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Inside MedLaw

Beyond the mandate

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Dr. Sonia Nagda showed her support of the health care reform law signed by President Obama and gathered with other health care professionals in front of the Supreme Court in Washington, when it heard arguments on the legislation.

What else health care providers need to know about 'ObamaCare'

Compliance

By Brandi Walkowiak

The Supreme Court of the United States' recent ruling upholding the constitutionality of The Patient Protection and Affordable Care Act (a.k.a ObamaCare) (Act), as well as the upcoming presidential election have put this Act front and center in the health care world.

The highly publicized and politically charged sections of the Act, such as the so-called mandate, the provisions addressing pre-existing conditions, and the extension of the dependent coverage age to 26, have garnered most of the media attention.

However, there are a slew of provisions related to health care fraud and abuse enforcement that have gotten much less attention, but could have an equally significant impact on health care providers and entities.

Title VI of the Act, entitled "Transparency and Program Integrity," creates an invigorated

See "ObamaCare," page 6

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Telemedicine reimbursement required, say new state laws

Compliance

By Mercedes Varasteh Dordeski

The use of telemedicine in Michigan has become much more straightforward with the passage of two new laws requiring private insurers to reimburse health care providers for services provided via telemedicine.

The laws were signed into law by Gov. Rick Snyder this June, and are intended to encourage providers to use telemedicine as a way of increasing access to patients. Importantly, the laws now define what exactly constitutes "telemedicine," which was previously an open question under Michigan law.

The two laws, Public Acts No. 214 and 215 of 2012, require Blue Cross Blue Shield and other private insurers in Michigan to cover patient visits conducted using telemedicine so long as certain requirements are met.

Although the use of technologies such as Skype and video conferencing between patients

See " Telemedicine," page 11

Preparing for the changing employment relationships between physicians, hospitals

Business of Health

By Michelle Bayer

The business of the practice of medicine is again changing. Back in the early 1990s, many hospital groups purchased physician practices and consolidated physician groups in an effort to maximize profitability.

The trend changed after many of these groups were not successful, and private practice again became the preferred practice model.

Now, following health care reform, hospitals and physician groups are again looking for ways to maximize the business of the practice of medicine; increasing profits and lowering risk; capturing a larger amount of the patient populations; gaining negotiation leverage for higher reimbursement rates; and dealing with rising malpractice costs.

This way of thinking has again brought delivery and payment system programs to the forefront, making integrated delivery systems a more desirable alternative to small private practices, and such integrated

Now, following health care reform, hospitals and physician groups are again looking for ways to maximize the business of the practice of medicine.

systems are being advocated and incentivized by the health care reform system. More and more physicians are looking to be employed by hospitals. There are a number of different models

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Hospitals see some success with Part B reimbursement after initial RAC denial

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Business of Health

By Andrew Wachler and Jessica Lange

Since the Recovery Audit Contractor (RAC) Demonstration Program launched in 2005 and the final RAC program launched in 2008, industry leaders have been involved in the effort to obtain full Part B outpatient reimbursement for hospitals where a short-stay inpatient claim has been denied for lack of medical necessity by Medicare Contractors, such as RACs.

Industry leaders met with officials from the Centers of Medicare & Medicaid Services (CMS) three times since 2009 in an attempt to obtain full Part B reimbursement for hospitals.

The hope for these meetings was that they would lead to a positive change to CMS' policy and directions to contractors.

Although there are still some unanswered questions about hospitals' ability to obtain full Part B reimbursement where inpatient services are denied during a Medicare audit, years of hard work have led to a very important development that positively affects hospitals.

During the RAC Demonstration program, hospitals in the demonstration received denials from RACs for inpatient hospital admissions.

The services were denied because the RACs alleged that the inpatient admission for the beneficiary was not medically necessary and reasonable — essentially, that the services should have been provided in an outpatient setting.

Although hospitals argued during the Medicare appeals process that the inpatient admission was medically necessary and reasonable, there was a collective effort to also argue that if an independent reviewer affirmed the RAC's denial of the inpatient admission, then payment should be made for the services as if provided in the outpatient setting.

Hospitals achieved some success at the administrative law judge (ALJ) hearing stage of appeal, and ALJs would order payment to the hospital for full Part B reimbursement, including observation services.

Despite the ALJ orders, it was difficult for hospitals to receive effectuated payment from administrative contractors. Even as CMS phased in the final RAC program, hospitals continued to face these challenges.

This past November, CMS announced a demonstration program that industry leaders hoped would be a positive step toward allowing hospitals to effectuate full Part B reimbursement.

The Part A to Part B Rebilling Demonstration Program (AB Rebilling Demo) includes some changes, but the demonstration on a whole is limited, and hospitals must pay a high price to participate.

The AB Rebilling Demo allows participating hospitals to submit claim forms for 90 percent of the Part B reimbursement, not including observation, for short-stay inpatient claims denied by a RAC for medical necessity.

However, the hospitals are not allowed to appeal these short-stay inpatient claims, and thus receipt of the limited Part B reimbursement is their only option.

Recently, prominent CMS officials issued a memorandum to "All Fiscal Intermediaries (FIs), Carriers, and Part A and Part B Medicare Administrative Contractors (A/B MACs)."

The memorandum begins by noting the numerous ALJ decisions where the ALJ has affirmed contractors' denial rationale that inpatient services were not reasonable and medically necessary, but then stated in the ALJ order that the contractor must pay the hospital full Medicare Part B outpatient reimbursement, including observation.

In line with these ALJ orders, CMS issued mandatory instructions for claims administration contractors to follow the ALJ orders. Thus, where an ALJ orders a claims administration contractor to make payment to a hospital for Medicare Part B outpatient/observation services, the contractor must honor the order and follow CMS' instructions to effectuate the order.

The instructions in the CMS memorandum provide a step-by-step process for the contractors to follow.

First, the instructions require contractors to contact the provider to obtain a Part B claim within 30 calendar days of receipt of the effectuation notice from the Administrative QIC (AdQIC).

The provider must then send the replacement claim to the contractor within 180 days from the date the contractor contacts the provider or else the contractor must close the case and consider effectuation completed.

The memorandum's instructions to contractors, however, are very specific in terms of the precise situation in which an ALJ's order would trigger the contractor to pay a hospital full Part B reimbursement, including observation.

Unless the medical record for the inpatient hospital claim at issue includes a physician's order for observation, the only way a hospital will receive reimbursement for observation is if the ALJ's order instructs the contractor to pay observation.

Specifically, the ALJ's order must clearly specify "observation level of care" for the hospital to receive payment for observation.

If the ALJ includes this language in the order, then line-item charges for observation may be added if otherwise appropriate, as the ALJ's order substitutes an order to admit for observation that would be included in the record.

A hospital with a claim that is without an order for observation in the medical record or without an ALJ's specified order for reimbursement for observation will not receive reimbursement for observation services.

The very precise articulation of the language required in ALJ orders for a hospital to receive observation, highlights the importance that hospitals specifically request the alternative relief from an ALJ to be full Part B reimbursement, including observation services and all underlying care.

The CMS memorandum is a very positive improvement in the effort to realize accurate Part B reimbursement for hospitals where a contractor has denied an inpatient short-stay claim because the admission was not medically necessary.

Although the memorandum still evokes some limitations, it is, to date, the clearest indication from CMS that contractors are now required to effectuate an ALJ's order for Part B reimbursement where an inpatient claim has been denied for medical necessity.

It also highlights to hospitals the crucial importance of the appeals process, especially the ALJ hearing stage.

Hospitals should understand that encouraging an ALJ to order reimbursement for observation and all underlying outpatient care is a legal, not clinical, argument.

During appeals, it is essential that hospitals evoke legal arguments and authorities to persuade an ALJ to issue a precise order for Part B reimbursement, including observation services and underlying outpatient care.

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Fall 2012 RAC update

- CMS recently provided updates and hosted an Open Door Forum on the Medicare Recovery Audit Prepayment Review demonstration program.

  The RAC prepayment review program allows the RACs to conduct prepayment reviews on certain claim types that have historically resulted in high rates of improper payments.

  The RAC prepayment reviews began in August, with the review of MS-DRG 312 Syncope & Collapse.

  The RAC prepayment reviews are in addition to and not in place of prepayment reviews conducted by the Medicare Administrative Contractors (MACs). The RACs will audit claims on a prepayment basis in 11 states, including Michigan.

- In the recent Outpatient Prospective Payment System proposed rule for CY 2013, CMS solicited comments regarding changes that could be made on the issue of inpatient versus outpatient admission. CMS sought comments on potential changes, which could provide some clarity regarding inpatient versus outpatient status for purposes of Medicare payment. Comments were due Sept. 4.

- CGI, the Region B RAC, which includes Michigan, recently added a new approved issue for review. CGI posted outpatient Bevacizumab (Avastin), which is used with chemotherapy treatment, to its approved issues list.

  The approved issue posting states that "Bevacizumab (Avastin) represents 10mg per unit and should be billed one (1) unit for every 10mg per patient. Claims for J9035 should be submitted so that the billed units represent the administered units, not the total number of milligrams."

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Proposed rules designed to remove barriers for physicians to use physician assistants

Regulations

By Robert Iwrey

On Nov. 8, 2011, Public Act 210 of 2011 went into effect removing statutory language that prevented physicians, both MDs and DOs, from delegating the prescribing of controlled substances to physician assistants (PAs).

In essence, these statutory amendments provide that physicians:

(1) May delegate in writing to a PA the ordering, receipt and dispensing of complimentary starter dose drugs including Schedule 2 through 5 controlled substances;

(2) Are no longer required to sign an official form listing the physician's signature as the required signatory if that official form is signed by a PA to whom the physician has delegated (in writing) the performance of medical care services;

(3) May delegate (in writing) the task of making calls or rounding on patients in private homes, public institutions, emergency vehicles, ambulatory care clinics, hospitals, intermediate or extended care facilities, HMOs, nursing homes or other health care facilities to PAs without restrictions on the time or frequency of visits; and

(4) May delegate (in writing) to a PA the prescribing of Schedule 2 through 5 controlled substances (the names and DEA registration numbers of both the physician and PA must be used with each prescription).

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Unfortunately, there was nothing within the statutory amendments that removed certain existing administrative rules that limited a physician's authority to delegate the prescribing of Schedule 2 controlled substances to a PA.

Moreover, the statutory amendments contain language that contemplates that administrative rules may be promulgated to further define which drugs or classes of drugs physicians shall not be able to delegate to PAs, and what procedures and protocols should be followed in order to be consistent with federal and state drug control and enforcement laws.

In response, on July 13, 2012, proposed amendments to the Boards of Medicine and Osteopathic Medicine & Surgery administrative rules were drafted.

These proposed administrative rule amendments are intended to eliminate any restrictions on a physician's ability to exercise his/her judgment to delegate to a PA the prescribing of Schedule 2 controlled substances; and to clarify and reduce the requirements for the written authorization physicians must use in order to delegate the performance of medical care services and/or the prescription of controlled substances to PAs.

The proposed administrative rule amendments will make it clear that a physician who supervises a PA must have a written authorization to delegate to a PA the performance of medical care services and/or the prescribing of schedule 2 through 5 controlled substances.

This written authorization must contain the effective date of the delegation, name, license number and signature of the supervising physician and the PA, and set forth any limitations or exceptions to the delegation of any medical care services and/or controlled substance prescribing.

Under the proposed administrative rule amendments, this written authorization must be reviewed and updated prior to the renewal of a PA's license (i.e., at least every 2 years) or in the interim as needed. A copy of this written authorization must be maintained in each separate office location of the physician where the delegation occurs.

If the proposed administrative rule amendments are adopted, supervising physicians are well-advised to seek legal review of the written delegation authorization to assure its accuracy, thoroughness and compliance with applicable federal and state laws as well as third-party payor billing rules and guidelines.

According to the Michigan Department of Licensing & Regulatory Affairs (LARA), both the aforementioned statutory and proposed administrative rule amendments are necessary in order to address a significant physician shortage in Michigan that many predict will worsen before it gets better.

In order to facilitate continued access to quality medical care in Michigan, the Legislature has determined that a streamlining of the regulations regarding the delegation of medical care services and prescribing of controlled substances by physicians to PAs is needed.

Without such changes, physicians are required to see patients who could otherwise be seen by PAs but for the fact that the PAs could not prescribe schedule 2 medications.

With such changes, Michigan physicians and PAs will both be able to see more patients, thereby increasing access to care.

As of Feb. 1, 2012, there are 32,587 MDs and 6,983 DOs who possess a full and unrestricted license to practice in Michigan with the authority to delegate the prescribing of Schedule 2 medications to the 3,809 PAs licensed in Michigan.

It should be noted that at least two other states in the Great Lakes Region, Minnesota and Wisconsin allow PAs to prescribe Schedule 2 medications as a delegated act of a supervising physician (although Illinois, New York and Ohio prohibit it).

LARA will hold a public hearing 9 a.m. Oct. 3, 2012, in Lansing to receive comments on the proposed administrative rule amendments. Additional information regarding the public hearing is available by contacting Desmond Mitchell, policy analyst, at mitchelld6@michigan.gov.

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THE DOLAN COMPANY

New requirements to come for group health plans

Compliance

By Suzanne Nolan

Most health care practices and their owners have been focusing on how the expansion of health insurance coverage under the Patient Protection and Affordable Care Act (Act) will lead to increased demands for their services, or the feasibility of joining an Accountable Care Organization.

Consequently, many practices may not be aware of the Act's requirements that apply to practices that, in their role as an employer, sponsor a group health plan.

Importantly, such practices must begin complying with some of these requirements now.

In many cases, both a practice and the health care insurer must work together to implement certain changes and keep employees informed of these changes.

Preparing for and meeting the requirements that become effective in 2012-13 is a fairly straightforward task.

First, the most urgent requirement is for plan sponsors to begin distributing a Summary of Plan Benefits and Coverage (Summary). The plan's health insurer is responsible for preparing the Summary.

The Summary must provide enrollees with easy-to-understand information about their health plan benefits and coverage. The employer, as the plan sponsor, or the plan administrator (depending on whether the plan is self-funded or fully insured), has the obligation to distribute the Summary to enrollees and prospective enrollees in the plan.

Starting with the first day of the first open enrollment period that begins on or after Sept. 23, 2012, plan sponsors or plan administrators are required to provide a Summary to enrollees and potential enrollees in a group health plan.

Therefore, plan sponsors must make sure that the health insurer has prepared the Summary, and make arrangements to distribute the Summary to its enrollees.

Second, employers who are sponsors of self-insured plans must begin paying a Patient-Centered Outcomes Research Institute fee in the amount of $1 per covered life for plan years beginning on or after Oct. 1, 2012, and ending before Oct. 1, 2013.

The fee will increase to $2 for the next plan year and thereafter will be indexed to national health care expenditures until it expires in 2019.

The fees are contributed to a research fund that will pay for research that evaluates and compares health outcomes and clinical effectiveness, and the risks and benefits of two or more medical treatments and/or services.

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Third, employers who issue W-2s to 250 or more employees must start reporting the cost of annual health care coverage on an employee's W-2, beginning with W-2s issued in January 2013.

Because employees may be confused about the inclusion of this information on their W-2s, employers should let them know that this is being done to make employees aware of the cost, and does not mean that health insurance benefits are taxable.

Fourth, for tax years beginning after Dec. 31, 2012, the Act caps the amount of salary reduction contributions that an employee can make to a health flexible spending account (FSA) at $2,500.

Employers are responsible for changing plan documents for their FSA plans to reflect this new limit, making sure that participants in the FSA are given appropriate notice of this change, and for making sure that enrollees are given accurate enrollment materials.

Preparing to meet the requirements that become effective in 2014 requires significant advance planning during 2013 to determine how the availability of health insurance exchanges in 2014 will impact the coverage that they provide.

Employers also must prepare to address the "pay-or-play" mandate. This mandate does not require employers to offer group health insurance to employees; rather, it requires a large employer — defined as one with 50 or more full-time equivalent employees — that offers a group health plan to comply with it.

Pursuant to the pay-or-play mandate, starting in 2014, large employers that provide group health insurance to employees will be required to either provide affordable group health care coverage offering minimum essential benefits, or pay a penalty.

Health Insurance Exchanges are expected to make adequate health insurance policies at affordable prices available to individuals and small employers.

The Small Business Health Options Program (SHOP) component of the exchanges will offer employers in the small business health insurance market (those with up to 100 employees) and their employees a variety of choices for coverage.

SHOPs are intended to give these employers access to the types of health plans that are now available only to larger employers. Additionally, employers who purchase health insurance for employees through a SHOP may qualify for a small business tax credit.

Employers also should be aware of certain changes that their health plans must make for 2014 when certain prohibitions on what plans can do go into effect for all plans, including those that were grandfathered.

Among the most important prohibitions, health plans cannot:

- Impose annual limits on the dollar value of benefits for a beneficiary or participant (but may impose limits on specific types of benefits that are not essential benefits);
- Impose waiting periods for coverage longer than 90 days, exclude coverage for pre-existing conditions; or
- Refuse to cover pre-existing conditions (this prohibition is already in effect for those younger than 19).

Clearly, the burden of making these changes falls on the shoulders of the insurers who will need to modify the plans they offer in order to have the plans comply. Employers should understand that insurers are required to make these changes, and be prepared to deal with the expected premium increases.

Practices should consult with legal counsel to make sure that they are complying with all of these requirements.

In deciding whether to continue to offer group health insurance after the exchanges begin operating, practices, with the assistance of legal counsel, need to consider the financial effect such a decision may have on the practice.

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Regulatory considerations for physicians participating in ACOs

Regulations

By Amy Fehn

The Medicare Shared Savings Program (MSSP) was established by Section 3022 of the Affordable Care Act, and allows physicians to participate in an Accountable Care Organization (ACO).

The ACO and its participants may share in any Medicare program savings achieved, provided that certain quality measures and program requirements are met.

Because the receipt of shared savings is conditioned on meeting the program requirements, physicians participating in the MSSP through an ACO will likely be asked by the ACO to attest to their compliance with these requirements in participation agreements.

Accuracy of data submitted

ACOs will be required to report on certain quality measures that will impact the amount of shared savings that the ACO receives, and will in turn impact the physicians' share of the distribution.

ACOs will rely upon physicians to accurately report this information. Because these reports will determine compensation from the federal government, false statements could result in False Claims liability for any individual who reports information that he or she knows or should know is inaccurate.

Beneficiary inducements

Another MSSP program requirement prohibits ACO participants from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from, or remaining in, an ACO, or with ACO providers/suppliers in a particular ACO.

Certain items or services may be provided to beneficiaries free of charge or at a discount if they are reasonably connected to the beneficiaries care, are preventive care items or services, or advance a clinical goal for the beneficiary (such as adherence to a drug or treatment regime, a follow-up care plan, or chronic disease management).

For example, a provider participating in the MSSP could give a Medicare beneficiary with hypertension a blood pressure monitor.

Items such as gift cards or tickets to sporting events would not be permissible.

The specific beneficiary inducements permitted by the MSSP represent a waiver of the Civil Monetary Penalties (CMP) statute. Therefore, failure to adhere to these guidelines not only could subject the ACO to sanctions, but also could potentially subject the physician to penalties for violating the CMP.

Marketing

Marketing materials regarding ACO participation in the MSSP must be submitted to the Centers for Medicare & Medicaid Services (CMS) for approval and must use template language developed by CMS, if available.

The marketing materials may be targeted toward beneficiaries of certain races or with certain conditions, but must not be used in a discriminatory manner or for a discriminatory purpose.

Marketing communications cannot violate the beneficiary inducement provisions

See "Accountable care," page 14

Check details before signing an employment agreement

Employment

By Melinda Balian

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Some physicians may approach signing an employment contract like agreeing to a new cellphone plan — in other words, they do not take the time to negotiate or discuss the terms, and rather choose a "take it or leave it" approach.

However, what all physicians should know is that signing an employment agreement with a new employer is much different — and much more consequential — than signing up for a new iPhone.

An employment agreement can control a physician's entire career, including severely limiting the physician's options if he or she finds a new and better position, or wants to change employers.

Accordingly, it is important for physicians to carefully review and understand all the terms contained in the agreement, without just assuming they have no choice but to sign on the dotted line.

Here are just a few of the key provisions typically included in physician employment agreements that should always be clarified prior to execution:

• Non-compete provisions:

In Michigan, non-compete agreements are governed by the Michigan Antitrust Reform Act (MARA).

Generally speaking, non-compete agreements must be "reasonable" in scope, duration, and geographic breadth. In addition, in order to qualify as "reasonable" under MARA, non-compete agreements must be designed to protect an employer's reasonable competitive business interest, and not just to restrain trade.

In order to be "reasonable" in relation to an employer's competitive business interest, a restrictive covenant must protect against the employee's gaining some unfair advantage in competition with the employer, but not prohibit the employee from using general knowledge or skill.

When considering an employment agreement which contains a non-compete, it is important to note that, generally speaking, Michigan courts have accepted non-competes ranging from one to three years.

Further, physicians should keep in mind that geographic limitations with a larger radius are more widely accepted in rural areas (given that patients will travel a larger distance), but in urban areas a smaller radius is typical because patients will not travel as far for care. The bottom line for any non-competition provisions is that it must be reasonable.

• Non-solicitation provisions:

These can be much broader in scope and length than non-compete provisions. In many non-physician employment agreements, the language may be written in such a way so as to prevent the former employee from providing services to any current and/or former client, etc.

However, in the medical arena, because patients have the right to choose their practitioner, the language may not be written in such a fashion. Nevertheless, what practice groups are now doing to circumvent this is to include a provision in the employment agreement that, upon termination, the physician will "take all steps necessary to transfer his/her patients to the practice."

Such provisions obviously provide a greater umbrella of protection to a practice group-employer than the physician-employee.

• Bonus compensation:

Another hot issue is how any bonus will be determined and calculated. Typically, it is best if there is specific language in the agreement on how the amount of any bonus shall be calculated, i.e., by determining the amount of the bonus, it shall be determined by the amount of medical/surgical fees attributable to the employee, and said amount shall be determined by the amount billed incident to employee's services or under employee's National Provider Identifier (NPI) number.

Concomitant with determining the calculation of any bonus is ensuring that a physician has the contractual right to inspection and audit of the records, which should include a monthly accounting of the medical/surgical services billed under his/her NPI number.

• Location of employment:

Often times practice groups will have multiple locations, and as such, will have a generic clause in the employment contract that it has the right to assign the physician to any office location at its discretion.

Given that the physician will be governed by the written words contained in the "four corners of the written contract," it is important to pinpoint where the physician are expected to work, especially if the locations are not in close proximity.

There are many other provisions and/or issues to be considered when reviewing an employment agreement, such as notice provisions, termination upon disability clauses, indemnity clauses and malpractice insurance, not to mention arbitration and prevailing party attorney fee clauses.

All of these should be understood and clarified before executing an agreement, and discussed with experienced legal counsel.

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ObamaCare

Continued from page 1

set of requirements to combat fraud and abuse as well as new reporting requirements for providers, hospitals, drug companies and nursing facilities.

Not surprising, the Act places particular emphasis on financial relationships between providers and hospitals/health care manufacturers.

For example, beginning in March 2013, drug, device, biological and medical supply manufacturers must annually report to the government the amount and nature of certain payments to physicians or teaching hospitals such as consulting fees, honoraria, gifts, entertainment, food, travel, research, royalties, and grants.

While there are exceptions to the payments that need to be reported, those exceptions are fairly limited in scope and include, for example, product samples, items not exceeding $100 in the aggregate for one year, among others. Failure to make these reports, at a minimum, carries express civil penalties under the Act.

Prescription drug manufacturers and distributors also are subject to new reporting requirements. They must report to the U.S. Secretary of Health and Human Services (HHS) information pertaining to drug samples including, for example, the identity and quantity of drug samples requested and the name address and practitioner making the request.

Also, not surprising, is the section in the Act dedicated to "Nursing Home Transparency and Improvement," given the government's continued interest in these entities in the enforcement arena.

Skilled nursing facilities (SNFs) and nursing facilities are required to make available information regarding the identity of each member of their governing body, and all officers, directors, members or partners (persons or entitles).

Further, SNFs and nursing facilities are required to have a compliance and ethics program (Program) in operation that "is effective in preventing and detecting criminal, civil, and administrative violations."

The Act sets forth specific components of the Program which include that it:

(1) Establish compliance standards and procedures that are reasonably capable of reducing the prospect of violations;

(2) Assign high-level personnel with overall responsibility to oversee the compliance;

(3) Not delegate discretionary authority to individuals the organization knew or should have known had a propensity to engage in criminal, civil or administrative violations;

(4) Take steps to effectively communicate its standards and procedures to all employees and agents, such as requiring training;

(5) Implement monitoring and audit systems reasonably designed to detect violations;

(6) Take appropriate and consistent disciplinary action against responsible individuals;

(7) Take all reasonable steps to respond to a detected offense; and

(8) Periodically reassess its compliance program.

Moreover, the Act includes provisions aimed at encouraging self-reporting. For example, the Act provides for a reduction in civil penalties up to as much as 50 percent for SNFs and nursing facilities that promptly report and correct deficiencies.

Exceptions to this include instances where there are repeat deficiencies, or where the deficiency is found to result from a pattern of harm that jeopardizes the health and safety of its residents.

The Act also enhances its Medicare and Medicaid integrity provisions. The Act imposes specific deadlines for reporting and returning overpayments.

Those who make false statements on applications or contracts to participate in Federal programs or those who knowingly do not return an overpayment will be subject to fines up to $50,000.

In addition, the Act revises the intent requirement of health care fraud and expressly provides that a person "need not have actual knowledge" or "specific intent" to commit a violation. The Act also provides for the suspension of Medicare and Medicaid payments pending an investigation of a "credible allegation of fraud."

Provisions aimed at conflicts of interest and referrals are also found in the Act.

For example, hospitals must submit annual reports to the government describing each physician owner or investor; the nature of the ownership; procedures in place to require referring physician owners or investors to disclose the relationship to patients; and that the hospital does not directly or indirectly condition any physician ownership or investment on making or influencing referrals.

The physician ownership or investment also must appear on the hospital's public website and in its advertising. As another example, physicians must maintain and provide access to documents relating to written orders or requests for payment for durable medical equipment, certifications for home health services or referrals for other items of service as specified by the Government.

In addition, under the Act, the HHS secretary will establish a self-referral disclosure protocol.

On top of the substantive provisions, the Act expressly grants increased funding to fight fraud and abuse to the tune of an additional $10 million a year for 2011-20.

In sum, providers, health care entities, and manufacturers must ensure they are versed in the Act's new requirements aimed at combating health care fraud and abuse.

In addition, the Act's provisions signal to the industry where the government will focus its enforcement efforts.

Accordingly, providers and health care entities should use this as another opportunity to evaluate their compliance programs, and make sure their procedures and protocols are in order in light of the government's dedicated resources, the new transparency requirements, and potential civil and criminal enforcement penalties.

Brandi Walkowiak, a senior counsel with Foley & Lardner LLP's Detroit office, focuses her practice on corporate compliance, internal investigations and white-collar defense, as well as complex civil litigation. Contact her at (313) 234-7145 or bwalkowiak@foley.com.

Health Law Is Complex

Understanding It Can Be Simple

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PRACTICAL TIPS TO AVOID licensing action

Compliance

By Robert Iwrey

Having a medical license to practice in the state of Michigan is not a right but a privilege, and it can be taken away or restricted for failing to abide by various statutory bases set forth within the Michigan Public Health Code (MPHC).

As such, compliance with the MPHC is the key to avoiding a licensing action.

In order to facilitate such compliance, physicians are encouraged to actively participate in an effective compliance plan at their respective work site.

If the physician is a solo provider or member of a group that does not have a compliance plan, he or she should develop, implement and maintain an active compliance plan that includes:

(1) Designating a compliance officer or contact;
(2) Implementing written standards and procedures;
(3) Conducting appropriate training and education;
(4) Developing open lines of communication;
(5) Conducting internal monitoring and auditing;
(6) Responding appropriately to detected offenses and developing corrective action; and
(7) Enforcing disciplinary standards through well-publicized guidelines.

Although each of these elements plays a role in facilitating compliance, emphasis should be placed on conducting internal monitoring and auditing, as this can help identify a previously unknown issue and provide one with an opportunity to take proactive, prophylactic measures to address the issue prior to the issue resulting in a licensing investigation.

In addition, emphasis must be placed on appropriate documentation of the medical record. The majority of licensing actions are based, at least in part, upon a lack of appropriate documentation in the medical record.

For example, if a patient is non-compliant with the physician's instructions, such non-compliance should be documented.

If not, a subsequent review of the physician's medical records may lead the reviewer to conclude that the physician, not the patient, failed to follow up.

Moreover, while there is no standard form utilized by all physicians for documenting patient encounters, incorporating the S.O.A.P. format (i.e., subjective, objective, assessment and plan) is strongly advised, as record reviewers will look to see if each of these elements is present in the documentation.

Importantly, as of December 2006, a physician is required to maintain a record for each patient for whom he or she had provided medical services, including a full and complete record of tests and examinations performed, observations made and treatments provided.

Furthermore, with the recent push towards adopting and meaningful use of electronic health records (EHR), physicians should be mindful of issues such as self-populating record fields, which can result in significant inconsistencies in the medical record.

For example, due to a self-populating field, the medical record may state in one area: "Patient has no complaints of pain," but in another area state: "Patient presents with severe pain." In some cases, EHR systems may automatically generate a prescription, including strength and form, based on the notes in the record.

In such instances, the physician must take care on two levels. First, the physician must ensure that the prescription generated by the EHR system is appropriate for the patient. Though the system is convenient in generating the prescription, nothing can substitute for the professional judgment of the physician.

Second, if the physician does, in fact, change the EHR system-generated-prescription, the physician must ensure that such alterations also are reflected in the exam note itself. Other health care licensees will rely on that exam note to make future decisions on refilling the prescription or prescribing another medication.

Liability also can arise by missing simple spelling errors, despite spell check (e.g., writing "care" instead of "case"). The ease with which certain tasks can be completed with an EHR system can result in increased carelessness where such mistakes could have much greater implications, including risks of patient safety, medical-malpractice claims or audit activity — all of which could lead to a licensing action.

Lastly, due to the growing epidemic in Michigan regarding prescription drug abuse, there has been an increase in actions against physicians for illegitimate prescribing of controlled substances.

Administrative Complaints may issue against a health care licensee for (i) a "violation of general duty, consisting of negligence or failure to exercise due care … whether or not injury results …" or (ii) "incompetence."

Both of these bases essentially allow a licensing action for not following the applicable standards of care.

The applicable standards of care, while not delineated by statute, have been developed by the various health care licensing boards (including the Boards of Medicine, Osteopathic Medicine & Surgery and Pharmacy) to include a consideration of the following:

(1) Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain, developed by the Michigan Board of Medicine and the Michigan Board of Osteopathic Medicine and Surgery;
(2) Michigan Board of Pharmacy Guidelines for the Use of Controlled Substances for the Treatment of Pain;
(3) Responsible Opioid Prescribing: A Guide for Michigan Physicians — a book endorsed by the Michigan Department of Licensing & Regulatory Affairs (LARA) as representing the standard of care in Michigan; and
(4) The use of the Michigan Automated Prescription System (MAPS).

Physicians who prescribe controlled substances are well-advised to familiarize themselves with these publications and the standards of prescribing controlled substances in Michigan.

Moreover, with regard to MAPS, while not required by statute or administrative rule, prescribing licensees are "encouraged to register to MAPS Online to request prescription data on patients … [since] using MAPS Online before and during treatment … can alert [the licensee] to any past 'doctor shopping' or questionable behavior."

Physicians should not take this "encouragement" lightly.

Michigan's Bureau of Health Professions and both state and federal law enforcement have taken the position that the applicable standards of care require physicians to perform MAPS queries regularly on patients for whom they prescribe controlled substances, and that failure to do so is a breach of the applicable standard of care.

Robert Iwrey is a founding partner of The Health Law Partners PC, where he focuses his practice on licensure, staff privileges, litigation, dispute resolution, contracts, Medicare, Medicaid and Blue Cross/Blue Shield audits and appeals, defense of health care fraud matters, compliance, employment matters and other health care related issues. Contact him at (248) 996-8510 or riwrey@thehlp.com.

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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 5709 — Requiring department of community health to conduct research regarding products containing synthetic cannabinoids

A bill to amend 1978 PA 368, "Public Health Code," (MCL 333.1101-333.25211) by adding section 7545a

Sec. 7545a: "(1) The department of community health, in coordination with the department of state police, shall conduct research regarding herbal mixtures and other products that contain synthetic cannabinoids. The research shall be completed no later than January 1, 2013 and shall address all of the following:

"(a) The types of synthetic cannabinoids commonly used in those herbal mixtures and other products.

"(b) The sources of those synthetic cannabinoids.

"(c) Whether those synthetic cannabinoids are used alone or in combination with other chemical substances.

"(d) The major physiological and psychological effects of consuming the herbal mixture or other product containing those synthetic cannabinoids, including its addictive qualities.

"(e) The social and economic impacts of the manufacture, sale, distribution, and use of those herbal mixtures and other products within this state.

"(f) Other information considered relevant by the department of community health.

"(2) Within 180 days after conducting the research required under subsection (1), the department of community health shall file a written report of its findings to the secretary of the senate and clerk of the house of representatives. The report shall include the recommendations of the department of community health to the legislature regarding the best means of identifying synthetic cannabinoids for purposes of this article, recommendations regarding the proper scheduling of those synthetic cannabinoids, and recommendations for control and enforcement under this article. The report shall also provide the recommendations of the department of community health for addressing herbal mixtures and other products containing synthetic cannabinoids from a health perspective."

Sponsored by George Darany

Referred to Committee on Judiciary

HB 5714 — Allowing promulgation of an emergency rule for scheduling certain controlled substances

An act to amend 1969 PA 306, "An act to provide for the effect, processing, promulgation, publication, and inspection of state agency rules, determinations, and other matters; to provide for the printing, publishing, and distribution of certain publications; to provide for state agency administrative procedures and contested cases and appeals from contested cases in licensing and other matters; to create and establish certain committees and offices; to provide for declaratory judgments as to rules; to repeal certain acts and parts of acts; and to repeal certain parts of this act on a specific date," by amending section 48 (MCL 24.248), as amended by 1999 PA 262.

Sec. 48: "(1) If an agency finds that preservation of the public health, safety, or welfare requires promulgation of an emergency rule without following the notice and participation procedures required by sections 41 and 42 and states in the rule the agency's reasons for that finding, and the governor concurs in the finding of emergency, the agency may dispense with all or part of the procedures and file in the office of the secretary of state the copies prescribed by section 46 endorsed as an emergency rule, to 3 of which copies shall be attached the certificates prescribed by section 45 and the governor's certificate concurring in the finding of emergency. The emergency rule is effective on filing and remains in effect until a date fixed in the rule or 6 months after the date of its filing, whichever is earlier. The rule may be extended once for not more than 6 months by the filing of a governor's certificate of the need for the extension with the office of the secretary of state before expiration of the emergency rule.

"(2) If the director of the department of community health determines that an imminent danger to the health or lives of individuals in this state can be prevented or controlled by scheduling a substance as a controlled substance under section 2251(4) of the public health code, 1978 PA 368, MCL 333.2251, and the administrator determines that the substance should be scheduled or rescheduled as a controlled substance, the department of licensing and regulatory affairs may dispense with all or part of the procedures required by sections 41 and 42 and file in the office of the secretary of state the copies prescribed by section 46 endorsed as an emergency rule, to 3 of which copies shall be attached the certificate of approval and the director of the department of community health's notification under section 2251(4) of the public health code, 1978 PA 368, MCL 333.2251. The office of regulatory reinvention shall submit the emergency rule draft language to the legislative service bureau for its formal certification within 7 business days of receipt from the department of licensing and regulatory affairs. The legislative service bureau shall issue a certificate of approval indicating whether the proposed rule is proper as to all matters of form, classification, and arrangement within 7 business days after receiving the submission and return the rule to the office of regulatory reinvention. If the legislative service bureau fails to issue a certificate of approval within 7 business days after receipt of the submission for formal certification, the office of regulatory reinvention may issue a certificate of approval. If the legislative service bureau returns the submission to the office of regulatory reinvention before the expiration of the 7-business-day time period, the 7-business-day time period is tolled until the rule is returned by the office of regulatory reinvention. The legislative service bureau shall have the remainder of the 7-business-day time period to consider the formal certification of the rule. Upon receipt from the legislative service bureau, the office of regulatory reinvention shall, within 7 business days, approve the proposed rule if it considers the proposed rule to be legal and appropriate. An emergency rule adopted under this subsection remains in effect until the earlier date of the following:

"(a) An identical or similar rule is promulgated.

"(b) An identical or similar bill is enacted into law.

"(c) The administrator determines that the emergency rule is no longer necessary.

"(d) Six months after the date of its filing, which may be extended for not more than 6 months by the administrator upon filing a certificate of extension with the office of secretary of state before the expiration of 6 months after the date of its filing.

"(3) An emergency rule shall not be numbered and shall not be compiled in the Michigan administrative code, but shall be noted in the annual supplement to the code. The emergency rule shall be published in the Michigan register pursuant to section 8.

"(4) If the agency desires to promulgate an identical or similar rule with an effectiveness beyond the final effective date of an emergency rule, the agency shall comply with the procedures prescribed by this act for the processing of a rule which is not an emergency rule. The rule shall be published in the Michigan register and in the code."

Sponsored by Pat Somerville

Approved by House, Senate and Governor, assigned PA 181

SENATE BILLS

SB 1223 — Prohibiting pharmacist interchanging an anticonvulsant drug without notification to and consent of prescribing physician and patient

A bill to amend 1978 PA 368, "Public Health Code" (MCL 333.1101-333.25211) by adding section 17769.

Sec. 17769: "A pharmacist shall not interchange an antiepileptic drug or formulation of an antiepileptic drug that is prescribed for the treatment of epilepsy or the treatment or prevention of seizures without the prior notification of and the signed informed consent to the interchange by the prescribing physician and the patient or the patient's parent, legal guardian, spouse, or other legal representative."

Sponsored by David Hildenbrand

Referred to Committee on Health Policy

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

Telemedicine

Continued from page 1

and physicians has grown exponentially in recent years, prior to the passage of the laws the use of telemedicine was largely unregulated by the state. In fact, no one could even say with certainty what exactly constituted "telemedicine" — was it a physician corresponding with patient via email, or was it a physician Skyping with a patient to examine the patient's physical condition? Or both?

The new laws cure this ambiguity. Now, telemedicine is defined by state law as: "[t]he use of an electronic media to link patients with health care professionals in different locations. To be considered telemedicine under this section, the health care professional must be able to examine the patient via a real-time, interactive audio or video, or both, telecommunications system and the patient must be able to interact with the off-site health care professional at the time the services are provided."

The law also provides that insurers "shall not require face-to-face contact between a health care professional and a patient for services appropriately provided through telemedicine." While health care industry guidance from professional organizations such as the Federation of State Medical Boards or American Osteopathic Association suggests that there should be at least one face-to-face encounter before a physician should treat a patient using telemedicine, the Michigan law is silent on this initial visit.

Importantly, the laws do require that all telemedicine services should be provided by a health care professional who is licensed, registered, "or otherwise authorized to engage in his or her health care profession" in the state where the patient is located. In other words, a Michigan patient may not receive telemedicine services by a physician in Pennsylvania or Illinois unless the physician is authorized to practice medicine in Michigan.

Conversely, a Michigan physician may not treat an out-of-state patient via telemedicine — even if the patient is a regular patient of the physician and usually lives in Michigan. So, for example, a Michigan resident vacationing in California could not be treated by his or her physician via telemedicine.

Additionally, telemedicine services are still subject to the regular terms and conditions between the patient and the insurer, such as co-payments, co-insurance, deductibles, and approved payment amounts.

It is important to note that the bill only applies to private health insurers in Michigan, and payment for government-funded health care programs such as Medicare or Medicaid are subject to different payment rules. Health care providers who wish to use telemedicine in conjunction with treating Medicare and Medicaid patients should consult with a health care attorney to determine the exact scope of reimbursement rules.

Overall, the new laws give a green light to providers to use real-time interactive technology to treat patients. This could have extensive implications in fields of practice such as mental health counsel, psychiatry, or psychology.

Additionally, physicians may now schedule appointments with patients via telemedicine, which can be especially beneficial for patients who are elderly, homebound, or without reliable means of transportation. The new laws are a start to embracing the positive changes brought about by technology.

Mercedes Varasteh Dordeski is at attorney at Frank Haron Weiner PLC, and represents health care providers with issues pertaining to business transactions, employment, licensing, medical staff credentialing and privileges, NPDB reporting, and regulatory compliance. She also authors the Health Care Lawyers Blog (www.healthcarelawyerblog.com). Dordeski may be contacted at (248) 952-0400 or mdordeski@fhwnlaw.com.

Michigan Medical Law Report
mimedicallaw.com

VERDICTS & SETTLEMENTS

Woman asserts doctor misdiagnosed her

Symptoms of brain bleed not present on first visit, says defense; jury agrees

NO CAUSE

Plaintiffs Carol and Mark Sells sought compensatory damages from defendants Dr. John Sosa, Orion-Oxford Urgent Care PC and William Beaumont Hospital on claims of medical malpractice.

On Oct. 10, 2008, Carol Sells developed a severe headache on the right side of her head, and could not sleep. It continued through the next night. She had no history of migraines.

On Oct. 12, Sells went to Orion-Oxford Urgent Care, where Sosa evaluated her. He noted in the medical record "? Sinusitis triggering a migraine headache," and prescribed a Z-pack antibiotic. He told Sells to take Tylenol or Motrin for the headache and rest. Sells followed treatment orders for the next two days, but there was no improvement, and she stayed home from work.

On Oct. 15, Mark Sells found Carol Sells at home sweating profusely and unresponsive. At a hospital, she was diagnosed with a right temporal parietal intraparenchymal hemorrhage, with a significant amount of edema and a compression and shift of the midline structures.

Sells was transferred to another hospital, where two craniotomies were performed to relieve pressure, and she was hospitalized for eight weeks. Her entire left side was significantly compromised, and she received home physical, occupational and speech therapy.

Type of action: Medical malpractice
Types of injuries: Severe and permanent neurological damage, left-side paralysis
Name of case: *Sells, et al. v. Sosa, et al.*
Court/Case no./Date: Oakland County Circuit Court; 2011-117043-NH; April 19, 2012
Tried before: Jury
Name of judge: Leo Bowman
Demand: $3.5 million
Verdict: No cause of action
Case evaluation: $750,000 (Beaumont), $200,000 (Sosa)
Most helpful experts: Dr. William Leuchter, neurology, Southfield; Dr. Thomas Graves, family practitioner, Algonac; Dr. William Thompson, emergency family practice, Southfield
Insurance carrier: MHA
Attorneys for plaintiff: Steven Galbraith, Laura James
Attorneys for defendant: Richard O'Connor, Elizabeth Wilhelmi, D. Jennifer Andreou

Plaintiff asserted that Sosa did not obtain a full physical exam before making a diagnosis and formulating a treatment plan; did not order or obtain necessary diagnostic and radiological tests; and misdiagnosed plaintiff with sinusitis.

Defendant contended that plaintiff did not have symptoms likely indicating intracranial bleeding or sinus thrombosis upon her first visit for treatment. It also was argued that patients who experience what plaintiff eventually had also have other symptoms of a stroke, such as weakness on one side of the face, difficulty speaking and blurred vision, which plaintiff experienced three days after Sosa treated her.

The jury found for the defendant and issued a no-cause-of-action verdict.

Damages sought for ulcer after hernia repair

Bleed found in woman's upper GI tract after her gastric bypass surgery

NO CAUSE

Plaintiff Theresa Abraham sought compensatory damages from Dr. Hugh Lindsey on claims of medical malpractice for development of an ulcer that followed hernia repair, which was necessitated by gastric bypass surgery.

Abraham underwent Roux-en-Y gastric bypass in 2003, and in 2006 went to Lindsey for evaluation of a hernia resulting from the surgery. Lindsey performed an incisional hernia repair March 1, 2007. Because of the difficulty with pain management, Abraham was provided with a non-steroidal anti-inflammatory drug (NSAID), as the pain reliever she was taking was inadequate.

Following Abraham's March 3 discharge, she contacted Lindsey with complaints of continuing pain. She was given a prescription for Toradol, a strong NSAID, and continued to rotate her NSAID medication with narcotic pain medication.

A bleed was later identified in Abraham's GI tract. The bleed's location was found in the duodenum, in the upper GI tract, which had been resected during the gastric bypass surgery.

Plaintiff argued that defendant inappropriately prescribed NSAIDs to a post-Roux-en-Y gastric bypass patient, causing an ulcer in the resected portion of the GI tract.

Defendant contended that the care provided was entirely appropriate and within the standard of care. It was further asserted that the contraindication for use of NSAIDs in a post-gastric bypass patient is generally restricted to the immediate post-gastric bypass surgery time period.

Type of action: Medical malpractice
Type of injuries: Ulcer following hernia repair necessitated by gastric bypass surgery
Name of case: *Abraham v. Lindsey, et al.*
Court/Case no./Date: Eaton County Circuit Court; 09-821-NH; May 10, 2012
Tried before: Jury
Name of judge: Calvin Osterhaven
Demand: $275,000
Verdict: No cause of action
Case evaluation: $275,000
Most helpful experts: Dr. James McQuiston, general surgery, Macomb Township; Dr. Stanley Sherman, general surgery, Grand Rapids
Insurance carrier: ProAssurance
Attorney for plaintiff: Kitty Groh
Attorney for defendant: Brett Bean

The jury deliberated for three hours before returning a no-cause-of-action verdict favoring defendant.

Estate claims doctor improperly assessed abdominal pain

Bleed was most likely a spontaneous one, standard of care followed, says defense

NO CAUSE

Roxanne Filegar, personal representative of the Estate of James Buckingham, sought compensatory damages from defendant Dr. Marie Claire Maroun, on claims of medical malpractice.

Buckingham, 71, was admitted to Harper- Hutzel Hospital on March 22, 2008, for treatment of respiratory problems. Because of atrial fibrillation (irregular

VERDICTS & SETTLEMENTS

Type of action: Medical malpractice
Types of injuries: Rectus sheath hematoma, stroke
Name of case: *Filegar, et al. v. Maroun*
Court/Case no./Date: Macomb County Circuit Court; 10-1299-NH; June 14, 2012
Tried before: Jury
Names of judges: Edward Servitto, visiting judge Donald Miller
Verdict: No cause of action
Case evaluation: $400,000
Most helpful expert: Dr. Gordon Moss, internal medicine, Farmington Hills
Insurance carrier: The Doctors Co.
Attorneys for plaintiff: Shirley Burgoyne, Max McCullough
Attorney for defendant: William McCandless

heartbeat) and associated risk of stroke, he had been on blood-clot prevention medicine Coumadin for more than 10 years, with the most recent dosage 4 mg per day.

On admission, Buckingham's international normalized ratio (INR, which measures thinness of the blood) was supratherapeutic, making him at risk for a bleed. The initial attending hospitalist ordered a pharmacy consult for Coumadin dosing and reduced the normal dosage.

The next INR was sub-therapeutic (risk of stroke), and pharmacy recommended to the hospitalist that Buckingham be placed on bridge therapy to better control the INR. Bridge therapy began March 24, but the INR levels through March 27 remained sub-therapeutic.

On March 27, Maroun assumed care of Buckingham, who was improving and nearly ready for discharge. Though set for transfer to another hospital March 28, he did not qualify. Because Buckingham had no one to go home to, Maroun permitted him to remain overnight and approved a March 29 discharge.

Maroun left the morning of March 29, then before noon, a nurse called Maroun and advised that Buckingham was complaining of significant abdominal pain. X-rays demonstrated constipation, and Buckingham's vitals crashed. Maroun ordered a stat CT scan of the abdomen, which reflected a retroperitoneal bleed.

Buckingham went to surgery March 30. A rectus sheath hematoma (accumulation of blood in the sheath of the rectus abdominis muscle) with approximately 2.5 liters of blood was revealed. On April 18, Buckingham suffered a severe stroke. At a long-term care facility, he made some improvement, and died March 2011 of heart failure.

Before his death, Buckingham had testified in deposition that Maroun never physically examined him March 27 and 28, and ignored his complaints of extreme abdominal pain. He asserted Maroun was negligent for failing to properly assess and/or address his complaints and that she "abandoned" him by not seeing him March 29. In addition, it was argued that the bleed came from the hospital's improperly injecting Lovenox (an anti-coagulant) in with the Coumadin.

Defendant contended that all of the anticoagulation therapy was appropriate; that Maroun properly continued the bridge therapy when she assumed the patient's management March 27; that she properly approved his discharge March 28; and that the standard of care did not require Maroun to re-examine Buckingham on March 29.

In addition, it was argued that the bleed likely began spontaneously (a recognized complication from anti-coagulopathy) shortly after the abdominal X-ray, perhaps from coughing or constipation strain. Further, had Buckingham been discharged March 28 as originally planned, and the bleed started when he was home alone, he almost certainly would have died.

The jury deliberated for 45 minutes before issuing a no-cause-of-action verdict.

Standard of care disputed in accident with catheter

Defense shows tube too narrow for gel to be used after plaintiff claims it was

NO CAUSE

Plaintiff Felix Casaceli sough compensatory damages from defendants St. John North Shores Hospital and Cheryl Bailey, RN, for claims of medical malpractice.

On March 10, 2009, Casaceli fractured his right heel while snowboarding. His podiatrist sent him to St. John North Shores in Harrison Township, and an open reduction with internal fixation on his right heel was performed. As part of the sterility process for surgery under general anesthesia, a Foley catheter was to be inserted into Casaceli's penis in order to reach the bladder.

It was alleged that Bailey, the nurse, placed lubricated numbing gel into the balloon of the catheter instead of sterile water, then inflated the balloon. Also, per the medical chart, the balloon wasn't placed completely into Casaceli's bladder, but may have been wholly or partially within the urethra when inflated.

When the balloon could not be deflated, the catheter could not be removed due to maintaining the sterility of the procedure. The catheter was removed traumatically at St. John's main hospital in Detroit. It caused soft tissue damage, including to the muscles and nerves of Casaceli's urethra and penis, resulting in permanent incontinence and urethral damage.

Plaintiff argued that the standard of care required the catheter balloon to be inflated with sterile water from the syringe included in the catheter kit, and not lubricating numbing gel, as Bailey was alleged to have done. Further, it was argued that Bailey was negligent for doing so.

Defendants denied that the catheter was filled with gel, but instead did have sterile water. It was demonstrated in court that gel cannot be injected into the balloon because of the size of the catheter tube and the kind of syringe used.

The contended reason for the accident was that the interior layer of latex between the two open channels in the catheter tubing had folded, making the urine unable to flow out through one channel, and sterile water in through the other channel.

In addition, it was denied that permanent incontinence and urethral damage was diagnosed by plaintiff's urologist. Instead, it was argued, if there were detectable abnormalities, they would have been found via objective testing, and two different urologists' comprehensive workups, which were done on the plaintiffs' behalf, did not detect such permanent urological injury.

The jury found for the defendants and issued a no-cause-of-action verdict.

Type of action: Medical malpractice
Types of injuries: Soft tissue damage, nocturia, permanent incontinence and urinary urgency, urethral damage
Name of case: *Casaceli v. St. John North Shores Hospital, et al.*
Court/Case no./Date: Macomb County Circuit Court; 10-2976-NH; April 4, 2012
Tried before: Jury
Name of judge: Diane Druzinski
Demand: $400,000
Verdict: No cause of action
Case evaluation: $300,000
Most helpful experts: Valerie Gorham, nursing, Farmington; Dr. Gary Faerber, urology, Ann Arbor
Insurance carrier: Self-insured
Attorney for plaintiff: Christopher Sciotti
Attorney for defendant: Jane Garrett

Woman contends leg length discrepancy following surgery

It was needed to maintain post-operative stability of hip joint, doctor attests

NO CAUSE

Plaintiffs Mary and Jay Jeffrey sought compensatory damages from defendant Dr. Paul Kenyon on medical-malpractice claims following hip replacement surgery.

On Jan. 2, 2007, Kenyon performed hip replacement surgery on Mary Jeffrey, who had a longstanding complaint of groin pain, with X-rays showing degenerative changes in the hip joint.

Shortly after surgery, Jeffrey became concerned because she felt that one leg was longer than the other. Kenyon tried to assure her that it was a common post-operative feeling and that, even if one leg were a bit longer, it could be balanced out in the near future when she would have her other hip replaced.

Rather than wait for Kenyon, Jeffrey sought the services of another orthopedic surgeon, who tried to convince her to wait. Jeffrey refused, and although a subsequent operation to try to gain leg length equality was successful, the leg length equality was gained by actually moving 1.5 cm of her femur and only adjusting the hip replacement prosthesis .5 cm.

Shortly after, her other hip was replaced by the subsequent treating orthopedic surgeon, but Jeffrey complained that she continued to have ongoing pain and gait instability as a result of the alleged leg length discrepancy from the original surgery.

Plaintiff's expert suggested that a leg length discrepancy of 1.5 cm would be within the standard of care, and a 2 cm discrepancy formed the basis for plaintiff's claim.

Defendant contended that, while slightly lengthening plaintiff's leg during hip replacement surgery, it had to be done in order to maintain post-operative stability of the hip joint. Defense experts' explanation as to why Kenyon did so was convincing to the jury, according to defense counsel.

The jury found for the defendant and issued a no-cause-of-action verdict.

Type of action: Medical malpractice
Type of injuries: Leg length discrepancy following hip replacement surgery
Name of case: *Jeffrey, et al. v. Kenyon*
Court/Case no./Date: Jackson County Circuit Court; 09-1978-NH; June 11, 2012
Tried before: Jury
Name of judge: John McBain
Verdict: No cause of action
Most helpful experts: Dr. James Bolz, orthopedic surgery, Novi; Dr. Philip Schmitt, orthopedic surgery, Commerce Township
Insurance carrier: The Doctors Company
Attorneys for plaintiff: Thomas Blaske, John Turck
Attorney for defendant: Brett Bean

Formation of athlete's compartment syndrome disputed in Kalamazoo

Symptoms leading up to player's foot drop weren't apparent at first ER visit

NO CAUSE

Plaintiff Rudy Robinson sought compensatory damages from defendants Dr. Arnis Pone and Southwestern Michigan Emergency Services PC on claims of medical malpractice.

On Feb. 27, 2007, Robinson, a freshman football recruit at Western Michigan University, injured his left ankle during preseason football training and testing. Despite being in great pain, the following morning he went straight to the training/testing session, where his left foot gave out.

Type of action: Medical malpractice
Type of injuries: Alleged failure to diagnose compartment syndrome leading to loss of muscles in anterior compartment of patient's left lower leg, causing foot drop, loss of college football career, pain and suffering
Name of case: *Robinson v. Pone, et al.*
Court/Case no./Date: Kalamazoo County Circuit Court; 09-0410-NH; June 15, 2012
Tried before: Jury
Name of judge: J. Richardson Johnson
Demand: $195,000
Verdict: No cause of action
Case evaluation: $195,000
Most helpful experts: Dr. Theodore Glynn, emergency medicine, East Lansing; Dr. Oliver Hayes III, emergency medicine, Christiansburg, Va.; Dr. Karl Roberts, orthopedic surgery, Grand Rapids
Insurance carrier: ProAssurance
Attorney for plaintiff: Don Ferris
Attorneys for defendant: Brian Whitelaw, Timothy Buchalski
Key to winning: Helping the jury understand the complex medical issues and the reasons why the care provided by defendant was well within recognized standards

On examination at Bronson Hospital, Pone found moderate tenderness and swelling, and diagnosed ankle sprain. He discharged Robinson with instructions to return if symptoms worsened in any way, or if conditions such as numbness, tingling, or a cold, pale foot developed.

The next day, Robinson told WMU's head trainer his condition was worsening. The trainer was concerned about the possibility of compartment syndrome, which involved inflammation of the muscles in the anterior compartment of the patient's lower leg. Robinson had lost the ability to dorsiflex (point the toes up), and developed numbness and tingling, but did not return to the ER as instructed.

The team physician, an orthopedic surgeon, was called. Upon examining the leg and feeling a hard, tense compartment, Robinson was sent to the hospital, and a fasciotomy was performed. Robinson testified that he developed paralysis (foot drop) a couple of hours before seeing the trainer that afternoon, approximately seven hours before the surgery.

Robinson did not regain function. Over the next several days, additional debridements were undertaken until the entire muscle was removed from the anterior compartment of the left lower leg. The net result was permanent foot drop and an end to Robinson's football career.

Plaintiff's experts (emergency medicine and vascular surgery) testified that plaintiff had elevated pressures in the ER, and had "evolving compartment syndrome" when seen by Pone. The defense countered that evolving compartment syndrome is not a diagnosis, and that increased pressures in a compartment are not compartment syndrome unless the pressures are high enough to cut off blood flow and cause symptoms.

Defense further argued plaintiff did not have compartment syndrome when seen in the ER, as patients with compartment syndrome often have many of the so-called "five P's": pain, pallor, pulselessness, paresthesia (numbness and tingling) and foot drop. It was further contended that plaintiff had only pain when seen in the ER, and developed paresthesias and paralysis approximately 30 hours after being seen in the ER, which was when compartment syndrome actually began.

The defense also argued that one of hallmark findings with compartment syndrome is pain that is non-responsive to narcotics. Plaintiff was able take a nap a couple of hours after being given Vicodin in the ER, which is not consistent with compartment syndrome. Further, had plaintiff returned to the ER upon the development of new symptoms, as instructed, he would have had a much better chance to avoid permanent harm.

The jury found for the defendants and issued a no-cause-of-action verdict.

Changing

Continued from page 1

through which a physician can become affiliated with a hospital, such as: direct employment; physician practice acquisition; clinical integration; medical directorships; compensated on-call coverage; pay for performance; and accountable care organizations (ACOs).

Working relationships organized under any of these models should be memorialized through a negotiated written contract or agreement and reviewed by an attorney with health care expertise. Any contracts or agreements for these models should all include careful consideration of the following provisions:

(1) Defined job responsibilities and accountability. What roles are the physician expected to fulfill at the hospital (clinical and administrative)? These should be defined in any written contract or agreement. How much autonomy and independence will the physician have? Who does he/she report to? Can the physician still retain an outside practice?

(2) Moonlighting activities, inside the hospital and outside. Will the physician be permitted to moonlight for other departments or cover other physicians? Is locum tenens outside of the hospital entity permitted? What activities require advance permission and from whom? Who will receive the royalties if the physician writes a book or invents a new medical device? What if the physician is paid for a speaking engagement? Who gets the fee?

(3) Privileges. Are the physician's hospital privileges (if applicable) linked to the contract or agreement such that, if the contract or agreement is terminated, the hospital privileges end?

(4) Hours worked and on-call requirements. Minimum hours worked requirements and on-call responsibilities should be clearly defined, realistically achievable, and should include administrative and all other non-clinical duties. Is on-call time compensated separately?

On call responsibilities that are open-ended or variable based on the demand by a hospital administrative entity should be avoided, and the call coverage should be shared equally among all physicians in the same practice area. Similarly, work site locations should be specified to the extent that the hospital has numerous locations or branches or satellites spread across far distances.

(5) Compensation (i.e., fair market value, productivity, quality based, or some other arrangement). Whatever the form of the compensation, it is essential that the physician understand how his/her compensation will be calculated.

Today, it is common for compensation arrangements to be based on RVU (relative value units) formulas which are tied to achieving and maintaining certain annual productivity levels. With RVUs, a physician may be guaranteed certain compensation only if they meet a specific annual RVU benchmark, such as the RVUs during the recent 12-month period prior to the start of hospital employment.

If RVU targets are not met, then compensation typically is reduced. If RVU targets are exceeded, depending on the agreement, a bonus may be paid.

Thus, the formula for calculating the RVU and the RVU benchmarks, or any other compensation formula, should be reviewed carefully by a CPA or accountant with expertise in health care compensation to ensure that they are realistic and appropriate.

It also is essential that the services being used by the physician to evaluate the RVU or other compensation formula are the same as the services being considered by the hospital.

(6) Subsidies and shared savings. For a physician who is integrating his practice into a hospital or selling his practice's assets, who receives the benefit for government subsidies for electronic medical records (EMRs)? In an ACO, will the physician participate in any shared savings?

(7) Terminating the relationship. The duration of any contractual relationship should be specified, as well as renewal notice requirements, and the circumstances under which the relationship can be terminated. For-cause terminations should be defined. How much notice is required for non-cause terminations?

If the contract is terminated early or if production benchmarks are not met, does the hospital have the right to seek the return of any compensation or bonuses paid?

(8) Restrictive covenants. Physicians should carefully consider the scope of any restrictions, which could, depending on their breadth, require that the physician uproot his family to a new city or, worse, state.

The contract or agreement should delineate the situations under which any non-compete or non-solicitation clause will and will not apply. If the physician is terminated without cause or if the hospital breaches the employment agreement, the restrictive covenant should not necessarily apply. If a physician's employment or arrangement ends, what access will he have to patient records?

(9) Malpractice, continuing legal education, supplies, and equipment. Who is responsible for paying these things? Who pays tail coverage? Working for the hospital can mean more performance management and standardizing equipment as part of cost-saving strategies. How much control will the physician have over his methods of clinical care, choice of supplies and equipment, scheduling, and staff?

In conclusion, no matter what form it takes, if you are considering employment with a hospital or integrated entity, it is imperative that you discuss the arrangement with legal counsel who specializes in health law and can review and negotiate any written contract or agreement, as well as a CPA or accountant who can evaluate the financial aspects of the arrangement and the compensation being offered.

Such experienced professionals can help you evaluate what form of relationship is best suited for your needs and concerns, and ensure that the relationship undertaken meets your short- and long-term expectations.

Michelle Bayer specializes her practice in employment law. She has worked with health care practices and professionals regarding their business and employment issues, as well as with credentialing, privileging and licensing matters. She can be reached at (248) 568-5714 or by email at mbayer@mbayerlaw.com.

Accountable care

Continued from page 5

discussed above and must not be materially inaccurate or misleading.

Beneficiary notification

ACO participants must notify beneficiaries at the point of care regarding the MSSP. Notification must be made by posting signs and via a standardized written notice.

Even though these notifications are required, CMS views the documents as marketing materials that must meet the requirements discussed above (including the submission of the materials to CMS).

Avoidance of at-risk beneficiaries

CMS is required by statute to monitor ACOs for behavior that would indicate that the ACO is avoiding "at-risk beneficiaries."

Some factors that can cause a beneficiary to be considered an "at risk beneficiary" include: a high risk score on the CMS-HCC risk adjustment model; two or more hospitalizations or emergency room visits each year; dual eligibility for Medicare and Medicaid; a high utilization pattern; one or more chronic conditions; a recent diagnosis that is expected to result in increased costs; a disability that qualifies the beneficiary for Medicaid coverage; or a diagnosis of mental health disorder or substance abuse.

If CMS determines that an ACO has been avoiding at-risk beneficiaries, the ACO will be subject to sanctions, including possible termination from the MSSP. Thus, it is important that participating providers understand the prohibition on avoiding at-risk beneficiaries.

Data Use Agreement

Subject to beneficiaries' rights to opt-out of data sharing, CMS may share beneficiary data with ACOs for activities such as quality assurance/quality improvement and population based activities. However, in order to receive such data, ACOs must sign a Data Use Agreement and must require all participants to comply with the terms of the Data Use Agreement.

Failure to comply with the Data Use Agreement provisions will cause the ACO to be ineligible to receive beneficiary data and could subject the ACO to termination and other sanctions/penalties.

Anti-kickback, Stark and Civil Monetary Penalties

CMS and the Office of Inspector General (OIG) have jointly established waivers of the Stark regulations, the federal anti-kickback statute (the AKS), and certain CMP law provisions to certain arrangements as necessary to implement the MSSP.

However, it is important for ACOs and physicians to understand that these waivers are limited, and are not a wholesale waiver of these laws and regulations.

The available waivers, each of which contains very specific criteria, protect certain pre-participation arrangements, participation arrangements, shared savings distributions, arrangements that comply with a Stark exception, and beneficiary incentives.

ACOs participating in the MSSP need physician "buy in" to be successful, not only because of the physicians' direct responsibilities for providing efficient and high quality health care, but also because physicians will play an important role in complying with program requirements.

It is important for ACOs and physicians to take the MSSP's regulatory program requirements seriously in order to successfully receive shared savings distributions and avoid penalties.

Amy Fehn is a partner with Wachler & Associates PC. She is a former Registered Nurse who has been counseling health care providers for the past 12 years on regulatory and compliance matters. Fehn is a member of the American Health Lawyers Association, the Health Care Law Section of the State Bar of Michigan, and the American Bar Association's Health Law Section. Contact her at (248) 544-0888 or afehn@wachler.com.

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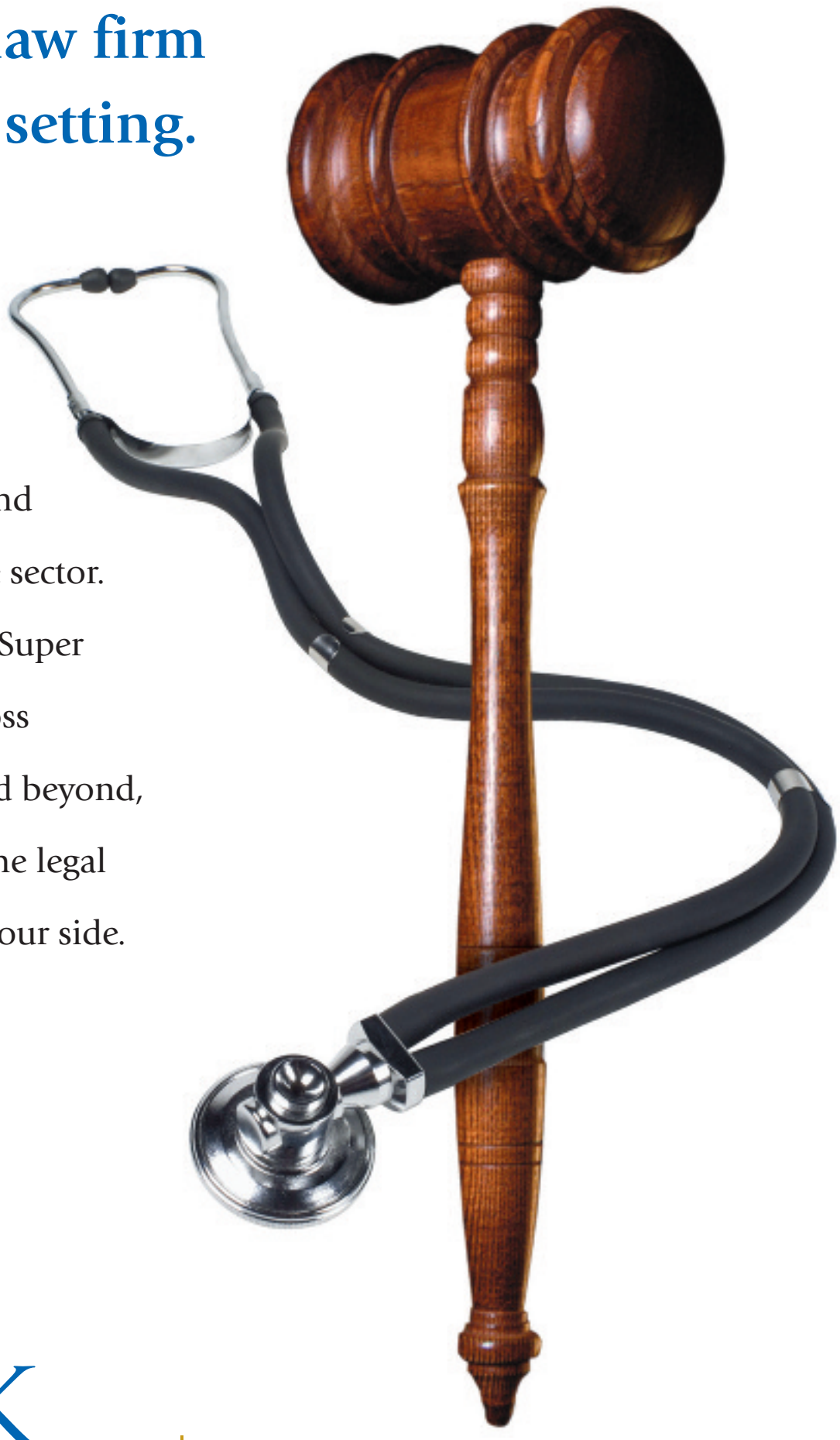

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