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PROTECTOR

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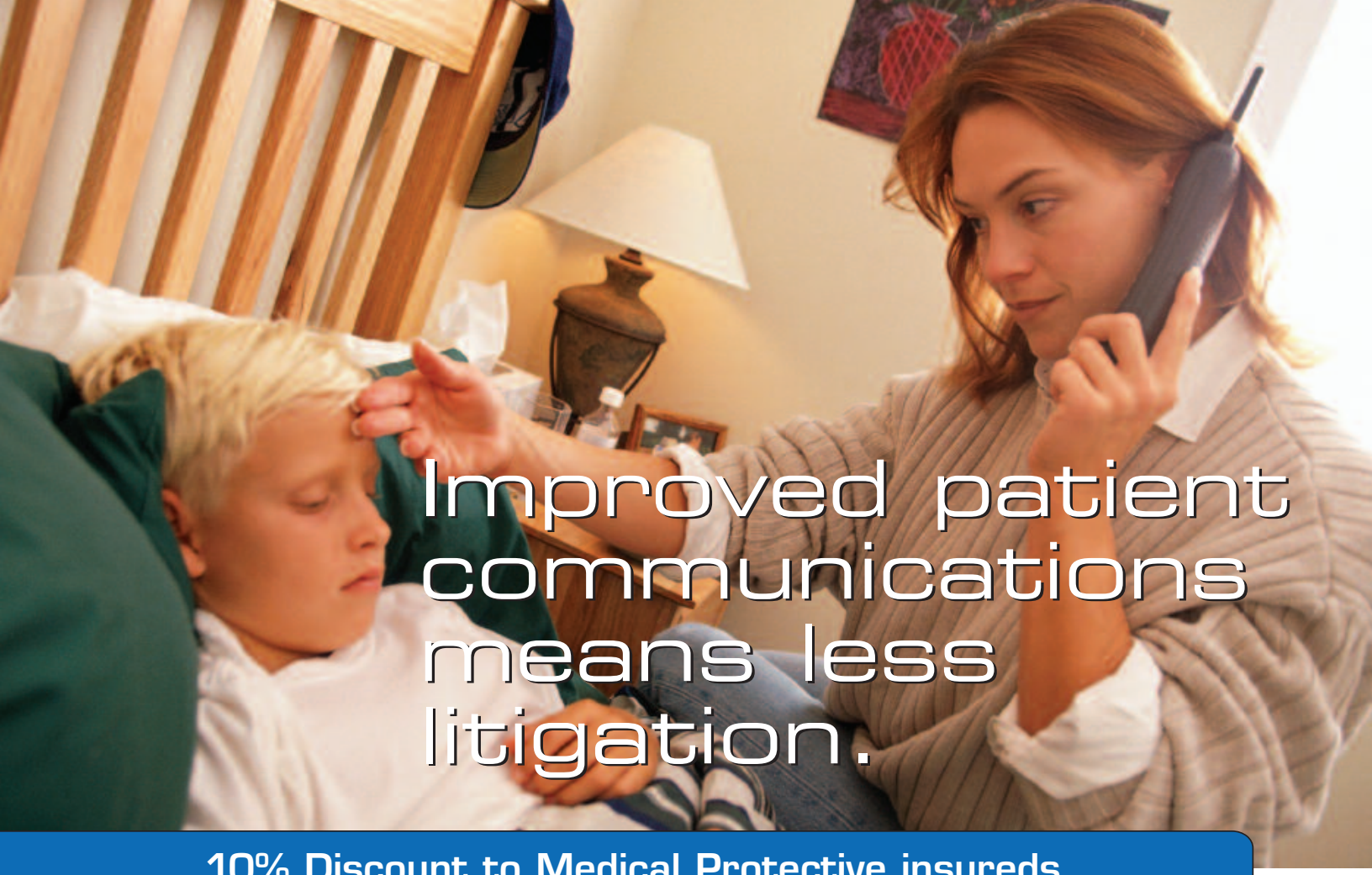

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Dear Medical Protective healthcare provider:

At one time or another all of us have said, "Well, gee, I haven't thought about it that way before...." Healthcare is constantly changing. The environment of care is shifting as treatment options are no longer restricted to hospital settings. Science and public expectation blur the borders between healthcare professions. Regulatory mandates arguably improve patient safety while at the same time increasing the cost of healthcare. An aging population increases the demand for services while, simultaneously, economic pressures broaden the divide between those who can afford to access healthcare and those who cannot.

As these changes, and others, alter the face of medicine and dentistry, it is important to periodically reexamine clinical and administrative processes. It's important to determine if they are still relevant in the light of new influences.

In this issue of *Protector*, we highlight some of these outside influences and consider ways in which they may affect doctors' ability to provide effective clinical care. We'll also offer strategies to help dentists and physicians address these potential liabilities.

Topics covered include:

- Repurposed pharmaceuticals as a liability in medicine/dentistry.
- Refusal to treat the uninsured as a proposed risk management strategy.
- Concerns about physicians and dentists practicing beyond the scope of their education and expertise.
- The threat of contaminated dental materials.
- Patient satisfaction feedback as the missing link in quality care.
- A quick review of that touchy subject, corporate compliance.

As always, your feedback and suggestions are welcome!

Sincerely,

Kathleen M. Roman
Editor

Protector is published three times a year by Medical Protective as a risk management service to insured physicians and dentists.

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Please share with us topics you would like to see addressed in *Protector*. Send your questions, topic suggestions and comments to:

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Your valuable input helps us to ensure that this risk management publication is useful to its readers. Thank you for your contributions. Contributions from named authors represent solely the view of those authors.

Pharmaceutical companies repurposing drugs:

A risk issue for physicians and dentists

Repurposing saves manufacturers time and money.

Increasingly, pharmaceutical companies are seeking to extend their control over the patents of their drugs. One strategy often used is known as repurposing. Using this method, the manufacturer can claim that the drug in its original formation has been proven beneficial for a completely different use – *or* that by reformulating the drug, the manufacturer has found another therapeutic use for it.

There are several reasons why drug companies pursue this kind of revamping process for already-approved drugs.

First, is cost. According to a survey conducted by Cutting Edge Information,[1] the average cost of bringing a new drug to the marketplace is $41.3 million. But repurposing that same drug will cost on average about $8.4 million, the survey noted. Start-up dollars are spent on research, testing, expenses related to the approval process, and marketing. Companies want to control the patents on these drugs for as long as possible in order to recoup these expenses and to enjoy the profits they hope will far surpass the front-end costs.

The second reason why drug companies repurpose drugs is time. In the U.S., a manufacturer's patent prevents the drug from being replicated by competitors for about 20 years. However, since the patent applies from the point at which the manufacturer applies for FDA approval, the actual time during which the patent is effective in the actual marketplace, is more likely to be about 12 years.[2] Once the patent has expired, it can be manufactured by other entities in a generic format. Competition among manufacturers (including the company that held the patent) drives down the cost of the drug after the patent expires. So drug manufacturers must bring their products to market as quickly as possible and maximize the amount of money they can earn on the sale of these drugs before the patents expire and less expensive versions hit the market.

Repurposing a drug may also reduce the subsequent amount of testing and the investments of time and money needed to obtain FDA approval for the same drug – wearing a different hat. Experts in the pharmaceutical industry as well as the FDA note that second use approval is rarely as time consuming or as expensive as the first process since, arguably, many of the chemical effects of the drug have already been identified.

Will repurposing produce the breadth and scope of needed drugs?

Some critics contend that drug manufacturers are bringing fewer and fewer new drugs to market and may be failing to fill some important gaps in needed medical treatments. One example would be the need for new antibiotics that are effective against drug-resistant strains of tuberculosis, staph, etc. According to an article in the *Indianapolis Star*, the FDA approved only 19 new drugs in 2007. This is the lowest number of new drugs to be approved in 24 years.[3]

Repurposed drugs cover a broad spectrum of treatments.

Here are just two examples of well-known drugs that have been repurposed:[4]

- Celecoxib, a highly selective COX-2 inhibitor, is manufactured and marketed by Pfizer under the name of Celebrex, as a treatment for osteoarthritis and rheumathoid arthritis. Subsequently the drug has been "repurposed" and is additionally marketed as a treatment for familial adenomatous polyposis, colon cancer and breast cancer.
- Minoxicil, manufactured by Pharmacia & Upjohn, was originally prescribed to treat hypertension. In response to a noted side effect, that the drug produced hair growth, especially related to male pattern baldness, Upjohn obtained FDA approval to market the drug under the name of Rogaine as a treatment for hair loss.

Numerous other drugs have been repurposed. Lidocaine, which was used under the name of Xilocaine as a local anesthetic, is now also available in an oral formulation to treat corticosteroid-dependent asthma. Buproprion, marketed as Welbutrin for treatment of depression, is now approved as Zyban to help treat tobacco addiction. Duloxetine, originally approved as Cymbalta to treat depression, is now available as Duloxetine SUI for treatment of stress urinary incontinence. The list goes on.

In an example of a very aggressive repurposing initiative, Eli Lilly, the manufacturer of Cymbalta, has extended the drug's uses well beyond its originally approved purpose, the treatment of depression. According to the *Indianapolis Star*,[5] the drug is now approved for anxiety, fibromyalgia and diabetic nerve pain. In Europe it is also marketed, under a different name, for the treatment of stress urinary incontinence.

How does this affect physicians and dentists?

Often, the true risks associated with a new medication may not be identified until the drug has been in the marketplace for some time. Doctors need sufficient information about prescription drugs in order to make safe decisions about treatment planning. Reliance on manufacturer's data alone may not be sufficient, from a risk management perspective.

Doctors should ask themselves: If a drug has been repurposed, will risks associated with its original use remain the same? Will some of them no longer apply? Will others occur? If an original formulation warns about possible suicide, for example, what kinds of reassurance does the healthcare community have that a repurposed version of the drug does–or does not–have the same side effect? What resources do doctors rely on for dosing advice for drugs that have not been tested on children, the elderly, and women, especially those who may be pregnant, or nursing?

Doctors need to think about and devise processes that will help them stay current with the latest information about the medications their patients are taking. They need to incorporate regular updates into their patients' medical histories, with special focus on drugs that may be ordered by other providers. Just as important, they need to implement patient education into discussions about prescriptions. Doctors should never assume that any medication is "safe," and patients need to be educated to have the same degree of caution.

In addition to concerns about the safety of drugs themselves, regulatory bodies like the Federal Drug Administration (FDA), health insurers, and pharmacy chains, warn that the issue is also complicated by the fact that the majority of Americans are non-compliant with their medication regimens. Education and informed consent are an essential part of the process for helping patients understand the risks inherent in all medications as well as the need for their compliance and partnership in this element of their treatment. When it comes to drugs that are new to the market, or drugs that doctors have been told are "safe" because they have been "merely repurposed," special cautions should apply. ■

1. www.emaxhealth.com/94/11020.html
2. www.wto.org/english/tratop_e/TRIPS_e/pharma_ato186_e.htm
3. Russell, J. One drug, many uses. Good idea? *Indianapolis Star. June 29, 2008.*
4. Netterwald, J. Recycling Existing Drugs. Drug Discovery & Development. January 1, 2008. www.dddmag.com/article-drug-repositioning.aspx.
5. Russell, J.

Stay tuned to prescription medication challenges–especially those associated with repurposed drugs.

- When starting a patient on a new prescription medication, it may be wise to obtain a verbal informed consent and document the discussion. As part of the verbal consent, explain the risks and benefits of the recommended medication and ask if the patient has any questions or concerns about the medication. Data suggests that up to fifty percent of patients taking long-term medications are non-compliant.

- Consider obtaining a written informed consent for:
  - Drugs that are being used for off-list purposes.
  - Drugs that have been newly-approved or have been repurposed. Warn patients that even though these medications have been tested, there may still be unknown risks and they should be vigilant about reporting any side effects.

- Quiz patients as to the purpose of their medications. "I take a pink pill for my heart," isn't sufficient.

- If patients are uncertain about their medications or doses, instruct them to bring all of their medications with them. This process often helps doctors identify patients' misunderstandings that could harm the patient. According to the National Patient Safety Foundation, the likelihood of error and noncompliance increases in direct proportion to the number of medications the patient is taking and the number of providers who are involved in the patient's care.

- Don't hesitate to call another treating provider with concerns relative to a possible interaction between drugs prescribed by the other provider and drugs you are prescribing, or would like to prescribe, for the patient. Such discussions do not comprise a HIPAA violation.

- When in doubt, double check with other providers to assure yourself that a patient isn't getting both the brand name and a generic.

- Always ask if the patient has experienced a medical emergency or received a diagnosis of a new medical condition since his or her last visit. Medications used to treat this new condition should be reviewed in light of treatment the patient may be receiving in your office.

- Consistently encourage patients to call if they suspect they are having a reaction to a medication or if they have questions about any of their medications. Medical and dental office staff can be particularly helpful with this initiative since patients may feel more comfortable expressing their questions or concerns to a staff member rather than directly to "the white coat."

- Require drug company representatives to respond to questions about research about the safety of drugs once they are out in the marketplace. Some drugs receive FDA approval with an understanding that the manufacturer will continue to conduct tests and provide those results to the FDA. Patient safety experts warn that many of these reports are never completed.

- Don't be pressured to prescribe any drug in light of concerns about its safety or if the manufacturer fails to respond to questions or concerns.

- Stay abreast of FDA warnings, pharmaceutical experts' advice, and manufacturers' research, where obtainable.

- Don't hesitate to consult with pharmacists, case managers, social services or other resources that may be able to help patients comply with needed medication regimens–or help patients find financial resources for the purchase of needed medications.

Refusal to treat the uninsured: A risk management strategy

Economic downturns are cyclical in nature. The healthcare environment is easily influenced by financial upheavals in the rest of the economy. Surveys of medical and dental providers indicate that more patients fall into arrears in their payment schedules when unemployment rates increase. Since 2006, the General Accounting Office (GAO) reports that inability to pay medical debts is the largest single cause of personal bankruptcy. The increased cost of healthcare and the attendant inability of patients to pay their bills, coupled with a variety of stressors on the doctor-patient relationship, contribute to the increase in number of lawsuits filed during economic downturns.[1]

Noting these challenges to the financial stability of their practices, doctors ponder ways in which they might reduce their liability exposures. One suggestion has been that doctors might refuse to treat patients who have no health insurance. Inherent in this assumption is the belief that persons of lower socioeconomic standing are more likely to sue when faced with an unexpected clinical outcome and increased medical expenses.

In fact, a number of experts, including seasoned defense counsel, disagree. It would appear that persons with more education and sound financial footing are better able to negotiate the complicated litigation process. In their 2000 study, Studdard, et al stated, "the elderly and the poor are particularly likely to be among those who suffer negligence and do not sue, perhaps because their socioeconomic status inhibits opportunities to secure legal representation."[2]

Other studies note that the likelihood of lawsuits remains low for the uninsured, despite the fact that as a group they are more likely to receive substandard care.[3]

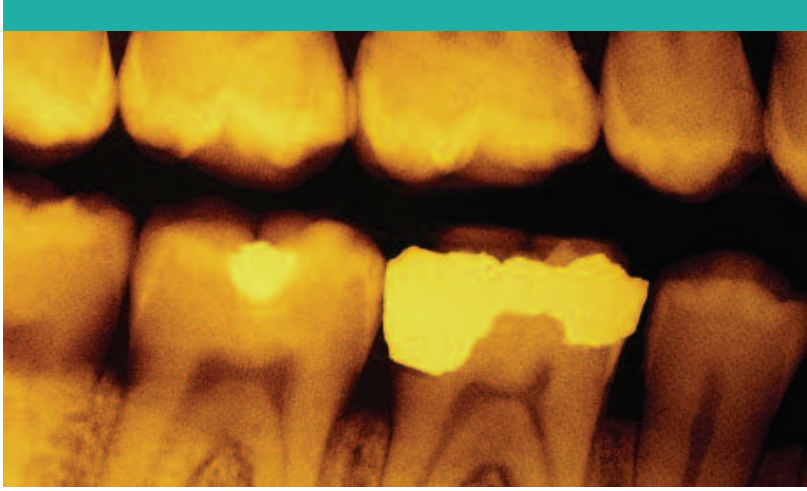
In fact, from a risk management perspective, refusal to treat the uninsured may comprise an increase in liability exposure. For example, a patient seen in an emergency department may need follow-up care in the office from the consulting doctor who was called in to see him. Refusal to see such patients may expose the doctor to allegations of abandonment.

Other studies note that the likelihood of lawsuits remains low for the uninsured, despite the fact that as a group they are more likely to receive substandard care.

Physicians, and dentists as well, are generally free to treat whom they please; however, it would be wise to establish clear guidelines for each practice. The expectation would be that each provider in the practice will follow these guidelines. Aside from the fact that doctors may lose the ability to treat patients who will pay their bills, negative public relations, typically associated with word-of-mouth, may threaten a medical or dental practice's reputation if it does not carefully handle refusal to treat decisions.

Rather than attempting to avoid patients for no other reason than their health insurance status, doctors would be better served to invest their efforts in building good working relationships with their patients, holding them accountable for partnership within the scope of the relationship–and documenting the concern and skill that went into the diagnosis and treatment of each patient. ■

1. Rejda, G. *Principles of Risk Management and Insurance, 10th ed.* HarperCollins College Publishers. 2007, pp. 104-105.
2. Studdard, D. M., Thomas, E. J., Burstin, H. R., et al. Med. Care, 200 Mar;38(3);247-249.
3. Burstin, H. R., Lipsitz, S. R., Brennan, T. A. Socioeconomic Status and Risk for Substandard Medical Care. JAMA (1992), pp. 2382-2397.



Know how to respond to patients' concerns about lead in dental materials

First, it was lead in children's toys. Then, in February, there were reports of lead in dental crowns. Some of the media made it sound as though dentists purchased these contaminated materials from foreign countries. Later information pointed out that most of the materials used in dental procedures, such as crowns, are purchased by labs, not by the doctors themselves.

The American Dental Association (ADA) has delivered a prompt and comprehensive response to this issue. Dentists who have not already done so should visit www.ada.org/prof/resources/pubs/adanews/adanewsarticle.asp?articleid=2915 for sound advice about how dentists can interact with their labs to ensure the safety of materials used in dental devices. It would be wise to maintain documentation of this correspondence and to consider changing business relationships if any labs' response is inadequate or inaccurate. Most reputable labs are taking this information seriously and should be working to identify and eliminate any possible safety hazards associated with vendors from whom they have purchased materials.

At the same time, dentists should be prepared to respond to their patients' questions and concerns relative to this alert. As ADA President Mark Feldman told members, "There is no appropriate use for lead in the manufacturing of dental prostheses.... Our task now is to learn what the ADA can do to help prevent our members and our patients from ever hearing this kind of news again."

Patients need to know that dentists are dedicated to safety. By asking for labs to provide adequate feedback about the sources of their materials, dentists can assure themselves as well as their patients.

Following are several examples of topics that dentists should be prepared to discuss with their patients. In his or her own words, dentists should tell patients that:

a) Yes, we are aware that there was a problem. Further investigation by safety experts tells us that this doesn't appear as pervasive in dental materials as it was found to be in children's toys.
b) Rarely do dentists purchase these materials. Rather, it is laboratories that order them and use them in the manufacture of appliances and other products that the dentists then place for their patients. Going forward, dentists are likely to work more closely with labs, asking for information about the sources of materials and specifically, to give doctors choices in manufacturers.
c) However, the dental profession and the American Dental Association have taken aggressive steps to protect the safety of these materials and this watchdog approach will be implemented on an ongoing basis.

If any patient complains that a dental treatment may be problematic because of suspected contamination of any kind, the doctor should contact his or her Medical Protective risk management consultant at 800-4MEDPRO for advice about addressing the matter. ■

Risk issue: Exceeding the limits of training and experience

Borders between specialty groups aren't as clear as they once were. New technologies have made it possible to transport many treatments from the hospital setting to the ambulatory care setting.

The development of new treatment options has added to doctors' revenue choices. Forceful marketing programs directed at doctors highlight the financial benefits of new treatments–but often underplay the potential risks.

"It's not just about whether or not a patient has a bad outcome," says Mark Walthour, Medical Protective's Senior Vice President of Underwriting. "Even if the quality of the care is defensible, it may be more difficult to defend the doctor who is practicing outside his or her normal area of expertise." Without documentation of sufficient training, expert oversight and an adequate number of cases treated, physicians and dentists are at greater liability risk if they:

- Do not obtain informed consent for drugs or procedures that are not FDA approved;
- Do not obtain informed consent for FDA-approved drugs or procedures that are being used for off-list purposes; or,
- Expand a generalist practice to include procedures or regimens that are typically provided by medical or dental specialists.

Insurance carriers are not licensed healthcare providers, and thus can do little to influence decisions about clinical standards of care. However, they must make decisions about whether or not to underwrite certain risks. They make these decisions not only to ensure their own continued financial stability, but also in an attempt to control the rates they must charge. Doctors working in highly experimental areas may comprise a high risk to the rest of the insured book. High frequency or high severity of claims may serve as another indicator that a particular doctor poses a higher risk. Similarly, generalists who cannot adequately verify their competence to engage in clinical services that are typically provided by specialists may also fall into a high risk category, possibly facing higher premiums or forcing them to purchase insurance in the Excess and Surplus Lines market.

Mark Walthour warns general practitioners that provisions of medical or dental services that have traditionally been provided by specialists–doctors who have achieved board certification–may hold the generalist accountable for the same standard of care as the specialist if a patient has a bad outcome and files a lawsuit.

"As an example, we're seeing this kind of problem today in the area of cosmetic procedures," Walthour says. "We have dentists as well as physicians who want to provide elective services to highly-motivated patients, most of whom fully expect to pay for treatment out of their own pockets." With an aging population and increased life expectancy, it is easy to understand why so many new anti-aging products and services are coming into the marketplace, sometimes without adequate testing before they are "sold" to the doctors and sometimes, Walthour adds, "without adequate training for the doctors who are being encouraged to offer these services."

Forceful marketing programs directed at doctors highlight the financial benefits of new treatments–but often underplay the potential risks.

One example is the provision of botulinum toxin Type A (trade name Botox®) treatment in the family physician's office and, increasingly, in the family dentist's office as well. Currently, there is some discrepancy in the healthcare community as to which practitioners of medicine and/or dentistry are qualified to provide this type of treatment. Until the medical and dental standards for these products are more clearly defined, Medical Protective will continue to advise doctors to carefully assess the potential risks to patients when they consider offering new products or treatment options to their patients.

What should doctors' risk assessments consist of?

Walthour advises the following:

1. **Determine what kind of training is required for the board certified practitioner who is offering the same or similar treatment protocols.** What types of courses, how many hours, how many observed and/or assisted cases are completed before the specialist is allowed to provide the treatment on his own?

   While the generalist may select low risk cases—and in some instances that would be a wise approach, Walthour says—doctors should note any significant differences in the training regimens of each group of doctors. It is these education "gaps" that juries will take into account when determining whether or not they believe that the generalist practitioner was truly qualified to provide the treatment.

2. **Be selective of patients.** As suggested above, some generalists may be very comfortable treating a subset of patients who elect a particular cosmetic procedure. A common example is the general dentist who is willing to undertake orthodontic treatment for select types of occlusions. More complicated cases are promptly referred to orthodontic specialists. In the medical profession, cosmetic or "plastic" procedures should always include cautious selection of patients based on expectations, cooperation, and the clinical needs of the patient. Allowing the patient to dictate the treatment plan can be problematic for the clinical outcome and also for the doctor's adherence to scope of practice requirements.

3. **Maintain files of all training, coursework, precepted cases, literature review, and CME/CDE, that will verify the doctor's transition from student to practitioner to expert.** While the documentation of lifelong professional learning is important for any healthcare provider, it is especially important for the doctor who wishes to establish a reputation as an expert in a field of practice normally reserved for those who have completed post-graduate studies.

4. **Any doctor who is thinking about pursuing training for treatment options that could arguably be said to fall in the category of specialty care should consult with a Medical Protective underwriter.** The doctor can then obtain reassurance as to whether or not the proposed treatment falls within the company's underwriting guidelines. This will prevent the risk of non-renewal cancellation or transition into the Excess and Surplus lines insurance market. ■

Customer satisfaction in the medical and dental practice;

You won't know what you don't know—if you don't ask

Customer satisfaction is becoming an important component in the provision of healthcare. There are several reasons for this transition. First, patients increasingly see themselves as consumers of medical or dental services. Many of them want to be more directly involved with the planning of their healthcare and reject the theory that patients should passively submit to paternalistic decisions in which they have no say as obsolete. This transition has been in the making for at least a decade and a number of studies have shown that patients who feel like partners in their healthcare generally have better outcomes and report higher levels of satisfaction. In spite of these studies, the transition has been slow.

Second, and perhaps more compelling, regulatory entities have stepped up the pressure for patients' inclusion in the healthcare equation. As patient populations shift into ambulatory care centers, and as the scope of clinical services increases in medical offices, health insurers and accrediting bodies such as The Joint Commission require consistency in patient safety and satisfaction protocols, regardless of the environment of care. Bodies such as the Centers for Medicare and Medicaid Services (CMS) as well as The Joint Commission, use data about customer satisfaction to compel providers to measure outcomes—from their patients' perspectives.

Taking these changes into account, it is apparent that a medical encounter can no longer be closed without some assessment of the patient's experience of care.

Health insurers have long contended that patients' perceptions of their healthcare is a key quality indicator. Increasingly, this data is being used to determine whether or not providers may participate in some insurance panels. Depending on the doctor's locale and specialty, being "fired" by Medicare or a health plan can play havoc with a medical or dental practice's survivability.

There's a third reason why doctors should regularly seek input from their patients. The results provide two kinds of opportunities. Perhaps the easiest to assess is clients' feedback about the things that went right, the specific elements of care that pleased them. By identifying what they've "done right," doctors can build on those successes and avoid inadvertent dismantling of processes that work. The flip side of this opportunity gives doctors a chance to hear patients' perceptions of areas that need improvement. In today's busy medical and dental offices, doctors can't be everywhere and neither can their employees. But, when asked, patients can often be quite specific about elements of their care that didn't work for them.

As patient populations shift into ambulatory care centers, and as the scope of clinical services increases in medical offices, health insurers and accrediting bodies such as The Joint Commission require consistency in patient safety and satisfaction protocols, regardless of the environment of care.

Patient Feedback Ideas:

Regardless of whether they have a fully-integrated EHR or are still committed to a paper-based system, there are numerous ways in which physicians and dentists can seek patient feedback.

- The sign hanging in a Texas pediatrician's office: ***If we treated you great today, please tell your friends. If we didn't, please tell us about it right now.***
- End-of-appointment systems include small surveys that can be completed and deposited in an office mailbox; Or postcards that can be turned in at the end of a visit or mailed at a later date; Or email addresses or practice website addresses where patients can complete surveys or share their feedback.
- Verbal requests for feedback–from clinical staff and from office employees who interact with patients after the clinical portion of the visit is complete.
- Computerized surveys that allow the patient to enter survey responses directly into the practice's quality management files, while still in the office.
- Lists of contact names and phone numbers so that patients can speak directly with providers, practice administrators, or technical managers, e.g., billing or reception. This option may be especially useful if the patient has a complaint that may take some time to explain or that involves more than one employee of the practice.
- Third party survey and feedback programs, typically contracted with vendors who specialize in gathering and analyzing the feedback data. Some of these vendors also provide benchmarking services that help providers compare their results with de-identified results of other similar providers.

Ideally, everyone associated with a medical or dental practice should feel a sense of ownership for customer satisfaction. However, the process works best when an individual or group of individuals "own" the customer service function. The structure of this role should include:

- Job description details that specify customer service accountabilities.
- Written policies and procedures should ensure that the customer service plan is comprehensive enough–and that its various elements are consistently implemented by all doctors, staff and employees.
- This should include timeframes, formats, document templates, e.g., surveys, response letters, etc., training programs and disciplinary actions for non-compliant staff.

A well-designed customer service program will have a positive effect on the culture of a medical or dental practice. It will help doctors and staff alike develop a mindset that focuses on ways to provide outstanding service–and on seeking patients' input and feedback relative to that service. It shows a willingness to acknowledge that there is room for improvement and the determination to follow through with change. ■

The request for feedback is important because a number of studies have shown that patients may switch doctors rather than complain about inadequate service. It is to the physician's or the dentist's advantage to have the opportunity to learn about service lapses and be able to fix them. By doing so, they may be able to retain good business and reduce the potential for disputes that might encourage the disgruntled patient to find a sympathetic ear in an attorney's office.

Increasingly, healthcare providers are being pressured to switch to electronic health records (EHRs). In the Spring issue of *Protector*, the lack of quality initiatives was highlighted as a flaw in most ambulatory care facilities, regardless of whether they use paper or electronic information management systems. While emphasizing the importance of quality processes, EHR accrediting body CCHIT (Certification Commission for Healthcare Information Technology), doesn't mandate that electronic systems include collection and analysis of patient feedback as a component of quality improvement. This seems like an oversight, in light of the push for patient safety initiatives and the health industry's insistence that patients should be partners in the healthcare process. Without the ability to close the loop on each element of care by soliciting the patient's input, doctors may find it difficult to sustain an effective doctor-patient relationship and to provide seamless care.

Corporate compliance: A reminder

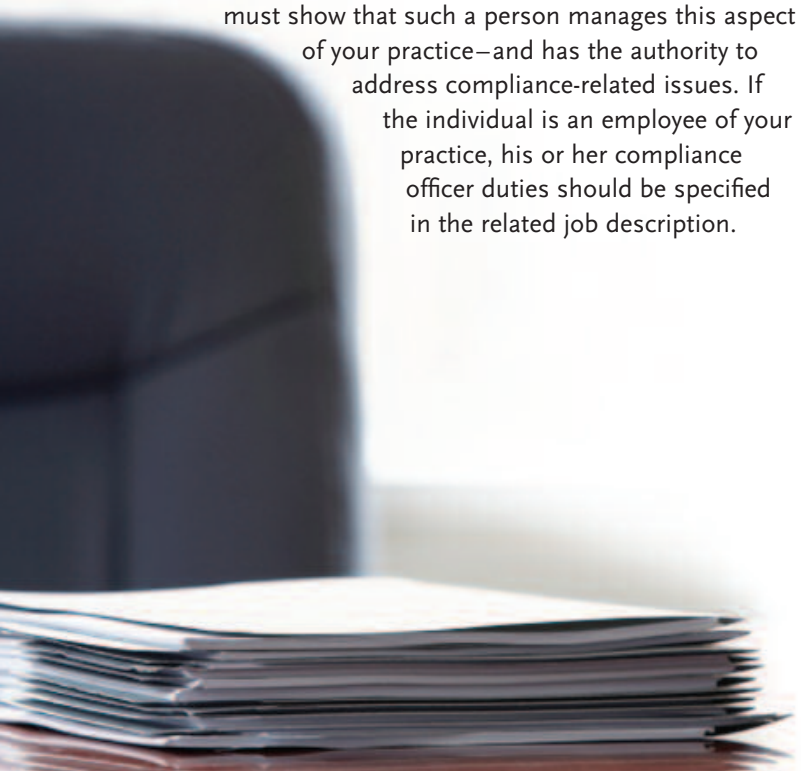
It's been thirteen years since President Clinton announced "Operation Restore Trust," an initiative designed to combat fraud, waste and abuse in Medicare and Medicaid programs.[1]

Healthcare entities that accept government funding or payments are required to abide by a group of regulations typically lumped together as "corporate compliance" law. While the Office of the Inspector General (OIG) has designated compliance programs as "voluntary" for individual and small group practices,[2] healthcare providers who ignore these guidelines may be unable to protect themselves from complaints of fraudulent billing or of failure to correct a pattern of billing errors. Since deviations from corporate compliance protocol can have significant penalties, physicians and dentists in private practice need to be sure that financial integrity doesn't get lost in the day-to-day shuffle of busy practice.

A quick review:

- Do you have a designated corporate compliance officer? This person may be an employee of your practice or you may contract with an outside entity which provides the service. But, your documentation must show that such a person manages this aspect of your practice—and has the authority to address compliance-related issues. If the individual is an employee of your practice, his or her compliance officer duties should be specified in the related job description.
- Does your corporate compliance officer, in fact, have the authority, as indicated in his or her job description, to drive related activities, including education, audits, responses to reports of non-compliance, etc.?
- Do you have a written corporate compliance plan? Are activities undertaken on behalf of this plan documented and retained in a compliance-specific file?
- Are all employees educated about their corporate and individual duties under the law? Are they aware that they are not only authorized, but also obligated, to report suspected non-compliance?
- Do they participate in compliance-specific activities in a timely and comprehensive manner as relative to their daily activities, e.g., periodic audits comparing clinical and financial records to ensure consistency and accuracy of billing and other financial data?
- Does your corporate compliance program assure follow-up to those who report suspected non-compliance—and does it protect those individuals who report possible violations from punitive or harassing activities?
- When non-compliance has been noted, what actions has your group taken to correct them? What actions have you taken to prevent them from recurring? Have you documented these activities?
- Have you identified resources for questions about your corporate compliance program? An attorney who specializes in compliance issues? Access to a hospital corporate compliance officer?

Physicians and dentists who would like to avail themselves of a broader overview of corporate compliance in the healthcare environment, can contact the Medical Protective Clinical Risk Management Department at 800-4MEDPRO. ■



1. Operation Restore Trust Activities, November 1995, available at www.oig.hhs.gov
2. Federal Register, June 12, 2000 (65) FR35818

Medical Protective's Risk Management Self Assessment

Patient safety and satisfaction are key factors in your practice's success — have you had a risk checkup lately?

Assessing risk is the first step to *reducing* risk in your practice. Medical Protective wants to help you determine what steps you could take to reduce your risk by offering all insureds a FREE online risk assessment.

Upon completion of the assessment you can be entered into a drawing for one of five $50 gas cards.

Your results will be kept anonymous and separate from the drawing entry. Deadline to be entered in the raffle is January 15, 2009.

Taking this risk assessment can:

- **Identify areas in which your practice already excels**
- **Give you an in-depth look at the risks associated with your practice**
- **Isolate areas where improvements are needed so you can work with your consultant to find critical solutions**

Medical Protective will be aggregating data from these assessments to create a benchmark. All results will be kept confidential.

Steps to gain access to this resourceful tool:

1. Login www.medpro.com with your username and password.
   If you're new to the site, you can register in one easy click.
2. Type in your policy number.
3. On your homepage, click the "enter here" link under Risk Assessment.

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