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Patient planning

Advance directives ease burdens on patient and provider

By Maro E. Bush, Esq.

Living will. Power of attorney. Patient advocate designation. These are some common names of advance directives, legal documents that patients can execute to direct their medical treatment, should they become incapacitated or unable to communicate their wishes.

Advance directives ease the burden on patients, families and health care providers, while improving patient care and health care costs. Unfortunately, they are largely under-utilized.

In 2003, the Agency for Healthcare Research and Quality found that less than 50 percent of severely or terminally ill patients had an advance directive in their medical record, and up to 76 percent of physicians whose patients did have an advance directive were not aware that it existed.

The most common advance directives include powers of attorney for health care and living wills. In Michigan, durable powers of attorney for health care are created by executing "patient advocate designations," and living wills through "documents directing health care."

In the event of terminal illness or incapacitation, advance directives are a means of communicating medical care and end of life wishes, should a patient become unable to do so.

Patient advocate designations allow patients to name an individual (known as a patient advocate, proxy or agent) to make medical decisions on their be-

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Hospitals may be at increased risk

EMTALA decision recognizes non-patient standing to sue for personal injury damages

6th U.S. Circuit Court of Appeals — Analysis

By Todd C. Berg, Esq.

Hospitals may get sued more often under a federal appeals court ruling that non-patients can sue for injuries they suffer due to a hospital's failure to properly stabilize a patient prior to release.

On Dec. 13, 2002, Johnella Richmond Moses took her husband, Christopher Walter Howard, to Providence Hospital's emergency room in Southfield. She told the ER staff Howard seemed ill. He was experiencing headaches, vomiting, disorientation, hallucinations and delusions. Moses also said Howard's threatening behavior toward her made her fearful for her safety. Howard was admitted.

After several days of evaluation, on Dec. 17, a psychiatrist ordered he be transferred to the hospital's psychiatric unit, where acutely mentally ill patients are hospitalized and stabilized. The doctor said suicide precautions were to be taken with Howard, and that Howard had an atypical psychosis and depression.

The transfer never occurred. Instead, a different doctor, an internist, discharged Howard on Dec. 19, concluding Howard couldn't stay any longer in the hospital because he was "'medically stable and now does not need [the psychiatric unit].'"

On Dec. 29, Howard murdered Moses.

In 2004, Moses' estate sued Providence Hospital for violating the Emergency Medical Treatment and Active Labor Act (EMTALA), and the hospital moved for summary judgment, claiming that Moses, as a non-patient, didn't have standing to sue.

U.S. District Court Judge Anna Diggs Taylor of the Eastern District of Michigan denied the hospital's motion and the Court of Appeals affirmed.

In Moses v. Providence Hospital and Medical Centers, Inc., et al., a unanimous panel of the 6th U.S. Circuit Court of Appeals held that EMTALA confers on non-patients the standing to sue for personal injury damages.

"The plain language of the civil enforcement provision of EMTALA contains very broad language

See "Hospitals," page 14

LW photo by Gary Gosselin

A 6th U.S. Circuit Court of Appeals ruling against Southfield's Providence Hospital could pave the way for more hospital lawsuits. The court ruled that the Emergency Medical Treatment and Active Labor Act (EMTALA) gives non-patients the standing to sue for personal injury damages.

Most health care providers must implement 'red flag' policies

By Amy K. Fehn, Esq. and Jeffrey R. Campbell, Esq.

Despite objections by the American Medical Association and other health care provider organizations, the Federal Trade Commission (FTC) has steadfastly maintained that most health care providers will need to comply with the "Red Flags Rule," which is set to go into effect Aug. 1, 2009.

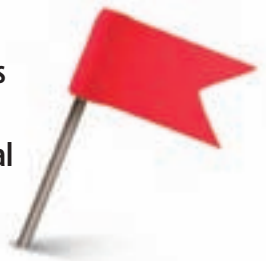
The "Red Flags Rule" is a set of regulations jointly developed by the FTC, the Federal bank regulatory agencies, and the National Credit Union Administration to curb the incidence of identity theft.

Providers who are subject to the Red Flags Rule are required to implement a written Identity Theft Prevention Program that is designed to detect, prevent and mitigate identity theft.

Like the HIPAA Privacy and Security Rules, the Red Flags Rule is flexible and scalable to the size and risk level of the entity.

As an example, the FTC notes that small providers with a well known limited patient base will likely have a lower risk of identity theft and could adopt a more limited program than a provider with a larger volume of patients.

The "Red Flags Rule" is a set of regulations jointly developed by the FTC, the Federal bank regulatory agencies, and the National Credit Union Administration to curb the incidence of identity theft.



Providers who have effective policies in place for compliance with HIPAA Privacy and Security already will meet many of the requirements for the Red Flags Rule with regard to prevention of identity theft.

However, in order to be compli-

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Weed and the workplace

Employers grapple with balancing drug-free job sites and the medical marijuana law

Labor & Employment

By Carol Lundberg

Gravely ill people in Michigan will soon be able to use marijuana to treat symptoms of their illnesses. But their employers are facing potential problems as they try to keep a drug-free workforce.

Proponents of Michigan's new medical marijuana law say it's a godsend, protecting patients from prosecution as they try to alleviate symptoms of diseases like cancer, glaucoma, Chron's disease and HIV/AIDS.

DEROMEDI

But what happens to patients who are well enough to work and test positive on a drug test in the workplace remains to be seen.

"Right now there are a lot of open issues," said David R. Deromedi, of Dickinson Wright PLLC's Detroit office. "The law does state that employers are not required to accommodate an employee's ingestion of marijuana at work, or allow an employee to be under the influence while on duty. The question is: What is 'under the influence?'

"There may be some litigation over that."

Some clarity, please?

Earlier this month, the state of Michigan began taking applications to register in the medical marijuana program, which was approved by voters Nov. 4. As of last week, the state had received more than 350 applications from people seeking permits to use medical marijuana.

"Because the statute came up as a ballot proposal, there are ambiguities in its writing," said Terry W. Bonnett of Nemeth Burwell PC in Detroit.

He agreed that there likely will be litigation over medical marijuana use and how it impacts the workplace. He expects it to happen before the end of 2009.

Bonnett had hoped the law that resulted from the ballot proposal would offer more clarity on issues such as random drug testing policies in the workplace and pre-employment drug screening, he said.

Aside from those two issues, medical marijuana is likely to be treated in the workplace like prescription medications, Bonnett said. Employees who are impaired on the job are subject to disciplinary action or could be asked to take medical leave until they are fit for work, whether they use medical marijuana or prescription medications, he said.

"We have to look at whether use creates a safety hazard," Bonnett said. "Does it affect a worker's ability to do the job? What is the nature of the position the worker holds? Are there special safety issues there?

"I don't think we would want to allow a cab driver to keep working if he's high, whether on valium or marijuana," he added.

At the same time, employers could face exposure to litigation if they immediately terminate impaired employees, especially if the workers' conditions are addressed by the Americans with Disabilities Act, or by the Family Medical Leave Act, Bonnett said.

There is gray area when it comes to medical marijuana and impairment because there's no sobriety test for it, he said. It's only possible to tell that a worker has used marijuana during the weeks before the test, but no way to tell exactly when or how much the worker used.

Deromedi has been fielding calls from clients in the health care and transportation industries. They want to know what they should do if their employees test positive in random drug testing.

"Health care workers are a concern, especially when the employee provides patient care. There are concerns about how marijuana could impact judgment, and ultimately, patient care," Deromedi said. "And in transportation, employees like truck drivers lose their licenses when they fail to pass random drug tests. How will those workers be affected and what rights to their employers have?"

The law doesn't address those issues, he said.

Room for legal wrangling

Though litigation in the 12 other states that allow the use of medical marijuana has been sparse, courts in other states have treated marijuana very differently.

In Oregon, the courts have come down on the side of employees, and have said employers can't discriminate against employees who use medical marijuana as allowed by state law, Bonnett said. But in California, the state Supreme Court opined that employers can indeed fire workers who use medical marijuana, even if they are off duty and are in compliance with the state's medical marijuana law.

Stanley H. Pitts, a labor and employment lawyer in the Detroit office of Honigman, Miller, Schwartz and Cohn LLP, said he thinks Michigan employers will retain the discretion to hire or not hire workers who fail pre-employment drug tests, even if the workers are registered medical marijuana users.

"Even though Michigan laws are not specific when it comes to that issue, the employer is not necessarily bound to accept state certification as a reason for a positive drug test," he said. "But there will be a lot of room for legal wrangling and litigation."

He said that Michigan has two state laws that apparently conflict with one another. First, the Elliott-Larsen Civil Rights Act of 1976, which protects disabled workers who need accommodation in the workplace. Then, there is the state's medical marijuana law, which specifically states that employers do not have to accommodate use of marijuana in the workplace.

Pitts said that in the end, common sense will have to guide employers and employees.

"If you're an employee who is working and can perform the essential functions of your job, but you need medical marijuana, you should be fine as long as you're not impaired in the workplace," Pitts said. "If you're an employer, and you have such an employee, wouldn't you want that worker to be as free from pain as possible?"

Tough choices to make

The law could force uncomfortable conversations between employees and employers. Employees who would not have necessarily been obligated to disclose health conditions, as long as they didn't need workplace accommodation, may now have to discuss medical marijuana use with their employers, said Bruce Mirken, director of communications for the Marijuana Policy Project in Washington, D.C.

"Folks who have the exception to use marijuana will from time to time have to discuss it in the workplace," Mirken said. "It may be awkward, but most patients would find it acceptable over being arrested or fired."

Thomas G. Kienbaum, of Birmingham-based Kienbaum, Opperwall, Hardy & Pelton PLC, said he won't encourage his clients to push the boundaries of the law.

Employers, he said, have a dual right and responsibility to protect against drugs in the workplace.

But if he has a client, an employer who conducts random drug tests, and a state-registered employee tests positive for marijuana use but has been performing his or her job, Kienbaum would have to advise his client against taking any action against the worker.

He said he expects some employers will have biases against marijuana users, even if they are protected by the new state law, because marijuana is an otherwise illegal drug.

"I suppose my client could fire the worker, but that's not good business practice," Kienbaum said. "You have to use some judgment."

If you would like to comment on this story, please contact Carol Lundberg at (248) 865-3105 or carol.lundberg@mi.lawyersweekly.com.

About the medical marijuana law

Sixty-three percent of Michigan voters approved a ballot initiative Nov. 4 to allow the use of medical marijuana for certain medical conditions, which include cancer, HIV/AIDS, epilepsy, glaucoma, Chron's disease, hepatitis C, chronic pain, seizures and muscle spasms.

The law limits how much a patient can possess — 2.5 ounces of usable marijuana. And it only allows users and their caregivers to grow marijuana; it does not allow for sale of marijuana.

Among other things, the law does:

- YES Protect a registered patient from "arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau ..."
- YES Protect physicians who identify patients as "likely to receive therapeutic or palliative benefit from the medical use of marihuana ... ."
- YES Protect patients from losing custody or visitation with their children, as long as the patient's behavior doesn't create an unreasonable danger to the child.

The law does not:

- NO Require employers to "accommodate the ingestion of marihuana in any workplace or any employee working while under the influence of marihuana." It also prohibits marijuana on the grounds of any school, in a correctional facility or on a school bus, and does not permit the smoking of marijuana in any public place or on any form of public transportation.
- NO Allow a physician to prescribe marijuana; it only allows the physician to identify a patient as having a condition for which medical marijuana use is permitted.
- NO Allow for marijuana to be sold.
- NO Protect registered users from federal prosecution.

Retail clinics can be valuable addition to healthcare system

Medical professionals should be part of the process to shape regulation of fledgling a la carte model

Business of Medicine

By Suzanne D. Nolan

Suzanne D. Nolan's practice at Troy-based Frank, Haron, Weiner & Navarro focuses upon business and intellectual property transactions, including trademark, patent and copyright licensing, e-commerce transactions, and real estate transactions for all types of entities, including healthcare providers. She can be reached at (248) 952-0400 or snolan@fhwnlaw.com.

Retail health clinics are an increasingly popular means of delivering medical care to the public, and they are here to stay, in one form or another.

These clinics have largely emerged to address the shortage of primary care physicians, the growth in the number of uninsured patients, and the growing trend of higher deductibles and copays for health insurance.

To the extent that retail clinics address these problems, they can be a valuable addition to our health care system.

Physicians and state regulators, however, have not yet wholeheartedly accepted retail clinics primarily because of concerns about fragmentation of care and quality of care. Due to the nature of retail health clinics, physicians (and state regulators) have an important role to play in the emergence of the retail clinic delivery model.

From a patient's point of view, the convenience and lower costs of a retail clinic are important advantages. Typically located within retail businesses such as drugstores, grocery stores and mass merchandisers, retail clinics are open seven days a week, offer evening hours and short waits, and also accept walk-in appointments.

Patients can easily fill prescriptions at an onsite pharmacy and shop for groceries while they wait.

Physicians in an office setting commonly use any professional contact with a patient, even for the treatment of minor ailments, as an opportunity to address any other health issues that the patient may have. Accordingly, there is a risk that patients who frequently receive care at a retail clinic will not receive this overall beneficial health monitoring.

Because health care at a retail clinic is typically delivered by nurse practitioners (NPs) or, less frequently, by physician assistants (PAs), the fees charged by a retail clinic are typically lower than those charged by a physician, urgent-care clinic, or hospital emergency department.

Health insurers, appreciative of the lower cost of care at a retail clinic, are supporting retail clinics by waiving co-payments for covered services, further lowering the cost for those patients with health insurance.

Despite these apparent benefits, both physi-

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Health industry must actively manage conflict resolution programs now in place

Personnel Matters

By Donna J. Craig, Esq.

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The health care industry is not immune from the stresses and strains other businesses and professionals endure during these harsh economic times.

As the unemployment rate increases, the number of uninsured and underinsured patients also rises, demanding more uncompensated care from hospitals and health care workers; forcing them to tighten their belts as they reallocate staffing and resources.

To meet these challenges, hospitals and health care professionals, along with ancillary staff, must maintain or even improve the quality of care provided to patients, but with fewer resources.

Providing patient care in this type of environment is ripe for disputes and conflicts in the workplace. If such disputes and conflicts are not resolved at an early stage and are left to fester, they may negatively impact the quality of care.

Policies must be backed by action

Effective Jan. 1, 2009, The Joint Commission (formerly Joint Commission on Accreditation of Healthcare Organizations) mandated that hospital governing bodies establish conflict management policies and procedures for resolving disputes among individuals working in their hospitals.

It should be noted however, that implementing written policies and procedures without addressing the underlying stresses that give rise to workplace conflicts will not achieve their intended purpose.

Additionally, hospitals would be well served to go beyond the mere drafting of policies and procedures to adopt and implement a sound conflict management program that is supported by management, medical staffs, and employees.

A broadly defined and implemented conflict management program allows for:

- Early recognition and identification of conflict among the health care workforce.
- A proactive and consistent response to conflicts and disputes.
- Support of open communication and problem solving as a means of working towards potential resolutions.
- Transformation from ineffective and dysfunctional communication styles into respectful and empowered communication models.

Transforming the way disputing parties communicate is helpful in not only resolving disputes, but also in building a basis for better communication going forward. Better communication between members of the health care team makes a more effective and efficient workplace.

The end result: health care team members can focus more on providing quality patient care and less on distracting conflicts and disputes.

The REDRESS model

Health care associations are touting ready-made model policies and procedures as a means of addressing The Joint Commission's new conflict management accrediting standard.

But hospitals seriously committed to developing a comprehensive conflict management program need not look further than the conflict management program implemented by the U.S. Postal Service.

Its conflict management program, Resolve Employment Disputes, Reach Equitable Solutions Swiftly (REDRESS), was born out of the settlement of a class-action lawsuit filed by postal employees in the Northern District of Florida.

As part of that settlement, the parties agreed to develop a workplace mediation program that would address disputes in a more effective and timely process. What started as a pilot program in 1994 at three Florida sites was then expanded nationwide based on the commitment of management and employees.

To this day, REDRESS continues to be successful in reducing conflict in the workplace and encouraging more effective communication between parties.

The hallmark of the program is the use of the transformative mediation model, which allows parties to openly discuss the issues that are important to them in a manner that helps to "transform" their working relationships. The Postal Service's commitment to such a program has resulted in a significant reduction in formal complaints filed by postal employees.

Bringing it to the table

In transformative mediation, an environment is created that supports empowerment and recognition of the parties in dispute. Empowered people are more likely to view disputes from the other party's perspective, which leads to improved interaction, greater mutual understanding and mutual beneficial resolutions to their disputes.

Transformative mediation can be most effective in bringing the parties to the table and creating an atmosphere where they can find workable solutions to their conflicts and disputes.

This is especially true in the hospital setting, where some conflicts may involve parties in uneven bargaining positions.

Because the Postal Service, like the hospital setting, has a 24/7 workplace environment; a hierarchy of management and staff; and an interdependence between team members with a need for effective communication, it is possible for its conflict management program to be effectively introduced into the hospital setting.

Mediating health care disputes and conflicts that occur on various work shifts, depending on the disputing parties' work schedules, could be accomplished as easily in the hospital setting as in the REDRESS program.

One difference in designing a conflict management program for the hospital setting would be the need to safeguard certain confidentiality protections and privileges (HIPAA, peer review, etc.). Differences in implementing conflict management programs in the private hospital setting versus a governmental agency also would need to be addressed.

Given the day-to-day challenges facing hospitals and health care professionals in a society that expects quality care, investing in a comprehensive conflict management program will provide an outlet for resolving disputes at an early stage.

It also will allow health care providers to get back to what they do best: provide quality patient care.

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Big RAC attack

Health care lawyers defend clients against CMS audits

Medicaid & Medicare

By Carol Lundberg

With billions of dollars at stake, government contractors are going after hospitals and health care providers, who they say have been overpaid.

So far, more than $1.03 billion has been recovered from health care providers by the Centers for Medicare and Medicaid Services (CMS).

The CMS Recovery Audit Contractor (RAC) program launched in 2005 in the three states with the highest number of Medicare expenditures — California, Florida and New York. In 2007, it expanded to include Arizona, South Carolina and Massachusetts.

By the end of summer, the RAC program will include all 50 states.

Despite the high stakes, only 22.5 percent of claims have been disputed by the providers. Royal Oak health care lawyer Andrew Wachler of Wachler & Associates says it's a mistake not to fight the claims.

"My recommendation would be to appeal assertively," Wachler said. "Don't be the low-hanging fruit."

At a time when the government is seeking to reform health care, every nickel of possible waste is being scrutinized.

"We all know we have to contain costs, and there is a great emphasis on health care reform. We have to provide the best services to the greatest number of people," Wachler said.

But the RAC program is aggressive to the point of being abusive, he added, and should not incentivize auditors to find alleged overpayments to providers.

At the same time the RAC auditors, who are paid a contingency fee, have recovered $1 billion, they have found only $37.8 million in underpayments to providers, said Wachler, who defended providers in California, Massachusetts and New York with a 90 percent success rate.

But the $1 billion in recovered payments doesn't necessarily mean that the providers had been erroneously overpaid, said Jessica Gustafson, of Southfield-based The Health Law Partners PC.

Coding errors and the question of medical necessity come up fairly universally in the audits, she said. One of the most contested areas is that of short stays in hospitals.

"The criteria are really not clear," Gustafson said. "No one is trying to pull one over on anyone. But more often than not, providers are going to paying for mistakes they didn't make. There have been a lot of cases where CMS definitely walked away with some of the providers' money and they shouldn't have."

That's because most hospitals she's worked with, thus far in Florida and California, "will only appeal items that are over a certain amount," she said. "And CMS knows that."

As a result, most of the money recouped by the auditors is not repaid to CMS because the provider was actually overpaid. It's just that the documentation isn't sufficient, or there was an error in the paperwork.

A far cry from the supposed fraud and waste the RAC program was established to uncover, she said.

Michigan health care providers will start receiving records requests from RAC auditors any time now, Gustafson said. The reviews are being delayed, except for automated reviews, which can begin any time.

"Those are for only the most egregious errors," said Charles MacKelvie, principal of Miller, Canfield, Paddock and Stone PLC's Chicago office. "Like a payment for treating a man who's pregnant."

Gustafson said coding reviews will start in September, and reviews of medically necessary procedures will not start in Michigan until January of next year.

Most of the payment denials are the result of failure to meet Medicare's medically necessary criteria, MacKelvie said, and account for 40 percent of denials.

Incorrect coding accounts for 35 percent of denials; 8 percent are denied for insufficient documentation; and 17 percent are denied for other reasons, including outdated fee schedules and duplicate claims. And in 4 percent of all the cases, MacKelvie added, was there an actual overpayment to the provider.

"The demonstration period of the program was abusive to providers," Wachler said. "Everyone makes coding errors. Those are simple mistakes, but they're also the low-hanging fruit."

And often, providers thought they had some discretion in how to code procedures, for which they were later penalized, Wachler said.

"Providers need to be reimbursed to the extent that they are able, and there could be a tendency to optimize reimbursement," he said.

LW photo by Carol Lundberg

Health care attorney Andrew Wachler says audited providers should "appeal assertively."

That will change.

"Providers who have been audited get religion," Wachler said. "They're used to documenting for treatment purposes, but now they also have to document for reimbursement purposes."

MacKelvie said the audits could have a devastating effect on some providers.

"This has the potential to recover $30 billion a year," MacKelvie said.

Eighty-five percent of the recoveries so far have been from hospitals. In New York, the average claim adjustment was $27,000, he added.

"It was a lot," MacKelvie said. "And theoretically if the auditors did this the same way, and they did it every 45 days, as is allowed in the program, it could cost a hospital $545,000.

On top of that, the average hospital will have to add five full-time staffers, in administrative, accounting and legal personnel, just to stay on top of RAC audits.

"It's an incredible administrative burden." MacKelvie said.

When it came down to fighting the RAC audits, Gustafson said often her job wasn't as difficult as she'd expected.

"The auditors really aren't very good," she said.

She didn't always win based on the merits of the medical necessity. Sometimes she prevailed as the result of a legal defense tactic.

For example, one highly contested tactic has to do with the reopening and revision of claims.

"They set forth a time frame stating that a claim can be reopened for one year, and for four years with good cause," Gustafson said. "We were overturning claims saying that the contractor did not have good cause."

But the auditors are getting savvier, and will learn how to work the audits in their favor, she added.

She also would argue the "waiver of liability" defense, stating that the provider has no reason to know that a claim would be denied.

Often the best defense, Gustafson said, is Medicare's own policy.

For example, when defending short stay charges she argued that Medicare and Medicaid have vague criteria.

"In 100 percent of those cases, the RACs were not basing denials on Medicare policy. In 60-70 percent of the cases, the denials were based on InterQual criteria, which is a standard established by a private company, and which has not been adopted by Medicare," Gustafson said.

Others on short stays were denied on the basis that a procedure performed was not on an "inpatient-only" list of conditions and procedures.

But conversely, there is no "outpatient-only" list.

"The inpatient-only list is an inappropriate way to deny any of these claims," Gustafson noted.

The bottom line, she said, is simple: "These things are winnable."

If you would like to comment on this story, please contact Carol Lundberg at (248) 865-3105 or carol.lundberg@mi.lawyersweekly.com.

Get ready for the new Medicare reporting requirements

Health Policy

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The new Medicare reporting requirements will have far reaching effects on business as a whole, but particularly upon the health care industry.

Changes that result from these requirements can be expected to make the business aspects of health care delivery even more complicated for providers.

Earlier this year, the new requirements of the Medicare, Medicaid, and State Children's Health Insurance Program Extension Act of 2007 (MMSEA), also known as SCHIP, went into effect. The MMSEA and related regulations mandate reporting of information on health care-related claims paid by all self-insured business entities, insurance companies, and group health plans to Medicare beneficiaries.

The law's complicated reporting scheme ratchets up the continuing effort to limit Medicare's net spending for health care, by recouping federal money paid for health care when another source of payment is available under the Medicare Secondary Payer (MSP) Act.

If Medicare paid for health care where another person or company was responsible for the care required, then Medicare has an automatic right of reimbursement for any federal money paid to or on behalf of the patient.

Who tracks what?

From the Medicare perspective, the problem with its "right" of reimbursement was that, historically, the Medicare program was not able to accurately track when claims existed entitling them to reimbursement, or when other available health care payment sources existed to cover future health care expenses. This is where the MMSEA comes into play.

The new reporting requirements of the MMSEA ensure Medicare will have information on liability claims involving persons entitled to Medicare, to pursue reimbursement for any payments it made for which it did not have primary responsibility to pay.

Second, the requirements will provide Medicare with a database of information concerning alternate, available health care coverage for use in making future payment determinations for Medicare benefit claims.

This will be accomplished by forcing insurers and some businesses without insurance, to self-report certain group health plan benefits and personal injury liability claims involving individuals who are, or may be, entitled to Medicare benefits.

The Center for Medicare and Medicaid Services (CMS) is assigned the duty of managing this new reporting requirement. Under Section 111 of the MMSEA, group health began reporting on Medicare beneficiaries to CMS on Jan. 1, 2009. Insurers and self-insured businesses must report claims paid to Medicare beneficiaries on and after July 1, 2009.

The MMSEA has teeth. The reporting requirements are reinforced by a penalty of $1,000 per day, per claim. Imagine the devastating impact of missing a single reportable event, only to have it discovered a year later when the penalty is $365,000.

Who is included?

The threshold step to complying with the MMSEA is determining whether you (as a hospital, physician practice or other health care provider) are a "Responsible Reporting Entity" (RRE).

RREs include organizations paying health insurance benefits, i.e. group health plans, and business entities that have responsibility to pay for personal-injury liability to a person entitled to Medicare benefits, regardless of whether actual liability has been established.

These entities include liability insurers, self-insured businesses, workers' compensation and no-fault insurers. Most hospitals are self-insured to some degree and are RREs. To the extent physician practices have "first dollar" coverage payable by a professional liability insurer, then they are not RREs and do not have direct reporting responsibilities.

However, as explained below, if because of an event involving a potential Medicare beneficiary, a practice writes off a patient bill or makes direct payment (e.g., to keep a claim off the practice's claim history with an insurer), the practice becomes an RRE with an obligation to report for that purpose.

Claimant considerations

Only if the organization is an RRE, the next step is to determine if the claimant is potentially a Medicare beneficiary, and subject to reporting. The primary factors to consider are whether the individual is 65 years of age or older, whether the individual has been on disability for more than two years, and whether the individual has permanent kidney failure.

If an individual meets any one of these criteria, they are entitled to Medicare benefits regardless of whether Medicare benefits are being collected.

See "Reporting," page 8

No 'Get Out of Jail Free' card

Self-reporting violations should help reduce penalties, costs and embarrassment

Regulation

By Mercedes L. Varasteh, Esq.

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A long-standing federal program that encourages health care providers to self-report violations of the Stark and Anti-Kickback laws was recently refined, narrowing the types of conduct that can be reported and placing a floor on the minimum amount of penalties.

The Provider Self-Disclosure Protocol (SDP), which was launched in 1998, allows health care providers to voluntarily disclose evidence of fraud and abuse to the Department of Health and Human Services' Office of the Inspector General (OIG).

Although providers who self-report are not given a "Get Out of Jail Free" card, the idea behind the SDP is that offending providers may receive reduced penalties and also avoid the costs, disruptions, and potential embarrassment of a full-scale government investigation.

Reporting scope has narrowed

At the time of its inception, the SDP encouraged providers to report any matters "potentially violative of Federal criminal, civil, or administrative laws."

However, over the years the type of conduct which practitioners were encouraged to self-report has been narrowed through a series of "Open Letters" issued to health care providers limiting requested self-disclosures to those that involve "colorable" violations of the federal Anti-Kickback statute, 42 U.S.C. §1320a-7b(b).

The OIG declined to give further guidance or any examples of what may constitute a "colorable" violation.

Previously, violations of both the Anti-Kickback statute and the federal physician anti-referral law (commonly referred to as the "Stark laws") were reportable under the SDP. Now, Stark violations may only be reported if they involve "colorable" Anti-Kickback violations as well.

OIG still means business

However, the OIG has cautioned providers against drawing any inferences regarding the new Stark policy. In other words, the agency has no intention of easing up on Stark violators.

The March 24, 2009, open letter also announced that the OIG will now require a minimum of $50,000 in settlement payments to resolve any matters accepted into the SDP program.

This minimum settlement amount is consistent with the OIG's authority under the Anti-Kickback statute to impose a civil monetary penalty of up to $50,000 for each kickback, and an assessment of up to the three times the total unlawful remuneration.

Given that there is no guaranteed leniency to providers who self-report, some providers may wonder what — if any — benefit is conferred by self-reporting, especially in light of the enhanced penalty floor.

Unlike the Stark laws, the Anti-Kickback law is not a strict liability statute (i.e., the government must prove intent to violate the law in order for an offender to be convicted).

The OIG frequently punishes illegal conduct with program exclusion, civil monetary penalties, and integrity agreements, and by admitting liability through self-disclosure, a provider essentially proves the hardest part of the government's case.

Self-reporting has advantages

However, the OIG has indicated that providers who self-report and "police themselves" in the spirit of the SDP policy will generally be eligible for certain benefits. Such benefits are contingent upon the provider demonstrating a requisite level of trustworthiness and willingness to develop an effective compliance program.

First, the OIG has stated that it will waive its exclusion authority concurrent with the resolution of monetary liability under the False Claims Act and civil monetary penalties laws.

Second, the OIG may allow providers to enter into Certification of Compliance Agreements (CCAs), which are less extensive that the more common Corporate Integrity Agreement (CIAs).

While CIAs are imposed for a five-year term and require independent review organizations to conduct/verify audits or claim reviews for an offending provider, CCAs are typically for three years and do not require the independent reviews.

Self-disclosing providers also will be considered for reduced penalties.

Although the minimum accepted settlement amount is $50,000, the Civil Monetary Penalty statute allows for penalties of $50,000 for each violation of the AKS, in addition to damages in the amount of three times the total payment offered, paid, solicited or received under the illegal arrangement, even if a portion of the remuneration was for a lawful purpose.

In addition, the AKS statute itself provides for a $25,000 penalty and up to five years of imprisonment.

Subject to individual facts and circumstances, the OIG has stated that it will generally settle matters with providers who self-disclose near the lower end of the damages continuum, i.e., a multiplier of the value of the financial benefit conferred.

Again, while there are no guarantees associated with self-disclosing, providers are well-advised to remember that the repercussions of *not* self-reporting may be much worse.

Additional laws applicable

In addition to the repercussions discussed above, a provider knowingly engaged in an anti-kickback scheme is vulnerable to liability under federal and state False Claims Act laws.

Subject to certain limitations, any individual with knowledge of anti-kickback scheme can file a lawsuit against the offending provider on the government's behalf.

In addition to the treble damages and civil penalties imposed by the False Claims Act, a civil False Claims Act case can trigger a criminal investigation accompanied by subpoenas, searches and seizures, interviews and other invasive probing generally disruptive to a health care provider's livelihood.

As a result of the recent OIG open letter, providers who wish to disclose violations of Stark laws (in the absence of a "colorable" anti-kickback violation) have limited options. While Stark is a civil statute and the penalties provided are not as hefty as those for AKS violations, Stark is a "strict liability" statute.

Therefore, Stark violations are easier to establish because the government does not need to prove specific intent to defraud. In addition, Medicaid or Medicare money paid out as a result of Stark violations still constitutes a false claim for purposes of the False Claims Act.

First, providers may consider self-reporting to their Medicare fiscal intermediary (FI) or Medicare Administrative Contractors (now referred to as MACs.) They also may choose to report to the local U.S. Attorney's Office or the Department of Justice.

The downside to such alternative disclosures is that fiscal intermediaries and carriers have no settlement authority for crimes, and after demanding repayments or other restitution from the provider, the FI/MAC may also then forward the matter to the OIG for additional prosecution.

In addition, the United States Attorney's Office or the DOJ may not be as familiar with Stark-only violations as the OIG, and may therefore be less equipped to assess damages and settle a case with leniency towards a self-disclosing provider.

The benefit of self-disclosing Stark violations to one of the above-listed agencies (while obviously less desirable than disclosing to the OIG) is that a provider may skirt liability under 42 U.S.C. §1320a-7b(a)(3), which makes it a felony to keep federal money with fraudulent intent.

For more information on the OIG's self-disclosure program, providers should contact an experienced attorney or visit the OIG's Web site at www.oig.hhs.gov/fraud/selfdisclosure.asp.

The Medicaid Integrity Program: A new risk area for providers

Health Policy

By Amy K. Fehn, Esq. and Jennifer Ferro, Esq.

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Just as Michigan providers are bracing for the upcoming onslaught of Medicare audits, providers also must prepare for an increase in Medicaid audit activity as a result of the Medicaid Integrity Program (MIP).

The Deficit Reduction Act of 2005 (DRA) established the MIP, which is the first federal program to perform Medicaid provider audits.

Similar to the Medicare Recovery Audit Contractor (RAC) program, the MIP requires the use of contractors to target providers through the use of statistical data, to audit provider claims, and identify potential overpayments, as well as to provide education.

These contractors are known as Medicaid Integrity Contractors (MICs). While a MIC contract has not yet been awarded for Region V, which includes Michigan, contracts have been awarded in at least four other regions, and the program is expected to be fully operational nationwide by 2010.

Three types of MIC contracts will be awarded: Review MICs, Audit MICs and Education MICs.

Review MICs will conduct data analysis utilizing algorithms pursuant to oversight by the Division of Fraud Research and Detection (DFRD) to analyze Medicaid claims for aberrancies. This information will be shared with the Audit MIC to assist with targeting providers who may pose a risk to the Medicaid program.

As has been the case historically, state agency officials also may identify providers.

Once providers have been identified by the Review MIC or a state official, the Audit MIC will contact providers in writing requesting additional supporting documentation within a specific time frame and also will contact the provider regarding an entrance conference.

Audit MICs may conduct both field and desk audits and will review paid claims to ensure that services were actually provided, covered by the Medicaid program, properly documented, properly billed, and paid according to Federal and/or State rules and regulations.

Unlike RAC contractors, the Audit MICs will not be paid on a contingency basis. The Audit MICs also are not responsible for collecting overpayments.

Rather, the states will be charged with recovering overpayments and the federal government will collect its share from the state.

After completion of the audit, the Audit MIC is expected to prepare a draft audit report. The report will be shared with the state and then the provider, both of whom will have an opportunity to review and comment on the findings.

CMS will take these comments into consideration and will prepare a draft report, which will again be reviewed by the state for comment. After taking the state's comments into consideration, the Audit MIC will submit a final report to the state.

All provider appeals will be handled through the state, with support from the MIC. In Michigan, the appeals process for the adjustment or reduction of provider payments includes the right to a preliminary conference, a bureau conference and an administrative law judge hearing.

Audit MICs also are expected to make referrals to the Health and Human Services Office of Inspector General (OIG) if fraudulent behavior is detected.

The OIG will pass this information on to the state's Medicaid Fraud Control Unit when deemed appropriate.

This will likely result in an increase in Medicaid fraud investigations, especially when considered in conjunction with other components of the DRA, including incentives provided to the states to develop legislation comparable to the Federal False Claims Act.

Michigan recently amended its Medicaid False Claim Act to remedy deficiencies noted by the OIG, which is charged with determining whether the law is sufficiently similar to the Federal False Claims Act.

This will qualify Michigan for increased recoveries in Medicaid false claim cases, giving the state a greater incentive to vigorously pursue fraud allegations.

According to an April 2009 Government Accountability Office (GAO) report, the Medicaid program reported an estimated error rate of 10.5 percent resulting in a total improper payment estimate of $32.7 billion.

Of that amount, $18.6 billion represents the federal share and $14.1 billion represents the state share, creating huge incentives for both the state and the federal government to attempt to recover these alleged "improper payments."

The Education MICs are charged not only with educating providers, but also beneficiaries and others about program integrity.

This, combined with the DRA's other requirements that certain health care providers educate their staff on the whistleblower provisions of the federal and state laws, as well as include this information in employee handbooks, will likely increase the number of qui tam lawsuits alleging Medicaid fraud.

The combination of improved regulatory initiatives at the state level and the increased federal government involvement in Medicaid fraud detection and enforcement is expected to significantly increase overall enforcement of Medicaid fraud, so providers need to be prepared.

As with the RAC audits, review by a MIC cannot be prevented. However, providers can take steps to reduce the risk that their claims will be statistical outliers.

Providers should conduct self-audits now as part of a comprehensive compliance plan. Self-audits should focus on areas identified by CMS to indicate aberrancies, such as services dated after death, duplicate claims, unbundling and outpatient claims during an inpatient stay.

Providers also should look at documentation to ensure that it supports medical necessity and the code billed.

In addition, providers should put mechanisms in place now in preparation for responding to record requests from the MIC. Such mechanisms should be similar to those put into place to prepare for RAC record requests and might include designation of certain individuals within the organization who are prepared respond to requests.

If notified of an audit, providers should immediately seek experienced legal counsel to protect their interests, as there are early opportunities to review and comment on the audit report and then to pursue the various levels of the Medicaid appeals process.

There are both clinical and legal defenses available in the appeals process that require working knowledge of the program and the process.

As with RAC and other Medicare audits, a strong defense can significantly mitigate a provider's exposure.

In-office imaging services still protected

Despite efforts to restrict or eliminate provisions that allow the testing, IOASE remains intact

Despite recent efforts to restrict or eliminate the Stark Law's In-Office Ancillary Services Exception (IOASE), it remains intact and the prospect of a near-term wholesale elimination of appears remote.

Recent legislative initiatives to restrict or eliminate IOASE are, by no means, a new phenomenon.

Rather, over the last few years, the Centers for Medicare and Medicaid Services (CMS) has introduced several significant proposals targeting the provision of diagnostic imaging (and other ancillary services) in the physician office setting, through proposed changes to the Stark regulations, independent diagnostic testing facility (IDTF) regulations, and other Medicare reimbursement regulations, such as the Medicare Anti-Markup Rule (AMR).

IOASE background

The Federal Stark law prohibits physicians from referring Medicare patients to entities that provide designated health services (DHS, including diagnostic imaging services) if the physician (or his/her immediate family member) has a financial relationship with that entity, unless a Stark exception applies.

The IOASE is the statutory vehicle that permits physicians and group practices to furnish DHS, such as diagnostic imaging services, with the goal of balancing convenience, efficiency, quality and continuity of care, against the prevention of abusive sham arrangements that do not have a bona fide nexus to the physician's core medical practice.

A substantial majority of office-based diagnostic imaging arrangements rely upon the IOASE to enable referring physicians to provide these services within their practices.

Specifically, this exception protects diagnostic imaging arrangements if the services are provided or supervised by the referring physician or his/her group, billed by the performing physician/group (or the group's wholly owned subsidiary), and provided either in the same building as the physician's/group's office or a centralized building site operated exclusively by the group practice.

Notably, the IOASE was contained in the original Stark statute adopted by Congress in order to preserve the long-standing practice of physicians integrating within their practices those ancillary services that complement the professional physician services they furnish.

CMS' proposals targeting the IOASE

In recent years, CMS has introduced various legislative proposals that, in one form or another, effectively attempted to restrict (or eliminate) the IOASE.

Most of these original proposals, however, were either never finalized or implemented in manner that did not substantially affect many common diagnostic imaging arrangements involving true in-office integration.

The 2008 Medicare Proposed Physician Fee Schedule, for example, contained commentary by CMS expressing concern that the IOASE was being inappropriately used for services that were not closely connected to the physician's practice.

At that time, CMS solicited comments on potential changes to the IOASE, including whether certain DHS should be excluded from the exception, whether the location requirements of the exception should be tightened, and whether the exception should be available for specialized services involving equipment owned by non-specialists.

CMS, however, has not introduced a formal proposal to materially restrict the scope of the IOASE, and any revisions to the IOASE will require a future notice of proposed rulemaking with provision for public comment.

CMS has noted that any future rulemaking will present a coordinated, comprehensive approach to accomplishing the goals of minimizing the threat of program abuse while retaining sufficient flexibility to enable arrangements that satisfy the requirements and intent of Stark.

In a related matter, recently CMS took a relatively flexible position when it finalized the AMR, which applies to many common diagnostic imaging arrangements.

The original AMR proposals would have placed restrictive payment limitations on a significant number of such arrangements.

In the form the AMR was adopted, if a physician group is willing to exercise certain operational flexibility, substantially all of its diagnostic imaging arrangements that are structured to comply with the IOASE can be structured in a manner that does not implicate the AMR's restrictive payment limitations.

Shared space still OK

Further, under the AMR, CMS permits the use of shared space imaging arrangements between physicians that occur in the "same building". CMS did caution that it may issue proposed changes to the IOASE in the future, but expressly noted that it had been asked to consider, and rejected, a complete elimination of the IOASE.

Recently, CMS has also promulgated some significant federal Stark regulatory changes that impact diagnostic imaging arrangements. These include eliminating the use of "per-click" fee and percentage-based payments in space and/or equipment leases when the payments reflect services provided to patients referred between the parties.

Notably, however, these changes do not prohibit the overwhelming number of common diagnostic imagining arrangements that are structured to comply with the IOASE.

In yet another attempt to target certain IOASE diagnostic testing arrangements, in 2008, CMS introduced a proposal that would have required any physician furnishing in-office diagnostic testing services to enroll as an IDTF.

The result would have been that these practices' diagnostic imaging operations would be subject to most IDTF performance standards.

If adopted, this proposal would have eliminated physician practices' ability to share diagnostic imaging and other testing equipment and facilities, even if located in the "same building" as defined under Stark.

As a practical matter, this proposal also would have resulted in a significant decline in the number of physician practices that furnish diagnostic testing services to their patients. Notably, CMS declined to implement this IDTF proposal.

However, CMS did finalize its earlier proposal to require mobile IDTFs to enroll and bill Medicare directly for the TC services that they provide.

Implementation of this final rule appeared to prohibit many common arrangements in which mobile entities lease diagnostic testing equipment and technicians to physicians who furnish and bill for such tests in their offices.

In a noteworthy development, CMS posted a frequently asked question on its Web site clarifying that companies that merely lease or contract with a Medicare provider for non-physician personnel and/or equipment (but do not provide physician supervision) are not required to enroll and directly bill for such services.

CMS noted that it continues to evaluate these arrangements.

Nonetheless, absent further guidance from CMS to the contrary, the common imaging paradigm whereby a physician leases equipment and non-physician personnel from a mobile leasing entity can continue to bill for these services, provided that the physician group supervises the service and otherwise complies with the IOASE.

The current state of the IOASE

In recent years, through a serious of proposals, CMS has heightened its focus on certain diagnostic imaging arrangements, including arrangements structured in compliance with the IOASE.

However, despite these proposals, the IOASE remains intact as the statutory vehicle that permits physicians to furnish diagnostic imaging services in their offices.

Physicians furnishing in-office diagnostic testing services should remain attentive to potential future regulatory changes that might further restrict the scope of the IOASE.

As a result, parties to such arrangements should consider inclusion of well-designed strategies to unwind or restructure these transactions if regulatory changes preclude physicians' participation in such arrangements.

At this point, however, the prevailing thinking among industry insiders is that near-term elimination of the IOASE remains a remote prospect.

Health Policy

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The MMSEA has teeth.
The reporting requirements are reinforced by a penalty of $1,000 per day, per claim. Imagine the devastating impact of missing a single reportable event, only to have it discovered a year later when the penalty is $365,000.

Reporting

Continued from page 5

Claims that must be reported by an insurer or other business entity to CMS include just about every payment to, or write-off for, the benefit of a Medicare beneficiary. The key here is that the claim must arise out of some injury to an individual, as the precise language in the rules for reporting refers to "the injured party."

However, payments made by a business to Medicare beneficiaries who did not receive medical care in relation to the events alleged in a claim, such as claims solely for property damage, do not have to be reported.

Although avoiding reporting by allocating a medical payment of a Medicare beneficiary to property damage is enticing on the surface, if there is any potential of liability for medical expenses released by the payment, the allocation will not absolve a RRE from the reporting responsibility.

Erring on the side of reporting is recommended due to the possibility of significant fines if Medicare disagrees with the allocation.

As such, any business that reasonably anticipates the need to report under this statute must register with CMS between May 1, 2009, and Sept. 30, 2009. Once registered, test files can be submitted until March 31, 2010, to work out any difficulties.

After testing is complete, "actual" reporting is scheduled to begin April 1, 2010. Once actual reporting starts, reports must be submitted each quarter thereafter (even if there is no payment to report for that quarter).

Greater awareness will be required as to which patients are potential Medicare beneficiaries, especially when managing claims or even debt collections and bill write-offs.

Clearly, the law will necessitate more cooperation of physicians, hospitals, insurers and attorneys to avoid the potentially costly mistake of not reporting.

Moreover, whether or not a provider organization is a RRE, the requirements of the MMSEA will likely mean increased time and costs arising from intensified enforcement of the Medicare Secondary Payer law.

So get ready!

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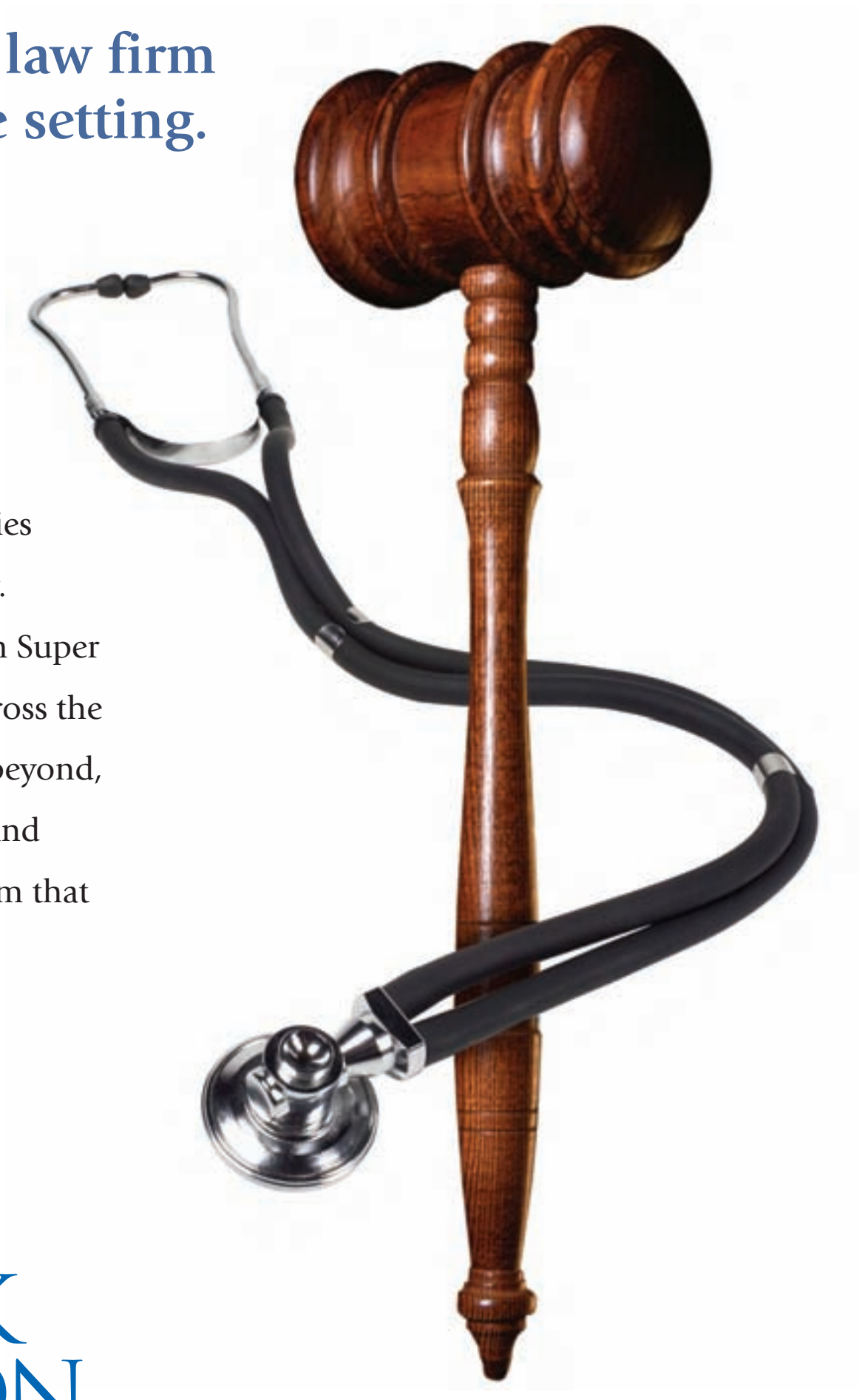

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Personal health records — are you prepared?

Since 2006, the Centers for Medicare and Medicaid Services (CMS) has engaged in a number of pilot projects to encourage Medicare beneficiaries to take advantage of Personal Health Records (PHRs).

The focus has always been to allow users more control over their medical information, as well as to communicate better with their health care providers, and ensure medical care is provided more efficiently.

A PHR, although it may or may not be electronically formatted, is a consumer-driven compilation of medical and related records, which a patient maintains and controls. Some of the items in a PHR include health history, medications, health insurance information and laboratory test results to name a few.

In July 2006, CMS sought to test the feasibility of integrating Medicare claims history information with other Internet-based tools.

CMS contracted with ViPS health care consulting company (using the WebMD tool) and Capstone Government Solutions (using the SharedHealth tool) to accomplish its goal. The pilot was successful in proving the feasibility of using Medicare claims data to populate PHRs, and in 2007 and 2008 additional CMS pilot studies were undertaken.

PHRs assist health care providers.

For health care providers, having access to a patient's PHR may be very useful in providing information in a timely manner, particularly if the patient has a complicated medical history and sees numerous medical specialists.

By having all information, consultations, and laboratory results in one place, time is saved in gathering necessary medical information, provided the PHR contains complete and verifiable health and medical information.

If that is the case, a PHR is valuable in:

- Providing information to new caregivers.
- Allowing health care providers and patients to knowledgably discuss health issues.
- Providing easy access to health information when traveling.
- Accessing the patient's health information when physician's offices are closed.
- Recording a patient's progress toward specific health-related goals.
- Referencing physician instructions, prescriptions, allergies, medications, and insurance claims.
- Tracking appointments, vaccinations, and numerous other wellness health care services.

Health Care Justice

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The information contained in the PHR should be used with caution. Because the PHR is compiled and maintained by the patient, it may not include pertinent information, may have outdated information, and my even contain unverifiable medical information.

Patients may avoid revealing embarrassing information like a history of substance abuse or sexually transmitted diseases.

Because of these shortcomings, it is important that health care providers rely on their own skills in obtaining good histories from patients and thorough physical examinations. To do less than this puts the health care provider at risk of missing important information necessary for an accurate diagnosis and treatment plan.

Data may be suspect

While asking specific questions will not always reveal pertinent information, documentation that such questions were asked along with the patient's responses may save a health care provider from defending a baseless lawsuit should a patient deliberately withhold information.

Even if patients include allergies and medications in their PHRs, such information may not be up-to-date. Particularly if patients have complicated medical histories or courses of treatment, or see a number of specialists, patients may frequently be adding and discontinuing medications from their regimens.

The PHR may not be up-to-date, and should not be relied upon unless each medication is discussed to determine whether the patient is currently taking the medication or if it has been discontinued.

If a patient reports an adverse reaction, further inquiry into whether the reaction was merely a side effect or truly an adverse

reaction or allergy is important. Again, any information gleaned from the history that is not reflected in the PHR should be documented in the provider's medical record.

Patients may include summaries of consultations or test results, without including verifiable information such as the context in which the consultation took place, and by whom and why tests were ordered, etc. It is important for health care providers to only consider medical information that can be verified.

Information regulated by HIPAA

Often times there is information in a patient's PHR that the health care provider finds useful in diagnosing or treating the patient.

Once such information from the patient's PHR is incorporated into a health care provider's medical or office record, the information will be regulated by the Health Insurance Portability and Accountability Act (HIPAA). Therefore it is very important that health care providers requesting copies of pertinent portions of a patient's PHR have a discussion with the patient regarding whether such information should be released by the provider when requested by other health care providers, insurance carriers, etc. in the future.

Discussions with the patient regarding how PHR information incorporated into the health care provider's medical record should be used and disclosed in the future, should be documented in the health care provider's medical record.

It is then important for the health care provider to adhere to the directions and wishes of the patient regarding how such incorporated information should be used and disclosed in the future.

PHRs can come in different formats. These formats include paper-based PHRs, Internet-based PHR, or portable storage PHRs, such as CD-ROMs, DVDs, or USB flash drives.

It is quite possible that patients will scan and download the PHR on a CD-ROM or USB flash drive and ask health care providers to store PHRs (e.g. USB flash drive) in their office setting. Providers need to determine if they have the ability to store portable PHRs and ensure their security before accepting them.

No doubt PHRs will become more prevalent in the future and achieve their intended purpose of allowing patients more control over their medical information, providing for more open communication with health care providers, and ensuring care is provided more efficiently.

To prepare for the future, health care providers need to ensure that they use PHRs appropriately, and put in place privacy and security safeguards for any excerpted PHR information maintained in the health care provider's medical record.

Clinics

Continued from page 3

cians and state regulators have expressed concerns about the quality of care rendered at retail clinics, the protection of patient information, and whether clinics clearly disclose relevant information about the practitioners treating the patients.

There also are concerns that the relationships between the clinics and third parties may not fully comply with healthcare regulatory laws like Stark and the Anti-Kickback Statute.

Physicians should understand these issues in order to decide how to influence the development of this popular healthcare delivery model.

Fragmented care

Understandably, physicians are concerned that the use of retail clinics will harm the patient-physician relationship and lead to fragmented care.

Physicians in an office setting commonly use any professional contact with a patient, even for the treatment of minor ailments, as an opportunity to address any other health issues that the patient may have. Accordingly, there is a risk that patients who frequently receive care at a retail clinic will not receive this overall beneficial health monitoring.

Even if retail clinics deliver high-quality care with respect to the illnesses treated at the clinic, such fragmented health care may not ultimately be in the best interest of the patients unless steps are taken to integrate such care with the care provided by the primary care physician.

Additionally, since the clinic will not typically have access to the full medical records of their patients, the NPs will be rendering care without any knowledge of other factors that impact treatment of the patient. Thus, the care rendered may not be optimal, particularly for high-risk patients.

To some degree, the issue of fragmented care can be addressed by requiring retail clinics to send reports detailing the reason for the visit, diagnosis, and treatment given to the patient's primary care physician.

The primary care physician can then follow-up with the patient. In this manner, care provided can be integrated with the physician's own practice.

Scope of care

To avoid having patients treated at a retail clinic, physicians can expand their own hours into the evening and offer more convenient scheduling for patients.

In addition to quality-of-care issues, retail health clinics also must be careful not to run afoul of state and federal laws. States have some control over retail clinics through scope of practice rules; through existing laws prohibiting the corporate practice of medicine; and consumer protection laws.

In Michigan, due to the corporate practice of medicine doctrine, retail clinics must be owned by a physician, or the retail clinic must enter into an independent contractor agreement with a physician who will act as the medical director of the clinic. This ensures that health care will be overseen by the medical director, rather than the owner of the retail clinic, which is bound to be either the host retailer or an affiliate.

In most states, the scope of an NP's practice, including prescription writing authority, is dependent upon physician supervision or delegation. In Michigan, "supervision" merely requires the continuous availability of direct communications between the physician and the NP by radio, phone or telecommunication and does not require the physical presence of the physician in the same facility.

In addition, the physician must be available to provide consultation to the NP, review records, further educate the NP in the performance of the NP's functions, and provide predetermined procedures and drug protocols to be followed by the NP. Thus, the current "supervision" requirements, which provide for a very general type of oversight, may not adequately address the issues raised by the retail health clinic setting.

Patient protection issues

Patient protection issues arise in two different contexts: false advertising and patient privacy.

Federal and state false-advertising and deceptive-trade practice laws can be implicated if practitioners and clinics create the false impression that a NP is a physician, or that the NP communicates directly with a physician to get "approval" for treatment.

Most notably, patients may interpret statements that the NPs are "supervised" by physicians to mean that the physician physically oversee the NPs.

Furthermore, laws that regulate licensed health care professionals may impose sanctions on NPs who misrepresent the limitations on services they can provide. These risks can be minimized by clearly conveying in advertising that patient care is rendered solely by NPs and without consultation with a physician prior to providing care.

Protecting patient privacy also is of utmost importance. While host retailers may be tempted to use patient information for marketing purposes, the Health Insurance Portability and Accountability Act (HIPAA) prohibits the disclosure of personally identifiable health information to the host retailer without a patient's consent.

Given the potential for taking advantage of vulnerable patients, it may be advisable to prohibit retail clinics from asking for a patient's consent to release such information to the host retailer.

Any physician who decides to own or serve as a medical director of a retail clinic also must be cognizant of Stark laws and the Anti-Kickback Statute, important federal regulations designed to prevent fraud and abuse. These statutes will apply to the physician's relationship with the host retailer.

Retail clinics can be an important component of a health care delivery system that complements the health care delivered by physician practices.

There is no doubt that the retail clinic model will continue to evolve over the next several years.

Physicians can provide valuable input into the way this model evolves and influence the evolution of the retail clinic model so that it will complement their own practices.

Pandemic preparedness: Planning is the best medicine

Business Strategy

By Gregory J. Parry, Esq.

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The 2009 Swine Flu, also called H1N1, has not run its course. We cannot predict its final social or economic toll.

At a minimum, it presents a call to action.

Pandemic planning is a prudent and cost-efficient risk and litigation management strategy. It reduces exposure to catastrophic financial losses and legal liabilities; protects employees; promotes continuity of business; and guards a company's reputation.

A pandemic influenza is distinguished from seasonal flu. More than 50 million Americans are sickened by seasonal flu annually. Approximately 35,000 die.

Seasonal flu is a respiratory illness, transmitted from person to person, caused by an existing virus. Most people have immunities to seasonal flus.

Pandemic influenza requires three elements: the virus is new, i.e., humans have no preexisting immunities; it causes illnesses or fatalities; and it is transmitted human-to-human worldwide.

Pandemic planning requires several unique considerations in contrast to basic disaster planning. Pandemics are akin to a slow motion tsunami, giving companies weeks advance notice to activate their pandemic plans.

Pandemics are not geographically isolated, but cross boundaries worldwide. They could cause high levels of employee absenteeism for prolonged periods.

Adequate remedies such as anti-viral medications or vaccines likely are not available for months. Pandemics do not cause property damage. As a result, planning should be treated separately in a company's disaster plan.

In the 1950s, the "Asian Flu" killed 2 million people worldwide, including 70,000 Americans. And in the 1960s, the Hong Kong Flu killed 1 million people, including 34,000 Americans.

In each pandemic, millions more were sickened.

Health experts contend that pandemic flu strains sweep the world every 30-40 years. The same health experts predict that a future pandemic is "inevitable."

The potential "Bird Flu" pandemic, known as H5N1, caused the nation and businesses to focus on pandemic planning for the last several years.

A 2007 survey by the Ad Council on behalf of the Department of Homeland Security's Ready Business group found that 91 percent of respondents believe it is "very" or "somewhat" important for businesses to take steps to prepare for a catastrophic disaster, such as an earthquake, hurricane or terrorist attack.

However, only 38 percent said their business had an emergency plan in place in the event of a disaster.

In November 2005, the White House released its "National Strategy for Pandemic Influenza." A year later, it issued its "National Strategy for Pandemic Influenza Implementation Plan."

Federal, state and local governments have dedicated millions of dollars toward pandemic planning. A new outbreak could overwhelm healthcare capabilities and cost the nation $170 billion.

The spread of the virus between family members may cause employees to miss work for prolonged periods to care for family members.

Global supply chains may be considerably disrupted.

Health care facilities and government services could be stressed but functional, and closures of community places, home-quarantine orders and travel restrictions all are possible.

Additional incentives exist to support pandemic planning. In today's economic climate, few businesses are poised to survive massive losses.

Also, a company's failed or inadequate plan opens the door to potential lawsuits rooted in select statutes, such as OSHA, ADA, FMLA and emerging theories of negligence.

Moreover, directors and officers of companies with failed or feeble plans face exposure to personal liability for breaching their fiduciary duties.

Federal, state and local governments will not rescue businesses during a pandemic; rather, businesses themselves must rely upon their plans.

Given these considerations, the White House has urged businesses to engage in pandemic planning.

Basically, this should include internal infection control policies, systems for working offsite during a pandemic, employee education, and implementing hygiene practices toward reducing the spread of viral infections.

Businesses should establish contingency plans to maintain the delivery of products/services amid sustained periods of employee absenteeism and supply-chain disruptions.

They also should provide avenues for employees to work from home if officials close schools or restrict nonessential travel.

It is not too late to start planning or improving one's disaster plan.

A good starting point is to retain qualified counsel to perform a legal audit, under the attorney-client privilege, to identify gaps.

The planning team may consist of people involved in business continuity, security, safety, human resources, travel, legal, production, communications, purchasing, telecommunications, information technology and risk management. Audits are conducted case-by-case.

Good emergency practices are vital

Inadequate pandemic plans can lead to considerable but avoidable financial losses, legal liabilities and tarnished reputations. As a first step, companies are advised to retain counsel to audit of their plan and, if necessary, make modifications.

Experts predict a future pandemic is inevitable. If true, careful planning now is the best medicine. Here are effective ways to achieve that:

- ☑ Establish a planning group responsible for creating and implementing the company's disaster plan. The chain of command should include alternates. The company should adopt disaster succession planning, several layers deep.
- ☑ Identify key business functions and supply chains that may represent points of failure and address these risks (i.e., adding redundancies to each process).
- ☑ Obtain full support from the company's top leadership and engage employees. The goal is a culture of preparedness.
- ☑ Review insurance contracts to identify and address potential gaps in coverage that may arise from a pandemic event.
- ☑ Review critical contracts for duties and responsibilities that may continue despite difficulties during a pandemic. Consider modifications to standard contract forms, as well as alternate suppliers in case key suppliers are idled.
- ☑ Assess the company's employment policies (i.e., sick leave and reduced compensation policies) in case of prolonged absenteeism during a pandemic.
- ☑ Permit employees to work from home, including providing broadband connections, work computers with auxiliary equipment. Conduct a test day every six months to confirm system operations.
- ☑ Create communications systems to keep employees connected and informed during a pandemic. The company should connect to credible governmental Web sites for current, correct information during a pandemic. One excellent site is www.pandemicflu.gov, which has links to state and local Web sites.
- ☑ Follow emergency planning protocols in National Fire Protection Standard 1600, adopted by the Department of Homeland Security and additional leading organizations as the appropriate standard of care for disaster planning.
- ☑ Practice the plan and revise it if necessary. Plans should spend notable time off the shelf. Planning activities should be in writing, documented by counsel.
- ☑ Stockpile equipment such as anti-viral soap, latex gloves, breathing masks (rated N-95), and anti-bacterial agents for cleaning. Encourage hygiene by hand washing and "social distancing" (3-foot distance). Minimize face-to-face meetings in favor of teleconferences. Change HVAC filters frequently. Provide training to employees on these prophylactic measures.
- ☑ Communicate your plan with local health care and emergency officials. Their feedback and future coordination may be highly useful.
- ☑ Conduct risk management "what-if" scenarios. For example, what if the company's revenues were to decrease by 20 percent to 40 percent for several months?
- ☑ Businesses are urged to add pandemic planning in their disaster plans. Pandemics can cause significant, prolonged disruptions.

Pending Legislation

Michigan Medical Legislation Report

Following is a list of bills pending in the Michigan Legislature related to health care and health care professionals.

Detailed information and analysis on this and other pending legislation can be found at www.michiganlegislature.org.

HOUSE BILLS

HB 4774 – Requirement for photo identification when purchasing prescription drugs.

"A pharmacist shall not dispense a prescription unless the patient or the patient's authorized representative produces a valid photographic identification issued by this state, another state, the federal government, or an institution of higher education in this state described in section 4, 5, or 6 of article VIII of the State Constitution of 1963 or a junior college or community college established under section 7 of article VIII of the State Constitution of 1963. As used in this subsection, "authorized representative" means a parent, guardian, or person acting in loco parentis if the patient is a minor, a member of the immediate family, the next of kin, or an individual who is designated as a patient advocate and given explicit written authorization to act on the patient's behalf in regard to medical treatment or, as applicable, mental health treatment."

Sponsored by: Goeff Hansen-R
Referred to the Committee on Health Policy

HB 4776 – Require prescribers to request information from the Michigan automated prescription system before prescribing and prohibit dispersing under certain circumstances

"Beginning Jan. 1, 2010, a prescriber shall request information from the electronic system as allowed in section 7333a(2)(f) before prescribing a controlled substance included in schedule 3 or 4 to a patient. In addition to any other duty the prescriber has with regard to that patient, the prescriber shall utilize information received from the electronic system under this subsection to determine whether a controlled substance included in schedule 3 or 4 should be prescribed for that patient. Information obtained by the prescriber from the electronic system under this subsection is confidential and is subject to the physician-patient privilege. A prescriber shall mark on the prescription form that he or she has received information from the electronic system as required under this subsection with regard to the patient for which the prescription for a controlled substance included in schedule 3 or 4 is written.

"Beginning Jan. 1, 2010, a pharmacist or dispensing prescriber shall not dispense a controlled substance included in schedule 3 or 4 to a patient unless the prescription form contains the mark of the prescriber that indicates the prescriber has received information from the electronic system as required under subsection (1) with regard to the patient for which the prescription for a controlled substance included in schedule 3 or 4 is written. As used in this section, 'pharmacist' and 'dispensing prescriber' mean those terms as defined in part 177."

Sponsored by: Wayne Schmidt-R
Referred to the Committee on Health Policy

HB 4778 – Require primary care physician to include in patient's medical record a copy of criminal record, if any, and government-issued photo identification; and to require, and prohibit provision of primary care services until obtained.

"A physician under part 170 or part 175 or any person acting under the supervision of that physician shall not provide primary care services to a patient unless all of the requirements of this section are met. This section does not apply to a physician or any person acting under the supervision of a physician who provides emergency or nonprimary care services to a patient.

"A patient who is 16 years of age or older shall present his or her government-issued photo identification to his or her primary care physician upon entering the office or during the check-in process. A physician shall make a copy of the patient's government-issued photo identification and place that copy in the patient's permanent medical record. The physician shall determine at each subsequent visit by the patient whether the identification in the patient's medical record is up-to-date and shall update the record if necessary.

"A patient who has been convicted of a drug offense shall disclose that conviction to a physician who is providing primary care services. A physician shall include in any documentation required of patients during the check-in process a space for the patient to disclose if he or she has been convicted of a drug offense. If a patient discloses a drug offense under this subsection, the physician or any person acting under the supervision of that physician shall not provide primary care services to that patient at any subsequent visit until the patient provides a copy of his or her criminal record. A physician shall make a copy of the patient's criminal record and place that copy in the patient's permanent medical record. The physician shall determine at each subsequent visit by the patient whether the patient's criminal record is up-to-date and shall update the record if necessary."

Sponsored by: James Marleau-R
Referred to the Committee on Health Policy

HB 4937 — Requirements for any physician or other licensee who writes prescriptions to utilize e-prescribing system established under Medicare regulations.

"Except as otherwise provided in this section, beginning July 1, 2010, a prescriber shall electronically transmit every prescription for a prescription drug written in this state in a manner that complies with the electronic prescription drug program established for prescribers under the Medicare improvements for patients and providers act of 2008, Public Law 110-275. A prescriber shall offer the patient a written receipt of the information transmitted electronically to the pharmacy. The receipt shall include the patient's name, the dosage and drug prescribed, and the name of the pharmacy where the electronic prescription was sent and shall indicate that the receipt cannot be used as a duplicate order for the same prescription drug. Nothing in this section interferes with the right of a patient to choose a pharmacy or with the prescribing decision at the point of care. If the pharmacy to be used by the patient for whom the prescription is written is not able to receive electronically transmitted prescriptions as provided in this subsection, the prescriber shall write the prescription utilizing electronic prescription technology and do one of the following as directed by the patient:

"(a) Print or otherwise provide the patient with a paper copy of the electronic prescription.

"(b) Transmit the electronic prescription to the pharmacy by facsimile or other means of electronic transmission, if that transmission is otherwise allowed under this act.

"Nothing in this section diminishes or modifies any requirements or protections provided for in the prescription of controlled substances as otherwise established by this act. A prescriber and a pharmacy shall comply with applicable state and federal confidentiality and data security requirements and applicable state record retention and reporting requirements with regard to electronically transmitted prescriptions under this section.

"A prescriber who violates this section is subject to the following:

"(a) For his or her first offense, the department shall require his or her attendance at a mandatory education program or course established by the department in the electronic transmission of prescriptions as required under this section.

"(b) For his or her second offense, the department shall require the prescriber to submit a report explaining the reasons he or she is unable to fully comply with the requirement to electronically transmit prescriptions as required in this section. The prescriber shall submit the information required under this subdivision in the time period established by, and in the format required by, the department.

"(c) For his or her third offense, the department shall require the prescriber to pay an administrative fine of $100.

"(d) For his or her fourth offense, the department shall require the prescriber to pay an administrative fine of $200.

"(e) For his or her fifth or subsequent offense, the prescriber is subject to the administrative penalties prescribed in sections 16221 and 16226."

Sponsored by: Kate Segal-D
Referred to the Committee on Health Policy

HB 5043 — License revocation or denial upon conviction of first-, second- or third-degree criminal sexual conduct

"Except as otherwise provided, an individual whose license is limited, suspended, or revoked under this part may apply to his or her board or task force for a reinstatement of a revoked or suspended license or reclassification of a limited license pursuant to section 16247 or 16249.

"Except as otherwise provided, an individual whose registration is suspended or revoked under this part may apply to his or her board for a reinstatement of a suspended or revoked registration pursuant to section 16248.

"A board or task force shall reinstate a license or registration suspended for grounds stated in section 16221(i) upon payment of the installment.

"Except as otherwise provided in this subsection, in case of a revoked license or registration, an applicant shall not apply for reinstatement before the expiration of three years after the effective date of the revocation. In the case of a license or registration that was revoked for a violation of section 16221(b)(vii), a violation of section 16221(c)(iv) consisting of a felony conviction, any other felony conviction involving a controlled substance, or a violation of section 16221(p), an applicant shall not apply for reinstatement before the expiration of five years after the effective date of the revocation. In the case of a license or registration that was revoked for a violation of section 16221(b)(xiii), that revocation is permanent and the licensee or registrant is ineligible for reinstatement. The department shall return an application for reinstatement received before the expiration of the applicable time period under this subsection or if the applicant is ineligible for reinstatement under this subsection.

"The department shall provide an opportunity for a hearing before final rejection of an application for reinstatement.

"Based upon the recommendation of the disciplinary subcommittee for each health profession, the department shall adopt guidelines to establish specific criteria to be met by an applicant for reinstatement under this article or article 7. The criteria may include corrective measures or remedial education as a condition of reinstatement. If a board or task force, in reinstating a license or registration, deviates from the guidelines adopted under this subsection, the board or task force shall state the reason for the deviation on the record.

"An individual who seeks reinstatement or reclassification of a license or registration pursuant to this section shall pay the application processing fee as a reinstatement or reclassification fee. If approved for reinstatement or reclassification, the individual shall pay the per year license or registration fee for the applicable license or registration period.

"An individual who seeks reinstatement of a revoked or suspended license or reclassification of a limited license pursuant to this section shall have a criminal history check conducted in accordance with section 16174 and submit a copy of the results of the criminal history check to the board with his or her application for reinstatement or reclassification."

Sponsored by: Lesia Liss-D
Referred to the Committee on Health Policy

HB 5057 — Require certain physicians to inform patients during second trimester about options regarding cord blood stem cells

"If funding is made available, the department shall promote public awareness and increase knowledge about the statewide network of cord blood stem cell banks, cord blood banking options, and the benefits of cord blood stem cells by developing and disseminating educational materials on the uses and benefits of cord blood stem cells, the viability of cord blood stem cells, information on research results utilizing cord blood stem cells, and any other related materials and information to enable the public to make informed decisions about the utilization of cord blood stem cells. Information shall include, but is not limited to, all of the following:

"(a) An explanation of the differences between public and private cord blood banking.

"(b) Information on the statewide network of cord blood stem cell banks.

"(c) Cord blood options available.

"(d) The medical process and risks involved in the collection of cord blood.

"(e) Medically accepted uses and benefits of cord blood collection and transplantation.

"(f) A statement that due to ongoing research and development there may be future uses and benefits of cord blood collection and transplantation.

"(g) An explanation of any costs to the donor associated with cord blood donation and storage.

"(h) Information on how to request printed materials and how to access other information available on the department's Web site.

Legislative Committee Members

Contact information for state senators can be found at http://senate.michigan.gov.

Contact information for state house representatives can be found at http://house.michigan.gov.

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Pending Legislation

"(i) Options for ownership and future use of the donated material.

"(j) An explanation of the storage, maintenance, and viability for transplantation of cord blood stem cells.

"The department, on its Web site, shall make the materials and information gathered and developed under subsection available in printable format to the public and to health care facilities and agencies, cord blood banks, and health care professionals.

"Except as otherwise provided in this section, a health professional who is the primary care provider for a patient who is in her second trimester of pregnancy shall inform the patient of the following options relating to cord blood stem cells after the delivery of her child:

"(a) Discard the cord blood stem cells.

"(b) Donate the cord blood stem cells to a donor bank.

"(c) Store the cord blood stem cells for use by the immediate and extended family members in a cord blood stem cell bank.

"(d) Store the cord blood stem cells for family use through a family or sibling donor banking program that provides free collection, processing, and storage where there is a medical need.

"If the department has developed educational materials under section 2683, the health professional described in subsection 1 shall also provide his or her patient with those materials. A health professional described in subsection 1 meets the notification requirements of this section by providing the information verbally or in writing or by providing the woman with a publication prepared by the department that, as certified by the department, contains all the information required by this section in addition to the information required under section 2683.

"This section does not apply to a health professional and he or she is not required to inform a pregnant patient regarding cord blood stem cell options if providing that information conflicts with the health professional's bona fide religious beliefs.

"A person who acts in good faith pursuant to this section is not subject to civil or criminal liability or professional discipline for those acts."

Sponsored by Paul Scott-R

Referred to the Committee on Health Policy

SENATE BILLS

SB 0423 — Amend the Nonprofit Health Care Corporation Reform Act to include coverage for K-12 school-required vaccines.

"A health care corporation that issues or renews in this state a group or nongroup certificate shall include coverage for immunizations against diseases as specified by the director of the department of community health as necessary for attendance in grades K through 12 in this state.

"Coverage under this section shall not be subject to any dollar limit, co-payment, deductible, or coinsurance provision that does not apply to screening coverage generally.

"This section does not apply to specified disease or accident-only coverage."

Sponsored by: Gilda Jacobs-D
Referred to the Committee on Health Policy

SB 0477 — Amend the Corrections Code of 1953, by adding agreements to have Michigan medical schools provide medical services to prisoners.

"The department shall enter into agreements with one or more medical schools in this state under which health care services would be provided to prisoners by those medical schools.

"The department shall report to the legislature not later than 180 days after the effective date of this section, and annually thereafter, on the status of any agreements entered into under this section. The report shall include an evaluation of the cost and efficiency of health care services delivered under the agreements. Copies of the report shall be delivered to the secretary of the Senate and the clerk of the House of Representatives and to the chairpersons of the standing committees of the Senate and House of Representatives responsible for legislation pertaining to corrections issues."

Sponsored by: Thomas George-R
Referred to the Committee on Judiciary

SB 0499 — Creation of the Employee Accommodation Act.

"A health care provider may request reasonable accommodation to avoid providing or participating in a health care service to which the health care provider objects on ethical, moral, or religious grounds.

"A health care provider shall request reasonable accommodation described in subsection (1) in writing. The written request shall be given directly to his or her supervisor and shall include a statement explaining his or her objection and the health care service or services to which he or she specifically objects to providing or participating in under this act.

"A health care provider may request reasonable accommodation under any of the following conditions:

"(a) Upon being offered employment.

"(b) At the time the health care provider adopts an ethical, moral, or religious belief system that conflicts with participation in a health care service.

"(c) Within 24 hours after he or she is asked or has received notice that he or she is scheduled to participate in a health care service to which he or she objects.

"An employer shall retain a health care provider's written request filed under section 5 for the duration of the health care provider's employment. The written request is valid for the duration of the health care provider's employment or until rescinded by the health care provider in writing.

"Within 7 days after receiving a written request pursuant to section 5, an employer shall develop a plan for reasonable accommodation with the health care provider to ensure that the health care provider will not be scheduled or requested to participate in a health care service to which he or she specifically objects.

"An employer shall not ask a prospective employee regarding his or her objection or potential objection to a health care service unless participation in that health care service is a regular or substantial portion of the normal course of duties for the position or staff privileges the prospective employee is seeking.

"An employer shall not refuse employment or staff privileges to a health care provider who is known by the employer to have previously requested or is currently requesting reasonable accommodation under section 5 unless participation in that health care service is a regular or substantial portion of the normal course of duties for that position or staff privileges.

"A medical school or other institution for the education or training of a health care provider shall not refuse admission to an individual or penalize that individual because the individual has filed in writing with the medical school or other institution a request for reasonable accommodation under section 5. …

"Except as provided in section 9, a health care provider's objection to providing or participating in a health care service as described in section 5 shall not be the basis for one or more of the following:

"(a) Civil liability to another person.

"(b) Criminal action.

"(c) Administrative or licensure action.

"(2) If a health care provider is required by his or her employer to participate in a health care service more than seven days after the health care provider has submitted a written request regarding that health care service, the health care provider is immune from civil liability in an action arising from his or her participation in that health care service.

"A civil action for damages or reinstatement of employment, or both, may be brought against a person, including, but not limited to, a governmental agency, health facility, or other employer, for penalizing or discriminating against a health care provider, including, but not limited to, penalizing or discriminating in hiring, promotion, transfer, a term or condition of employment, licensing, or granting of staff privileges or appointments, solely because that health care provider has submitted a request regarding participating in a health care service under section 5. Civil damages may be awarded equal to the amount of proven damages and attorney fees. A civil action filed under this subsection may include a petition for injunctive relief against a person alleged to have penalized or discriminated against a health care provider as described in this subsection.

"A person who violates this act is responsible for a state civil infraction and may be ordered to pay a fine of not more than $1,000 for each day the violation continues or a fine of not more than $1,000 for each occurrence."

Sponsored by: Roger Kahn-R
Referred to the Committee on Health Policy

SB 0528 — Prohibiting reuse of single-use medical devices under certain circumstances and prescription of remedies for violation.

"Except as otherwise provided in this section, a health care provider shall not knowingly reuse, recycle, refurbish for reuse, or provide for reuse a single-use device.

"This section does not apply to a health care provider that utilizes, recycles or reprocesses for utilization, or provides for utilization a single-use device that has been reprocessed by an entity that is registered as a reprocessor and is regulated by the United States Food and Drug Administration.

"This section does not apply to a health care provider that uses an opened, but unused single-use device that meets all of the following requirements:

"(a) The sterile packaging on the single-use device has been opened and its sterility has been breached or compromised.

"(b) The single-use device has not been used on a patient and has not been in contact with blood or bodily fluids.

"(c) The single-use device has been resterilized.

"A person who violates this section is subject to a fine of not less than $10,000 for the first offense and not less than $20,000 for the second and subsequent offenses."

Sponsored by: Bill Hardiman-R

Referred to the Committee on Health Policy

SB 0565 — Amend Public Health Code to require promulgation of rules relating to program for allocating leftover medical supplies (PALMS).

"Subject to subsection (2), the department, in consultation with the board, shall promulgate rules and establish procedures necessary to establish, implement, and administer the PALMS. The board shall provide technical assistance to individuals, health facilities and agencies, adult foster care facilities, assisted living facilities, manufacturers, pharmacies, and charitable clinics that participate in the PALMS.

"The department, in consultation with the board, shall promulgate emergency rules under the administrative procedures act of 1969 on or before the expiration of six months after the effective date of this section to establish, implement, and administer the PALMS. The department, in consultation with the board, shall promulgate permanent rules pursuant to the administrative procedures act of 1969 as soon as practical after emergency rules have been promulgated under this subsection. The department and the board shall include all of the following in rules promulgated under this section:

"(a) Eligibility criteria for pharmacies and charitable clinics authorized to receive and dispense donated prescription drugs for the PALMS.

"(b) Eligibility criteria for eligible participants.

"(c) Establishment of a formulary that includes all prescription drugs approved by the federal food and drug administration.

"(d) Standards and procedures for transfer, transportation, acceptance, safe storage, security, and dispensing of donated prescription drugs.

"(e) A process for seeking input from the department in establishing provisions that affect health facilities and agencies, adult foster care facilities, and assisted living facilities.

"(f) A process for seeking input from the department and the department of human services in establishing provisions that affect mental health and substance abuse clients.

"(g) Standards and procedures for inspecting donated prescription drugs to ensure that the prescription drugs meet the requirements of the PALMS and to ensure that, in the professional judgment of the pharmacist, the prescription drugs meet all federal and state standards for product integrity.

"(h) Procedures for the destruction and environmentally sound disposal of prescription drugs or other medications that are donated and that are controlled substances or otherwise ineligible for distribution under the PALMS.

"(i) Procedures for verifying whether the charitable clinic, pharmacy, responsible pharmacist, or other health professionals participating in the PALMS are licensed and in good standing with the applicable licensing board.

"(j) Establishment of standards for acceptance of unused prescription drugs from individuals, health facilities and agencies, adult foster care facilities, and assisted living facilities.

"(k) Any other standards and procedures the department, in consultation with the board, considers appropriate or necessary to establish, implement, and administer the PALMS.

"Pursuant to the rules promulgated and procedures established for the PALMS under this section and section 17775, an individual; a resident of a health facility or agency, adult foster care facility, or assisted living facility; or the representative or guardian of an individual or a resident of a facility may donate unused prescription drugs for dispensing to eligible participants under the PALMS.

"This section and sections 17775 and 17776 do not impair or supersede the provisions regarding the cancer drug repository program established in section 17780. If any provision of this section or section 17775 or 17776 conflicts with a provision of that section with regard to cancer drugs, that section controls."

Sponsored by: Tony Stamas-R
Referred to the Committee on Health Policy

See "Pending Legislation," page 14

Pending Legislation

Continued from 13

SB 0565 — Amend Public Health Code to require and clarify requirements regarding circulating nurses, and policies and procedures applicable to operating rooms during surgical procedures.

"A freestanding surgical outpatient facility or hospital licensed under this article that performs surgical procedures under general anesthesia or deep sedation in an operating room of the facility or hospital shall do all of the following:

"(a) Develop and maintain effective policies and procedures regarding surgical privileges, maintenance of the operating rooms, and evaluation of the surgical patient.

"(b) Meet the requirements of the conditions of participation established under 42 CFR 482.51 as they apply to registered professional nurses performing circulating duties in the operating room and as provided in the interpretive guidelines published by the United States department of health and human services.

"The freestanding surgical outpatient facility or hospital described in subsection (1) may assign a qualified registered professional nurse to be present in the operating room for the duration of each surgical procedure. This subsection does not prevent a qualified registered professional nurse who is performing circulating duties from leaving the operating room as part of the surgical procedure, leaving the operating room for short periods, or, under employee rules or regulations, being relieved during a surgical procedure by another qualified registered professional nurse who is assigned to continue performing circulating duties for that surgical procedure.

"A licensed practical nurse or a surgical technologist may perform scrub nurse duties under the supervision of the qualified registered professional nurse who is performing circulating duties in the operating room. If the qualified registered professional nurse who is performing circulating duties is immediately available to respond to emergencies, a licensed practical nurse or a surgical technologist may assist by performing circulating duties under the supervision of that qualified registered professional nurse."

Sponsored by: Roger Kahn-R

Referred to the Committee on Health Policy

SB 0618 — Licensing medical marihuana growing facilities.

"Medical marihuana shall not be grown, sold, distributed, possessed, used, transported, or delivered for use under the Michigan medical marihuana act, 2008 IL 1, MCL 333.26421 to 333.26430, unless grown and sold through a medical marihuana growing facility licensed under this section. A pharmacist shall not dispense medical marihuana as a schedule 2 controlled substance under this act unless it has been grown at a medical marihuana growing facility licensed under this section.

"A person shall not operate a medical marihuana growing facility in this state until issued a license under this section. No more than 10 medical marihuana growing facilities shall be issued a license under this section during any one-year period. A license issued under this section is not assignable or transferable.

"Before a medical marihuana growing facility is established, the owner or operator of the proposed facility shall submit complete drawings to the department for examination and approval. The drawings shall be drawn to an indicated scale, give the relative location of the medical marihuana growing facility, and illustrate all rooms, buildings, facilities, and equipment to be used in the medical marihuana growing operations.

"Specifications prescribed by rules promulgated under this section shall accompany the drawings. When the construction and establishment of a proposed medical marihuana growing facility are completed, the owner or operator of the proposed facility shall notify the department. The department shall inspect the buildings and premises in which the medical marihuana growing facility are contemplated. If the building and premises conform to the approved plans submitted under this section or rules promulgated under this section and a license is available to be issued under this section, the department shall issue to the applicant a license to conduct a medical marihuana growing facility.

"The department may receive license applications for the operation of a medical marihuana growing facility. The department shall establish procedures to follow if more applications are received than licenses available to be issued under this section.

"Upon compliance by an applicant with the requirements of this section and rules promulgated under this section and if a license is available to be issued under this section, the department shall issue a medical marihuana growing facility license. The department shall issue a license under this section for a period of one year. The initial application and annual license fee for a medical marihuana growing facility license is $2,500. …

"The owner, operator, or agent of a medical marihuana growing facility who fails to comply with this section or rules promulgated under this section within the time specified by the department, or who establishes or operates a medical marihuana growing facility in violation of a detailed statement of specifications, plans, or license approved by the department, is guilty of a misdemeanor punishable by imprisonment for not more than 90 days or a fine of not more than $1,000, or both, for each violation or noncompliance."

Sponsored by: Wayne Kuipers-R

Referred to the Committee on Judiciary

BILLS PASSED

HBS 4763-69 — Create short title and allow for promulgation of rules for Children's Safe Products Act.

Sponsored by Judy Nerat-D
Passed in House (63-44)
Status: Referred to Committee on Health Policy

HB 4899 — Require department to create and update list of reportable diseases at least annually.

Sponsored by Kate Segal-D
Passed in House (106-2)
Status: Referred to Committee on Health Policy

HB 4900 — Penalties for violation of a local health department regulation or order of a local health officer.

Sponsored by Tim Moore-R
Passed in House (104-4)
Status: Referred to Committee on Health Policy

SB 0151 — General amendments for individual licensing and regulation for physical therapists.

Sponsored by Bruce Patterson-R
Passed in Senate (37-0)
Status: Referred to Committee on Health Policy

SB 0419 — Allowing blood donation at age 16 with parental consent.

Sponsored by Wayne Kuipers-R
Passed in Senate (37-0)
Status: Referred to Committee on Health Policy

Hospitals

Continued from page 1

regarding who may bring a claim," wrote Judge Eric L. Clay, speaking for the court. And, "[t]his language would seem to include" non-patients whose injuries were "the direct result of the hospital's decision to release" a patient before the patient had stabilized.

The plaintiff's lawyer in Moses said the prospect of hospitals being flooded with EMTALA claims from non-patients was more theoretical than real given the uncommon nature of the case facts.

"The 6th Circuit broke new ground with its ruling," said Royal Oak attorney Mark R. Granzotto, "but that ground may not get much foot traffic."

He said he "didn't see the decision as affecting a lot of cases" because it was unlikely that "this type of highly unusual situation" would often occur.

Okemos attorney Michael L. VanErp of Johnson & Wyngaarden, P.C. said one new source of hospital litigation may be negligent infliction of emotional distress claims. He said that, even though such claims tended to be rejected under Michigan state law, an argument could be made that EMTALA allows them. VanErp noted the federal law's statement that "any individual who suffers personal harm" may sue.

According to 42 U.S.C. Section 1395dd (d)(2)(A), "[a]ny individual who suffers personal harm as a direct result of a participating hospital's violation" of EMTALA may sue for personal injury damages.

EMTALA requires hospitals to stabilize — prior to release — patients who presented to the hospital's emergency department with an emergency medical condition.

Lawyers who have represented hospitals in personal injury cases view Moses' expansion of the class of potential EMTALA plaintiffs as possibly opening the door to increased litigation.

Bloomfield Hills attorney Robert G. Kamenec of Plunkett Cooney said "one can envision" the Moses ruling expanding the types of EMTALA cases brought against hospitals.

"These cases would parallel in greater degree common law negligence claims that are already available under Michigan law," he said.

VanErp said that, even if negligent infliction of emotional distress claims were deemed actionable under Moses' interpretation of the EMTALA statute, they would probably be infrequent.

Clay, in the court's April 6 opinion, said that "[i]f Congress had intended to limit the right of action to any individual who 'comes to a hospital' as a patient, it could have done so, just as it did in other parts of the statute."

The judge also noted he was "not aware of any federal appellate court that has addressed whether non-patients who allege harm as a result of a hospital's violation of EMTALA have standing to sue."

Joining Clay's opinion were Judge Julia Smith Gibbons and visiting Judge Frederick P. Stamp Jr., who is a senior judge from the U.S. District Court for the Northern District of West Virginia.

Detroit attorney Susan Healy Zitterman of Kitch Drutchas Wagner Valitutti & Sherbrook, who represents Providence Hospital, didn't respond to requests for comment. And, Kevin Downey, assistant director of public affairs for the Michigan Health and Hospital Association, declined to comment on the association's behalf.

On April 17, Providence Hospital filed a petition for rehearing en banc.

If you would like to comment on this story, please contact Todd C. Berg at (248) 865-3113 or todd.berg@mi.lawyersweekly.com.

"The 6th Circuit broke new ground with its [EMTALA] ruling, but that ground may not get much foot traffic."

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Planning

Continued from page 1

half, including the use of life-prolonging health care, mental health treatment and anatomical gifts, in the event the patient becomes incapacitated.

Living wills are similar to designations in that they memorialize a patient's health care wishes; however, they do not involve the appointment of a patient advocate.

State laws determine how advance directives may be created, suspended and revoked, so patients should take care to meet the requisite state legal requirements.

Michigan does not have a statute governing living wills. However, in order to properly execute a patient advocate designation in Michigan, the designation must be signed by the patient and two witnesses (in general, family members and/or individuals who stand to inherit from the estate may not witness a designation), and the patient advocate must sign an acceptance.

Copies of advance directives should be kept in the patient's medical record and provided to the patient advocate, physicians, family members, friends and anyone else who may become involved in a patient's health care.

Suspending and revoking advance directives

While choosing a patient advocate is undoubtedly a weighty consideration, individuals should not be reluctant to execute advance directives.

Generally, it is easier to suspend or revoke an advance directive than to create one.

Patients should understand that a designation only takes effect after two physicians determine, in writing, that a patient is unable to make medical treatment decisions, and the designation is suspended when the patient regains the ability to participate in medical treatment decisions.

Additionally, even if the patient is unable to participate in medical treatment decisions, a patient may revoke a designation at any time and in any manner by which he or she is able to communicate intent to revoke the designation.

Designations are automatically revoked if a patient dies; if the patient advocate resigns or is removed by a probate court for failing to act in the patient's best interests; if the patient executes a subsequent designation; or if the patient appointed his or her spouse as the patient advocate and the marriage ends.

Directives are important to providers

At its core, the purpose of advance directives is to honor a patient's right to control decisions about his or her own health care and death.

However, on a practical level, advance directives provide guidance for health care providers and eliminate conflicts between multiple decision-makers, thereby allowing physicians, patient advocates and families to efficiently make health care decisions in line with a patient's individual values and wishes.

The Michigan Dignified Death Act encourages health care providers to initiate discussions with their patients regarding advance medical directives during initial consultations, annual examinations, and hospitalizations; at diagnosis of a chronic illness; and when a patient transfers from one health care setting to another.

In addition, health care providers should take advance directives seriously to avoid the possibility of legal risks.

In some states health care providers who intentionally violate or ignore advance directives may be liable for tort damages.

In Michigan, health care providers are bound by both "sound medical practice" and by a patient advocate's instructions (as long as the patient advocate complies with the provisions of Michigan's patient advocate statutes).

Physicians should talk to their patients about the value of advance directives. In most cases, individuals can execute advance directives without the help of an attorney.

Physicians themselves should know the policies and laws relating to advance directives in their state and in their facility to ensure compliance.

Prepared ahead of time, advance directives protect patients' wishes regarding medical care and ease the burden on both families and health care providers.

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Red flags

Continued from page 1

ant with the Red Flags Rule, providers also need policies specifically dealing with identification, detection and response to "Red Flags," which are defined as "a pattern, practice or specific activity that indicates the possible existence of identity theft."

With regard to medical identity theft, "Red Flags" should include suspicious activities such as:

- Presentation of identification by a patient that looks altered or forged.
- Information provided by a patient that is inconsistent with previous information contained in the medical chart or obtained from another source such as an insurer, e.g., an inconsistent birth date.
- Mail to a patient that is consistently returned as undeliverable even though the patient still shows up for appointments.
- Patient complaints about getting a bill for service that he or she never received.
- Inconsistency between a medical examination and information in the patient's record.
- Notice from victims of identity theft, law enforcement officers or insurers indicating possible identity theft.

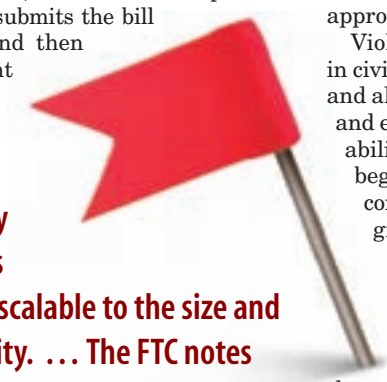
The compliance date for the Rule was originally set for Nov. 1, 2008, and has been extended twice, in part because certain industries, including the health care industry, were unaware of their obligations pursuant to the Rule.

The Rule applies to "creditors," and while health care providers do not generally consider themselves to be creditors, they do meet the rule's broad definition. The Red Flags Rule has adopted the Fair Credit Reporting Act (FCRA) definition: "[A]ny person who regularly extends, renews, or continues credit" or "any person who regularly arranges for the extension, renewal or continuation of credit."

"Credit" is defined by the Equal Credit Opportunity Act as "[T]he right granted by a creditor to a debtor to defer payment of debt or to incur debts and defer its payment or to purchase property or services and defer payment therefore."

The FTC has broadly interpreted the definition of creditor to include any health care provider who regularly bills patients after completion of services, allows patients to set up payment plans, or helps patients get credit from other sources.

So, for example, if a health care provider sees a patient, submits the bill to insurance and then bills the patient for any remaining balance resulting from co-payments or deductibles, the health care provider would meet the definition of creditor pursuant to the Red Flags Rule.



Like the HIPAA Privacy and Security Rules, the Red Flags Rule is flexible and scalable to the size and risk level of the entity. . . . The FTC notes that small providers with a well known limited patient base will likely have a lower risk of identity theft and could adopt a more limited program than a provider with a larger volume of patients.

There are several situations where the FTC has acknowledged that health care providers would not be considered a creditor, including situations where the provider always collects full payment prior to rendering any services or where the provider only accepts direct payment from Medicaid or other programs that pay in full with no co-payments or deductibles for which the patient is responsible. Also, the mere acceptance of credit cards as a form of payment will not cause a provider to be viewed as a creditor.

It also is important to note that the Rule applies only to "covered accounts." The FTC has broadly defined a covered account as including any account for which there is a "reasonable risk" of identity theft. The FTC has specifically stated that it considers patient accounts to bear a reasonable risk of identity theft because of increasing concerns about identity fraud in the context of medical care.

To be compliant, an Identity Theft Prevention Program also must be approved by a "board of directors" or a senior management member in the case of entities without a board, and must include staff training and appropriate oversight.

Violation of the Red Flags Rule can result in civil penalties of up to $2,500 per violation and also can damage a provider's reputation and expose them to additional theories of liability. Thus, providers should not delay in beginning to implement a Red Flags Rule compliant Identity Theft Prevention Program.

In addition to implementing new policies specifically designed to detect and respond to "Red Flags," providers should review their HIPAA Privacy and Security Policies to determine the extent to which they address the prevention of identity theft and can be incorporated into an Identity Theft Prevention Program.

FEHN

CAMPBELL

Amy K. Fehn and Jeffrey R. Campbell are health care attorneys at Wachler & Associates, P.C. Fehn is a former registered nurse who has been counseling healthcare providers for the past 11 years on regulatory and compliance matters such as HIPAA, Stark, fraud and abuse, and the defense of RAC and other Medicare and third-party payor audits. Campbell specializes in transactional and corporate matters, compliance, audit defense, reimbursement and contracting matters, and staff privilege and third-party payor departicipation matters. Contact them at (248) 544-0888 or afehn@wachler.com and jcampbell@wachler.com.

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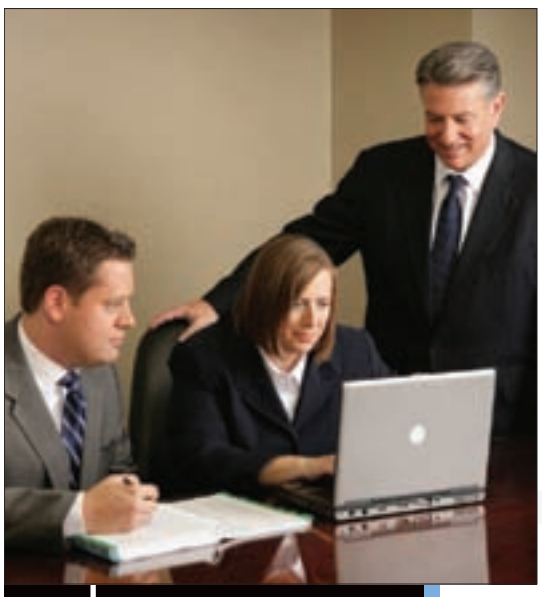

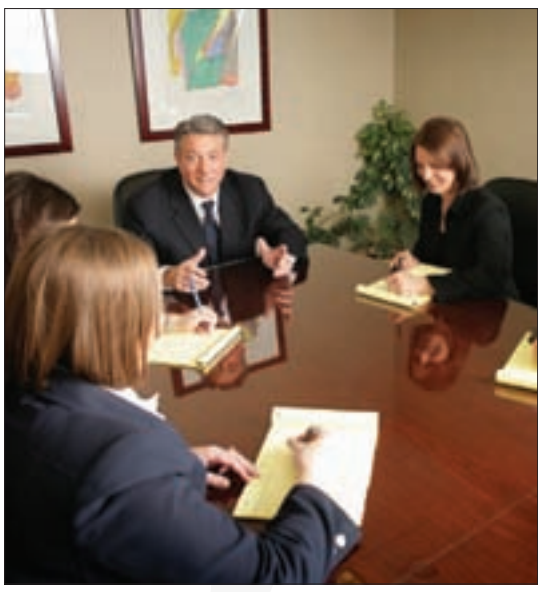

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