In business, virtually every management expert tells us that preparing for change, rather than reacting to it, is by far the best strategy. That is especially true in the area of health care; fast-changing legislation and revised regulations have challenged members of the health care industry to not only be informed, but to swiftly prepare and implement mandated programs and procedures. To that end, we have filled this issue of the Health Law Update with relevant, cutting-edge articles on health care topics designed to keep you well informed and ahead of the pack.

In particular, the latest information on HIPAA regulations, physician discipline (which was recently addressed by President Bush as part of his tort reform agenda) and medical management companies can be found on the pages of this Update.

The Health Law Department at Ruskin Moscou Faltischek, P.C. stands ready to assist you with any health law related issue you may face. Now and in the future, we are at your service. My personal best wishes for a happy, productive and prosperous 2005.

The Brave New World of E-Medicine Professional Misconduct Issues Are Plentiful

By Alexander G. Bateman, Jr.

I have used this space in the past to discuss specific issues concerning professional misconduct cases against physicians as well as other licensed healthcare providers in New York. With the beginning of a new year, I thought it might be informative and hopefully good preventive medicine to highlight some of the hot topics of scrutiny by the Office of Professional Medical Conduct (OPMC) or the Office of Professional Discipline (OPD), offer some suggestions concerning how to avoid getting in their respective cross hairs and, if all else fails, what to do if you do become the subject of a misconduct complaint. This first installment will address the perils involved in prescription writing for Internet pharmacies.

Physicians who write prescriptions for patients whom they have never seen are putting themselves and their professional licenses at great risk. The typical scenario is one in which the physician is offered a sum of money to review a file and decide whether to write a prescription for particular drugs. Each file to be reviewed may contain different combinations of a patient’s questionnaire, some other records with background information on the patient and maybe even, in some instances, what purports to be blood tests for that patient. The physician is also provided with a checklist of “suggested” medications to prescribe for the patient. Depending on the particular case, this list might include “rejuvenation” drugs such as human growth hormone, anabolic steroids, testosterone, pain management drugs or other “life enhancement/rejuvenation” medications. The doctor is expected to write the prescriptions and fax them to what is, in simple terms, an Internet pharmacy somewhere elsewhere, perhaps even in some offshore location.

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In the wake of several lawsuits filed against physicians, practice management companies, their shareholders, members or owners, the question arises whether entering into a practice management agreement is a good idea.

Most physicians do not want to run a business; they want to practice medicine. While there are many good clinicians who manage their own medical practices, there is a segment of the physician population that relies on Management Services Organizations (MSO) to provide them with turnkey operations for a fee. The typical arrangement contains five basic categories of services and amenities: (i) medical office space, (ii) equipment and supplies (medical and office), (iii) clerical personnel, (iv) billing and collection, and (v) practice management services, including public relations and marketing.

Problems in the industry have arisen with certain MSO's who have engaged in managing physicians who predominantly bill no-fault. In the physical medicine arena, many of these MSO's were founded by chiropractors or lay people who wanted to run no-fault clinics without passing the rigorous licensure requirements imposed under Article 28 of the New York State Public Health Law. Many of these chiropractor MSO operators bemoaned the fact that a physician providing the same services as a chiropractor would be reimbursed at rates in excess of the rates available to chiropractors. Additionally, under NYS law, chiropractors cannot hire physicians or physical therapists, and cannot be partners in a practice with a physician or a physical therapist. In an attempt to provide comprehensive physical rehabilitation services to patients, chiropractors and attorneys developed several ways of circumventing these restrictions. However, in some cases, they went a little too far.

Currently, there are several lawsuits pending, commenced by insurance carriers against MSO's, their owners and physician clients. While some of the allegations in the complaints set forth particularly egregious violations of law and fraudulent conduct, the basic premise propounded by the carriers is that an MSO-managed-and-controlled medical practice is nothing more than a sham corporate structure designed to evade licensure requirements and that the true owner of the medical practice is the MSO. Since the MSO's are not licensed to bill for medical services, the carriers argue that the physicians they manage and the MSO's who have profited from them should be made to disgorge any monies collected from the carrier.

In State Farm v. Mallela, a pivotal element of State Farm's thesis was that under the NYS No-Fault regulation, a provider of health care services is not eligible for reimbursement under the insurance law if the provider fails to meet any applicable New York State or local licensing requirement necessary to perform such service in any other state in which such service is performed. State Farm claims that the Court has to consider the entire body of regulations and statutes governing licensure, health care and corporate structure of medical practices. They assert that, under the totality of NYS law, a medical practice must be owned and controlled by licensed physicians only. State Farm alleges that in all the cases of the named defendants, the medical P.C. defendants were formed, and are actually controlled, by non-licensed, non-physician individuals; therefore, they are violating NYS law, are committing fraud, are not eligible to receive reimbursement from State Farm and all monies paid by State Farm to them must be returned.

It is interesting to note that the State Farm case, which was pending before the Southern District of the State of New York, was dismissed by Judge Sifton in 2002. In his decision, Judge Sifton found that "Nowhere does the no-fault law or regulations indicate that an insurer only need pay an assignee provider of services if that provider is lawfully licensed pursuant to New York law...Moreover, the alleged fraudulent ownership of the P.C. defendants does not affect the question of whether [State Farm's] insureds incurred and incur a basic economic loss that [State Farm] is required to compensate." Judge Sifton stressed there were "no allegations that services were provided to noncovered persons or arose or arose out of noncovered accidents; that they were not medically necessary; or that the providers of the services did not or do not have lawfully obtained licenses to provide the services." Judge Sifton found it would be a "windfall" to State Farm to allow them to refuse to pay for covered necessary health care services solely because there was a defect of corporate structure or licensing. Judge Sifton concluded that an insurance company does not have the right to act as a private attorney general, and does not have standing to bring such a lawsuit civilly.

State Farm appealed and the case is now pending before the Second Circuit Court of Appeals. In June of last year, the plaintiff appellant moved to have the following question of law certified to the New York State Court of Appeals: "Whether an insurance company may refuse to compensate medical providers for health care services that are within the scope of the no-fault provider program in every way except that they are provided by health care professionals employed by medical practices that, under state education and business laws, are unlawfully incorporated." The Court of Appeals accepted the certification in the Fall of 2004 and we all anxiously await its decision. The future of Practice Management must await that decision as well.

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For this, the doctor receives a nominal “review fee.” While some may consider this an easy way to make money on the side, OPMC considers it serious professional misconduct. To be more specific, they have prosecuted scenarios like the one described here and charged doctors with: Gross Negligence; Gross Incompetence; Negligence on More than One Occasion; Incompetence on More than One Occasion; Permitting, Aiding and Abetting Unlicensed Practice; Receipt of Unlawful Referral Fees; Fee Splitting; and Failure to Maintain Records. Each of these charges, individually, carries a possible penalty of license revocation upon conviction. A disciplinary finding, even one accomplished by a negotiated consent agreement, will be posted on OPMC’s website, result in a National Practitioners Data Bank listing, and be reported to any HMO or other insurance plans in which you are enrolled as a provider. The details negotiated in the settlement with OPMC can often times dictate whether or not a physician will be able to remain as a provider in particular plans. Additionally, you will have to report and explain the findings to any institution at which you are credentialed, and report it to your malpractice carriers as well.

Finally, if the drugs you have written prescriptions for are controlled substances, you will also face an investigation by the Drug Enforcement Administration (DEA) and a possible referral to federal prosecutors. This could result in the revocation of your DEA registration, or the payment of a significant civil penalty and imposition of prescribing restrictions to avoid revocation. The Food and Drug Administration (FDA) has focused its online drug sales-related enforcement activities on unapproved new drugs, health fraud and prescription drugs sold without a valid prescription.

Both the United States Attorney in New York and the OPMC have presented a number of these cases in 2004 and are likely to continue to do so this year. It is logical to assume that this scrutiny will extend to licensed pharmacists who involve themselves in these relationships. The FDA has established a task force with the National Association of Attorney Generals to promote cooperation in the enforcement of federal and state laws relating to presenting habits. The FDA has also joined in partnership agreements with the National Association of Board of Pharmacy and the Federation of State Medical Boards to coordinate investigations. There are a number of unresolved questions concerning what is and what is not appropriate in the brave new world of telemedicine. The federal government and states have overlapping jurisdictional claims to these issues and much debate will have to take place before many of these issues are resolved. Nevertheless, in the meantime, before entering into any of these relationships, one should seek the advice of healthcare counsel to avoid serious regulatory, monetary or even criminal penalties.

REPORT HIGHLIGHTS FIRST-YEAR HIPAA PRIVACY ISSUES AND EXPERIENCES

By Keshia B. Thompson

The United States Government Accountability Office (GAO) issued a report in September 2004 that provides information about first year HIPAA Privacy compliance experiences. The report indicates that 5,648 privacy-related complaints were filed with the Office of Civil Rights (OCR). According to the report, the number of complaints increased as the year progressed, and about half of the complaints filed during the first year were closed by May of 2004.

Generally, complaints focused on issues such as improper uses and disclosures, inadequate safeguards of patient information and problems with patient access to their own health information. For example, the report notes that complaints alleged that: (1) patient billing information was sent to the wrong address or fax number, (2) patient information was seen or overheard in a doctor’s office or hospital, or (3) provider employees accessed patient information for their own personal or business benefit.

The entities against with such complaints were filed included physician, dental, chiropractic and similar practices, and hospitals. As of May 2004, no sanctions were levied against any entities against which complaints had been filed and closed. With regard to closed cases, the OCR’s general approach was to investigate and develop a plan of correction with entities alleged to have violated the Privacy Rules.

In addition to providing information about complaints filed during the first year since the April 2003 Privacy Rule effective

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date, the report recommends that certain actions be taken by OCR to “reduce unnecessary burden on covered entities and to improve the effectiveness of the Privacy Rule.” First, the report recommends that the Privacy Rule be modified to require that patients be informed via the notice of privacy practices that their information will be disclosed to public health authorities when required by law. Second, the report recommends that such public health disclosures be exempt from the accounting for disclosures requirement. Finally, the report recommends that a public awareness campaign be conducted to foster awareness of patients’ rights under the Privacy Rule. Covered entities and business associates should follow developments with these proposed modifications to the Privacy Rule so that in the event such modifications are adopted, entities can modify their HIPAA Privacy policies and procedures accordingly.


ABOUT THE FIRM

Founded in 1968, Ruskin Moscou Faltischek, P.C. is one of the most respected and largest multi-practice law firms in the New York metropolitan area and is headquartered in Uniondale, New York. With 65 attorneys in 22 practice areas, the firm offers innovative legal services, keeping focus on the client’s goals, in the areas of corporate & securities, corporate governance, employment, energy, environmental, financial services, banking & bankruptcy, business reorganization, commercial lending, health law, healthcare professionals, intellectual property, life sciences, litigation, municipal & regulatory affairs, real estate, construction, seniors’ housing, technology, trusts & estates, and white collar crime & investigations. Clients include large and mid-sized corporations, privately held businesses, institutions and individuals.

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