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Physicians: Keep records of medical care you give to your family members

By Suzanne D. Nolan, Esq.

Are you a physician who provides medical care to family members without keeping a formal written medical record of such care?

If so, it is time for you — and every other physician who might consider providing medical care to family members — to think about the type of records that should be kept regarding such care, and how to make those records accessible to other treating physicians.

While providing medical care to and writing prescriptions for family members is a common practice and, for the most part, ethically permissible, physicians should take note that family ties do not negate the legal requirements regarding medical record-keeping.

Further, failure to do so may even place a physician's medical license in jeopardy.

Despite the prevalence of the practice, providing routine medical care to family members is frowned upon even though it may be ethically ap-

See "Family," page 15



Physicians should take note that family ties do not negate the legal requirements regarding medical record-keeping.

Relocating your medical practice: are REOs the right market for you?

By Kasturi Bagchi

With real estate prices declining and so much vacant office space on the market, now may be the right time to find new space to satisfy the needs of your medical practice.

Even in this buyer's market, however, a deal that is too good to be true probably is.

This old adage rings even more true if you are searching bank inventories of real property, commonly known as Real Estate Owned (REO). However, when you enter the world of REOs as a prospective purchaser, there are two fallacies of which you should be wary.

Bank owned or not?

The first common misconception is that all REOs are actually owned by the bank.

On Web sites and advertisements, the term REO has become synonymous with real estate owned by the bank after an un-

successful sale at a foreclosure auction where no one bids.

The reality is, it is a regulatory term of art applicable to a broader category of assets. REO stems from the regulatory phrase "Other Real Estate Owned." Under this act, banks are only permitted to hold real estate other than their own bank premises for limited periods of time, and earnings from such other real estate must be reported separately.

Notably, as published in a handbook of the Comptroller of the Currency Administrator of National Banks, "certain troubled loans secured by real estate are considered to be "in substance fore-

closures' and are also treated as other real estate owned."

An "in substance foreclosure situation" is gener-

The more information you can get up front before you make an offer ... will help you avoid the risk of redemption and risks associated with "as-is" sales.



ally characterized by a borrower with little or no equity and the sale of the property being the only source of repayment.

Consequently, a borrower may still be in possession and have legal title to the property, which has been labeled as an REO by the

See "Relocating," page 8

New law aims at achieving parity in coverage for mental illnesses

By Ross A. Hammersley, Esq.

For years, it has become increasingly difficult for American families to obtain health insurance coverage that adequately meets the needs of loved ones afflicted with mental illness or addiction disorders.

Part of this problem has been caused by an imbalance in the availability of health insurance for these diseases.

In response, the Paul Wellstone & Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Wellstone-Domenici Act) was enacted last fall, seeking to place the health insurance coverage provided to patients with mental illnesses and substance-abuse disorders on par with that of medical and surgical benefits.

The Act takes effect Jan. 1, 2010, so physicians should take note of

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Physicians can play large role in school defibrillator use

Health Care Justice

By Maro E. Bush, Esq.



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Each year, 7,000 children and adolescents are affected by sudden cardiac arrest. Of those affected, 500 succumb to sudden cardiac death.

Physicians know that automated external defibrillators (AEDs) are the most crucial tools used to save lives during sudden cardiac arrest (SCA).

In a recent study, researchers found that school-based AED programs provide a high survival rate for both student athletes and older non-students who suffer SCA on school grounds. In the survey involving 1,710 U.S. high schools with AEDs on site, nearly two-thirds of SCA victims survived.

Unfortunately, Michigan schools are not required to have AEDs on site. As a result, many schools lack AED programs. This poses a serious threat to students that have known heart and health conditions that put them at high risk for SCA.

Physicians can play an important role in ensuring their patients have access to AEDs in schools, which not only benefits patients with known heart and health conditions, but, also, potentially other students and non-students suffering from an underlying or undiagnosed condition.

Under the federal Rehabilitation Act of 1973, students diagnosed with a heart condition or other health impairment that puts them at risk for SCA are entitled to have access to an AED at school and on school-related field trips.

However, problems arise when schools are unclear about a student's disability (especially if it is not readily apparent), which can result in reluctance to establish an AED program.

Through creating detailed health plans and AED prescriptions to facilitate a clear understanding of a student's disability and how it should be accommodated, physicians become their patient's most important advocate.

IHPs and Section 504 Plans

Chronic health conditions or disabilities can interfere with students' school participation and achievement. Students with minor conditions may require basic school nursing services such as health care monitoring or medication administration. However, some students need specialized services, which require comprehensive health care plans.

Individualized Healthcare Plans (IHP) and Section 504 Plans (504 Plans) are used to identify a student's disability and corresponding need for reasonable accommodation. Ideally developed as a result of a collaborative effort between the student, family, health care team, and the school/school district, these plans ensure that there is adequate communication about the student's disability and identify the steps that will be taken to accommodate the student.

An IHP is a written document that outlines the student's specific medical needs and may include medical diagnosis, health-care services required, emergency care plan, field trip plan (if applicable) and other considerations that are integral to safeguarding a student's health and well-being.

Depending on the circumstances and the severity of the student's health condition, IHPs may be written by the student's health care team or the school's nurse. Many organizations, including hospitals, medical centers and professional associations, have created model IHPs for specific conditions.

504 Plans are named after Section 504 of the Rehabilitation Act of 1973, which prohibits discrimination against individuals with disabilities by programs that are recipients of federal funds.

Programs help prevent problems

These Plans outline the student's health concerns, the basis for determination of the disability, how the disability affects a major life activity and the reasonable accommodations that are necessary to ensure the student has the same access to education as children without disabilities.

504 Plans help prevent potential problems or misunderstandings ahead of time. They may be developed as a result of a request by the school or the parents/guardians.

To be protected under Section 504, a student must be found to:

- Have a physical or mental impairment that substantially limits one or more major life activities;
- Have a record of such an impairment; and
- Be regarded as having such an impairment.

The determination of whether a student has a physical or mental impairment that substantially limits a major life activity is made on an individual basis.



Physicians can play an important role in ensuring their patients have access to AEDs in schools, which not only benefits patients with known heart and health conditions, but potentially other students and non-students suffering from an underlying or undiagnosed condition.

The Section 504 regulatory provision defines a physical or mental impairment as any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more bodily systems.

Major life activities include functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

Although the format of 504 Plans can vary from school to school, one fact remains constant — the physician is in the best position to define or explain the patient's disability and how it affects or limits activities.

It is important to note that a medical diagnosis, although an important factor, does not automatically entitle a student to receive services under Section 504. Other considerations

include teacher recommendations, the student's physical condition and social/cultural background, and adaptive behavior.

In this scenario, the physician once again is the most qualified party to provide information and recommendations and to help facilitate a clear understanding of the situation.

Pending legislation

The Josh Miller HEARTS Act ("Helping Everyone Access Responsive Treatment in Schools") passed in the U.S. House of Representatives and was referred to the Senate Committee on Health, Education, Labor, and Pensions on June 8, 2009. It would establish a federal grant program to help increase the availability of AEDs in elementary and secondary schools across the nation.

An AED is a reasonable accommodation that could save a student's life if he or she goes into SCA. By becoming involved in the process of preparing detailed health care plans and AED prescriptions, physicians can ensure that their patients receive the proper care while attending school.

When a student requires an AED under a 504 Plan, the school district is responsible for purchasing the AED, maintaining it, making it publicly accessible and having staff trained to use it.

By becoming involved in the process of creating detailed IHPs or 504 Plans, physicians can provide their patients, and possibly others, with the life-saving AED programs to which they are entitled.

Making 'meaningful use' of electronic health records: Increase rewards, avoid penalties

By Gary A. Kravitz, Esq.

Many a tree has been sacrificed in written notifications about the incentives and penalties related to electronic health record (EHR) systems, as found in the Health Information Technology for Economic and Clinical Health (HITECH) Act.

Passed as part of the 2009 American Recovery and Reinvestment Act (the Stimulus Bill), HITECH contains incentives in the form of cash payouts to physicians who make "meaningful use" of EHR, and provides for reductions in Medicare and Medicaid payments for those who do not.

The focus on HITECH begs the question: how does a provider qualify for the available incentives, and avoid the potential penalties?

And, more importantly, how do physicians and practices begin implementing EHR systems that comply with HITECH mandates?

Time is of the essence in complying with HITECH, as the cash incentives are meant to encourage physicians to make meaningful use of EHR sooner, rather than later. Failing to make "meaningful use" of EHR by 2014 will result in ineligibility for incentives and a 1 percent penalty on Medicare reimbursements (which will increase over time).

There are similar incentives and penalties on the Medicaid side.

'Meaningful use'

Much of the recent discussion on how to qualify for stimulus incentives has centered on the term "meaningful use."

Taken straight out of the HITECH Act language, this phrase has been the subject of



Time is of the essence in complying with HITECH, as the cash incentives are meant to encourage physicians to make meaningful use of EHR sooner, rather than later. Failing to make "meaningful use" of EHR by 2014 will result in ineligibility for incentives and a 1 percent penalty on Medicare reimbursements.

several hearings and commentary.

The HITECH Act contained a general outline as to some of the requirements, and this broad outline has been further clarified in hearings and reports issued by the Health Information Technology Policy Council.

The Council issued its final "Recommendations to National Coordinator for Defining Meaningful Use" in August 2009.

Based on the guidelines in the report, it is expected that in order to meet the threshold, qualifying EHR systems must have the following components: electronic prescribing, certification, interoperability and clinical quality measures.

• **Electronic prescribing:** The HITECH Act clearly states that a critical component

to any EHR system is the ability to write prescriptions electronically. It is Congress' belief that e-prescribing will cut down on medical errors, save time for doctors and patients, and cut down on transaction costs.

• **Certification:** A practice must demonstrate that it is using certified EHR technology. This implies that there will be a certification process for each EHR software component or system; however, the Department of Health and Human Services (HHS) has not implemented a certification process yet.

It is important for providers to take note that electronic health records products that have received certification by the independent Certification Commission for Health Information Technology (CCHIT) will not nec-

essarily be certified for purposes of HITECH compliance.

• **Interoperability:** In plain English, this means the ability to share patient information with other providers, hospitals and governmental agencies.

The Health IT Policy Council's recommendations included specific goals such as the ability to exchange health information (specifically labs, care summary and medication lists) with external clinical entities.

The council also noted the need to ensure adequate privacy and security protections for personal health information (i.e., compliance with HIPAA and data sharing practices in the Nationwide Privacy and Security Framework).

There have already been several articles penned by authors fretting over the perceived privacy issues inherent with the mandatory sharing of patient data using various electronic methods. Therefore, the ability to adequately share information while simultaneously protecting it to the legal limit will be a challenging balancing act.

• **Adoption of Clinical Quality Measures:** In order to have a qualifying EHR system, a provider must report certain quality measures to CMS to demonstrate a goal of improving the quality, safety and efficiency of patient care.

The council recommended reporting on certain medical guideposts, such as percentage of smokers who are offered smoking cessation counseling and percentage of patients with LDL cholesterol under control.

The physician also must track the percent

See "Electronic," page 8

Cyber liability insurance to the rescue

New product picks up practice coverage where general liability policies leave off

Business of Medicine

By Suzanne D. Nolan, Esq.



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

Almost every medical practice has exposure to cyber liability risks. These are risks associated with e-business, the Internet, the security of computer networks and electronic data such as patient health information and financial information and the practice's own electronically-stored business data.

The financial harm and other burdens placed on a practice from breaches of patient privacy, breaches of a computer network's security, or damage to stored data can be severe. However, cyber liability insurance can mitigate the exposure of a practice to such financial harm and help a practice protect its good name.

It is becoming increasingly important for a practice to protect itself from both the risk of disclosing private patient information and the risk of harm to its computer networks.

Increased enforcement begins soon

In the past year, the burden on medical practices to protect the confidentiality of patient health and financial information has grown significantly due to the breach notification requirements of the Health Information Technology for Economic and Clinical Health Act (HITECH), which took effect Sept. 23, 2009; and the Federal Trade Commission's Red Flags Rule, pertaining to detecting and preventing identity theft, enforcement of which is scheduled to begin this November.

At the same time, practices are becoming more dependent on computer networks to access patient records and to bill third-party payers for medical services, with the attendant risk of interruptions to its business operations if computer systems are unavailable or stored data is corrupted.

Practices that operate Web sites are exposed to potential claims that the content of the Web site infringes a third party's copyright or trademark.

Privacy breaches, viruses, business interruption and infringement actions can all expose a practice to the risk of significant financial losses in the form of civil monetary penalties imposed by federal or state governmental agencies, damages in civil lawsuits, lost income due to business interruption, expenses of notifying patients or others of a security breach, or the cost to restore corrupt or lost data.

To protect their reputation and goodwill, most practices implement what they believe are reasonable measures to prevent disclosures of patient information or harm to the practice's computer systems.

However, errors do occur and confidential information can be inadvertently disclosed.

Laptops containing confidential data can be stolen.

Additionally, it is hard to stay one step ahead of the seemingly endless stream of identity thieves and hackers who wish to



Cyber liability insurance policies are not written on standard forms, and conditions of and scope of coverage vary significantly from insurer to insurer. . . . As with any insurance policy, the written terms of the policy should be carefully reviewed — preferably by an attorney — to confirm that the policy being purchased will adequately protect your practice from cyber liability risks.

steal informational assets. In fact, it has been estimated that attacks to computer systems by hackers and identity thieves have increased by 158 percent in the last two years.

Computer systems also are vulnerable to malicious codes (i.e., viruses, trojan horses, logic bombs) picked up through e-mail or Internet browsing.

It is unlikely a practice can ever recover any money from the individuals who created or spread the malicious code, many of whom cannot even be identified or live outside the United States.

Products supplant standard policies

Fortunately, relatively new insurance products generally referred to as "cyber liability" policies are available to protect a practice.

Cyber liability policies provide coverage for losses not covered by a commercial general liability (CGL) policy or a professional liability policy, both of which most practices purchase.

For example, a practice's reputation or goodwill and its informational assets (i.e., electronic data) are classified as intangible assets because they are not physical things.

CGL policies do not cover loss or damage to intangible assets or emotional distress due to breaches of confidentiality, and professional liability policies also typically exclude from coverage any claim arising from violation of patient privacy.

Accordingly, cyber liability insurance policies can fill this insurance gap.

The risk of being subject to a governmental enforcement action under HIPAA is increasing. Enforcement initiatives for HIPAA violations have been greatly expanded by the HITECH Act which authorizes each state attorney general to file suit against a practice on behalf of the residents of its state if the practice has violated HIPAA.

Additionally, no later than Feb. 13, 2012, patients whose privacy has been breached will be able to share in a portion of any civil monetary penalty or monetary settlement

collected by the federal Office of Civil Rights (OCR) or the Centers for Medicare and Medicaid (CMS) due to a breach of the HIPAA privacy or security rule.

Civil monetary penalties can range from as little as \$100 per violation to as much as \$10,000 per violation, and such incentives are expected to lead to an increased reporting of HIPAA violations by individual patients to OCR and CMS.

Additionally, under the Red Flags Rule, patients may be entitled to recover actual damages that they sustain from a practice's violation of the rule. There is a possibility that class action lawsuits could result in massive damages.

Other costs associated with an unauthorized disclosure of protected health information, in addition to civil monetary penalties, include the expenses of notifying patients, of modifying systems and security to prevent future breaches, and legal defense costs.

Further, damages to a practice's network can result in the loss of valuable data or an interruption in business operations.

A cyber liability policy can compensate a practice from loss of business income resulting from an interruption of network operations due to computer viruses and other electronic attacks, and it also can cover the costs of restoring the data.

Cyber liability insurance policies are not written on standard forms, and conditions of and scope of coverage vary significantly from insurer to insurer.

Accordingly, a practice will need to carefully explain its activities, risks, and needs to an insurance agent.

As with any insurance policy, the written terms of the policy should be carefully reviewed — preferably by an attorney — to confirm that the policy being purchased will adequately protect your practice from cyber liability risks.

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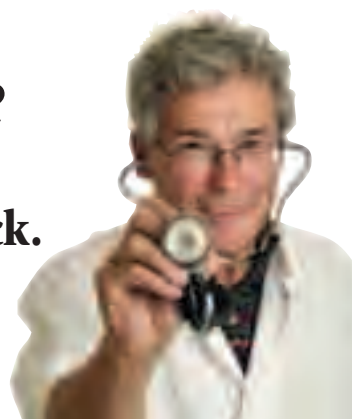
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FERA gives health care fraud enforcement a boost

The federal False Claims Act (FCA) has long been a key weapon in the government's arsenal to fight health care fraud and abuse.

Now, with the passage of the Fraud Enforcement and Recovery Act of 2009 (FERA), the government will have an even easier time making a case against health care providers accused of defrauding federal health care programs.

One way that FERA expands the scope of the FCA is by removing the "presentment requirement."

Under the previous version of the FCA, a person or entity would be exposed to potential liability only if the allegedly false claim was specifically presented to government. FERA expands the scope of the FCA to claims presented to an agent or contractor acting on behalf of the government.

Language also was added to the definition of "claim" to include "requests or demands for money or property where the government has paid or will pay any portion of the money, regardless of whether the government actually has title to the property at the time of the request or demand."

These revisions will ensure that the FCA can be used to prosecute false claims submitted to state Medicaid programs, as well as to contractors such as Medicare Advantage Plans.

Intent no longer necessary

Another significant amendment to the FCA removes language that was interpreted by the Supreme Court as requiring the government to prove that a defendant had "specific intent" to defraud the government.

Now liability under the FCA may exist as long as the false record or statement is "material to" a false or fraudulent claim. Material is defined broadly as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

Perhaps the most significant change that will impact health care providers is the change to the "reverse" false claims provision, i.e., that section of the FCA that extends liability to funds retained, as opposed to false claims submitted, by a person or entity that does not have a right to such funds.

FERA eliminates the requirement of an affirmative act of concealment and extends liability to an individual who "knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."

FERA also adds a definition of "obligation," which is very broadly defined as "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee rela-



Health Policy

By Andrew B. Wachler, Esq. and Amy K. Fehn, Esq.

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tionship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment."

To avoid liability under the FCA, health care providers and their counsel should carefully analyze statutory and regulatory provisions in which an "obligation" could arise.

For example, a technical violation of the Stark regulations could be construed as an "obligation" to return payments to the government.

Decisions related to repayment of government funds are difficult and should always involve a fact specific analysis and judgment

of experienced health care counsel.

Because the FCA defines "knowingly" as including "deliberate ignorance" and "reckless disregard," an effective compliance plan provides significant protection for providers.

However, difficult decisions can arise when compliance activities uncover billing problems that may have been taking place for some time, especially in light of the new broad definition of "obligation."

While we have always recommended that providers conduct compliance audits prospectively, and, at a minimum, retain counsel in order to protect compliance activities through

Perhaps the most significant change that will impact health care providers is the change to the "reverse" false claims provision, i.e., that section of the FCA that extends liability to funds retained, as opposed to false claims submitted, by a person or entity that does not have a right to such funds.

the attorney client and/or work product privilege, the FERA amendments make this decision more important than ever.

Whistleblower protection expanded

FERA also includes several amendments that will make it easier for qui tam (i.e., whistleblower) lawsuits to proceed.

Specifically, FERA expands whistleblower protection to government contractors and agents and expands the statute of limitations with regard to government intervention in qui tam lawsuits by allowing the government's complaint to "relate back" to the whistleblower's filing.

In addition, FERA gives the federal government greater flexibility in the discovery process, by allowing the Attorney General to delegate its authority to issue Civil Investigative Demands to other officials.

This will make it easier for federal officials to conduct discovery such as depositions, interrogatories and requests for production. Also, this information can now be shared with whistleblowers making it easier to cure defects in the whistleblower's complaint.

Although most of the amendments to the FCA apply prospectively, the elimination of the "intent" requirement is an exception.

Specifically, the amendments that require a false record or statement to be "material to a false or fraudulent claim" will apply retroactively to all claims pending as of June 7, 2008.

The FERA amendments make it easier for the federal government to prosecute health care providers and entities who violate the FCA.

To minimize risk, health care providers must be aware of their obligations with regard to all health care related statutes and regulations and must have an effective compliance plan in place that will enhance compliance and promptly identify overpayment obligations.

Veterans Aid and Attendance Program matters require special expertise

By Don L. Rosenberg, Esq.

For most veterans, the idea of collecting a pension benefit from the military does not seem like a real possibility unless the veteran suffered a service connected disability.

However, there is the Veterans Aid and Attendance Program (AA), a pension benefit program available to all veterans, and their families. It pays for non-reimbursed home health and medical expenses and the non-reimbursed cost of assisted living, and does not require a service connected disability.

But those who counsel veterans and their families should be aware of companies that are taking advantages of veterans and their surviving spouses.

These companies claim to be providing "educational seminars" to the public. Their motive, however, is to sell some type of financial product such as an annuity and, sometimes, even gold to the family of the veteran. In fact there are companies that use the word "Veterans" and "American" in their company name, which, in reality, are sometimes an assumed name for a financial planning firm.

Over the last several years, individuals have formed various companies stating their main goal is to "help" our veterans, but their true agenda is anything but. Many of these individuals, regardless of their affiliations or background, repeatedly contact assisted living and independent living facilities offering to put on "free informational seminars" educating the general public as to what they may be missing out on.

The fact is, these individuals have surfaced as "financial advisors" and are using their "free informational" presentation, and a confusingly similar name appeared to be linked to a legitimate veterans organization, to mar-

ket and sell annuities and gold that are unsuitable to the veteran and his or her families.

Not only are these investments not suitable, but they also are not necessary and, in most cases, extremely detrimental to the veteran and his or her families.

These organizations also suggest the veteran give away most of his or her assets without considering any of the tax consequences or devastating Medicaid qualification penalty if his or her health should worsen and he or she would need a nursing home.

Professionals, veterans and their families should understand that it is never necessary to purchase a financial product to qualify for Aid and Attendance benefits. Veterans and their families are encouraged to seek the advice of an accredited veterans and qualified elder law attorney.

Eligibility for the AA Program

In order to be eligible for the AA Program, a veteran must have served 90 days on active duty with at least one day during wartime, and must have been discharged under conditions other than dishonorable. Additionally, the veteran must be "permanently and totally disabled," though the disability need not be service connected.

The specific periods of Wartime Service:

- World War I: April 6, 1917, to Nov. 11, 1918
- World War II: Dec. 7, 1941, to Dec. 31, 1946
- Korean Conflict: June 27, 1950, to Jan. 31, 1955
- Vietnam Era: Aug. 5, 1964 (or Feb. 28, 1961, for veterans who served in country before then) to May 7, 1975
- Gulf War: Aug. 2, 1990 to a to-be-determined date

The current AA monthly pension benefits:

- Veteran and spouse: \$1,950
- Veteran: \$1,645
- Surviving spouse of a veteran: \$1,057

Non-reimbursed medical expenses are generally defined to include the costs associated to health and Medicare insurance premiums, prescriptions drugs, dental and vision care, and expenses related to an assisted living facility, and in-home care aid, and/or adult day care.

Net worth valuation

With the exception of the applicant's home, automobile, traditional household furnishings and personal property, which are treated as noncountable, veterans assets cannot exceed the amount necessary to pay for their medical costs. In other words the asset limit is a formula that calculates the expenses both medical and household and multiplies the shortfall by the veteran's life expectancy.

There is an unwritten asset limit that is commonly referenced and maintains that a single veteran could have \$40,000 in assets and a married couple could have \$80,000. However, if the veteran is aged and therefore has a shortened life expectancy, then these numbers may be significantly reduced.

Unfortunately, some of the groups in the community advertising that they are helping veterans with eligibility for the program are not considering all the factors when evaluating a veteran's income and assets.

Pre-planning

The Veterans Administration only looks at the applicant's net worth at the time of the actual AA application. At this time, because there is no penalty period for the transfer of assets prior to the time of the application, it is fair to conclude that with



Professionals, veterans and their families should understand that it is never necessary to purchase a financial product to qualify for Aid and Attendance benefits. Veterans and their families are encouraged to seek the advice of an accredited veterans and qualified elder law attorney.

proper planning, just about any veteran, and/or his or her spouse, can qualify for a monthly AA pension benefit.

Even though there is no penalty, transferring assets to qualify for this benefit may



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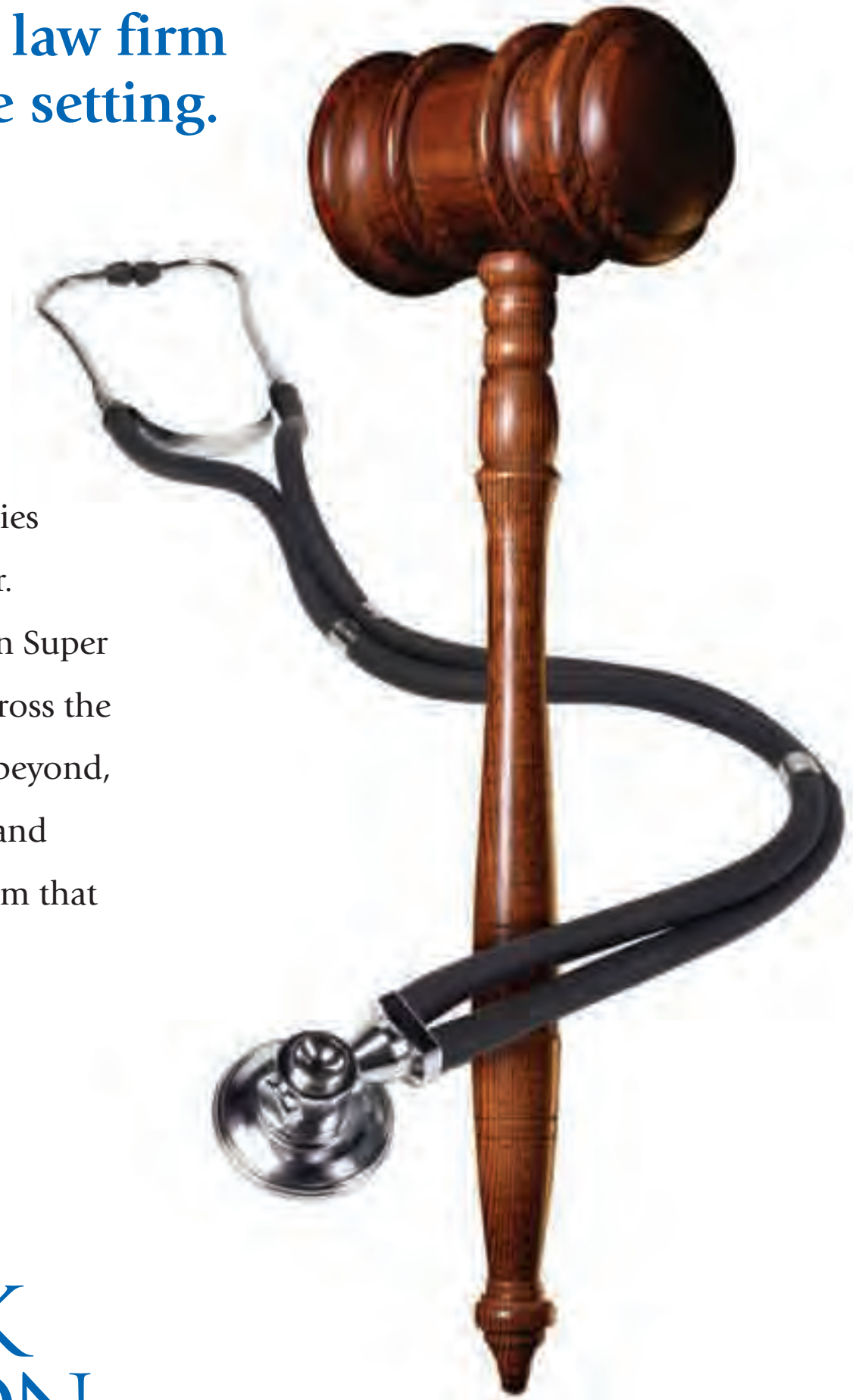
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CMS changes rules regarding use of 'consignment closets'

The Centers for Medicare & Medicaid Services (CMS) recently issued a change request to amend the Medicare Program Integrity Manual. It would prohibit the use of certain "consignment closet" and "stock and bill" arrangements used by durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers.

Specifically, DMEPOS suppliers will no longer be able to maintain an inventory at a

health professional's office and bill Medicare beneficiaries for the supplies distributed by health professionals from the inventory.

Inventory must be limited

DMEPOS suppliers will still be permitted to maintain an inventory at a health care professional's office, but only under the following limited circumstances:

- The title to the DMEPOS is transferred to the health care professional at the time the DMEPOS is furnished to the beneficiary;
- The health care professional bills the patient for the DMEPOS supplies using the health care professional's own enrolled DMEPOS number;
- Services related to the fitting or use of the DMEPOS are performed by individuals being paid by the health care professional and not by any other DMEPOS supplier; and
- The beneficiary should be directed back to the health care professional for any questions or problems regarding the DMEPOS.

The National Supplier Clearinghouse Medicare Administrative Contractor (NSC-MAC) has been charged with verifying that two or more DMEPOS suppliers are not located at the same practice location.

A separate practice location is defined as a location with a separate entrance and a separate post office address.

According to the change request, the reason for this change was that most consignment closets or stock and bill arrangements were not in compliance with the DMEPOS supplier standards set forth in 42 CFR §424.57.

Although CMS did not indicate which standards were problematic, it is likely that DMEPOS suppliers utilizing consignment closets were determined in some instances not to meet requirements to "enroll separate locations it uses to furnish Medicare covered DMEPOS" or the requirement that it "fills orders, fabricates, or fits items from its own inventory. ..."

The Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS) has also long been concerned about the use of consignment closets.

Specifically, the OIG has expressed concern that DMEPOS suppliers were using payments for consignment closets and associated

Health Policy

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services as a vehicle to compensate physicians for access to the supplier's patient base.

For example, rent that is less than fair market value or payment for "management services" to physician offices that does not serve a legitimate business purpose have been cited by the OIG as potential anti-kickback violations in Advisory Opinions, Special Fraud Alerts and the DMEPOS Supplier Compliance Guidance.

Even if arrangements meet the current requirements, there may still be fraud and abuse concerns associated with the use of consignment closets.

For example, to the extent that DME companies offer "discounts" on supplies to physicians, such discounts should be appropriately reported to Medicare.

Arrangements between DMEPOS suppliers and health care providers also should be carefully analyzed to determine whether they could be construed as being a prohibited "contractual joint venture" that would violate the anti-kickback statute.

The OIG has identified certain characteristics that it considers to be "suspect" and potentially indicating an arrangement that would violate the anti-kickback statute.

Suspect arrangements

Some of these suspect characteristics that might be applicable to an arrangement between a DMEPOS Supplier and a health professional include:

- The health professional expands into a new health care service, i.e., DMEPOS, which is intended to predominately serve the health care professional's existing patients with no effort to expand the business to a new customer base.
- The health professional enters into the venture with a DMEPOS supplier who would otherwise be its direct competitor.
- The health professional makes little or no financial investment, with its sole contribution to the venture being access to its patient base.
- The DMEPOS supplier operates the venture and contributes the financial investment.
- The health professional's remuneration is tied to the volume or value of patient referrals from the health professional's patient base.

All of these factors are illustrative of a suspect contractual arrangement, but no one factor is considered determinative.

While the change request does not impact the use of consignment closets in hospitals, the anti-kickback concerns remain the same.

Providers who currently utilize consignment closets or stock and bill arrangements in any setting should have these arrangements reviewed by health care counsel for compliance with the new requirements, as well as the DMEPOS certification standards, the anti-kickback statute and the Stark regulations.



While the change request does not impact the use of consignment closets in hospitals, the anti-kickback concerns remain the same.

New HIPAA breach notification rule in effect

As of Sept. 23, HIPAA covered entities are required to notify individuals, the media and HHS of certain breaches of protected health information (PHI).

Business associates causing such breaches are required to notify the covered entity of such breaches. The Office for Civil Rights will not impose sanctions for breaches occurring prior to Feb. 22, 2010, essentially giving covered entities six months to comply.

The Department of Health and Human Services (HHS) published the interim final rule Aug. 24, 2009, which was required by the American Recovery and Reinvestment Act of 2008 (ARRA), and amends the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

Breach notification is required when there

is: an acquisition, access, use, or disclosure in violation of the HIPAA Privacy Rule, of PHI that was unsecured, when an exception does not apply, and it compromises the security or privacy of such information.

Considerations in breach notification

• **Step 1:** Determine if the use or disclosure was in violation of the HIPAA Privacy Rule. If there was no violation, then no notice is required.

• **Step 2:** Determine if the PHI was "unsecured," a PHI that was not secured through the use of a technology or methodology that renders the PHI unusable, unreadable, or indecipherable to unauthorized individuals, per HHS guidance.

HHS guidance has identified encryption and destruction. In other words, no notice is required if the PHI was encrypted or destroyed per HHS guidance.

• **Step 3:** Determine if an exception applies. One exception is if it was an unintentional acquisition, access, or use of PHI by workforce member or other person under authority of a covered entity (or business associate), if in good faith, within scope of authority, and the PHI not further used or disclosed.

Another exception is if it was an inadvertent disclosure of PHI by person authorized to access PHI to another such person at the same covered entity, business associate, or organized health care arrangement, and the PHI not further used or disclosed.

Privacy Matters

By Elizabeth Callahan-Morris, Esq.



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Breach notification is required when there is: an acquisition, access, use, or disclosure in violation of the HIPAA Privacy Rule, of PHI that was unsecured, when an exception does not apply, and it compromises the security or privacy of such information.



A third exception is if the disclosure of PHI was to a person not reasonably able to retain such information. If any of these exceptions apply, then no notice is required.

• **Step 4:** Determine if the breach "compromises the security or privacy" of the PHI.

This means the covered entity must determine whether it "poses a significant risk of financial, reputational, or other harm to the individual," per a risk assessment. Note that if the PHI had no identifiers (none of the 16 direct identifiers per limited data set rule, no dates of birth and no ZIP codes), then it automatically does not "compromise the security or privacy" of the PHI.

If it is determined that the breach did not compromise the security or privacy of the PHI, then no notice is required.

In cases where notification is not required, covered entities should still consider notification as a way to mitigate any harmful effect of a wrongful use or disclosure under the existing HIPAA Privacy Rule on "mitigation."

In general, if notification is not required under HIPAA, then notification also is not

Veterans

Continued from page 6

have other negative effects when planning for long-term care. Many of these organizations will suggest and encourage gifting assets to the children. Once again this should only be done if there is a complete understanding of all the risks.

The Medicaid program has stricter rules and regulations regarding asset transfers than the Veterans AA Program. As such, it is very important that veterans and their families engage a veteran accredited and qualified elder law attorney when developing a long-term care plan. For instance, transferring assets to qualify for AA benefits could result in a five-year ineligibility for Medicaid benefits.

Attorney accreditation

The U.S. Department of Veterans now requires attorneys to be accredited in order to represent or advise a veteran on eligibility requirements relating to improved pension benefits.

While the planning process necessary to qualify a veteran or their spouse for Veterans Aid and Attendance/Improved Pension Benefit may seem simple, when you consider the potential consequences, such as capital gain taxes, income taxes, and potential ineligibility for Medicaid benefits the program becomes very complicated.

Accordingly, it is wise for the professional to have the proper expertise or seek the appropriate counsel before assisting a veteran or his or her spouse in qualifying for this benefit.



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Family

Continued from page 1

appropriate. Pursuant to the American Medical Association's (AMA) Council on Ethical and Judicial Affairs Opinion 8.19, routine medical care given to a family member for short-term, minor problems is ethically appropriate.

The AMA does, however, caution physicians that they should avoid treating family members and should not act as the primary physician for a family member, since the physician's objectivity and judgment may be compromised when treating a loved one.

Prescribing controlled substances for an immediate family member is not appropriate under the AMA's ethical guidelines, federal law, and the law of most states.

Beyond this, there are few standards that apply to treating family members. However, there are numerous statutory requirements that apply to the creation of, maintenance of and access to medical records.

While it is easy for a physician who cares for a family member at the office to keep written medical records, care for immediate family members is often rendered informally at home and thus physicians do not tend to keep such records.

This creates a significant probability that there will be no record of the patient's treatment, or even if notes or another informal record is kept, it will not be made accessible to other treating physicians.

Failure to keep such written medical records or make them available to treating physicians is considered a negligent practice that can result in sanctions against a physician's license to practice medicine.

Michigan law defines medical records as meaning "information, oral or recorded in any form or medium that pertains to a patient's health care, medical history, diagnosis, or medical condition and that is maintained by a licensee in the process of providing medical services."

The relevant statutes do not provide any detailed requirements for the content of medical records kept in physician's office, but merely state that such records should include a full and complete record of tests, examinations performed, observations made, and treatments provided. Therefore, it is part of

the standard of care to keep such records.

Importantly, there are no exceptions under existing state statutes that relieve a physician of the requirement to keep medical records for any patient to whom the physician has provided medical care or written a prescription.

Thus, all family members to whom a physician provides care are "patients" with



[S]tate medical licensing boards are likely to view the failure to keep a written medical record as a negligent practice.

in the meaning of these statutes.

While physicians treating close family members may have a tendency to rely on their memory, if there is no written record of the treatment provided it is quite likely that only the physician and the family member he or she treated will know about the care given.

Patients, especially minors, cannot be expected to fully remember what care they received. If the physician dies, becomes mentally incapacitated, or cannot be reached and no written record exists, the care of the patient may be compromised by the lack of a written record to forward to another treating physician.

For these reasons, state medical licensing boards are likely to view the failure to keep a written medical record as a negligent practice.

They also are apt to view the failure to reduce any oral record to a written record within a reasonable amount of time after care has been given to be a negligent practice. Accordingly, physicians who provide medical care to immediate family members run the risk of a licensing violation if they fail to keep appropriate written medical records.

Physicians should not be misled by the idea that there is safety in treating family members, as there is always a risk that a family member or another treating physician would complain to a state licensing board about the lack of a formal medical record.

Such complaints are most likely to occur in situations:

- Where the relationship between the physician and immediate family member (or the parent of that family member) has disintegrated and there is dissatisfaction with the care rendered by the treating physician;
- Where divorced parents of minor children disagree about whether a physician family member should be treating the child and try to prevent the family member from treating the child;
- Where a subsequent treating physician believes his or her delivery of care has been compromised due to the lack of a formal written record.

With the current focus on electronic medical records and the integration of patient information, issues involving the importance of keeping of medical records are becoming more prominent and medical records are subject to greater scrutiny. Consequently, the lack of a medical record may be more easily detected than in the past.

Physicians can take two simple steps to protect themselves. First, if a physician provides medical care to a family member, a formal written medical record of that care must be created contemporaneously and kept by the physician even if the record is only handwritten.

Second, a copy of that formal written record should also be forwarded to the family member's regular treating physician and made a part of the regular physician's records.

Doing so will protect physicians from charges that they failed to keep such records.



Suzanne D. Nolan's practice at Troy-based Frank, Haron, Weiner and Navarro, PLC focuses upon business and intellectual property transactions, including trademark, patent and copyright licensing, e-commerce transactions, and real estate transactions for all types of entities, including health care providers. She also advises health care clients on Stark and Anti-Kickback Statute compliance and licensing matters. Contact her at (248) 952-0400 or snolan@fhwnlaw.com.

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