficult course it's trying to steer. "It is a schizophrenic role in some ways that the Joint Commission plays," he says. "They have a regulatory role, but also an accreditation role based on quality improvement, and I think that to a degree there is always some ambiguity, or at least some strain between the two functions that JCAHO performs. It's not so much that they're trying to take a tougher role as that they're trying to make the accreditation survey process be seen as very credible, very effective, very fair, and very valid."

Public information policy revised

A day after the Accreditation Committee voted to conditionally accredit Shady Grove, the Joint Commission's Board of Commissioners voted to revise JCAHO's public information policy in order to provide more precise information to the public about hospitals hit with non-accredited status. The policy revision will take effect Jan. 1, 2001.

To some hospital personnel, the decision may raise uncomfortable memories of the initial controversy over potential public access to root-cause analyses of sentinel events. But, according to **Harold Bressler**, the Joint Commission's legal counsel, "this is not an analogous circumstance. Nothing in what the board did with regard to the public information policy would in any way suggest that the Joint Commission would disclose anything about the sentinel event root-cause analysis."

Indeed, while the policy revision seems on the surface to address the public's clamor for more information about poorly performing hospitals, in reality, the public won't get much more than what's already contained in publicly available performance reports. The main difference will be in how the information is presented.

"People are talking about having three general categories, which would at least identify the general nature of the decision to deny accreditation," Bressler says. "Again, it doesn't reveal anything specific about sentinel events [and] it doesn't reveal anything more than what's already in a

performance report. The reason for doing it is simply to be more understandable to the public."

Bressler also notes that, "The board did not suggest that we would disclose the specific standard results. So what we're talking about is a description of a standards area that might make more sense and be more understandable that the performance areas now found in the performance report." ■

Part 3 in a 3-part series

How to manage patient grievances

Key steps for your grievance process

By **Patrice Spath**, ART
Brown-Spath Associates
Forest Grove, OR

Ultimate responsibility for resolving patient grievances lies with the hospital's governing board. However, the board members must rely on the recommendations of the people involved in investigating the grievance. In many instances, it is best for the governing board to delegate the operational aspects of the grievance process to a multidisciplinary committee. However, the governing board should make sure the hospital has a clearly defined and impartial process for resolving patient grievances. Not only is such a process required by the Medicare Conditions of Participation (COPs), but it is also an important aspect of quality customer service.

The grievance procedure should encourage open communication between patients and hospital staff on issues, problems, or complaints. Patients must be offered assistance in formulating and submitting grievances and timely resolution of problems. Most complaints may be more effectively addressed and resolved by informal means than by invoking the formal grievance procedure. Still, it must be made clear to patients that they have the right to have their concerns heard by upper levels of management.

The key steps of a grievance process are described below. A two-step review procedure is presented. However, hospitals may choose to shorten the process, as the COPs do not mandate that a particular procedure be followed.

When a formal grievance is received from a patient, a disposition decision must be made. Is the concern one that the hospital must investigate? If the complaint would be more appropriately directed to another facility, group, or individual, then a hospital representative should help facilitate contact between the grievant and the appropriate party. Patients may feel uncomfortable approaching a health plan or another provider with a complaint, and the hospital should assist them in making their concerns known. Some hospitals provide patient advocate or ombudsman services to assist patients and their families with any concerns related to the health care experience.

If the grievance should be reviewed and resolved by the hospital, then the next disposition decision is to determine who should be involved in the initial review of the complaint. Grievance resolution must be timely, and holding a grievance committee meeting for every formal complaint may delay the process. It is especially important that formal complaints about quality of care or premature discharge be resolved very quickly.

In order to act quickly, it is advantageous to have a first-level review process in which a small group of individuals evaluates the situation and makes a determination regarding how the situation can be resolved. This group may include the patient advocate or the person charged with overseeing the grievance process, the chief executive officer or his or her designee, and the director of the department involved in the complaint. If the grievance is about the quality of care provided by physicians or a discharge decision with which the patient disagrees, then the medical director or the physician chief of service should be included in the first-level review discussions.

If the grievance represents an immediate and serious threat to patient health and safety, the organization must have an expedited first-level grievance review process. Otherwise, the group should meet within the time frame defined by the hospital's policies (generally no later than 10 days after the grievance is received). People must be given adequate time to review relevant details about the situation before meeting. At the first-level review meeting, the group should have sufficient information to be able to decide how to handle the grievance. The group should be authorized to resolve a

grievance in any manner it regards appropriate, as long as it does not exceed the lawful authority of the organization. If the group is unable to reach a decision, it may recommend the issue be forwarded to a grievance committee that is composed of broader representation.

It is hoped that most grievances can be resolved in the first-level review process. On rare occasions, a grievance committee may need to be appointed to resolve first-level review deadlocks or when the grievant requests a reconsideration of the initial decision. It is up to the hospital leaders to decide which departments and disciplines should be appointed to serve on this committee. If the hospital has a formal ethics committee, this group could be charged with investigating and rendering second-level decisions on complaints. If the hospital lacks an ethics committee, the grievance committee could be established as a task force of the governing board.

Ensure grievance committee's impartiality

The members of the grievance committee should not be members of the group who initially reviewed the grievance. It is also important to be sure the members of the grievance committee have no actual or apparent bias or conflict of interest. Examples of conflicts of interest include people who will potentially benefit or lose from a decision and anyone who has previously been involved in any attempted resolution of the complaint.

A problem with many complaint investigation procedures is the perceived lack of impartiality. Dissatisfied patients do not expect or want the people they are complaining about to be the ones deciding the validity of their complaint. The hospital may want to allow patients or their representatives to appear in person before the grievance committee to state their case. Likewise, it may be helpful to include as a grievance committee member someone from the clergy and/or a community representative who is not affiliated with the hospital in any way. The committee can ask other people to provide information pertinent to the complaint. Such information may be provided in person or in writing. All parties should be given a full and fair opportunity to respond to all information gathered by the committee.

When grievance committee members are satisfied that they have adequate information, they should reach a consensus decision. If the committee is unable to reach a decision, it may recommend the formation of a new grievance committee to re-hear the dispute, or the issue may be forwarded to the governing board for final resolution.

When a final decision is reached, a written response is provided to the patient who initiated the grievance. This response should include a restatement of the issue under inquiry, the date the review process was completed, the steps that were taken to investigate the complaint, the final decision of the review group, and any corrective actions the facility may be implementing. If the issue involves quality of care or premature discharge, be sure to remind the patient of other avenues for voicing concerns (e.g., state regulatory agencies, professional review organization, Health Care Financing Administration, etc.). Remember to provide a phone number and address for each group that may be mentioned in the letter.

The response letter should also explain the process for reconsideration if the patient is unhappy with the results of the investigation. If the patient is still not satisfied with the proposed resolution of a grievance, the organization may choose to provide additional opportunities for further consideration, or the decision may be final at this point. Be sure the information you provide to patients about your grievance process clearly defines the number of reconsiderations that are allowed. Generally, only one reconsideration is allowed unless the patient can show evidence of bias and/or procedural irregularities or if new information not previously available comes to light.

There should be a process for tracking each grievance until its final resolution. Someone must be responsible for monitoring the grievance review process to be certain that each required step is completed within the time frame specified in the organization's grievance procedures. Also, the hospital's governing board should receive reports of the status of all grievances received, actions taken to resolve disputes, committee recommendations, and the status of corrective action plans.

Over the past year, the public has grown increasingly concerned about protection of patients' rights. Hospitals must respond by implementing a fair and impartial grievance process. Whatever procedure is used to respond to grievances, what's most important is that patients feel they can address problems they identify in the treatment they receive without fear of discrimination or reprisal. ■

NEWS BRIEF

Report cards don't reflect patient variance

Managed care report cards may unfairly penalize providers for patient variances beyond their control, according to a recent study reported in the *American Journal of Medicine.*

Many managed care organizations impose financial penalties on providers who use "excessive" medical services in treating their patients. However, because these report cards often fail to take into account differences in the severity of illness, such report cards may be misleading.

For example, a hospital that does more blood transfusions for hip fracture surgery patients may have a higher proportion of anemic patients than another hospital that uses fewer transfusions for seemingly similar patients, researchers found.

Researchers conducted a retrospective study of 8,776 charts for hip fracture patients 60 and older who underwent surgical hip repair between 1982 and 1993 at one of 19 study hospitals located in four states. They examined transfusion rates among hospitals, patient characteristics associated with transfusion, and whether those characteristics varied among hospitals.

Postoperative transfusion rates varied from 31% to 54% of hip fracture patients among the 19 study hospitals. Without adjusting for differences in patient severity of illness, four of nine teaching hospitals and two of nine nonteaching hospitals had significantly higher transfusion rates than the reference hospital, while one teaching hospital had a lower rate than the reference hospital.

After adjusting for patient anemia and other clinical variables, only one of nine teaching hospitals had rates higher than the reference hospital instead of the original four. However, four of nine nonteaching hospitals had higher rates than the reference hospital, rather than the original two. In addition, four teaching hospitals and one nonteaching hospital actually had lower transfusion rates than the reference hospital.

(See: Poses RM, Berlin JA, Noveck H, et al. How you look determines what you find: Severity of illness and variation in blood transfusion for hip fracture. *Am J Med* 1998; 105:198-206.) ■

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