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## Inside MedLaw



# Opening the door to concierge medicine

**By Mercedes Varasteh Dordeski, Esq. and Gary A. Kravitz, Esq.**

The Centers for Medicare and Medicaid Services (CMS) recently released the 2010 Medicare Physician Fee Schedule, which sets the reimbursement rates for services provided under Medicare Part B.

Notably, this year's rates include the most significant reductions in reimbursement since 1992, and contain cuts of up to 35 percent and more in some areas, such as non-invasive cardiology.

Such reductions (if not deferred by Congress), coupled with ever-expanding rules and regulations governing health care, have made it increasingly difficult for physicians to offer patients quality health care without sacrificing profitability.

In order to strike a proper balance between practice economics and keeping patients happy, some physicians are turning to concierge medicine as a new business model.

Concierge medicine is, in essence, a system whereby a patient pays a monthly or yearly retainer to a physician in addition to their insurance premiums for privileged health care. In exchange, concierge patients receive increased access to care, such as guarantees to receive same day and/or weekend appointments; access to the physician's cell and/or home phone numbers; and enhanced amenities, such as receiving care in a spa-like setting.

Concierge medicine provides obvious benefits to both patients and physicians: for the former, it means the ability to receive immediate care; and for the latter, it can mean a reduced workload from carrying fewer patients and enhanced physician-patient relationships.

Broadly speaking, most physicians who make the transition to concierge medicine are gen-

*See "Concierge," page 14*

**In order to strike a proper balance between practice economics and keeping patients happy, some physicians are turning to concierge medicine as a new business model.**

# 'Micropractice' could lead to a more satisfying career

**By Maro E. Bush, Esq.**

Frustrated by dwindling profits and an increasingly elusive work-life balance, many physicians have begun utilizing innovative practice models, from hospital-owned practices to system-owned multispecialty groups to medical foundations.

Rounding out this list is the micropractice model.

Often overlooked, micropractices have been gaining in popularity with proponents who believe the model is a step in the right direction for a system gone wrong for both physicians and patients.

Micropractices (also called patient-centered practices) are low-volume, highly efficient solo medical practices.

In a nutshell, micropractices utilize the idea that by eliminating the usual overhead associated with running an office, costs can be reduced, thereby allowing physicians to spend more time with fewer patients without having to sacrifice revenue.

The micropractice model is generally used by primary care or family practitioners and focuses on optimizing the smallest functional work unit capable of delivering excellent care: the solo doctor, even without any staff.

For example, a physician may choose to eliminate nursing staff and take blood pressure readings and

*See "Micropractice," page 6*

# Hot spot

## Michigan one of a handful of areas targeted for HEAT health care fraud team

**By Pamela C. Enslen, Esq. and Matthew F. Leitman, Esq.**

Both the federal government and the State of Michigan have recently increased the resources they are dedicating to battling Medicare, Medicaid, and other health care-related fraud.

Last spring, a Medicare Fraud Strike Force team, known as the Health Care Fraud Prevention & Enforcement Action Team (HEAT) was formed by the Departments of Justice (DOJ) and Health and Human Services (HHS) to investigate and prosecute health care fraud.

HEAT is a joint task force of senior leaders from the DOJ and HHS and also is comprised of state and

*See "Fraud," page 13*

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# Stark changes demand re-evaluation of some health services contracts and relationships

Stark compliance is not something that any physician can simply check off a to-do list, and never to think of again.

Instead, compliance with these complex regulations must be analyzed and re-analyzed with each revision or pending effective date.

Stark bans physician self-referral of designated health services under Medicare unless one of the exceptions contained within the law are met. Yet another one of these times where Stark demands that physicians re-evaluate their contracts and business arrangements, was Oct. 1, 2009.

If you failed to do so, it is imperative that you act immediately to ensure continued compliance.

Significant changes to Stark went into effect relating to percentage-based leases, "per click" payments and "under arrangements" relationships.

Because Stark is a strict liability statute, physicians cannot claim ignorance of these changes as a defense if they are found to be noncompliant.

## Regulation

**By Andrew B. Wachler, Esq. and Alicia B. Chandler, Esq.**

WACHLER

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### Percentage-based leases

Previously under Stark, the rental of office space or equipment did not constitute a financial relationship, even if payments were based on the revenue earned from the space or equipment (as long as the lease agreement was in writing and met specific criteria).

As of Oct. 1, 2009, Centers for Medicare and Medicaid Services (CMS) closed this "loophole" in light of their concern that such percentage-based leases created an unacceptable risk for patient abuse.

Under the new regulations, any office or equipment lease that bases the payment amount on a percentage of revenue creates a financial relationship between the parties.

As a result, any referral between parties to a percentage-based lease may trigger liability under Stark, potentially subjecting physicians to civil monetary penalties of $15,000 per violation; refund of Medicare payment related to such referrals; exclusion from the Medicare program; and false claims liability exposure.

Therefore, physicians should immediately have their leases reviewed to ensure continuing compliance with Stark.

Moreover, this may not be the last change we see relating to percentage-based compensation. While it is still permissible to use percentage-based compensation for management or billing services, CMS has left the door open to further revise the regulations if needed in the future. Thus, physicians must remain mindful of any upcoming changes.

### Per-click leases

As with percentage-based leases, "per-click" payments for use of office space or equipment also can create a financial relationship between the parties.

The term per-click refers to payments per use of the space or equipment to the extent that the charges reflect referrals between the parties. Notably, non-physicians may continue to lease equipment and space on a per-click basis.

Also, physicians are still allowed to lease equipment or space on a per use basis for services referred by others. However, if the physician-lessor also is referring patients to use the equipment, an alternative leasing arrangement that meets a Stark exception must be put in place.

While CMS declined to prohibit all time-based leasing arrangements, CMS has indicated that it will interpret the per-click regulations broadly and has stated that certain arrangements — such as "on-demand" rental agreements, leasing of small blocks of time (such as a single four-hour block per week) or an extended block of time beyond what the lessee can reasonably use — are problematic and may be covered by the revised language.

Therefore, any physician who is party to any time-based rental arrangements also should have these contracts reviewed for compliance.

### Services provided 'under arrangements'

Prior to these recent changes, Stark allowed many joint ventures between hospitals and physicians where physicians were able to refer to the joint venture without meeting a Stark exception, because, if only the hospital was billing Medicare for the service, then only the hospital was considered to be providing designated health services.

This is no longer the case.

Now, an entity is considered to be providing a designated health service if the entity bills for the service or performs the service.

And, it is possible that a single referral is actually going to two separate entities: the entity that is billing for the service, and the entity that is actually performing the service. If the referring physician has a financial relationship with either party, a Stark exception must exist or there is a violation.

### Compliance a necessity

CMS gave significant time for physicians to comply with these three changes to Stark. However, many physicians remain unaware of the need to review existing arrangements.

If a violation is found, physicians should contact legal counsel and carefully consider the next steps that should be taken, as retention of Medicare reimbursement received from an improper arrangement could create liability under the recently revised Federal False Claims Act.

Moreover, even for physicians who do not participate in the Medicare program, there may be implications under Michigan's version of the Stark law, which applies to all payors.

If you have not evaluated your contracts and business arrangements to ensure compliance, do not wait any longer. Each violation of Stark means the possibility of more denied payments and more $15,000 penalties.

Now is the time to make sure that you are complying with Stark, until, of course, it changes again.

## Verdicts & Settlements Plus

# 'Apsey' finally gets her day in court

## But despite years of legal wrangling and a judgment in her favor, there may be 'no easy end in sight' for med-mal plaintiff

**By Douglas J. Levy**

Sue Apsey never would have predicted how the removal of an ovarian cyst would become such a long-lasting nightmare.

And not just for her.

A bowel leak almost a decade ago resulted in multiple abdominal surgeries, abdominal hernia and disfigurement for the Owosso resident.

In the Michigan legal community, it turned into a passionate, often rancorous uproar over a technicality regarding out-of-state affidavits of merit.

But on May 29 — after years of legal wrangling, a Court of Appeals decision, an appellate reconsideration and, finally, a Michigan Supreme Court ruling — a Shiawassee County Circuit Court jury returned a verdict Apsey had waited nine years to hear: Shiawassee Radiology Consultants, PC, one of the three defendants in *Apsey v. Memorial Hospital, et al.*, was fully negligent, and would be ordered to pay $2,978,000.

Yet, Frank Mafrice, the Southfield-based medical-malpractice attorney who represented Apsey, said the nightmare continues.

Damage caps will reduce the award to just around $1 million, he said, adding that an appeal is likely.

"I'm pessimistic about it ending soon," Mafrice told *Michigan Lawyers Weekly*. "I felt bad enough just knowing it took so long to get her case heard, and now it doesn't look like there's an easy end in sight.

All she wanted was her day in court. … All she wanted at the beginning was reasonable compensation for what she'd gone through, and she seems like she's being victimized again by the system."

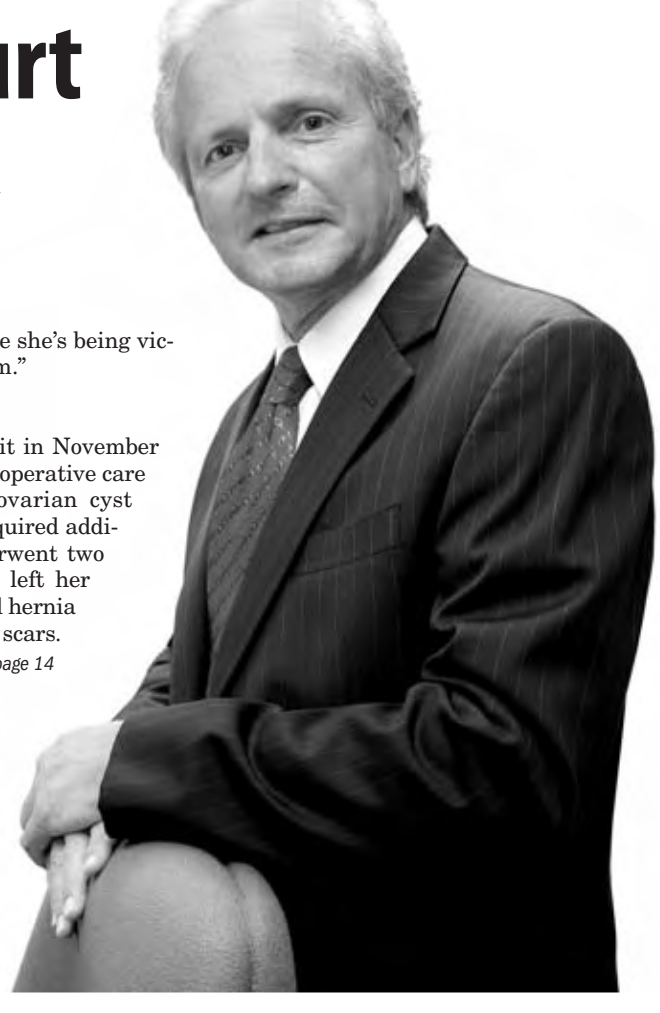
### Questions of merit

Apsey originally filed suit in November 2001, 10 months after post-operative care from the removal of an ovarian cyst caused an infection and required additional surgeries. She underwent two skin-graft procedures that left her with a very large abdominal hernia and permanent disfiguring scars.

*See "Apsey," page 14*

**"When access is denied wrongfully, cases like this occur, where [plaintiff Sue Apsey] can't get to the courthouse door because of some technicality."**

**— Frank Mafrice, Southfield-based medical-malpractice attorney**



# New rules greatly increase privacy breach notification

Government actions earlier this year established significant new requirements to report medical privacy violations to individuals and/or the media and the HHS.

In February, Congress enacted the Health Information Technology for Economic and Clinical Health (HITECH) Act as part of the American Recovery and Reinvestment Act of 2009.

Then, in response to a mandate in the HITECH Act, the Department of Health and Human Services (HHS) issued an interim final rule with request for comments for Breach Notification for Unsecured Protected Health Information (the "Rule") this summer.

The Rule establishes significant new notification obligations for covered entities and business associates that are subject to HIPAA.

Specifically, the new regulations establish guidelines for determining when a breach of unsecured Protected Health Information (PHI) occurs; dictates who must notify of such a breach and to whom notification must be made; and establishes the timeframe and contents of such notification.

The Rule became effective in September.

Covered entities and business associates must be aware of the new obligations under the Rule and should begin taking steps immediately to ensure compliance. In addition, these entities must remain cognizant of additional changes and modifications that may develop. They must be prepared to alter their compliance efforts with these additional potential changes in mind.

## Health Policy

**By Amy K. Fehn, Esq. and Laura C. Range, Esq.**

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### When are requirements triggered?

The Rule only requires notification if an incident qualifies as a "breach" of unsecured PHI. The Rule defines "breach" as the "acquisition, access, use or disclosure of protected health information in a manner not permitted under [the HIPAA Privacy Rule], which compromises the security or privacy of [PHI]."

Therefore, a use or disclosure that violates the HIPAA Privacy Rule is a prerequisite, and any uses or disclosures that do not violate the Privacy Rule cannot constitute a "breach" requiring notification under the Rule.

In addition, an incident will only qualify as a "breach" if it meets a certain "harm threshold." In other words, the use or disclosure must "pose a significant risk of financial, reputational, or other harm to the individual."

To determine whether this harm threshold has been met, covered entities and business associates must conduct and document a fact specific "risk assessment."

The risk assessment should take into account the following factors:

- The identity of the entity or individual that impermissibly used the information or to whom the information was impermissibly disclosed;
- The steps taken to mitigate harm and the immediacy with which such steps were taken;
- Whether the information was returned before being accessed; and
- The type and amount of information disclosed.

Finally, the Rule also contains three statutory exceptions to the "breach" definition. These exceptions are as follows:

- Uses or disclosures by persons acting under the authority of the covered entity or business associate that are made in good faith, that fall within the scope of the disclosing individual's authority, and that do not result in further violations of the HIPAA Privacy Rule;
- Inadvertent disclosures from one person authorized to access PHI to another person also authorized to access PHI within the same covered entity, business associate, or organized health care system; and
- Situations in which the covered entity or business associate has a good faith belief that an unauthorized person receiving the PHI could not reasonably have been able to retain the information.

### Notification requirements

In situations in which a covered entity or business associate has a reasonable belief that the breach involved an individual's PHI, the entity must provide written notice to each affected individual.

Such notice must be provided without "unreasonable delay," but in no case later than 60 days after discovery of the breach.

To the extent possible, the notice should include the following information:

- A brief description of what happened;
- The types of information that were involved in the breach;
- Steps that affected individuals should take to protect themselves from potential harm;
- A description of what the entity is doing to investigate the incident, mitigate harm, and protect against further breaches; and
- Contact procedures by which affected individuals may learn additional information.

In certain situations, such as when the covered entity or business associate determines that misuse of the PHI is imminent or when the entity has insufficient contact information for the affected individuals, additional or substitute notice by alternative means may be made.

Covered entities and business associates must also notify a prominent media outlet within the same time frame as required for individual notice in situations in which a breach involves the PHI of more than 500 individuals within a state or jurisdiction.

Finally, covered entities and business associates must track and report all breaches to HHS. Breaches involving the PHI of more than 500 individuals (in any state or jurisdiction) must be reported "immediately." All other breaches must be recorded and annually reported no later than 60 days after the end of each calendar year.

The Rule establishes significant new breach notification obligations for covered entities and business associates covered by HIPAA.

In sum, the Rule requires such entities to provide individual and/or media notice when there has been a breach of unsecured PHI and to track and report such breaches to HHS.

Affected entities should review HIPAA compliance efforts with these new obligations in mind. For example, entities should ensure that policies are in place requiring workforce members to immediately report any potential privacy violations or security incidents so that they can effectively and promptly evaluate the incident to determine whether notification obligations are triggered.

Entities also should establish policies and conduct training to communicate what notification will be required and should maintain accurate records to prepare required reports to HHS.

Affected entities must remain aware of potential changes to these requirements in the future, and be prepared to revise policies and procedures accordingly.

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## Health Policy
**By Robert S. Iwrey, Esq.**

# State licensing investigations: An ounce of prevention …

Unfortunately, some health care providers fail to appreciate the serious magnitude of an allegation filed against them with their state licensing body.

Whether a health care provider is contacted directly by an investigator, or whether he or she hears from a patient or an employee that an investigator has been asking questions regarding the professional behavior/conduct of the health care provider, the health care provider should immediately contact an experienced and knowledgeable health care attorney to provide assistance and guidance at the earliest possible stage.

All too often, health care providers believe that they can explain away or justify the alleged inappropriate behavior/conduct, only to learn later on that such admissions are used as direct evidence against them to support a sanction against his or her health care license.

Moreover, depending on the severity of the sanction imposed, there are numerous collateral effects that a state licensing action may have on the health care provider, including, but not limited to:

- Loss of hospital privileges and/or employment;
- Loss of enrollment with state professional associations and their associated benefits (e.g., health, disability and life insurance);
- Loss of participation in Preferred Provider Organizations (PPOs) and other third-party payors;
- Loss of Drug Enforcement Administration (DEA) registration, state controlled substance licenses and other health care licenses/registrations;
- Loss of board certification;
- Exclusion from participation with Medicare, Medicaid and other federal and state governmental programs;
- Commencement of other judicial or administrative proceedings (e.g., criminal proceedings, civil monetary proceedings, malpractice actions, and other state licensing actions); and
- Permanent reports to the National Practitioner Data Bank and state licensing data banks.

Prior to the commencement of a formal hearing, there often is a window of opportunity in which an experienced and knowledgeable health care attorney can help the physician to develop and implement prophylactic measures, and to take certain actions that may convince the licensing authorities not to proceed with disciplinary action or to accept a sanction less severe than originally recommended.

Due to this relatively small time frame, it is imperative that the health care provider contact an attorney at the earliest recognizable stage of a potential licensing matter.

As Benjamin Franklin once said, "An ounce of prevention is worth a pound of cure."

A health care provider that retains an experienced and knowledgeable health care attorney early in the process often can avoid the increased time and financial resources involved in trying to win a licensure case at an administrative hearing, when compared to resources needed to implement reasonable measures to rectify the alleged inappropriate behavior/conduct.

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# Serious business

## Use of Civil Investigative Demands is expanded; confidential information should be protected

## Health Care Fraud
**By Suzanne D. Nolan, Esq.**

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Recent changes to the federal False Claims Act (FCA) have enhanced the government's ability to investigate health care and other kinds of fraud through the expanded use of Civil Investigative Demands (CIDs).

The Fraud Enforcement Recovery Act of 2009 (FERA) significantly amended the FCA. It not only eased the requirements for the Department of Justice (DOJ) to issue CIDs, but it also permits the sharing of information obtained pursuant to a CID with government agencies and FCA plaintiffs.

CIDs are formidable investigative tools, and health care providers should understand how they are used in a government fraud investigation.

Prior to FERA, CIDs were infrequently issued. Because only the U.S. attorney general could issue a CID, only the most important cases were subjected to the time-consuming process of being submitted to the attorney general for consideration.

Now, FERA permits the attorney general to delegate the authority to issue CIDs to designees. The attorney general has so far delegated such authority to Assistant Attorney General Tony West, head of the DOJ's civil division. However, it is not yet clear whether this delegation also extends to U.S. Attorneys.

For now, CIDs may be issued whenever the attorney general or West has reason to believe that any person may be in possession, custody, or control of any documentary material or information relevant to a false claims law investigation.

FERA also has provided substantial funding to the DOJ to hire more investigators and to pursue more investigations. Coupled with the easing of restrictions on the sharing of information, these changes are expected to result in greater use of CIDs.

CIDs are similar to subpoenas that can request documents. But, more importantly, CIDs also can request answers to interrogatories and oral or written testimony.

In one sense, a CID is somewhat similar to discovery in a civil case. However, there is a significant difference between discovery and a CID. Notably, discovery occurs after a FCA case has been filed and unsealed and is governed by the Federal Rules of Civil Procedure, which require notice to the defendant when discovery requests are served on a third party.

CIDs are not required to be served on the target of an investigation prior to serving them on a third party. The CID does not even have to name the target of the investigation but just describe the nature of the conduct constituting the alleged violation of the FCA and the applicable provision of the FCA alleged to be violated.

Therefore, it may not be clear to the recipient of a CID whether the recipient itself is being investigated, or whether the recipient is a third party in possession of information useful to a DOJ investigation.

The CID's main use is as an investigatory tool to aid in the investigation of fraud resulting from suits filed under the FCA. It can be issued prior to the time that the plaintiff, an individual referred to as a "relator," files a FCA suit, known as a qui tam suit, on behalf of the taxpayers.

A CID also can be issued during the interval between the filing of a Qui Tam suit and the government's decision to either intervene or decline to intervene in the suit.

Through use of the CID, the DOJ can more thoroughly investigate a potential fraud case than in the past. CIDs give the government an early opportunity to obtain the information needed to prosecute fraud and abuse and an advantage over the target of the investigation, who must wait until after a complaint has been served and unsealed to request information from the DOJ or the relator through discovery.

Before responding to a CID, a recipient needs to keep in mind that the DOJ may now easily share CID information with others. Prior to FERA, the DOJ was restricted to sharing CID information only with Justice Department employees, Congress, or other federal agencies.

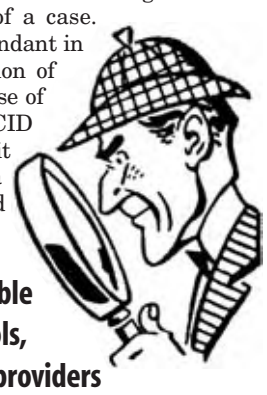
Sharing with other federal agencies required an order from a federal district court issued upon a showing that the other agency had a substantial need for the information. FERA eliminated the requirement for a court order and the substantial need standard.

Now, the DOJ can share such information with a broad array of third parties including federal, state or local government agencies and their contractors, and with Qui Tam relators. Such sharing may expose the recipient of the CID to liability under state law or to administrative actions by government agencies other than the DOJ.

The statute provides that CID information is exempt from disclosure under FOIA and requires the DOJ to safeguard CID information. However, relators and other third-party recipients of the CID information (such as state agencies) are not required to protect the confidentiality of the information.

Therefore, recipients may try to take appropriate action to protect the confidentiality of CID information prior to responding to a CID.

Such sharing may erode the ability of the defendant to challenge a relator's fraud claim. Under FERA, it is more likely that a defendant will become involved during the investigative process of a case. This puts the defendant in the difficult position of bearing the expense of responding to the CID without the benefit of knowing what a relator has alleged in the complaint.



**CIDs are formidable investigative tools, and health care providers should understand how they are used in a government fraud investigation.**

The receipt of a CID is a serious matter, whether the recipient is a target of an investigation or a third party.

Targets need to be aware that a civil investigation often proceeds in tandem with a criminal investigation.

When responding to a CID, a target's rights against self-incrimination may be undermined, prejudicing the target's ability to defend itself in a criminal proceeding. Additionally, third parties need to try to take steps to protect confidential business information provided in response to a CID.

The recipient of a CID should seek advice from an attorney as to how to respond. By keeping the foregoing in mind, health care providers will be better prepared to respond to a CID.

# Micropractice

*Continued from page 1*

administer shots herself. This not only eliminates the need for the physician to hire, supervise, and pay a nurse, but also allows a physician to spend extra time with patients.

Namely, micropractices achieve success by "strip[ping] a primary care office to its essential components so that it is capable of delivering patient-centered, collaborative care," according to Drs. L. Gordon Moore and John H. Wasson in "The Ideal Medical Practice Model: Improving Efficiency, Quality and the Doctor-Patient Relationship."

### Technology is key

Technology is the cornerstone of the micropractice. With the help of cutting-edge technology, including electronic health records, e-prescribing and virtual office visits, physicians have the ability to keep overhead low, freeing up time for more doctor-patient interaction, or what some micropractice owners refer to as the "Norman Rockwell-style of practice."

For instance, a micropractice might utilize an automated phone system, allowing patients to schedule their own appointments and eliminating the need to employ a receptionist. It is estimated that implementing the right technology can help primary care practices reduce their costs to nearly half of what a typical practice pays, from 60 percent to 35 percent.

Given that micropractice physicians have little or no overhead costs, they are able to treat fewer patients and still remain profitable. Additionally, physicians are free to make patient visits on their own time, instead of being tied to a 9-to-5 office staff.

Physicians who have adopted the micropractice model report higher levels of satisfaction. Not surprisingly, patients are happier as well. In published studies, patients report high levels of satisfaction in access, efficiency, continuity of care, and physician awareness of patients' key concerns.

Proponents of the micropractice point out that, traditionally, failure in primary care results in costlier specialty and hospital care down the road. In many cases, providing excellent primary care at the outset can lead to better outcomes for patients and help lower the cost of health care in the United States.

This is an important consideration in a country where 60 percent of all bankruptcies are driven by health care costs.

Because physicians working in micropractices have more time to spend with patients, they also have a greater opportunity to emphasize prevention and education to keep patients healthy. According to a 2008 study by Wasson at Dartmouth Medical School, patients in micropractices were more likely to say they were informed about how to manage chronic diseases and received the care they needed, compared with those in a national sample of medical practices.

### Government offers incentives

The government also is taking note of how new technology and streamlined processes can make better, less costly health care a reality.

The Obama administration included incentives for physicians who want to make the switch to electronic health records and set aside $2 billion for community health centers through the economic stimulus package. They also are considering ways to persuade medical students to pursue careers in primary care by raising primary care physicians' pay or offering loan forgiveness programs.

To date, there are no exact statistics on the number of micropractices operating in the U.S., but physicians say that the popularity of the micropractice is growing.

It could be the right move for physicians who want to step out of "treadmill medicine," where doctors are expected to see a different patient every 15 minutes. However, the micropractice model is not without its own unique challenges and physicians should take these into careful consideration.

For example, practitioners should consider whether they can efficiently multitask and run a practice without administrative assistance; how willing and/or able they are to embrace technology; or the fact that, on average, primary care physicians receive the least amount of reimbursement of any medical specialty.

Additionally, physicians may have questions about the rules and regulations involved with e-prescribing, virtual office visits, or electronic health records (and what to do in the event of a breach of these records).

However, all challenges aside, the benefits of a micropractice certainly make it a model worth investigating.

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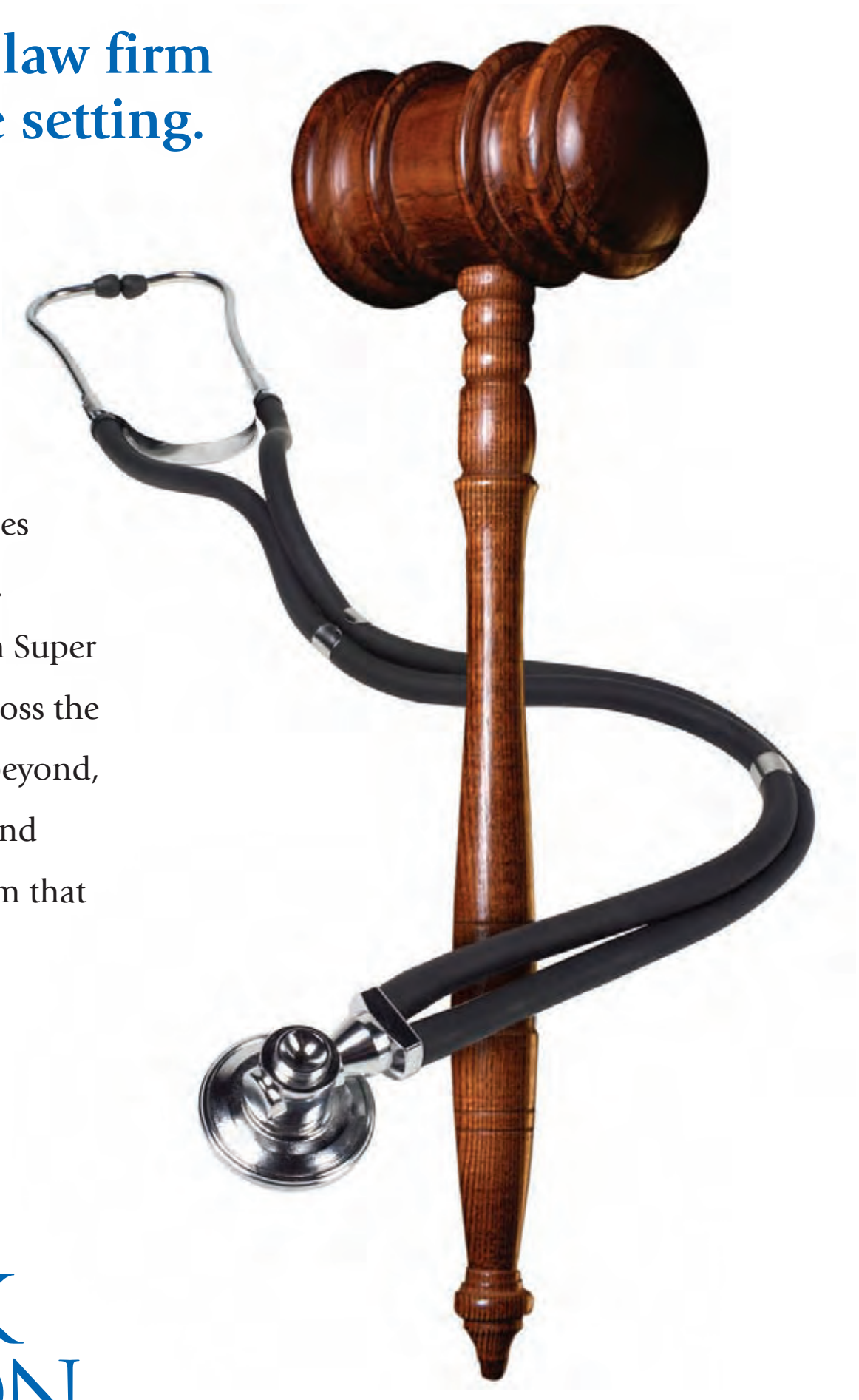

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# Pending Legislation

## 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 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.

*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."

*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.

"(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*

## 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

Continued

**HB 5284 –** Amend 1969 PA 317, entitled "Worker's disability compensation act of 1969," compensation for exposure to secondhand smoke.

"A lung disease or other condition that has been linked to secondhand smoke by credible scientific evidence shall be presumed to have been contributed to, aggravated, or accelerated in a significant manner by employment and is compensable as provided in this act if all of the following conditions are met:

"(a) The employer permits smoking in the workplace.

"(b) The affected employee does not smoke and has not been a smoker in the immediately preceding 10 years.

"(c) The employee was subject to secondhand smoke in the workplace for 1 year or more.

"The presumption under subsection (1) is removed if the employer provides affirmative evidence of non-work-related causation or specific incidents that establish a cause independent of employment and not merely evidence of a preexisting condition or an abstract medical opinion that employment was not the cause of the disease or condition.

*Sponsored by Timothy Bledsoe-D*
*Referred to the Committee on Regulatory Reform*

## 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

*See "Pending Legislation," page 10*

# HIPAA enforcement strengthened, penalties increased

Covered entities, beware: Health care providers, health plans and health care clearinghouses that commit health information privacy and security violations will now face increased enforcement and will be subject to heightened penalties for violations of health information laws.

In compliance with the Health Information Technology for Economic and Clinical Health Act (HITECH Act), on Oct. 30, 2009, the Department of Health and Human Services (HHS) issued an interim final rule (the "Final Rule") with comment period, which outlines HHS' planned strengthened enforcement and increased penalty provisions for violations of the Health Insurance Portability and Accountability Act (HIPAA).

The Final Rule was effective Nov. 30, 2009.

### HIPAA prior to the HITECH Act

Prior to the HITECH Act, a penalty of $100 could be imposed for each violation or $25,000 for all violations of identical provisions of HIPAA.

To avoid liability for a HIPAA violation, a covered entity could raise as an affirmative defense that it did not know, and by exercising reasonable diligence, would not have known, that it violated HIPAA.

### Heightened penalties

Section 13410 (d) of the HITECH Act established heightened penalties for violations of HIPAA, which are described in the Final Rule, and which will be codified at 45 C.F.R. § 401 et seq.

## Compliance

**By Abby Pendleton, Esq. and Jessica L. Gustafson, Esq.**

*Abby Pendleton and Jessica L. Gustafson are partners with the health care law firm of The Health Law Partners, P.C. They specialize in a number of areas, including but not limited to, Recovery Audit Contractor (RAC), Medicare, Medicaid and other payor audit appeals, health care regulatory matters, compliance matters, reimbursement and contracting matters, transactional and corporate matters, and licensing, staff privilege and payor de-participation matters. Contact them at (248) 996-8510 or apendleton@thehlp.com and jgustafson@thehlp.com.*

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The HITECH Act created a tiered civil money penalty system for HIPAA violations and established a new maximum penalty of $1.5 million for all violations of identical provisions of HIPAA.

Further, unless the covered entity corrects a HIPAA violation within 30 days from the date it discovers the violation, the HITECH Act removed the affirmative defense that permitted covered entities to avoid liability for HIPAA violations by establishing that it did not know, and by exercising reasonable diligence, would not have known, that it violated HIPAA.

### Response to the Final Rule

Georgina Verdugo, director of the HHS Office for Civil Rights (the agency responsible for enforcing HIPAA privacy, security and breach notification rules), stated by way of press release published contemporaneously with the Final Rule that one goal of the strengthened enforcement and increased penalty provisions is increased compliance with HIPAA:

"This strengthened penalty scheme will encourage health care providers, health plans and other health care entities required to comply with HIPAA to ensure that their compliance programs are effectively designed to prevent, detect and quickly correct violations of the HIPAA rules."

Covered entities should re-evaluate their existing HIPAA policies and protocols to ensure compliance.

This would include not only enacting policies to comply with the new breach notification provisions of the HITECH Act, but also to ensure that other existing policies and protocols are consistent with HIPAA.

Physicians should consider having their HIPAA policies and protocols reviewed by health care legal counsel as part of their annual compliance reviews to ensure conformity with the regulations.

## Pending Legislation

*Continued from page 9*

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.

"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 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*

**SB 0651 –** An individual shall not intentionally engage in or attempt to engage in human cloning.

"This subsection does not prohibit scientific research or cell-based therapies not specifically prohibited by that under this subsection.

"An individual shall not intentionally transport, attempt to transport, or cause to be transported into this state a human embryo created through human cloning.

"An individual who violates subsection (1) this section is guilty of a felony punishable by imprisonment for not more than 10 years or a fine of not more than $10,000,000 or both.

"As used in this section, 'human cloning' means that term as defined in section 16274 of the public health code, 1978 PA 368, MCL 333.16274."

*Sponsored by: Judson Gilbert-R*
*Referred to the Committee on Health Policy*

**SB 0681 –** Requirement to obtain informed consent before testing for human immunodeficiency virus (HIV); eliminate, and provide option to decline test in writing.

Except as otherwise provided in subsections (12) and (13), a physician who orders an HIV test or a health facility that performs an HIV test shall provide counseling appropriate to the test subject both before and after the test is administered.

"Except as otherwise provided in this part, a physician, or an individual to whom the physician has delegated authority to perform a selected act, task, or function under section 16215, shall not may order an HIV test for the purpose of diagnosing HIV infection without first receiving the written, informed consent of the test subject. For purposes of this section, written, informed consent consists of a signed writing executed by the test subject or the legally authorized representative of the test subject that includes, at a minimum, all of the following:

"(a) An explanation of the test including, but not limited to, the purpose of the test, the potential uses and limitations of the test, and the meaning of test results.

"(b) An explanation of the rights of the test subject including, but not limited to, all of the following:

"(i) The right to withdraw consent to the test at any time before the administration of the test.

"(ii) The right under this part to confidentiality of the test results.

"(iii) The right under this part to consent to and participate in the test on an anonymous basis.

"(c) The person or class of persons to whom the test results may be disclosed under this part. Unless the HIV test is declined in writing under this section, the test subject's consent to general medical care is considered consent to an HIV test.

"Beginning July 28, 1989 through October 1, 2009, a physician or an individual to whom the physician has delegated authority to perform a selected act, task, or function under section 16215 who orders an HIV test shall distribute to each test subject a pamphlet regarding the HIV test on a form provided by the department. The department shall develop the pamphlet, which shall include all of the following:

"(a) The purpose and nature of the test.

"(b) The consequences of both taking and not taking the test.

"(c) The meaning of the test results.

"(d) Other information considered necessary or relevant by the department.

"(e) A model consent form for the signed writing required under subsection (2) test subject to use if he or she wishes to decline the HIV test in writing. The department shall include in the model consent form all of the information required under subsection (2)(a), (b), and (c) following:

"(i) An explanation of the test including, but not limited to, the purpose of the test, the potential uses and limitations of the test, and the meaning of test results. ..."

*Sponsored by: Thomas George-R*
*Referred to the Committee on Health Policy*

## BILLS PASSED

**HB 4377 –** HEALTH, Smoking

Require smoke-free workplace and food service establishments

*Sponsored by Lee Gonzales-D*
*Passed in House, Senate and signed by Gov. Jennifer Granholm*

**HBS 4763-69 –** HEALTH, Children

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 –** HEALTH, Diseases

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 –** HEALTH, Local Health Departments

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*

**HB 4940 –** HEALTH, Medical Equipment Reuse

Prohibit reuse of single-use medical equipment and supplies

*Sponsored by Dian Slavens-D*
*Passed in House (108-0)*
*Status: Referred to Committee on Health Policy*

**SB 0151 –** OCCUPATIONS, Physical Therapists

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

*Sponsored by: Bill Hardiman-R*
*Passed in Senate (35-0)*
*Status: Referred to the Committee on Health Policy*

**SB 0419 –** HEALTH, Blood

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*

## Business of Medicine

**By Adrienne Dresevic, Esq. and Carey F. Kalmowitz, Esq.**

DRESEVIC

KALMOWITZ

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# Mobile leasing diagnostics are a good way to enhance practice revenue

Despite legislative attempts to limit diagnostic testing agreements, doctors still have options. We'd like to provide a brief overview of the elements that comprise a typical leasing model structure and examine some of the health care regulations that must be considered in connection with these arrangements.

Finally, we'll discuss the current legal status of the leasing model, which permits appropriately structured diagnostic testing in the physician's office.

### The leasing model

A mobile leasing entity (Mobile Company) enters into a written contract with a physician under whom it leases portable diagnostic testing equipment, a technologist and the associated imaging supplies to enable the physician to furnish certain diagnostic testing to patients of the practice in the office (Leasing Services).

The physicians will exercise the required degree of supervision of the services and, thus, the physicians will be the entity that is considered to be the provider of — and entitled to bill for — the services.

In practice, the Leasing Services model provides physicians with in-office access to the equipment, personnel and supplies with which they are then able to furnish the technical component (TC) of the testing to their patients.

The physicians will bill Medicare and other payors for the tests. The Leasing Services must be structured as a block lease arrangement, subject to certain minimum hourly requirements. The physicians must pay the Mobile Company a fixed fee for the leased block of time (i.e., without reference to the number of studies performed), and the fee must be (i) fair market value and (ii) established in advance.

In addition to being the provider of the TC, provided that certain standards are met, the physician also can furnish (and bill for) the professional component (the PC) of the tests.

### Regulatory considerations

Because diagnostic testing arrangements (including the Leasing Model) potentially implicate a number of different health care regulations, physicians employing a Leasing Model must ensure that that their contract complies with applicable legal requirements.

It has been our experience that, so long as certain structural safeguards are integrated into the arrangement (i.e., in particular, factors that (i) demonstrate the nexus between the physician group's core services and the diagnostic services, and (ii) permit the group to show that the group is at sufficient financial risk), in the majority of cases, the Leasing Model can be structured in a manner that complies with the Federal Stark Law (Stark), Medicare's Anti-Markup Rule (the AMR), Medicare's independent diagnostic testing facility (IDTF) regulations, and the Medicare and Medicaid Anti-kickback Statute (AKS).

### Federal Stark law

Physicians that furnish diagnostic imaging services under the Leasing Model must determine whether, under the group's structure, they will be able to provide the services in a manner that meets Stark's in-office ancillary services exception (IOASE).

Notably, a practice will be able to furnish (and bill for) diagnostic testing under the Leasing Model, provided that the practice (i) qualifies as a "group practice" under the Stark, (ii) bills for the testing services under the group's provider number, (iii) supervises the tests in accordance with Medicare rules, and (iv) furnishes the services in the same building in which the group's physicians furnish professional medical services unrelated to the tests.

Further, groups that will bill for the PC of the services, if an employed physician provides the interpretation, there is no on-site requirement under Stark, but the Medicare AMR will apply to the services, which means that if the physician provides the PC of the services offsite, he must "share a practice" with the physician by providing at least 75 percent of his/her professional services for such group.

### Medicare anti-markup rule

Physicians that operate under a Leasing Model must also ensure that their arrangements are structured in a manner that does not cause the services to fall within the purview of the AMR's payment limitations.

The Centers for Medicare and Medicaid Services (CMS) adopted two alternative tests for determining the applicability of the AMR as follows:

**[P]hysicians employing a Leasing Model must ensure that that their contract complies with applicable legal requirements.**

- If the performing physician (the physician who supervises TC or performs the PC, or both) performs substantially all (at least 75 percent) of his or her professional services for the billing physician or other supplier, the services will not be subject the AMR payment limitations.
- TCs conducted and supervised in, and PCs performed in, the "office of the billing physician," which includes the "same building," by an employee or independent contractor physician avoid the AMR payment limitation.

Physicians should readily be able to satisfy the first alternative if they provide at least 75 percent of their services through the billing practice. Further, it is possible for the physicians to satisfy the second alternative, if the physicians furnish and supervise the services in-office.

Pursuant to CMS guidance, the Leasing Model does not fall within the purview of the IDTF regulations. Thus, the physicians that employ the Leasing Services can bill Medicare directly for the services furnished in conjunction with the Leasing Model.

### Anti-kickback statute

Although the Leasing Model does implicate certain legal risks that the Office of Inspector General typically reviews in its AKS guidance, a carefully structured Leasing Model will incorporate mitigating factors which reduce risk.

For example, the Leasing Model contemplates a block leasing schedule, which requires the physicians utilize the leasing Services for a minimum amount of time per week (or month, depending upon the nature of the test).

The physicians must pay a fair market value fee for the blocks of time to which they subscribe, despite the volume of services. A group cannot subscribe for the Leasing Services solely when the group is assured of earning a profit and, as a result, the group is required to bear financial risk.

Finally, an appropriately structured Leasing Model also should permit the group to show a reasonable nexus between the diagnostic testing services provided in the physician's office and the physician's core medical practice.

The law permits appropriately structured testing arrangements in the physician's office. Incorporating diagnostic imaging into a practice can permit physicians to expand the continuum of care, while, at the same time, enhancing revenue. In a substantial number of cases, a Leasing Model can be structured to achieve a group's business objectives, while at the same time complying with regulatory constraints.

# Consultation codes eliminated due to confusion, uncertainty

## Health Policy

**By Joan L. Lowes, Esq.**

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As proposed in July, Centers for Medicare & Medicaid Services (CMS) announced that the agency is eliminating the use of all consultation codes Jan. 1, 2010.

The agency said it was taking this action as a result of confusion and disagreement about the proper use of the consultation codes, and the lack of consistency between CMS payment policy and American Medical Association (AMA) Current Procedural Terminology (CPT) guidelines which CMS described as ambiguous.

The impact of this decision is that CMS will no longer recognize the inpatient consultation codes (99251-99255) and office/outpatient consultation codes (99241-99245).

To preserve the ability of physicians to provide and bill for initial inpatient consultations delivered via telehealth, CMS is establishing three new G-codes (G0425, G0426, and G0427). All other consultations will be billed using the initial hospital care (99221-99223), initial nursing facility care (99304-99306) or initial office visit codes (99201-99205), as applicable.

To distinguish the admitting physician from other specialists who see the patient in the hospital and who also will use the initial care codes, CMS will create a modifier that the admitting physician will add to the initial care code to identify him/her as the admitting physician.

The other physicians who see the patient in the hospital will bill the applicable initial care code without a modifier.

CMS announced these changes will be budget-neutral, so as not to either increase or decrease aggregate expenditures under the physician fee schedule.

Budget neutrality will be achieved by increasing the work relative value units (RVUs) for new and established office visits by approximately 6 percent and the work RVUs for initial hospital and facility visits by approximately 0.3 percent.

CMS also will adjust the practice expense and malpractice expense RVUs to recognize the increased use of these visits.

This change presents a double-edged sword for physicians. On the one hand, the compliance risk associated with failure to meet the agency's documentation requirements for consultations has been eliminated.

Physicians will bill an initial visit code instead of a consultation code and document accordingly. However, it may still be advisable for a physician who sees a patient at the request of another physician to document that request and furnish the requesting physician with a report.

This documentation will serve to establish the medical necessity of the visit and provide a complete and accurate medical record for the patient.

On the other hand, some physicians, particularly specialists, may find that payment under the initial visit codes is less than what they would have received for a consultation. Payment by other payers may be impacted, as well.

CMS advised that physicians will have to decide how to handle situations where Medicare is secondary, and the primary payer continues to recognize the consultation codes.

The agency made clear that it would reject any secondary claims billed with the invalid consultation codes and instead suggested that physicians could bill the primary payer using the visit codes.

The other payers may or may not allow the visit codes to be used when a consultation is furnished. If they do, but fail to increase their payments for the visit codes as CMS did, physicians will see a decrease in reimbursement from the primary payers.

What steps can be taken to plan for these changes?

To help reduce denial impacts after Jan. 1, it's important to:

- Educate physicians and coding staff about the new requirements.
- Change pre-printed hospital cards or encounter forms to capture status as admitting physician.
- Closely monitor charge entry for a period of time after Jan. 1 to ensure that claims are being coded and billed as required by CMS.
- Consider how Medicare secondary claims will be handled in your organization, then analyze payments received from Medicare and the primary payers to determine if changes are required.

# Court of Appeals clarifies 'functional use' standard

## Medical Malpractice

**By Brian P. Frasier, Esq.**

The Michigan Court of Appeals ruled, in a published opinion, that a medical-malpractice plaintiff qualified for the higher non-economic damages cap because he lost "permanent function" of both arms, even though he still had a slight use of them.

According to several medical-malpractice attorneys, it's the first time that an appeals court has tackled the issue of "functional use" in a case involving the loss of the use of an extremity.

In *Shivers v. Schmiege* (Lawyers Weekly No. 07-71322, 15 pages), John Shivers was an otherwise healthy 70-year-old man taken to St. Mary's Hospital in Saginaw for a bladder removal surgery.

Complications arose during surgery, and when he awoke, Shivers was suffering weakness in both hands.

According to the decision, Dr. Susan Schmiege was one of the doctors on duty who examined Shivers in the evening and found no evidence of neurological problems. His condition worsened overnight.

In the morning, two other doctors discovered his condition and ordered an emergency MRI and laminectomy to relieve Shivers' condition. He was diagnosed with central cord syndrome, which is caused by trauma and can cause loss of control the arms and hands. He filed suit against the hospital and doctors who examined him after surgery.

Attorneys Karl J. Weyand Jr. and Lawrence J. Acker, from Saginaw and Bloomfield Hills, respectively, represented Shivers.

During trial, Shivers testified that his arm braces help him deal with constant pain caused by his condition. He was unable to bend his right arm at the elbow and had only minimal use of his left hand.

The Saginaw County Circuit Court jury awarded Shivers a $1.7 million verdict, including $522,000 for future economic damages (see " Plaintiff did 'a hell of a job' with future economic damages," below).

According to the damage cap statute, MCL § 600.1483, to qualify for the higher cap, a plaintiff's injuries must cause him to be "'hemiplegic, paraplegic, or quadriplegic resulting in a total permanent functional loss of [one] or more limbs,' caused by a spinal cord injury."

**" '[F]unctional use' means functional use. … The mere fact that you may be able to do something … is not the same as having functional use of your extremity."**
**— Attorney Brian McKeen, McKeen & Associates, P.C.**

**"[A]lthough he could use his arms in certain ways to his benefit, they were no longer functional in the way that normal arms are."**
**— Judge Donald Owens, Michigan Court of Appeals**

The appellate court held that, based on the statutory language, the Legislature intended to create a two-pronged test, requiring a plaintiff to meet two conditions: "hemiplegia, paraplegia or quadriplegia"; and "total permanent functional loss of [one] or more limbs."

The judges reasoned that the technical definitions of "hemiplegia," "paraplegia" and "quadriplegia" describe injuries as "a particular kind of damage to the nervous system" — of which there may be several symptoms, including paralysis.

Further, the court noted that laypeople may think of paralysis as a "complete loss of voluntary movement," which is how the defendant sought to define the term.

But, the court accepted that the technical definition is "a loss of power of voluntary movement in a muscle through injury to or disease of its nerve supply," according to Stedman's Medical Dictionary.

Finally, the court reasoned that, by adding the second prong to the statutory test — the injury must cause a "total permanent functional loss of [one] or more limbs" — the Legislature was simply identifying the symptom that would qualify a plaintiff for the higher damage cap.

The defendant argued that Shivers didn't qualify for the higher cap because he still had functional use of his arms, evidenced by the fact that he could still do some things, such as support himself on a walker.

But the plaintiff argued that he had lost functional use of his arms because he needed arm braces to help deal with pain in his arms, and because he required assistance to do basic things such as eating, getting dressed and basic hygiene.

The court agreed with Shivers, defining "functional use" as "similar to the concept of 'loss of use,' meaning, 'the destruction of the usefulness of the member, or the entire member for the purposes to which, in its normal condition, it was susceptible of application,'" Judge Donald Owens wrote in the opinion (Judge Christopher M. Murray concurred, while Judge Deborah A. Servitto dissented in part).

"[A]lthough he could use his arms in certain ways to his benefit, they were no longer functional in the way that normal arms are."

Detroit medical malpractice attorney Brian McKeen, of McKeen & Associates, P.C., said that this the first case of which he is aware that defines what "functional use" means under the damage cap statute.

"It clarifies what we knew all along — that 'functional use' means functional use," he said. "It doesn't mean 'any use.' It means if you can't function normally, that is what qualifies for the higher cap. The mere fact that you may be able to do something, like balance yourself on your walker, is not the same as having functional use of your extremity."

McKeen said that, if damage caps are going to apply in medical-malpractice cases, the test for the exception should be liberally construed.

"Can you function in your day-to-day life as you could previously?" he said. "If the answer is no, I think you've lost the functional use of your extremity.

"The way the defense lawyers want to interpret is nothing short of an amputation would qualify, but that's clearly not what the legislature meant."

HEBERT

Schmeige's attorney, Deborah A. Hebert, of Southfield-based Collins, Einhorn, Farrell & Ulanoff, P.C., disagrees with McKeen about the scope of the court's decision, stating in an e-mail that it does not signify a change in the way the courts will apply the higher cap, "but rather, an application of the statute to these very specific facts."

Hebert also said that she is considering another appeal.

*If you would like to comment on this story, please contact Brian P. Frasier at (248) 865-3113 or brian.frasier@mi.lawyersweekly.com.*

## Plaintiff did 'a hell of a job' with future economic damages

Another issue addressed by the Michigan Court of Appeals in *Shivers v. Schmiege* was that of the proofs required for an award of future economic damages.

At trial, Shivers' attorney argued that the plaintiff, who was diagnosed with central cord syndrome following a bladder removal surgery, was entitled to future economic damages and was awarded $522,000 by the jury.

The appellate court reversed a trial court's order denying Schmiege's motion for judgment notwithstanding the verdict on the issue of future economic damages because, it said, Shivers only showed "evidence from which it may be inferred that plaintiff would require professional attendant care."

According to the decision, Shivers presented sufficient evidence during trial that his family members assist him with things like eating and using the bathroom. The court said it was reasonably certain from the evidence that he would sustain future economic damages, but he did not provide a reasonable basis for figuring these economic damages.

The majority said the only attempt to quantify the amount of future economic damages came during the closing arguments, as a "'suggestion' … as to how to calculate his 'pain and suffering [and] intimacy.'"

Shivers' attorneys, Karl J. Weyand Jr. and Lawrence J. Acker, from Saginaw and Bloomfield Hills, respectively, did provide some guidance to the jury by arguing that the future attendant care damages could be figured by considering the cost of a full-time aide working minimum wage for 16 hours a day.

In partial concurrence and partial dissent, Judge Deborah A. Servitto argued that, while "there was no clear distinction between counsel's arguments regarding economic and non-economic damages[,]" Shivers' attorney also did not suggest that he was only referring to non-economic damages when he discussed the issue of future attendant care.

Servitto said that Shivers' attorney properly showed the need for attendant care for daily activities, the certainty that he would have future economic damages, and provided a reasonable basis for figuring the future economic damages by asking for minimum wage payment for 16 hours of care a day.

She concluded that it would be inequitable to deny these damages simply because counsel bounced back and forth during his closing argument between his request for non-economic and economic damages.

Weyand said the court's decision removed the jury's ability to use its own judgment on the issue of future economic damage.

"Apparently, you have to have someone in there to testify to what minimum wage is," Weyand said. "That's what was argued. We had testimony from family members that they did everything for him while he was awake and had to be available for him while he was asleep. We were just asking for 16 hours a day, because that's what he needed. We didn't ask for 24 [hours].

**"The jury got what the attorney was trying to get across and the court didn't."**
**— Attorney Catherine Groll, Thomas M. Cooley Law School**

"We said, 'Use your common sense.' Jurors can use their common sense and common knowledge of what minimum wage was," he added.

Acker, who gave the closing argument, said that the problem may have been that part of his argument was lost in translation to the transcript.

"Sometimes, the transcript of a closing argument [can be confusing], whether it's from a punctuation perspective or from the fact that in normal speech we resort to run-on sentences and things of that sort," he said. "I was using a display board on which I had written the words and the requests, and I don't think there was any confusion. The jury verdict form which I walked them through, there was no confusion."

Lansing-based sole practitioner Catherine Groll, who teaches health law at the Thomas M. Cooley Law School, agrees with the dissent.

"The jury got what the attorney was trying to get across and the court didn't," she said. "The way they parsed out his closing argument to support their version, and we have Judge Servitto's [offering] the full context of what he explained to the jury, it makes a little more sense why they would have awarded that."

Groll also agreed that the majority focused too much on plaintiff's counsel's use, or misuse, of the term "non-economic damages" when he was speaking of future attendant care as future economic damages.

"I think that [Weyand and Acker] did a hell of a job, because they had no expert testimony on the economic versus non-economic and they still got this kind of an award," Groll said. "He obviously read the jury well. He knew that he did not need that type of expertise.

"Sometimes we make some kind of determination at the end of a case about whether or not we're going to try to overreach when we do the closing, and he decided not to put a specific number on the non-economic, and he obviously made the right choice there."

**— Brian P. Frasier, Esq.**

# 'Furtherance of justice' applies to NOI mistakes

## Ruling extends the MSC's decision on *Bush v. Shabahang*

**By Brian P. Frasier, Esq.**

The Michigan Court of Appeals has ruled that medical malpractice pleadings may be amended "in the furtherance of justice" under MCL 600.2301 to comply with notice-of-intent timing requirements in MCL 600.2912b(1).

The ruling reversed a trial court's dismissal of a medical malpractice complaint that had been filed too early by one day.

In doing so, the Court of Appeals extended the Michigan Supreme Court's decision in *Bush v. Shabahang* (Lawyers Weekly No. 06-70788, 58 pages).

The *Bush* decision relied on the "furtherance of justice" language in MCL 600.2301 to allow "cure" of defects in a medical malpractice notice of intent (NOI).

The Court of Appeals decision is *Zwiers v. Growney* (Lawyers Weekly No. 07-71575, 8 pages).

In *Zwiers*, the plaintiff filed her complaint and affidavit of merit one day before the 182-day period following the service of her NOI.

Defendant moved for summary disposition, citing *Burton v. Reed City Hosp Corp.* (Lawyers Weekly No. 06-54488, 30 pages), which held that a complaint filed before the notice period ended did not toll the statute of limitations.

Based on *Burton*, the trial court granted the defendant's motion.

Later, the *Bush* court held that, under MCL 600.2301, a court can "disregard errors or defects" in documents and proceedings if two factors are met: 1) no "substantial right of a party is implicated"; and 2) the cure must be "in furtherance of justice."

In order to meet the second part of the test, the party must have made "a good-faith attempt to comply with content requirements of [the NOI statute]."

In *Zwiers*, Judge William B. Murphy noted that MCL 600.2301 should be applied liberally to excuse plaintiff's early filing of the complaint.

He wrote that "in no way" did the one-day early filing affect defendant's substantive rights.

"There was no evidence of interrupted settlement negotiations on the date of filing, and defendants had the time and opportunity to investigate plaintiff's allegations as evidenced by defendants' response to plaintiff's NOI under MCL 600.2912b(7)," Murphy observed.

Murphy also stated that amending the date of the complaint was in furtherance of justice.

"There is no indication that [Zwiers] intentionally filed suit early or that she filed early in an effort to subvert the legal process and to gain an unfair advantage over defendants," he wrote.

Plaintiff's attorney Jon Schrotenboer of Grand Rapids-based Kuiper Orlebeke, P.C. said that, without *Bush*, he wasn't sure if the court would have ruled in his client's favor. He thinks that the complexity of medical malpractice procedures requires some leniency from the courts.

"Because of the various trappings of the [medical malpractice] statutes, plaintiff's lawyers like myself have to resort to [MCL 600.2301] to [argue] that if there are technical problems with pleadings or notices of intent, the statute and the court rules … are designed so that meritorious claims are decided on the merits and not some procedural defect," he said.

> **"*Bush* only addressed the substantive requirements of the notice of intent, in other words, what the content of the notice itself was. This case is actually extending section 2301 to the timing of the filing of the case."**
>
> **— Attorney Maureen C. Adkins, Plunkett Cooney**

Defense counsel did not return calls for comment.

Bloomfield Hills-based defense attorney Maureen C. Adkins, a partner at Plunkett Cooney, said that this case is a pretty significant extension of the *Bush* case.

"*Bush* only addressed the substantive requirements of the notice of intent, in other words, what the content of the notice itself was," Adkins said. "This case is actually extending section 2301 to the timing of the filing of the case."

"It gives the potential [for] adjusting dates and saying, 'It was only filed a week or 10 days early.' I'm not saying that I would endorse throwing somebody's case out over one day, but you have to have a bright-line test somewhere."

Adkins is concerned about how far courts will be able to extend MCL 600.2301 based on this decision.

"The problem with this case is that it's just one day," she said. "Most people are not terribly fond of enforcing procedural requirements to the point where, over a one day difference in time and there was a good faith attempt by the lawyer, the case gets kicked. But on the other hand, I suppose you really need to look at the statutes and what the statutes require and draw a line somewhere."

*If you would like to comment on this story, please contact Brian P. Frasier at (248) 865-3113 or brian.frasier@mi.lawyersweekly.com.*

# Fraud

*Continued from page 1*

local investigators, including representatives from Blue Cross Blue Shield.

HEAT Strike Forces have been assigned to Miami, Los Angeles, Houston and Detroit. The inclusion of Detroit on this short list suggests that the federal government has strategically targeted Michigan as a hot spot for cracking down on health care fraud.

Strike Forces around the country have been extremely successful at prosecuting offenders, resulting in cases against 249 individuals and leading to the recovery of more than $265 million in court-ordered restitution.

At the state level, Michigan Attorney General Mike Cox also has announced a renewed focus on health care fraud.

In July 2009, Cox introduced legislation with Republican supporters that would create the Office of Medicaid Inspector General (OMIG), which would serve as an "independent auditor" to investigate and eliminate fraud in Michigan Medicaid programs.

The independent auditor would use information technology resources to data mine and investigate suspicious claims. Cox estimates that the independent auditor could save the state $100 million annually.

A similar program in New York recovered $551 million in 2008. Even without the OMIG, Cox's Medicaid Fraud Control Unit, housed within the Attorney General's office, has recovered $143 million since 2003, when he took over as Attorney General. Prior to that, the Unit recovered just $22 million from the years 1978 to 2002.

### Types of fraud and investigation

The types of fraud targeted by investigators include false statements on Medicare forms, "kickbacks" in exchange for Medicare referrals, and physician "self-referrals."

Another large area of focus is billing fraud, which could include any of the following:

- Billing phantom patients;
- Billing for services never provided;
- Billing for old services as if they were new;
- Billing for extra hours or unnecessary tests;
- Billing for personal expenses; or
- Overbilling or double-billing for services.

Investigators use a variety of tools, including the latest computer technology for data mining and quantitative analysis. Medicare billing records are often compared in six-month increments to identify significant changes in billing patterns, and high-volume and high-cost procedures are more likely to be investigated, given the increased financial risk to the Medicare program.

Investigators also rely on community self-policing and anonymous tips or informants.

In some cases, Medicare beneficiaries also may be interviewed to determine if the care they received was legitimate and matches the billing record.

### Red flags

At both the federal and state levels, investigators are looking for certain suspicious "red flags," which could suggest fraudulent activity. The following practices may raise a "red flag," which could trigger an investigation:

- A single diagnosis for all patients.
- The same treatments for all patients.
- Rare and expensive treatments or services.
- A lack of follow-up care.
- Geographic disparity among patients.
- Inconsistent diagnoses for the same patient.
- A doctor treating too many patients.
- A patient seeing too many doctors.
- Patients seeing specialists for standard treatment available from their primary-care physicians.

### How to protect your practice

Honest practitioners may find themselves the subject of an investigation if a "red flag" is falsely raised. To avoid such an investigation, practitioners should take proactive steps to make sure their practice is protected.

The following tips are meant as practical suggestions only, and, even if followed, there is no guarantee that an investigation will be avoided:

- Implement detailed record-keeping for ordered services and tests to ensure they are necessary and actually rendered. Where applicable, specify the quantity of medical supplies or duration of medical services needed.
- Specify in writing why services or tests were ordered in case they are later questioned. Do not leave this to the Medicare provider who files the claim.
- Make sure to personally complete all information on certification forms, and never sign blank certification forms. Never certify the need for medical services or supplies for a patient you have not personally examined.
- Be suspicious of offers, discounts, free services, or cash incentives to order services or purchase equipment.

In some cases, doctors and hospitals hire a billing service or consultant to submit Medicare claims. Be aware that this does not relieve doctors and medical professionals of their personal responsibility for any overpayments received due to claims made on their behalf.

Practitioners should oversee and review all submitted claims and perform careful background checks of individuals entrusted to submit claims on their behalf.

### Self-reporting fraud

If a practitioner suspects that he or she, or his or her organization, has committed fraud, he or she should consult an experienced attorney. It may be advisable to conduct an internal investigation or appoint someone to do so.

Based on the outcome of the investigation, the practitioner may decide to make a self-disclosure to Medicare authorities. The guidelines for self-disclosure are set by the Department of Human Services' Office of Inspector General.

Self-disclosure may enable the practitioner to avoid the costs and disruptions that could be associated with a government-directed investigation. Practitioners faced with this decision should consult with an attorney who specializes in this area and who can guide you through this process.

### If you become the target

In the event that an organization does find itself the subject of a government investigation, an attorney should be immediately consulted.

Important decisions regarding strategy should be made at the beginning of an investigation, such as whether to testify and how to preserve applicable privileges (such as the Fifth Amendment privilege against self-incrimination).

Choose an attorney who has experience in handling governmental investigations and who can counsel you through these complex decisions.

### Create a compliance culture

A good corporate compliance plan is essential even if a practitioner or health care organization has not knowingly or otherwise committed fraud.

All members of an organization should receive training and be educated on how to recognize fraud and how to report it.

Additionally, creating a "compliance culture," such as by rewarding self-reporters or having a tip hotline, may go a long way in avoiding becoming the subject of a health care fraud investigation.

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# Concierge

*Continued from page 1*

eral practice/primary care physicians who can treat patients with a variety of medical issues.

However, transitioning to concierge medicine also requires physicians to re-evaluate their relationships with Medicare, other federal and private third-party payors, and their patients.

First and foremost, while it is technically possible to have concierge relationships with Medicare and private insurance patients, physicians must tread carefully to ensure that state and federal laws are not violated.

Physicians wishing to go this route must conduct a rigorous analysis of their contracts with Medicare and other third-party payors to ensure that they do not run afoul of any rules or contractual terms of their participation agreements.

As one example, the Health and Human Services Department of Inspector General (HHS-OIG) has made it clear that concierge fees charged to Medicare patients may constitute billing patients extra for services already covered by Medicare.

While Medicare participating providers can charge beneficiaries extra for items or services not covered by Medicare, to the extent concierge fees encapsulate covered services, such arrangements are improper.

For example, the payment of concierge fees to receive such services as extra face time with a physician or coordinating the patient's care with other physicians are already covered by Medicare and would be improper. Therefore, to the extent physicians wish to have concierge relationships with Medicare patients, they must enter into a contract with such patients clearly designating which services and amenities are included as part of the concierge fee, and not otherwise payable by Medicare.

Such permissible non-covered services could include the ability to contact the physician via his/her personal phone number and the time spent on the calls; access to physician e-mail; or home visits from the physician.

Obviously, one way to avoid this potential conflict is to opt out of Medicare entirely. To accomplish this move, very specific steps must be followed which your legal advisor can guide you through.

A second option is not only to opt-out of Medicare, but also to stop participating with private insurance programs as well and only accept private-pay clients. While this allows physicians to avoid the hassles of piecing out covered vs. non-covered services in concierge contracts, it also drastically limits the number of patients to whom they will be able to provide services.

A practitioner considering opting out of Medicare or private insurance or simply adopting a concierge practice based on fee-for-services must perform a thorough review of their business and client base.

Importantly, practitioners must first consider the economic impact this new practice format may have on their practices, and determine whether there are a sufficient number of patients who can pay for these special services.

For example, will any current Medicare patients agree to switch over to private-pay? (Once a physician opts-out, the patient may not submit any claims on his/her own behalf.) Or will any existing patient agree to pay the fee for additional services?

If a practitioner's existing client base will not be sufficient, he or she must consider how to generate clients willing to accept and pay for this new type of practice.

It is important not to overlook the direct financial impact of this change, as practitioners will likely see a decrease in patients and, as a result, income. Practitioners should implement any necessary cost cutting measures to deal with this (hopefully temporary) change, both for their business and family.

Practitioners also should consider their practice as a whole and how they envision it growing.

It might not be practical to continue a specific type of practice with greater costs shifted onto their patients, and health care providers may be faced with the prospect of changing the nature of their business, business plan and marketing strategy.

Part of this analysis includes the location of the practice. For instance, a practitioner may work in an area where the majority of potential patients would be Medicare dependent or who simply cannot pay for the additional services offered, and may be forced to move his or her practice to a more affluent area as part of this significant change. (Additionally, physicians should keep in mind AMA ethical guidelines which require physicians to share in providing care to indigent patients.)

If their move to a concierge practice does involve opting out of Medicare, health care providers also must review existing contracts to ensure they are not obligated to stay with Medicare or private insurers. Practitioners must carefully review any agreements with hospitals, management companies, ancillary service providers, etc., to check for any binding language.

Finally, practitioners should consider the public relations impact of a decision to switch to a concierge practice. Will the decision upset existing patients, and in turn lead them to spread negative comments about a practice or the individual provider?

When notifying patients, practitioners should provide them with options (such as a list of recommended doctors who will provide a standard insurance-based practice, including accepting Medicare, if necessary) and a detailed explanation of why they are transitioning.

While concierge medicine may open the door to a healthier, more profitable medical practice, physicians should carefully evaluate the pros and cons of doing so and make absolutely sure to stay compliant with state and federal laws.

A reduced client base may be bad, but civil or criminal fines and penalties for Medicare violations are even worse.

**While concierge medicine may open the door to a healthier, more profitable medical practice, physicians should carefully evaluate the pros and cons of doing so and make absolutely sure to stay compliant with state and federal laws.**

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# Apsey

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But the trial court granted summary judgment to the defendants.

That's because, as the Court of Appeals would rule April 19, 2005 (Lawyers Weekly No. 07-55376, five pages), even though the plaintiffs had filed a timely complaint and affidavit of merit, special certification was still required under MCL 600.2102, the Revised Judicature Act (RJA).

This meant the affidavit, issued from a Pennsylvania general surgeon, needed to be not only notarized, but it required an accompanying certificate certifying the notary's authority.

And the plaintiffs did not provide the mandated certification until after the statute of limitations had run.

The trial court had properly dismissed the case, ruled the Court of Appeals judges, and MCL 600.2102 would "control over the general requirements of MCL 565.262, of the Uniform Recognition of Acknowledgements Act [URAA]."

Amici curae arguments from a wide spectrum of the legal community — including the Michigan Association for Justice, Michigan Defense Trial Counsel, Michigan Creditor's Bar Association, United Auto Workers, Citizens for Better Care, Michigan Department of Community Health, and the State Bar of Michigan — came pouring in.

Among the arguments, hundreds of meritorious medical-malpractice cases would be in jeopardy of being dismissed, while doctors' affidavits of meritorious defense would be invalidated.

Further, plaintiffs' lawyers in nearly every field of practice — from probate to business — who failed to certify their clients' out-of-state affidavits of merit would be open to legal malpractice claims. The same would go for defense lawyers who had lost at trial or settled without having tried to get the cases dismissed based on plaintiffs' uncertified affidavits.

Then on June 9, 2005, the Court of Appeals issued a reconsideration (Lawyers Weekly No. 07-55864, 12 pages), where Judge Mark J. Cavanagh, in dissent of the opinion, said the case had been "wrongly decided" and that the URAA and the RJA were, as Apsey and her supporters had contended, "alternative and viable means of proving notarial acts."

But Judges Hilda R. Gage and Kathleen Jansen held their ground, and the opinion stood.

A fresh round of amici curae led to a Michigan Supreme Court decision May 1, 2007, in Apsey's favor (Lawyers Weekly No. 06-62770, 31 pages).

Writing for a majority that consisted of then-Chief Justice Clifford W. Taylor and Justices Michael F. Cavanagh, Elizabeth A. Weaver, and Maura D. Corrigan, then-Justice Marilyn Kelly wrote that "The Legislature intended the URAA to serve as an alternative to MCL 600.2102(4) for authenticating out-of-state affidavits."

## 'Archaic' process

The Supreme Court decision was "a good sigh of relief," Mafrice said.

"Some of the states didn't even have a process within to certify the notary signature," he said. "It was a nightmare, because you never knew whether or not you had a good affidavit."

Medical-malpractice practitioner Brian J. McKeen of McKeen & Associates PC in Detroit agreed, adding that it was "incomprehensible" how, because of *Apsey*, extra requirements for out-of-state affidavits of merit held up many of his cases.

"This was *the* most regrettable era in the history of the Michigan judiciary," he said. "Forget the fact that the [affidavit] was signed, forget the fact that it was notarized. You have to have the certification from the clerk of the county of court? We may as well make a requirement that we put sealing wax on it. It's so archaic."

Mafrice said such conditions made cases like *Apsey* equal to stepping into a boxing ring with both hands tied behind your back — and Mike Tyson in the opposite corner.

"All of these technical interpretations," he said, "when you boil them down … just fly in the face of what we're all about in terms of the civil justice system. When access is denied wrongfully, cases like this occur, where she can't get to the courthouse door because of some technicality."

McKeen acknowledged that going through certain steps to make sure an out-of-state doctor has proper credentials is necessary to weed out frivolous lawsuits.

However, he said, "We take these cases on contingency. We don't take them unless they have merit. We have to advance the costs ourselves, and there's tremendous cost and risk in going forward. These cases are not easy to win, and why would anybody in their right mind take on a case that didn't have merit?"

In his office, Mafrice pointed to photos of Apsey taken this past May. Each of her legs has two thick, rectangular, dark purple skin grafts, and a bulging hernia protrudes from the left side of her midsection.

"This doesn't look like a frivolous lawsuit to *you*, does it?" he asked in a plain, soft-spoken tone.

## Life goes on

Glenn M. Simmington, who represented Memorial Hospital, said his client agreed to a consent judgment of $175,000. Even though the hospital was not found at fault, the agreement was set up to absolve the hospital of appeal rights because the *Apsey* verdict was returned in the plaintiff's favor.

He said he is relieved that the trial is over for his client. (Defense counsel for Shiawassee Radiology Consultants, PC and co-defendant Dr. James H. Deering did not respond to *Lawyers Weekly*'s requests for comment on the case.)

"We certainly didn't want it to live any longer than it already had," said Simmington, of Cline, Cline & Griffin in Flint, who also handled the appellate work for the hospital. "It just didn't seem like the case that the plaintiff was going to get a [no cause of action verdict] on."

Mafrice said Apsey's disfiguring scars are a daily reminder of what she went through.

It's what's she doesn't see that affects her, too: her husband, a longtime GM worker, died of cancer in 2003, when her legal ordeal was picking up steam.

But when Mafrice spoke with the jury following the Shiawassee trial, "the [jurors] made mentions on damages that I hadn't even thought about," he said. "Little everyday activities she'd be precluded to do."

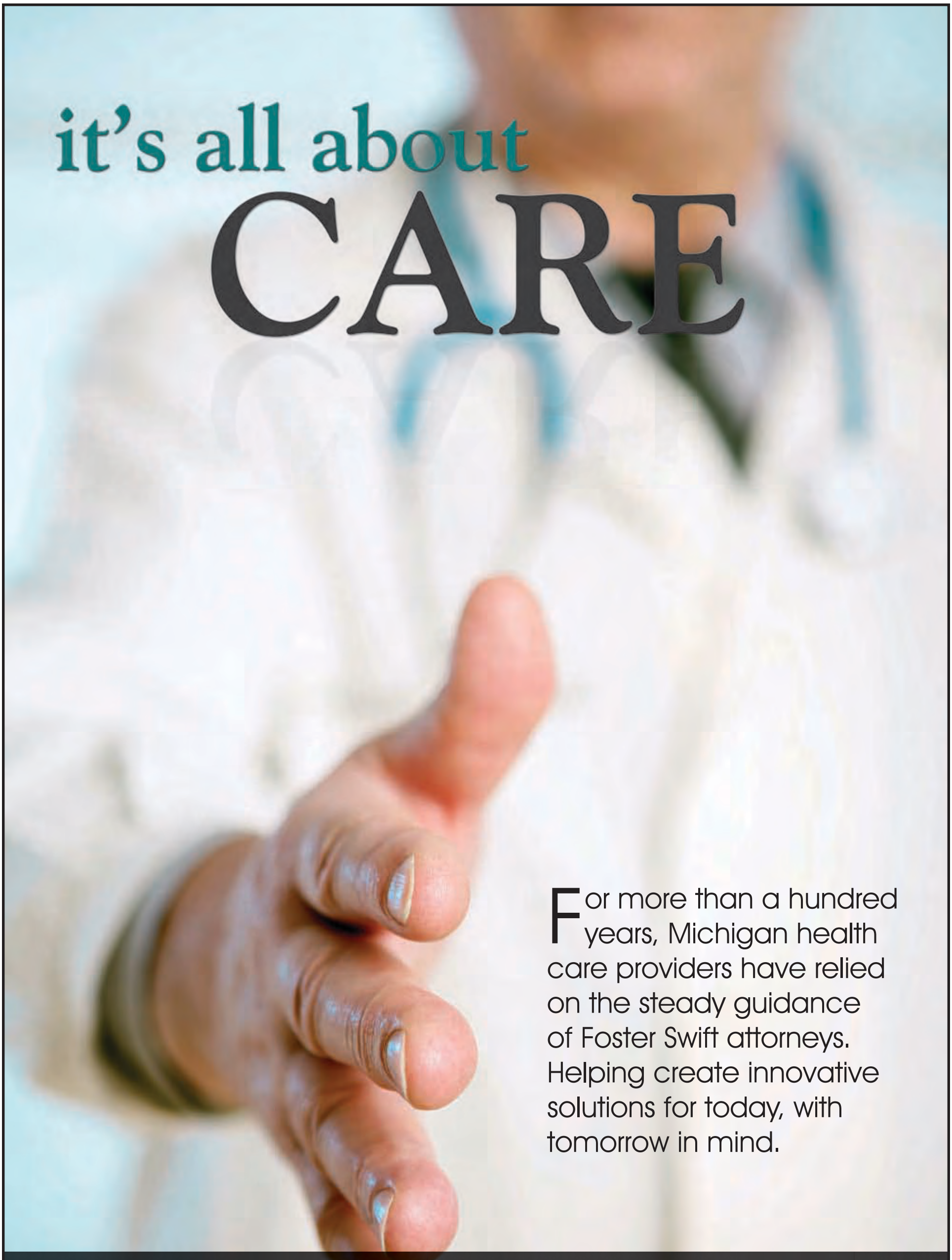
For example, "She's got one child who they adopted, who is a single mom, and had never been married. But if she had been married, for example, they talked about Ms. Apsey having a problem finding a dress to wear to her daughter's wedding, because of this huge abdominal hernia. Or not being able to hold her grandkids on her lap like grandparents would want to do."

Mafrice describes her as a quiet, reserved woman who didn't ask for much and expected as much in return.

The last thing she wanted was notoriety.

"She doesn't want to take up any causes," Mafrice said. "She didn't want to *be* the cause."

*If you would like to comment on this story, please contact Douglas J. Levy at (248) 865-3107 or douglas.levy@mi.lawyersweekly.com. Dolan Newswire reports contributed to this story.*

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