They're efficient, but mail-order Internet pharmacies have intricate legal requirements

Medicaid Matters

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Mail order and Internet pharmacies are a growing and profitable business thanks to their cost savings over traditional pharmacies, as well as the ease of ordering and delivery services they provide. However, filling prescriptions across state lines can create serious legal issues and economic consequences for those entities, if not done properly.

State licensing laws, state public health codes, and Medicaid provisions (along with other reimbursement programs) all have specific compliance requirements that must be met. Moreover, the various State requirements are often elusive, ambiguous, and may even conflict with other requirements. Consultation with a health law specialist will help you avoid these and other legal pitfalls.

Dotting i's, crossing t's

One obvious area of concern for pharmacies, like all health care providers, is Medicaid compliance. Medicaid has voluminous and complex compliance requirements. Keeping abreast of all of the various and constantly changing requirements can be more than a full-time job.

The penalty for noncompliance is harsh: denial of reimbursement claims. Compliance has become such a daunting task that educating providers about compliance and providing compliance/billing services has become big business. Indeed, coding compliance has become its own separate industry.

But take a step back. Before you even get to the point of addressing the compliance issues about whether there are qualified services, proper billing/procedure coding, proper supporting documentation, and other Medicaid concerns, the first and most important provider participation requirement for all reimbursement programs is licensure. *The services performed must be within the scope of the licensure of the provider.*

This seems quite obvious, right? In fact, it is so obvious that compliance with this seemingly simple requirement is often assumed or taken for granted. Many times, verifying licensure is not even included in a general compliance checklist.

Nonetheless, proper and current licensure is a necessary and mandatory requirement for reimbursement. For those pharmacies that provide services across state lines, the issue is even more complex.

This leads to the next important question: *Where does a pharmacy have to be licensed?* A pharmacy's home or locus state seems like the obvious answer. And, for the majority of pharmacies, this is the correct answer.

For pharmacies who limit their business to serving patients/customers residing in the pharmacies' home state, the pharmacies only need to ensure that their home state license is up to date and remains current. These pharmacies should make it a practice to keep a list of all licensure and certification expiration dates. Often, renewal is as easy as sending in a check.

Out-of-state pharmacy licenses

But for pharmacies conducting business out-of-state, the issue becomes more complex. Many pharmacies are not even aware that a separate license may be required for each and every state to which prescriptions are shipped. Not having a current out-of-state pharmacy license has proven costly for some unfortunate pharmacies.

Many states have enacted legislation requiring out-of-state pharmacies that fill prescriptions for in-state residents to obtain a non-resident pharmacy license. The criteria for obtaining such an out-of-state pharmacy license is usually procedurally simple. Proof of licensure in the pharmacy's home state and payment of a license fee are generally sufficient. So the difficulty is not in obtaining the out-of-state license. The difficulty lies in discovering that the requirement exists.

How is an out-of-state pharmacy supposed to know whether a particular state has such an out-of-state licensing requirement? This is where some research is required and a health law specialist is valuable.

Frequently, an out-of-state pharmacy's only contact with an outside state is through the mail or Internet when it is receiving or filling prescription orders. These pharmacies can be doing business nationally in almost every state. For each and every state where an order is placed, licensure compliance may be required.

Many mail-order or Internet pharmacies do business through state Medicaid programs. These pharmacies need to apply for participation in each state Medicaid program in order to be eligible for reimbursement. An unsuspecting out-of-state pharmacy that wants to conduct business in another state must contact that state Medicaid program for participation acceptance.

Upon obtaining participation acceptance, it is easy to be mistakenly lulled into believing that all compliance requirements have been met. Unfortunately, it is a common misconception by pharmacies that if they meet all of Medicaid's requirements for participation, they are home free. This is not always the case, and it's where the trouble lies.

Some state Medicaid programs do not even reference or include the out-of-state pharmacy license requirement as a condition of participation in the Medicaid program. Some state Medicaid programs do not even verify compliance with their state's out-of-state pharmacy license requirement as part of the Medicaid participation application process. Incredibly, other states' Medicaid statutes' "plain language" conflicts with their own state licensing requirements.

For example, in Iowa, the Medicaid statute provides that "[p]harmacies are eligible to participate [in the Iowa Medicaid program] providing that they are licensed in the state of Iowa *or* duly licensed in other states." (Emphasis added.) Yet, Iowa has an out-of-state pharmacy license requirement which is not mentioned in the state Medicaid statute, is not mentioned in any of the Medicaid compendia, and conflicts with the Medicaid statute's "either/or" participation language.

The consequences for failing to comply with a separate out-of-state license requirement can be severe. The failure to comply with a separate, non-Medicaid licensing requirement has provided the (arguably unjust) basis for overpayment claims by state Medicaid programs. Such overpayment claims may be issued several years after the fact, after millions of reimbursement dollars have been paid.

Unbelievably, the state's own Medicaid employees in charge of approving applications often do not know about the state's conflicting out-of-state pharmacy license requirement and do not require proof of licensure for admission to participate in the State's Medicaid program. Yet, in a pending case, that did not stop the state Medicaid Agency from going after a dozen or so out-of-state pharmacies seeking to recoup several million dollars in what it called "overpayments."

What should pharmacies do?

The first thing that pharmacies should do is *not* to rely on the state Medicaid program documentation as the conclusive authority about state licensure requirements. Pharmacies providing services out-of-state must do their own independent research to ensure compliance with all state specific licensure and other requirements. This is where a health law specialist can be helpful.

Pharmacies (and really all health care providers) need to ensure that their home-state licenses are up to date, as lapses in home-state licenses can result in denial of reimbursement and overpayment claims, too.

Pharmacies that provide services to out-of-state residents must take extra precautions to ensure compliance not only with their home-state's licensure and Medicaid requirements, but also with any applicable local laws and state Medicaid requirements in all other states where services are being provided.

A few minor billing errors aren't really going to matter, right? Think again

By Robert S. Iwrey, Esq.

When undertaking compliance measures, it is not uncommon to hear a physician attempt to justify the presence of billing errors by saying that the far majority of the billing is accurate and that one cannot worry too much about an occasional error here or there. Moreover, it is common to hear physicians say that they are not responsible for coding and that they heavily rely on coders to perform this function.

While physicians can delegate this responsibility, physicians must understand that they should know the coding rules applicable to their services since they are ultimately legally responsible for the accuracy of coding that is performed for their services. Submitting claims with inaccurate coding can lead to false claims exposure for a physician even if the physician did not personally assign the code. Moreover, it is important to note that there need not be a pattern and practice of billing errors for legal exposure to occur.

A review of the recent unpublished decision in *People v. Plymouth Road Dental, P.C.* clearly demonstrates the importance of minimizing any and all billing errors. In that case, both the dentist and the PC were bound over for criminal trial for numerous counts of alleged Medicaid fraud following the preliminary examination.

At the preliminary examination, the government had introduced evidence regarding discrepancies between the billing invoices submitted by the dentist for five Medicaid patients and the work that had been performed.

The dentist and the PC appealed to the circuit court emphasizing that the evidence demonstrated only nine erroneous billings for four or five patients totaling slightly more than $300 in dispute (which is negligible compared to the thousands of patients seen in any given year) and that there were also instances of underbillings which would mitigate against an intent to bill falsely.

The circuit court dismissed all of the charges based on the minimal number of claims involved and the resulting inference that the billings were thus more likely due to inadvertent error rather than a pattern of error sufficient to establish the knowledge element necessary for criminal prosecution.

However, the Michigan Court of Appeals disagreed, causing the dentist and the PC to face a criminal trial, holding that:

"(t)he actual number of errors that are alleged, and the relatively small dollar figure they represent, is irrelevant and does not automatically convert or allow for the assumption, as proffered by the trial court, that the errors must have comprised only inadvertent mistakes. As previously determined by this Court, 'if a defendant contractually agrees to abide by billing procedures and has access to the applicable manuals and documentation controlling those procedures, deviations from the established procedures are presumed to be intentional or provide evidence that the defendant knew the submitted claims were false.'"

When billing for medical services and procedures, it is essential that the precise code is submitted. Assigning codes that do not precisely match the service is not good enough. Coding using the "close enough" method creates compliance exposure.

In today's health care environment, physicians are well advised to educate themselves with regard to the codes that are applicable to their services and procedures and to make sure that those who are performing the coding function are monitored (e.g., via direct periodic reviews by the physician whose PIN is being submitted and/or via an audit conducted by a third party auditor retained by legal counsel to provide the appropriate attorney client privilege should errors be found).

With regard to some services and procedures, Medicare and other third-party payers have specific coding policies. These policies should be obtained and reviewed.

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Compliance Corner