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Perspectives on health care legal issues

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JCAHO's 2007 National Patient Safety Goals

What hospitals should know

The 2007 National Patient Safety Goals (NPSGs), announced in June by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), promote specific and measurable improvements in patient safety, and highlight areas in health care that JCAHO found to be problematic. The focus is on systemwide solutions to facilitate safe, high-quality care.

High expectations

Each goal includes a set of requirements and implementation expectations. Implementation expectations exemplify how a hospital might comply with a specific goal. The relationship between the implementation expectations and the safety goals is similar to the relationship between JCAHO's elements of performance and its accreditation standards.

Implementation expectations are explicit actions entities can take to achieve compliance. To meet the goal of improved effectiveness of communication among caregivers (Goal 2), for example, one of the implementation expectations is that the person who receives an order or test result information will either write it down or enter it into a computer.

Entities that don't fully comply will be assigned requirements for improvement, in the same way that noncompliance with an element of performance is addressed. Necessary improvement actions will be included in Evidence of Standards Compliance reports. Failure to resolve identified issues may lead to loss of JCAHO accreditation and, ultimately, Medicare participation.

Goals affecting hospitals

The 2007 NPSGs that affect hospitals are:

Goal 1: Improve the accuracy of patient identification. The requirement for this goal is to use at least two patient identifiers when providing care, treatment or services. The rationale is to properly identify the patient as the person for whom the service or treatment is intended and match the contemplated service or treatment to that person. Implementation expectations include labeling containers used for blood or specimens in the presence of the patient. The patient's room number or physical location can't be one of the two required identifiers.

Goal 2: Improve the effectiveness of communicating among caregivers. Ineffective communication is the most frequently cited category of root causes of sentinel events. Thus, the rationale behind this goal is to create effective communication that is timely, accurate, complete, unambiguous and understood by the recipient in order to reduce errors and improve patient safety. Requirements include reading back verbal or telephone orders,



writing down the complete order or test result, and using a standardized list of abbreviations.

Goal 3: Improve the safety of using medications.

This goal recognizes that appropriate drug management systems are critical to ensuring patient safety. It calls for such measures as standardized drug concentrations, creating and reviewing a list of look-alike/sound-alike drugs used by the entity and setting protocols to eliminate errors, labeling all drugs and drug containers (syringes, medicine cups and basins), and verbal and visual verification of medication labels by two qualified individuals when the person preparing the medication isn't the person administering the medication.

Goal 7: Reduce the risk of health care–associated infections. This goal requires compliance with the CDC hand-hygiene guidelines to reduce the transmission of infectious agents by staff to patients. It also requires that all cases of unanticipated death or major permanent loss of function associated with nosocomial infection be handled as sentinel events. This means that a root-cause analysis should be performed to determine why the patient acquired an infection and why he or she died or suffered permanent loss of function.

Goal 8: Accurately and completely reconcile medications across the continuum of care. Patients are at risk during transitions in care (hand-offs) across settings, services, providers or levels of care. Throughout the continuum of care, communication of an accurate medication list is crucial in reducing adverse drug events. Thus, Goal 8 requires hospitals to have a process for comparing a patient's current medications with those ordered while the patient is under the organization's care. Hospitals also must have procedures to resolve any discrepancies, including omissions, interactions and duplications.

Goal 9: Reduce the risk of patient harm resulting from falls. Because falls account for a significant number of injuries in the health care setting, organizations are required to evaluate a patient's

risk for falls and take action to reduce that risk. Appropriate evaluations might include fall history, medications and alcohol consumption review, gait and balance screening, and environmental assessments.

Goal 13: Encourage patients' active involvement in their own care as a patient safety strategy. An important aspect of a culture of safety is communication with patients and families about care, treatment or services. Patients can help avoid errors when they know what to expect. To that end, health care organizations must define and communicate the means for patients and families to report safety concerns, and encourage them to do so.

Goal 15: Identify safety risks inherent in patient populations. A probabilistic risk assessment can help hospitals assess the designs of high-hazard systems, such as chemical engineering plants and space initiatives. This type of assessment looks at events that contributed to adverse outcomes based on previous sentinel events and other data.

Psychiatric hospitals and other entities that treat for emotional or behavioral disorders must also identify patients at risk for suicide, the 11th-most-frequent cause of death in the United States (third most frequent in young people).

More than hospitals affected

While this article focuses on goals that apply to hospitals and critical access hospitals, the JCAHO national patient safety goals also affect several other types of health care providers, such as laboratories, long-term care, behavioral health, office-based surgery, assisted living and home health.

Entities are evaluated for ongoing compliance with the goals, in a manner similar to the JCAHO periodic performance review process for accreditation. Frequently asked questions regarding the NPSGs can be found at www.jcaho.org, along with detailed guidance on how to achieve compliance. <

Use ABNs to bulk up revenue collection

If providers who accept Medicare assignment use an advance beneficiary notice (ABN), they may be able to bill patients for health care services that don't meet medical necessity requirements. Failing to use ABNs when appropriate may result in unnecessary loss of revenue.

When are ABNs appropriate?

An ABN informs the patient of possible or even likely noncoverage *before* a service is performed. It also notifies the patient of his or her financial responsibility if coverage is ultimately denied and shifts liability for payment away from the hospital and onto the patient.

ABNs should be used for items and services that are usually covered by Medicare but are likely to be denied in particular circumstances. Lab tests for certain diagnoses, extended nursing home care, or hospice care for a patient who isn't terminally ill all are examples of such situations. In these cases, ABNs are a prerequisite to billing the patient for what Medicare won't cover.

The ABN also explains that Medicare's denial doesn't mean the item or service isn't needed, and that patients have the right to appeal the decision. This allows patients to make informed choices as to whether to move forward, knowing they may have to pay for the item or service. Additionally, ABNs may prompt patients to inquire as to why Medicare may not pay and how much the item or service will cost, thus helping them become even better informed health care consumers.

If a patient refuses or is unable to sign an ABN, the provider must decide whether to go forward with the service at the risk of receiving no payment for it. Often, a physician deems the service appropriate or necessary and orders it regardless of whether Medicare coverage is likely.

EMTALA creates conflict

An ABN may be of limited value when the Emergency Medical Treatment and Active Labor Act (EMTALA) applies. EMTALA requires hospitals to provide — without first asking about ability to pay — appropriate screening and stabilizing treatment for an emergency medical condition to anyone who presents to an emergency room. In stark contrast, hospitals must have ABNs in hand before any treatment is provided that Medicare might deny.

This conflict has resulted in loss of revenue for hospitals trying to comply with both laws while treating patients who have potentially life-threatening conditions. Medicare generally covers patients who come to an emergency room with a medical emergency, but frequently doesn't reimburse hospitals



when screening examinations find only nonemergency medical conditions.

In these situations, hospitals may not bill patients for the services if no ABN was provided, but they can't seek an ABN when EMTALA applies. This can create a Catch-22 situation that is typically resolvable only by writing off the cost of care.

Excluded services

When contemplated services are *always* excluded from Medicare coverage, ABNs aren't necessary. Patients who receive those services (such as routine physical checkups, hearing aids, cosmetic surgery unrelated to the prompt repair of accidental injury, certain screening examinations or routine dental care) may be billed for those services without receiving advance notice of noncoverage.

Patients are expected, to some extent, to know the limits of their coverage. Providers, too, should be familiar with Medicare coverage limits before they initiate treatment.

Because the ABN must be provided before treatment begins, providers need to know what services Medicare will or will not cover (and keep abreast of changes in coverage), as well as statutorily excluded services for which ABNs aren't needed. A complete list of excluded services can be found at 42 CFR Section 411.15. Medicare's Web site (www.medicare.gov) has more information.

It's important to note that the facility that furnishes, bills and collects for the item or service is ultimately responsible for providing an ABN. Thus, physicians may give ABNs for the items or services they order; but, if a hospital furnishes the service, it is liable for payment when an ABN isn't given.

Does the patient understand?

Obtaining an ABN is similar to obtaining informed consent, in that both processes are designed to provide treatment options and result in informed decisions. The key to the validity of both is whether the patient is able to comprehend the information being presented.

If the patient's mental capacity is diminished to the point that it prevents meaningful understanding of noncoverage and financial liability, the provider may not be precluded from billing the patient. That being said, the provider may also elect to give the ABN to the patient's legal representative, such as the power of attorney (POA) or legal guardian, if one exists, and move forward on their instructions.

When deferring to a surrogate decision-maker, however, providers should request documentary verification of that person's legal status and keep a copy of it in the patient's chart. They also should review state law to determine whether certain family members are authorized to make decisions on behalf of a patient, even without a formal POA or guardianship. Generally, court-appointed guardians and POAs trump family members, but it may be necessary to consult with legal counsel to clear up any questions regarding the appropriate authority of a surrogate decision-maker.

Find the right words

Finally, wording an ABN form is important. To ensure compliance, it's best to use the forms provided by CMS. They can be downloaded at www.cms.hhs.gov/BNI.

The Advance Beneficiary Notice–General Use (ABN-G) must be used by providers, physicians, practitioners and suppliers for most situations — including lab tests — in which Medicare is expected to deny payment. The Advance Beneficiary Notice–Laboratory Use (ABN-L) is used when laboratory services are the only services being delivered.

Maximize collections for care

Despite the complexities surrounding ABNs, it's worth providers' while to stay informed, and to initiate the ABN process when relevant. Doing so can help maximize the dollars they collect for the care they provide. <

Employee fraud education is mandatory under DRA

An often-overlooked provision of the Deficit Reduction Act of 2005 (DRA) requires certain health care providers and entities to have employee fraud education programs in place by Jan. 1, 2007, as a condition of payment under Medicaid.

While the act's chief goal is to achieve savings in the Medicare and Medicaid programs, it also imposes mandatory false claims recovery education requirements on entities that receive or make annual Medicaid payments of at least \$5 million. At the state level, DRA offers financial incentives to encourage states to enact their own false claims legislation, preferably with laws that are comparable to the federal False Claims Act.

DRA requirements

The DRA requires all qualifying entities (those with at least \$5 million in Medicaid business per year) to have the following in place as of Jan. 1:

Written policies and procedures on fraud, waste and abuse. These should be distributed to all employees (including managers), contractors and agents. They must provide a detailed discussion of:

- > The federal False Claims Act,
- > Federal administrative remedies for false claims and statements,
- > Any state laws pertaining to civil or criminal penalties for false claims,
- > Statements and whistleblower protections under such laws, and
- > The role of these laws in preventing and detecting fraud, waste and abuse.

Written policies and procedures detailing the entity's methods for detecting and preventing fraud, waste and abuse. These should be distributed to all

employees and should include policies on internal and external auditing practices, training on how to identify fraud and abuse issues, and sanctions for failure to comply.

A section in the entity's employee handbook on fraud, waste and abuse. This must provide a specific discussion of the laws described above, highlight the right of employees to be protected as whistleblowers, and summarize the entity's policies and procedures for detecting and preventing fraud, waste and abuse.

Enforcement via MIP

DRA created the Medicaid Integrity Program (MIP) to assist with enforcement. The MIP's goal is to reduce erroneous payments and identify Medicaid overpayments. Under the MIP, CMS will contract with private entities to:

1. Review actions of health care providers receiving Medicaid payments to determine whether fraud, waste or abuse has occurred or is likely to occur,
2. Audit claims for payments under state Medicaid plans,
3. Identify overpayments to individuals or entities receiving Medicaid funds, and
4. Educate providers, managed care entities and beneficiaries on payment integrity and quality of care.

Protect yourself

Providers that serve a large number of Medicaid patients should take note of the new employee education requirements, because failure to comply carries significant liability. Entities that don't establish or review their programs could be barred from submitting Medicaid claims and be subject to false claims liability. <

Prepare now to meet pandemic flu head on

Public health experts warn that pandemic flu could strike as many as 67 million Americans, with death tolls between 200,000 and 2 million, if the H5N1 (bird flu) virus mutates to pass easily among humans. Rough estimates indicate that an outbreak could cost between \$70 million and \$160 million in lost productivity and direct medical costs.

Preparation for a public health emergency such as pandemic flu takes immense planning and may require revisiting existing plans.

Legal issues likely

Several legal issues are likely to arise in the event of a pandemic. The parameters of governmental authority is one. Others are:

- > Quarantine and isolation,
- > Contingency plans for becoming a quarantine facility,
- > Reimbursement and standard-of-care,
- > Procedures to maintain EMTALA compliance during capacity surges,
- > Ensuring that current and added providers are appropriately credentialed,
- > Efficiently creating and using volunteer resources,
- > Properly reporting to government health departments, and
- > Global triage procedures for allocating scarce resources, such as ventilators.

Health care facilities may wish to consult federal and state resources and legal counsel



for assistance in addressing these issues. They also should review and modify health care delivery drills and triage policies to help them prepare for increased need and decreased staff and supplies.

Learning from the past

Many lessons can be taken from past public health emergencies, including Hurricane Katrina and SARS. Disasters are unpredictable and often take a long time to overcome. Thus, facilities must contemplate long-term disruption to all areas of operation.

Emergency communication systems are critical and should be updated for adequate coverage. In addition, facilities should consider alternative decision-making protocols and assigning a task force to deal with preparedness and implementation. Human resource plans should be bolstered to address potentially significant staffing shortages, and decisions should be made about sick leave, absenteeism and FMLA.

A proactive approach

Preparedness is crucial in responding to a disaster, and, if history serves as an example, governmental guidance and assistance may be less than optimal. Public health emergencies can take many forms. Whether it be bird flu, an act of terror or a natural disaster, the health care industry must take a proactive approach to readiness. <

A message to our clients and friends:

Hall Render is pleased to provide you with this issue of *Practical Health Law*. This newsletter will be sent to you bi-monthly compliments of our health law attorneys; each issue will also be housed in the **Articles and Newsletters** section of www.HallRender.com.

We understand the value of good information when making sound business decisions. *Practical Health Law* is written by Hall Render's health law attorneys, each with extensive experience handling the legal issues of health care providers. We trust the information in each issue will be a valuable resource. Our attorneys stand ready to respond promptly to your questions and needs; please contact us if there are specific topics you'd like to see addressed.

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