OIG mulls anti-kickback implications of economic credentialing

Beware if your hospital requires competing physicians to refer a certain amount of business to the hospital before granting them clinical privileges. This requirement may constitute a violation of the Social Security Act’s anti-kickback statute, the Bush Administration has hinted.

The U.S. Department of Health and Human Services’ Office of Inspector General (OIG) officially began to weigh this controversial practice, known as “economic credentialing,” on February 7, when the public comment period expired for input on a series of questions it posed in the Federal Register in December 2002.

If the OIG determines that anti-kickback implications are associated with economic credentialing, it would expose hundreds of hospitals to potential criminal charges and nearly “limitless liability” under the False Claims Act, legal experts say.

Therefore, if your organization engages in economic credentialing, you need to know the key areas that the OIG is looking at.

Five ways to prevent would-be whistleblowers

Angry patients aren’t the only people who sue hospitals. Disgruntled employees also pose a substantial risk for filing whistleblower lawsuits. And just like their malpractice-alleging counterparts, they have a strong financial incentive to do so.

The U.S. False Claims Act allows private individuals, known as “relators,” to file suit on behalf of the U.S. government against entities that they believe have defrauded the government of received Medicare, Medicaid, or other public funds.

Such lawsuits, known as qui tam actions, are now the U.S. Department of Justice’s (DOJ) top fraud-busting tool. Almost 70% of its civil division’s fraud caseload consists of qui tam cases, according to U.S. Assistant Attorney General Robert McCallum Jr., who addressed the American Health Lawyers Association annual meeting in September 2002.

Consider this: More than 60% of the $10 billion that the federal government has recovered in false claims since 1986 has been the direct result of
Economic credentialing

examining for possible anti-kickback implications.

Where the OIG stands
The OIG has already offered its own bits of commentary. Embedded in the agency’s initial request for comments are clear statements about how it regards the practice.

“Categorically” refusing privileges to physicians who own or invest in competing entities, such as ambulatory surgical centers or specialty hospitals, would not violate the statute “in most situations,” the agency stated in the December 9, 2002, Federal Register. Placing conditions on such refusals, however, by privileging some competing physicians as long as they bring in a certain amount of referred business, would raise “substantial” anti-kickback risks, the OIG wrote. However, the agency did show a willingness to consider whether certain safeguards could allow such practices without implicating the statute.

The growing controversy
Economic credentialing has become a contentious issue over the past decade as more physicians have banded together to form for-profit health care entities that directly compete with hospitals.

Hospitals have responded by conditioning their privileges in some way, often by refusing to privilege physicians who

• own or otherwise have financial interest in, or a leadership position with, a competing health care entity
• refer patients to competing entities
• fail to admit a specified percentage of their patients to the hospital

Some physicians and organizations, including the American Medical Association, say such practices illegally induce referrals for the hospital by rewarding loyal physicians with access to more patients. Others, including several attorneys who forwarded their own comments to the OIG, contend that privileges are not remuneration, but rather a two-way street of corresponding obligations between the hospital and physician.

Hospitals have to take economic factors into account, they say, or they will not be able to exercise their community obligation of economic viability. Anti-trust laws and Medicare’s Conditions of Participation are a more appropriate way to regulate credentialing, they argue.

The OIG seems to agree with this latter point. Included in its Work Plan for 2003 is a planned review of “hospital privileging activities within the context of Medicare Conditions of Participation.” It also refers to privileging as “one of the most fundamental internal safeguards” that hospitals have. The OIG released the plan in 2002.

Legal experts don’t expect the OIG to resolve the issue much earlier than next year, with guidance coming in the form of a Special Fraud Alert or a new safe-harbor regulation. In the meantime, the agency will review the comments it has received.

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Questions the OIG will tackle
The following is a list of issues that the OIG hopes to clarify with regard to the False Claims Act:

- **Staff privileges as “remuneration”**
  Whether privileges have any kind of monetary value is one of the first questions the OIG will tackle, since the anti-kickback statute prohibits the offering or transfer of remuneration with the intent to induce referrals for Medicare services. Past OIG advisory bulletins have defined remuneration to include “anything of value.” The agency, therefore, will examine how the value of privileging could be defined and whether it might vary depending on the market in which a hospital operates.

- **Evaluating conflicts on a case-by-case basis**
  What are the implications of a hospital denying privileges to a physician who competes with it? The OIG made it clear in the *Federal Register* that basing a competing physician’s privileges on his or her referral volume is legally risky. However, it wondered whether “sufficient safeguards” could exist to allow such a criterion to be used.

- **Referrals as a privileging condition for all physicians**
  The OIG acknowledged that privileges could be conditioned on referrals if they are based on the minimums necessary for clinical proficiency. It is less clear whether other criteria could also be used. If privileges have monetary value, the OIG wrote, then such conditions would be “suspect.”

The agency hinted that it might be willing to allow such practices under certain circumstances, such as for a financially struggling hospital or to guarantee a critical service not otherwise available in the area.

Safeguard your practices before the OIG makes a decision
Beware if your hospital engages in any of the activities that the OIG has labeled as suspect. A dissatisfied physician could challenge an adverse credentialing decision through a private whistleblower action under the False Claims Act.

The plaintiff could argue that if hospitals have violated the anti-kickback statute, then the hospital’s annual cost report certification of compliance with all applicable laws and regulations is a “false claim” that invalidates that entire cost report. Such an action could result in huge treble and punitive damages, explains Philadelphia-based attorney Robin Locke Nagele, JD, at Post & Schell.

This kind of nightmare scenario has never been applied to economic credentialing, but it could be if the OIG finds certain aspects of it illegal, Nagele says.

Don’t wait for the OIG to make up its mind. Consider implementing the following protective measures now:

- **Find out what your own state licensure laws have to say.** Some states may address economic credentialing in their hospital licensure laws. Pennsylvania’s licensure law, for example, prohibits hospitals from denying medical staff privileges based on any criterion that lacks “professional or ethical justification,” including a physician’s association with a managed care entity.

- **Tighten your own policy.** Your board of directors should have a clearly stated position that it adheres to without exception, says Alice G. Gosfield, JD, of Alice G. Gosfield and Associates, in Philadelphia. “If the board wants to say that people who serve on the board shouldn’t be invested in other enterprises, then the retired owner of the local paper factory who serves on the board can’t be invested in competing interests, either,” she says.

- **Consider a strategic development plan.** Some proponents of economic credentialing endorse this concept. It involves screening medical staff applicants in areas such as conflicts of interest and referral rates at the governing board or board committee level before their applications are processed by the medical staff office. If quality-of-care arguments support your strategic planning requirements, they likely would pass muster under fraud and abuse laws, says Mark Mattioli, Esq., partner with Post & Schell, PC. Numerous trial, circuit, and state supreme court judges have ruled that hospital boards have the authority and fiduciary obligation to develop such initial screening criteria, adds Barbara Blackmond, JD, senior partner, Horty, Springer & Mattern, Pittsburgh.

“If it’s clear that its being done by the board of trustees, there is very little risk for liability,” she says.
Weed out weaknesses that can lead to surgical errors

A woman’s erroneous double mastectomy hit the headlines in January, a reminder of the embarrassing and potentially costly medical errors that plague hospitals and can lead to costly lawsuits.

Protect your organization by reducing problems commonly associated with surgical errors. BLRR asked legal and clinical experts on both ends of the liability spectrum to share their experiences. Below are snapshots of what they learned.

Error #1
A 46-year-old Woodville, WI, woman received a double mastectomy by mistake after the hospital’s contracted pathology lab mixed up her biopsy results with another patient’s. The error not only caused the patient to lose her healthy breasts, but also delayed treatment for the woman who did have cancer.

Causes:
Not following in-house procedures. A lab technician placed the healthy woman’s biopsy next to the biopsy of the woman who had cancer. The lab’s policies and procedures require technicians to keep all specimens separate.

In addition, the pathologist who later examined both biopsies mismatched the specimen slides and their corresponding paperwork.

The pathologist then failed to follow clinic procedure by not cross-referencing the names and identification numbers on both sets of slides against the names and identification numbers on the paperwork, says malpractice attorney Chris Messerly, JD, partner at the Minneapolis-based Robins, Kaplan, Miller & Ciresi, who is representing the woman who underwent the unnecessary mastectomy.

Causes:
Not following in-house procedures. A lab technician placed the healthy woman’s biopsy next to the biopsy of the woman who had cancer. The lab’s policies and procedures require technicians to keep all specimens separate.

In addition, the pathologist who later examined both biopsies mismatched the specimen slides and their corresponding paperwork.

Three risky areas

When it comes to lowering your risk for surgical errors, leadership is one of the first areas you should overhaul. Does your overall organizational culture invite nurses, technicians, and others to voice concerns? The results of an anonymous survey of staff at your organization might surprise you.

Many nurses express a lack of administrative support that would make them feel safe in speaking up, says Suzanne Beyea, RN, PhD, director of nursing research for Dartmouth-Hitchcock Medical Center, Lebanon, NH.

A must-have: Administrators and clinical leaders should demand strict adherence to all policies and procedures.

Assess your own organization’s vulnerability to these two additional risk areas:

- **Poor communication**: Most medical errors, including wrong-site/wrong-patient surgeries, are rooted in “frighteningly poor communication,” says Mark Chassin, MD, MPP, MPH. Physicians fail to communicate with nurses, attendings with residents, and staff from one unit with staff from another.

One way to address this is by developing multidisciplinary focus groups, workshops and rounds, advises Chassin, professor and chair of the Department of Health Policy, Mount Sinai School of Medicine, New York.

- **Staffing shortages**: It’s not uncommon for managers to pull nurses from one unit when another unit is short-staffed. But beware. Make sure these nurses are familiar with and understand the policies and procedures for that unit and that you have clear protocols for communicating information to them, advises malpractice attorney Shirin Harrell, BA, RN, MBA, JD, of New Orleans-based Sessions Fishman & Nathan.
Strategies for avoiding a similar fate:

✔ Checklist: Require surgical team members and contracted pathologists to use a checklist to verify the patient's identification, lab reports, and surgical site.

✔ Conduct regular audits to ensure staff and contractor compliance with all of your hospital's policies and procedures. An error like the above, which originated in a non-hospital-based lab, is preventable if a hospital regularly audits the policies and procedures of its labs and other contractors, says Michelle Hoppes, RN, MS, AHRMQR, DFASHRM, vice president of risk management and patient safety for MHA Insurance Company of Michigan in Lansing.

✔ Color code: Color code all lab results and corresponding paperwork. The pathology lab began doing this shortly after the error was detected.

✔ Check each other's work: Two pathologists now must sign-off on a diagnosis and verify that the patient name and number on the sample corresponds with the paperwork, says Messerly.

✔ Provide complete and immediate disclosure in the event of an error: "As difficult as it may be, make an apology," says Messerly. It may not prevent the patient from suing, but it will lessen the patient's anger while demonstrating your organization's honesty and conscience.

Error #2
A 67-year-old woman, “Ms. Morris,” was mistakenly included in an invasive cardiac electrophysiology study intended for a different patient, “Ms. Morrison.”

Causes:
At least 17 distinct causes were identified, says Mark Chassin, MD, MPP, MPH, who reviewed the Morris/Morrison debacle in a study published last year (“The Wrong Patient,” Annals of Internal Medicine, Vol. 136, No. 11). Among the causes were the following:

• “Systematically” poor communication

Overhaul your internal reporting structure

Improve the effectiveness of your hospital's internal reporting system and you'll lower your overall risk for medical errors. After all, you can't fix something until you know it's broken.

Begin by examining how you encourage staff to report errors. Chances are, they may think that the advantages outweigh the disadvantages, says Mark Chassin, MD, MPP, MPH, who co-authored a 1999 report on medical errors for the Institute of Medicine (To Err is Human).

Physicians are loath to participate in root-cause analyses (RCA), for example, because many view the process as punitive and “looking to assign blame—which it usually is,” Chassin says. Instead, RCAs should seek to identify institutionalized deficiencies within the entire organization.

Tip: Consider separating your performance improvement (PI) and risk management functions so that clinicians don’t associate PI with disciplinary action. Chassin’s hospital has done this and found that physicians are more willing to become involved with PI projects as a result.

If that’s not possible, try establishing PI or RCA ground rules in which everyone agrees that they will look for deficiencies on an operational—rather than individual—level, suggests Michelle Hoppes, RN, MS, AHRMQR, vice president of risk management and patient safety for Lansing-based MHA Insurance Company of Michigan.

Leadership buy-in is the key to success here. “Leaders need to take the initiative to show that the root-cause analysis is not about placing blame,” she says.
Whistleblower suits, according to DOJ statistics.

Most of the $980 million that the DOJ recovered last year in false claims overpayments was due to whistleblower lawsuits, including a landmark $568 million from TAP Pharmaceuticals, and a combined $46 million from subsidiaries of Tenet Healthcare Corporation. **Translation:** A government audit of your billing practices can originate from a current or former employee.

Now, state governments are trying to get in on the action. Hoping to recover fraudulent Medicaid overpayments, Virginia this year enacted its own mini false claims act, a move that allows Virginia whistleblowers to sue and collect at both the state and federal levels. California, Delaware, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, Tennessee, Texas, and the District of Columbia have similar laws. Meanwhile, a growing number of plaintiff attorneys are also getting involved, taking on cases at no charge unless the whistleblower wins.

“It has become very, very big business,” says Ronald Clark, JD, MA, PhD. He should know. Clark prosecuted dozens of such cases as a former senior trial counsel with the DOJ. Today, he defends them on the other end as a health care fraud and abuse litigator for Arent Fox Kintner Plotkin & Kahn, a Washington, DC, law firm.

Front-end defense

Protect your organization from fraud allegations, and you’ll not only save it from a time-consuming and expensive investigation, but you’ll also limit its vulnerability to a host of other problems, including medical errors that can result from lack of sufficient training and communication, top fraud attorneys advise. Below are five steps you can take to protect your organization from qui tam suits.

1. **Toughen up your compliance plan’s reporting protocols.** Most people who file whistleblower suits don’t do it for the money, says Clark, but because management never acts on their repeated attempts to report wrongdoing.

   Employees are less likely to report their concerns to a higher authority if they know your organization has an effective internal system for addressing grievances, Clark adds.

   The plan should have support from all upper management levels and address the root causes of fraud, said the DOJ’s McCallum.

2. **Review your human resources function.** Do employees feel respected by and connected to their supervisors? Supervisors should stay in regular contact with employees so that everyone feels he or she part of a team, advises Hope Foster, JD, a Washington, DC–based qui tam expert with Mintz Levin Cohn Ferris Glovsky and Popeo.

3. **Establish protocols for training.** Design employee orientation programs with a focus on corporate compliance, Foster says. Employees should not
only understand all relevant laws and regulations that govern them, but also be well-versed in your organization’s protocols for reporting questionable practices.

4. Clear every termination with your organization’s general counsel. The attorney will be able to cross-check the employee’s name against any ongoing investigations (to avoid any retaliation allegations).

5. Conduct exit interviews. The interviewer should solicit information about possible law violations so the compliance officer can investigate them.

Responding to a qui tam complaint
Don’t expect DOJ attorneys to personally notify you about a qui tam action taken against your organization. Whistleblower complaints are filed in secrecy. However, it’s not always difficult to realize that one has been filed. Government agents may make a “routine” request for documents or, more obviously, you may receive a subpoena, says Foster. Keep the following specific “dos” and “don’ts” in mind if this happens:

- Retain outside counsel. Breeches of attorney-client privilege can arise when using the organization’s general counsel, since it may not be clear whether he or she is investigating the allegation as an attorney or as a member of management, says Alan Bloom, JD, MPH, general counsel for Los Angeles-based Maxicare, a former health maintenance organization. In addition, an outside attorney can do a better job of “running interference” if a member of the management team is the target of the investigation, he says.

- Don’t destroy or alter any documents. You could be prosecuted for tampering with an investigation. Assign a custodian to collect and safeguard all records.

- Ensure that no retaliatory action is taken against the relator. The False Claims Act allows relators to sue employers who retaliate against them for filing a whistleblower suit. Relators can push forward with these suits even if their underlying qui tam action is dismissed, says Clark. Seemingly innocent gestures, such as a supervisor asking an employee whether he or she is the one who filed the lawsuit, could be construed as retaliatory, he adds.

Caution: Since the DOJ doesn’t disclose the name of the whistleblower, you may not even know who it is. If this is the case, tread lightly around all disgruntled employees, says Foster.

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<tr>
<th>Recovered qui tam funds by the DOJ and whistleblowers</th>
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<td>The U.S. Department of Justice (DOJ) took on fewer qui tam actions last year but recovered 24% more in false claims overpayments, according to information provided to BLRR by a DOJ spokesperson. Below is a tally of how much money in false claims overpayments that the DOJ and whistleblowers (also known as “relators”) have recovered in recent years.</td>
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<tr>
<td><strong>Total number of qui tam actions in which the DOJ intervened:</strong></td>
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<tr>
<td>2001: 62</td>
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<td><strong>Total False Claim Act (FCA) recoveries as a result of DOJ-intervened qui tam actions:</strong></td>
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<tr>
<td>2001: $721,662,985</td>
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<tr>
<td><strong>Total amount of FCA recoveries awarded to relators:</strong></td>
</tr>
<tr>
<td>2001: $125,103,239</td>
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<tr>
<td>2002: $145,756,429</td>
</tr>
<tr>
<td><strong>Total qui tam actions declined by the DOJ but pressed forward by relator:</strong></td>
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<tr>
<td>2001: 161</td>
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<tr>
<td>Amount recovered: $11,308,365</td>
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<tr>
<td>Amount rewarded to relator: $3,116,532</td>
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<tr>
<td>2002: 100</td>
</tr>
<tr>
<td>Amount recovered: $23,803,254</td>
</tr>
<tr>
<td>Amount rewarded to relator: $4,073,598</td>
</tr>
<tr>
<td>Amount awarded to relator: $121,986,707</td>
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<tr>
<td>2002: $894,604,636</td>
</tr>
<tr>
<td>Amount awarded to relator: $141,682,831</td>
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Surgical errors

among caregivers. Ms. Morris’ medical record wasn’t legible in places, making it difficult for staff to find or decipher information that could have alerted them of the error, says Chassin, professor and chair of the Department of Health Policy at the Mount Sinai School of Medicine in New York.

• Poorly functioning teams. Physicians and nurses had become accustomed to the hospital’s “culture of low expectations,” leading caregivers to ignore documentation omissions and to “expect” poor levels of communication between physicians, residents, and nurses.

• Absent or misused informed consent procedures. Staff and physicians dismissed the patient’s consistent objections to the procedure, likely because they had grown accustomed to dealing with uninformed patients, says Chassin.

Strategies for avoiding a similar fate:
✔ Develop routine procedures for verifying patient identity: It should involve at least two people, such as a surgeon and a nurse, says Chassin. In addition, engage the patient or patient guardian in patient identification procedures. Require patients to remain on their respective floors prior to surgery unless they have a written order in their chart authorizing it, advises the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

When nurses telephone another unit to release the patient for a procedure, require them to match the patient’s last and first names, medical record number, and date of birth.

✔ Use medical record numbers, such as patient birth dates in your scheduling system: The cardiology department involved in Chassin’s study made this change after conducting a root-cause analysis of its wrong-patient procedure. Bonus: Because the JCAHO also recommends this measure, incorporating it could ingratiate you with your next surveyor.
**Develop standard screening protocols to reduce the risk of a missed diagnosis**

<table>
<thead>
<tr>
<th>The issue</th>
<th>Failure to diagnose breast cancer is one of the most common and expensive malpractice claims made against physicians.</th>
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<td>Action item</td>
<td>Primary care clinicians should develop standard screening protocols to reduce the risk of a missed diagnosis.</td>
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<tr>
<td>Background</td>
<td>Breast cancer is the most common nonskin malignancy among women in the United States. A woman’s risk for developing the disease increases beginning at age 40. Other risk factors include family history or a personal history of breast cancer, having a first child after age 30, and biopsy-confirmed atypical cells (hyperplasia). Debate has raged over how often and at what age women should receive screening mammograms, particularly since October 2001, when The Lancet published the results of a Danish study that questioned the value of mammogram screening in reducing breast cancer mortality. The study prompted many national organizations to carefully reconsider their own recommendations. While research does confirm that women between ages 50 and 69 who receive mammograms on a regular basis have a reduced risk of dying from breast cancer, the evidence is less clear for women ages 40 to 49. Data suggest that cancer grows faster in women younger than 50, but the sensitivity of mammography is also lower in this age group. More recently, the January 15 issue of the journal Cancer (vol. 97) reported a study that found that mammography screening for women in their 40s leads to diagnosis of breast cancer at an earlier stage, possibly improving opportunities for more effective, less radical treatment options.</td>
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<tr>
<td>Common screening techniques</td>
<td>There are three primary screening procedures in wide use for breast cancer. None are diagnostic, but help physicians determine whether the patient needs further testing. The primary screening procedures are as follows:</td>
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Mammography: This x-ray technique helps visualize the breast’s internal structure. Efforts to improve mammography focus on refining the technology and x-ray interpretation. Films are harder to interpret among women who have dense breasts, are younger than 50, or who are taking hormone replacement therapy.

Clinical breast exam (CBE): A physician inspects and feels the entire breast area, including lymph node areas above and below the collarbone and under each arm.

Although CBEs can often detect cancers that a mammogram can’t, there is still wide disagreement over whether the potential benefits of routine CBEs outweigh the potential harms. One community study found that only 4% of women with an abnormal CBE were subsequently diagnosed with cancer (Journal of the National Cancer Institute, vol. 92, no. 12, 2000).

Breast self-exam (BSE): Despite advances in technology, most lumps are still discovered by the patient during self-examination. The American Cancer Society recommends that all women over the age of 20 examine their breasts once a month.

Little research exists to show whether BSE helps reduce breast cancer mortality. Some studies associate it with an increased risk for false-positive results and biopsies, although design limitations have made it difficult for scientists to make a clear determination.

In addition, newer techniques also include the following:

Digital mammography: This technology records mammogram images in computer code instead of on film. The images are displayed on a computer monitor that allows the radiologist to magnify and enhance certain areas.


**Potential harms of screening**

Breast cancer screening can sometimes cause harm to the patient, as outlined below.

False-positives: A majority (80%–90%) of abnormal screening mammograms are false-positives that may require follow-up testing or invasive procedures to resolve the diagnosis, according to the Agency for Healthcare Research and Quality.

False-positive readings can cause psychological and emotional trauma, physical pain and suffering from unnecessary biopsies, inconvenience, increased physician visits, and significant medical expenses.

False-negatives: These readings provide false reassurance and delay proper diagnosis and treatment.

Over-diagnosis and treatment of ductal carcinoma in situ (DCIS): DCIS is a precancerous, preinvasive, intraductal cancer that is thought to pose little threat to a woman’s health.
Nonetheless, many women with this diagnosis are treated aggressively with mastectomy or lumpectomy and radiation.

Radiation-induced breast cancer: It’s possible for the radiation of a mammogram to actually cause breast cancer, although there are few data to directly assess this risk. The National Academy of Sciences estimates that annual mammography of 100,000 women for 10 consecutive years beginning at age 40 could result in up to eight radiation-induced breast cancer deaths.

The most common causes of missed diagnosis of breast cancer include the following:

Failure to perform a biopsy. Too often, physicians try to “reassure” patients that their lump is benign using CBE or mammography, particularly if the patient found the lump herself, reports William H. Goodson III, MD, and colleagues (Archives of Internal Medicine, Vol. 162, No. 12).

Generalizations. Don’t be fooled by a patient’s age or weight. A common misperception is that patients who are younger, heavier, or with an earlier onset of menopause are harder to diagnose. In fact, there are often few differences between patients with and without a delay in diagnosis, finds Paul Ian Tartter, MD, colleagues (“Delay in Diagnosis of Breast Cancer,” Annals of Surgery, 1999, vol. 229, no. 1).

An untrained physician performs the biopsy. Research has shown that physicians untrained in fine-needle aspiration (FNA) biopsy technique miss 25% of cancers. On the other hand, physicians with formal training miss only 2% of cancers (Cancer Cytopathology, vol. 93, no. 4). An experienced physician should perform the FNA to rule out cancer in a suspicious mass, urges the National Cancer Institute. If no FNA-trained physician is available, surgical or core biopsies are suitable alternatives, the National Cancer Institute (NCI) offers.

The U.S. Department of Health and Human Services recommends screening mammography every one to two years for women age 40 and older. Also in agreement with this recommendation are the NCI, American Cancer Society, American College of Obstetricians and Gynecologists, American College of Radiology, and the American Medical Association.

Some state laws actually require physicians and surgeons who treat breast cancer to inform patients of their treatment alternatives. California’s Health & Safety Code, for example, requires them to post written notice of alternative “efficacious methods” of treatment, including surgical, radiological, or chemotherapeutic treatments, or combinations thereof.

However, there are more direct ways to reduce liability risk. Incorporating the following suggestions into a cancer screening protocol could help reduce missed or improper diagnoses:
• Call-back systems: Many hospitals still lack an organized call-back system that enables nurses to remind patients of the need for breast cancer screening exams. Most billing software systems allow users to set up a “tickler file” that singles out such patients for follow-up. Similarly, clinicians should adopt office systems to ensure timely and adequate follow-up of abnormal results.

• Thorough family history and clinical breast examination: The history should include up to three generations, if possible, with particular emphasis on first- and second-degree relatives with cancer and age of onset. Look for signs of familial or inherited risk.

• Genetic testing: If an initial evaluation indicates the possibility of familial or inherited cancer risk, consider referring the patient to a genetic specialist who may be able to detect all or some of the genetic mutations that have been associated with breast cancer.

• Complete documentation: Many breast exams and mammograms aren’t sufficiently charted. If clinicians fail to note years of normal mammography findings, “you certainly invite a lot of question marks when a cancer ultimately appears,” R. James Brenner, MD, medical director of breast imaging services at the John Wayne Cancer Institute in Santa Monica, CA, said during the 2002 National Interdisciplinary Breast Center Conference in Las Vegas.

If the woman refuses to obtain annual breast cancer risk assessment, the physician should inform her about her risk, the screening options available to her, and the benefits and risks of not choosing preventive care. If the patient is at high risk for developing breast cancer, the physician should document the conversation and ask the patient to sign the documentation.

• Follow-up: If a physician refers a patient to a specialist, make sure the patient actually goes to the specialist. You could leave yourself open to abandonment allegations, warned Brenner. If the patient’s condition is benign, the physician should stress the importance of follow-up visits, since diagnostic tests rarely have 100% sensitivity.

• Patient education: Provide patients with written and verbal information about assessing their own risk, the importance of regular screening, and how to properly perform a SBE.