

Rise to the Challenge of **MEDICARE PART D**

“Challenging” is a polite way of describing the practical implications of Medicare Part D. Although the drug coverage component has received the most attention, Part D includes numerous other provisions for drug utilization, quality assurance, and Medication Therapy Management (MTM) programs. MTM programs are intended to provide services that will optimize therapeutic outcomes by helping certain beneficiaries better understand their medications, avoid and detect adverse drug events, and adhere to their therapy.

Any of these Part D components may present potential new liabilities for pharmacists; the specific risks, though, remain unclear. Though the Centers for Medicare & Medicaid Services (CMS) have published guides, these documents have been directed primarily to plan sponsors, leaving pharmacists to figure out the benefit—and its attendant risks—as best they can.

That said, billing issues clearly represent one potential minefield for liability. According to Karen Jonas, director of professional practice at the Michigan Pharmacists Association, members of her association have had difficulties with a variety of billing issues. When the prescription drug benefit went into effect in January 2006, pharmacists were instructed to enroll dual-eligible beneficiaries whose plan could not be determined in the facilitated enrollment “backup” plan, Wellpoint. In some instances, patients ended up being inadvertently enrolled in multiple plans. Pharmacists also have had to struggle with determining whether a drug should be covered by Medicare Part B (the medical coverage program) or Part D.

“CMS has made it clear that it intends to crack down on fraud, waste, and abuse,”

Jonas said, so pharmacists are concerned that mistakes caused by Part B vs. Part D billing confusion might be misinterpreted. “If you billed one claim incorrectly then they’ll think, ‘you probably didn’t know any better.’ But if you bill four or five or 10 claims incorrectly, how is that going to be perceived? Is an auditor going to think you were trying to commit fraud?”

Susan Bishop, former director of federal regulatory affairs at the American Pharmacists Association (APhA), acknowledged the confusion. But, she emphasized that the government is focused on identifying fraud and waste, not playing “gotcha!” with well-intentioned pharmacists.

Other risks largely unknown

Plan sponsors haven’t yet told pharmacists what they expect, either. In April 2006, CMS issued a 70-page tract in which it made a number of recommendations to sponsors about controlling fraud, waste, and abuse.¹ Whether or not plans choose to implement those recommendations and require pharmacy partners to implement certain controls remains to be seen.

What’s more, different plans may impose different requirements, said Don Bell, general counsel for the National Association of Chain Drug Stores. Many of the CMS recommendations are intended to ensure that pharmacists and other suppliers that are excluded from participating in federal healthcare programs are barred from participating in Part D.

Ironically, while much of the discussion has focused on dispensing and contractual requirements, the seminal aspect of Part D—and the one with the greatest risk management implications—has received little attention, said Mark P. Petruzzi, RPh,

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American Pharmacists Association
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president, Security Rx, Glastonbury, CT. The \$64,000 question? Petruzzi thinks it is what form will MTM programs take and how increased professional liability risks associated with them will be addressed.

As the market works through those issues, the role of the pharmacist as a care provider will evolve, Petruzzi thinks. “Pharmacists will become more patient focused and start making decisions that affect therapy,” he noted. “Their risks—even if they are following protocols established by physicians or physician groups—will become similar to those of physicians and NPs.”

While waiting for these issues to be clarified, Jonas recommends that pharmacists protect themselves. “We’re advising pharmacies to make sure they have policies and procedures in place to demonstrate what they are doing to ensure quality assurance.” Individual pharmacists should work with their employers to develop a plan if none exists. Pharmacists also need to stay up to date on CMS guidelines and regulations for implementing the Medicare Part D benefit via the APhA Web site (www.aphanet.org).

REFERENCE

1. Centers for Medicare & Medicaid Services. Prescription Drug Benefit Manual, Chapter 9- Part D Program to Control Fraud, Waste and Abuse. www.cms.hhs.gov/PrescriptionDrugCovContra (Oct. 10, 2006).

Did you know...

...what pharmacists are saying about the right to refuse

In the 2006 *HPSO Risk Advisor*, we discussed a pharmacist's right to refuse to fill a prescription. Medscape conducted a survey in July 2005 on this issue, but its classifications of respondents—physicians, nurses, and all others—left pharmacists' views unclear. So, HPSO conducted its own survey. Here's what you said:

It has been argued that pharmacists are exercising their right to do as physicians have done for years: refusing to participate in medical practices that conflict with their religion or morals. Should a pharmacist be required to fill a prescription that may conflict with his or her personal beliefs?

■ 19% said YES ■ 80% said NO

If the law allows a pharmacist to refuse to fill a prescription due to personal beliefs, should the pharmacy be required to have another pharmacist on duty fill that prescription?

■ 17% said YES ■ 82% said NO

As long as the pharmacy notifies the public that certain prescriptions may have to be filled elsewhere, and provides information about other locations where the prescription could be filled, is it then acceptable to decline filling a prescription?

■ 74% said YES ■ 25% said NO

Some advocacy groups defend the right of pharmacists not only to decline to fill prescriptions themselves but also to refuse to refer customers elsewhere or transfer prescriptions. Do you agree?

■ 45% said YES ■ 54% said NO

The APhA countered in an April 2005 *New York Times* editorial, "Moralists at the Pharmacy," by stating that the current "middle ground" of accommodating patient access (by referring patients to another pharmacist or drugstore) while protecting pharmacists' freedom is working well. Do you agree?

■ 61% said YES ■ 39% said NO

Whatever your views, to avoid a lawsuit it's important to know and follow the law on refusing to fill a prescription on moral grounds in the state where you practice.

LESSONS

FROM COURT

Child dies from fentanyl overdose

A 9-year-old complained of postoperative pain following a tonsillectomy and adenoidectomy. His primary care provider prescribed a fentanyl patch (Duragesic) to alleviate the pain. The child weighed 67 pounds. After the patch was applied, the child became drowsy and fell asleep. He was found dead the next morning.

The autopsy revealed respiratory failure secondary to acute fentanyl intoxication as the cause of death. The plaintiff claimed the patch was contraindicated for a patient his age and for an individual weighing less than 110 pounds.

Some of the defendants reached a confidential settlement. The defendant surgeon argued he had no knowledge of the inappropriate prescription, and a verdict was returned in favor of the defense.

Staff. (2006). *Medical Malpractice Verdicts, Settlements & Experts*, 22(8), 46.

Advice from the expert:

The Duragesic product label was updated in June 2005 to warn against its use in patients who are not opioid tolerant. A "Dear Healthcare Professional" letter from the manufacturer specifically states that Duragesic is contraindicated "in the management of postoperative pain, including use after out-patient or day surgeries." A prudent pharmacist would contact the prescriber and question this use specifically contraindicated on the product label. If the prescriber provides information that supports the off-label use of the medication, this should be documented on the prescription and on the profile of the patient. If the prescriber could not provide this information, the pharmacist would be wise not to fill the prescription. Because these necessary inquiries were not made, the drugstore that employed the pharmacist who filled the prescription shared liability.

Michael D. Alfano, RPh, JD
Philadelphia, PA

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www.hpso.com/convention

Reducing your risk begins with hello

It should come as no surprise to know that patients and clients who perceive a provider as courteous, attentive, and having their best interests at heart are less likely to sue than patients and clients without these perceptions, especially if the outcome isn't exactly what they had hoped. Though the correlation between patient/client satisfaction and lawsuits is particularly well-documented for physicians, it can apply to all other healthcare professionals as well. With that in mind, you should consider the different ways you can improve your interactions with patients, noted James W. Saxton, a Lancaster, PA-based attorney and author of *The Satisfied Patient: A Guide to Preventing Malpractice Claims by Providing Excellent Customer Service*.

In healthcare, as in other fields, satisfaction begins with a first impression. "You need to invest in that first 10 seconds," Saxton said. Greet patients/clients by surname, unless they request otherwise. Look them in the eye, smile, "and treat them the way you

would want to be treated or the way you would want your parents to be treated." Before you begin working with a patient or client, take a few moments to explain what you are about to do and ask if he or she has any questions so you can assess the individual's comfort level and allay any concerns. Communicate clearly, using layman's terms, rather than clinical terminology. In addition, describe the treatment, any associated consequences, and how the patient can enhance its efficacy.

Throughout the visit, listen to concerns and expectations. Failed communication with patients or clients and their families is one of the most common causes of malpractice suits. "The importance of listening can't be overstated," Saxton said. He recommends that practitioners end the visit by asking, "Is there anything else I can do for you?" or "Can I answer any other questions?" Too often, he said, patients and clients feel that they were rushed. "Asking some type of open-ended question generally doesn't take more time and it sends patient satisfaction sky-high."

Wearing two hats: Are you covered?

The typical working American changes careers between five and seven times during his or her lifetime, according to the National Career Development Association. Healthcare workers are no exception. In fact, a large number of healthcare professionals not only change jobs, but often they practice in more than one area simultaneously, carrying two active licenses. For example, a physical therapist may also work as a personal trainer at a gym, while an exercise physiologist might also be a licensed dietitian. If you're dually-licensed, adequate insurance is essential.

HPSO cautions that, as a rule, if you have a license in one field but are working in another that requires less training, your professional liability insurance coverage must match your license, not your current



job. Michael Liebowitz, president of the Risk and Insurance Management Society, agrees: "You always insure at the highest level. It's really that simple." Fortunately, HPSO will cover you for both professions with a single policy; your premium is based on the license with the higher level of risk.

If you have more than one credential and have questions about your coverage, call HPSO at 800-982-9491.

Employed, self-employed, or LLC—Are you underinsured?

Theoretically, the difference between working for yourself and working for someone else is huge. In reality, many circumstances blur those lines. And being classified as employed, self-employed, or limited liability company (LLC) affects the kind of professional liability insurance you need.

If you draw a salary from an employer, your status is clear: You're an employee. If you practice on your own, your status also might seem obvious: You're self-employed. However, it's not as obvious if you perform professional services for one or several facilities as an independent contractor. What if you're employed during the day and provide services at another facility in the evening? Or, to add further confusion, if you incorporate yourself but are a single-person practice, are you still self-employed?

HPSO has a product to fit each of these classifications. If you work exclusively for a facility, a basic individual professional liability insurance policy for employed healthcare professionals suffices. If you perform professional services in a setting for 120 hours or more a year as a consultant, or you are an independent contractor, you need the comprehensive coverage of a self-employed policy. It protects all your professional services in the workplace, as well as services you offer to consulting clients.

But, let's say you establish a business, complete with a Federal Employer Identification Number. This can afford many privileges but may also open the door to risks for which you need to be protected. Even if you don't plan on hiring employees, you have created a new entity, and it's important to keep your assets and those of your business separate. If you are ever sued, you and your business can be named separately, so you need to make sure you are fully covered with a professional liability insurance policy for a small business.

If you are, or expect to be, practicing on your own, you may need to consider changing your HPSO policy. If you have any questions, e-mail us at service@hpso.com or call 800-982-9491.

How to Avoid Profess

Shield yourself from pitfalls

“Assessment and treatment errors are among the top causes of professional liability claims.”

Despite the best of intentions, every healthcare provider makes errors now and then. Fortunately, many prove harmless and go unnoticed by patients. Others, however, are not so innocuous and can trigger professional liability claims.

It's useful to know the errors that are most likely to prompt a professional liability claim so you can learn to avoid them. Here are some of the most common triggers, along with some advice on minimizing your risk.

Top errors in healthcare

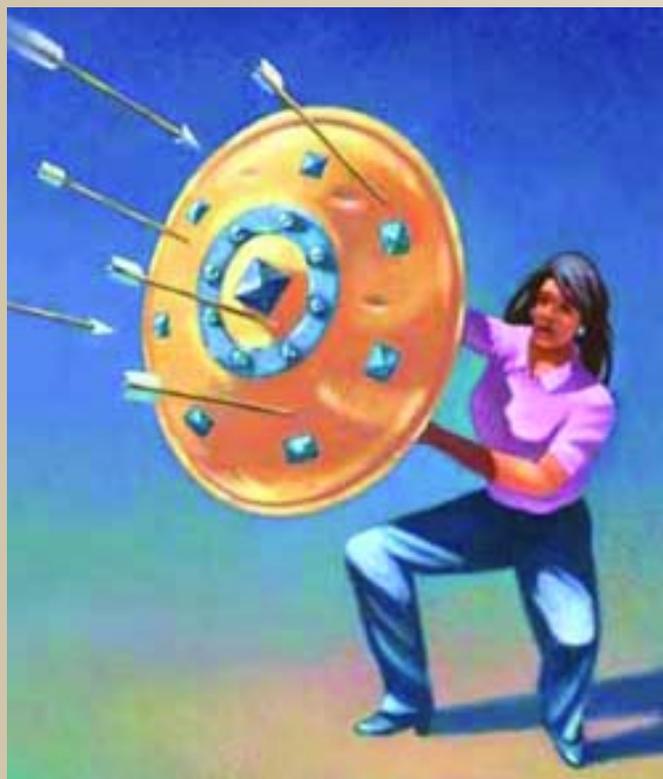
Assessment and treatment errors are among the top causes of professional liability claims. According to a recent report by CNA, the underwriter of your professional liability insurance policy, failure to properly assess patients are among the most severe (expensive) claims against physical therapists.¹ Failure to assess or treat patients' problems plague counselors, too, said Paul L. Nelson, executive director of the American Counseling Association (ACA) Insurance Trust. He also noted that 14% of the claims from 1997-2003 cited those allegations.

For PTs, treatment errors involving therapeutic exercises trigger lawsuits more than a third of the time.² “A patient may claim the therapist gave him an inappropriate exercise or too much exercise,” said Jonathan M. Cooperman, PT, DPT, MS, JD, president of the Ohio Physical Therapy Association. Failure to use safety equipment, like opting not to use a gait belt, also can lead to malpractice allegations if a fall occurs. So can burns. This type of injury may reflect failure to properly monitor patients—the second most common reason for professional liability claims against PTs.

Medication-related errors, another major cause of claims, can affect pharmacists in particular. A pharmacist, often faced with time constraints, may feel rushed to fill many prescriptions quickly and may provide the wrong dosage. He or she could give the right medication to the wrong patient or could even administer the wrong medication because of all the “look-alike, sound-alike” agents on the market today. Such errors generally account for around half of medication-based professional liability claims.³

Pharmacists can also face risk from a prescriber's mis-

takes. “Pharmacists have to make sure the medication ordered is appropriate for the patient,” said Michael D. Alfano, RPh, JD, a Philadelphia-based attorney. “A physician may prescribe a medication the patient is allergic to or request a dose that is outside the usual range. It's the pharmacist's duty to check with the prescriber if there's any doubt about a prescription.”



Other causes of malpractice claims

Inappropriate relationships with patients can also land practitioners in court. And if there's proof that sexual misconduct was involved, chances are malpractice insurance won't come to the rescue. Most policies do not pay any damages connected to sexual misconduct and may not even provide for the client's defense. Counselors in particular should take heed, since sexual intimacy (real or perceived) is the top cause for claims against them, accounting for 17% of the claims reviewed by Paul Nelson of the ACA Insurance Trust. PTs, particularly those

ional Liability Claims

specializing in women's health, also must make sure they keep relationships with patients strictly professional, said Cooperman, given that necessary contact could be interpreted as inappropriate touching.

Violating patient privacy is another liability hot button for all practitioners. (For an overview of the requirements imposed by the Health Insurance Portability and Accountability Act of 1996, read "Patient Privacy and HIPAA Hype," on page 4 of the 2003 *Risk Advisor* at www.hpso.com/hipaa.) Here, too, counselors should take extra care; breaching confidentiality, whether real or perceived, is the third most common reason for claims reported to the ACA Insurance Trust. For an example of such a case, see the November 2003 "Case of the Month" on the HPSO Web site at www.hpso.com.

Many claims can also arise from inadequate communication with patients, in one form or another. For instance, failing to get informed consent is cited as a secondary claim in many professional liability actions. Dispensing medications to patients without offering to counsel them can put pharmacists at risk. And, as mentioned on page 3, if a patient is unhappy with your care, even seemingly small transgressions such as rushing the visit can increase the likelihood of a lawsuit.

Know your duty and your limits

Since liability can arise when a healthcare practitioner violates the defined scope of practice, your first line of defense is to make sure you understand what you can and can't do according to the law as well as your practice act and other written guidelines.

Review your employer's requirements, limits, and procedures, as well as any imposed by your state. Also, be familiar with the code of ethics outlined by the professional organization for your field of practice. It's important, too, to keep current with evolving patient care protocols. Take continuing education classes, attend lectures, and read professional journals to stay abreast of

changes in your field of practice.

In addition, look for ways to improve patient communication. Ask patients plenty of questions, listen carefully to the answers, and do your best to ensure that they understand what you've said to them. These actions can decrease the chances that a patient will file a professional liability claim or even a complaint with a professional board or state agency that oversees standards of care.

Gayle Sullivan, RN, JD, an attorney from North Haven, CT, noted that "You don't even have to harm a patient to face professional discipline. Say a pharmacist makes a few dosage errors that do not result in any patient injury. If the state board learns of them from patients, it may investigate and take disciplinary action." For minor transgressions you may only have to pay a fine or take a continuing education course, but serious violations can result in suspension or revocation of your license.

As always, thorough documentation of each patient encounter is critical. Record your observations about the patient's status before, during, and after care; your treatments and the reasoning behind them; any comments or concerns the patient expressed; how you responded to those comments or concerns; and how the patient received any overall guidance or specific care instructions you gave. Detailed notes can go a long way toward protecting you if you're named in a lawsuit. They're proof of your efforts to meet the appropriate standard of care.

What to expect if you're sued

You hope you will never find yourself at the center of a lawsuit, but if you do, you need to know how these suits typically unfold. First, the plaintiff's attorney files the complaint, and you're notified of the charges against you. Once this happens, you'll need to promptly notify your supervisor, your employer's risk manager, and HPSO. Never respond directly to the complaint or any other inquiries from the plaintiff's attorney; all communications should go

through the claims consultant and/or attorney assigned by CNA.

During the next stage, the discovery process, both sides collect information. You may have to answer questions in writing (interrogatories) or orally in an attorney's office (depositions) under oath and provide records or documents. The attorneys for both sides may subpoena witnesses to offer testimony or supply additional documents. They may also hire expert witnesses.

A pretrial hearing, which allows both sides to bring issues before the court, is next. The judge may set limits on the case or request clarification of certain points. Attempts to settle without a trial may follow, through court-ordered mediation or direct negotiations between the attorneys. If a settlement isn't reached, the case goes to trial, but it can sometimes take years for the case to be heard.

As you can imagine, a lawsuit is a grueling process, and the resulting damage to your reputation and personal assets can be devastating. Your best protection is to make sure you're adequately insured and to take steps to avoid the kinds of errors that invite claims in the first place.

REFERENCES

1. CNA. Physical Therapy Claims Study. Available at www.cna.com. (Nov. 10, 2006)
2. Claims at a glance. *HPSO Risk Advisor*, Physical Therapy Edition, Winter 2001.
3. Claims at a glance. *HPSO Risk Advisor*, Pharmacist Edition, Winter 2001.

To learn more about obtaining informed consent, a common secondary issue in professional liability complaints, see the Web Flash in the newsletter section of

www.hpso.com/webflash2007

Thinking about Retiring or Taking a Leave of Absence?

The current workforce is aging and more healthcare professionals are considering retirement, while others may decide to take a leave from their careers to care for young children or aging parents. Still others decide to pursue a different career path that does not require their license. Nonetheless, many healthcare professionals want to keep their license active, especially after all the hard work they did to acquire it.

If you are thinking about retirement or decide to take a temporary leave of absence from your profession while maintaining an active license, you should also consider retaining your professional liability insurance policy. That's because you can still be sued as a licensed professional if you do any side work, volunteer, or even give advice to a friend, neighbor, or acquaintance.

The good news is that you will be entitled to a premium discount of 50%. In addition, your coverage is reduced to professional liability, license protection, and assault protection.*

If you elect to take this option when renewing your policy, simply indicate "Retired/Leave of Absence Policy" on your premium invoice and return it with a check in the amount of your current premium minus a 50% discount to HPSO, 159 East County Line Road, Hatboro, PA 19040-1218. Or you can simply call HPSO at 800-982-9491; e-mail us at service@hpso.com; or fax your requested change to 800-739-8818.

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* Assault coverage is not available in Texas.

MOVING?

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Move Beyond That Mistake

Maybe you made a mistake that resulted in a patient's falling or receiving the wrong treatment. Even a lesser incident, such as giving a patient the wrong dosage of medication that caused no adverse effects, is still a mistake. Regardless of the severity, mistakes are stressful. They bring about concerns for patient well-being, as well as your own potential for liability.

If you make a mistake, your best option is to report it to your manager as soon as possible. Hiding the mistake will only increase your level of anxiety, as well as your chance of disciplinary action. It also can cause superiors and peers to think you are dishonest because you tried to hide something. Follow the procedures used by your facility and be prepared to answer questions about the incident clearly and concisely. It's also wise to inquire whether your institution has a confidential reporting system, or a no-blame policy, as recommended by the Institute of Medicine. Make

sure you comply with all state and federal requirements, as well as those of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). And notify HPSO at once, by filing an incident report online, by fax, or by mail, if you

think a claim may be brought against you. If the mistake resulted from a substandard setting within your facility, such as faulty equipment or short staffing, be proactive by taking steps to improve the situation. Start by notifying your supervisor, and continue moving up the chain of command, as necessary.

Making a mistake, even a minor one, can leave you doubting your abilities. Fortunately, you can take steps to regain your



confidence and help prevent future incidents. Stay up to date on your State Practice Act, take advantage of continuing education courses, read your professional journals, and make sure you're properly

trained on all new equipment and treatments, therapies, and medications. You can also reassure yourself by taking time to double-check your work.

If you find that you're still doubting yourself, consider jotting down a list of your positive qualities as a provider, and remember how often you help patients. Reporting mistakes can seem daunting but can ultimately improve patient care and reduce your risk of liability.

Handle Controlled Substances with Care

You know that mishandling any medication can have legal consequences. But, are you fully aware of how to protect yourself from liability and avoid jeopardizing your license or hurting a patient when dealing with a controlled substance? Here are a few basic guidelines:

- Always verify the prescriber's Drug Enforcement Agency (DEA) registration number before filling any prescription for a controlled substance. Getting to know the names of local physicians and their signatures will help you to spot forgeries. Prescribers who write many scripts or frequently request outsized quantities should make you suspicious. So should patients who seem particularly distracted or uncomfortable when picking up a prescription. Check every questionable prescription for signs of

alterations, and ask uneasy patients for identification when necessary.

- Make sure the prescription was written for a legitimate medical purpose, even when it seems valid. That can be tricky, said Michael D. Alfano, RPh, JD, a Philadelphia-based attorney. "For instance, some patients legitimately need narcotics in large doses to control pain. But, it's a very delicate balance. You need to weigh concern for the patient and the risk of abuse."
- Don't hesitate to review the patient's pharmacy records and contact the prescriber with questions, if necessary. Denying a patient medication he needs or giving an addict more drugs can put either type of patient at risk and endanger your license. Be sure you also objectively document your reasons for filling or denying a prescription.

- If you know a prescription is fraudulent, alert the police. If you're not sure, call your State Board of Pharmacy for guidance. Also report patterns of questionable prescriptions to the Board of Pharmacy or to the DEA.
- Follow federal and state requirements for record keeping, security, and transfer, as well as for disposal of controlled substances and theft reporting.

To review these requirements, consult the Pharmacist's Manual at www.deadivision.usdoj.gov/pubs/manuals/pharm2/index.htm and check with your state Board of Pharmacy to see if additional state regulations apply. You'll find a link to your board's Web site at www.nabp.net/whowere/boards3.asp.

To limit your legal risks when you handle controlled substances, educate yourself about the rules, including the Federal Controlled Substances Act and your state's Uniform Controlled Substance Act and Pharmacy Practice Act.

ARE YOU CONSULTING, TEACHING, OR TRAINING?

Your professional liability insurance policy provides coverage for medical incidents that result in injury or damage. But, losses that arise from consulting, teaching or training activities, or through expert testimony, would not typically be covered by your professional liability insurance policy.

For only \$25, you can add the Consulting Services Liability Endorsement to your policy. The Endorsement provides coverage for when you use your professional skills and knowledge in settings that do not involve direct patient care.

With the Consulting Services Liability Endorsement, you receive protection for using your knowledge to provide non-medical services, such as:

- Training
- Legal consultation
- Speaking at seminars or Teaching
- Providing expert testimony

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- ▶ Are you properly insured?
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- ▶ What are some of the best ways to avoid professional liability claims?
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- ▶ How can I reduce my risk when handling a controlled substance?
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