Physicians share strategies to improve quality metrics, chronic care

5 WAYS TO PUT DATA INTO ACTION

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Men’s health: Engage patients, improve outcomes

Legal protections when firing a worker

Adverse outcomes: Communicating with patients
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PAYERS TO MAKE PRICING MORE TRANSPARENT

The Health Care Cost Institute is joining forces with insurance companies Aetna, Humana, and UnitedHealthcare to launch a website in 2015 to help patients make better-informed treatment decisions by aggregating healthcare price and quality data. The website will include detailed cost information from the three companies as well as Medicare Advantage and Medicaid, depending on the state. Find more information at MedicalEconomics.com/pricetransparency

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from the Trenches

“Medicare and Medicaid, and managed care insurance pay the lowest rates possible, while some private insurers and self-pay patients pay the maximum, retail price. Under free market competition the self-pay patients would pay the least, because they were saving the time and costs involved with insurance administration.

Craig M. Wax, DO, Mullica Hill, New Jersey

MEDICAL PRACTICE IS BEING CAPTURED BY REGULATORS

The current medical practice environment is difficult at best and tragic at worst. The art and science of medicine are at the breaking point due to government overregulation, insurance rules, and reimbursement constraints. Employers and employees are hit with significant increases in premiums every year, straining both groups incrementally.

Insurance companies are prepaid for care and procedures, but deny reimbursements for patients. This also stresses physicians, who are obligated to provide care, despite the risk of reimbursement denials for care already rendered. Insurance reimbursement for patient medications may be denied at time of care or anytime thereafter.

These financial pressures have caused hospitals, pharmaceutical companies, laboratories, imaging centers, and other medical facilities to inflate their prices. Medicare and Medicaid, and managed care insurance pay the lowest rates possible, while some private insurers and self-pay patients pay the maximum, retail price. Under free market competition, the self-pay patients would pay the least, because they were saving the time and costs involved with insurance administration, coding, billing, and claim denial appeals.

Electronic health records fragment the patient-physician relationship and depersonalize medicine. They reduce healthcare to the forced observance of medical diagnoses and treatment algorithms designed by so-called authorities to reduce care costs. This is for the purpose of reducing government liabilities for care cost and health insurance company corporate profits, all at the risk of patient lives.

Physician specialty groups developed board certification in an attempt to differentiate themselves from one another in their postgraduate training. An exam was given at the end of specialty residency training to demonstrate academic competency, which may or may not correlate to clinical competency.

In the 1980s and 1990s, specialty boards moved from lifetime certification with yearly continuing medical education to limited eight-year periods for new certificates. Older physicians were still lifetime-certified. Now specialty boards are attempting to create more hoops for physicians to jump through. Maintenance of certification mocks physicians with thousands of dollars in additional fees and hundreds of hours of lost to meet these new requirements. Despite the lack of data demonstrating that any of these oppressive new board requirements improve care, they are being instituted due to government mandates and specialty board profits.

In short, the regulatory capture of the practice of medicine is well underway. EHRs capture our patient private data for the gov-
‘Certified’ implies a guarantee of excellence, which is dishonest. It makes more sense to call a doctor who passes the boards a ‘diplomate,’ a term that merely means that a physician has passed a certain test.

Edward Volpintesta, MD, BETHEL, CONNECTICUT

Certification Terminology Misleads Public

In his February 25 letter, “MOC requirements will drive out experienced providers,” Benjamin Levinson, MD spoke for the majority of senior physicians when he suggested that the pressures of maintenance of certification (MOC) may force doctors to quit medicine.

But there is a side issue here that is rarely discussed, namely poor English usage. In his essay, “Politics and the English Language,” the English writer George Orwell said that “bad usage can be spread by tradition and imitation even among people who should and do know better.”

In the case of the American Board of Medical Specialties, the words “certification” and “re-certification” represent bad usage. Both words mislead the public because neither all members of the public nor all members of the medical profession agree on exactly what they mean.

“Certified” implies a guarantee of excellence, which is dishonest. It makes more sense to call a doctor who passes the boards a “diplomate,” a term that merely means that a physician has passed a certain test.

I suspect that if the ABMS substituted “diplomate” for “board certified” far fewer doctors would feel the need to sit for the ABMS exams.
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NEW TELEMEDICINE GUIDELINES EMPHASIZE VIDEO OVER AUDIO

The Federation of State Medical Boards (FSMB) has issued new guidelines for the use of telemedicine, but some of the provisions, including the board’s definition of telemedicine, have prompted criticism from the American Telemedicine Association (ATA).

The new guidelines stress the need for physicians to communicate with patients through video, rather than only audio or email.

"Generally, telemedicine is not an audio-only, telephone conversation, e-mail/instant messaging conversation, or fax," the guidelines state. "It typically involves the application of secure videoconferencing, or store-and-forward technology to provide or support healthcare delivery by replicating the interaction of a traditional encounter in person between a provider and a patient."

In a letter sent to the FSMB before the guidelines were approved, the ATA acknowledged that video may be more of a benefit to patient safety. However, it cautioned against using such a loose definition for telemedicine.

"The fact remains that the telephone is an important tool for current patient interactions. This year it is estimated that approximately 250,000 telephone-based consultations will be made by two web-based providers alone," the letter stated. "Use of the word ‘generally’ in the existing language does not clarify the problem of a rigid policy disallowing any use of telephones or emails as telemedicine. State policies that prohibit any such use could set back the practice of medicine and significantly limit the delivery of care."

The number of physicians using telemedicine to diagnose and treat patients is growing at a rapid pace. More than half of all hospitals in the U.S. use a form of telemedicine, according to the ATA.

The guidelines released by the FSMB are designed to provide states a framework to use when creating their own telemedicine laws.

PHARMA AND PAYERS NOT ALIGNED

A new survey says that accountable care organizations and payers have distinct criteria for what makes a drug worthwhile, and pharmaceutical companies are not recognizing unique payer communication needs.

EY, an accounting firm, conducted the survey, which included U.S. and European payers and pharmaceutical companies.

The survey found that payers are more focused on cost containment than outcomes-based approaches to containing costs. Even though prescriptions account for about 10% of healthcare spending, payers also see drug costs as their biggest challenge.

Eighty-eight percent of payers reported that drug prices are a major reason for the rising costs of healthcare. Fewer than half (42%) of surveyed industry insiders agreed with that premise.

There is some overlap between payers and treatment decision-makers. While payers are open to new drugs, they need to be supported by robust information that demonstrates an advantage over products already on the market.

The guidelines released by the FSMB include:

- evaluation and treatment of the patient,
- informed consent,
- continuity of care,
- referrals for emergency services,
- medical records,
- privacy and security of patient records and exchange of information,
- disclosures and functionality on online services making available telemedicine technologies, and
- prescribing.

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The U.S. Food and Drug Administration (FDA) proposed rules to regulate the sale of electronic cigarettes, or e-cigarettes. The rules would prohibit the sale of e-cigarettes to minors and require manufacturers to include health warnings with them. Makers of e-cigarettes would also be required to report their product ingredients to the FDA for review.

Studies show that more teenagers are beginning to use them, and the effects of the vapor produced by the devices are still unknown. Because many people have been using e-cigarettes as a way to stop using tobacco products, healthcare providers need to know the latest information on whether these new devices are safe for their patients.
FDA Approves Incruse Ellipta for COPD

The U.S. Food and Drug Administration approved umeclidinium (Incruse Ellipta, GlaxoSmithKline) once-daily anticholinergic for long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

Umeclidinium is GSK’s first once-daily anticholinergic, a type of bronchodilator also known as a long-acting muscarinic antagonist. It is approved with the Ellipta inhaler.

The drug’s anticipated launch will be during the fourth quarter of 2014.

The phase 3 randomized, placebo-controlled clinical studies included seven clinical studies, which involved more than 2,500 COPD patients. Nasopharyngitis (8%), upper respiratory tract infection (5%), cough (3%), and arthralgia (2%) were the most common adverse events.

GSK’s other approved drugs for COPD are Breo Ellipta, a fluticasone furoate and vilanterol inhalation powder and Anoro Ellipta, umeclidinium and vilanterol inhalation powder.

The National Heart, Lung and Blood Institute (NHLBI) estimates that nearly 27 million people in the U.S. have COPD.

Medicare should not cover lung-cancer screening for smokers, says CMS panel

A Centers for Medicare and Medicaid Services (CMS) advisory panel concluded that Medicare should not cover annual lung cancer screening tests for heavy smokers, a recommendation that has been criticized by advocates of the test.

The CMS Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) made its determination in late April based on the high false-positive rate for the low-dose computed tomography (CT) screening, and a general lack of evidence as to whether the scans are effective.

The United States Preventive Services Task Force (USPSTF) recommended late last year annual screening for lung cancer in adults 55 to 80 years old who have a 30 packs per year smoking history and remain heavy smokers or have quit smoking in the last 15 years, according to the guidelines. That recommendation, according to CMS, was based largely on the results of the National Lung Screening Trial, which found reduced risk of mortality for at-risk patients who received CT scans.

But the nine-member MEDCAC panel gave the use of the screening a vote of low confidence because the panel determined there was not “adequate evidence” that the benefits of the screening outweighed the potential harms, and that “clinically significant evidence gaps remain regarding the use of low-dose CT for lung cancer screening in the Medicare population.”

The American College of Radiology (ACR) argued in a statement that Medicare should continue to cover the screening.

“The absence of Medicare coverage for CT lung cancer screening, as recommended by the USPSTF, penalizes many seniors and may result in lives lost,” said Bibb Allen, MD, FACR, chair of the ACR Board of Chancellors, in a written statement. “We now have a chance to strike back against the nation’s leading cancer killer, but only if people have access to these lifesaving exams. We strongly urge CMS to act on the evidence and the USPSTF recommendations and provide full national coverage of CT lung cancer screening for high-risk patients.”

MEDCAC plans to provide CMS with its formal recommendation in November.

Lung Cancer is the leading cancer killer in both men and women in the U.S.

Close to 90 percent of lung cancer cases that active smoking is responsible for.

More than half of people with lung cancer die within one year of being diagnosed.

Percentage of lung cancer deaths that smoking contributes to:

- 80% women
- 90% men

$12.1 billion lung-cancer care cost in 2010

Source: The American Lung Association
EIGHTH JOINT NATIONAL COMMITTEE

JNC 8 uses evidence-based methodology in new guideline on hypertension management

by CHERYL GUTTMAN KRADER Contributing author

Hypertension is the most common disease seen among adults in a primary care practice, and is a leading preventable cause for other serious morbidity and mortality.

The latest guideline on the management of high blood pressure in adults issued by the Eighth Joint National Committee (JNC 8) presents evidence-based recommendations on thresholds for pharmacologic intervention, medications for treatment initiation, and therapeutic goals.

In contrast to the JNC 7 guidelines, JNC 8 was developed based on a rigorous, systematic review of randomized controlled trials. JNC 8 makes new recommendations on thresholds for initiating antihypertensive medication, supports the use of broadened options for initiating therapy rather than favoring a thiazide-type diuretic, gives specific medication recommendations for a more limited number of subgroups (black patients and patients with chronic kidney disease or diabetes), and does not recommend β-blockers for any subgroup.

JNC 8 also recommends similar treatment goals for all hypertensive populations, regardless of comorbidities, except when evidence supports a different recommendation for a particular subgroup.

A summary of the JNC 8 recommendations:

**BP thresholds for initiating pharmacologic treatment**
- In the general population ≥60 years: SBP ≥150 mm Hg or DBP ≥90 mm Hg
- In younger persons (<60 years) or in any adults with diabetes or chronic kidney disease (CKD): SBP ≥140 mm Hg or DBP ≥90 mm Hg

**Medications for initiating antihypertensive therapy**
- In the general nonblack population: a thiazide-type diuretic, calcium channel blocker (CCB), angiotensin-converting enzyme inhibitor (ACEI), or angiotensin receptor blocker (ARB)
- In black patients: a thiazide-type diuretic or CCB

Recommended goals are to lower SBP and DBP below the levels at which medication should be initiated. Modification of the initial approach is recommended if the goal is not reached after a 1-month trial, either by increasing the dose or by adding a medication from a different class. A third drug from another class should be added as needed to reach goal BP, but an ACEI and ARB should not be used together.

While not making a specific recommendation on lifestyle modifications, the JNC 8 panel members also noted that the potential benefits of a healthy diet, weight control and regular exercise cannot be overemphasized, and they supported the recommendations of the 2013 Lifestyle Work Group of the American College of Cardiology/American Heart Association task force on practice guidelines.

The group also stressed the importance of using clinical judgment for individual patients when applying the recommendations.

The report was first published online in JAMA on December 18, 2013, and later in print [JAMA. 2014;311(5):507-520].

To find one-page downloadable forms of this clinical guideline and others, visit Medical Economics on the web: MedicalEconomics.com/clinical perspectives
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EHRs: 5 ways to put data into action

Physicians share strategies to improve quality metrics, chronic care

by Ken Terry Contributing author

Physician frustration over the functionality of electronic health record (EHR) systems has been escalating. While the source of physician unhappiness stems from the belief that expensive technology should make their work life easier, the reality is that this technology requires greater physician involvement at a time when many practices struggle to maintain adequate patient volumes and remain financially solvent.

THE DISQUIET OVER the current state of technology was well documented in a recent Medical Economics survey of nearly 1,000 physicians in which 45% of responding physicians said patient care had grown worse since they implemented an EHR system. Nearly a quarter of internists said the quality of care was significantly worse.

While the message came through loud and clear in this survey, what can we learn from the silent minority about using data in their EHRs—including their Meaningful Use quality reports—to improve the quality of care they deliver?

Jennifer Brull, MD, a solo family practitioner (FP) in Plainville, Kansas, shares office space, staff, and services with four other FPs, four midlevel practitioners, and a nurse midwife. When she and her colleagues first implemented an EHR in 2007, she screened only 43% of her eligible patients for colorectal cancer; in the next few years, with the
help of EHR reminders, she raised that rate to 90%. She also used the EHR to increase her patients’ recommended mammography rate from 65% to 99%.

Chronic care also benefited from her practices’ EHR use. In 2012, Brull and her colleagues were regularly testing only 14% of their patients with diabetes for microalbumin. After educating their staff in the process and turning on an alert in their EHR, they raised that number to 95% within nine months. In 2012, only 11% of their heart failure patients had received a recommended echocardiogram within the previous two years; by the end of 2013, the network had increased that to 68%.

Most of the data you need to improve the quality of care is in your EHR, says Rosemarie Nelson, a Medical Group Management Association consultant based in Syracuse, New York. “But in some cases, the tools to make the data useful are not there,” she notes. Even when those functions are present, she adds, clinicians don’t necessarily use them.

If you find EHR documentation a bit overwhelming and resent the time it takes away from patient care, you might view the idea of using your EHR for quality improvement as a non sequitur. But some studies show that EHRs also do improve patient care and safety. Moreover, we’re entering a new era of value-based reimbursement, in which part of your income will be based on your quality scores. So it’s worth considering how your EHR can help you raise those scores.

**EHR CHALLENGES**

EHRs were not originally designed for quality improvement, but rather for improving efficiency and documentation so that doctors could get a return on their investment. But with the advent of Meaningful Use, vendors had to rewrite their software to produce quality reports in order to get certified for Meaningful Use. At the same time, physicians started to pay more attention to quality improvement.

The Breakaway Group, a health information technology consulting firm owned by Xerox, surveyed physician practices with EHRs in 2009 and found that fewer than 20% of them were trying to understand how EHRs affected quality of care. Today, partly because of Meaningful Use, “people are being forced to answer some of those questions,” says Heather Haugen, PhD, managing director of the Breakaway Group.

EHR vendors are offering better tools for quality reporting than they did a few years ago, Nelson notes. But the quality of these tools varies considerably, and some of them must be purchased as add-ons, she says.

The leading EHRs include health maintenance alerts that remind physicians about some of their patients’ preventive and chronic care gaps when they see them. In some systems, however, users have to build their own alerts, Nelson says.

If an EHR includes prebuilt alerts, you may be able to customize or add to them. Brull says this is not a big chore in her EHR. She has customized about 25% of the health maintenance alerts—most of them in less than five minutes each.

Certified EHRs must be able to extract quality data for Meaningful Use. While the clinical quality measures are very limited, they can be used in quality improvement, Nelson says. In some EHRs, for example,
Why achieving EHR meaningful use is not enough to improve quality

A new study casts doubt on whether the billions of dollars spent so far in meeting meaningful use requirements is actually improving patient outcomes.

The study compared results on seven clinical quality measures for five chronic conditions (asthma, coronary artery disease, diabetes mellitus, depression, and hypertension) between doctors who had successfully attested to the first round of meaningful use requirements and those who had not attested. The study was conducted at Brigham and Women’s Hospital in Boston, Massachusetts and its affiliated ambulatory clinics.

The results showed meaningful use was associated with marginally better quality on two measures (controlling cholesterol in patients with diabetes and blood pressure among patients with hypertension), worse quality for two (asthma and depression) and neither better nor worse quality on three measures (HbA1c levels and urine protein screening among patients with diabetes, and beta-blocker therapy for patients with coronary artery disease.)

The authors note that other studies of EHR use have also failed to find a consistent association with quality for given chronic conditions.

On the other hand, they say, “specific EHR functions (reminders, test results, order entry, visit notes, problem lists, and medication lists) have been associated with higher quality for some conditions and not others.”

The American Recovery and Reinvestment Act of 2009 included $30 billion to encourage doctors to adopt electronic health record (EHR) systems, of which about $19 billion has been paid out thus far through the meaningful use incentive program.

The study was published online first as a research letter in the April issue of JAMA Internal Medicine.

You can get a list of diabetic patients with an HbA1c >8 by clicking on the percentage of patients in that category.

Unfortunately, Brull says, “That’s where it stops in our EHR software. You can’t click on the patient’s name and go to their chart, which is the most actionable next step.”

The other problem with the reports in Brull’s EHR, she says, is that they can’t be customized. That is one reason why her group has acquired web-based registry software that interfaces with its EHR. This application, which also has population health management features, can generate a wide range of custom reports.

“The ability to customize reports is something the EHR vendors are working on,” Haugen says. “But it’s definitely not there. What most practices do, if they want to get this information, is hire people who can write those custom reports.”

Of course, many practices can’t afford to pay a technical expert to program these reports, so it doesn’t get done, she adds.

REGISTRY FUNCTIONS

Registries, which track the services provided to patients along with indicators of their health status and due dates for recommended care, are not yet being widely used in healthcare, Haugen says. But some vendors have begun to incorporate registry functions into their EHRs, according to Nelson.

Several vendors, for example, offer the ability to query the database for a range of dates, she says. For example, the EHR could supply a list of patients with uncontrolled hypertension who haven’t been seen in three months and don’t have an appointment in the next three months.

Brull’s EHR can’t do this, but her group can use the web-based dashboard of its outside registry for that purpose. “If I have a patient with high blood pressure (BP) who fails to come see me for a prolonged period of time, they won’t show up on my EHR report, but they will show up on my registry report as a patient with hypertension who has not had their BP checked in an interval of time,” she says.

MAKING THE DATA ACTIONABLE

Seeking to capitalize on the new opportunities for value-based reimbursement, a growing number of healthcare organizations are using EHRs and other kinds of health IT applications to identify patients who have care gaps. But relatively few of them are able to ensure that those gaps are filled, Haugen says.

In large part, that’s because EHRs lack the functionality to make the data actionable. For example, even if the EHR has a built-in registry, it may not be able to upload a list of patients who need a specific service to an automated messaging system or send a message to those patients through the EHR’s patient portal, Nelson says.
QUESTIONS TO ASK YOUR VENDOR

Uncover your EHR’s limitations

Q: Does the system flag overdue health maintenance items? How are these flags displayed?

Q: Can the EHR system automatically generate reminders for follow-up based on specified criteria?

Q: Does the EHR come with preconfigured health maintenance alerts?

Q: Will my practice be able to generate queries, such as "identify all male diabetic patients, aged 50 to 65, with A1c hemoglobin levels above seven"?

Q: Can I create ad-hoc reports or am I limited to reports provided off-the-shelf? Can reports be customized?

Q: Can I query the EHR to identify certain patients, such as those with particular conditions or who use certain medications?

Q: If so, are there any limitations to the templates we can build?

Q: Can I create ad-hoc reports or am I limited to reports provided off-the-shelf? Can reports be customized?

Q: Does the EHR have a built-in patient registry that can be used for quality measure reporting?

Q: Does the system notify me of abnormal lab results when they’re received and provide normal ranges?

Q: Is the registry standard or is there an extra fee for the feature?

Q: Does the system give me a way to measure my performance on quality measures and compare it to that of my colleagues?

Brull agrees. There’s a “registry processor” function in her group’s EHR that lets the practice email a list of patients who need services, she says. But even if the network could send such emails securely, she notes, it’s not easy to construct the end-to-end process with the outside registry. “All the pieces are there, but they’re not ‘click here and do this.’ You have to know what you’re doing,” she says.

Instead, the group exports the registry report data to an Excel file that includes patient demographic information, including addresses and phone numbers. Since regular mail hasn’t proved to be effective, the staff either calls patients or contacts them via the patient portal, “but it’s not an automated process,” Brull notes.

THE LARGE GROUP APPROACH

In a large group practice the challenges are somewhat different. The EHR usually operates on a central server, and the quality reports are programmed by the organization’s IT department. The organization may also have a mechanism for contacting patients...
EHRs and quality improvement

THE ABILITY TO CUSTOMIZE REPORTS IS SOMETHING THE EHR VENDORS ARE WORKING ON. BUT IT’S DEFINITELY NOT THERE. WHAT MOST PRACTICES DO, IF THEY WANT TO GET THIS INFORMATION, IS HIRE PEOPLE WHO CAN WRITE THOSE CUSTOM REPORTS.”

— HEATHER HAUGEN, PH.D., MANAGING DIRECTOR, THE BREAKAWAY GROUP

who are not in compliance with their providers’ care plans.

Robert Segal, MD, works for Scottsdale Healthcare in Scottsdale, Ariz. His ambulatory EHR is used by hundreds of physicians that are employed by the healthcare system. When the system decides that it wants the doctors to focus on a particular quality area, a report-writing team creates the requisite reports, and data on individual doctors’ performance is sent to them monthly.

In the near future, Segal says, the organization will begin giving the physicians comparative quality reports. He welcomes those because they will show him where he stands in relation to his peers and how he can improve his quality scores.

While some healthcare organizations use this approach, others don’t even share the quality data with their doctors, Haugen says. She cites the example of a large hospital group that was collecting quality data for Meaningful Use but was not communicating it to the physicians. They told her, “We’d like to see the data but no one is showing it to us.”

Haugen comments, “In some respects, small practices are doing this better because their ability to affect the process is sometimes much more immediate.”

STRUCTURED DATA IS KEY

Although doctors don’t like to hear it, their ability to use their EHRs to improve quality depends on whether they enter key data into the system in structured form. If the data is not in codified fields, it doesn’t show up in reports or health maintenance alerts. Consequently, those reports and alerts may not be reliable.

Haugen, a strong proponent of structured data entry, acknowledges that this is a sore point for doctors. But not all data has to be structured to improve quality, she says. What practices need to do is find “a happy medium between what data must be structured and what can be unstructured,” she notes. Vendors must also do their part to make it easier for physicians and their staffs to enter the data, she adds.

Nelson suggests that practices work on improving clinical documentation if they want to improve quality. Also, she says, the physicians in a group should standardize their EHR templates and enter data the same way. If one doctor uses a template that suits him or her, but nobody else uses it, quality improvement will suffer.

In the end, you’ll get out of the EHR what you put into it. If big chunks of data are missing, you can’t use the information to deliver better care. Also, remember that the EHR is only a tool; process improvement is up to you and your staff.

“We can track the quality of care with the EHR, but the EHR doesn’t change the care we’re providing,” Haugen observes. “So we have a big step to take beyond the EHR.”

5 ways to put data into action

1. Use EHRs as reminders

2. Customize health maintenance alerts

3. Use registry functionality

4. Share results with the healthcare team

5. Maximize benefits of structured data

MORE ONLINE

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AMA: Meaningful use discourages participation

**THE AMERICAN** Medical Association (AMA) is calling for major reforms to the Centers for Medicare and Medicaid Services’ (CMS) Meaningful Use incentive program for electronic health records.

In a letter to CMS Administrator Marilyn Tavenner and National Coordinator for Health Information Technology Karen DeSalvo, MD, MPH, the AMA argued that without significant changes, more providers will drop out of the program.

“The AMA is concerned that the rigid program requirements and financial penalties will discourage physicians who are making good faith efforts to incorporate health IT into their practices,” the letter states. The AMA also warned that imposing stiff penalties would prevent thousands of physicians from investing in other technological resources to advance care.

Although the reporting year began on Jan. 1, 2014, few providers have attested to Meaningful Use Stage 2 (MU2). CMS released data that shows only 50 eligible professionals and four facilities have attested to MU2 so far this year.

Among its recommendations, the AMA suggests eliminating any requirement that is outside the physician’s control. This would include the MU2 measure that requires more than 5% of a practice’s patients to access the patient portal. “Many physicians continue to report to us challenges in convincing patients to use these tools because of the patient’s own preference to speak directly with the physician,” the letter states. “It should be sufficient for physicians to exchange information they deem important and to encourage their patients to participate in their own care through innovative technologies without requiring an individual to view, download, or transmit information.”

To view a list of the AMA’s recommended changes for the incentive program’s stages 1 through 3, visit our online coverage at MedicalEconomics.com: http://bit.ly/1lBb66k

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**AT HEARING, EHR VENDORS CRITICIZE 2015 EDITION STANDARDS**

Electronic health record (EHR) vendors and other healthcare IT stakeholders contested and criticized new certification rules proposed by the Office of the National Coordinator for Health Information Technology (ONC) for 2015 in a Health IT Policy Committee hearing on May 7.

The ONC aims to create EHR standards separate from the Centers for Medicare and Medicaid Services (CMS) meaningful use (MU) standards, even establishing certification standards for non-MU EHRs. Other significant parts of the new rule would make 2015 certification voluntary for vendors and providers in meeting CMS incentive programs.

In addition, the ONC wants to publish new certification criteria more frequently, every 12 to 18 months, to better respond to stakeholder feedback. The final rule will be published in summer 2014.

By relaxing the standards for EHRs, vendors and providers can work toward 2015 at their own terms and pace, Karen DeSalvo, MD, national coordinator for ONC, said in a statement about the rules in February.
Three ways to avoid tax hits in estate planning

A well-conceived estate plan should eliminate most uncertainties, reduce taxes, and shield assets

by BRIAN LUSTER and STEVEN ABERNATHY, Contributing authors

Estate planning is an often-neglected aspect of wealth management, because it involves thinking about an inevitable reality few wish to confront. Thinking about the fine details and nuances of what will outlive us and be passed on to heirs can prove daunting even for the most pragmatic of physicians. Nevertheless, ignoring it is a mistake.

The savvy physician will not shy away from this needed component of wealth management, but instead will plan well, plan ahead, and reap the benefits. A well-prepared estate plan optimally serves several goals: eliminating uncertainties over the administration and probate of the estate itself; maximizing its value by reducing taxes and expenses; shielding assets from creditors, litigants, and ex-spouses; and ultimately passing the estate's assets to heirs during (and after) the grantor's lifetime.

The most effective estate plans are a road...
Estate planning

map across an investor’s portfolio to what will happen with all assets across many categories. Without a clear plan, an estate may be subject to several taxes right off the bat (depending on the state). These may include: capital gains, state, inheritance, and estate and gift taxes. With proper planning and forethought, these tax hits can be reduced—or avoided altogether. This article introduces three instruments that might be used in an estate plan:

- family limited partnerships (FLPs),
- freezing assets in an Intentional Defective Grantor Trust (IDGT), and finally
- freezing assets using a Grantor Retained Annuity Trust (GRAT).

FAMILY LIMITED PARTNERSHIPS

FLPs have two types of partners:

- General partners, who hold control over the assets, decision-making and how the assets are distributed, and
- limited partners who hold an economic interest

It’s important to note that even if a general partner holds a substantially smaller percentage of the asset(s), she or he retains control. FLPs allow for up to a 40% discount on the market value of assets placed into trusts, which means the physician can effectively pass along up to $8.9 million (individuals) and $17.8 million (married couples). The math is simply $5.34 million divided by 60% and $10.68 million divided by 60%. (For 2014, over an investor’s lifetime, he or she can gift $5.34 million, or $10.68 million per couple, exempt from gift and estate taxes.)

Gifts of this magnitude can substantially reduce the taxable amount of the estate, and

- gift, inheritance, and estate taxes are avoided.

What investors put into an FLP, or multiple FLPs, can include a range of assets. If, for example, a $2 million home is included in the FLP, and the market value of the home rises to $3 million, it is still “worth” only $2 million because it “resides” in the FLP.

INTENTIONAL DEFECTIVE GRANTOR TRUST

Another effective way to pass on a business or other assets to family members as part of an estate plan is by employing a “freeze” technique in an IDGT.

The IDGT is structured as a Grantor trust that purposefully runs afoul of specific income tax rules. By retaining certain powers, including the right to borrow funds, the grantor ensures that he or she will be responsible for paying tax on the trust’s income. This is not as bad as it sounds because the trust is considered an “alter-ego” of the grantor. There will be no taxable gain when assets are “sold” to the trust or when the grantor receives interest payments from the trust.

Here is an example. Suppose dad transfers $1 million worth of cash or an asset to an IDGT with, say, a 10% rate of return. The income generated would be $100,000 per year. Assuming a 45% combined state and federal income tax rate, and that no distributions were made from the trust, the original principal of $1 million plus $100,000 of income less $45,000 in taxes—or $1,055,000—would remain at the end of the year.

If the trust income is taxed to the grantor and the grantor uses other non-trust funds

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THE GOOD NEWS IS THAT TODAY’S PHYSICIAN CAN CHOOSE FROM A MYRIAD OF ESTATE PLANNING TECHNIQUES THAT OFFER NOT ONLY TAX ADVANTAGES BUT VARIOUS LEVELS OF CONTROL OVER THE ASSETS.
to pay the tax, however, then $1.1 million would remain in the trust at the end of the year instead of $1.055 million. The grantor thus reduces the “value” of his estate without any transfer tax consequences by using other funds to pay the income tax on behalf of the IDGT.

Moreover, if the money the grantor uses to pay the tax is also removed from his estate, it creates a double benefit. If the grantor uses other funds to pay the income tax and no distributions are made from the trust, after 20 years there would be $6.7 million in the IDGT instead of $2.9 million—provided it’s a non-grantor trust. The difference of $3.8 million is in effect a tax-free gift.

**GRANTOR RETAINED ANNUITY TRUST**

A GRAT offers yet another efficient option for an investor to freeze the value of his or her estate. One of the most dramatic examples of effective use of a GRAT is illustrated by the Walton family. Several years ago, Audrey Walton, daughter of one of the co-founders of Wal-Mart Stores, Inc., wanting to give $100 million worth of stock to her daughters, transferred 7.2 million shares to a GRAT. The basic premise was simple; the investor takes advantage of the ability to separately value different interests of a single asset. These interests are typically: 1) the cash flow from the trust’s asset (usually in the form of an annuity), such as the rent from an apartment building; and, 2) the trust’s asset itself (i.e. the apartment building).

The trick is in the valuation. The asset placed into the trust is valued at less than its fair market value because the annuity cash stream, also called retained interest, is still held by the grantor. This minimizes the gift tax; more importantly, by allowing the retained interest to equal the value of the asset (plus an assumed growth rate provided by the U.S. Treasury Department).

The retained interest value is “frozen” at the time it is placed in the trust. Assuming the asset increases in value faster than the assumed growth rate, any appreciation is passed on tax-free. (Note: the grantor, not the trust, is paying taxes on the growth.)

Audrey Walton’s trusts were to terminate in just two years, with the remaining shares to be transferred to her daughters. The trust stipulated that for the first year, Walton was to be paid an annuity equal to 49.35% of the initial trust, and 59.22% for the second year. Payments could be made in-kind with the Wal-Mart stock. Using the voodoo of actuarial tables, the daughters’ remainder was valued at only $6,195—not a bad gift tax to pay on 10% of $1 billion.

Why so low? The dollar amount Walton received, in the form of an annuity, equaled the value of the stock at the time it was arranged.

What would have happened if the value of the stock increased at the end of the two years?

In what was a surprise at the time, the value of the Wal-Mart stocks declined, thereby exhausting the trust corpus, so the daughters were left with nothing from it. So, what would have happened had the shares appreciated? (Remember that even 15% is certainly possible in a volatile market.) The daughters would have received approximately $15 million for the bargain price of a gift tax on $6,195, plus relatively minimal administrative and legal costs.

The good news is that today’s physician can choose from a myriad of estate planning techniques that offer not only tax advantages but various levels of control over the assets. When the instruments employed are structured properly, wealth transfer goals can occur with maximum precision and efficiency and minimal risk. Choosing the right estate planning techniques today could mean millions of dollars in tax savings years down the road.

Steven Abernathy and Brian Luster co-founded The Abernathy Group II Family Office, based in New York, New York. The firm counsels affluent families on multi-generational asset protection, wealth management, and estate and tax planning strategies.

The most effective estate plans are a roadmap across an investor’s portfolio to what will happen with all assets across many categories. Without a clear plan, an estate may be subject to several taxes right off the bat.
Financial Strategies

THREE MONEY POLICIES TO RETHINK IN YOUR PRACTICE

by ROBERT C. SCROGGINS, JD, CPA, CHBC, Contributing author

The process of handling cash and checks has been streamlined by modern banking methods. Using current technology brings efficiency, reduces some of the control risks related to cash and checks, and helps keep the patient responsibility portion of your accounts receivable in check. Consider these three functions in your practice:

PETTY CASH
Cash on hand will be necessary, but a traditional approach to a petty cash fund is more cumbersome than necessary. The process of accounting for petty cash is fairly simple.

Because of the near-universal acceptance of credit cards, we suggest our clients have cards issued to those who “run to the store” with any regularity. The cards should have a low limit and be kept securely at the office until needed.

Credit card activity can be linked and downloaded to the payables software so as to streamline accounting tasks.

DAILY BANK DEPOSITS
If you are going to the bank daily to make deposits, you may want to consider a remote deposit system. This involves simple software and scanning equipment installed by your bank at your practice. Each day you create a deposit batch and scan the checks. The scanner reads the routing number, account number, and dollar amount, and looks for a signature on the check.

An image is produced so that the person operating the system can make corrections. The batch total for the deposit is then transmitted to the bank account you select through the software. We suggest keeping the physical checks for several months, then shredding the originals since the software maintains an image of each item.

CREDIT CARD PRE-AUTHORIZATION
Because of the increased use of high-deductible insurance plans, your practice likely is dealing with a greater amount of charges falling to the patients’ responsibility. This means a greater collection effort falls to your staff. The approach that generates the best collection result is to collect from your patients at the time of service. But patients will “forget” their wallets or checkbooks, or your office may be uncertain of the amount the patient will owe.

Accepting credit cards helps, but you might also consider taking the use of credit cards a step further by implementing a pre-authorization system that allows you to bill a patient’s credit card after the amount owed is determined. The authorization form should include the patient’s name, billing address, type of credit card, credit card number (and security code if needed) and expiration date. The form should also allow the patient to identify the types of charges that can be billed to his or her credit card, for example, the charge for a specific visit, or any charge outstanding as of the normal billing date each month.

The form can also allow the patient to elect to be billed by paper statement via mail, but with the stipulation that if payment is not received by the due date then the credit card on file will be charged. A major benefit to using a form like this is that it provides a tangible process by which the patient agrees to a method of payment in advance.

Robert C. Scroggins, JD, CPA, CHBC, is a management consultant and principal with ScrogginsGrear Inc., in Cincinnati, Ohio. Send your practice management questions to medec@advanstar.com.
Men’s health: The rules of patient engagement

The task of addressing men's health concerns is complicated by the challenge of persuading them to seek treatment.

Ask a primary care physician (PCP) to name the most common health challenges adult male patients face, and chances are that he or she will tick off a familiar list, ranging from prostate cancer to diabetes. But before they can begin addressing those problems, PCPs face a more basic challenge, which is persuading men just to come in at all.

THE REASONS WHY men are reluctant to seek medical care are not entirely clear, but are probably tied to notions of masculinity and fears of vulnerability. A study called “'Macho Men' and Preventive Health Care,” published in 2011 in the Journal of Health and Social Behavior found that “men with strong masculinity beliefs are half as likely as men with more moderate masculinity beliefs to receive preventive care.”

“When trying to get men to come in for a routine physical is next to impossible because they think they’re going to live forever,” says William Silverman, DO, an internist in solo practice in Seminole County, Florida. “When they’re younger, men think they’re...
We all struggle with how to get our patients to follow our recommendations. I think each physician has his or her own tools, but mine are listening, and being empathic, and supportive. It sounds common sense, but it works.”

—MATTHEW AJLUNI, DO, A FAMILY PHYSICIAN IN ANN ARBOR, MICHIGAN AND MEDICAL DIRECTOR OF AN URGENT CARE CENTER.

invincible, they don’t need to go to the doctor,” he says. “Then when they hit 40, they start thinking about the future and working their tails off, but they get so focused on their work they don’t want to take time to come in.” Whatever the reasons, men appear to be paying a price in terms of life expectancy. In 2010 it stood at 76.2 years for men, compared with 81 years for women, according to the National Center for Health Statistics.

THE ROLE OF WOMEN
Even when a man does come in, there’s a good chance he’s only doing so at the behest of a spouse, girlfriend, or significant other. “In my practice I see that the woman in the family tends to drive the healthcare decision-making process,” says David Fleming, MD, FACP, an internal medicine practitioner in Columbia, Missouri, chair of the department of internal medicine at the University of Missouri School of Medicine, and president of the American College of Physicians. In part, he says, it’s because women are more accustomed to seeing a doctor regularly for procedures such as Pap tests and mammograms, and because women are more likely to see to children’s health needs.

Fleming adds that while some of his male patients do come on their own, “there are many who just don’t because they are preoccupied with work or other activities that take more precedence. So often in the family it’s the woman who forces the issue.”

Silverman puts it more bluntly: “The man only goes if his wife pulls him by the ear because he’s ignoring his health and having chest or stomach pains. He’s too busy working to pay attention to himself and he ignored everything else.”

His observations are bolstered by a 2007 American Academy of Family Physicians (AAFP) survey, which found that 29% of adult men wait “as long as possible” before seeking medical help when they feel sick or are in pain or otherwise concerned about their health.

WHY MEN GO TO THE DOCTOR
When men do decide to visit a PCP, their health issues usually fall into one or more of three categories:

- male-specific issues, mainly those concerning the prostate, erectile dysfunction (ED), low testosterone levels; and loss of libido
- chronic conditions that aren’t gender-specific

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* According to a 2007 survey conducted online by Harris Interactive on behalf of the American Academy of Family Physicians of 2,282 U.S. Adults, of whom 1,111 were men. Sampling error is +/-5.

**Survey participants were also given the options: I prefer to treat myself naturally; I don’t have time to go to the doctor; I don’t know of a good doctor in my area; something else, and nothing.
but occur more frequently in men, such as diabetes and cardiovascular disease, and injuries or complaints stemming from sports and "lifestyle" activities.

Among these, the male-specific issues probably are cause the greatest angst for patients, due to the potentially life-threatening consequences of prostate cancer and the feared loss of sexual potency.

In addition, changes in recommendations for the use of the prostate-specific antigen (PSA) screening for prostate cancer, especially for men under 50 with no family history of the disease, has created confusion among some patients. "When the PSA first came out I thought it was fantastic," says Fleming. "It gave us an early detection mechanism that was very easy to do, and the initial recommendation was that we do it every year.

The problem, he adds, is that the PSA test also results in a relatively high number of false positives, leading to unnecessary treatments that frequently carry side effects ranging from incontinence to loss of sexual function. As a result, Fleming says, he has gone from giving the test every year to men over 60 to doing it only once, so long as the patient has no other risk factors and their rectal exam is normal. (See box, Screening for prostate cancer: a guidance statement from the American College of Physicians, on page 40)

In most cases where there are no other risk factors, the preferred method of treatment now is "watchful waiting." But persuading patients to take that course often presents its own challenges, because their initial reaction on hearing a diagnosis of cancer is to want to do something to get rid of it.

In those cases, the best approach often is shared decision-making—presenting the patient with his options and the possible consequences of each, then discussing with the patient how best to proceed, says Reid Blackwelder, MD, FAAFP, president of the American Academy of Family Physicians and a family practitioner in Kingsport, Tennessee.

"It isn’t about me deciding what the right treatment has to be and how I’m going to get the patient there," Blackwelder explains. "It’s more about me asking you, as the patient, 'what are your thoughts about this?’ I’m not going to point you

Men who are reluctant to visit a doctor frequently will make an exception when it comes to treating sports-related injuries. And that presents an opportunity for primary care physicians (PCPs) to begin a relationship that can lead to improved health outcomes.

"I think a sports injury is an ideal time [to begin establishing a relationship] because many of those problems do require follow-up," says Reid Blackwelder, MD, FAAFP, president of the American Academy of Family Physicians and a family practitioner in Kingsport, Tennessee. Along with treating the problem at hand, "I need to make sure I’m addressing anything else that’s obvious or make recommendations about other appropriate aspects of the patient’s care," he says.

Matthew Ajluni, DO, medical director of IHA After Hours Care, a trio of urgent care centers in Ann Arbor, Michigan, notes that sports injuries sometimes are a patient’s only connection with a medical professional. Knowing that, IHA staff members screen for blood pressure and body mass index on every patient. If those send up warning signs, "we’ll try to align the patient with one of our primary care colleagues," he says. "So it [treatings sports injuries] is definitely a gateway for getting these patients regular preventive medicine." (Half of each IHA clinic is devoted to walk-in or urgent care, and half to regular primary care.)

While the “gateway” concept of treating sports injuries is useful, PCPs need to walk a fine line when it comes to transitioning to other health issues, cautions Marc Childress, MD, a family practice and sports medicine physician in Fairfax, Virginia. "We have to be very careful, because we want to be aware of the opportunity for a larger conversation, but we don’t want to treat it as a ‘bait and switch,’ where the patient thinks he’s getting treated for one thing and winds up with something entirely different."
Men's health

If the patient decides on a course that Blackwelder feels is risky, he will make sure the patient is aware of the risks. “But if the patient says, ‘I hear you, doc, but this is really what I want to do,’ then I need to respect your opinion even though I may not agree with it.”

Fleming says he approaches prostate cancer treatment as a question of risks and benefits, especially among patients with low-grade cancer.

“I’ll usually say, ‘let’s just keep an eye on it and see how you do. Because there’s a 30% to 40% chance you’ll have some kind of complication resulting from surgery, and the risk may be more than the benefit you’d derive from it,” he says.

ACP GUIDANCE STATEMENT FOR PROSTATE CANCER SCREENING

In 2013 the American College of Physicians (ACP) issued the following guidance statements regarding screening for prostate cancer using the prostate-specific antigen test. The statements are based on a review of guidelines developed by the American College of Preventive Medicine, the American Cancer Society, the American Urological Association, and the U.S. Preventive Services Task Force:

**Guidance statement 1**

“ACP recommends that clinicians inform men between the age of 50 and 69 years about the limited potential benefits and substantial harms of screening for prostate cancer. ACP recommends that clinicians base the decision to screen for prostate cancer using the prostate-specific antigen test on the risk for prostate cancer, a discussion of the benefits and harms of screening, the patient’s general health and life expectancy, and patient preferences. ACP recommends that clinicians should not screen for prostate cancer using the prostate-specific antigen test in patients who do not express a clear preference for screening.”

**Guidance statement 2**

“ACP recommends that clinicians should not screen for prostate cancer using the prostate-specific antigen test in average-risk men under the age of 50 years, men over the age of 69 years, or men with a life expectancy of less than 10 to 15 years.”

Source: Annals of Internal Medicine. 2013 May 21; 158(10) 761-69
ERECTILE DYSFUNCTION AND TESTOSTERONE THERAPY

Issues of ED and testosterone replacement have become a larger part of the discussions around men’s health since the advent of direct-to-consumer pharmaceutical advertising in the late 1990s.

“The marketing [around testosterone replacement] has been brilliant, and it’s creating a good discussion for a lot of men,” says Marc Childress, MD, a family practice and sports medicine physician in Fairfax, Virginia. “The number of prescriptions for testosterone replacement over the last five years or so has ballooned.”

On the other hand, PCPs have to be cautious about inferring a “linear relationship” between a symptom or condition and a specific medication. “Certainly men can have problems with ED or low testosterone, but it doesn’t mean everyone should immediately be treated with a particular pill,” he says.

Blackwelder says he has seen an increase in the number of men asking about testosterone and ED remedies in recent years, a trend he attributes to TV advertising about these issues.

Most PCPs generally prefer to discuss testosterone/ED/libido concerns in the context of health and lifestyle issues. “It’s easy for us to play ‘patch and plug’ medicine, but it’s never that simple,” says Childress. “It’s not a matter of a man coming to me and describing ED and me prescribing a medication for that. There’s a lot that needs to be talked about.”

Fleming says he will try testosterone replacement on patients found to have low levels and complain of impotency or other associated symptoms.

“If their symptoms improve then it’s an indication we should continue doing it. If they don’t respond it’s up to them whether they want to continue or not. But it’s really patient specific,” he says.

TREATING CHRONIC DISEASES

Treating the chronic diseases men face, such as diabetes and cardiovascular disease, usually requires difficult lifestyle changes.

“The key in those cases, PCPs say, is to establish a strong relationship with the patient, built on good communication, trust, and presenting information in ways that patients can digest. And while building such a relationship is not easy within the limits of an evaluation and management visit, it’s by no means impossible.

“We all struggle with how to get our patients to follow our recommendations,” says Matthew Ajluni, DO, a family physician in Ann Arbor, Michigan and medical director of an urgent care center. “I think each physician has his or her own tools, but mine are listening, and being empathic, and supportive. It sounds common sense, but it works.”

Fleming emphasizes a team-based approach to helping patients, one that includes pharmacologists, nurses, dieticians, and other resources the patient requires. He also strives to educate patients about their disease or condition.

“Health literacy is still one of our most common concerns as it relates to compliance and clinical outcomes. It is the single most predictive variable for health outcomes,” he says. “If you can pull all that [patient education and team-based care] together, you have a much better chance of the patient keeping their appointment and taking their medication as prescribed.”

Blackwelder says he use any visit by a patient as an opportunity to begin establishing a relationship, a process that he compares to negotiating a business deal—right down to the handshake.

“We’re kind of negotiating an agreement, and that’s important, to give them some say but hold them accountable, especially if they say they’re willing to change their diet or give up smoking,” he says. “When they get to that point I almost always shake their hand and tell them I’m going to follow up on this. I’m willing to try all those little tricks to cement that relationship and create that sense of collaboration.”

“IT ISN’T ABOUT ME DECIDING WHAT THE RIGHT TREATMENT HAS TO BE AND HOW I’M GOING TO GET THE PATIENT THERE. IT’S MORE ABOUT ME ASKING YOU, AS THE PATIENT, ‘WHAT ARE YOUR THOUGHTS ABOUT THIS?’

—REID BLACKWELDER, MD, FAAFP, PRESIDENT, AMERICAN ACADEMY OF FAMILY PHYSICIANS
Practical Matters

FINDING A BUYER FOR YOUR PRACTICE: TIPS TO CLOSE THE DEAL

by KEITH BORGLUM, CHBC Contributing author

Even though healthcare is now the world’s largest industry, finding a buyer for a medical practice can be very difficult now for many physicians. These tips and best practices can help you find the right buyer.

IT’S NO SURPRISE that finding a buyer can be difficult: Our nation is facing a severe shortage of physicians. Many physicians would retire today if they had the means to do so, but many residents have said they would rather be employed by a hospital rather than go into independent practice. Healthcare groups are swamped with candidates who want to leave behind, or avoid, the burdens and risks of independent practice.

On the other hand, there are still many physicians out there interested in independent practice. Additionally, many physicians who finished residency or fellowship three to five years ago and took a job somewhere are now looking for opportunities to leave. These younger physicians possess growing confidence in their clinical skills, and may be interested in taking on the challenges of practice ownership.

I have given up trying to figure out which practices will sell and which won’t. It usually comes down to a candidate being available at the time the seller wishes to exit. It’s also about location, and about timing. I see some urban practices with multi-million dollar net incomes going unsold, and small, rural practices selling instantly, because of the availability of geographically-oriented candidates.

These tips can increase the chances of finding a buyer for your practice:

Advertise often
Advertise early, advertise often, advertise widely. If you are trying too hard to keep the sale a secret, it may stay a secret until you close. Advertise everywhere a candidate would look.

Start advertising at least a year prior to exit. According to business broker organizations, more than 85% of candidates now come from Internet searches (“family practice for sale in Indianapolis”), so your ads need to be search engine optimized.

Be ready to sell
Be prepared to sell on the day you place your first ad. Maybe your best candidate has been looking for months, and your new ad just popped up in front of him or her. I’ve seen sellers turn down the first candidate, never to find another. Work something out using your broker and attorney, maybe as a transition via associateship if you want to stay on longer.

Price realistically
Price your practice right, and prove it with an expert appraisal. All buyers are worried about paying too much, and will ask their own advisers for guidance.

Look locally
Look locally for a candidate—including your biggest competitor—since they already have a reason to be in your locale. If you are in a multi-hospital market, look in the other camp. If you are just outside the non-competition zone for other large group employed physicians, advertise there.

Pitch the lifestyle
Finally, promote the lifestyle of private practice and your community to both the candidate and his or her spouse or significant other.

Keith Borglum, CHBC, is a medical practice management consultant in Santa Rosa, California, and a Medical Economics editorial consultant. Send your practice management questions to medec@advanstar.com.
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We don’t have time for “hiccups”
ICD-10 DELAY: USE EXTRA TIME TO ENSURE YOUR PRACTICE IS READY

by RENEE DOWLING  Contributing author

In some ways, the implementation delay for the International Classification of Diseases—10th Revision (ICD-10) is a welcome relief for practices not ready for the transition. But now that ICD-10 has been delayed until October 1, 2015, practices must use the extra time to prepare, both by training to use ICD-10 and continued use of ICD-9 for the next year.

THE DELAY IN implementing ICD-10 gives physician practices extra time to apply the principles to clinical documentation improvement.

The documentation principles of ICD-10 reflect positive principles that should be applied to ICD-9 today to ensure the appropriate documentation of quality, severity, and risk. These are the key elements in incentive initiatives currently being offered by government and third-party payers when reported with diagnoses that support quality, severity, and risk.

Improved clinical documentation of diagnoses support incentive dollars. It also supports the higher levels of Current Procedural Terminology procedure and evaluation and management coding that practices currently use.

In addition to continued ICD-10 training, here are some things you can do now to position your practice to be ready for ICD-10 and the year ahead.

**Terminology procedure and evaluation and management coding that practices currently use.**

In addition to continued ICD-10 training, here are some things you can do now to position your practice to be ready for ICD-10 and the year ahead.

**Use time to check your equipment**

We now have time to ensure that our systems are ICD-10-compatible, without rushing to meet deadlines.

However, the previous rush may have left your system in less-than-optimal condition. So find out whether your EHR and practice management vendors have identified bugs when beta testing your ICD-10 systems, and ask to make sure they are worked out in time for the new deadline.

**Review updated LCDs**

Although ICD-10 has been postponed, MACs were required to issue new local coverage determinations (LCDs) with ICD-10 codes by April 10, 2014. This means that diagnosis coding will require a higher level of diagnosis specificity.

Providers and staff should review the new LCDs to get started on the ICD-10 transition, including a review of the codes that support medical necessity in the LCD, and the guidelines for those codes in your ICD-10 code book. This will help you identify the additional characters required for the codes and categories listed.

**Be ready for ICD-9**

Oddly enough, some partners in the payment chain won’t be prepared to keep ICD-9 going after October 1, 2014.

Reconfiguration is needed for groupers and pricers, and health plans need to make sure their systems accept ICD-9 codes. Some electronic health records (EHRs) may be hard-coded to accept only ICD-10 codes after the original implementation date, so check with your vendor.

**New ICD-10 implementation deadline set**

http://bit.ly/1jYNFya

**ICD-10 delay will cost practices more money, survey says**

http://bit.ly/1gZEv8Q

**MORE ONLINE**

Renee Dowling is a billing and coding consultant with VEI Consulting Services in Indianapolis, Indiana. Send your billing and coding questions to medec@advanstar.com.
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ICD-10-CM READINESS

Coding for diabetes

Diabetes mellitus coding under ICD-10-CM will require documentation with greater specificity and detail

by LORI BECKS, RHIA, AHIMA, Certified ICD-10-CM Trainer

In order to understand diabetes coding in the International Classification of Diseases-10th-Revision-Clinical Management (ICD-10-CM), it’s worth making a comparison of the structural differences between ICD-9-CM and ICD-10-CM (see graphic on page 47).

Diabetes mellitus (DM) codes in ICD-10-CM are combination codes that include the type of DM, the body system affected, and the complication affecting that body system as part of the code description. Subcategory levels first specify the type of complication by system, such as diabetes with kidney complications, ophthalmic complications, neurological complications, and circulatory complications. The subclassification level then describes the particular manifestation.

For example:

- **E11.3:** Type 2 diabetes mellitus with ophthalmic complications.
- **E11.32:** Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy.
- **E11.321:** Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema.
- **E11.329:** Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema.

A subcategory for diabetes mellitus with other specified complications is also provided that includes codes for DM with diabetic neuropathic arthropathy, diabetic dermatitis, foot ulcer, other skin ulcer, periodontal disease, hypoglycemia, and hyperglycemia.

As many codes as are needed to describe all of the associated complications that the patient has should be assigned from a particular category. Because of this code structure, there is no instructional note found under diabetes mellitus codes in ICD-10-CM requiring an additional code to identify the manifestation since it is already part of the code description.

There are specific diabetes codes that do require additional codes in order to identify the manifestation further, such as diabetes with foot ulcer to identify the site of the ulcer, or diabetes with chronic kidney disease to identify the stage of chronic kidney disease. For...
example, the code E10.621 (Type 1 diabetes mellitus with foot ulcer) requires the use of an additional code to identify the site of the ulcer (L97.4-, L97.5-)

ICD-10-CM codes do not require an additional fifth digit to identify the type of diabetes mellitus and whether it is controlled or uncontrolled. Cases that are noted as ‘inadequately controlled,’ ‘poorly controlled,’ or ‘out of control’ are coded to the diabetes, by type, with hyperglycemia:

E11.65: Type 2 diabetes mellitus with hyperglycemia.

SECONDARY DIABETES MELLITUS
Secondary diabetes mellitus is coded as either diabetes due to an underlying condition (category E08), drug or chemical induced diabetes (category E09), or other types of secondary diabetes mellitus NEC (category E13) which includes diabetes due to genetic defects of beta-cell function or insulin action, and postsurgical or postpancreatectomy cases of diabetes.

Sequencing of secondary diabetes codes in relation to the cause of the DM is assigned according to tabular instructions. Category E08 instructions state to code first the underlying condition, such as Cushing’s syndrome, cystic fibrosis, malnutrition, or a malignant neoplasm. Category E09 instructions state to code first poisoning due to drug or toxin (T36-T65) and use the appropriate fifth or sixth character ‘1-4’ or ‘6’ for poisoning. If the secondary diabetes is due to an adverse effect of a drug or chemical, then instructions direct the coder to use an additional code for the adverse effect (T36-T50) with fifth or sixth character ‘5’.

Cases of diabetes occurring with hyperosmolarity, with ketoacidosis, and with hypoglycemia must all be coded as with or without coma:

E10.10: Type 1 diabetes mellitus with ketoacidosis without coma
E10.11: Type 1 diabetes mellitus with ketoacidosis with coma
E08.00: Diabetes mellitus due to underlying condition with hyperosmolarity without nonketoletic hyperglycemic-hyperosmolar coma (NKHHC).
E08.00: Diabetes mellitus due to underlying condition with hyperosmolarity with coma.
E13.641: Other specified diabetes mellitus with hypoglycemia.

CODING DIABETES MELLITUS

<table>
<thead>
<tr>
<th>Structural difference in ICD-10-CM versus ICD-9-CM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ICD-9-CM</strong></td>
</tr>
<tr>
<td>249 Secondary diabetes mellitus</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>250 Diabetes mellitus</td>
</tr>
<tr>
<td>648.0 Diabetes mellitus complicating pregnancy, childbirth, and the puerperium</td>
</tr>
<tr>
<td>775.1 Neonatal diabetes mellitus</td>
</tr>
</tbody>
</table>

In ICD-10-CM, only Type 1 diabetes is listed with the possible manifestation of ketoacidosis with or without coma. Type 2 and all secondary types are listed with the possible manifestation of hyperosmolarity with or without coma.

DIABETES MELLITUS IN PREGNANCY, CHILDBIRTH, OR THE PUEPERIUM

Diabetes mellitus in pregnancy, childbirth, or the puerperium is not simply coded as to episode of care in ICD-10-CM.

Codes must first be selected as either pre-existing DM type 1, pre-existing DM type 2, unspecified pre-existing DM, gestational DM, other pre-existing DM, and unspecified DM. The second axis of coding specifies whether in pregnancy, in childbirth, or in
ICD-10 readiness

CODING DIABETES MELLITUS

EXAMPLES

DIABETES WITH GASTROPARESIS

<table>
<thead>
<tr>
<th>ICD-9-CM</th>
<th>ICD-10-CM</th>
</tr>
</thead>
<tbody>
<tr>
<td>249.60: Secondary diabetes mellitus with neurological manifestations, uncontrolled.</td>
<td>E08.43: Diabetes mellitus due to underlying condition with diabetic autonomic (poly) neuropathy.</td>
</tr>
<tr>
<td>WITH CODE FOR GASTROPARALYSIS</td>
<td>OR E09.43: Drug or chemical induced diabetes mellitus due to underlying condition with diabetic autonomic (poly) neuropathy.</td>
</tr>
<tr>
<td>536.3: Gastroparesis</td>
<td>OR E13.43: Other specified diabetes mellitus with diabetic autonomic (poly) neuropathy.</td>
</tr>
</tbody>
</table>

SECONDARY DIABETES MELLITUS WITH KIDNEY COMPLICATIONS

<table>
<thead>
<tr>
<th>ICD-9-CM</th>
<th>ICD-10-CM</th>
</tr>
</thead>
<tbody>
<tr>
<td>249.40: Secondary diabetes mellitus with renal manifestations not stated as uncontrolled, or unspecified.</td>
<td>E08.21: Diabetes mellitus due to underlying condition with diabetic nephropathy.</td>
</tr>
<tr>
<td></td>
<td>OR E09.21: Drug or chemically induced diabetes mellitus due to underlying condition with diabetic nephropathy.</td>
</tr>
<tr>
<td></td>
<td>OR E13.21: Other specified diabetes mellitus with diabetic nephropathy.</td>
</tr>
</tbody>
</table>

SECONDARY DIABETES WITH FOOT ULCER

<table>
<thead>
<tr>
<th>ICD-9-CM</th>
<th>ICD-10-CM</th>
</tr>
</thead>
<tbody>
<tr>
<td>249.80: Secondary diabetes mellitus with other specified manifestations not stated as uncontrolled, or unspecified.</td>
<td>E08.621: Diabetes mellitus due to underlying condition with foot ulcer.</td>
</tr>
<tr>
<td>WITH</td>
<td>OR E09.621: Drug or chemical induced diabetes mellitus with foot ulcer.</td>
</tr>
<tr>
<td>A code from 707.10—707.19, 707.8, or 707.9 to identify the site of non-pressure skin ulcer.</td>
<td>OR E13.621: Other specified diabetes mellitus with foot ulcer.</td>
</tr>
<tr>
<td></td>
<td>OR A code from L97.4- or L97.5- to designate site, laterality, and depth of non-pressure skin ulcer.</td>
</tr>
</tbody>
</table>

Cases of gestational diabetes are reported as in pregnancy, in childbirth, or in the puerperium and each of these subcategories is further specified as to diet controlled, insulin controlled, or unspecified control:

- **O24.41**: Gestational diabetes mellitus in pregnancy
- **O24.41**: Gestational diabetes mellitus in pregnancy, diet controlled.
- **O24.41**: Gestational diabetes mellitus in pregnancy, insulin controlled.
- **O24.41**: Gestational diabetes mellitus in pregnancy, unspecified control.

PREPARE FOR CODE CHANGES

Occasional changes have been made to the coding of diabetes mellitus in ICD-10-CM between draft versions, so even those already familiar with diabetes codes in ICD-10-CM will want to review the coding of diabetes in ICD-10-CM to maintain an accurate knowledge base.

MORE ICD-10 COVERAGE ONLINE:

- ICD-10 training: Start with a plan
- ICD-10 training: Detailing patient encounters
  [http://bit.ly/1S0Zms](http://bit.ly/1S0Zms)
- A physician’s guide to ICD-10 coding for heart disease
  [http://bit.ly/1gMRMg](http://bit.ly/1gMRMg)
- Ischemic heart disease: ICD-10 documentation steps (chart)
- ICD-10 codes for common claims
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Firing an Employee: Protecting Your Practice from a Lawsuit

by Marianne Monroy, JD and Lauren Rieders, JD

With ever-increasing frequency, employees are filing discrimination, harassment, and retaliation claims in response to being fired. An employer’s best defense is often the ability to articulate objective and non-discriminatory business reasons for having fired the employee, and produce documentation supporting the termination.

Absent an employment contract defining the term of employment, most employment relationships are presumed to be “at-will,” and terminable by either party with or without cause or notice.

Of course, even though employers may have contractually reserved the right to fire an employee “without cause” or entered into an “at-will” employment relationship, an employer cannot fire an employee for discriminatory, retaliatory, or otherwise illegal reasons.

Firing reasons

Certain acts of employee misconduct are so egregious that it requires little effort to establish the legitimacy of the termination decision. These include criminal acts, such as theft, fraud, workplace violence, patient abuse, falsification of patient records, disclosure of confidential patient information, and diversion of drugs.

Managers should be trained to investigate employee complaints, as well as address and document performance matters.

Employer handbook

An employer handbook is a critical risk management tool and often a first line of defense against employee claims of illegal firing. If properly drafted, it places an employee on notice regarding the employer’s policies and can create certain barriers to litigation or help diminish the risks of a successful litigation against an employer.

Contemporaneous documentation

Employers are also well served in defending against employee claims by conducting regular performance evaluations and documenting performance issues, such as evaluations, disciplinary notices, and corrective action plans.

In this regard, managers should be trained to properly investigate employee complaints, as well as address and document performance and disciplinary matters. Before terminating an employee, the employer should gather and review available documentation and confer with the involved parties to confirm the facts supporting the termination decision.

For example, an employer who plans to terminate an employee for excessive absences should review the employee’s time records.
Practical considerations before firing an employee

☐ Is there an employment contract?
An employer should consider and comply with applicable contract termination provisions, including any minimum notice requirements.

☐ Is the employee a member of a protected class?
An employer should consider potential exposure and liability should the employee assert that he or she was fired for discriminatory reasons.

☐ Has the employee previously complained about any perceived unlawful activity or policy, such as safety violations, or harassment?
An employer should confirm that the employee's prior complaint was properly investigated and corrective action taken, if appropriate. This will help refute any claim by the employee that he or she was fired for retaliatory reasons.

☐ Is the employee's termination related to the exercise of a legal right?
For example, employers must assess and comply with applicable federal and state employee leave rights (e.g., leave taken under the Family and Medical Leave Act) before making a termination decision regarding an employee who is out on leave.

☐ Is the decision in line with previous personnel discipline decisions?
When deciding whether to terminate an employee for misconduct or poor performance, an employer should consider whether other employees who engaged in similar conduct were also terminated. It is important for an employer to be consistent in enforcing policies to avoid employee claims of less favorable treatment based on race or other protected characteristics.

Consult legal counsel
It is prudent to consult with counsel before firing an employee, to help assess the potential litigation risks.

Marianne Monroy, JD, (pictured) is a partner, and Lauren A. Rieders, JD, is an associate at Garfunkel Wild, PC, in Great Neck, New York. Send your legal questions to medec@advanstar.com.

Separation agreement and release
Depending on the circumstances and likelihood of litigation, employers may also be prepared to offer the employee separation benefits in exchange for a written release of any employment-related claims.

Generally, termination meetings should be held in person with the employee, and ideally should be attended by the employee’s supervisor and a human resources representative or member of management.

It is important to have two employer representatives present, so as to reduce the risk of any “he said, she said” issues regarding what was discussed at the termination meeting.

An appropriate member of management also should be present when the employee packs his/her personal belongings to confirm that no confidential or business information is removed by the employee. Employers should also remember to collect all keys, company property, and security cards, and to change passwords and locks.

Further, be prepared to provide the employee with notice of the last date of employment, a final paycheck and information regarding termination benefits (e.g., the Consolidated Omnibus Budget Reconciliation Act and payment for accrued and unused vacation).

MORE ONLINE
Managing staff performance with reviews and raises
http://bit.ly/1gFWoYq

How to keep toxic employees from harming your practice
The right and wrong way to talk to patients about adverse events

by DEBRA BEAULIEU-VOLK Contributing author

Apology laws aren’t as important as you may think when it comes to situations in which physicians have to explain, or apologize for something unexpected. However, as healthcare becomes more transparent, sometimes statements of sympathy can be beneficial.

**LET’S SAY YOUR** 53-year-old patient is in the hospital having a basic test—a computerized tomography-guided biopsy of his liver. It should take about an hour, so the technician suggests to the patient’s wife that she go shop at the mall across the street and expect a call when her husband is ready to go home. Instead, the wife answers her cellphone to hear a nurse frantically telling her to return to the hospital right away. When she does, she learns that her husband has died.

You’re the doctor who is in the room with this shocked and grieving widow. What do you say to her?

When Doug Wojcieszak, founder of Sorry Works! posed this scenario recently to attendees at a neurologists’ conference, it took a full two minutes for anyone to put a hand into the air. “That’s the problem,” he says. “You don’t have two minutes.”

For many physicians, their reflex is to avoid the situation and say nothing or as little possible in the aftermath of patient harm. Part of this response comes from a longstanding mindset that physicians should “deny and defend” against the possibility of being charged with any culpability in cases of possible medical malpractice. Until the last decade or so, most lawyers and malpractice insurers promoted this advice.

Increasingly, however, the healthcare industry is recognizing the benefits of prompt and transparent physician communication with patients and families about bad outcomes. The legal landscape is shifting, too, as at least 36 states now have “apology laws” that prohibit certain statements, expres-
Apology laws

States with apology laws

Source: Annals of Internal Medicine; various news reports

Express empathy but not guilt

Nonetheless, the task of "expressing empathy without admitting fault" is not one for which most clinicians are trained. For every success story about how a physician's words can promote healing, lawyers can describe cases in which doctors made the situation far worse.

"The initial response to patients or family members should be, 'I'm sorry. I don't know exactly what happened and I don't know exactly how or why, but I will find out promptly and let you know as soon as I get it figured out,'" says Don Karonkin, a malpractice attorney with Karotkin & Associates in Houston, Texas.

But what happens frequently is that physicians say things to patients that extend beyond the facts known at the time. When more details become clear via an investigation, the physician may have to retract or contradict statements he or she made too soon. Even if the physician never intended to be dishonest, the inconsistency can look suspicious to a jury.

Wojcieszak agrees that the stress, shock, and embarrassment of a potential mistake can lead physicians to react inappropriately. "Either they want to run away or they want to start stumbling down the wrong path," he says. "I tell them that when something bad
DISCLOSING AN ERROR

What do you say?

The initial disclosure to the patient of an error or adverse outcome is very important, because it will dictate how smoothly the process unfolds thereafter.

Be direct
Approach the conversation with the patient directly. Begin by telling him or her that you regret to say there has been a mistake or error. Be clear about what happened and what will happen next.

Use plain English
Use non-technical language when describing what happened. The goal is honest, humane, and effective communication.

Give the details
Tell the patient what happened, the consequences, and corrective action that must be taken now.

Apologize
Show sympathy, express personal regret, and apologize.

Answer questions
Give the patient time to ask questions and express concerns, and then answer them honestly and directly.

The next step
Plan the next step with the patient, be clear about what will happen moving forward, and schedule the next contact.

Source: Allen B. Kachalia, MD, JD, and Wendy Levinson, MD, FACP, from presentation at American College of Physicians 2014 Internal Medicine conference

What happens, you just need to be a grief counselor. You need to sit with them and hold their hand. The next patient can wait.

TIMING IS EVERYTHING

Considering that the average malpractice case drags on for five to seven years, it’s worthwhile to invest the time in comforting a patient or family member immediately after a disaster, Wojcieszak says.

This and other lessons can be gleaned from health systems that have implemented processes aimed at changing the malpractice landscape. Massachusetts, for example, in 2012 adopted a policy of “disclosure, apology and offer (DA&O) when patients suffer avoidable medical harms.

Under the DA&O model, when unanticipated adverse outcomes occur, patients and their families are provided full disclosure of what happened, what it means for the patient medically, and what will be done to prevent the error from recurring, says Evan Benjamin, MD, FACP, senior vice president and chief quality officer for Baystate Health and associate professor of medicine at Tufts University School of Medicine in Boston, Massachusetts. Physicians and healthcare organizations then are given the opportunity to apologize without fear of their words being later used against them in court.

In addition, organizations work with their liability insurers to give patients a fair and timely offer of financial compensation. The purpose of the policy is to give patients the information and financial recourse they need upfront in hopes that fewer patients will resort to lawsuits.

Thus far, Massachusetts is still analyzing the outcomes of these efforts, but Benjamin says there will be no going back to the old ways of silence and secrecy. In the meantime, he continues to work on the front lines of studying his organization’s "CAR" process: communication, apology, and resolution.

The CAR process usually takes about six months, he says. Although information is shared far more quickly than in a typical litigious scenario, conversations are staggered in a way thought to be the most beneficial to the patient.

For example, in the early phases of the discussion, most patients aren’t yet ready to hear what an organization is doing to make sure the same mistake doesn’t reoccur, Benjamin says. It is important to follow up with this information later, “but early on, patients just want transparency,” he says. “They say, ‘Tell me what happened to me and what’s being done to care for me. I want to make sure I’ve got a clear picture of the game plan and nobody is lying’.”

SEEK SUPPORT

As part of the Massachusetts program, patient safety coordinators coach physicians throughout the process, from the initial expression of sympathy to sharing the results of an investigation and eventual discussion with insurers surrounding compensation.
WHEN SOMETHING BAD HAPPENS, YOU JUST NEED TO BE A GRIEF COUNSELOR. YOU NEED TO SIT WITH THEM AND HOLD THEIR HAND. THE NEXT PATIENT CAN WAIT.”
—DOUG WOJCIESZAK, FOUNDER OF SORRY WORKS!

This support is a crucial part of DA&O’s success, Benjamin says. “Physicians are not alone in any event. We need to appreciate that most medical mistakes occur as a result of a poor system, not just individual provider error,” he adds.

But regardless of where they practice, physicians do have resources available to help them through a medical disaster. After a physician’s first conversation with a patient or family member—one that should express empathy and a promise to follow up as soon as more facts are known—the next step should be a phone call to the doctor’s professional liability carrier, Karotkin says. “That’s why you bought insurance—in case you had a disaster—so now you have some help that you’ve already paid for.”

Physicians can be hesitant to take this advice, however, because they’re afraid that telling the insurer they may have made a mistake could compromise their coverage, he says. To the contrary, Karotkin says physicians risk endangering their coverage if they make statements to patients that could be construed as confessing liability.

To prevent physicians from saying the wrong thing, most insurers are happy to counsel their clients, either at the time an event occurs or through an educational session. “Many insurers will even send lawyers like me or another expert to the practice to give a presentation on what to say, at the insurer’s expense, and even give the physicians a discount on their premium for attending,” Karotkin says.

The Doctors Company, the nation’s largest medical malpractice insurer, says the following within its policy about disclosure: “Patients have a right to be informed of the medical facts pertaining to their health status and medical treatment. Physicians have a responsibility to provide accurate, timely information to patients and, when appropriate, to the patient’s family members about events that affect the patient’s health status and future treatment needs—including the disclosure of adverse events and outcomes. Physicians are encouraged to seek guidance from individuals with patient safety and risk management expertise in both the communication and reporting of adverse events.”

GETTING TO RESOLUTION
Following a death or serious event, physicians must make good on their promise to stay in contact with the patient or family throughout the investigation and share with them the results of the review, Wojcieszak says. “If the review shows you made a mistake, then you’re going to come to the family and say, ‘I made a mistake and I’m very sorry.’” Then the discussion turns to how to offer recourse, economically as well as emotionally, he says.

Conversely, if the review shows the physician did not make a mistake, Wojcieszak still recommends expressing empathy, explaining what the expert reviewers found, and offering the patient and family a copy. “If we did a credible review that shows there was no mistake, and we still get sued and have to go to court to argue causation, fine,” he says. “Let’s go to court and argue because we didn’t apologize. We were simply empathetic and we were credible, and we’ll go to court and we’ll talk about that story.”
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The Last Word

PHYSICIANS, EHR VENDORS STRUGGLE WITH MEANINGFUL USE 2, DATA SHOWS

by CHRIS MAZZOLINI, MS  Content manager

Only a small number of physicians and hospitals have attested to Meaningful Use stage 2 (MU2) months into the reporting year, according to data from the Centers for Medicare and Medicaid Services (CMS), calling into question the ability of electronic health record (EHR) vendors to provide physicians with the upgrades to their systems in time.

Providers who use software that has not yet attained 2014 certification will have to wait for vendor upgrades or switch to another EHR system to attest to MU2.

But EHR vendors have struggled with certifying to the 2014 edition necessary for MU2. The total number of vendors offering a complete EHR system with 2014 certification reached 97 as of mid-April 2014, according to data from The Office of the National Coordinator for Health Information Technology. CMS data, presented recently to the Health Information Technology Policy Committee, shows that 17% of EPs use software that has not been certified to the “2014 edition,” a necessity to complete MU2 requirements.

These providers will either have to wait for vendor upgrades or switch to another EHR system to attest to MU2. Hospitals are in a better position that physicians, since 95% are using EHR systems that will be able to be upgraded to 2014 edition, according to CMS.

Hardship exemptions One way to avoid a penalty

if a physician’s EHR vendor is not prepared for MU2 is to apply for a hardship exemption.

So far, 600 EPs and 72 hospitals have applied for hardship exemptions, according to CMS data. Providers whose applications are approved for the exemption would not be subject to the penalty, but would also not receive the incentive payment.

CMS has previously acknowledged that many EHR vendors may be behind in necessary software upgrades, so it extended MU2 through 2016 to give providers more time to attest.

Providers whose vendors were unable to reach 2014 certification may qualify for exemption. According to new language in the CMS hardship exception application, EPs can now select “2014 EHR Vendor Issues” as a reason for exception. Other reasons for an exemption include lack of infrastructure, unforeseen circumstances, lack of control over the availability of certified EHR technology, and

The deadline for EPs to submit a hardship exemption application is July 1, 2014.

Providers who use software that has not yet attained 2014 certification will have to wait for vendor upgrades or switch to another EHR system to attest to MU2.

Vender struggles

MU2 requires greater interoperability between EHR systems and is intended to boost health information exchange between providers and promote patient engagement by providing patients with secure online access to their health information.

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Neuromodulation

The Percutaneous Approach
Past, Present, Future

A ROUND TABLE CONVERSATION DISCUSSING REFRACtORY OVERACTIVE BLADDER BETWEEN
Michael B. Chancellor, MD; Scott MacDiarmid, MD;
Diane K. Newman, DNP; Kenneth M. Peters, MD;
Eric Rovner, MD and Peter K. Sand, MD

Moderated by David R. Staskin, MD
CONFLICTS: AMS-Endo, Allergan, Astellas, AltheRx, Takeda, Theravida, Uroplasty

CONFLICTS: Consultant: Uroplasty, Allergan, Medtronic, Astellas, Pfizer

CONFLICTS: Consultant: Medtronic, Uroplasty, StimGuard, EMKinetics, Taris, Trillium Therapeutics

CONFLICTS: Advisor: Allergan, AltheRx, Astellas, Hologic, Ferring, Pfizer, Targacept
Investigator: Allergan, Boston Scientific, Cook Myosite, Ferring

CONFLICTS: Advisor: Allergan, Astellas, Medtronic, AMS, Pfizer—Scientific study/Trial: Medtronics, Taris, Ferring, Targacept
The term “refractory overactive bladder” is commonly used to describe OAB symptoms unresponsive to traditional conservative measures and pharmacotherapy.

Up to 90% of OAB patients have refractory OAB and are eligible for “third-line therapy” with neuromodulation or intravesical chemodenervation. It is estimated that fewer than 5% of these patients receive these advanced therapies, despite symptoms that profoundly impact their quality of life. A diverse panel of nationally recognized experts participated in a roundtable discussion to discuss barriers to therapy and solutions for improving outcomes—specifically related to percutaneous tibial nerve stimulation, one of the neuromodulation alternatives cleared for this indication.

DAVID STASKIN: I would like to review the definitions and implications of overactive bladder, refractory overactive bladder, and the categorization of OAB treatments as first-, second-, and third-line therapies.

PETER SAND: Overactive bladder syndrome is the presence of urinary urgency which is often accompanied by frequency and nocturia, with or without urgency urinary incontinence. This is per the ICS and IUGA and the ICS Joint Committee opinions. We really don’t have an established definition for “refractory OAB.” For me, these are patients who have failed multiple pharmacologic and behavioral approaches.

ERIC ROVNER: I think that the AUA guidelines did a fair job of defining first-line therapy—behavioral, and second-line therapy—pharmacologic; but unfortunately these guidelines did a very poor job of defining refractory OAB, and thus, the indication and timings for exploring third-line therapies such as intravesical injections and neuromodulation. Also, the lack of distinction between the appropriate place for peripheral percutaneous tibial neuromodulation versus implantable sacral neuromodulation is problematic.

SCOTT MACDIARMID: Let me illustrate. If a patient has fairly severe OAB and we start them on behavioral therapy and a medication, and they’re improved 40%, 60%, are they still refractory? 80%? Do they have to be normalized—continent, without urgency or frequency—to no longer be considered refractory?

STASKIN: Don’t caregivers’ and patients’ expectations play a large role here?

DIANE NEWMAN: Goals that are anticipated by the physician, nurse practitioner, and patient may or may not conform. Communication is essential in order to individualize expectations concerning improvement and success.

STASKIN: What about step therapy—going through first, second, and third line in order?

ROVNER: I think the guidelines do somewhat of a disservice in requiring patients to fail—regardless of the definition—certain therapies before moving on to others. There are many patients who cannot or will not be compliant or adherent with specific interventions. Should they be penalized? There are some patients who simply will not be compliant with behavioral interventions or don’t want to take medications. I think that patients, with caregiver guidance, should be able to choose the therapies that they feel are appropriate for them and not have to go...
through an arbitrary step process in order to get to a treatment that they find satisfactory.

MIKE CHANCELLOR: We have done a large study based on real world prescriptions of over 100,000 subjects in the IMS database and we’ve found that over 90% of patients will stop their antimuscarinic meds after 6 months. Moreover, that rate is still 80% for those who switch to a second and third drug. So, cycling through more than one antimuscarinic doesn’t really decrease drug discontinuation rates.³

STASKIN: Are patients being undertreated? Are we maximizing therapy? If not, why?

KEN PETERS: In our large urology group practice of 55 urologists, we looked at just one year of new patient prescriptions and how many patients go on to the three third-line therapies across the board: percutaneous tibial nerve stimulation (PTNS), botulinum toxin, or sacral neuromodulation. Only 2% of our patients have gone on to third-line therapies.

MACDIARMID: I agree with Ken – and would estimate that penetration of all three refractory therapies to be less than 5%. If so, as many as 95% of patients who don’t reach their treatment goal with drugs are not treated – they may drop out, are not offered additional therapies, or do not select further treatment when offered. I think as a specialty, we are prone to accepting mediocre results with and after meds for OAB. Patients should be informed about additional options and, if their physician does not have an interest in refractory OAB, they should ask for a referral.

STASKIN: What about the third-line therapy neuromodulation options?

CHANCELLOR: The two most commonly utilized neuromodulation techniques are PTNS via Urgent PC and sacral nerve stimulation (SNS). Of note, although both PTNS and SNS are believed to modulate neural pathways, PTNS and SNS are believed to target different neural circuitry in the central nervous system. PTNS uses intermittent
percutaneous stimulation of the tibial nerve at the ankle with no permanent lead or stimulator implanted, while SNS provides continuous stimulation through surgical implantation of a permanent electrode and pulse generator.

**STASKIN:** What is the scientific basis for the difference between peripheral versus sacral neuromodulation? Why is PTNS therapy intermittent and SNS chronic stimulation?

**CHANCELLOR:** The basic science of neuromodulation for overactive bladder has been well studied beginning in the 1960s. The posterior tibial nerve is a mixed sensory-motor nerve, containing axons passing through the L4–S3 spinal roots. The sacral roots also contain some of the peripheral nerves involved in the sensory and motor control of the bladder and pelvic floor, and some of the same spinal tracts targeted by sacral neuromodulation. Electrical stimulation of the peripheral nerves inhibits bladder activity by stimulating large-diameter somatic afferent fibers, which in turn evokes a central inhibition of the micturition reflex pathway in the spinal cord, or the pontine micturition center (PMC). Repeated short-duration stimulation of the tibial nerve induces a persistent post-stimulation inhibitory effect, and increases bladder capacity. It is likely that the increased bladder capacity

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**Urgent® PC Patient Response**

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results from direct modulation of the PMC gating circuit or suppression of afferent input to that circuit.  

**STASKIN:** So how does this translate clinically?  

**PETERS:** I believe what we are seeing with PTNS over the 12 initial weekly treatments is that short-term neural learning and memory turn into long-term, persistent changes. It works gradually over time, so that new synapse formation, dendritic growth, and neural network reformation can happen. I believe there could still be some optimization in terms of treatment number and duration and further study to understand this complex interaction.  

**SAND:** I agree. I believe this is a reasonable explanation for SNS requiring persistent stimulation and PTNS working with one weekly treatment over the 12 weeks – and requiring generally 6-8 weeks to see a response.  

**MACDIARMID:** I believe the index patient optimizes with monthly follow-up stimulation.  

**STASKIN:** What clinical data supports the use of PTNS?  

**MACDIARMID:** There are about 50 studies of PTNS in the published literature; the earliest are case series or single-arm efficacy studies, three are RCTs, and two are long-term follow-up studies of patients who were responders in the OrBIT\(^5\) and SUmIT\(^6\) trials. Ken was first author on the OrBit and SUmIT studies.  

**PETERS:** I’ve kind of come through an evolution on the whole concept of tibial neuromodulation. We developed a sham for PTNS in a separate study long before any interaction with industry, specifically because I didn’t think that PTNS worked. The SUmIT trial compared PTNS to this validated sham and demonstrated PTNS superiority to sham for both objective voiding parameters and subjective patient assessments. It was well blinded because patients, at the end of the day, could not accurately define what treatment they were on. I consider this level 1 evidence of effect. The study is really an achievement; we don’t have a sham study with sacral neuromodulation.  

**MACDIARMID:** Over half of the patients receiving PTNS therapy in the SUmIT trial reported moderate or marked improvement in bladder symptoms. In addition, PTNS reduced the number of voids and urge incontinence episodes versus the sham. I think we have to look at this as a very well-designed study.  

**STASKIN:** What about follow-up treatment protocols after 12 weekly treatments?  

**MACDIARMID:** We studied the tapering protocol and, importantly, we modeled the trial based on what you might do in clinical practice – “call us when you need another treatment.” We followed patients for three years and the data show that it takes about one treatment a month – a range of three weeks to six weeks. But the results are almost exactly the same at 12 weeks and three years. Of note: 29 of 50 patients completed the study; however, a persistence of 58% on therapy for refractory patients is noteworthy.  

**STASKIN:** Are there comparative studies to other therapies?  

**MACDIARMID:** PTNS was compared against tolterodine extended release in the OrBIT study; both therapies demonstrated statistically significant improvements in incontinence episodes, voids per day, and nocturia. The results for PTNS are comparable to those found in a recent systematic review and meta-analysis of antimuscarinic drugs, and more specifically, a recent meta-analysis concluded that the significant improvement in OAB symptoms is comparable between PTNS and antimuscarinics, but that PTNS has a better adverse event profile.  

**ROVNER:** A take home point from the long-term data is that people who objectively respond can be noted to have improvements in subjective measures at twelve...
weeks and at one, two years, and three years out.

**STASKIN:** Should we differentiate OAB dry versus OAB wet?

**PETERS:** The study that we did was basically OAB, so it could have been wet or dry. It wasn’t powered for urgency incontinence. When you look at the data, I believe it was over 50% of patients who were OAB wet. I really think that OAB dry and OAB wet are probably along a disease continuum. I am confident that is why we see an improvement in both subsets.

**MACDIARMID:** In clinical practice, I believe nocturia is often the first symptom to improve. I think the neuromodulation effect on nocturia differentiates from what we see with medications. Nocturia is always challenging because of the issue of high versus low urinary voided volumes and co-morbidities. Improvement in nocturia was noted in the clinical trials for PTNS and the effects I have seen in clinical practice have been profound.

**STASKIN:** Does the data apply to the elderly?

**PETERS:** I can comment on geriatrics because we actually presented data from the SUmiT trials looking at older than 65 and younger than 65 and showed that there was equivalent efficacy and response in the treated versus sham group. I feel confident we can offer it to either age group.

**STASKIN:** What is the status of neuromodulation for fecal incontinence?

**CHANCELLOR:** Sacral neuromodulation is approved for both urinary and fecal incontinence. Tibial nerve stimulation is approved in Europe for fecal incontinence – although not in the US. I think that one of my decisions on whether to offer a patient botulinum toxin versus neuromodulation is whether they have dual issues. Do they have bowel and bladder issues?

**STASKIN:** Did the studies include quality-of-life outcomes?

**SAND:** A recent meta-analysis of the impact of antimuscarinic drugs on HRQL measures found that antimuscarinics improve several areas of HRQL, that these improvements are likely to be clinically meaningful, and that there were not significant differences between antimuscarinic drugs in degree of impact. Similarly, the three randomized studies of PTNS included HRQL measures, and found that symptom severity score was significantly reduced when compared to sham treatment, and mean quality of life was improved. In addition, subjective improvement was greater with PTNS than tolterodine for overall HRQL and for each of four subscales (coping, concern, sleep, and social). The HRQL changes associated with SNS are inconsistent.

**ROVNER:** In a review of the SNS studies that report quality-of-life changes with SNS, it is notable
that it is difficult to know how many separate studies of SNS exist, as at least three appear to be sub-group analyses of the same study. In one report, the effect on general health status as measured by the SF-36 was not significant, while in another it was highly significant. Given these inconsistencies between reports, Herbison and Arnold concluded that the effect of SNS on quality of life is still unclear.

**SAND:** It’s very clear that PTNS is an attractive therapy for patients not just because they see the physical changes but in terms of improved quality of life. The therapeutic index effect is high—35% of patients become completely dry, with meaningful decreases in their frequency and nocturia—it is a profound effect on their quality of life. Patients are getting sleep—and according to QoL scores the improvements decrease depression. Furthermore, this is a treatment option that has a measurable effect on quality of life absent many of the negatives—dry mouth, constipation, and other adverse events seen with pharmacotherapy. There is no implant procedure, and no risk of urinary retention observed with intra-vesical injection.

**ROVNER:** If we used a therapeutic index, the ratio of the upside divided by the potential for serious adverse events, the therapeutic index for this treatment for overactive bladder is probably higher than any other therapy. **NEWMAN:** A significant part of presenting PTNS therapy is that you don’t have significant adverse events. I’ve been doing PTNS now for 18 months and besides seeing improvement in refractory overactive bladder (ROAB), adverse events are rare. **ROVNER:** That’s why acceptance is so high, especially among the elderly. Our initial concern about the barrier of patients commuting to the office has not prevented patients from electing the therapy. **MACDIARMID:** I think if we more fully appreciated the diminished quality of life our OAB patients experienced we would be more apt to aggressively manage them or offer other therapies—use the best drugs, combine therapies, and use neuromodulation to raise the level of care for them.
STASKIN: Will patients comply with the 12-week schedule and follow-up visits?

ROVNER: I think you can look at consecutive treatments for 12 weeks as a disadvantage or as an advantage. In virtually all other behavioral therapies that we do, in virtually all other medical therapies that we do, patient compliance is an incredibly important part of that treatment. And those patients who are compliant do better.

MACDIARMID: The alternative to therapy for many of these patients is to live with their condition. Many are not good candidates for the other third-line therapies or they have declined them. Once the treatment starts, the caregiver is a real motivator for the patient to document improvement and continue therapy.

NEWMAN: We discuss the disadvantages of 12 visits but these symptoms are so bothersome and patients are searching for some kind of relief – it is a strong motivator. I was surprised at how many individuals will come in to a busy inner city practice. As providers, I do not think we truly understand how debilitating these symptoms are to patients and how frustrated they are because other treatments have not been successful.

PETERS: We actually have data with our sham controlled trial. Although you see improvement by 6 weeks, it doesn't separate from sham until week 9 or 10. So I would encourage people to continue the complete course before saying it doesn't work. I find it easy for patients to accept PTNS. They like the concept of it, they like the fact there's no drugs, they like the fact the side effects are almost nonexistent; I find them very engaged in their therapy.

STASKIN: Should we recommend a specific treatment algorithm?

ROVNER: Almost everybody is eligible for PTNS unless they have neuropathy or severe peripheral edema that prevents accurate needle insertion—or they're not willing to commit to the 12 treatments. And then it comes back to our initial conversation about where on the OAB algorithm this therapy should be. This should not be a third-line therapy, based on both efficacy and patient preference.

PETERS: These patients are frustrated by their condition and from medication if their primary care has already treated them with something that didn't work or had side effects. I think patients will become disillusioned and leave your practice if they don't understand that other things are available – early in the discussion. And when you look at PTNS the data are extremely compelling that this should be an early treatment on every level because of its safety profile and its efficacy. How to educate patients, referring physicians, and payers is the challenge of the future. I think a very high percentage of patients have urinary and fecal incontinence. If there is dual improvement in symptoms, that is a significant benefit for the patient. For any patient in whom intermittent catheterization may be an issue, PTNS neuromodulation eliminates that risk. The mild-to-moderate patient is more likely to get tibial nerve stimulation in my practice.

MACDIARMID: I'm very aggressive with medications, but I offer neuromodulation if they don't reach their treatment goal early in the cycle along with meds and behavioral therapy. At that point, why would I offer PTNS before SNS? One, it works as we have discussed. Two, no surgical complications – and we're becoming more conscious of adverse events. Three, if you do the math it's cost effective, and fourth, in elderly patients it's often this or no treatment at all.

SAND: The average patient only tolerates 2.2 interventions before they give up. Hopefully those numbers would be better today. The point is we have to offer all treatment options from the start. We discuss third-line therapies if they are refractory to prior treatment. I agree with all the members of the panel that PTNS
should be offered early in the treatment algorithm. People vote with their feet don’t they? When we had complete Medicare coverage 90% of our refractory patients were going on to PTNS.

**STASKIN:** What is key to incorporating PTNS into your practice?

**NEWMAN:** Prior to starting the PTNS intervention, we developed specific documentation and tracking forms. A PTNS consent form was created that lists contraindications. A medical necessity form was developed for required insurance coverage. For the patient, we constructed an education tool that provides information about the treatment, efficacy, the procedure, and possible side effects. Prior to the first treatment, we document baseline symptoms and have the patient complete a three-day voiding diary. Symptoms are monitored throughout the 12 treatments to determine improvement and to document outcomes. In the practice, patients complete the AUA Symptom Score Questionnaire online directly into their electronic medical record prior to coming into the office for the next treatment.

**MACDIARMID:** For us, the key things are: a dedicated provider, efficiency in obtaining insurance approvals, a dedicated area where one or more patients can be treated at the same time, stocking of equipment, and documentation of progress for the patient, provider, and payer to reference during and after therapy.

**PETERS:** I agree. Be efficient. NPs and PAs are an important part of urogynecology and urology practices and this is a great practice building opportunity. No one is better at spending time with those patients, educating them, and providing therapy.

**SAND:** The patients can be double-booked with other patients—in the same or different rooms—because the provider can insert the needle and then spend time with another patient.

**STASKIN:** There are more than 150,000 primary care physicians who have the potential to treat 20 million OAB patients with medications, which, as we know, have an extremely high discontinuation rate. However, the literature states that fewer than 5%-15% of these patients get referred on to voiding dysfunction specialists. What should we be doing as a community to positively influence the referral of these patients?

**SAND:** We are looking at barriers to care in the primary care setting. We were surprised to discover that the number one reason our primary care physicians did not refer these patients was their limited knowledge of available treatments. And when we questioned them about their knowledge of third-line therapies, I know the number was fewer than 5%.

**STASKIN:** How do you set up approval for payers?

**PETERS:** With regard to pre-authorization, I know what the insurance company requires—if they have failed two or three drugs, and they’ve done behavioral therapy, I’ll take that extra moment on that visit and specifically document that note. I’m a big believer in voiding diaries and insurers often want to see some objective evidence so we will send the diaries, if available.

**STASKIN:** Are there available data on cost and cost comparisons?

**MACDIARMID:** There are costs of not being treated, pads, loss of productivity, loss of sleep, and other quality-of-life issues.

**ROVNER:** As presented in the American Urological Association (AUA) guideline for treatment of OAB, the syndrome of OAB represents a continuum of symptoms, with various therapies instituted along the treatment algorithm, and with varying costs. Behavioral therapies are noninvasive and inexpensive, but not free, as they require dedicated staff for training and follow-up. Treatment with generic drugs is approximately $1,200 per year, while the newer, branded medications cost more. Employing the recently published 2012 Medicare Physician Fee Schedule
and national average physician in-office reimbursement of $134 per treatment, the cost of the first year of PTNS treatment would be approximately $3,500. This includes the initial 12 treatments, followed by an average of 12 treatments over the next 9 months and a total of five office visit charges throughout the therapy. Patients who elect to discontinue therapy can do so without additional surgical intervention or costs.

**PETERS:** We’re limited a bit when we’re looking at costs as there are no head-to-head trials of sacral neuromodulation compared to PTNS compared to botulinum toxin. You have to look at cost in relationship to outcomes—efficacy, complications, and secondary costs as have been mentioned—the costs to society in pad waste, slips and falls, hip fractures, and all those things we all know about that are associated with OAB. However, I think it’s very clear because of the minimal, if any, adverse events with PTNS. My personal feeling is that PTNS should be level 2 along with, or in some cases, before drug therapy based on the AEs.

**STASKIN:** In summary, would you like to make any final comments about the future?

**ROVNER:** I believe the definitions and guidelines will continue to mature—certainly influenced by evidence-based data, and perhaps unfortunately by payers, to hopefully create an environment where patients and providers will choose therapies based on the patients’ needs and preferences.

**NEWMAN:** Urologists interested in OAB, urogynecologists, and advanced practice nurses will gravitate towards therapies with efficacy and minimal morbidity. PTNS fills a gap between first- and second-line options.

**MACDIARMID:** The refractory OAB group is significant and severely impacted. Outcome-based reimbursement will be an additional driver in cost-effective approaches to this population.

**SAND:** Ensuring the availability of access to multiple therapeutic options, such as PTNS, is critical for comprehensive and effective care. Our patients are highly motivated for non-pharmacologic and non-invasive options.

**CHANCELLOR:** There is ample evidence for differences in the method of action of peripheral and sacral neuromodulation to stimulate extensive research in the areas of neural receptors and CNS sites of action for discovering new therapeutic targets.

**PETERS:** Further research in the method of delivery, the level and timing of stimulation, and the ability of patients to combine outpatient and home treatments will create meaningful advances in the area of neuromodulation.

Urgent® PC is indicated for overactive bladder (OAB) and associated symptoms of urgency, frequency and urge incontinence. Most patients do not experience side-effects. If side-effects occur, they are typically temporary and include mild pain and skin inflammation at or near the stimulation site.

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10. Uroplasty, Inc. is currently conducting a pilot fecal incontinence study in the US.


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