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Inside MedLaw

Incentives available for EHR users

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

On Jan. 13, 2010, the Centers for Medicare and Medicaid Services (CMS) published a Proposed Rule clarifying the definition of "meaningful use."

The Health Information Technology for Economic and Clinical Health Act (HITECH) Act generally establishes incentive payments for certain "eligible" providers who demonstrate that they are "meaningful users" of "certified Electronic Health Records (EHR) technology."

Providers who do not achieve meaningful use will be subjected to penalties beginning in 2015. Thus, the meaningful use definition is very important for all providers, including those who are interested in qualifying for incentive payments as well as those who wish to avoid future penalties.

Meaningful use criteria

The Rule envisions a phased approach to demonstrating meaningful use. This approach recognizes that existing technological limitations make full adoption of EHR difficult to achieve immediately, and allows providers to incrementally expand and improve their technologies while continuing to receive incentive payments.

This approach would entail a total of three stages of criteria, and dictates a specific timeline by which providers

See "EHR incentives," page 14

Testimonials under scrutiny

By Suzanne D. Nolan, Esq.

Anyone with access to a television or Web browser has undoubtedly seen advertisements for health care products or services featuring beaming, satisfied patients endorsing a certain provider or product.

Such "testimonials" have become especially popular on consumer-generated media such as blogs, online forums, Twitter, and social networking sites, where it is often not apparent to the consumer whether the person giving the testimonial has been compensated for doing so.

Guidelines revised

As a result of these trends, the Federal Trade Commission (FTC) has become increasingly wary of health care providers making claims about the efficacy and safety of the services they provide to patients, and the use of "results not typical" disclaimers in advertising.

To address its concerns, the FTC has issued revised its "Guides Concerning the Use of Testimonials and Endorsements in Advertising" (Guides). Advertising practices that are inconsistent with the Guides are generally violations of section 5 of the FTC Act, and such advertising is considered false and deceptive.

Under the revised Guides, health care providers now face a significant liability risk. Specifically, they can be held liable for the truth and accuracy of endorsements in advertisements prepared for them by a third party, such as an ad agency or a blogger, if the health care provider has sponsored the advertising.

Health care providers also can be held liable if a blogger fails to disclose a material connection to the provider.

Accordingly, licensed health care professionals should take care to review and comply with the Guides and the FTC Act. Notably, Michigan's Public Health Code specifically authorizes the Bureau of Health Professions to investigate complaints that a health care professional has engaged in false or deceptive advertising, and impose sanctions against the professional's license if such violations are found.

The Guides mainly focus on sponsored en-

See "FTC guidelines," page 6

Beware

Investigations and disciplinary actions may lead to charges

By Robert S. Iwrey, Esq.

Health care investigations not only can be disruptive and time consuming — they also can lead to criminal charges.

Investigations into, and disciplinary actions against, Michigan licensed health care providers fall within the purview of the Bureau of Health Professions (BHP).

An investigation into a health care licensee is often initiated by a patient who has filed an allegation against the health care licensee with the BHP.

Typical allegations are for quality of care concerns, a scope-of-practice concern issue or the conduct of the licensee, which may include potential criminal conduct (e.g., a patient who is billed for services he or she never received may submit a written allegation for same to the BHP).

After receiving an allegation, the BHP reviews it and determines whether the alleged facts could be deemed a violation of Michigan's Public Health Code and warrant an investigation.

In addition to allegations filed by patients, the BHP also may receive written notice of

See "Licensing actions," page 12

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MSC justices clash over amended rules

Medical Malpractice

By Brian Frasier, Esq.

New amendments to medical-malpractice pleadings rules will give relief to plaintiffs in the event that a notice of intent or affidavit of merit are defective.

But critics, including Justice Stephen J. Markman, say that the changes effectively "wipe out" the statute of limitations in these cases.

"I am concerned that a plaintiff will be able to file a complaint with a defective affidavit of merit and then wait indefinitely to file an amended conforming affidavit, rendering the two-year period of limitations essentially meaningless," Markman wrote in a dissent attached to the amendments.

Chief Justice Marilyn Kelly, who concurred with the changes, countered the statute of limitations is not affected.

"It is merely the application of that statute of limitations period that may change in certain circumstances," she wrote. "Defendants still must be provided with a complaint and affidavit of merit within the applicable time. Defendants will still be on notice of the claims against them within the requisite time period and will be fully aware of the conduct … at issue as set forth in the original pleadings."

Markman said Kelly is "missing the point" about statute of limitations.

"While she downplays the significance of this by referring to it as 'merely' the application of that limitation period, what is the point of a two-year limitations period if by its 'application' it can be extended to a five-year, 10-year or even a 20-year limitations period?" he asked.

"At which point does the majority recognize that it has simply read 'limitations' out of 'limitations period'?"

What about 'Kirkaldy'?

Markman also complained the changes are inconsistent with court precedent in *Kirkaldy v. Rim* (Lawyers Weekly No. 06-63495, 9 pages), and will cause confusion in the trial courts.

"[I]t is ill-advised as a general matter for this Court to reverse its own precedents by altering court rules," he wrote. "These amendments have received no adversarial briefing and no adversarial argument of the sort that normally accompanies this Court's reversing its own precedents."

Kelly said the two standards are not inconsistent.

"*Kirkaldy* held that if an affidavit of merit is successfully challenged, the proper remedy is dismissal without prejudice," Kelly wrote. "The plaintiff is left with whatever time remains in the period of limitations to file a complaint with a conforming affidavit of merit.

She argued the new rules give judges a choice of options based on their assessment of the affidavits themselves.

"If a court permits an amended affidavit of merit, MCR 2.118(D) applies," she wrote. "If a court denies a request to amend a defective affidavit of merit, then *Kirkaldy* provides the appropriate court of action."

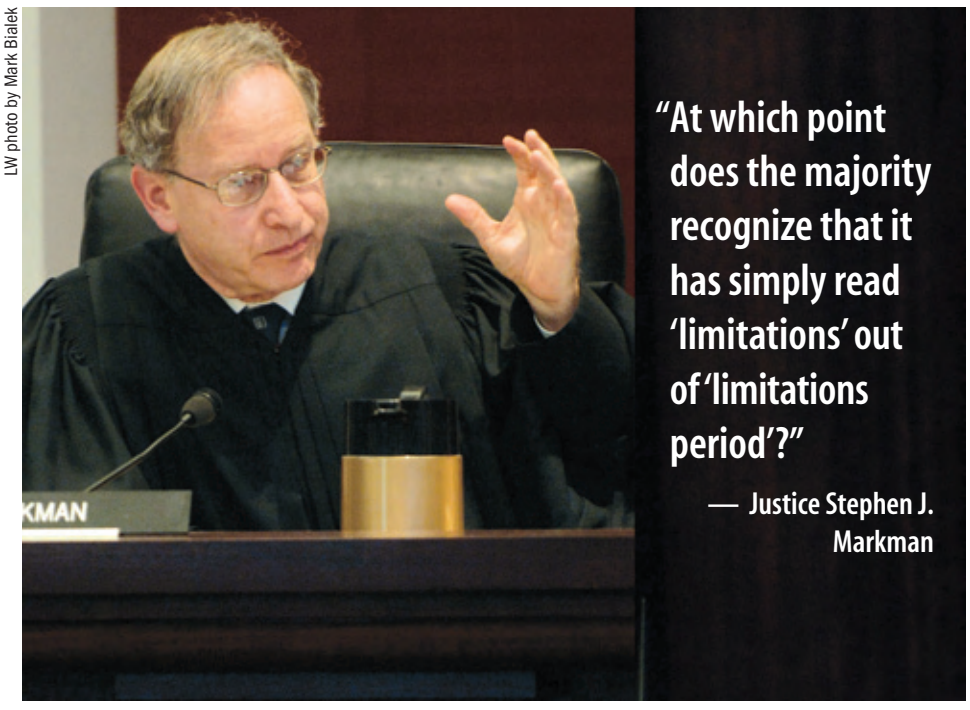
Markman replied that, by arguing that the judges have a choice of authorities to follow based an assessment of the defects, Kelly acknowledges that the amendments are inconsistent with *Kirkaldy*.

Justices Maura D. Corrigan and Robert P. Young Jr. wrote their own dissenting opinions backing Markman's arguments.

No more 'lying in wait'

"There's no reason at all why defendants should be able to lie in wait and let time go by and later bring a hyper-technical challenge to an [notice of intent (NOI)] or affidavit of merit [AOM]," said Brian McKeen of McKeen & Associates, P.C., who welcomes the changes.

LW photo by Mark Bialek



"In every aspect of the law, people are allowed to amend the complaint. Why should it be any different for a notice of intent or an affidavit of merit, both of which need to be filed before you even have any discovery?"

The changes to MCR 2.112(L)(2) and 2.118(D) will require a defendant challenging a notice of intent to do so by motion at the same time as the first responsive pleading.

Parties also will be required to challenge an affidavit of merit or meritorious defense within 63 days of service. Perhaps more importantly, affidavits of merit or meritorious defense can be amended retroactive to the date of the original filing.

Often times, things are learned during discovery that an attorney would have no way of knowing beforehand, McKeen said, making amendments to pleadings both fair and necessary.

Ramona Howard, also of McKeen & Associates, said the changes make the rules related to affidavits of merit and meritorious defense the same as those currently in place for NOIs.

"What they said was that a deficient notice of intent will toll the statute of limitations, and you get to amend your notice of intent if [you meet certain criteria], and there's no prejudice to the defendant," she said. "I think they're putting affidavits and NOIs on the same playing field."

Both McKeen and Howard wrote comments to the court during the amendment process.

More proactive defendants

Defense attorney D. Jennifer Andreou, head of Plunkett Cooney's medical liability litigation group in Mount Clemens, said the changes will end some of the "procedural nightmares" litigants face in medical malpractice cases.

Defense attorneys will have to be more proactive in their responsive pleadings, which may force changes to their clients' policies for handling new cases, she said.

Some clients want to keep NOIs until a complaint is filed, which delays obtaining the affidavit of merit for review, Andreou said.

"This is going to expedite that timeline even more," she said. "We're going to have to compare the NOI to the complaint to see if there are any challenges we should make as well to the affidavit."

Andreou also noted that the new rules give defendants the same courtesy in amending their affidavits of meritorious defense.

Howard said the changes should prevent a lot of repetitive work in cases in which a defective pleading is filed.

"Typically, if they challenged your affidavit of merit and it was deemed to be deficient, the remedy under the *Kirkaldy* case was dismissal without prejudice," she said. "They eventually did say that a deficient affidavit will toll the statute of limitations, [but] you'd have to refile.

"Why should you have to go back and start over again? Amending it makes so much more sense."

Despite the *Kirkaldy* precedent, some judges have already been allowing amendments to defective pleadings.

"I think the amendments are in line with how everyone's been practicing anyway," Andreou said.

The changes go into effect May 1.

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

LW photo by Mark Bialek

Key contract considerations in choosing an EHR system

Business of Medicine

By Suzanne D. Nolan, Esq.

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Choosing an electronic health records (EHR) system that matches the needs of a provider can be a time-consuming challenge.

Because the main focus during the selection process is usually on how the EHR system will perform and meet the needs of the practice, little consideration may be given to the terms of a contract between an EHR vendor and provider until the very end.

That's when the vendor presents its contracts (i.e., license agreement, support agreement, purchase agreement, etc.), often hoping that the provider will sign on the dotted line without question.

A review of the contracts, particularly key provisions regarding the license and support services should be an integral part of the initial selection process — and will likely save a provider from the headache of 11th-hour negotiations with a stubborn EHR vendor.

Scope of agreement

First, a provider should determine how many software licenses it needs, and for what locations. A license may be granted for a specific number of users; for use by a specific number of concurrent users; for use on specific hardware; or for use at a specific location.

Providers should understand what is meant by a "user," and make sure that the license accommodates everyone who needs access to the EHR system.

Next, there should be a mechanism in place whereby the provider can purchase additional licenses for a reasonable fee as the provider adds physicians and staff, or opens additional locations.

If a provider consists of separate legal entities, the license must grant rights to each separate legal entity, such as a subsidiary, and not just the parent entity. If the license is for a set period of time, it should clearly state the renewal terms and conditions.

Users 'rights'

Importantly, the license agreement will determine the rights that a provider has in the EHR software. Patents, copyrights and trade secrets (collectively, "intellectual property") can all protect software.

Copyright protection is the most common form of protection for software and for the documentation and training materials ("user materials") accompanying the software. Notably, the provider will only have those rights to use, modify or copy the EHR software and the user materials, as are set forth in the license agreement.

If the provider exceeds the scope of the license granted, the provider may be held liable for infringement of the licensor's intellectual property rights.

In addition, the license must permit all of the provider's intended uses of the EHR software.

A license typically grants the provider the right to use the software for "internal business purposes." Therefore, such a license will not permit the use of the software by "outsourcing" contractors, even when they are acting solely for the benefit of the provider.

Additionally, the license should authorize the provider to make copies of the software and any user materials for archival and backup purposes.

The provider should consider rejecting licenses that do not permit a transfer of the license to a new location if the provider moves, or licenses that have an outright prohibition on transfers.

The provider also should insist upon having the right to transfer the license in the context of a merger, consolidation of business operations, bankruptcy, or reorganization. It is important that the provider have the right to transfer all rights in and to the software.

Support and maintenance

Next, the provider needs to verify that support and maintenance services are available to keep the software running properly.

See "EHR contracts," page 13

Close scrutiny

Stricter requirements in place for inpatient rehabilitation facility services

As of Jan. 1, 2010, Inpatient Rehabilitation Facilities (IRFs) are facing stricter coverage requirements, resulting from changes mandated by the IRF-PPS Final Rule.

By way of a Transmittal dated Oct. 23, 2009, and revised Jan. 4, 2010, Centers for Medicare & Medicaid Services (CMS) set forth revisions to the Medicare Benefit Policy Manual.

Generally speaking, the new requirements set forth specific criteria by which CMS will make determinations as to whether services are "reasonable and necessary" and thus covered by Medicare.

Pre-admission screening

Prior to admission, a screening must be conducted including the following information:

- Prior level of functioning;
- Expected level of improvement;
- Expected length of time necessary to achieve that level of improvement;
- Risk for clinical complications;
- Specific treatments needed;
- Expected frequency and duration of the treatments;
- Anticipated destination to which the patient will ultimately be discharged;
- Anticipated post-discharge treatments that will be required; and
- Additional information relevant to the patient's care needs.

This pre-admission screening must occur within 48 hours of the patient's admission and must be performed by a rehabilitation physician, or by licensed or certified clinicians who are qualified to perform the evaluation and designated to do so by a rehabilitation physician.

In all cases, a rehabilitation physician with appropriate specialized training and experience must review and concur with the findings of the screening evaluation prior to admission.

"Trial" IRF admissions, in which patients are admitted for three to 10 days to assess whether the patient would best benefit from treatment in an IRF or in other settings, will no longer be considered reasonable and necessary.

Regulation
By Andrew B. Wachler, Esq.

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Post-admission physician evaluation

A post-admission evaluation also must be performed, and is designed to document the patient's status after admission, compare it to that noted in the pre-admission screening, and begin to develop the patient's expected course of treatment.

The post-admission evaluation must include a documented history and physical exam, as well as a review of the patient's prior and current medical and functional conditions and co-morbidities.

This evaluation must be conducted within 24 hours of admission by a rehabilitation physician, with input from all members of the interdisciplinary team who will assist in carrying out the treatment plan.

Individualized plan of care

The patient's record also must contain an individualized overall plan of care, and must detail the following:

- Medical prognosis;
- Anticipated interventions that will be performed, including the expected intensity, frequency, and duration of each category of therapy services required;
- Desired functional outcomes; and
- Anticipated location to which the patient will be discharged following the IRF stay.

The individualized plan of care must be completed by a rehabilitation physician within four days of admission.

Admission orders

Although IRF admission orders were always required, CMS clarified that orders must be generated for each patient at the time of IRF admission and maintained in the patient's medical record at the IRF.

The IRF Patient Assessment Instrument (IRF-PAI) forms must now be included in either electronic or paper form in the patient's medical record, must properly correspond to all other information contained in the patient's record, and must have a date and time data entry.

There also must be a reasonable expectation at the time of admission that the following requirements will be met:

- The patient must require the active and ongoing therapeutic intervention of multiple therapy disciplines, at least one of which must be physical or occupational therapy;
- The patient must generally require an intensive rehabilitation therapy program, which typically will consist of at least three hours of therapy per day at least five days per week;
- The patient must reasonably be expected to actively participate in and benefit significantly from the therapy program; and
- The patient must require supervision by a rehabilitation physician, and the physician must conduct face-to-face visits with the patient at least three days per week throughout the patient's stay.

Miscellaneous

Finally, the new manual provisions also contain additional language clarifying when IRF services, as opposed to services provided in other rehabilitation settings, will be appropriate.

For example, in order to support that interdisciplinary IRF services are necessary, the complexity of the patient's condition must be such that the rehabilitation goals can only be achieved by a coordinated effort by an interdisciplinary treatment team.

That team must consist of, at a minimum, members from each of the following disciplines:

1) A rehabilitation physician with specialized training and experience in rehabilitation services;
2) A registered nurse with specialized training or experience in rehabilitation;
3) A social worker or a case manager; and
4) A licensed or certified therapist from each therapy discipline involved in treatment.

All members of the team must meet at least weekly to reassess the patient's progress and rehabilitation goals and to modify the treatment plan as necessary.

There also must be a reasonable expectation that the patient will be able to actively participate in, and significantly benefit from, the services rendered, including a reasonable expectation that a measurable, practical improvement in the patient's functional condition can be accomplished within a predetermined and reasonable period of time.

The patient need not be expected to return to complete independence, but must be able to make functional, ongoing and sustainable improvements as measured against the patient's condition at the beginning of treatment.

The new coverage policy represents a significant change from prior policy and imposes significant additional detailed requirements on IRFs.

Thus, it is important that such facilities become familiar with the new policy and adopt policies and procedures designed to ensure that all requirements are met in order to ensure initial coverage or to avoid a potential adverse audit determination.

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Excise tax may result from violations

Do you know that if you fail to comply with the requirements for COBRA continuation coverage or rules governing employer-sponsored health plans, your company (or possibly your third-party administrator) may be subject to significant excise taxes?

While the Internal Revenue Code has provided for such taxes for many years, there was no procedure or specific directive to report violations and pay the tax until this year.

Beginning in 2010, employers must report compliance failures and pay the applicable excise tax on new IRS Form 8928, "Return of Certain Excise Taxes under Chapter 43 of the Internal Revenue Code." The instructions to Form 8928 provide helpful guidance for complying with the reporting requirements.

Violations that must be reported include failures to comply with the requirements of:

- COBRA;
- HIPAA portability, access, renewability and non-discrimination rules;
- Genetic Information Non-discrimination Act (GINA);
- Mental Health Parity and Addiction Equity Act;
- Newborns' and Mothers' Health Protection Act;
- Michelle's Law; and
- Comparable employer contributions to Health Savings Accounts (HSAs) and Archer Medical Savings Accounts (MSAs).

Compliance

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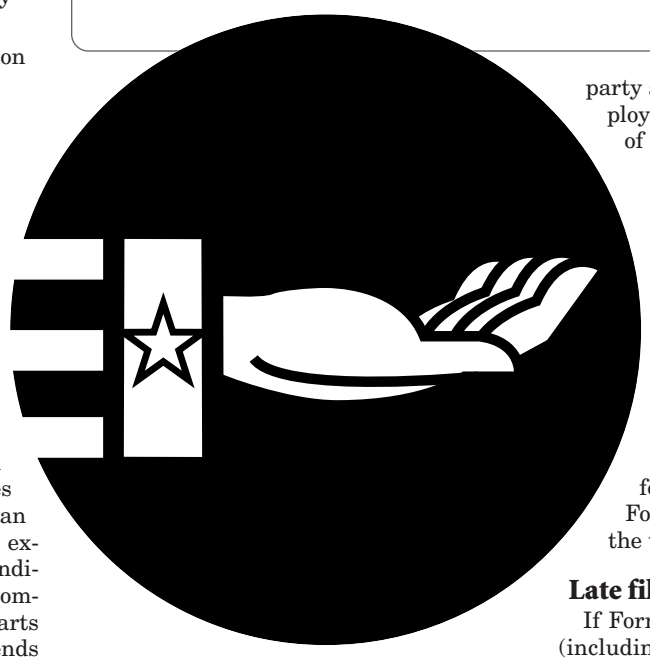

What is the amount of the excise tax?

For failures to comply with COBRA continuation coverage rules and failures to comply with federal group health plan rules, the amount of the non-deductible excise tax is generally $100 per affected individual for each day the plan is not in compliance. The non-compliance period starts on the day the failure first occurs and ends on the day the failure is corrected.

An employer who fails to make comparable contributions to HSAs and MSAs could be subject to an excise tax equal to 35 percent of employer contributions made to all HSAs or MSAs during the calendar year.

When is the excise tax paid?

For failures to comply with COBRA or the group health plan rules, the excise tax and Form 8928 are due on or before the due date for filing the employer's federal income tax return (without extension). A Form 8928 reflects the portion of the non-compliance period that falls within the employer's taxable year. Violations spanning multiple years require multiple filings. The reporting requirement for a COBRA violation may be the responsibility of the insurer or third-party administrator (rather than the employer) if the violation occurred because of its act or failure to act.

The excise tax for a failure to make comparable contributions also is reported on Form 8928 but is due on or before April 15 of the calendar year following the calendar year in which the non-comparable contributions were made.

An automatic extension to file Form 8928 is requested by filing Form 7004, "Application for Automatic Extension of Time to File Certain Business Income Tax, Information, and Other Returns." Form 7004 does not, however, extend the time for paying the excise tax.

Late filing of tax

If Form 8928 is filed after the due date (including extension), a penalty is charged, unless the filer can demonstrate that there is a reasonable cause for not filing on time. The penalty is 5 percent of the excise tax due for each month or part of a month the return is late, with a cap of 25 percent of the unpaid tax.

There also is a penalty for failing to pay the excise tax on time equal to .5 percent of the any tax not paid by the due date for each month or part of a month the tax remains unpaid, up to 25 percent of the unpaid tax. Like the penalty for late filing, the late payment penalty will be waived if there is a reasonable cause for not paying on time.

On top of the penalties, interest can be charged on unpaid excise taxes and the additional penalties imposed.

Are there exceptions?

Yes. The excise tax is not due if (1) the person liable for the excise tax does not know about the compliance failure or when exercising reasonable diligence would not have discovered the failure, or (2) the failure is due to a reasonable cause, not willful neglect, and it is corrected within 30 days of discovering the failure.

Any correction requires the failure to be retroactively undone to the extent possible, and putting the affected individual(s) in a financial position, which is as good as he, she or they would have been in had the failure not occurred.

Should you fail to make comparable contributions to the HSAs or MSAs of comparable participants, the excise tax may be waived if the tax imposed is excessive relative to the failure involved, and the failure does not result from willful neglect.

Getting started

Employers should have procedures in place to identify potential problems and ensure compliance with the laws identified above. Prepare and regularly review a compliance checklist. Understanding the requirements applicable to employer-sponsored health plans and COBRA continuation coverage is essential to properly administering your group health plan.

Because the rules under Mental Health Parity and GINA became effective for most group health plans in 2010, review wellness and disease management programs as well as your health plan provisions to determine whether any changes are needed to comply with these new federal laws, if you have not focused on this yet.

If plan failures occur, the employer or other responsible party must take prompt action or face expensive penalties. The statute of limitations on an assessment does not begin to run unless a return is filed. Make sure employees involved in plan administration are aware of these new self-reporting requirements.

Spring RAC update

Hospitals and health providers in Michigan should visit the Web site of the Region B (Recovery Audit Contractor) RAC, CGI Technologies and Solutions, at http://racb.cgi.com to update their contact information using the "Providers" link.

Providing a direct contact for the appropriate person at your entity will ensure that valuable time is not wasted once an additional documentation request letter is sent to your office.

Providers only have 45 days from the date of the letter to provide the medical records requested, so it is important to have an efficient method for processing requests in place.

CGI recently added new approved issues to its site, bringing the total to 50. Many of the issues approved for complex review involve DRG validation.

The purpose of DRG validation is to ensure that diagnostic and procedural information and the discharge status of the patient, as coded and reported by the hospital on its claim, matches both the attending physician's description and the information contained in the patient's medical record.

The issue of medical necessity is excluded from review but is expected later in 2010.

On Jan. 28, 2010, the Centers for Medicare & Medicaid Services (CMS) expanded the scope of its Additional Documentation Request (ADR) Limits to include all ADR requests to institutional providers.

These limits previously applied only to requests related to DRG validation issues. The ADR limits apply "per campus," which is defined based on the provider or supplier's Tax Identification Number and the first three positions of the ZIP code where the provider is physically located.

The limits are set at 1 percent of all claims submitted for the previous calendar year, divided into eight periods of 45 days, and are capped at 200 ADRs per 45 days. This cap will increase to 300 ADRs per 45 days in April 2010.

Provided by Wachler & Associates, P.C. For more information visit www.wachler.com.

Physician's fraud conviction affirmed

On Dec. 1, 2009, the 6th U.S. Circuit Court of Appeals affirmed the conviction of Ohio anesthesiologist Dr. Jorge A. Martinez, who was charged with illegally distributing controlled substances, mail fraud, wire fraud, and health care fraud, including two counts that resulted in the death of patients.

In 2002, the FBI began investigating Martinez's pain-management clinic in Parma, Ohio, in response to reimbursement and billing patterns placing him above his peers for certain procedures.

At trial, the government alleged that from 1998 until 2004, Martinez engaged in fraud and endangered patients by omitting physical examinations of the patients, ignoring "red flags" of patient addiction to pain medication, providing more injections than were medically necessary or advisable.

In addition, they alleged he provided at-risk patients with treatments that would likely lead to increased dependence upon him for additional pain medication.

The government was able to demonstrate that Martinez administered far more injections than his peers (e.g., each of Martinez's patients averaged 64 nerve block injections per year whereas the state average for pain patients in Ohio was 2½ nerve block injections per year).

Moreover, Martinez saw more patients per day than any other physician in Ohio, sometimes exceeding 100 patients during an 8½-hour time frame.

Witnesses testified that he frequently spent only two to five minutes with patients during their scheduled appointments and performed little or no physical examination during these brief visits. The government also demonstrated that two patient deaths were reasonably foreseeable consequences of Martinez's course of treatment, which fell far below the applicable standards of care.

Much of the government's case focused on Martinez's failure to comply with the requirements for billing the highly reimbursed nerve blocks he allegedly performed.

While the applicable standards of care require careful, precise placement of the injection needle, Martinez was seen entering the room, quickly and repeatedly injecting patients, and exiting the room — all within a few minutes.

One of the main issues on appeal concerned the government's use of video evidence of a non-witness physician performing a nerve block injection in the "proper" manner — creating a direct visual contrast between what was labeled as the proper way to perform the injection and the manner in which Martinez performed the injection.

The appeals court found that while the video evidence did constitute impermissible hearsay, its admission was harmless in light of the overwhelming evidence that Martinez was not performing medically necessary procedures, and that the procedures he was performing were not the same as the ones for which he billed.

In addition to upholding Martinez's conviction, the Appeals Court also upheld his sentence for life imprisonment and more than $14 million in restitution.

The full text of the case can be found at: www.healthlawattorneyblog.com/U.S.%20v.%20Martinez.pdf.

Enforcement

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The whole patient

Clinic helps when health, legal issues collide

By Carol Lundberg

There are times when physical illness can't be treated with medicine alone, and a sick person needs a lawyer as much as a doctor if he's going to get better.

A newly formed partnership at William Beaumont Hospital in Royal Oak will help patients with the legal problems that are making — or keeping — them sick.

"The idea is that there are socioeconomic issues that impact patient care," said Karen Glorio Luther, senior corporate counsel with Beaumont's office of legal affairs, which launched the program, Legal Aid for Children, last fall. "The idea is to treat problems holistically."

The plan for this year is to focus on training doctors and medical students about what legal remedies are available to patients, and to spot potential legal issues when treating patients.

For example, if a family doesn't get a prescription filled because they don't have the money for it or their insurance won't cover it, the physician spends time to call the pharmacy and find out. And the patient hasn't gotten any better.

That's a clue that the patient needs legal help.

"We check to see if they qualify for food assistance. If you're disabled, you might be able to receive state and federal disability benefits," said Michele Hall-Edwards, deputy chief counsel for the civil law group at the Legal Aid and Defender Association (LADA) in Detroit, which provides legal services to the Beaumont clients.

"If you need a nebulizer for asthma, and your electricity has been turned off, you need help in more than one area."

One of the big problems is substandard housing, said Luther. Asthma, she said, is exacerbated by environmental factors such as mold.

"Or if there are rodents in your apartment building, that can also make treating asthma difficult," Hall-Edwards said.

Luther heard about such hospital-legal aid collaborations from a lawyer affiliated with the National Center for Medical Legal Partnerships, which first formed at Boston Medical Center in 1993.

It took two years of planning and applying for grants from Oakland County Bar Foundation, The United Way, American Academy of Pediatrics and Legal Services Corp., and acquiring space on the Beaumont campus, to start the program in Royal Oak.

And it's starting small, with just one person, Luther, on staff. Legal services are provided by LADA. The Beaumont program's total budget for the year is $55,000.

There are about 550,000 at or below poverty in the tri-county area, and that number is only getting bigger, Hall-Edwards said.

"If we address our legal issues, the doctors can do what they do."

— Michele Hall-Edwards, Legal Aid and Defender Association

"The problems are the same for everyone, whether we work with them here at Beaumont, or downtown, or out in Clinton Township. The problems can range from bankruptcy and foreclosure to bedbugs," she said. "If we address our legal issues, the doctors can do what they do. We have our mission, and they have theirs."

So far, most of the program's 32 cases have centered on insurance problems.

"We had an instance of a health insurance company that was routinely denying payments for a medication that is used for treating a particular illness," Hall-Edwards said.

Clients also have needed help with acquiring disability benefits and Supplemental Security Income benefits, bankruptcy and foreclosure, guardianship, divorce, and housing.

"The idea is to make it easily accessible because when you have a sick child, everything else pales in comparison," Luther said. "By allowing parents and doctors to focus on the child's health rather than on the legal problems, we should be able to improve outcomes."

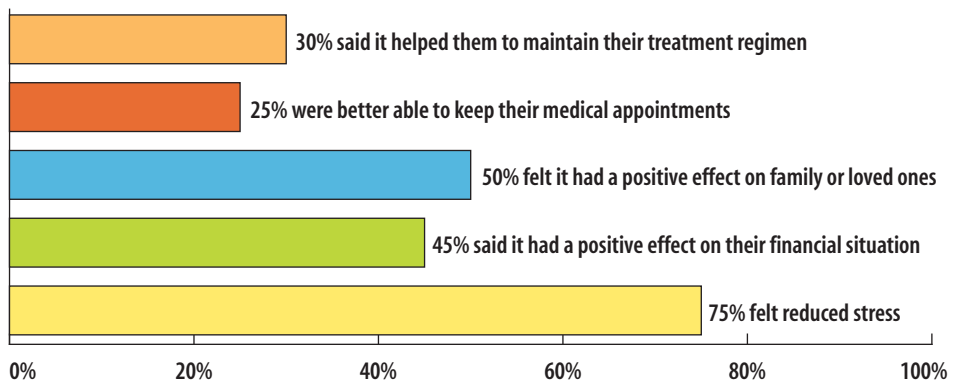
If you would like to comment on this story, please contact Carol Lundberg at (248) 865-3105 or carol.lundberg@mi.lawyersweekly.com.

LW photo by Carol Lundberg

Karen Glorio Luther, left, and Michele Hall-Edwards, right, are collaborating to help sick children get better when their parents have legal troubles.

Impact of legal intervention on patients' quality of life

Of patients surveyed who received legal help during their illness . . .



Source: Legal Health survey of clients who were cancer survivors, 2006

FTC guidelines

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dorsements. An endorsement (or a testimonial) is any advertising message that consumers are likely to believe reflects the opinions, beliefs, findings, or experiences of a party other than the sponsoring advertiser, even if the views expressed by that party are identical to those of the sponsoring advertiser.

An advertising message is "sponsored" if the endorser is acting on behalf of the advertiser (i.e., the health care provider) or its agent (i.e., an ad agency) such that the endorser's statements are part of an overall marketing campaign.

In a nutshell, if the endorser has been paid, either in cash or with free goods or services, to make the endorsement, the advertisement will usually be considered sponsored by the advertiser.

In consumer-generated media, it is not usually clear when an endorsement or testimonial is "free" or is "paid for." If a blogger receives money or free products/services from the health care provider, the blogger should disclose the relationship.

'Results not typical'

With respect to the content of endorsements, one of the major changes affects the use of "results-not-typical" disclaimers.

These ubiquitous disclaimers have been used in advertisements that portray a consumer discussing atypical or best-case scenario results. Previously, because of the use of the disclaimer, the FTC did not consider these ads to be deceptive.

However, after conducting studies, the FTC concluded that such disclaimers are ineffective because consumers believe they can achieve the atypical results shown in the ad.

Under the revised Guides, the FTC is now requiring clear and conspicuous statements of typical results.

As one example, if an ad features before-and-after pictures of a woman who lost 50 pounds in six months by drinking WeightAway shakes, the ad is likely to convey that her experiences are typical of what consumers will generally achieve.

If consumers can generally be expected to lose only 15 pounds in 6 months, the ad should clearly and conspicuously state that most women using WeightAway shakes for six months can lose at least 15 pounds. If it does not, the ad may be considered to be deceptive under the revised Guides.

Honest representation

The Guides also emphasize that an endorsement must reflect the honest opinions, findings, beliefs or experience of the endorser. In sum, an endorsement cannot convey any express or implied representation that would be deceptive if made directly by the advertiser.

For example, if a health care provider would like to make the statement that its baldness treatment results in amazing hair growth and hair that is as thick and strong as a teenager's, it must have substantiation to make such claims.

Without such substantiation, not only is the provider prohibited from making such statements, it also cannot use consumers to give such testimonials.

Another significant (and controversial) change is the requirement to disclose material connections between the health care provider and the endorser that might affect the weight or credibility of the endorsement unless such connections are obvious.

In consumer-generated media, it is not usually clear when an endorsement or testimonial is "free" or is "paid for." If a blogger receives money or free products/services from the health care provider, the blogger should disclose the relationship.

Importantly, if the health care provider or its ad agency has sponsored the endorsement and the blogger fails to disclose the material connection, the health care provider may be held liable.

Similarly, endorsements given by employees on social networking sites may expose the health care provider to liability unless the employment relationship is disclosed. Additionally, the inability of an advertiser to control what an endorser states is considered irrelevant.

To limit its liability, a health care provider should ensure that any ad agency it uses provides guidance on complying with the Guides to its bloggers.

The FTC has indicated that it will consider the steps an advertiser has taken to advise endorsers of their responsibilities and to monitor the online behavior of endorsers in determining what action, if any, would be warranted against an advertiser if an endorser fails to disclose a material connection.

Similarly, if an employer has instituted policies and practices addressing the use of social media by its employees, those procedures will be considered by the FTC.

Suzanne Nolan is an associate at Frank, Haron, Weiner & Navarro, PLC. Her practice focuses upon business and intellectual property transactions, including trademark, patent, and copyright licensing, e-commerce transactions, asset purchase and sales transactions, and real estate transactions for all types of entities, including health care providers. Nolan also advises health care clients on HIPAA Stark, and Anti-Kickback Statute compliance and licensing matters. Contact her at (248) 952-0400 snolan@fhwnlaw.com.

Pending Legislation

Michigan Medical Legislation Report

Following is a list of bills pending in the Michigan Legislature related to health care and health care professionals. Detailed information and analysis on this and other pending legislation can be found at www.michiganlegislature.org.

HOUSE BILLS

HB 5289 — Amend 2008 IL 1, the Michigan Medical Marihuana Act

"A qualifying patient who has been issued and possesses a registry identification card shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, for the medical use of marihuana in accordance with this act, provided that the qualifying patient possesses marihuana that was dispensed as a schedule 2 controlled substance under the public health code, 1978 PA 368, MCL 333.1101 to 333.25211, for his or her medical use.

"A primary caregiver who has been issued and possesses a registry identification card shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, for assisting a qualifying patient to whom he or she is connected through the department's registration process with the medical use of marihuana in accordance with this act, provided that the primary caregiver possesses marihuana that was dispensed as a schedule 2 controlled substance under the public health code, 1978 PA 368, MCL 333.1101 to 333.25211, for the medical use of a qualifying patient to whom he or she is connected through the department's registration process.

"A person shall not be denied custody or visitation of a minor for acting in accordance with this act, unless the person's behavior is such that it creates an unreasonable danger to the minor that can be clearly articulated and substantiated.

"There shall be a presumption that a qualifying patient or primary caregiver is engaged in the medical use of marihuana in accordance with this act if the qualifying patient or primary caregiver:

"(1) is in possession of a registry identification card; and

"(2) is in possession of an amount of marihuana that does not exceed the amount that a qualified patient would reasonably be expected to need over a period of 60 days for his or her own personal medical use. The presumption may be rebutted by evidence that conduct related to marihuana was not for the purpose of alleviating the qualifying patient's debilitating medical condition or symptoms associated with the debilitating medical condition, in accordance with this act.

"A registered primary caregiver may receive compensation for costs associated with assisting a registered qualifying patient in the medical use of marihuana. Unless it otherwise violates the public health code, 1978 PA 368, MCL 333.1101 to 333.25211, such compensation shall not constitute the sale of controlled substances.

"A physician shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by the Michigan board of medicine, the Michigan board of osteopathic medicine and surgery, or any other business or occupational or professional licensing board or bureau, solely for providing written certifications or prescriptions, in the course of a bona fide physician-patient relationship and after the physician has completed a full assessment of the qualifying patient's medical history, or for otherwise stating that, in the physician's professional opinion, a patient is likely to receive therapeutic or palliative benefit from the medical use of marihuana to treat or alleviate the patient's serious or debilitating medical condition or symptoms associated with the serious or debilitating medical condition, provided that nothing shall prevent a professional licensing board from sanctioning a physician for failing to properly evaluate a patient's medical condition or otherwise violating the standard of care for evaluating medical conditions.

"A person shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, for providing a registered qualifying patient or a registered primary caregiver with marihuana paraphernalia for purposes of a qualifying patient's medical use of marihuana.

"Any marihuana, marihuana paraphernalia, or licit property that is possessed, owned, or used in connection with the medical use of marihuana, as allowed under this act, or acts incidental to such use, shall not be seized or forfeited.

"A person shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for being in the presence or vicinity of the medical use of marihuana in accordance with this act, or for assisting a registered qualifying patient with using or administering marihuana.

"A registry identification card, or its equivalent, that is issued under the laws of another state, district, territory, commonwealth, or insular possession of the United States that allows the medical use of marihuana by a visiting qualifying patient, or to allow a person to assist with a visiting qualifying patient's medical use of marihuana, shall have the same force and effect as a registry identification card issued by the department.

"Any registered qualifying patient or registered primary caregiver who sells marihuana to someone who is not allowed to use marihuana for medical purposes under this act shall have his or her registry identification card revoked and is guilty of a felony punishable by imprisonment for not more than 2 years or a fine of not more than $2,000, or both, in addition to any other penalties for the distribution of marihuana.

"A pharmacist shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by the Michigan board of pharmacy or any other business or occupational or professional licensing board or bureau, solely for dispensing marihuana as a schedule 2 controlled substance under the public health code, 1978 PA 368, MCL 333.1101 to 333.25211, for medical purposes under this act.

"However, this subsection shall not prevent a professional licensing board from sanctioning a pharmacist for violating the standard of care for dispensing schedule 2 controlled substances.

Sponsored by: David Agema-R
Referred to the Committee on Health Policy

HB 5372 — Expand health care insurer file sharing

"An entity shall provide on a monthly basis to the department, in a format determined by the department, information necessary to enable the

See " Pending Legislation," page 8

Pending Legislation

Continued from page 7

department or entity to determine whether a health coverage recipient of the entity is also a medical assistance recipient or a child support order dependent or is also subject to a child support order. An entity shall respond to any department inquiry concerning a request for health coverage verification.

"If a health coverage recipient of the entity is also a medical assistance recipient, the entity shall do all of the following by not later than 180 days after the department's request:

"(a) Pay the department for, or assign to the department any right of recovery owed to the entity for, a covered health claim for which medical assistance payment has been made.

"(b) Respond to any inquiry by the department concerning a claim for payment for any health care item or service that is submitted not later than three years after the date the health care item or service was provided.

"An entity shall not deny a claim submitted by the department solely on the basis of the date of submission of the claim, the method of the submission of the claim, the type or format of the claim form, or a failure to present proper documentation at the time the health care item or service that is the basis of the claim was provided so long as both of the following apply:

"(a) The claim is submitted to the entity within three years of the date that the health care item or service that is the subject of the claim was provided.

"(b) Any action by the state to enforce its rights under this subdivision is commenced within 6 years of the date that the health care item or service that is the subject of the claim was provided.

"If a health coverage recipient of the entity is also a medical assistance recipient, the entity shall not deny a health claim for which medical assistance payment has been made solely because prior authorization was not received. Where this prior authorization was not received, the entity shall adjudicate the health claim as if the prior authorization for the claim had been requested.

"If the department determines that a health coverage recipient is also a child support order dependent or is subject to a child support order, the department may share information received under section 3 with the department of human services to enable the department of human services to update its child support order database.

Sponsored by: Bob Constan-D
Referred to the Committee on Insurance

HB 5411 — Revise informed consent for abortion provision to include intimidation and coercion screening.

"If a patient schedules an appointment for an abortion after receiving the information required under section 17015(3), the physician or qualified person assisting the physician shall ensure that the patient's request for an abortion is not the result of intimidation or coercion by doing both of the following:

"(a) Providing the patient with a copy of the notice described under subsection (4) and orally informing the patient that certain actions to pressure a woman into having an abortion are illegal and grounds for a civil action, but clarifying that discussions about the options available, including personal or intensely emotional expressions about such options, are not necessarily coercive and illegal.

"(b) Asking the patient if the patient's husband, parents, siblings, relatives, or employer, the father or putative father of the fetus, the parents of the father or putative father of the fetus, or any other individual in a position of authority over the patient has threatened, intimidated, or coerced her into seeking an abortion as prohibited under section 15a of the Michigan penal code, 1931 PA 328, MCL 750.15a.

"If a patient indicates that she is the victim of intimidation or coercion as described under subsection (1)(b), the physician or qualified person assisting the physician shall comply with the protocols established by the department pursuant to section 17015(11).

"In addition to the requirements of subsection (2), if a patient who is under the age of 18 indicates that she is the victim of intimidation or coercion, the physician or qualified person assisting the physician shall contact a county child protective services agency.

"A private office, freestanding surgical outpatient facility, or other facility or clinic in which abortions are performed shall post in a conspicuous place in an area of its facility that is accessible to patients, employees, and visitors a notice stating that it is illegal for anyone to coerce or intimidate a woman into seeking an abortion.

"If a patient still seeks an abortion after the requirements of subsections (1), (2), and (3), if applicable, have been fulfilled, the physician may, after obtaining the patient's signature on the acknowledgment and consent form as required under section 17015, perform the abortion.

"This section does not create a right to abortion. Notwithstanding any other provision of this section, a person shall not perform an abortion that is prohibited by law.

Sponsored by: David Agema-R
Referred to the Committee on Judiciary

HB 5542 — Create office of Medicaid inspector general

"The office of Medicaid inspector general is created as an agency within the department. The department is the single state agency for the administration of the medical assistance program in Michigan. The office of Medicaid inspector general shall assume, exercise, and be responsible for the department's duties as the single state agency with respect to all of the following:

"(a) Prevention, detection, and investigation of fraud and abuse within the Medicaid program, including fraud or abuse within the department or by a Medicaid funds recipient.

"(b) Referral of appropriate cases for criminal prosecution and civil actions.

"(c) Internal and external administrative enforcement, audit, quality review, and compliance.

"(d) Oversight and control of information technology relating to Medicaid program fraud and abuse.

"(e) Investigation, oversight, and enforcement of fraud and abuse control and auditing, including oversight of reporting and data submissions from managed care organizations.

"The head of the office shall be the inspector, who shall be appointed by the governor. The inspector shall report directly to the governor. A vacancy in the position shall be filled in the same manner as the original appointment.

"The inspector shall be selected without regard to political affiliation and on the basis of capacity for effectively carrying out the duties of the office. The inspector shall possess demonstrated knowledge, skills, abilities, and experience in detecting and combating Medicaid fraud and abuse and shall be familiar with the Medicaid program.

"The inspector shall exercise his or her prescribed powers, duties, responsibilities, and functions independently of the department director.

"The Medicaid program audit, fraud, and abuse prevention functions of the department shall be immediately transferred to the office of Medicaid inspector general. Officers and employees substantially engaged in the performance of the functions to be transferred to the office shall be transferred, along with any equipment, office space, documents, records, and resources necessary and related to the transfer of those functions. The director and the inspector shall confer to determine the officers and employees who are substantially engaged in the Medicaid program audit-, fraud-, and abuse-related functions to be transferred and to expedite establishment of the office. The employees shall be transferred without further examination or qualification to the same or similar titles and shall retain their respective civil service classification. All office employees shall be colocated, to the greatest extent practicable. The inspector has sole responsibility for establishing methods of administration for the office.

"State departments, agencies, and state officers shall fully and actively cooperate with the office of the inspector general in the implementation of this act.

"The inspector shall function as an autonomous entity within the department to serve as a single point of leadership and responsibility for managing and directing Medicaid program efforts to control Medicaid fraud and abuse.

Sponsored by: Bob Genetski-R
Referred to the Committee on Judiciary

See " Pending Legislation," page 10

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 from page 8

SENATE BILLS

SB 0739-0740 — Amend 1980 PA 350, the Nonprofit Health Care Corporation Reform Act, to include coverage for certain treatments related to autism

"A health care corporation group certificate shall provide coverage for the diagnosis and treatment of autism spectrum disorders.

"An expense-incurred hospital, medical, or surgical group certificate delivered, issued for delivery, or renewed in this state and a health maintenance organization group contract shall provide coverage for the diagnosis and treatment of autism spectrum disorders. An insurer and a health maintenance organization shall not terminate coverage or refuse to deliver, execute, issue, amend, adjust, or renew coverage solely because an individual is diagnosed with, or has received treatment for, an autism spectrum disorder.

"Coverage under this section is not subject to limits on the number of visits a member may make to an autism services provider.

"Except as provided in subsection (4), coverage under this section shall not be subject to dollar limits, co-pays, deductibles, or co-insurance provisions that do not apply to physical illness generally.

"Coverage under this section for applied behavior analysis may be subject to a maximum annual benefit of $50,000.00.

"This section shall not be construed as limiting benefits that are otherwise available to a member under a certificate.

"If a member is receiving treatment for autism spectrum disorder, a health care corporation may request a review of that treatment consistent with current protocols and may require a treatment plan. The cost of obtaining a treatment review shall be borne by the health care corporation. A health care corporation shall utilize evidence-based care and managed care cost-containment practices in accordance with the health care corporation's procedures.

"This amendatory act applies to certificates delivered, executed, issued, amended, adjusted, or renewed in this state 180 days after the date this amendatory act is enacted into law."

Sponsored by: Tupac Hunter-D (0739), Samuel Thomas-D (0740)
Referred to the Committee on Economic Development and Regulatory Reform

SB 0743 — Amend 1956 PA 218, the Insurance Code of 1956

"Every insurer issuing a Medicare supplement insurance policy in this state shall make available a Medicare supplement insurance policy that includes a basic core package of benefits to each prospective insured. An insurer issuing a Medicare supplement insurance policy in this state may make available to prospective insureds benefits pursuant to section 3809a that are in addition to, but not instead of, the basic core package. The basic core package of benefits shall include all of the following:

"(a) Coverage of part A Medicare eligible expenses for hospitalization to the extent not covered by Medicare from the 61st day through the 90th day in any Medicare benefit period.

"(b) Coverage of part A Medicare eligible expenses incurred for hospitalization to the extent not covered by Medicare for each Medicare lifetime inpatient reserve day used.

"(c) Upon exhaustion of the Medicare hospital inpatient coverage including the lifetime reserve days, coverage of 100 percent of the Medicare part A eligible expenses for hospitalization paid at the applicable prospective payment system rate or other appropriate Medicare standard of payment, subject to a lifetime maximum benefit of an additional 365 days.

"(d) Coverage under Medicare parts A and B for the reasonable cost of the first three pints of blood or equivalent quantities of packed red blood cells, as defined under federal regulations unless replaced in accordance with federal regulations.

"(e) Coverage for the coinsurance amount, or the co-payment amount paid for hospital outpatient department services under a prospective payment system, of Medicare eligible expenses under part B regardless of hospital confinement, subject to the Medicare part B deductible.

"(f) Coverage of cost sharing for all part A Medicare eligible hospice care and respite care expenses.

"In addition to the basic core package of benefits required under section 3807a, the following benefits may be included in a Medicare supplement insurance policy and if included shall conform to section 3811a(6)(b) to (j):

"(a) Medicare part A deductible: coverage for 100 percent of the Medicare part A inpatient hospital deductible amount per benefit period.

"(b) Medicare part A deductible: coverage for 50 percent of the Medicare part A inpatient hospital deductible amount per benefit period.

"(c) Skilled nursing facility care: coverage for the actual billed charges up to the coinsurance amount from the 21st day through the 100th day in a Medicare benefit period for post-hospital skilled nursing facility care eligible under Medicare part A.

"(d) Medicare part B deductible: coverage for 100 percent of the Medicare part B deductible amount per calendar year regardless of hospital confinement.

"(e) 100 percent of the Medicare part B excess charges: coverage for all of the difference between the actual Medicare part B charge as billed, not to exceed any charge limitation established by Medicare or state law, and the Medicare-approved part B charge.

"(f) Medically necessary emergency care in a foreign country: coverage to the extent not covered by Medicare for 80 percent of the billed charges for Medicare-eligible expenses for medically necessary emergency hospital, physician, and medical care received in a foreign country, which care would have been covered by Medicare if provided in the United States and which care began during the first 60 consecutive days of each trip outside the United States, subject to a calendar year deductible of $250.00, and a lifetime maximum benefit of $50,000. For purposes of this benefit, 'emergency care' means care needed immediately because of an injury or an illness of sudden and unexpected onset."

Sponsored by: Alan Sanborn-R
Referred to the Committee on Economic Development and Regulatory Reform

SB 0799 — Amend 1978 PA 368, the Insurance Code of 1956, to prohibit gender-based abortions

"A physician shall not intentionally perform an abortion with knowledge that the pregnant woman is seeking the abortion based on account of the sex of the fetus or that the pregnant woman is being compelled to seek an abortion in violation of section 15a of the Michigan penal code, 1931 PA 328, MCL 750.15a.

A physician shall not intentionally perform an abortion with knowledge that the pregnant woman is seeking the abortion based on account of the sex of the fetus or that the pregnant woman is being compelled to seek an abortion in violation of section 15a of the Michigan penal code, 1931 PA 328, MCL 750.15a.

"[These sections do] not create a right to an abortion.

"Notwithstanding any other provision of [these sections], a person shall not perform an abortion that is prohibited by law."

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

SB 0829 — Prohibiting research on a live or aborted embryo, fetus, or neonate after elective abortions, requiring consent after spontaneous and nonelective abortions

"A person shall not use a live human embryo, fetus, or neonate for nontherapeutic research if, in the best judgment of the person conducting the research, based upon the available knowledge or information at the approximate time of the research, the research substantially jeopardizes the life or health of the embryo, fetus, or neonate. Nontherapeutic research shall not in any case be performed on an embryo or fetus known by the person conducting the research to be the subject of a planned abortion being performed for any purpose other than to protect the life of the mother.

"For purposes of subsection (1) the embryo or fetus is conclusively presumed not to be the subject of a planned abortion if the mother signed a written statement at the time of the research, that she was not planning an abortion.

"A health professional or other individual shall not knowingly perform research utilizing organs, tissues, or cells taken from a dead embryo or fetus if the death of the embryo or fetus was the result of an elective abortion.

"A health professional or other individual shall not knowingly perform research utilizing organs, tissues, or cells taken from a dead embryo, fetus, or neonate, the death of which was the result of a spontaneous or nonelective abortion, unless the consent of the mother has first been obtained. Consent is not required in the case of a routine pathological study.

"For purposes of this section, consent is conclusively presumed to have been granted by a written statement, signed by the mother that she consents to the use of her dead embryo, fetus, or neonate for research.

"Written consent constitutes lawful authorization for the transfer of the dead embryo, fetus, or neonate to a medical research facility.

"Research being performed upon a dead embryo, fetus, or neonate shall be conducted in accordance with the same standards applicable to research conducted pursuant to part 101.

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

SB 0858 — Amend 1961 PA 236, to limit liability for emergency treatment rendered in a hospital

"A licensed health care professional or a licensed health facility or agency is not liable in an action based on medical malpractice arising out of the provision of emergency medical care in an emergency department or obstetrical unit located in and operated by a hospital, or in a surgical operating room, cardiac catheterization laboratory, or radiology department immediately following the evaluation or treatment of the patient in an emergency department, unless the plaintiff proves by clear and convincing evidence that the licensed health care professional's actions constituted gross negligence.

"In an action described in subsection (1), the court shall instruct the jury to consider, in addition to all other relevant matters, all of the following:

"(a) Whether the person providing care had the patient's full medical history, including knowledge of pre-existing medical conditions, allergies, and medications.

"(b) Whether there was a preexisting licensed health care professional-patient relationship.

"(c) The circumstances that constituted the emergency.

"(d) The circumstances surrounding the delivery of the emergency medical care.

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

SB 0907 — Amend 1931 PA 328, penalties for death in unlicensed care facility and for retaliating against resident vulnerable adult who interferes with investigation of an adult care facility

An operator of an unlicensed facility that is subject to licensure, or an employee or an individual acting on behalf of an unlicensed facility that is subject to licensure, who violates the adult foster care facility licensing act or part 213, 215, or 217 of the public health code or rules promulgated under the adult foster care facility licensing act or part 213, 215, or 217 of the public health code and whose violation is a proximate cause of the death of a vulnerable adult is guilty of a felony punishable by imprisonment for not more than 15 years or a fine of not more than $75,000, or both.

A caregiver, other person with authority over a vulnerable adult, or a licensee who intentionally does one or more of the following is guilty of a misdemeanor punishable by imprisonment for not more than two years or a fine of not more than $25,000, or both:

(a) Commingles, borrows, or pledges funds of a resident that are required by law or administrative rule to be held in a separate trust account.

(b) Interferes with or obstructs an investigation under the adult foster care facility licensing act, part 213, 215, or 217 of the public health code, or section 11b of the social welfare act, MCL 400.11b.

(c) Files information required by the adult foster care facility licensing act or part 213, 215, or 217 of the public health code that is false or misleading.

Except as otherwise provided in subsection (3), a caregiver, other person with authority over a vulnerable adult, or a licensee who intentionally retaliates or discriminates against a resident because the resident does 1 or more of the following is guilty of a misdemeanor punishable by imprisonment for not more than two years or a fine of not more than $25,000.00, or both:

(a) Provides information to a state or local official enforcing the adult foster care facility licensing act or part 213, 215, or 217 of the public health code.

(b) Makes a complaint against a facility.

(c) Initiates, participates in, or testifies in an administrative or criminal action against a facility or a civil suit related to the criminal action.

A caregiver, other person with authority over a vulnerable adult, or licensee who intentionally retaliates or discriminates against a resident because the resident interferes with or obstructs an investigation under the adult foster care facility licensing act or section 11b of the social welfare act, MCL 400.11b, is guilty of a felony punishable by imprisonment for not more than four years or a fine of not more than $50,000, or both.

A caregiver, other person with authority over a vulnerable adult, or a licensee who intentionally retaliates or discriminates against an employee because the employee does one or more of the following is guilty of a misdemeanor punishable by imprisonment for not more than 1 year or a fine of not more than $10,000, or both:

(a) Provides information to a state or local official enforcing the adult foster care facility licensing act or part 213, 215, or 217 of the public health code.

(b) Makes a complaint against a facility.

(c) Initiates, participates in, or testifies in an administrative or criminal action against a facility or a civil suit related to the criminal action.

Subsection (4) does not preclude an employer from taking reasonable and appropriate disciplinary action against an employee.

A caregiver, other person with authority over a vulnerable adult, or a licensee who has been convicted of violating this section who commits a second or subsequent violation of this section is guilty of a felony punishable by imprisonment for not more than five years or a fine of not more than $75,000, or both.

Sponsored by: Tupac Hunter-D
Referred to the Committee on Judiciary

BILLS PASSED

HB 4377, HEALTH, smoking

Require smoke-free workplace and food service establishments

Sponsored by Lee Gonzales-D
Passed in House (75-30), Senate (24-13), approved by governor

HB 5593, HEALTH, occupations

Increase licensing fees for nursing profession; credit portion of increase to nurse professional fund

Sponsored by Alma Wheeler Smith
Passed in House (58-50), Senate (32-3), approved by governor

HB 5614, HEALTH, licensing

Enhance health licensing board's authority over nonlicensed individuals

Sponsored by Roy Schmidt
Passed in House (95-4)
Status: Referred to Committee on Health Policy

SB 0689, HEALTH, pharmaceuticals

Limitations on dispensing schedule two controlled substances; revise to allow more than one on single prescription form and allow dispensing up to 90 days after date prescription is issued

Sponsored by Thomas George-R
Passed in Senate (33-0), House (107-1), approved by governor

SB 0722, HEALTH FACILITIES, hospitals

Require hospitals to provide influenza vaccine to elderly persons under certain circumstances

Sponsored by Roger Kahn
Passed in Senate (36-0), House (102-3)
Status: Ordered enrolled

SB 0744, INSURANCE, Medigap polices

Prohibiting use of genetic information in denying or pricing Medicare supplement policies

Sponsored by Alan Sanborn
Passed in Senate (36-0), House (103-1), approved by governor

SB 0973, INSURANCE, occupations

Limiting coverage or reimbursement for chiropractic service

Sponsored by Alan Sanborn
Passed in Senate (33-1), House (102-5), approved by governor

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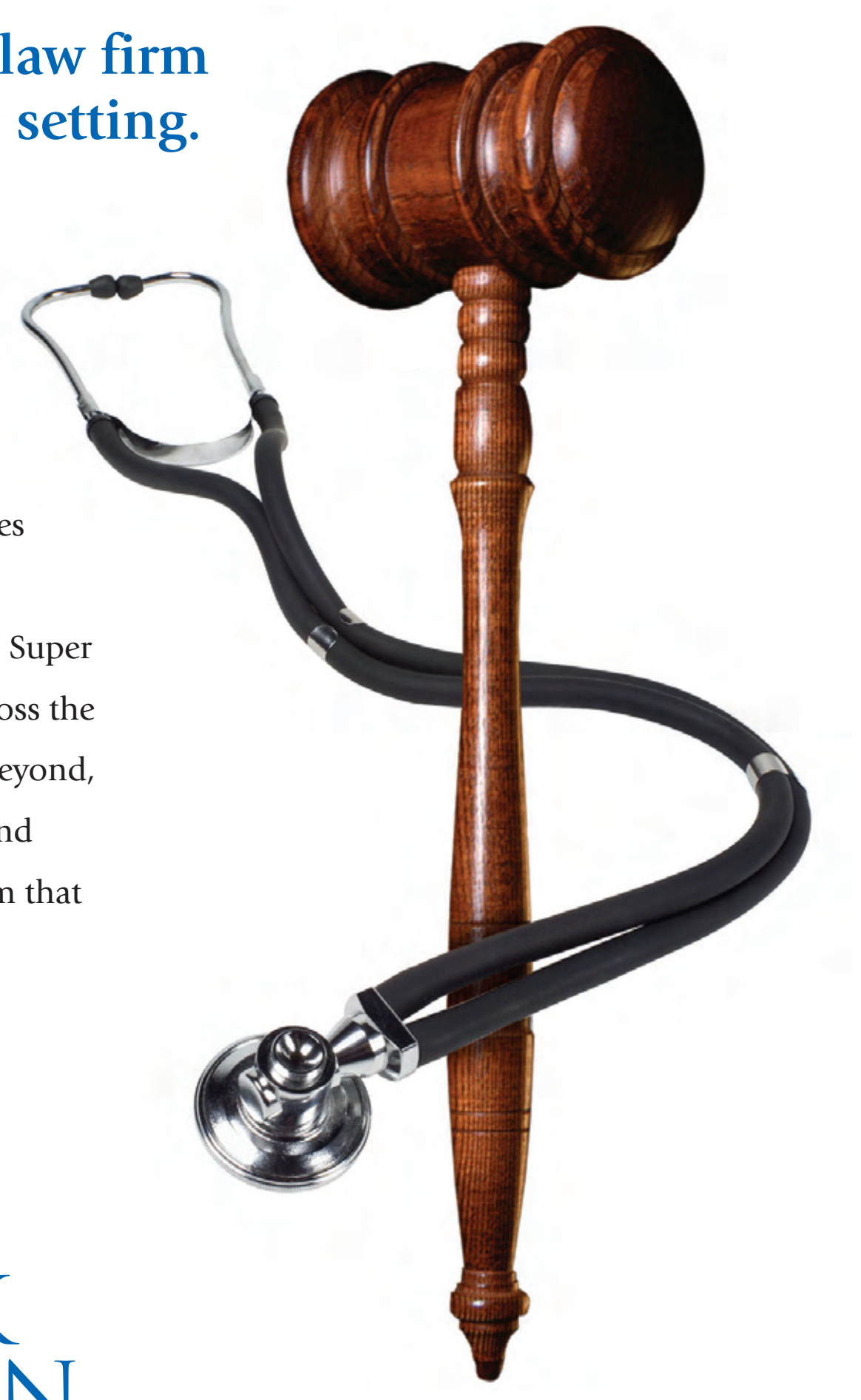

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Accommodating patients under the ADA

Compliance

By Michelle D. Bayer, Esq.

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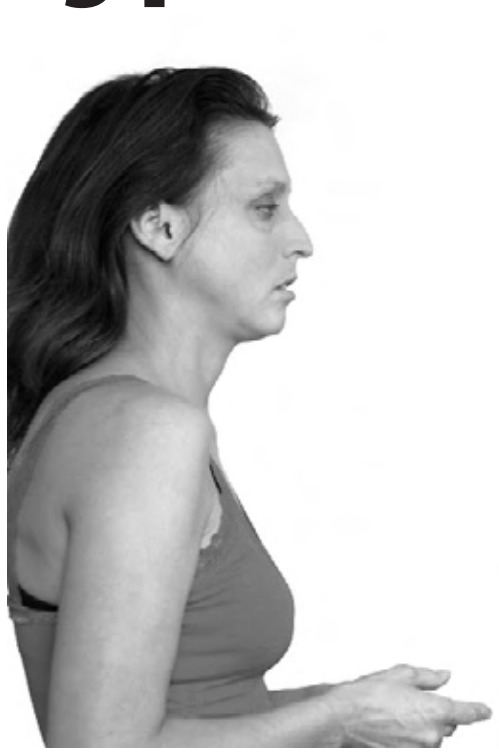

I recently received a telephone call from a physician friend regarding an issue with a deaf patient. Although my friend had been treating this patient for more than 10 years and had always communicated during office visits via written notes and gestures without issue, he received a letter from a sign-language interpreter company, stating that they would be attending all office visits with the deaf patient.

The company also provided a copy of their contract (which it expected my friend to sign) stating that they would charge for their time attending the office visit, as well as travel time and mileage from their office, which was about 45 minutes away.

My friend wanted to know what he should do.

Questions such as this raise the issue of how physicians must accommodate patients with disabilities under the law.

No blanket requirement

This situation lies within the public accommodation requirements for health care providers under Title III of the Americans with Disabilities Act (ADA). Title III provides that "[n]o individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who owns, leases (or leases to), or operates a place of public accommodation."

Health care providers are included in the definition of a "public accommodation" under Title III, which applies to all private providers regardless of their size or area of practice.

With respect to "public accommodations," Title III entitles disabled individuals to: (1) the equal opportunity to participate; (2) the equal opportunity to benefit; and (3) the receipt of benefits in the most integrated setting appropriate.

Title III includes a wide variety of accommodations, such as access to buildings; maintenance of accessible features; reasonable modifications of policies and procedures to avoid discrimination; and the provision of auxiliary aids and services, where necessary to ensure effective communication.

Effective communication is particularly important in the health care setting to ensure proper consent, diagnosis, and treatment. While providers are required to furnish such auxiliary aids and services at their own expense, the type of auxiliary aid or service necessary will vary in accordance with the length and complexity of the communication involved.

For example, whether an interpreter needs to be provided is a fact-specific determination that must be made on a case-by-case basis. Importantly, there is no blanket requirement under the Title III that an interpreter be provided in a particular situation. Moreover, the disabled patient is not entitled to unilaterally decide to have an interpreter present, and expect that the cost be borne by the provider.

The determinative issue in deciding if a certain type of accommodation is necessary is whether there are other available means to ensure effective communication between the patient and the health care provider.

Title III encourages providers to consult with disabled individuals wherever possible to determine what type of auxiliary aid is needed for effective communication. However, the regulations recognize that "the ultimate decision as to what measures to take to ensure effective communication rests in the hands of the public accommodation (i.e., the provider), provided that the method chosen results in effective communication."

In one scenario, a provider may determine that an interpreter is needed to accommodate a patient, and plan to use a staff or family member who "signs" as the interpreter.

However, whether this is a permissible accommodation requires a fact-specific analysis. Specifically, once a determination is made that an interpreter is required, the provider must provide a "qualified" interpreter, which is defined as one "who is able to interpret effectively, accurately and impartially, both receptively and expressively, using any necessary specialized vocabulary."

Given that there are several different sign language systems, individuals who use a particular system may not communicate effectively through an interpreter who uses another system. Therefore, merely because an interpreter has been certified by an official licensing body does not render the interpreter "qualified" for purposes of the ADA.

Determinging 'undue burden'

Title III does provide a narrow exception to the auxiliary aid or service requirement; specifically when compliance would "fundamentally alter the nature of the goods or services offered" or would result in an "undue burden."

A "fundamental alteration" is a defined as "a modification that is so significant that it alters the essential nature of the goods, services, facilities, privileges, advantages, or accommodations offered." "Undue burden" also is defined as a "significant difficulty or expense."

Determination of an "undue burden" includes a number of factors including (1) the nature and cost of the accommodation; (2) the overall financial resources of the health care practice; number of employees; the effect on expenses and resources; legitimate safety requirements; and any other impact on the operation of the site; and (3) relationship to any parent corporation or entity.

Some providers have sought to avoid providing an interpreter (when one was necessary) on the basis that the cost of the interpreter exceeds the amount of money the provider would earn for the office visit or service.

Unfortunately, this position has not been successful in civil litigation, as the focus is not on the profitability of the one patient to the practice, but rather on the ability of the practice as whole to bear the financial cost.

Moreover, even if the provision of a particular auxiliary aid or service would result in a fundamental alteration or undue burden, the provider must still provide an alternative accommodation that would not result in an undue burden or fundamental alteration.

If the patient believes that the provider's decision will not facilitate effective communication, the patient may challenge that decision by initiating litigation or filing a complaint with the Department of Justice.

It is important for providers to consult with legal counsel when dealing with accommodations for disabled employees and patients, particularly because such issues are so fact-specific.

In my friend's case, a simple Google search turned up a local interpreter service down the street, which would save significant travel costs if an interpreter was needed.

Licensing actions

Continued from page 1

any of the following circumstances, often in accordance with state and/or federal statutes requiring certain individuals and entities report such circumstances to the BHP:

- Limitation of staff privileges or a change in employment status due to disciplinary action taken by a health facility;
- Disciplinary action taken by a professional health society;
- An adverse medical-malpractice settlement, award or judgment;
- Felony conviction;
- Misdemeanor conviction punishable by up to two years of imprisonment or that involves alcohol or a controlled substance;
- A licensee's ineligibility to participate in a federally funded health insurance or health benefits program;
- A report by a licensee that another licensee has committed a violation of the Public Health Code; or
- Disciplinary action by a licensing board in another state.

Moreover, a licensee must notify the BHP of a criminal conviction or a disciplinary licensing action taken by another state against the licensee within 30 days after the date of conviction or disciplinary action. Failure to do so may give rise to an independent disciplinary action under the Michigan Public Health Code.

If the BHP believes there is sufficient evidence to demonstrate a violation of the Michigan Public Health Code, a formal administrative complaint is filed by an assistant attorney general on behalf of the BHP charging the licensee with specific violations of the Code.

The Code also provides the BHP with grounds for the issuance of an administrative complaint for numerous preceding criminal violations.

For example, a conviction of any criminal sexual conduct; reckless or intentional inappropriate destruction or alteration of medical records; a misdemeanor or felony involving fraud to obtain professional fees; a misdemeanor related to the ability to practice safely/competently; and practicing under the influence of alcohol or drugs — all provide a basis for a licensing action against the convicted licensee.

If the BHP believes that there could be an immediate risk to the public health, safety or welfare, it may order a summary suspension of the license until an Administrative Hearing is held.

If the licensee is convicted of a felony, a misdemeanor punishable by two years or more in prison, or a misdemeanor involving the illegal delivery, possession or use of a controlled substance, the BHP will summarily suspend the license.

The suspension will remain in place until the administrative hearing is concluded, unless otherwise resolved through a petition for an immediate hearing before an administrative law judge (ALJ) to dissolve the summary suspension order.

After the administrative complaint and filing of an answer thereto, a compliance conference and/or a settlement conference may be held to attempt to reach a resolution of the complaint short of attending a formal administrative hearing.

Any proposed settlement between the BHP and the licensee must be approved by the disciplinary subcommittee of the applicable licensing board. If a settlement cannot be reached, the matter proceeds to an administrative hearing.

An ALJ presides at the hearing and issues a report that is sent to the disciplinary subcommittee for review and final decision.

The report includes a summary of the testimony and evidence, the findings of fact, conclusion of law and a proposal for decision. The disciplinary subcommittee can dismiss the matter, remand the matter for further testimony or evidence, or revise the findings of fact and conclusions of law.

Licensees who receive inquiries by the BHP should immediately retain experienced health care legal counsel to help navigate the legal waters and minimize the associated collateral effects.

If the disciplinary subcommittee finds that a preponderance of the evidence supports the proposed findings of the ALJ, it can adopt the findings and impose a sanction. The penalties that can be imposed range from a monetary fine, probation, reprimand, restricted license, additional education, community service and/or revocation or suspension of license.

A licensee affected by an adverse action may file leave of appeal to the Michigan Court of Appeals.

While Michigan's Public Health Code has numerous grounds upon which the BHP may rely for the issuance of an Administrative Complaint, some provisions are more apt to lead to criminal prosecution.

For example, allegations of an inappropriate sexual relationship with a patient; a pattern of providing controlled substances without medical necessity; a pattern of fraudulent billing; and a pattern of performing medically unnecessary procedures for personal financial gain.

All of these offenses fall within express provisions of Michigan's Public Health Code giving rise to a licensing action and also fall within the ambit of numerous state and federal criminal statutes, leaving the licensee exposed to criminal prosecution.

It is important to understand that some actions subsequent to being served with an Administrative Complaint may also lead to criminal prosecution.

One common allegation is that the licensee violated his or her general duty due to inadequate, insufficient and/or missing documentation. This can lead a concerned licensee to attempt to "correct" the situation by creating records where none existed or supplementing the records without including sufficient information to make it clear when these new records were added. Such action by a licensee is a felony.

Licensees who receive inquiries by the BHP should immediately retain experienced health care legal counsel to help navigate the legal waters and minimize the associated collateral effects.

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Government chooses accreditation servers

Regulation

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The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires the Secretary of the Department of Health and Human Services (the "Secretary") to designate organizations to accredit suppliers.

Those suppliers include, but are not limited to, physicians, non-physician practitioners, and Independent Diagnostic Testing Facilities, that furnish the technical component (TC) of advanced diagnostic imaging services.

The MIPPA accreditation requirement applies only to suppliers of the TC of advanced imaging services (i.e., MRI, CT, PET, nuclear medicine) that are supplied on an outpatient basis and billed to Medicare under the physician fee schedule.

It does not apply to advanced imaging services provided by inpatient or outpatient centers billing under the hospital.

This accreditation requirement also does not apply to the physician's interpretation of the images. Although the law allows the Secretary to supplement the list of diagnostic imaging services that will require accreditation, MIPAA currently defines advanced diagnostic imaging services as diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine imaging.

The definition specifically excludes X-rays, ultrasounds, fluoroscopy procedures, and diagnostic and screening mammography.

Thus, if a supplier furnishes the TC of advanced diagnostic imaging services to Medicare beneficiaries, the supplier must be accredited by Jan. 1, 2012, in order to receive payment under the physician fee schedule.

Accreditation organizations

As required by MIPPA, on Jan. 26, 2010, the Centers for Medicare & Medicaid Services (CMS) published notice that it approved the following three organizations to provide the accreditation services for suppliers of the TC of advanced diagnostic imaging procedures:

(1) The American College of Radiology (ACR);

(2) The Intersocietal Accreditation Commission (IAC); and

(3) The Joint Commission (JC).

When selecting the accrediting organizations to approve, CMS focused on the organizations' ability to conduct timely review of applications, the integration of new imaging services into the accreditation program, the use of onsite visits, the ability to address the capacity of imaging suppliers in rural areas, and whether their fees were reasonable.

Quality standards for accreditation

The accreditation organizations are authorized to prescribe quality standards for practices and assist practices to continuously improve the quality of care that they provide to their patients by providing an objective, peer-reviewed assessment of facilities.

In order to serve this purpose, the organizations assess the following:

- Qualifications of non-physician personnel performing the imaging;
- Qualifications and responsibilities of medical directors and supervising physicians;
- Procedures to ensure safety of the individuals furnishing the imaging and the patients;
- Procedures to ensure the reliability, clarity, and technical quality of the diagnostic images;
- Procedures to assist the patient in obtaining his/her imaging records; and
- Procedures to notify CMS of any changes to imaging modalities subsequent to the accreditation organization's decision.

At this point, the degree to which MIPPA's requirements will subject providers to additional burdens is not ascertainable.

From informal discussions with CMS and other industry "insiders" the prevailing expectation is that MIPPA will materially elevate the standards to which providers must adhere with a corresponding increase in the cost of providing advanced imaging services.

Conclusion

CMS is expected to issue further guidance in connection with meeting the MIPPA accreditation standards.

Suppliers that furnish the TC of advanced diagnostic imaging services must seek accreditation from the ACR, IAC, or JC by Jan. 1, 2012.

CMS plans to provide education outreach to all suppliers that are affected by these new requirements so that suppliers understand the MIPPA requirements and will be able to comply with them prior to the Jan. 1, 2012, deadline.

These organizations have different accreditation standards and application processes for each of the advanced diagnostic imaging services.

Suppliers are well-advised to begin obtaining information from the accreditation organizations.

FOR MORE INFO

To obtain information from the selected accreditation organizations, suppliers can contact them as follows:

AMERICAN COLLEGE OF RADIOLOGY
505 9th St. NW, Ste. 910
Washington, DC 20004
(202) 223-1670 | www.acr.org

INTERSOCIETAL ACCREDITATION COMMISSION
6021 University Blvd., Ste. 500
Ellicott City, MD 21043
(800) 838-2110 | www.intersocietal.org

JOINT COMMISSION
601 13th St. NW, Ste. 1150 N
Washington, DC 20005
(202) 783-6655 | www.jointcommission.org

What is the meaning of 'meaningful use'?

Compliance

By Robert H. Schwartz, Esq.

Robert H. Schwartz is a shareholder practicing in Butzel Long's Bloomfield Hills office. As chairman of the firm's Health Care Industry team, Schwartz's practice includes corporate and health care activities. He has extensive experience in business planning, mergers and acquisitions and in assisting health care and hospital clients in the health care regulatory areas, including reimbursement, fraud and abuse, and hospital physician relations, among others. He can be reached at (248) 258-2611 or schwartzrh@butzel.com.

Last February, Congress, as part of the American Recovery & Reinvestment Act, passed the Health Information Technology and Clinical Health Act (HITECH), which, collectively, also is called the "Stimulus Bill."

One section of HITECH addressed the need for the widespread implementation of Electronic Health Records (EHR). One of the issues recognized as a stumbling block to widespread implementation of EHR was the lack of financing.

The lack of incentives for adopting EHR particularly by physicians, but also for hospitals and others was recognized. Therefore, HITECH addresses both funding and incentives.

The funding format encourages early implementation of EHR by paying part of the cost of EHR and the scaling back government payments to providers over time.

Incentives include reimbursement by Medicare and Medicaid that is better/higher for those that implement EHR. One of the linchpins for payment to a provider for implementing EHR is whether the provider has achieved "meaningful use" of EHR.

The proposed regulations addressing "meaningful use" are more than 500 pages.

Eligibility factors

Participants in both Medicaid and Medicare programs are eligible to participate in the HITECH benefits. The definition of meaningful use is the same in both programs.

Eligibility however does differ. Also, an Eligible Professional cannot receive funds from both Medicare and Medicaid.

In Medicare, medical doctors, osteopathic doctors, dentists, podiatrists, optometrists and chiropractors are all eligible. In Medicaid, all of the above plus certified nurse midwives, nurse practitioners and physician assistants in federally qualified health centers (FQHCs) or rural health clinics (RHCs) are eligible.

Hospital-based physicians are excluded from participation. An eligible professional is identified by his/her unique National Provider Identifier (NPI).

Hospitals that are paid under the hospital inpatient prospective payment system (IPPS) are eligible. This includes Medicare Fee for Service and Medicare Advantage participants as well as Critical Access hospitals.

Psychiatric, rehabilitation, long-term care, and children's and cancer hospitals are excluded. With regard to Medicaid, only acute care hospitals and children's hospitals are eligible. Unlike physicians, hospitals may participate in both Medicaid and Medicare simultaneously.

A provider can adopt an all-in-one EHR solution or an EHR module. It will be the responsibility of the Eligible Professional or hospital to adopt a proper combination of EHR Modules. Each EHR Module must be certified and all criteria must be certified within each EHR Module.

Changing the definition

There is a three-stage approach to what is meant by meaningful use. Over time, the criteria will become more rigorous.

• **Stage 1:** The objective is to capture health information in a coded format, use information to track key clinical conditions and communicate for care purposes, implement clinical decision support tools, and report clinical quality measures and public health information to relevant government officials.

• **Stage 2:** In addition to the above, it is anticipated to require the exchange of data in increasingly structured formats.

• **Stage 3:** Criteria are expected to target more systemic health care improvements as the measures for achieving meaningful use.

One can actually participate in Stage 1 through 2014; however, the later one adopts certified EHR, the more he must do. For instance, a provider adopting Stage 1 in 2012 also must comply with Stage 2. The later one performs Stage 1, the shorter the time frame for advancing through the various stages.

Payments under Medicaid v. Medicare

Reimbursement amounts are different. The maximum Medicare reimbursement is $44,000 and Medicaid Eligible Professionals can receive up to $63,750.

Also, the amount of reimbursement changes with the year of adoption. For instance, a Medicare payment of $18,000 can be made if adoption is undertaken in 2011. But, in 2012, that amount is $12,000; $8,000 in 2013; $4,000 in 2014; and $2,000 in 2015.

Full reimbursement is still possible even if adopted in 2012, as the payments are made up over time. Those not adopting EHR meeting the Meaningful Use criteria until 2013 the level of Medicare reimbursement begins to decrease dramatically to a maximum of $39,000 in 2013; $24,000 in 2014; and zero thereafter.

When meaningful use is first claimed, it must be achieved for a 90-day period and a report must be filed. Each year thereafter, meaningful use is measured over the entire year.

The formal reporting process for demonstrating meaningful use will be the subject of future rulemaking. There will be an attestation requirement for Medicare to CMS, and for Medicaid to the applicable state.

And although HIPAA issues have not been discussed here, they should not be ignored.

EHR contracts

Continued from page 3

The support agreement should require the support organization authorized by the licensor to provide support and maintenance functions including error correction, technical assistance, training and installation of updates and new releases.

Practically speaking, it will be difficult for a provider to obtain all of the support and maintenance it needs from support organizations that have not been authorized by the licensor. Only authorized support organizations will have access to the source code of the software, for which access is required for some support services.

Additionally, unauthorized service contractors may commit copyright infringement if they make copies of software in order to conduct maintenance or other service functions for a provider.

There are dozens of provisions in EHR contracts that should be reviewed and negotiated

The support agreement should specify how soon after the report of a problem the support organization must begin responding, and require the support organization to diligently work on the problem until it is resolved.

Since support organizations are reluctant to give warranties that they will be able to correct all errors, providers should negotiate the right to stop paying fees or to terminate the contract and obtain a refund if significant errors cannot be corrected.

In order to prevent the support organization from unreasonably raising rates, the support agreement should clearly set forth the current rates and a mechanism for limiting periodic rate increases.

Access to updates

Finally, the provider's entitlement to each new release of the EHR software along with documentation, instructions and training materials should be clearly set forth in the maintenance provisions of the support agreement.

Frequently, releases that correct errors, improve the efficiency or the effectiveness of the basic functions of the software are free to the provider whereas releases that add new functions to the software must generally be purchased.

The support agreement should require the licensor to escrow the source code and give the provider the right to access and use it in the event the licensor stops providing support services or goes out of business.

By paying attention to the provisions of EHR contracts during an initial review, a provider can avoid spending hours evaluating the functionality of an EHR system only to discover that the contracts do not adequately protect the provider's rights, and the vendor will not agree to the provisions needed.

There are dozens of other provisions in the EHR contracts that should be reviewed and negotiated. Providers can benefit by consulting an attorney early in the selection process.

EHR incentives

Continued from page 1

must complete each stage, depending upon when the EHR technology was first implemented. The Rule only discusses the stage 1 meaningful use criteria.

The Rule establishes a total of 25 objectives that non-hospital-based eligible professionals must satisfy in order to demonstrate meaningful use of EHR technology (see "The criteria" at right).

Each of the objectives is associated with a specific functional measure that will be necessary to ensure compliance.

For the most part, these measures are calculated on a percentage basis (i.e. the objective must be met in a defined percentage of patients).

A percentage-based calculation is designed to ensure that differences in patient volume do not affect the provider's ability to satisfy the objectives and receive incentive payments. The Rule provides detailed instructions on how to calculate the majority of these functional measures.

Clinical quality measures

The Rule also establishes clinical quality measures that non-hospital-based eligible professionals must report to CMS in order to be entitled to incentive payments.

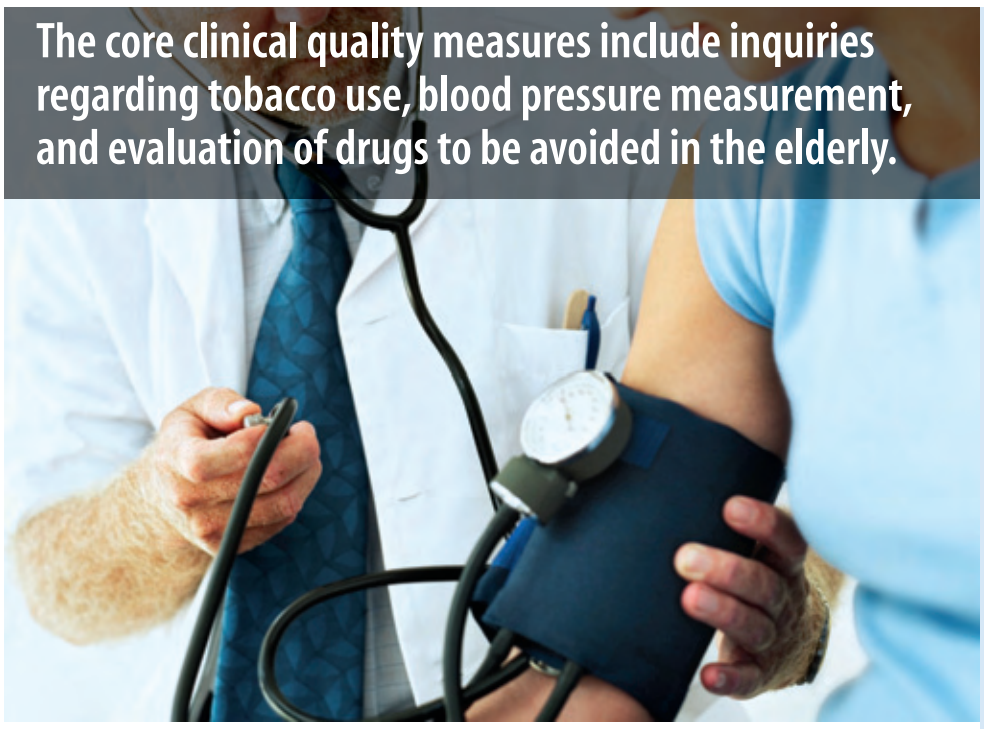
The clinical quality measures fall into two categories: core clinical quality measures and specialty clinical quality measures.

All eligible professionals must submit data relevant to the core clinical measures, and each professional also must select and submit data relevant to one specialty subset that is most appropriate to the provider's practice.

For example, if the provider is a cardiologist, she will be required to submit core clinical quality measures as well as cardiology specialty clinical quality measures.

For the most part, these clinical quality measures focus on preventative care, patient screening and disease management. The core clinical quality measures include inquiries regarding tobacco use, blood pressure measurement, and evaluation of drugs to be avoided in the elderly.

The specialty clinical quality measures vary greatly depending upon the particular specialty area chosen, but generally reflect similar themes of disease management and preventative care.



Meaningful use criteria

The Rule recognizes that providers and CMS do not yet have the appropriate technology in place to transmit or accept reports demonstrating compliance electronically. Thus, providers will initially be permitted to report compliance with the meaningful use requirements through attestation.

Although a "certified" EHR as defined by additional rulemaking is required, compliance with the Rule cannot be satisfied merely by relying on an EHR vendor. The "meaningful use" regulations require eligible professionals to actually use the EHR technology to improve the quality of health care, according to the requirements set forth above.

Providers also should be aware that the Rule may change in response to public comments, which were required to be submitted by March 15, 2010.

Providers seeking financial incentives should also remain informed of additional rulemaking regarding future stages of meaningful use criteria in subsequent years.

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The criteria

The 25 objectives that non-hospital-based eligible professionals must satisfy in order to demonstrate meaningful use of EHR technology:

- Use Computer Physician Order Entry (CPOE) technology;
- Implement drug-drug, drug-allergy, and drug-formulary checks;
- Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT;
- Generate and transmit permissible prescriptions electronically;
- Maintain an active medication list;
- Maintain an active medication allergy list;
- Record demographic information, including preferred language, insurance type, gender, race and ethnicity, and date of birth;
- Record and chart changes in vital signs, including height, weight, blood pressure, body mass index (children age 2 and over), and growth charts (children age 2-20);
- Record smoking status for patients 13 years of age or older;
- Incorporate clinical lab test results as structured data;
- Generate lists of patients by specific conditions for purposes of quality improvement, reducing disparities, research and outreach;
- Report ambulatory quality measures to CMS;
- Send reminders to patients for preventative or follow-up care;
- Implement five clinical decision support rules relevant to specialty or high clinical priority, and develop the ability to track compliance therewith;
- Check insurance eligibility electronically from public and private payers;
- Submit claims electronically to public and private payers;
- Provide patients with an electronic copy of their health information;
- Provide patients with timely electronic access to their health information within 96 hours of the information becoming available;
- Provide clinical summaries for each office visit;
- Capability to exchange key clinical information among providers and other patient authorized entities electronically;
- Perform medication reconciliation at relevant encounters and at each transition of patient care;
- Provide summary care record for each transition of care and referral;
- Capability to submit electronic data to immunization registries and actual submission where required and accepted;
- Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice; and
- Protect electronic health information created or maintained through the implementation of appropriate technical capabilities.

Like it or not, EHRs are here to stay

Medical Technology

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The requirements for making "meaningful use" of electronic health records (EHRs) are here, whether providers like it or not — or, more importantly, whether providers understand them or not.

Following recent guidance from the Centers for Medicare and Medicaid Services (CMS), providers that participate with Medicare and/or Medicaid should now be considering how to implement meaningful use of certified EHR technology.

Beginning in 2015, providers that do not make meaningful use of certified EHR technology will receive progressively reduced payment adjustments to their Medicare and/or Medicaid reimbursement.

Conversely, providers may be eligible to receive incentive payments to help recoup a portion of their costs if they can demonstrate meaningful use of certified EHR technology.

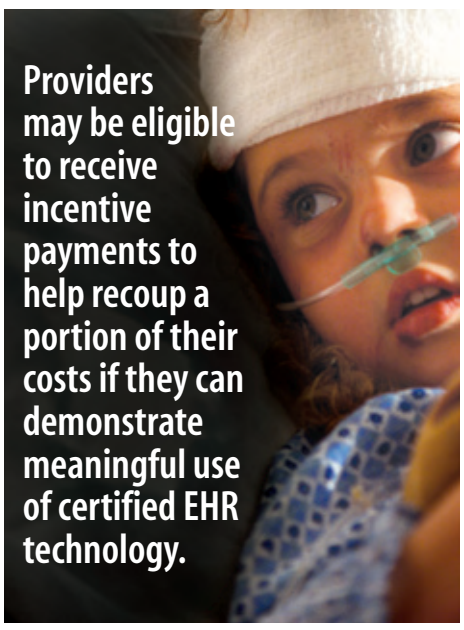
Between 2011 and 2014, eligible professionals (defined as non-hospital providers) can receive annual incentive payments for making meaningful use of certified EHR technology, totaling up to $44,000 under the Medicare program and $63,750 under the Medicaid program during the five-year period. (Note: While similar incentive payments are available for hospitals, here, the exclusive focus is on non-hospital providers.)

In order to qualify, providers must comply with the meaningful use rule recently made available by CMS, and its companion rule issued by the Office of the National Coordinator (ONC).

Unfortunately, there is no quick and easy way to qualify what exactly constitutes meaningful use. While CMS defines a "meaningful EHR user" as a professional or eligible hospital who uses EHRs in "a form and manner consistent with certain objectives and measures presented in the regulation," the actual regulation include an array of nebulous objectives such as improving the quality and safety of care; engaging patients and families; improving care coordination; and protecting privacy.

The 556-page proposed rule (regulation) outlines CMS' ambitious, three-phase process by which providers may adopt EHR technology, and contains complex criteria defining how providers must implement EHR during Phase One in order to qualify as meaningful users.

Critics have argued that the rule is out of step with the way providers implement health information technology, and have suggested that CMS re-evaluate the requirements.



Though the rule may undergo slight revisions before its final publication later this year, providers can now get a head start by understanding what CMS hopes to accomplish through widespread adoption of EHR technology.

While the specifics of these phases are too lengthy to address here, providers should note that both the CMS and ONC rules make clear that a major consideration of whether meaningful use is achieved will be a provider's ability to securely exchange information among providers, and between providers and patients, using standardized data elements and technologies.

For example, a cited problem has been that one EHR system may record patient data as "PatientName, PatientAge, PatientGender, etc.," and another system may store data as "PatientSocial Security, PatientDate of Birth, PatientName, etc." To ensure that different EHR systems can securely communicate this information with each other, CMS requires that providers utilize EHR technology that is "certified" via a process approved by ONC.

Currently, the Phase One criteria focuses on electronically capturing health information in a coded format; using that information to track key clinical conditions and communicating that information for care coordination purposes; implementing clinical decision support tools to facilitate disease and medication management; and reporting clinical quality measures and public health information.

Eligible professionals must also meet 25 objectives and measurements through implementation of safety protocols and collection of certain data from patients. (See "The criteria" at right for the complete list.)

In order to receive incentive payments, providers must meaningfully use EHR for any continuous 90-day period within the first payment year (i.e., the first year a provider begins utilizing EHR technology), and then "attest" via an online affidavit that they have met the 25 objectives and measures.

In 2011, attestation will be accomplished via a secure CMS or State Medicaid Web site. The attestation process is likely to be further developed during the course of the incentive payment program.

Providers should note that an attestation is a legally binding representation and making a false attestation could be considered fraud under the Medicare and Medicaid programs.

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