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Despite physician-patient privilege, subpoenas may require disclosure

By Todd C. Berg, Esq.

The question on some doctors' minds when it comes to the inviolability of the physician-patient privilege is whether they're more like psychologists than dentists.

In a pair of published opinions — one from early March and one from 2007 — the Michigan Court of Appeals held the attorney general's investigative subpoenas for patient information couldn't overcome the psychologist-patient privilege, but could defeat the dentist-patient privilege.

In both cases, the attorney general acted on behalf of the Michigan Department of Community Health, which was investigating the health professionals in question for alleged billing and insurance fraud. (See "Privilege versus subpoena," page 13.)

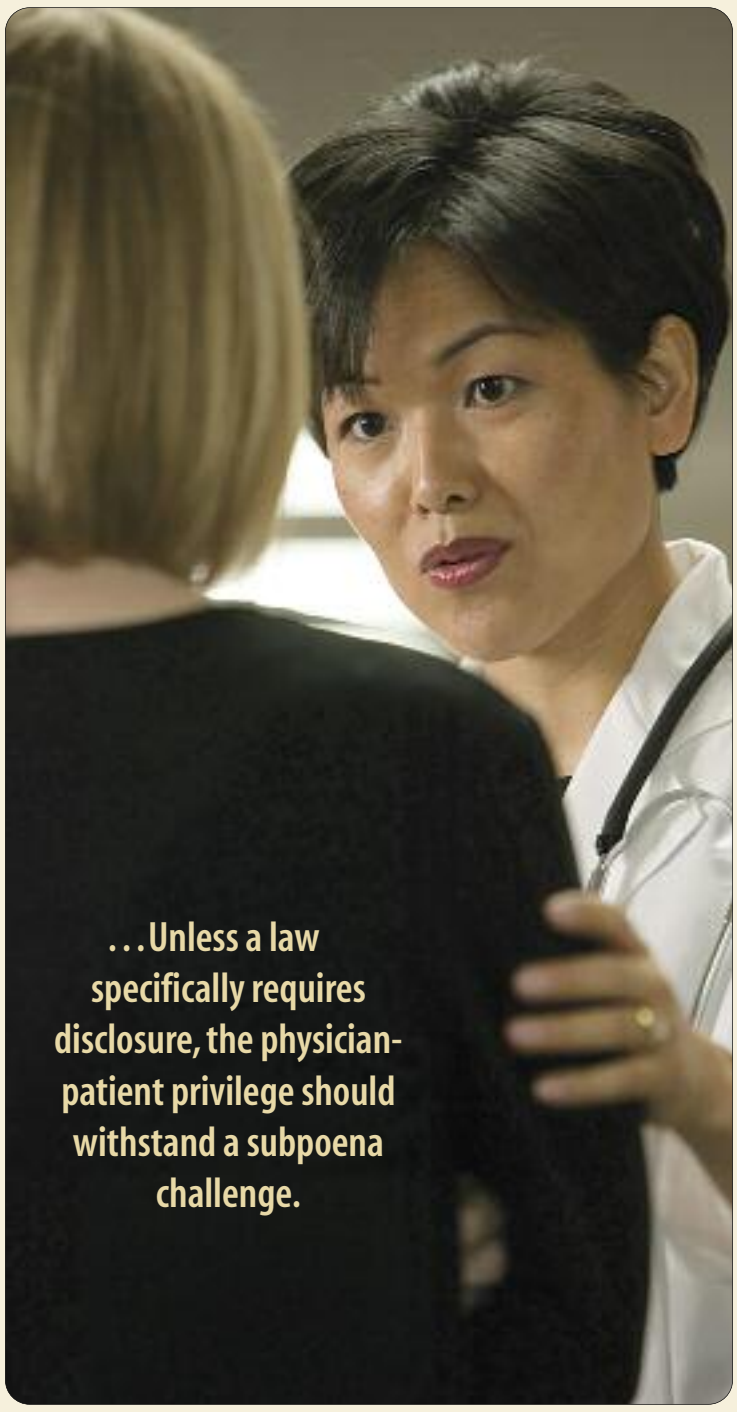
Health care law specialists say doctors have good reason to be concerned because the wording of the physician-patient privilege statute is similar to that of the dentist-patient privilege statute.

But the lawyer who represents the Michigan State Medical Society said there's enough difference between the two statutes that, unless a law specifically requires disclosure, the physician-patient privilege should withstand a subpoena challenge. (See "Three different standards," page 13).

Detroit attorney Gregory D. Drutchas of Kitch Drutchas Wagner Valitutti & Sherbrook, who regularly represents health care providers, said the "substantially different" language in the physician and psychologist statutes will likely compel different outcomes when it comes to honoring the respective privileges.

Whereas the psychologist's

See "Privilege," page 13



. . . Unless a law specifically requires disclosure, the physician-patient privilege should withstand a subpoena challenge.

On the hook

Medicare rules will press insurers on liens against personal injury settlements

By Carol Lundberg

Starting in July, plaintiff attorneys in personal-injury cases won't be the only ones on the hook to make sure Medicare is reimbursed for treatment of eligible injured clients.

After July 1, attorneys representing liability-insurance providers will have to ensure that Centers for Medicare and Medicaid Services, or CMS, is informed of possible liens on liability settlements.

If attorneys fail to do so, and Medicare isn't compensated, the insurer clients could face a $1,000-per-day fine.

By law, CMS must be notified when a personal-injury claimant is covered by Medicare. To ensure that it recovers its share of what it paid to treat the injury, Medicare is entitled to put a lien on the claimant's settlement.

The prospect of a fine may cause some defendant-insurer lawyers to go overboard to protect themselves and their clients, said Donna M. MacKenzie, attorney at Berkley-based Olsman, Mueller, Wallace & MacKenzie, which represents plaintiffs in personal-injury cases. Most of the firm's clients are eligible for Medicare, she added.

MacKenzie said she worries that overreaction to the new rule

See "Medicare," page 12

Technology Update

The future of health care

Electronic and Internet health records targeted for growth

By Mercedes L. Varasteh, Esq. and Maro E. Bush, Esq.

President Barack Obama's Stimulus Bill requires that an electronic health record be established for each patient in America by 2014, and Internet providers and health care providers are already gearing up.

Last year, Internet giant Google introduced Google Health, an online health records service designed to let patients upload and easily share health information with physicians, pharmacists, and other health professionals.

Google Health followed Microsoft's debut of its own online service, HealthVault, which partners with numerous other Web-based health applications.

While the use of online health records may seem a futuristic concept, with the passage of the 2009 American Recovery and Reinvestment Tax Act (a.k.a. the Stimulus Bill), such health centralization services will become a routine part of health care.

In any event, the new push toward electronic health information will certainly generate an increased use of services such as Google Health and HealthVault, and will thus raise unique privacy law considerations for both physicians and patients.

Understanding various types of e-records

One large area of concern is how health care providers can comply with the newly expanded Health Insurance Portability and

See "Technology," page 6

Med-mal specialists question evidence in lost-opportunity case

Relevance of survival rates to 'better result' claim doubted

Michigan Court of Appeals

By Todd C. Berg, Esq.

Medical-malpractice legal specialists say the Michigan Court of Appeals' consideration of survival-rate statistics evidence in a lost-opportunity-for-a-better-result case may have been erroneous.

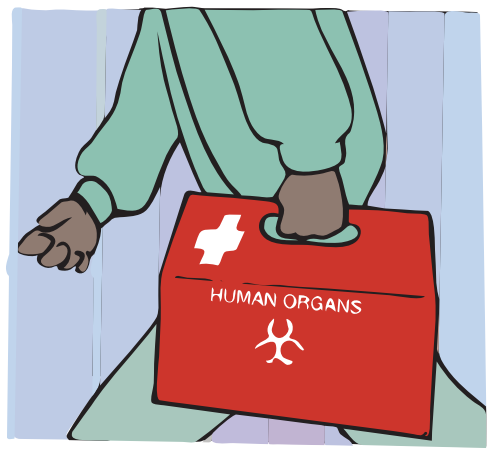
In *Lanigan v. Huron Valley Hospital, et al.*, the court said the survival-rate statistics for heart-bypass and heart-transplant patients could be considered when assessing the plaintiff's lost-opportunity claim.

The plaintiff, Jayne Lanigan, contended the alleged malpractice by the hospital and her doctor cost her the opportunity to keep her natural heart and live longer.

Based on its consideration of the survival-rate statistics evidence, the Court of Appeals reversed the trial court's order granting summary disposition for the hospital and the doctor. The court remanded the case for a jury or judge to decide whether Lanigan had proved the defendant's alleged malpractice caused her to lose the opportunity to achieve a better result.

"To the extent that this case allows a living

See "Med-mal," page 14



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The Standard and Limited Guidance provided by the Joint Commission

Effective Jan. 1, 2009, the new Leadership Standard LD.03.01.01 provides, in pertinent part, that:

- The hospital has a code of conduct that defines acceptable, disruptive and inappropriate behaviors.
- Leaders create and implement a process for managing disruptive and inappropriate behaviors.

The Joint Commission also has recommended physician conduct policies that relate to the new leadership standard. The new "disruptive behavior" policies should include the following:

- "Zero tolerance" for intimidating and/or disruptive behaviors, especially criminal acts such as assault.
- Concepts that address intimidating behaviors of physicians that are complementary and supportive of policies aimed at non-physician staff.
- Provisions that protect those individuals who report intimidating behaviors.
- Methods of responding to patients and/or families who witness such behaviors.
- Specifics regarding how and when to begin disciplinary action.

New rules on disruptive behavior require a measured approach

Medical Staff

By Robert S. Iwrey, Esq. and Jeffrey R. Campbell, Esq.

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Iwrey focuses his practice on litigation, dispute resolution, Medicare, Medicaid and Blue Cross/Blue Shield audits and appeals, defense of health care fraud matters, compliance and other health care related issues.

Campbell specializes in transactional and corporate matters; compliance; audit defense; reimbursement and contracting matters; and staff privilege and third-party payer departicipation matters. Contact them at (248) 544-0888 or riwrey@wachler.com and jcampbell@wachler.com.

Over the past few years, there has been more intense focus on medical staff actions related to disruptive conduct of physicians.

In the past, many hospitals did not have any policies, procedures or guidelines to assist them when faced with the unprofessional conduct of a physician — especially when such conduct was not directly related to quality of care.

Too often the decision of whether disciplinary action should be taken against a physician was dependent upon such factors as whether that physician significantly contributed to the hospital's fiscal bottom line or whether that physician had a special relationship with the hospital's administration.

With the intent of having hospitals actively and appropriately address the issue of unprofessional physician conduct, the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations) now requires accredited health care organizations to establish policies and procedures to address disruptive physician behavior in the workplace.

While all health care professionals might agree that such policies and procedures would be beneficial in the hospital setting, the language of the policy adopted by a hospital and a hospital's medical executive committee (MEC) must be measured to prevent abuse. They must provide both hospitals and staff physicians with a fair and reasonable mechanism to appropriately rectify potential behavioral problems.

From its pronouncements, it is clear that the Joint Commission believes that an express policy to address disruptive behavior by physicians is necessary; otherwise, the hospital is implicitly promoting "disruptive behavior."

However, the Joint Commission has failed to define or specify what would constitute "unacceptable" or "disruptive behaviors."

Without more guidance from the Joint Commission, physicians must be concerned about, and involved in the drafting of, hospital policies and procedures aimed at addressing such behaviors in order to protect physicians from unnecessary adverse actions against their staff privileges.

This concern was echoed by the American Medical Association with regard to the broad definition of "unacceptable" or "disruptive behavior" which, if undefined, could lead to arbitrary enforcement of the standard.

The implementation of new policies requires a deliberate approach

In order to avoid scenarios, for example, where a hospital could initiate disciplinary action against a physician with whom the hospital has had political or economic disagreements simply on the basis that the physician raised his voice at a nurse during a tense moment, a hospital's MEC must use careful and measured language in adopting a policy to address disruptive physician behavior.

While everyone would agree that a hospital cannot tolerate egregious disruptive behavior, such as an assault upon a co-worker, the adopted standards and accompanying policies need to be measured to truly achieve the goal of the policy, which is to make a productive, safe and healthy working environment.

This approach would provide more security to the physician and instruct the hospital how to proceed to achieve the above-noted goal of the policy. In our opinion, any such policy should first provide a definition of the types of behaviors for which the policy is designed to address.

For example: "Disruptive conduct" by a medical staff member is defined as conduct that adversely affects the hospital's ability to accomplish its objectives and includes, but is not necessarily limited to, the following actions toward colleagues, hospital personnel, patients or visitors:

- Hostile, angry or aggressive confrontational voice or body language.
- Attacks (verbal or physical) that go beyond the bounds of fair professional conduct.
- Inappropriate expressions of anger such as destruction of property or throwing items.
- Abusive language or criticism directed at the recipient in such a way as to ridicule, humiliate, intimidate, undermine confidence, or belittle.
- Derogatory comments that go beyond differences of opinion that are made to patients or patients' families' about caregivers (this is not intended to prohibit comments that deal constructively with the care given).
- Writing of malicious, arbitrary, or inappropriate comments/notes in the medical record.
- Sexual harassment and discrimination.

Guidelines must include step-by-step process for incident documentation

The policy should also set forth procedures for reporting complaints/incidents regarding alleged disruptive conduct, including the documentation of such matters and the submission of such reports.

Next, the policy should address how the report is investigated and by whom (e.g., the chief of staff or a designated subcommittee of the MEC).

For reports substantiated by a preponderance of the evidence, the policy should include a step-by-step process that provides notice to the physician and ensures due process and fairness before any disciplinary action is taken by the hospital.

For instance, the chief of staff will determine if the subject behavior falls within the definition of "disruptive conduct." If so, the chief of staff will exercise reasonable judgment whether the behavior is of a minor nature and an isolated incident that does not need to be formally addressed or if the behavior requires corrective action.

If the initial complaint/incident is dismissed, a confidential memorandum summarizing the disposition of the complaint/incident shall be maintained in a record other than the physician's credential file.

Documentation of the initial incident should remain outside of the physician's credential file unless additional substantiated complaints of a similar nature are received. If additional complaints are made, documentation regarding these along with any related memorandum and correspondence should be retained and stored in the physician's credential file.

If the physician fails to correct the behavior and another substantiated complaint/incident occurs, the physician should be offered the opportunity to voluntarily participate in a program designed to rectify the disruptive behavior. This could take the form of an anger-management course and/or see a counselor such as a social worker, psychologist or psychiatrist designated by the hospital to assess, evaluate and attempt to correct the disruptive behavior.

If the physician refuses to do so voluntarily, the chief of staff should determine if the severity of the subject behavior warrants a mandatory mental health evaluation.

Finally, if the physician's behavior is not appropriately modified by the earlier steps or is of such a severe nature that makes the earlier steps unreasonable, the hospital may then initiate disciplinary action against the physician. This must be done in accordance with the fair hearing procedures set forth within the hospital's medical staff bylaws and/or fair-hearing plan, which typically provide the physician with a hearing to defend their behavior.

Such a process would protect the physicians and help the hospital achieve a healthy and safe working environment.

It should be noted that the aforementioned process is just a sample example of provisions that might be included in a hospital policy designed to fairly address the issue of physician disruptive behavior; it is by no means intended to be a complete policy.

A finding of unprofessional conduct may result in an adverse report to the NPDB

Physicians must be active in the adoption of a measured standard and policy on disruptive behavior because a finding of unprofessional conduct is reportable to the National Practitioner's Data Bank (NPDB).

Many physicians wrongly believe that the only types of incidents that are reportable to the NPDB are malpractice actions or incidents occurring at the hospital that are directly related to quality of care.

However, the NPDB handbook expressly states that a hospital must report any adverse clinical privilege action taken against a physician for unprofessional conduct that has, or could have, an adverse affect on a patient. Thus, if a hospital is allowed to take quick and unchecked disciplinary action against a physician for "disruptive behavior," it may result in an adverse Data Bank report that could affect the physician's career forever.

For these reasons, it is imperative that staff physicians and the MEC take a measured approach in defining "unacceptable" or "disruptive behavior" and adopting related policies. Otherwise, physicians may be empowering the hospital to use this new standard as a sword to take arbitrary action against physicians for ulterior reasons, instead of encouraging a productive, safe, and healthy working environment.

Economic stimulus package to have far-reaching impact on health care

The way health care is provided in the United States will be changed by the development of national health information technology, tighter privacy laws, and subsidies for COBRA coverage and funding for health care research, among other newly enacted Stimulus Bill provisions.

Many provisions of the $787 billion American Recovery and Reinvestment Act of 2009 are designed to have a substantial and direct effect on the health care industry.

Certain provisions of the Act, Division A Title XIII and Division B Titles IV, comprise the Health Information Technology for Economic and Clinical Health Act (HITECH). These provisions establish the Office of the National Coordinator of Health Information Technology (ONCHIT).

Although the ONCHIT was originally created by President George W. Bush through a 2004 executive order, the HITECH Act codifies the establishment of that office within the Department of Health and Human Services (HHS).

Focus largely on adding electronic users

One of the goals of the ONCHIT is to further develop nationwide health information technology (HIT), which will allow the electronic use and exchange of certified electronic health records (EHR), and will be developed and encouraged through competitive grants to states, thereby funding loans to providers to develop health information technology.

HIT also is encouraged by Medicare and Medicaid incentives. Importantly, the HITECH Act provides monetary incentives for eligible professionals and hospitals who become "meaningful users" of EHRs over the next five years.

The Act does not provide an exact definition of meaningful user, but sets forth the following criteria for eligible professionals to be considered a meaningful user: make meaningful use of certified EHR to the satisfaction of the HHS secretary (including the use of electronic prescribing) through means prescribed by the secretary; be connected for the electronic exchange of health information; and use EHR to report on certain clinical quality measures — if the secretary has set up the capacity to accept those reports.

Demonstrating that an eligible hospital is a meaningful user involves similar criteria.

The HITECH Act provides for HHS to adopt an initial set of standards, implementation specifications, and certification criteria by Dec. 31, 2009.

Incentives for electronic records use

Eligible professionals who demonstrate themselves as meaningful users of EHR will receive annual Medicare incentive payments of 75 percent of the secretary's estimate of allowable charges. That incentive may be up to a maximum of $18,000 for the first year of meaningful use of EHR.

The maximum amount of the annual incentives decreases in subsequent years to $12,000, $8,000, $4,000, and $2,000, respectively.

Eligible professionals in a designated health professional shortage area also are entitled to a 10 percent increase in the annual payments.

Business of Medicine

By Louis C. Szura

Louis C. Szura, a 2003 graduate of Cornell Law School, is an associate at Frank, Haron, Weiner and Navarro, PLC. He recently joined the firm and is currently licensed to practice in Illinois and Ohio. His practice focuses on business planning, complex commercial litigation, health care law, and the prevention of fraud and abuse under the Federal False Claims Act. Contact him at (248) 952-0400 or lszura@fhwnlaw.com.

The Medicare incentives start phasing out if the first year of meaningful use begins after 2013 and the incentive is completely phased out if the first year of meaningful use is after 2014.

Those provisions are designed to encourage eligible physicians to adopt EHR sooner rather than later. Regardless, after 2016, the Medicare incentives expire for all eligible professionals.

In addition to the Medicare payment incentives, the HITECH Act also provides for Medicare payment penalties against qualified physicians who do not become meaningful users of EHR by 2015. Eligible professionals who provide covered professional services in 2015 and following years, but who are not meaningful users, will see a percentage reduction in their Medicare fee schedule.

There will be a 1 percent reduction in 2015, 2 percent in 2016, and 3 percent in 2017 and subsequent years. In addition, after 2018, the secretary may determine if less than 75 percent of qualified professionals are meaningful users of EHR, and may increase the penalty by 1 percent a year up to a maximum of 5 percent penalty.

The secretary also may, however, exempt eligible professionals from the penalty provisions, on a case-by-case basis, because of significant hardships, such as practicing in a rural area without sufficient Internet access.

Medicare incentives also are available for eligible hospitals that are meaningful users of EHR.

If a hospital demonstrates that it is a meaningful EHR user, then it is eligible for an annual incentive payment calculated as the product of a $2 million base amount plus possible additional amounts per patient discharge; a Medicare share percentage based on the proportion of in-patient beds; and a transition factor that reduces the annual incentive each year by 25 percent.

The Medicare incentives for eligible hospitals also are limited by phase-out provisions similar to the incentives for eligible professionals. Eligible hospitals that are meaningful users after 2013 will receive incentive payments according to the transition factor as if their first payment year is 2013. Hospitals that become meaningful EHR users after 2015 will not receive incentive payments.

There also are penalties provisions for eligible hospitals. Beginning in 2015, if eligible hospitals are not meaningful users of EHR, they will be subject to a 25 percent reduction in the hospital's market basket update used to update payments and cost limits for Medicare.

The HITECH Act also encourages the use of EHR by funding additional financial incentives for qualified Medicaid providers. Notably, eligible professionals are not allowed to maximize both the Medicare and Medicaid incentives. There is no such restriction on eligible hospitals that also are Medicaid providers.

Subsidizing COBRA premiums

The Act also aims to increase the number of individuals with temporary health insurance coverage by providing a 65 percent subsidy for terminated employees' COBRA premiums. The subsidy provides for former employees to pay 35 percent, and their employers to get payroll tax credits for the remaining 65 percent of the premium.

The COBRA subsidy will last up to nine months and will apply to workers who have been involuntarily terminated between Sept. 1, 2008, and Dec. 31, 2009.

The subsidy period began March 1, 2009, and is generally available for individuals who have a modified adjusted gross income below $145,000 ($290,000 for joint filers).

In addition, a portion of the premium subsidy must be repaid if the individual has a modified adjusted gross income between $125,000 and $145,000 ($250,000 and $290,000 for joint filers).

The scope of the Act is enormous and showcases the importance of the health care industry to our economy. Hopefully, these provisions will provide a big boost for the health care industry and the entire country.

Additional Funding Provisions

The American Recovery and Reinvestment Act of 2009 contains many provisions that provide substantial funding to the health care industry outside of health information technology. For example, there is an increase in general Medicaid funding through raising Federal Medical Assistance Percentages (FMAP) for all states by 6.2 percent.

The Act also provides an additional FMAP bump if a state has a relatively large rise in unemployment. Also, the Act provides a ground floor for all states' FMAP until 2011. It provides that, during that time, a state's FMAP will not drop below its highest FMAP in any of the years from 2008 to 2011.

Other funding provisions include:

An additional $1.1 billion for Comparative Effectiveness Research.

Another $1 billion in funding for wellness and prevention programs, such as educating patients about the risks of smoking and obesity.

$1.5 billion for construction, renovation, and equipment for community health centers.

$500 million to train primary health care providers.

Assistance for medical school expenses for students who agree to practice in underserved communities through the National Health Service Corps.

$10 billion in funding for National Institutes of Health for new research grants and renovation and construction of buildings, which is one of the Act's largest provisions.

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DOLAN MEDIA COMPANY

A bitter pill

Drug-injury victims now can sue pharmaceutical companies everywhere but in Michigan

By Carol Lundberg

The U.S. Supreme Court's *Wyeth v. Levine* decision gives no help at all to Michigan lawyers and clients seeking to sue pharmaceutical companies for injuries caused by drugs approved by the federal Food and Drug Administration.

That's because Michigan is the only state in the country with laws that give vast immunity to drug manufacturers.

And although some plaintiffs attorneys and Democratic lawmakers are pushing to repeal that immunity, there is no sign the Republican majority in the state Senate is backing away from its staunch defense of the status quo.

In *Wyeth v. Levine*, the U.S. Supreme Court on March 4 affirmed a $6.7 million Vermont state court verdict against a drug company.

Diana Levine, a former musician, had to have her arm amputated after she suffered an injury caused by an improper intravenous push of Phenergan, a drug manufactured by Wyeth.

The Supreme Court's 6-3 opinion states that federal oversight of drug labeling does not prevent state level consumer liability lawsuits against drug companies.

But in Michigan, people cannot sue if they are injured as the result of using drugs that have passed the FDA's standards.

Those who favor the status quo say Michigan's immunity laws will help persuade pharmaceutical companies to move here. Those who oppose the laws point out that immunity did nothing to keep the pharmaceutical companies from leaving Michigan, and the laws hurt state residents injured by FDA-approved drugs.

Clients have nowhere to turn

As much as he was thrilled by the Supreme Court's decision, Mark Bernstein, a Farmington Hills personal injury lawyer with The Bernstein Law Firm, said he is frustrated by Michigan's drug-immunity laws.

Bernstein said every week, he turns away dozens of potential clients who claim injury as a result of pharmaceuticals, while his friends and peers in other states are pursuing cases against a long list of drugs, including Accutane, Baycol, Prempro and Paxil.

David Mittleman, of Lansing-based Church Wyble PC, is frustrated as well.

"The state attorney general for the most part has done a good job in Michigan, but with regard to this law, he says Michiganders can go to other states to file a complaint against drug companies," Mittleman said. "That's simply not true in most cases. Most judges send it to federal courts, which apply Michigan laws, and kick it out."

Bernstein says that since Pfizer left Michigan in 2008, the pharmaceutical industry in Michigan is nearly nonexistent, so keeping laws that heavily favor the industry while penalizing residents is "asinine."

"The biotech companies are not knocking down the doors to locate in Michigan," Bernstein said. "The only ones who knocked got run over by Pfizer on its way out."

Not only the injured suffer as a result of the state laws, he said, adding that the state is losing out on revenue.

If Michigan had participated in just the Vioxx case at the same level states of similar size did, the economic effect would have been substantial.

"We would have had 1,650 cases in Michigan. That's just for Vioxx," Bernstein said. Bernstein's firm took only a handful of cases, filed in New Jersey, where Vioxx is manufactured. In a global settlement, Merck agreed to pay some $4.85 billion to settle all 27,000 pending cases, including the ones filed by the Bernstein firm.

"My average client paid almost $50,000 [in medical reimbursement liens] to one of three places: health insurance companies, medical providers, and Medicaid," he said. "That would have been $82 million coming back to doctors and hospitals and Blue Cross and Medicaid. It's not far-fetched, and that's just Vioxx."

The human toll is harder to calculate, Bernstein said.

"'Wyeth' has turned the tide. It may result in fewer findings of pre-emptions and may result in legislative changes at the federal and state level. This may cause the Michigan Legislature to look again."
— Jill Wheaton, Dykema

"I firmly believe there is a philosophical majority that would change the current status of the law, if they were allowed to vote on it."
— David Mittleman, Church Wyble PC

"The most troublesome part of this is that you talk to someone from Monroe, and you have to tell them that if they lived 10 miles south of where they live, they would have a case."
— Mark Bernstein, The Bernstein Law Firm

"The most troublesome part of this is that you talk to someone from Monroe, and you have to tell them that if they lived 10 miles south of where they live, they would have a case. They'd be able to file in Ohio," Bernstein said. "It's impossible to explain the reason because it's a complete injustice."

Changes coming?

The *Wyeth* decision could be the catalyst to change the law.

"*Wyeth* has turned the tide," said Jill Wheaton of Dykema. "It may result in fewer findings of pre-emptions and may result in legislative changes at the federal and state level. This case may cause the Michigan Legislature to look again."

Wheaton said she disagrees with the Supreme Court's ruling. She said she thinks drug makers should be protected if the FDA approves their labeling.

Furthermore, she said, "Intellectually, Michigan's law is correct."

Still, the law could be changing.

Following the release of the opinion, state Democrats announced they would fast track a package of bills that would repeal the state's pre-emptive immunity laws, and would make the repeal retroactive to 1996. That is the year the immunity laws were passed, said State Rep. Lisa Brown, D-West Bloomfield, who sponsored one of the bills.

She does think the bills will have support in the House of Representatives, but are likely to be blocked in the Senate, she said.

"In the other chamber, the Senate will keep blocking the protection of Michigan residents," she said.

She said a bill to overturn pharmaceutical immunity is stuck in the Senate Judiciary Committee. She said she thinks that unless there is strong constituent pressure to do otherwise, the Senate will kill her bill, even it it's widely supported in the House.

Mittleman said he thinks that, despite the roadblock in the Senate Judiciary Committee, some Senate Republicans oppose the immunity laws.

"I firmly believe there is a philosophical majority that would change the current status of the law, if they were allowed to vote on it," Mittleman said.

The reason there is no public outrage over drug immunity laws, Brown said, is that the only people who are aware of the issue are those who are already injured or their survivors.

"People aren't aware until they're already injured and find out there's nowhere for them to turn," she said.

Matt Marsden, a spokesman for the Republican State Senate Majority Leader Mike Bishop, said the Senate's position has not changed in the wake of the Supreme Court's decision.

"We are facing a down economy, and what the Democrats are pushing is regulating the pharmaceutical and life-sciences industries, which we're trying to grow here in Michigan," Marsden said. "We'll look at whatever the House sends us, but our position has not changed."

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

No free ride

6th Circuit Court rules hospital residents' 'stipends' are subject to income tax

Opinion summary

The federal district court correctly determined that "stipends" provided by the Detroit Medical Center to its resident physicians were wages, rather than scholarships, and therefore subject to income tax.

However, the court's ruling that the residents did not qualify for the "student" exemption from Social Security tax is vacated and remanded for further factual development.

"[F]or Detroit Medical's residents' 'stipends' to constitute 'qualified scholarships' that are not part of gross income, the amounts must have been 'used for qualified tuition and related expenses' and the residents must have been 'candidate[s] for a degree at an educational organization' that 'normally maintains a regular faculty and curriculum and normally has a regularly enrolled body of pupils or students in attendance at a place where its educational activities are regularly carried on.'"

Because "the residents were required to provide both the patient care and teaching services, the stipends cannot be viewed as 'no strings' educational grants, with no requirement of any substantial *quid pro quo* from the recipients that characterizes 'scholarships' and "fellowships.'"

Further, to "qualify as a scholarship, the stipend must be paid to an individual 'who is a candidate for a degree at an educational organization.' … Detroit Medical's residents, however, are not candidates for a degree. Upon completing the residency, the resulting recognition is not a degree but a certificate that enables the resident to take the specialty board examination. Moreover, for the stipend to be a 'qualified scholarship' under § 117(b)(1), it must have been 'used for qualified tuition and related expenses.' Detroit Medical's residents, however, do not pay tuition to either the hospital at which they work and train, or to Wayne State University. …

"The remaining question is whether the residents qualify as 'students' under 26 U.S.C. § 3121 (b)(10), which is one of the exemptions from FICA taxes imposed on wages of employees. …

"To determine whether the doctors in Detroit Medical's residency program are students, we … need to know what the residents in the program do and under what circumstances." The record is insufficient in this regard.

Affirmed in part and remanded for further factual development.

United States v. Detroit Medical Center. (6th U.S. Circuit Court of Appeals) (Lawyers Weekly No. 01-69271 - 10 pages) (Friedman, J., sitting by designation, joined by Batchelder and Sutton, JJ.). On appeal from the United States District Court for the Eastern District of Michigan.

Technology

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Accountability Act (HIPAA) provisions that apply to such services.

It is important for physicians to understand the relationship between the Stimulus Bill-mandated electronic health record (EHR) and the services offered by Google Health or HealthVault.

An EHR is simply an electronic record of health-related information on an individual that includes, among other things, patient demographic and clinical health data. This could be anything from a simple spreadsheet to an internal database for a large hospital, so long as the information can be transmitted between health care providers.

Just as patients generally do not write in their paper medical charts, patients cannot edit or enter information in an electronic health record. Because EHRs are maintained by a covered entity (i.e., created by a physician or hospital), such records are covered by HIPAA.

In contrast, centralization services like Google Health and HealthVault are classified under the Stimulus Bill as "Vendors of Personal Health Records." Personal health records (PHRs) can include the information contained within an electronic health record, but the main difference with PHRs is that the information is primarily managed, shared, and controlled by the patient.

Previously, vendors of PHR were excluded from the definition of "covered entities," which meant they were not covered by HIPAA. Under the new Stimulus Bill, however, while PHR vendors are still not classified as "covered entities," they are considered "business associates."

A business associate is generally defined as an entity that provides legal, accounting, consulting, financial, or other similar services to a covered entity. Business associates were previously contractually required to implement safety measures that protected the confidentiality of PHI, but only risked a contractual breach for failure to comply. Now, with the passage of the Stimulus Bill, all HIPAA standards — as well as the civil and criminal penalties for violating those standards — apply directly to business associates in the same manner that they apply to covered entities.

These new requirements take effect February 2010.

HIPAA Background

The Health Insurance Portability and Accountability Act (HIPAA) was enacted by Congress in 1996 and, in part, regulates the use or disclosure of "protected health information," which is data that contains medical information.

The act provides for at least a "reasonable basis" to determine that the information can be used to individually identify a patient and has been transmitted or maintained in any medium.

HIPAA laws only apply to covered health entities, which include health care providers (such as physicians and hospitals), health care plans, and health care clearinghouses.

Google Health and HealthVault give patients, providers options

Google Health was launched in 2008 after a very successful pilot program at the Cleveland Clinic, a multispecialty academic medical center. The pilot program gave 1,600 patients the opportunity to link their Google Health PHR with Cleveland Clinic's EHR.

Through its free, interactive PHR system, patients using Google Health can store as much or as little information in their PHR as they want. Information may be entered by the patients themselves or may be gathered and imported from third-party partners of Google Health, such as hospitals or pharmacies.

In addition, Google Health gives patients the option to choose whether other people, such as family members or physicians, can modify or view their profile.

HealthVault is designed as a "hub and spoke" system whereby patients and health care providers submit health information through various "spokes" which then becomes part of a "hub" or individual PHR. HealthVault contracts with various health Web sites and devices (applications) whereby patients can feed information to their PHR.

For example, a diabetes patient may set up an online HealthVault account and register with "Virtual Lifestyle Management," an interactive Web-based program where the patient can monitor his or her daily nutrition and physical activity. Next, the patient may register with GeneMedRx, an application that tracks prescriptions and over-the-counter medications.

Finally, if the patient monitors his/her blood sugars with a OneTouch blood glucose meter device, the patient can register with the "OneTouch Zoom" application and record his/her daily blood glucose recordings.

All information entered by the patient through the various applications becomes part of a central PHR, which can be accessed by his or her physician or hospital.

To date, both Google Health and Health Vault have formed partnerships with major health care providers. For example, HealthVault has partnered with companies such as Aetna and Kaiser Permanente to create PHR records for all beneficiaries. Some of the larger Google Health partners include Walgreens, CVS and the American Heart Association.

While Google Health and HealthVault are operated by private companies, plans for a federally operated health records centralization service is in the works. The Department of Health and Human Services (HHS), through the division of Health Information Technology, has launched plans to create a nationwide system known as Nationwide Health Information Network (NHIN). However, the program is still in its prototype and trial stage.

Privacy law/HIPAA considerations for physicians and patients

As with any Web-based service, the primary concern of PHR users will undoubtedly be that their private information may be spilled onto the Web, either by hackers, software loopholes or careless usage.

While the Stimulus Bill requires HHS to launch a "national education initiative" to educate patients on privacy laws, physicians need to familiarize themselves on the use of PHR vendors, and keep patients informed of how their information may be used to avoid trouble — whether in the form of HIPAA violations or upset patients.

Physicians should make sure patients understand the benefits and risks of using a PHR vendor.

A good place to start might be to instruct patients to carefully read the contractual terms of service and privacy policy of the vendor. Not only does this explain how a patient's information is stored and secured (through use of encryption, firewalls, etc.), it also sets out the limitations of a vendor; for example, if a patient chooses to share access to their PHR with a family member or physician.

Patients should understand fully the levels of authorization third parties may have to their records, such as "read-only," "write-only," or full unlimited access. Because of the shared nature of PHR systems, physicians should make sure patients are comfortable with restricting/allowing family access to PHI and understand the repercussions. For example, a 16-year-old patient who requests that her pediatrician prescribe her birth control may not want this information available to her parents.

Security umbrella expanded to include business associates

With PHR vendors newly classified as business associates, physicians, as covered entities, must enter into valid business associate contracts with vendors like Google Health and HealthVault.

These contracts must require vendors to implement appropriate administrative and security policies, among other provisions. In addition to these contracts, under the Stimulus Bill provisions, physicians have their own duty to mitigate damages in the event of a security breach where personal health information is accidentally disseminated.

Specifically, covered entities such as physicians are required to notify each individual affected by the breach. If the covered entity does not have contact information for the affected individual, they may be required to post notice of the breach on its Web site, in newspaper or on television.

For large breaches involving more than 500 residents in a particular area, a "prominent media outlet" must be notified of the breach, as well as the U.S. Department of Health and Human Services. (Note, however, that there is an exception for certain unintentional breaches.)

In addition to avoiding these cumbersome notice requirements, physicians would be well-advised to carefully heed privacy laws in light of the Stimulus Bill's new penalties. The penalty for a HIPAA breach is generally $100 for each violation with a cap at $25,000. Under the new rules, penalties can range from $10,000 to $1.5 million per calendar year, depending on the nature of the security breach. These new penalties take effect immediately.

Because the widespread use of ERH and PHR vendors is in its infancy, there are many potential legal and ethical considerations not addressed here. While such technologies provide opportunities to reduce paperwork and costs, physicians should be mindful of the possible liabilities and seek guidance on such issues when appropriate.

VARASTEH

BUSH

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As with any Web-based service, the primary concern of personal health records users will undoubtedly be that their private information may be spilled onto the Web, either by hackers, software loopholes or careless usage.

Medicare eases rule on termination of provider medical records review

Medicare providers and suppliers targeted for prepayment medical review understand the financial burden that review of records prior to payment places on a medical practice.

Prior to the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), a provider or supplier subject to non-random prepayment complex medical review remained on this targeted review until it met all Medicare billing requirements and demonstrated an "acceptable error rate."

The Medicare contractor was given the discretion to determine when the provider or supplier achieved an "acceptable error rate," resulting in providers and suppliers being subject to lengthy review.

In heartening news for providers and suppliers impacted by medical review that believed no end was in sight, the Centers for Medicare and Medicaid Services (CMS) recently published a final rule addressing termination of non-random prepayment complex medical review. The rule became effective Jan. 1, 2009 (73 Fed. Reg. 55753. See also 42 C.F.R. §421.501 et seq.).

The final rule mandates that, in most cases and unless an exception applies, CMS will terminate a provider or supplier from review no later than one year from the initiation of the review, or when the provider's or supplier's error rate decreases by 70 percent from the initial error rate.

The final rule implements Section 934 of the MMA, which required CMS to establish termination dates for medical reviews performed by Medicare Administrative Contractors (MACs), or performed by intermediaries and carriers until MACs are in place.

CMS will impose the same limitations on medical reviews performed by program safeguard contractors, to ensure that consistent criteria for terminating non-random prepayment review are applied to all providers and suppliers.

Significantly, in addition to the one-year time limit and 70 percent error rate reduction provisions, the Final Rule also specifically states that, "[t]here is no minimum timeframe that a provider or supplier must be on review," and the review can be terminated based upon the discretion of the Medicare contractor.

Therefore, should a Medicare provider or supplier be placed on non-random prepayment complex medical review, it should understand that effective strategies can be implemented to limit the amount of time the provider or supplier is subject to prepayment review.

When does prepayment review end?

The Medicare contractor will evaluate the provider's or supplier's error rate on a quarterly basis. In most cases, non-random prepayment complex medical review will end, at the latest, one year from its initiation.

At the conclusion of the one-year timeframe for review, if the Medicare contractor determines that the provider or supplier continues to have a high error rate, the Medicare contractor is mandated to consider the following:

- Referring the provider or supplier to Benefit Integrity Review.
- Continuing educational interventions (without performing further medical review).
- Initiating a post-payment audit.

In some cases, the one-year time limit for non-random prepayment complex medical review can be extended. Specifically, a Medicare contractor is authorized to extend the one-year limit in situations where a provider or supplier takes steps to alter its billing practices to avoid contractor review.

For example, the Medicare contractor may extend its review under the following circumstances, among others:

- If a reduced error rate is the result of a reduced number of claims submitted under a specific billing number (i.e., 25 percent or more reduction in claims submitted.)
- If the provider or supplier shifts billing to another inappropriate code.
- If the provider or suppler fails to respond to requests for medical records.

Once a Medicare provider or supplier has been terminated from prepayment complex medical review, if it wishes to reinitiate a review, the contractor must conduct another probe review to confirm that there continues to be a high level of payment error.

If this review finds a high level of payment error, the Medicare contractor can re-institute non-random prepayment complex medical review.

What next?

Non-random prepayment complex medical review poses challenges for Medicare

See "Termination," page 13

Health Policy

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Contractors look for high level of errors

Medicare contractors focus medical review activities on providers and suppliers they believe pose the greatest risk to the Medicare Trust Funds. Medicare contractors have discretion to determine what constitutes a "sustained or high level of payment error," but some examples include the following:

- **Unusual billing patterns, including inexplicable increases in the volume of claims submitted.**
- **Billing errors, including a significant billing error rate or errors on claims with a high dollar value.**

Once a Medicare provider or supplier has been chosen for non-random prepayment complex medical review, the provider or supplier must submit medical records to the Medicare contractor for review before payment will be made.

A licensed medical professional will review the records. The reviewer must use National Coverage Decisions and Local Coverage Decisions in conducting his or her review, but is also permitted to use his or her clinical judgment to determine whether an item or service is covered and is reasonable and medically necessary.

If, at any time during medical review, the Medicare contractor suspects possible fraud, then the contractor refers the issue to the benefit integrity contractor.

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.

SENATE BILLS

SB 0026 — Requirements for physicians supervising physician assistants.

"A physician who is a sole practitioner or who practices in a group of physicians and treats patients on an outpatient basis shall not supervise more than four physician's assistants. If a physician described in this subsection supervises physician's assistants at more than one practice site, the physician shall not supervise more than two physician's assistants by a method other than the physician's actual physical presence at the practice site. ...

"To the extent that a particular selected medical care service requires extensive medical training, education, or ability or pose serious risks to the health and safety of patients, the board may prohibit or otherwise restrict the delegation of that medical care service or may require higher levels of supervision.

"A physician shall not delegate ultimate responsibility for the quality of medical care services, even if the medical care services are provided by a physician's assistant."

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

SB 0047 — Amend the Public Health Code to require the Department of Community Health to create and operate a Web site containing price information on prescription drugs; and require the DCH to establish and maintain a toll-free telephone number for information on prescription drug programs available in the state.

"The department shall create and operate a prescription drug Web site to educate consumers about the price of certain prescription drug products and to provide links to other helpful Web sites including, but not limited to, those Web sites that may assist and educate consumers on the availability of public and private programs that, in compliance with federal and state rules and regulations, offer access to discounted or free prescription drug products.

"The department shall include all of the following on the prescription drug Web site:

(a) The 150 most commonly prescribed brand name drug products as reported by this state's medical assistance program.

(b) If not included under subdivision (a), the most commonly prescribed brand name drug products used for the treatment of all major illnesses and diseases, as determined by the department.

(c) If available, the generically equivalent drug products for the brand name drug products included under subdivisions (a) and (b).

(d) The usual and customary price for each drug product included under subdivisions (a), (b), and (c).

The price information on the Web site shall conspicuously display all of the following:

(i) If available, the generically equivalent drug product for each brand name drug product.

(ii) The price attributable to each brand name and generically equivalent drug product.

(iii) The dosage, including the number of doses and dosage strength, upon which the posted price is based.

(iv) The name, street address, and city or other identifiable location of the pharmacy at which the listed drug product may be purchased at a posted price.

(e) A minimum of five links to other Web sites as described in subsection (1).

(f) The department's toll-free telephone number created under subsection (4).

(g) An advisory statement alerting consumers of the need to tell their health professional and pharmacist about all the medications they are taking and to ask how to avoid harmful interactions between those medications, if any.

(h) An advisory statement alerting consumers that the price posted is only for the strength and quantity of the listed drug product."

Sponsored by: Roger Kahn-R
Status: Placed in order of third reading

SB 0118 — Public awareness campaign about the risks of hookah tobacco use.

"... the department shall develop and disseminate a public awareness campaign about the health risks associated with and legal requirements related to hookah tobacco use. The department shall include all of the following in the public awareness campaign developed under this section:

(a) All known effects hookah tobacco use has on an individual's health.

(b) All known health risks associated with the use of a hookah to smoke hookah tobacco, including the importance of cleaning and sanitizing the hookah after each use.

(c) All pertinent federal, state, or local laws, rules, ordinances, regulations, guidelines, and other legal pronouncements regarding the sale, taxation, storage, or handling of hookah tobacco, including the prohibition on the sale of tobacco products to minors.

(d) Any other information the department considers appropriate."

Sponsored by: Irma Clark-Coleman-D
Status: Referred to the committee on Economic Development and Regulatory Reform

SB 0147 — Partial-birth abortion ban act.

"Except as provided in subsection (4), a physician, an individual performing an act, task, or function under the delegatory authority of a physician, or any other individual who is not a physician or not otherwise legally authorized to perform an abortion who knowingly performs a partial-birth abortion and kills a human fetus is guilty of a felony punishable by imprisonment for not more than two years or a fine of not more than $50,000, or both.

(4) It is not a violation ... if in the physician's reasonable medical judgment a partial-birth abortion is necessary to save the life of a mother whose life is endangered by a physical disorder, physical illness, or physical injury.

(5) The spouse of the mother at the time of the partial-birth abortion or either parent of the mother if the mother had not attained the age of 18 at the time of the partial-birth abortion may file a civil action against the physician or individual described in subsection (3) for a violation of this section unless the pregnancy is a result of the plaintiff's criminal conduct or the plaintiff consented to the partial-birth abortion."

Sponsored by: Cameron Brown-R
Status: Referred to Committee on Health Policy

SB 0158 — Known as the employee family health privacy act.

"Except as provided in this section, an employer shall not do either of the following:

(a) Fail or refuse to hire or recruit, discharge, or otherwise discriminate against an individual with respect to employment, compensation, or a term, condition, or privilege of employment because of a known or believed illness or health condition of a member of an employee's family.

(b) Inquire as to the physical condition or health status of a member of an employee's family."

Sponsored by: Glenn Anderson-D
Status: Referred to Committee on Commerce and Tourism

SB 0182 — Establish a procedure for donating medication to a repository for distribution to medically indigent.

"The board shall establish, implement, and administer a statewide unused prescription drug repository program consistent with public health and safety through which unused prescription drugs, other than controlled substances, may be transferred from a health facility or agency, an adult foster care facility, an assisted-living facility, or a manufacturer to a pharmacy or a charitable clinic that elects to participate in the program. The program is created to distribute unused prescription drugs, other than controlled substances, to the medically indigent.

"Subject to subsection (11), the board shall promulgate rules and establish procedures necessary to establish, implement, and administer the program. The board shall provide technical assistance to health facilities and agencies, adult foster care facilities, assisted-living facilities, manufacturers, pharmacies, and charitable clinics that elect to participate in the program.

"Participation in the program by a health facility or agency, adult foster care facility, assisted living facility, manufacturer, pharmacy, or charitable clinic is voluntary. Nothing in this section requires any health facility or agency, adult foster care facility, assisted living facility, manufacturer, pharmacy, or charitable clinic to participate in the program.

"Pharmacies, health professionals, and charitable clinics shall use the following criteria in accepting and dispensing unused prescription drugs for use in the program:

(a) Only prescription drugs in their original sealed unit dose packaging or unused injectables shall be accepted and dispensed under the program.

(b) The packaging shall be unopened.

(c) Expired prescription drugs shall not be accepted.

(d) A prescription drug shall not be accepted or dispensed if the person accepting or dispensing the drug has reason to believe that the drug is adulterated.

(e) Controlled substances shall not be accepted.

(f) Subject to the limitations prescribed in this subsection, unused prescription drugs dispensed for purposes of a medical assistance program or drug product donation program may be accepted and dispensed under the program.

(g) Any additional criteria established in rules promulgated under this section."

Sponsored by Dennis Olshove-D
Status: Referred to Committee on Health Policy

SB 0356 — Regulate insurance, health and medical benefit plan carriers offering incentives to physicians or other health care professionals for prescribing certain medications.

"A carrier or any person acting on a carrier's behalf shall not do any of the following:

(a) Pay a physician or other health care professional to prescribe a specific drug or type of drug.

(b) Pay a physician, pharmacist, or other health care professional to switch a stable patient from one drug to another specific drug or type of drug.

(c) Provide financial incentives to a physician or other health care professional to prescribe a specific drug or type of drug.

(d) Provide a cash bonus or other reward to a physician or other health care professional for compliance with medical

Legislative Committee Members

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

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

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Pending Legislation
Continued

benefit plan guidelines regarding drugs to be used.

(e) Withhold a portion of a physician's or other health care professional's compensation or financially penalize a physician or other health care professional in some other way for failure to comply with specific medication use mandates.

(f) Provide incentives or other inducements to a physician or other health care professional to prescribe a specific drug or type of drug.

(g) Engage in any other activity that may be viewed as a kickback for prescribing a specific drug or type of drug.

"On or before Feb. 1, May 1, Aug. 1, and Nov. 1 every year, a carrier shall report all of the following to the attorney general for the immediately preceding quarter:

(a) Any payments, financial incentives, or other inducements to physicians or other health care professionals that may be viewed as an inducement to a physician or other health care professional to prescribe a specific drug or type of drug or to switch a stable patient from one drug to another specific drug or type of drug.

(b) Any other information the attorney general requires.

Sponsored by: Bruce Patterson-R
Status: Referred to Committee on Health Policy

HOUSE BILLS

HB 4008 — Development of an acuity system and staffing plan for nurses.

"A hospital shall submit to the [Department of Community Health] a staffing plan as provided under this section.

Each hospital is responsible for the development and implementation of a written staffing plan that provides sufficient, appropriately qualified nursing staff in each unit within the hospital in order to meet the individualized needs of its patients. Each hospital shall develop an assessment tool that evaluates the actual patient acuity levels and nursing care requirements for each unit during each shift. The hospital shall use the assessment tool to make adjustments to the staffing plan as needed to ensure safe patient care.

"To assist in the development of a staffing plan, the hospital shall establish a staffing committee for each unit and at least half of the members shall be registered professional nurses who are direct care providers in that unit. If the nurses in the hospital are under a collective bargaining agreement, the collective bargaining representative shall designate the nurses from within each unit to serve on the staffing committee for that unit. Participation on the staffing committee shall be considered a part of the nurse's regularly scheduled workweek.

"A hospital shall not retaliate against a nurse who participates on the staffing committee. The staffing committee shall establish a staffing strategy for that unit if the patients' needs within that unit for a shift exceeds the required minimum direct care registered professional nurse-to-patient ratios set forth ...

"Within two years after the effective date of this section, each hospital shall have established and implemented an acuity system for addressing fluctuations in actual patient

See "Pending Legislation," page 10

Pending Legislation
Continued

acuity levels and nursing care requirements requiring increased staffing levels above the minimums set. ... The assessment tool shall be used annually to review the accuracy of the acuity system established under this subsection.

"The hospital shall post the hospital's staffing plan for each unit in a conspicuous place within that unit for public review. Upon request, the hospital shall provide copies of the staffing plan that are filed with the [Department of Community Health] to the public."

Sponsored by: Lesia Liss-D
Status: Reassigned to Committee on Health Policy

HB 4012 — Laundering of surgical or work clothes exposed to blood or other infectious material; require facilities to comply with governing bloodborne infectious diseases and to not allow employees to launder at home.

"A health facility or agency in which invasive surgical procedures are performed and in which the employees are routinely exposed to blood or other potentially infectious material or routinely required to enter restricted operating areas shall comply with the laundering requirements of R 325.70011 of the Michigan administrative code. A health facility or agency described in this subsection shall not allow or require an employee who participates in invasive surgical procedures, has exposure to blood or other potentially infectious material, or enters a restricted operating area to take his or her work clothes home for laundering."

Sponsored by: Lesia Liss-D
Status: Printed bill filed Jan. 23, 2009

HB 4172 — Influenza vaccine strategic plan: Require hospitals to establish a plan and to inform and provide elderly persons with the vaccine.

"Beginning Oct. 1, 2009, a hospital shall establish a strategic plan for managing its supply of the influenza vaccine. The plan shall be consistent with guidelines or recommendations issued by the federal centers for disease control and prevention or by the advisory committee on immunization practices of the federal centers for disease control and prevention.

"During the influenza season, if the hospital has the influenza vaccine available and supply is consistent with the hospital's strategic plan, the hospital shall inform each person 65 years of age or older who is admitted to the hospital for a period of 24 hours or more that the influenza vaccine is available and offer to provide the vaccine to those persons for whom the vaccine is not contraindicative. If that person consents to be vaccinated against influenza and a physician, nurse, pharmacist, or other independent practicing licensed health care professional determines that there is not a relative or absolute contraindication to giving the vaccine, the health care professional shall administer the vaccination to the person before he or she is discharged from the hospital and shall document the vaccination in the patient's medical record.

"The documentation of the vaccine required under this section may be in the form of a written note included in the patient's medical record indicating that he or she had received the vaccine on a previous occasion, received the vaccine, or refused the vaccine or that the vaccine was not administered because a contraindication rendered the administration of the vaccine inadvisable."

Sponsored by: Robert Jones-D
Status: Printed bill filed Feb. 6, 2009

HB 4212 — Partial-birth abortion ban act.

"Except as provided in subsection (4), a physician, an individual performing an act, task, or function under the delegatory authority of a physician, or any other individual who is not a physician or not otherwise legally authorized to perform an abortion who knowingly performs a partial-birth abortion and kills a human fetus is guilty of a felony punishable by imprisonment for not more than two years or a fine of not more than $50,000, or both.

(4) It is not a violation ... if in the physician's reasonable medical judgment a partial-birth abortion is necessary to save the life of a mother whose life is endangered by a physical disorder, physical illness, or physical injury.

The spouse of the mother at the time of the partial-birth abortion or either parent of the mother if the mother had not attained the age of 18 at the time of the partial-birth abortion may file a civil action against the physician or individual described in subsection (3) for a violation of this section unless the pregnancy is a result of the plaintiff's criminal conduct or the plaintiff consented to the partial-birth abortion. A plaintiff who prevails in a civil action brought pursuant to this section may recover both of the following:

(a) Actual damages, including damages for emotional distress.

(b) Treble damages for the cost of the partial-birth abortion.

A woman who obtains or seeks to obtain a partial-birth abortion is not a conspirator to commit a violation of this section."

Sponsored by: Joel Sheltrown-D
Status: Printed bill filed Feb. 11, 2009

HB 4339 — Health facilities and hospitals to inform and provide elderly persons with the pneumococcal vaccine.

"Beginning Oct. 1, 2009, a hospital shall establish a strategic plan for managing its supply of the pneumococcal vaccine. The plan shall be consistent with guidelines or recommendations issued by the federal centers for disease control and prevention or by the advisory committee on immunization practices of the federal centers for disease control and prevention.

"During the pneumonia season, if the hospital has the vaccines available and supply is consistent with the hospital's strategic plan, the hospital shall inform each person 65 years of age or older who is admitted to the hospital for a period of 24 hours or more that the pneumococcal vaccine is available and offer to provide the vaccine to those persons for whom the vaccine is not contraindicative. If that person consents to be vaccinated against pneumonia and a physician, nurse, pharmacist, or other independent practicing licensed health care professional determines that there is not a relative or absolute contraindication to giving the vaccine, the health care professional shall administer the pneumococcal vaccination to the person before he or she is discharged from the hospital and shall document the vaccination in the patient's medical record.

"The documentation of the vaccination required under this section may be in the form of a written note included in the patient's medical record indicating that he or she had received the pneumococcal vaccine on a previous occasion, received the vaccine, or refused the vaccine or that the vaccine was not administered because a contraindication rendered the administration of the vaccine inadvisable."

Sponsored by: Robert Jones-D
Status: Printed bill filed Feb. 19, 2009

HB 4415 — To expand the special volunteer license for retired physicians to include chiropractors.

"An individual who is retired from the active practice of medicine, osteopathic medicine and surgery, podiatric medicine and surgery, chiropractic, or dentistry and who wishes to donate his or her expertise for the medical, chiropractic, or dental care and treatment of indigent and needy individuals in this state or for the medical, chiropractic, or dental care and treatment of individuals in medically underserved areas of this state may obtain a special volunteer license to engage in the practice of medicine, osteopathic medicine and surgery, podiatric medicine and surgery, chiropractic, or dentistry by submitting an application to the board pursuant to this section.

"An application for a special volunteer license shall be on a form provided by the department and shall include each of the following:

(a) Documentation that the individual has been previously licensed to engage in the practice of medicine, osteopathic medicine and surgery, podiatric medicine and surgery, chiropractic, or dentistry in this state and that his or her license was in good standing prior to the expiration of his or her license.

(b) Acknowledgment and documentation that the applicant will not receive any payment or compensation, either direct or indirect, or have the expectation of any payment or compensation, for any medical, chiropractic, or dental care services provided under the special volunteer license.

(c) If the applicant has been out of practice for three or more years, documentation that, during the three years immediately preceding the application, he or she has attended at least two-thirds of the continuing education courses or programs required under part 170, 175, 180, 164, or 166 for the renewal of a license."

Sponsored by: Dave Hildenbrand
Status: Printed bill filed Feb. 25, 2009

HB 4508 — Revise prohibition on redispensing a pharmaceutical to allow pharmacists to place previously dispensed drugs in customized patient medication packages.

"A pharmacist, upon the request of a patient or the patient's caregiver, may place prescribed drug products in a customized patient medication package regardless of whether the pharmacist originally dispensed the drug products. If the pharmacist is dispensing the drug products, he or she shall comply with R 338.479c of the Michigan administrative code.

"If previously dispensed drug products are brought to a pharmacist by a patient or the patient's caregiver for placement in a customized patient medication package under this section, all of the following requirements shall be met:

(a) The pharmacist shall comply as much as possible with R 338.479c of the Michigan administrative code and identify for the patient on a form prescribed by the department the portions of R 338.479c of the Michigan administrative code that he or she is unable to comply with because he or she is repackaging drug products previously dispensed by another pharmacy.

(b) The patient or the patient's caregiver shall complete and sign a form prescribed by the department that describes the drug products to be placed in the customized patient medication package, authorizes the pharmacist to place the previously dispensed drug products in a customized medication package, and releases the pharmacist who places the drug products in a customized medication package from liability.

(c) The patient or the patient's caregiver shall deliver the drug products to the pharmacist in their original containers bearing the labels required for prescription drug products under this act and federal law.

(d) The pharmacist shall maintain complete records of drug products placed in customized patient medication packages under this section and maintain those records in the same manner and for the same period of time as is required for other records of drug products dispensed under this article.

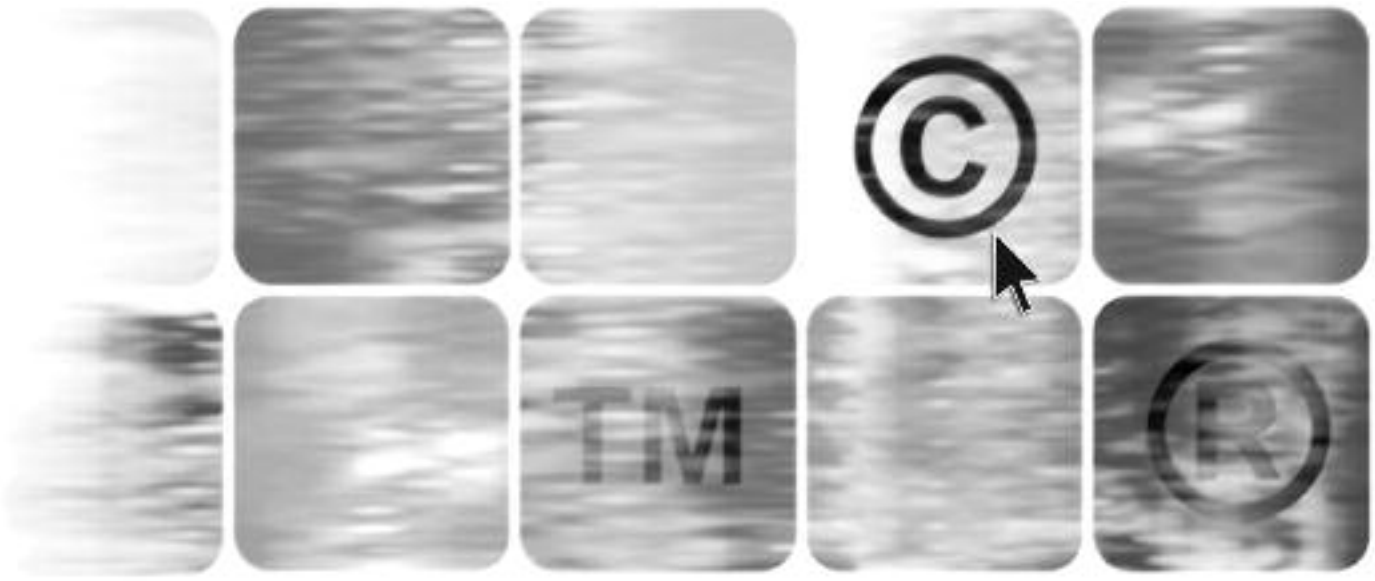
(e) If the pharmacist does not immediately place the drug products in customized patient medication packages under this section, the pharmacist shall store the drug products in a secure location and under conditions that will maintain their stability, integrity, and effectiveness until placed in the customized patient medication package under this section and returned to the patient or the patient's caregiver.

"A pharmacist who is not certain that previously dispensed drug products are exactly as described on the prescription drug container's label shall not place the drug products in a customized patient medication package under this section.

"A pharmacist who places previously dispensed drug products in a customized patient medication package in compliance with this section is immune from civil liability arising from harm caused by one or more of the drug products due to acts or omissions of other persons outside of the control of the pharmacist.

"This section does not require a pharmacist to place any drug product in a customized patient medication package. A pharmacist may charge a reasonable fee for placing drug products in customized patient medication packages under this section."

Sponsored by: Bill Caul-R
Status: Printed bill filed March 5, 2009



Preserving intellectual property rights

Copyright protection is one key to a successful practice Web site

E-Commerce

By Suzanne D. Nolan

Suzanne D. Nolan's practice at Troy-based Frank, Haron, Weiner & Navarro focuses upon business and intellectual property transactions, including trademark, patent and copyright licensing, e-commerce transactions, and real estate transactions for all types of entities, including health care providers. Nolan is a registered patent attorney and counsels clients on creating, protecting and enforcing intellectual property rights. Additionally, Nolan advises health care clients on Stark and Anti-Kickback Statute compliance and licensing matters. She can be reached at (248) 952-0400 or snolan@fhwnlaw.com.

Physician practices frequently use Web sites as marketing tools to attract new patients, and to enhance the level of services provided to their existing patients.

The use of a Web site allows a practice to broadly advertise and help introduce prospective patients to the practice's health professionals and services.

However, the benefits of a practice Web site can be negated if the practice becomes embroiled in litigation over the use of copyrighted content.

A copyright protects the practice's ownership of the content on its site by preventing third parties from, among other things, copying or displaying content owned by the practice. At the same time, a practice has to make sure that it respects the intellectual property rights of others and does not reproduce or display copyrighted content owned by anyone else.

Generally, Web site content consists of a collection of individual creative works, such as photographs or illustrations, audio clips, video clips, podcasts and text. In addition to the individual copyright in each of these works, a copyright also exists in the combination of individual works and the manner of their arrangement on the site.

Content ownership varies

Most practices utilize the services of Web developers to create a Web site. Typically, the developer selects the content to be used and writes the computer code for the Web site.

Although the Web developer may create some of the content of the Web site, the Web developer also uses content created by third parties, either by hiring them to specially create content or by purchasing or licensing content already created by the third parties.

For example, the Web developer may arrange to have a photographer take photos of the practice's physicians or facility, or the developer may purchase and use general "clip art"-type images to personalize the site and make it more attractive to prospective patients. The practice's physicians may even supply content directed toward educating patients about certain medical issues.

It is important to note that the owner of a copyrightable work is initially the person who creates the work. Therefore, unless there is a written agreement in place to the contrary, the Web developer hired by the practice to create the content and code for the Web site, and not the practice, will own or control the copyright in the content and code of the site.

A practice has the right to use these works on the site only if the practice either owns the works, or has duly licensed the works. In order for the practice to have the exclusive right to use the content, the Web developer must assign or exclusively license the content to the practice. Otherwise, the practice will not be able to prevent the Web developer from using the content on other Web sites, or prevent third parties from copyrighting the contents of the practice's site.

For example, if a practice uses a logo, the logo may be the most important image on the Web site and a valuable marketing tool. However, just as is the case with other content on the Web site, the practice will not own the logo unless the creator of the logo transfers its copyright interest to the practice, even if the practice pays the creator for his or her services. Therefore, unless the practice owns the logo, the Web developer who created it could sell the rights to use the logo to other developers.

If a Web developer (or any other person supplying content) uses content that has been developed by a third party, the supplier must have the consent of the third party to use this content. For example, a physician in a cardiology practice may post cholesterol-management articles obtained from a medical association on her practice Web site. Even if the physician attributes the articles to the association, this is not enough to avoid a potential copyright violation — instead, the physician should contact the association and obtain permission to use the content.

The Internet abounds with images that are subject to copyright protection, such as stock photographs and illustrations that can be licensed without charge or licensed for fairly reasonable one-time fees or annual fees.

Given the vast amount of material on the Internet, it might seem unlikely that any infringement would be noticed by a copyright owner. However, businesses whose primary source of revenue is earned by selling or licensing images protected by copyright actively monitor use of their images on Web sites. "Bots," which are software applications that run automated tasks over the Internet, are used to very easily and accurately detect infringing content. A copyright owner pays significant fees to hire a specialized company to do such monitoring.

Steps save headaches and money

Accordingly, when an infringing use of content is discovered, the owner wants to recover the cost of monitoring, the license fee that the owner would have earned, and legal expenses. Copyright owners often demand (under threat of filing suit for copyright infringement) several times the amount that it would have cost a practice or Web developer to initially license the content.

Such an approach puts the practice in the difficult position of capitulating to the demands of the copyright owner, or paying even more in fees to defend the threatened litigation.

Thus, it is generally cost-effective for a practice to properly license content prior to using it.

In many cases, a practice may have innocently used content provided by a Web developer in the belief, usually based on the developer's representations, that the developer owned the content and had duly authorized the practice to use the content.

It is a common misconception that because the practice relied on such representations, it will not be liable for copyright infringement. In fact, copyright law imposes liability on anyone who, among other things, copies or publicly displays content without the permission of the copyright owner.

A practice can protect itself by making sure it owns the content of its Web site or has duly licensed such content.

Copyright law is a complex area of the law, and there are many other issues not addressed in this article. If a practice is uncertain about whether it has the right to use any content, the practice should consult an intellectual property attorney to make sure its Web site remains an asset — and not a liability.

Writing the 'right

The following suggestions will go a long way toward avoiding third-party infringement claims:

- **The practice's written agreement with the Web developer should require the developer to assign or license all rights in the content to the practice. Specific language must be used in the written agreement to convey the copyright.**
- **The Web developer should execute the appropriate assignment or license to transfer rights to the practice.**
- **The written agreement should require the Web developer to represent and warrant that its employees created all of the content on the site as a work for hire, or if the developer is an individual, that she or he did. If a third party (such as a photographer) created some of the content, the Web developer should be required to disclose in writing the name of the third party and describe the content acquired from the third party.**
- **The Web developer should provide the practice with a copy of any assignment or license agreement from the third party who owns the copyright, and the practice should keep copies of any assignment or licenses with its permanent records.**
- **The practice should require the Web developer to indemnify it against any third-party infringement claims based on use of content supplied by the developer. The indemnification provision should be broadly written so that it includes the attorney fees of the practice.**
- **If the Web developer goes out of business or is financially distressed, the indemnification provision may be of little practical value. Therefore, the practice should take care in selecting the developer.**
- **The Web developer should license the software code to the practice. (Because the same code is used repeatedly by a developer, any license to use the software code is generally a nonexclusive license.)**
- **The practice should make sure that any of its physicians or employees who provide content for the site either own the content or have express permission to use it.**
- **The practice should consider purchasing a cyber liability insurance policy to cover the damages for and the cost of defending against claims of copyright infringement arising from content posted on the practice's Web site.**
- **The practice should protect the content of its Web site by registering its copyright in the content by filing an application with the U.S. Copyright Office. By doing this before any infringement occurs by anyone else, the practice has the ability to collect statutory damages (in lieu of actual damages which are difficult to prove), and attorney fees in an infringement action. The right to collect fees and statutory damages is a powerful incentive to force an early and favorable resolution should the practice sue a third party for copyright infringement.**


LW photo by Carol Lundberg

"The lawyers who represent these insurers don't want [their clients] to get fined."
— Donna MacKenzie, Olsman, Mueller, Wallace & MacKenzie

Medicare

Continued from page 1

could slow the process of compensation for her clients.

"The lawyers who represent these insurers don't want [their clients] to get fined," MacKenzie said. But she doesn't want anyone to panic.

"Their responsibility begins and ends with notifying Medicare. That's all they have to do," she added. "They don't have to worry about whether Medicare gets paid. They won't really be able to talk to Medicare because of HIPAA laws. They just have to put Medicare on notice when a claimant is Medicare eligible."

The purpose of the change is to ensure that all parties comply with the Medicare Secondary Payer statute.

She has heard rumblings that some defendant attorneys are saying they'll pay Medicare directly.

"There are some who think that's necessary, and are suggesting that they'll make the check out to my firm, to my client, and to Medicare," MacKenzie said. "That's not going to work. Even if we could figure out whom to send the check to for endorsement, it still has to come back to us for endorsement. Medicare is already four months behind on final demand letters.

"Sometimes we can't even get someone from Medicare on the phone. How in the world would we manage sending checks out there? It's never going to happen."

Though most plaintiff attorneys already were notifying Medicare, and were ensuring that their clients paid Medicare to satisfy liens against their settlements, some were not, said personal-injury attorney Mark J. Bernstein of The Bernstein Law Firm in Farmington Hills.

"The big picture is that Medicare is sick of being screwed," he said. "They've tried to say if there is any other type of insurance, Medicare should be the secondary insurance. And that's the law, and most everyone follows it. The problems are that when there are multiple insurers, everyone starts paying the bills, and it can take years to sort it out. It's a nightmare to untangle that mess."

"There are some cases that are pretty clear. If you have a slip-and-fall that causes a hip fracture, … everyone knows how much the medical bills are and how they got paid and who is entitled to compensation and repayment."
— Jules Olsman, Olsman, Mueller, Wallace & MacKenzie

He said that it appears CMS is trying to avoid the mess by getting lawyers on both sides of a case to figure out early what liens will need to be paid. But he's not hopeful that adding more rules about Medicare will be helpful.

"Handling liens is nothing new, but navigating them has become more complex every year. It holds up disbursement and frustrates the clients who are just trying to pay the rent," Bernstein said. "We'll wait and see if this helps, but if the past is any indication of the future, it will only make it more complicated."

He said he worries that because insurance liens are complex and often misunderstood, the law fails to take into account how slow the process of sorting out primary and secondary insurance payers is.

It's difficult enough now, Bernstein said.

"The law requires Medicare to be reimbursed 60 days after a settlement," he said. "But it can take months for Medicare to get final recovery demand letters to us. That slows the process."

Even worse is when his clients don't want to tell him that they're Medicare eligible.

"Medicare is such a nightmare," he said, "some clients try to avoid it altogether and don't tell you."

The new Medicare notification procedure requirement will come up most often in cases in which there is an injury involving an elderly person, and the injured person is Medicare eligible, said Jules B. Olsman of Olsman Mueller.

"There are some cases that are pretty clear. If you have a slip-and-fall that causes a hip fracture, that case is pretty clear and everyone knows how much the medical bills are and how they got paid and who is entitled to compensation and repayment," Olsman said.

It gets stickier though, when a client has multiple health issues.

"Let's say a person enters a nursing care facility with congestive heart failure, and that patient is being treated for that. But then, while in the [facility] that patient falls or is dropped and fractures a hip," he said.

"The case is only about the hip fracture, but when Medicare sends the final demand letter, everything they paid is going to be in there. We have to sort out what they're entitled to as a result of the injury, but not the other treatment," Olsman said.

The set-aside amount and payment will remain the responsibility of the plaintiff's attorney, he said, as it has been. A federal court late last year found that Paul J. Harris, a West Virginia attorney, was responsible to ensure that CMS was compensated after Harris' client fell from a ladder and sued the ladder retailer.

The client was awarded $25,000. Harris had notified CMS that his client was Medicare eligible, but did not pay CMS the $11,367 Medicare claimed it was owed, Olsman said.

"The client didn't have the money anymore, and the court said Harris should have paid on behalf of the client," Olsman said.

The CMS change will require defendant attorneys to become involved with communicating with Medicare early in the process, he said.

"One way to look at this is the government wants to make sure they're not being ignored and they're getting the last dollar," he said. "If you threaten the insurance industry with penalties, the government will get compliance."

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

Privilege

Continued from page 1

privilege is relatively absolute in prohibiting disclosure, the physician-patient privilege prohibits disclosure "[e]xcept as otherwise provided by law," he said.

That's significant, said Grand Rapids attorney Richard E. Hillary II of Miller Johnson, because the Court of Appeals in the 2007 case relied on similar language in the dentist-privilege statute to conclude the attorney general's investigative subpoenas warranted disclosure. According to the statute, MCL 333.16648(1), a dentist is prohibited from disclosing privileged information "[e]xcept as otherwise permitted or required under the health insurance portability and accountability act of 1996 [HIPAA]."

Hillary said in an e-mail the Court of Appeals has recognized that the Legislature "has afforded special treatment and protection to mental health records," but those same protections haven't been given to other medical records, such as dental and physician records.

Detroit attorney Daniel J. Schulte of Kerr Russell & Weber PLC, who represents the Michigan State Medical Society, cautioned against assuming it was a foregone conclusion that the physician-patient privilege will yield to an investigative subpoena.

He acknowledged the physician-patient and the dentist-patient privilege statutes shared some similar language, but, he said, where they differed was critical.

The dentist privilege says disclosure is allowed where HIPAA permits or requires it, Schulte said, but the physician privilege contains no such language.

"In my view," he said, "the 'Except as otherwise provided by law' language in the physician-patient privilege statute means the privilege cannot be overcome by an attorney general investigative subpoena unless a separate federal or state statute requires disclosure."

That rules out HIPAA, Schulte added, because HIPAA doesn't ever require disclosure, it only permits disclosure under certain circumstances.

Lake Orion attorney Allen M. Wolf of the The Wolf Law Firm, PLLC, who represented the dentist in the 2007 Court of Appeals case, disagreed with Schulte's HIPAA argument.

He said in an e-mail the physician-patient privilege "would follow the same HIPAA analysis used to overcome" the dentist-patient privilege in his client's case.

In the 2007 opinion, the Court of Appeals said HIPAA permitted disclosure of the subpoenaed dental-patient information because a health care provider, such as a dentist, "may disclose protected health information to a health oversight agency for oversight activities …" The court said the DCH was an oversight agency and the seeking of investigative subpoenas by the attorney general was in furtherance of its oversight activities.

Assistant Attorney General Serene Katranji-Zeni, who appeared before the Court of Appeals in the most recent case, didn't respond to a request for comment.

Leave to appeal to the Michigan Supreme Court was not sought in the 2007 case. As of March 12, no reconsideration motion or application for leave to appeal to the Michigan Supreme Court had been filed.

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

"… [T]he 'Except as otherwise provided by law' language in the physician-patient privilege statute means the privilege cannot be overcome by an attorney general investigative subpoena unless a separate federal or state statute requires disclosure."

— Daniel J. Schulte, Kerr Russell & Weber PLC

The Court of Appeals has recognized that the Legislature "has afforded special treatment and protection to mental health records," but those same protections haven't been given to other medical records, such as dental and physician records.

— Richard E. Hillary II, Miller Johnson

Whereas the psychologist's privilege is relatively absolute in prohibiting disclosure, the physician-patient privilege prohibits disclosure" [e]xcept as otherwise provided by law."

— Gregory D. Drutchas, Kitch Drutchas Wagner Valitutti & Sherbrook

Three different standards

- *Psychologist-patient privilege (MCL 333.18237)*: "A psychologist licensed or allowed to use that title under this part or an individual under his or her supervision cannot be compelled to disclose confidential information acquired from an individual consulting the psychologist in his or her professional capacity if the information is necessary to enable the psychologist to render services. Information may be disclosed with the consent of the individual consulting the psychologist …"
- *Physician-patient privilege (MCL 600.2157)*: "Except as otherwise provided by law, a person duly authorized to practice medicine or surgery shall not disclose any information that the person has acquired in attending a patient in a professional character, if the information was necessary to enable the person to prescribe for the patient as a physician, or to do any act for the patient as a surgeon."
- *Dentist-patient privilege (MCL 333.16648(1))*: "Information relative to the care and treatment of a dental patient acquired as a result of providing professional dental services is confidential and privileged. Except as otherwise permitted or required under the health insurance portability and accountability act of 1996, Public Law 104-191, and regulations promulgated under that act, 45 CFR parts 160 and 164, or as otherwise provided in subsection (2), a dentist or a person employed by the dentist shall not disclose or be required to disclose that information."

Privilege versus subpoena

Below are summaries of the Michigan Court of Appeals decisions dealing with privilege-based motions to quash investigative subpoenas issued at the Michigan Attorney General's request.

- **Attorney General v. Gerard Robert Williams, Ph.D., Michigan Court of Appeals, 2009**

The "plain and ordinary meaning" of the clear, unambiguous language in the psychologist-patient privilege makes the Legislature's intent obvious, wrote Judge Elizabeth L. Gleicher, in the court's unanimous opinion.

"[W]e … have no doubt that the Legislature unequivocally intended as an exemption to petitioner's investigative authority that a licensed psychologist 'cannot be compelled to disclose confidential information acquired from an individual consulting the psychologist in his or her professional capacity,'" she said.

As such, she concluded the privilege prevented Williams from disclosing the patient information sought by the attorney general's subpoenas.

Gleicher's opinion was signed by Judges Stephen L. Borrello and Alton T. Davis.

- **In re Petition of Attorney General For Investigative Subpoenas, Michigan Court of Appeals, 2007**

Because the Michigan Department of Community Health is a health oversight agency and the requested information pertained to the MDCH's oversight activities, wrote the court in its unanimous per curiam opinion, HIPAA authorized the dentist, who is a health care provider, to release the information sought in the attorney general's investigative subpoenas.

Additionally, the court explained, because HIPAA permitted disclosure of the subpoenaed patient information, the disclosure conditions contained in Michigan's dentist-privilege statute also were satisfied.

Then-Chief Judge William C. Whitbeck and Judges Richard A. Bandstra and Bill Schuette signed the opinion.

Termination

Continued from page 7

providers and suppliers as a result of interrupted cash flow.

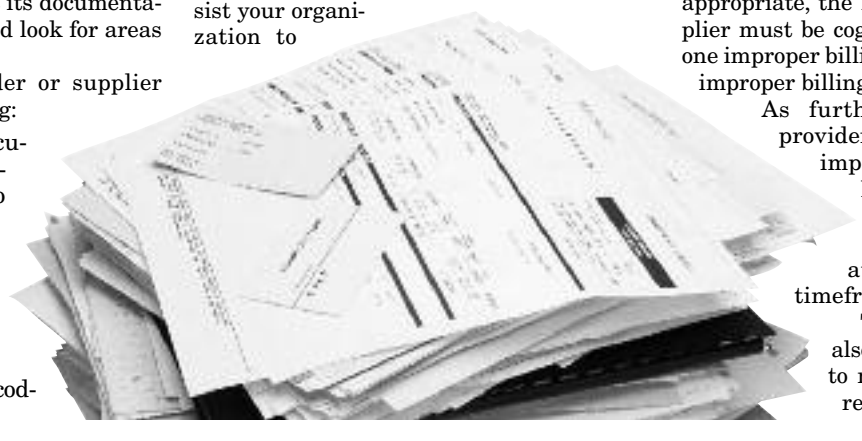
Ideally before a problem arises, but definitely once a Medicare provider or supplier is notified that it has been placed on non-random prepayment complex medical review, the Medicare provider or supplier must take an honest, hard look at its documentation and coding practices and look for areas for improvement.

For example, the provider or supplier should consider the following:

- Are the services fully documented to establish medical necessity, taking into consideration applicable Medicare National Coverage Determinations, Local Coverage Determinations, and policies?
- Are claims appropriately coded? For example, with respect to evaluation and management services, are all claims billed at a level 4 or level 5?

As further noted herein, unusual billing patterns and billing errors related to high-dollar values are red flags for Medicare reviewers. It may be beneficial to engage the services of an independent auditor to review a sampling of medical records and identify areas for improvement.

In addition, a qualified health care attorney or consultant can assist your organization to review its documentation and coding practices for compliance with Medicare policy. It may be advantageous for providers and suppliers to incorporate the suggestions of the independent auditor, health care attorney or consultant to potentially avoid future claim denials.



Importantly, although it is advisable that a Medicare provider or supplier subject to non-random prepayment complex review analyze its documentation for compliance with Medicare policy, and initiate corrections as appropriate, the Medicare provider or supplier must be cognizant that it not replace one improper billing practice with any other improper billing practice.

As further noted herein, if a provider or supplier engages in improper claims or billing-related activities in an effort to avoid review, the Medicare contractor is authorized to extend the timeframe for review.

The provider or supplier also may find it advantageous to meet with the Medical Director of the Medicare contractor reviewing its records as part of the non-random prepayment complex medical review. This meeting will provide the provider or supplier with an opportunity to gain an understanding of its situation, understand the specific areas identified as deficiencies, and understand the medical review process. A meeting also gives the provider or supplier an opportunity to explain its practice and any potential legitimate reasons for billing anomalies (e.g., a home care physician with numerous high-level evaluation and management codes, due to a highly-complex elderly patient population with numerous comorbidities).

Furthermore, providers and suppliers must be cognizant that should they experience claim denials as a result of the review, appeal rights through the Medicare appeals process apply. Accordingly, the provider or supplier should have systems in place to track claim denials and appeal deadlines. An experienced health care attorney can assist your organization to successfully appeal claim denials, by utilizing various strategies including drafting a position paper, employing an expert consultant/witness, arguing the merits of the underlying claim and employing legal defenses.

HIPAA changes included in stimulus law

By Correy E. Stephenson

In addition to making changes to COBRA and the tax laws, the American Recovery and Reinvestment Act of 2009 also included changes to the Health Insurance Portability and Accountability Act (HIPAA.)

The changes, which affect HIPAA's privacy and security requirements, came as something of a surprise because President Barack Obama didn't indicate they were part of his health care policy plans, said Rachel Cutler Shim, a partner at Reed Smith in Philadelphia who is an expert on health and welfare plan compliance.

As a result, covered entities must now "update their policies and procedures and retrain employees," she said.

The biggest change involves new requirements for breach notification.

The various provisions have different effective dates, with some taking immediate effect and others not going into effect until 2010.

In addition, Shim noted, some provisions — even if they have a specific effective date — still require regulations from the Department of Health and Human Services.

Here is a look at the major changes:

• Increased notification requirements

Covered entities are now required to notify affected individuals when a privacy breach occurs. (Previously, an entity only needed to try to limit the negative effects of a breach).

If the breach affects more than 500 people, the covered entity must also report the incident to HHS and the media, noted Joseph Lazzarotti of White Plains, N.Y., a partner at Jackson Lewis, who coordinates the firm's HIPAA and workplace privacy practice.

Notification must be given no later than 60 days after discovery of the breach, and if the breach includes 10 or more individuals with insufficient contact information, the covered entity must make a conspicuous posting on its website or provide notice in print and broadcast media.

Importantly, Shim noted, the notification requirement applies only to "unsecured" information, which is defined as protected health information that is not secured by an accredited "technology standard." The Act instructs HHS to issue further guidance — including what constitutes an accredited technology standard — in April.

• Business associates now covered

The changes expand who is covered by HIPAA to include "business associates" of covered entities.

Essentially, a business associate is an entity that wouldn't be covered by HIPAA but for its relationship with a covered entity, such as a third-party administrator who helps an employer administer its health plan, Shim explained.

But now, business associates are subject to the security regulations and privacy requirements of HIPAA, said Edward I. Leeds, counsel at Ballard Spahr Andrews & Ingersoll in Philadelphia, who focuses his practice on health and welfare benefit plans.

This change "will have a big impact because business associates [already] had obligations through contractual agreements with covered entities but now must comply with the statutory requirements" as well, he explained.

• Mandatory audits by HHS

Before, HHS was permitted to perform audits on entities covered by HIPAA to make sure they were following the rules.

"My sense is that enforcement was primarily complaint-driven, when HHS would receive a complaint and then look into it," Leeds said.

But the Act includes a provision requiring HHS to perform audits, which in turn could increase the amount of enforcement actions, Shim predicted.

• Expansion of individual rights

There are several changes that help to increase individual rights under HIPAA, Shim said.

For example, "individuals are now able to go to a doctor, pay 100 percent for their procedure and then notify the doctor that they want to limit the disclosure of their information and say it cannot be provided to their health insurer," she explained.

An employee might choose to keep information such as drug counseling private in this way, Shim said.

In addition, individuals also have greater rights to get an accounting of how their protected health information is being used.

• State attorneys general actions

Lazzarotti said he was surprised by the inclusion of a provision that allows state attorneys general to bring HIPAA enforcement actions.

The provision, which is effective immediately, allows state AGs to bring a civil action in federal court to enforce both the privacy and security provisions of HIPAA and seek damages on behalf of state residents.

• Greater fines and penalties

Covered entities that violate HIPAA are now subject to up to a $1,000 per violation penalty (up from $100 per violation) with maximum annual penalties of up to $1.5 million. Both civil and criminal penalties now apply to business associates as well.

• 'Minimum necessary' rule tightened

Previously, under HIPAA, the "minimum necessary" rule instructed covered entities that if they were using or disclosing protected information for any reason, the use or disclosure should be kept to the minimum amount necessary to accomplish the intended purpose.

Entities had a good deal of discretion in this area, Leeds said, but the "standard has now been tightened."

Under the new Act, the disclosure and use of protected information must be limited to a "limited data set" which is largely information with the patients' identifying information removed, "to the extent practicable." This is another area where HHS is scheduled to issue further guidance.

If you would like to comment on this story, please contact Correy Stephenson at correy.stephenson@lawyersusaonline.com.

Setting the standard

The Michigan Court of Appeals has relied on the wrong standard for determining whether a medical-malpractice plaintiff has made a case for loss of opportunity, say medical-malpractice legal specialists.

In *Lanigan v. Huron Valley Hospital, et al.*, the court said the plaintiff's case was "sufficient for a lost-opportunity claim under the statute as construed" by the Court of Appeals in *Fulton v. Beaumont Hospital*. The court based its conclusion on the fact that the percentage-point difference between the plaintiff's pre- and post-malpractice survival rates was "50 percent or more."

"The court should've said the difference must be greater than 50 percent if it wanted to comply with the statute and *Fulton*," said Detroit attorney Richard E. Shaw, who represents the plaintiff in *Lanigan*.

Southfield attorney Raymond W. Morganti of Siemion Huckabay Bodary Padilla Morganti & Bowerman PC, who focuses his practice on medical-malpractice defense, agreed.

Noting the court cited the correct standard elsewhere in the opinion, he said the court "misspoke" when it said the required lost opportunity had to be 50 percent or more.

According to the loss-of-opportunity statute, MCL 600.2912a(2), "In an action alleging medical malpractice, the plaintiff cannot recover for loss of an opportunity to survive or an opportunity to achieve a better result unless the opportunity was greater than 50%."

In *Fulton*, the 2002 decision interpreting the loss-of-opportunity statute, the Court of Appeals repeatedly said the lost opportunity must be "greater than" or it must exceed 50 percent.

"If there's nothing more tangible than lost years of survival, then 'Wickens' appears to say the plaintiff hasn't made her prima facie case."

— Richard E. Shaw, Shaheen, Jacobs & Ross PC

Med-mal

Continued from page 1

plaintiff to sue for a loss of opportunity to achieve a better result, based upon evidence concerning the reduction in the plaintiff's chances of survival, it is contrary to the Michigan Supreme Court's majority opinion in" *Wickens, et al., v. Oakwood Healthcare System, et al.*, wrote Southfield attorney Raymond W. Morganti of Siemion Huckabay Bodary Padilla Morganti & Bowerman PC, in an e-mail.

In the Supreme Court's 2001 opinion in *Wickens*, a four-justice majority said survival-rate statistics evidence is irrelevant to a living plaintiff's lost-opportunity claim. The lost-opportunity statute requires an "already suffered" injury, yet evidence concerning a reduction in a living plaintiff's chances of survival is proof only of "a potential, future injury — death …," the justices reasoned. Justice Robert P. Young Jr. wrote the majority opinion and was joined by then-Chief Justice Maura D. Corrigan and Justices Clifford W. Taylor and Stephen J. Markman. (See "Survival rate evidence" right.)

SHAW

Detroit attorney Richard E. Shaw of Shaheen, Jacobs & Ross PC, who represents the plaintiff in *Lanigan*, said he was pleased with the outcome, but didn't reject Morganti's point.

"There's a little tension there," he said, referring to *Wickens* potential effect on *Lanigan*.

Arguably, he said, under *Wickens*, a living plaintiff can't rely on survival or life-expectancy evidence to show loss of an opportunity to achieve a better result.

"If there's nothing more tangible than lost years of survival," Shaw said, "then *Wickens* appears to say the plaintiff hasn't made her prima facie case."

Detroit attorney Linda M. Garbarino of Tanoury, Corbet, Shaw, Nauts, Essad & Beutel PLLC, who represents defendant Huron Valley Hospital, declined to comment. Detroit attorney Stephen D. McGraw of Kerr Russell & Weber PLC, who represents defendant Dr. Steven D. Belen, couldn't be reached.

In her medical-malpractice lawsuit against Huron Valley Hospital and Belen, Jayne Lanigan claimed their alleged malpractice on Sept. 8, 2004, in Oakland County, caused her to lose her natural heart and decreased her life expectancy. Lanigan blamed the hospital and the doctor for not having diagnosed her heart attack quickly enough and not having rushed her to emergency heart-bypass surgery. Their failure to do so, she alleged, resulted in her having to undergo heart transplant surgery.

Among the allegations in her complaint, Lanigan said the defendants alleged malpractice caused her to lose "an opportunity to survive and/or an opportunity to achieve a better result that was greater than 50%."

The hospital and the doctor moved to dismiss, claiming Lanigan's lost opportunity to achieve a better result wasn't greater than 50 percent. Oakland County Circuit Court Judge Denise Langford Morris agreed and granted the defendants' motion.

The Court of Appeals, however, reversed and remanded, finding the lost opportunity to achieve a better result issue raised a fact question for a jury or judge to decide.

In reaching its conclusion, the court focused heavily on Lanigan's evidence regarding survival-rate statistics. The judges acknowledged *Wickens*, but determined the Supreme Court opinion didn't affect their approach.

Wickens established that a "living plaintiff cannot recover for a loss of opportunity to survive" because, under the lost-opportunity statute's plain language, "a lost-opportunity claim must include those injuries actually suffered and cannot include the possibility of future injuries, such as death," said the *Lanigan* panel. "However, this does not preclude courts from considering the plaintiff's risk of death as part of the calculation of the 'opportunity to achieve a better result,' as is the case here."

Judge Kirsten Frank Kelly wrote the majority opinion, which was joined by Judge Christopher M. Murray. Judge Elizabeth L. Gleicher concurred in a separate opinion.

Morganti, who focuses his practice on medical-malpractice defense, said the *Lanigan* opinion "appears to adopt the approach delineated by Justice Michael F. Cavanagh in his partial dissent in *Wickens*."

There, Cavanagh, who was joined by then-Justice Marilyn Kelly and Justice Elizabeth A. Weaver, wrote: "I believe that a living person may recover for injuries suffered as a result of learning of a reduction in life expectancy as a loss of an opportunity to achieve a better result and that the evidence concerning [a] plaintiff's reduced life expectancy is relevant to whether defendant caused" the injuries in question.

As of March 12, no reconsideration motion in *Lanigan* had been filed with the Court of Appeals. Nor had an application for leave to appeal been filed with the Supreme Court.

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

Survival-rate evidence

In *Wickens, et al., v. Oakwood Healthcare System, et al.*, the Michigan Supreme Court strongly implied that survival-rate statistics evidence is irrelevant to a living plaintiff's claim for lost opportunity to achieve a better result.

The justices said the loss-of-opportunity statute required proof of an injury already suffered, but, for living plaintiffs, loss of an opportunity to survive was an injury that had yet to occur.

Testimony that a living plaintiff's chances of surviving have decreased "is evidence of a potential future injury — death — which is not an injury already suffered, as required by the plain language of the statute," said the justices.

Moreover, they said, "evidence concerning the reduction in [a living plaintiff's] chances of survival is relevant *only* to her potential, future death …" [Emphasis in original.]

The implication of those statements was that survival-rate statistics evidence would never be relevant to a living plaintiff's lost-opportunity claim because, as a "potential, future" injury, it's not the "already suffered" injury the lost-opportunity statute requires.

The central question in *Wickens* was whether a living plaintiff may recover for loss of an opportunity to survive. The court answered "no." And, when it did, the court effectively limited living plaintiffs to claims for lost opportunity to achieve a better result.

According to the loss-of-opportunity statute, MCL 600.2912a(2), "In an action alleging medical malpractice, the plaintiff cannot recover for loss of an opportunity to survive or an opportunity to achieve a better result unless the opportunity was greater than 50%."

Medicare was created in 1965 as an amendment to the Social Security program. Medicare provides health insurance to people 65 and older, and to certain other qualifying individuals under that age. The overall purpose of Medicare is to provide payment for "basic" health care costs.

The Medicare limitation of liability provision

What providers can do so they don't get stuck with the bill

As health care costs continue to skyrocket, it is not uncommon for Medicare claims to be denied either because they are not covered under the program, or because they are found to be excluded from coverage as not reasonable and necessary.

In today's economy, it is especially important for health care providers to ensure that they will be compensated for services provided; using Advanced Beneficiary Notices (ABNs) will help recoup their costs.

Although Medicare is the largest health insurance program in the nation, not all medical expenses are covered. When a Medicare claim is denied, unless the provider has followed very specific requirements, it may not be able to recover the costs of the services from the patient, and thus may wind up footing the bill for what can be very expensive treatments.

The basis for this potential Catch-22 is found in Section 1879 of the Social Security Act. This section is known as the Limitation of Liability Provision. The basic purpose of this section is to protect Medicare beneficiaries from liability for the cost of medical services if a claim is denied because those services are determined to be excluded from Medicare coverage as not reasonable and necessary.

The Limitation of Liability Provision applies only to assigned Medicare services.

Even if the Limitation of Liability Provision applies and Medicare Part B denies a claim for medical services as not being reasonable and necessary, Medicare will still pay for these services if neither the provider nor the beneficiary knew, and could not reasonably be expected to have known, that the services were excluded from Medicare coverage.

Importantly for providers, if the beneficiary did not have this knowledge, but the provider knew, or could have been expected to have known of the exclusion, the provider will be held liable for the cost of the denied services.

The term "provider" is defined in the federal Code of Regulations, and generally includes Medicare participating hospitals, critical access hospitals, skilled nursing facilities, and comprehensive outpatient rehabilitation facilities. The term also includes certain home health care or hospice agencies, clinics, rehabilitation agencies, public health agencies, and community mental health centers.

Although not technically included within the definition of a "provider," the Limitation of Liability Provision also applies to physicians and suppliers, so long as they did not know, and could not reasonably have been expected to know, that the services or items in question were not medically reasonable and necessary. For ease of reference, the term "provider" also will include physicians and suppliers.

When does a provider have knowledge for limitation of liability purposes?

Providers receive numerous advisories and updates regarding Medicare coverage on a continual basis and are expected to be aware of which medical services are likely to be denied by Medicare.

Also, a previous denial notice to a provider for a service or item furnished in a particular situation is taken as evidence that the limitations on Medicare coverage were known. Thus, unless sufficient documentation accompanies a claim for Medicare reimbursement and states that the beneficiary was notified that the services at issue would likely be denied, Medicare takes the position that the provider is liable for payment for such denied services.

In a situation where services are provided to a beneficiary, and Medicare will likely consider not medically necessary, the provider must inform the beneficiary of that possibility to avoid being liable for the costs. The notification must be in writing and must be provided to the beneficiary before the service is provided.

The notice must specifically state that Medicare will probably deny the claim and that the patient bears responsibility for the cost of these services. Medicare has prepared a form, "Advance Beneficiary Notice CMS-R-131-G," on which to give this notice.

In addition, the Limitation of Liability Provision does not apply to services that would not normally fall under Medicare coverage — for example, cosmetic surgery or most dental services.

When does the Limitation of Liability Provision apply to Medicare beneficiaries?

The Limitation of Liability Provision will not apply to beneficiaries if the service or item is not covered by Medicare. This means that the service or item must not be specifically excluded from Medicare coverage under any provision of the Medicare statute. Further, even if the item or service is covered by Medicare, the Limitation of Liability Provision will still not apply to beneficiaries if the item or service is determined not to be medically reasonable and necessary.

For example, Mr. Doe mentions to his physician that he is experiencing occasional chest pain, and the physician immediately orders a stress test without further questioning or examination. Although stress tests are generally a covered service, in this situation it may be determined that the test was not reasonable or necessary for Mr. Doe because simply having occasional chest pain (which could just be from acid reflux, muscle spasms, etc.) does not always justify a stress test.

A Medicare beneficiary is not liable for payment of items that are denied as not reasonable and necessary if the beneficiary did not know, and could not reasonably be expected to have known, that the excluded items or services were not covered by Medicare.

Further, the Medicare carrier's manual provides that it must be assumed that the beneficiary did not know that Medicare would not cover the denied items and/or services, and that the provider did know.

That said, both of these presumptions can be rebutted by contrary written evidence. In deciding whether the beneficiary knew, or could reasonably have been expected to have known, that payment would not be made for items or services received, the beneficiary's statement that he or she did not know, in the absence of evidence to the contrary, must be accepted by Medicare for limitation of liability purposes.

There are two kinds of evidence that can rebut a beneficiary's assertion of lack of knowledge. First, the beneficiary is expected to know that the item or services are not reasonable and necessary after receiving a Medicare notice denying charges for the same or similar item or service. Second, a beneficiary is liable for payment if the physician or supplier accepting assignment gave the beneficiary advance written notice, in the form of a properly prepared and presented ABN, stating that Medicare is not likely to pay for an item or service and the beneficiary agreed to pay.

Given the recent recession and rapidly increasing health care costs, medical providers must carefully monitor and follow the requirements for receiving Medicare reimbursement. Failure to properly attend to these items can result in significantly decreased revenues to providers and leave them stuck with the bill.

Provider Compensation
By Michael J. Hamblin

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Components of Effective Advanced Beneficiary Notices

To be effective, an Advanced Beneficiary Notice(ABN) must meet the following requirements:

- It must be on an approved form (CMS-R-131-G).
- It must be given in writing in advance of furnishing the service or item in question.
- It must include the patient's name, dates and description of the service or item, and the reasons why the service or item may not be considered reasonable and necessary.
- It must be signed and dated by the patient, indicating that the patient assumes financial responsibility for the service if payment is denied as being not medically reasonable and necessary for reasons indicated on the ABN.

Sometimes, providers will give their patients generic notices or waivers which state that Medicare denial of payment is possible. This is not sufficient to avoid the beneficiary's limitation of liability.

The Department of Health and Human Services has directed that such generic notices are not to be considered acceptable evidence of a properly completed and presented ABN. Based on this directive, the ABN notice requirements are not satisfied by a generic document that is little more than a signed statement by the beneficiary to the effect that, should Medicare deny payment for anything, the beneficiary agrees to pay for the service. To the contrary, such notices are defective and will not negate the provider's liability for payment.

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