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AUGUST 10, 2013

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TORT REFORM

How it impacts the cost & quality of care

ADVANSTAR MEDICAL COMMUNICATIONS GROUP VOL. 90 NO. 15

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AUGUST 10, 2013

Volume 90
Issue 15

IN DEPTH

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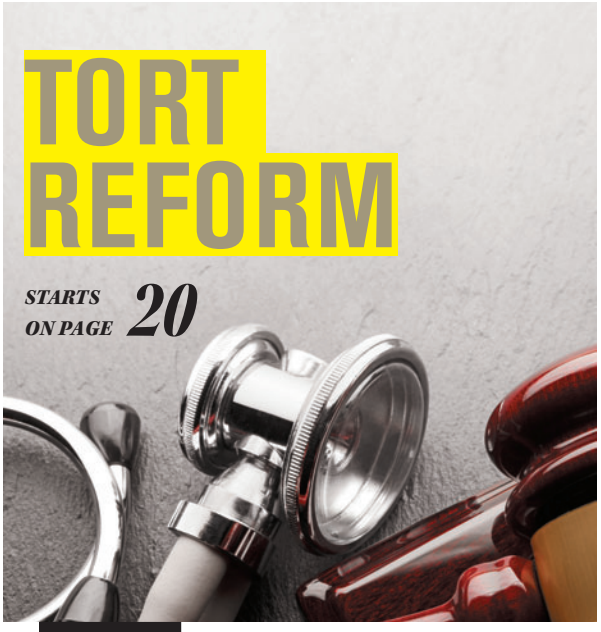
Operations ( )

Money $

Policy



TORT REFORM

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COVER STORY | POLICY

States have enacted some caps on malpractice, and studies suggest that fear of lawsuits is the real driver behind defensive medicine.

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Correctly documenting shared/split visits

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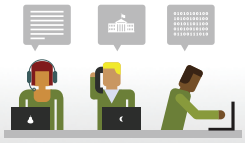

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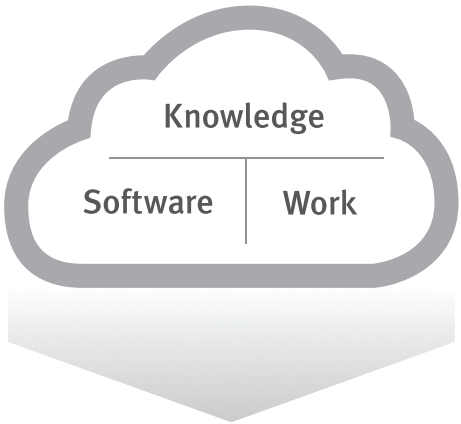

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"Why it matters whether you bill a patient visit under the physician's PIN rather than the NPP's PIN."

—Renee Stantz, CONSULTANT

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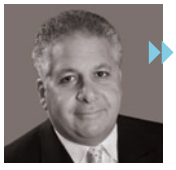

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thoughts from **DANIEL R. VERDON, GROUP EDITOR**

TORT REFORM STILL REPRESENTS THE PAIN OF AN AILING SYSTEM

They are just two words, and yet to many physicians tort reform symbolizes much pain associated with an ailing judicial and healthcare system.

While the aim of tort reform is to put a ceiling on damages, muzzle greedy trial attorneys and keep spiraling healthcare costs and malpractice insurance premiums in check, it's just one piece of an increasingly complex problem that ultimately involve the legal system, health of patients, clinical decision making, medical ethics, payers, income, boards, licensure, clinical guidelines, evidence-based medicine, and ultimately, fear.

And while all the arguments surrounding tort reform have been decades in the making, the rhetoric and hyperbole surrounding the issue this time seem to be a little different. It will be driven by the real need for the system to contain spiraling healthcare costs overall–not necessarily from huge malpractice, negligence, non-economic damages, or baseless lawsuits – but from a concerted effort to address the practice and costs associated with defensive medicine.

And that is exactly why *Medical Economics* opted to tackle this complicated topic. It's so much more than tort reform. Our coverage explores the dichotomy of the issue, looks at national data and offers physician opinions on the potential impact of tort reform. It also explores why excesses in the judicial system have ultimately trained physicians to err on the side of caution.

This issue picks at key policy problems, and it examines physician fear about getting sued. It's looks at the realities of a malpractice or negligence lawsuit, the long-term impact to reputation and career. Malpractice happens; so do medical mistakes; so do negative outcomes when you are dealing with a complex biological system. It is about life; it's about healing; it's about the quality of life, and it's about death. It's about second-guessing your treatment decisions. It's about what a physician feels is right for the patient at the time a test is ordered, drug prescribed, c-section recommended or other procedure undertaken. It's about the cost of a physician's reputation, licensure, and career. It's about the decade lost to defending a malpractice lawsuit. It's about ordering tests to make certain your clinical hunch is accurate before embarking on a treatment regimen.

While it's important to understand data from the Congressional Budget Office that estimates caps on damages would only reduce healthcare spending by .5%, it is just as important to unmask and address why physicians feel compelled to practice defensive medicine in the first place.

In our coverage, Dr. Michael Niziol may have said it best. "As I tell my new practitioners, no one can fault you for ordering a test. But they can fault you for not ordering the test."

While there has been progress in some states in place caps on non-economic damages, all the issues surrounding the practice of defensive medicine will take on even greater importance in the next few years as the scrutiny and focus intensifies on cost containment, adhering to guidelines and using evidence to justify your medical decisions.

So, how should the system change? Take a look at our coverage beginning on p. 20, and e-mail me your comments for inclusion in an upcoming issue: medec@advanstar.com.

IT IS JUST AS IMPORTANT TO UNMASK AND ADDRESS WHY PHYSICIANS FEEL COMPELLED TO PRACTICE DEFENSIVE MEDICINE IN THE FIRST PLACE.

"Physicians can insure against the payment of damages, but they cannot insure against the emotional, reputational and work-related costs of litigation."

See story on p. 20.

> I can tell you that a significant percentage of what I treat as a family doctor is caused by or aggravated by diet and obesity. Conditions such as hypertension, hyperlipidemia, diabetes, arthritis, sleep apnea, and other routine medical problems could be improved or avoided if people took better care of themselves.
>
> **Steven Gitler, DO** CAMDEN, NEW JERSEY

MOC PROCESS FALLS SHORT

Thanks for your interesting article on maintenance of certification (MOC) ("MOC: Debate intensifies as Medicare penalties loom," June 25, 2013). The one thing that is not addressed is the fact that MOC tries to be a one size fits all. I am a family physician who has worked in the emergency department and now in an urgent care clinic. I have yet to discover how MOC is designed to allow me to participate. I have no ongoing care of diabetic or hypertensive patients that can be followed over time, nor for that matter am I able to submit patient charts for review of the same.

So how is this discriminatory process going to be fair to everyone and allow participation to maintain board certification? Why aren't all specialties required to participate in the same MOC process? Without being discriminatory, how can Medicare or anyone else penalize physicians who have no way to participate?

With regard to cost, it is out of control. In the past, you just had the cost of the exam, but now the cost is well over $4,000. Why? How is this process truly adding to the quality of patient outcomes? Where are those controlled studies that everyone likes to quote? Where is the evidence-based medicine to support all of this? I do believe in keeping current with education and skills, but the MOC process falls short and discriminates.

Lawrence Voesack, MD
ODESSA, TEXAS

AOA, AMA SHOULD SUPPORT BALANCE BILLING

The American Osteopathic Association (AOA) and the American Medical Association (AMA) constantly call for replacement of the sustainable growth rate (SGR), which would be helpful. But the AOA and AMA never say what they'd like it replaced with. It has been my impression that they would accept any government scheme for payment.

Instead, the AOA and AMA must push for removal of prohibition of balance billing. This would allow physicians to bill patients for cost overruns. Medicine is the only profession or industry that is not permitted by contract or law to bill freely. Further, they should suggest that Medicare pay a percentage of what the physician billed, so that DOs and MDs can compete against each other on price. It is only in this way that a fair, competitive, and efficient market value will be determined, and not through the SGR, or reasonable and customary, or pay for performance nonsense.

There has not been a true free market in medicine since prior to the establishment of Medicare in 1965. It's about time that all stakeholders, or as I call them, "stranglehold-ers," (government, hospitals, accountable care organizations, health insurance companies, big pharma, etc.) be forced out of the

driver's seat to allow patients to drive in the healthcare free market. After all, healthcare is entirely about the patient.

Craig Wax, DO
MULLICA HILL, NEW JERSEY

PCMHS NOT RIGHT FOR EVERYONE

Medical homes may be right for Stephen F. Staten, MD and his medical practice ("Medical Homes Are Right For Primary Care," letter, June 10, 2013) but they are not right for all primary care practices.

The potential benefits that he vaunts may accrue to large medical groups that can afford the added costs of hiring additional administrative staff. Small groups cannot afford to do so. Besides, many patients (and physicians) prefer a small group because of the familiarity and personal approach which are often lost in larger group practices.

This may not correspond to the author's residency training but many small groups serve their patients well even though they do not call themselves "medical homes."

Edward Volpintesta, MD
BETHEL, CONNECTICUT

REASONS FOR PHYSICIAN DISSATISFACTION ARE CLEAR

The cover article of your June 25, 2013 edition asks what's driving the dissatisfaction with electronic health records. (EHR Divorce: What's driving the dissastisfaction?") In the same issue there are articles regarding the burdensome absurdity known as "Maintenance of Certification", a letter to the editor complaining about a lawyer opining about all things medical, the push for nurse practitioners for an expanded scope of practice, and how the Affordable Care Act supposedly will increase demand for doctors. (So why aren't salaries reflecting the same? Physician compensation has been flat for a decade when adjusted for inflation.)

As a second-generation physician "in the trenches," I can say the answers to "What's driving the dissatisfaction?" are abundantly clear to anyone actually practicing patient care.

Many of our professional societies are complicit in these circumstances, most notably the American Medical Association. When physicians either hold their current professional societies accountable and demand change, or create new organizations that will actually represent their interests, perhaps there will be some hope for a different practice environment. However, I will not be holding my breath.

I CAN SAY THE ANSWERS TO 'WHAT'S DRIVING THE DISSATISFACTION?' ARE ABUNDANTLY CLEAR TO ANYONE ACTUALLY PRACTICING PATIENT CARE.

—DAVID HAYES, MD SCOTTSDALE, ARIZONA LOCATION

David Hayes, MD
SCOTTSDALE, ARIZONA

PATIENTS' BEHAVIORS ARE RESPONSBILE FOR OBESITY

I fully agree with Joan Temmerman, MD, MS, when she wrote that "all patients deserve sensitive, compassionate, and competent care, regardless of their weight"("Obesity results from many complex factors," June 25, 2013.) However, the rest of her letter plays into the "victim" mentality that pervades our society today. Sure, there are patients who gain weight because they take Actos, Seroquel, or Prednisone, but they are few and far between. The vast majority of obese patients got that way because of their own habits and behavior. It isn't anyone's fault but their own (or their parents' in the case of obese children).

I can tell you that a significant percentage of what I treat as a family doctor is caused by or aggravated by diet and obesity. Conditions such as hypertension, hyperlipidemia, diabetes, arthritis, sleep apnea, and plenty of other routine medical problems could be improved or avoided if people would take better care of themselves. I'm not trying to place blame, but patients need to understand that their behavior affects their health. Providing them with feel-good excuses like genetic, environmental, and neuroendocrine disorders is ignoring the real problem. Diet and exercise works. It is the only thing that ever has and I will continue to counsel my patients accordingly.

Steven Gitler, DO
CAMDEN, NEW JERSEY

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OSHA WANTS FIRST WAVE OF TRAINING COMPLETED BY DEC. 1

You have until December 1, 2013 to train your staff on revised Hazard Communication Standards (HCS) to align with the United Nations' Globally Harmonized System of Classification and Labeling of Chemicals.

Specifically, the Occupational Safety and Health Administration (OSHA) is requiring training on the new label elements of the Safety Data Sheets (formerly Material Safety Data Sheets).

New information on the labels include product identifier, signal words, pictograms, hazard statements, precautionary statements and more.

Go to osha.gov/dsg/hazcom/index.html to assist in the required training.

@ Making sense of Obamacare and other government mandates

For a comprehensive list of all the government deadlines impacting your practice, go to MedicalEconomics.com/regulations

9 ACOs DUMP MEDICARE'S PIONEER PROGRAM

Medicare's Pioneer Accountable Care Organization (ACO) program lost two organizations that suffered $4 million in losses, while seven others have shifted to a less financially stringent ACO model.

Those seven organizations plan to move to the Medicare Shared Savings Program, which permits bonus-only financial arrangements, according to the Centers for Medicare and Medicaid Services (CMS).

While all of the Pioneer ACOs beat industry benchmarks for their first year, only 13 made enough to share the savings with CMS.

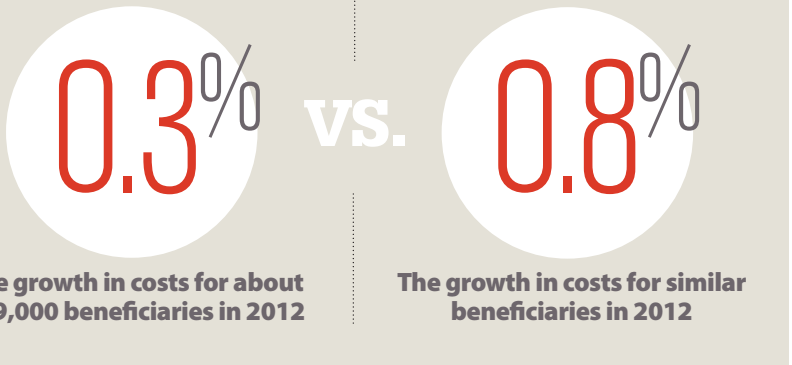
The agency views it as a win.

Overall, the results included higher quality care and lower Medicare expenditures. And the costs for about 669,000 beneficiaries aligned to Pioneer ACOs grew by only 0.3% in 2012, while costs for similar beneficiaries grew by 0.8%.

"The Affordable Care Act has given us a wide range of tools to realign payment incentives in Medicare and Medicaid," says CMS Administrator Marilyn Tavenner. "These efforts are already paying off."

The central premise of the Pioneer ACO Model is to realign payment incentives, while promoting high-quality and coordinated care for the highest level of wellness for Medicare beneficiaries.

Pioneer ACO cost performance



Politicos, medical groups renew cries to repeal Medicare's SGR formula

TWENTY MEDICAL groups threw support to a new House bill that would repeal the sustainable growth rate (SGR) formula that determines Medicare reimbursement for physicians.

But for practicing physicians, one of the bill's main provisions has raised concerns. The proposal calls for annual reimbursement hikes of 0.5% from 2014 through 2018. Payment incentives such as the Physician Quality Reporting System (PQRS) and the electronic health record (EHR) incentive program will continue during that time.

The 0.5% annual payment increase lags inflation, which generally has hovered around 2% to 3% over the last few years.

So the question looms: Is that 0.5% annual increase an appropriate amount? The answer, of course, depends on whom you ask, but there's strong sentiment among some health policy observers that it's not enough of an increase for primary care services.

"The 0.5% does seem appropriate for non-primary care services —as long as it is closely monitored to determine its impact on patient access," says David Kinsman, a spokesman for the American College of Physicians (ACP). "If patient access is adversely effected, then the update should be adjusted."

The ACP is calling for annual increases of 2.5% for primary care services—commonly defined as evaluation and management codes—between 2015 and 2018, while holding annual updates for non-primary care services at 0.5%.

The American Academy of Family Physicians also issued a statement expressing disappointment with the base payment for primary care services as outlined in the draft legislation.

TABLET PCs MAKE A PUSH IN MEDICAL FIELDS

The global market for tablet PC devices in healthcare is expected to increase to $1.7 billion for 2013, according to Kalorama Information's latest report.

Yet, tablet PCs heavily trail their main competitor—the Apple iPad.

The report analyzes tablet PC usage in the following four sectors: hospitals, physician offices, home healthcare and nursing homes, and other (including first responders, institutional and military.)

According to Kalorama Information, which supplies independent medical market research in diagnostics, biotech, pharmaceuticals, medical devices, and healthcare, tablet PCs saw a 27% increase last year.

While Apple's iPad continues to maintain the largest share of the market, the report outlines other competitors showing interest in the healthcare market: Samsung, Research in Motion (BlackBerry), Panasonic, Hewlett Packard, Motion Computing, Lenovo, Fujitsu, and Tangent.

$1.7 BILLION Expected 2013 increase in the global market for tablet PC devices in healthcare.

BEND THE COST-SHARING CURVE?

RISING COSTS FOR SENIORS have spurred proposals to restructure Medicare's cost-sharing plan.

A panel of healthcare experts spoke on the subject during a Congressional briefing in late July.

The average Medicare household spends 15% of annual income on healthcare costs, yet half of all people with Medicare are living on annual incomes of $22,500 or less, says Joe Baker, president of the Medicare Rights Center, a nonprofit consumer service organization.

"We are deeply concerned about the effects of further cost shifting to people with Medicare," Baker said. "Many plans to combine the Medicare Part A and Part B deductibles alongside other cost-sharing hikes pose substantial risks to the health and economic security of people with Medicare."

Nearly 40 years of data demonstrate that higher out-of-pocket costs deter utilization of needed care as well as unneeded care indiscriminately, Baker contends. Congress should focus on reforms that diminish wasteful Medicare spending, and help transform a system that rewards high-volume care to one that rewards high-value care.

Tort reform

While some states have taken action to cap damages, fear of litigation still drives defensive medicine

by **SCOTT BALTIC,** *contributing author*

HIGHLIGHTS

01 While some states have made progress on tort reform, other studies suggest that fear of litigation is the greatest driver behind the practice of defensive medicine.

02 States are experimenting with "safe harbor" provisions aimed at protecting doctors from malpractice lawsuits and thereby reducing the perceived need to practice defensive medicine.

Medical liability tort reform seems like the American medical community's own recurrent syndrome. Every so often, for reasons that aren't always clear, tort reform bubbles up as a crisis.

Getty Images/iE+/DNY59

TYPICALLY THE TRIAL LAWYERS say that in fighting tort reform, all they want to do is protect patients against negligent physicians.

The physicians line up on the other side and respond that in pushing for tort reform, they're the ones who are trying to protect patients from having to pay for the spiraling costs of malpractice insurance, or even from a lack of access to healthcare.

Maybe some laws get passed, the shouting dies down, and the issue disappears as quickly as it arose—until the next time.

A CYCLIC DISORDER

Every decade or so since the 1970s tort reform has resurfaced as a major issue, says Keith Hebeisen, a partner at Clifford Law Offices in Chicago, and chair of the American Bar Association's standing committee on

medical professional liability. These crises, he says, are driven by lobbyists for the insurance industry, "using the doctors almost as a front group."

Over the past 3 decades, every 6 to 10 years would see a huge increase in malpractice insurance premiums, sometimes up to 100%, says Edmund Funai, MD, professor of obstetrics/gynecology at Ohio State University (OSU) in Columbus, Ohio, and chief operating officer of the OSU Health System. "There are lots of theories about why malpractice insurance rates are as high as they are," says Christopher Bernard, partner at Koskoff, Koskoff & Bieder in Bridgeport, Connecticut.

Insurance cycles of hard and soft investment markets drive, in part, the periodic crises over tort reform, he says, but he also notes that medical malpractice insurers have the highest profit margins among all insurers.

And through these recurrences the tort reform debate hasn't changed notably in recent years, contends attorney Alice G. Gosfield of Alice G. Gosfield and Associates in Philadelphia, Pennsylvania, a *Medical Economics* editorial consultant,

Still, there might be reason to hope that this decades-long issue is evolving toward more productive approaches. If there are no breakthrough therapies, in other words, maybe we can hope for better palliative treatments. For example, some new research sheds additional light on the complexities of medical malpractice litigation and its costs.

Along the way, we'll look at two major disconnects: between tort reform and healthcare reform, and between tort reform and how physicians perceive the risk of litigation.

A BLUNT INSTRUMENT

One reason the tort reform debate sometimes seems stuck in neutral is that so often it has focused only on the divisive issue of caps on payments for non-economic damages (also known as "pain and suffering"). California's Medical Injury Compensation Reform Act (MICRA) of 1975, for example, allows unlimited recovery for economic damages, but sets a ceiling of $250,000 on non-economic damages. The California Medical Association (CMA) believes the law has helped keep malpractice premiums in check. Recently, though, the CMA says that trial lawyers have mounted a new effort to reform the law, so the CMA is rallying its members and raising funds to fight back.

Funai, who has practiced obstetrics/gynecology in several states (though not in California), observes that MICRA seems to have held malpractice insurance rates down, but also points out that, "Premiums vary tremendously by state, even by county, sometimes." Ohio, where he lives now, uses caps and requires certificates of merit, and malpractice premiums are pretty manageable. He says that his dropped about 70% when he moved there from Connecticut.

Illinois' experience with compensation caps has been somewhat more complex, says Hebeisen. A bill mandating caps was passed in 2005, but it was declared unconstitutional by the Illinois Supreme Court in 2010, the third time in about 25 years that the court had shot down caps. He adds, however, that a provision in the 2005 law required greater transparency by malpractice insurers, and the Illinois Department of Insurance later held hearings into the relation between compensation caps and medical malpractice premiums.

The result, Hebeisen says, is that "everybody in Springfield now knows" that there's little to no connection between malpractice litigation and insurance premiums. Only about 1,500 malpractice cases are filed in Illinois annually, and that number is going down, he adds.

Despite successes in California and elsewhere (Texas enacted a similar law in 2003), caps are but one tool, and perhaps a rather blunt one. A June 2013 issue brief from the Center for American Progress (CAP), coauthored by bioethicist Ezekiel J. Emanuel, MD, PhD, criticizes caps on damages as doing little to reduce national healthcare spending, while posing the risk that patients injured by negligence might not be fully compensated. The document cites a 2009 Congressional Budget Office estimate that caps on damages would reduce national healthcare spending by only about 0.5 percent.

A February 7, 2013, opinion column in *The Wall Street Journal* by health policy researchers noted that caps on noneconomic damages are ineffective in significantly reducing self-reported defensive medicine, according to a 2010 study in the journal *Health Affairs*. The opinion column, titled "Defensive Medicine May Be Costlier Than It

11%

the average percentage of a physician's career spent defending an unresolved malpractice claim.

Source: Ezekiel J. Emanuel, MD, et al., Center for American Progress

.5%

the amount by which caps on damages would reduce healthcare spending.

Source: Congressional Budget Office

$17,130

the average cost of litigation for claims that do not result in awards.

Source: Source: Ezekiel J. Emanuel et al., Center for American Progress

How much does defensive medicine cost?

Estimates of the extent and cost of defensive medicine vary widely. This should come as no surprise, given that physicians, consultants, and academics who study the practice of medicine don't always agree on how to define the term.

In May 2011, for example, the Web site DefensiveMedicine.org cited surveys by healthcare staffing company Jackson Healthcare and the Gallup polling organization indicating that defensive medicine costs the United States $650 billion to $850 billion annually.

In December 2010, the American Academy of Orthopedic Surgeons cited estimates that, by reducing defensive medicine, liability reform could result in yearly savings from $54 billion to $650 billion.

Closer to the trenches, Edmund Funai, MD, professor of obstetrics/gynecology at Ohio State University in Columbus, Ohio, and chief operating officer of the OSU Health System, thinks defensive medicine exacts a huge, largely unmeasured financial cost. The example he cites is shoulder dystocia, calling it "by and large a rare but unpreventable consequence of childbirth." The average malpractice settlement for shoulder dystocia in Connecticut, he says, is $1.2 million.

Cesarean section (C-section) is seen as providing protection from liability for shoulder dystocia, says Funai, who ties that to the fact that to the 40% increase in the number of C-sections in the past 10 years. "There's no doubt that C-section is overused in the United States," and fear of being sued for shoulder dystocia is one of the reasons, he says.

Seems," was written by Seth A. Seabury, PhD of the University of Southern California; Amitabh Chandra, PhD, of the John F. Kennedy School of Government at Harvard University; and Anupam B. Jena, MD, PhD, of the Harvard Medical School.

This first disconnect helps raise an often-overlooked question: What are tort reform measures, such as caps, for? Who are they really supposed to benefit? If caps and other measures are meant simply to hold down malpractice insurance premiums, they seem to work, at least to some degree. But if tort reform is intended to help reduce the nation's perilously large healthcare bill, it does not seem to help. Why?

RESPONSE WORSE THAN THE PROBLEM

The answer seems to be that malpractice litigation's most profound effect on the healthcare system doesn't arise from malpractice insurance claims, case settlements, or court awards for damages, but from the defensive medicine it encourages.

So while tort reform has helped reduce the costs of litigation at least somewhat in some states, it hasn't been enough to change attitudes.

Part of the answer is that defensive medicine can be a rational choice, says Funai. If a given diagnostic test has marginal value, but the test generates some income and also provides some liability protection, he asks, why would a physician not order it?

But more strategically, defensive medicine seems to bear little relation to the actual risk of liability litigation. A 2008 survey that asked physicians about their beliefs and attitudes toward malpractice risk found that 68% of physicians in the five states with the highest malpractice risk reported "ordering some tests or consultations simply to avoid the appearance of malpractice," Seabury, Chandra and Jena wrote in *The Wall Street Journal*. A hefty number, certainly, yet 64% of physicians in the five states with the *lowest* malpractice risk reported doing the same thing, the three reported.

"[S]everal economic studies (including work by us)," they wrote, "have found that states that have enacted malpractice reforms experienced a mere 2% to 5% reduction in healthcare spending compared to states that have not.

"The relatively minor reductions in healthcare spending that have been observed … might result from the fact that, even in reform states, doctors continue to practice defensive medicine. The changes in the malpractice system may have done little to change physicians' perceptions of the risk of being sued," they conclude.

Perceptions are also crucial in another area: catastrophic claims. Contrary to common belief, malpractice insurance claims of more than $1 million are relatively rare and contribute little to the nation's spiraling healthcare costs, according to a study published online on March 29 by the *Journal for Healthcare Quality*.

The study, "Catastrophic Medical Malpractice Payouts in the United States," by Marty Makary, MD, MPH, an associate professor of surgery and health policy at the Johns Hopkins University School of Medicine, Baltimore, Maryland, and co-authors, reviewed nationwide medical mal-

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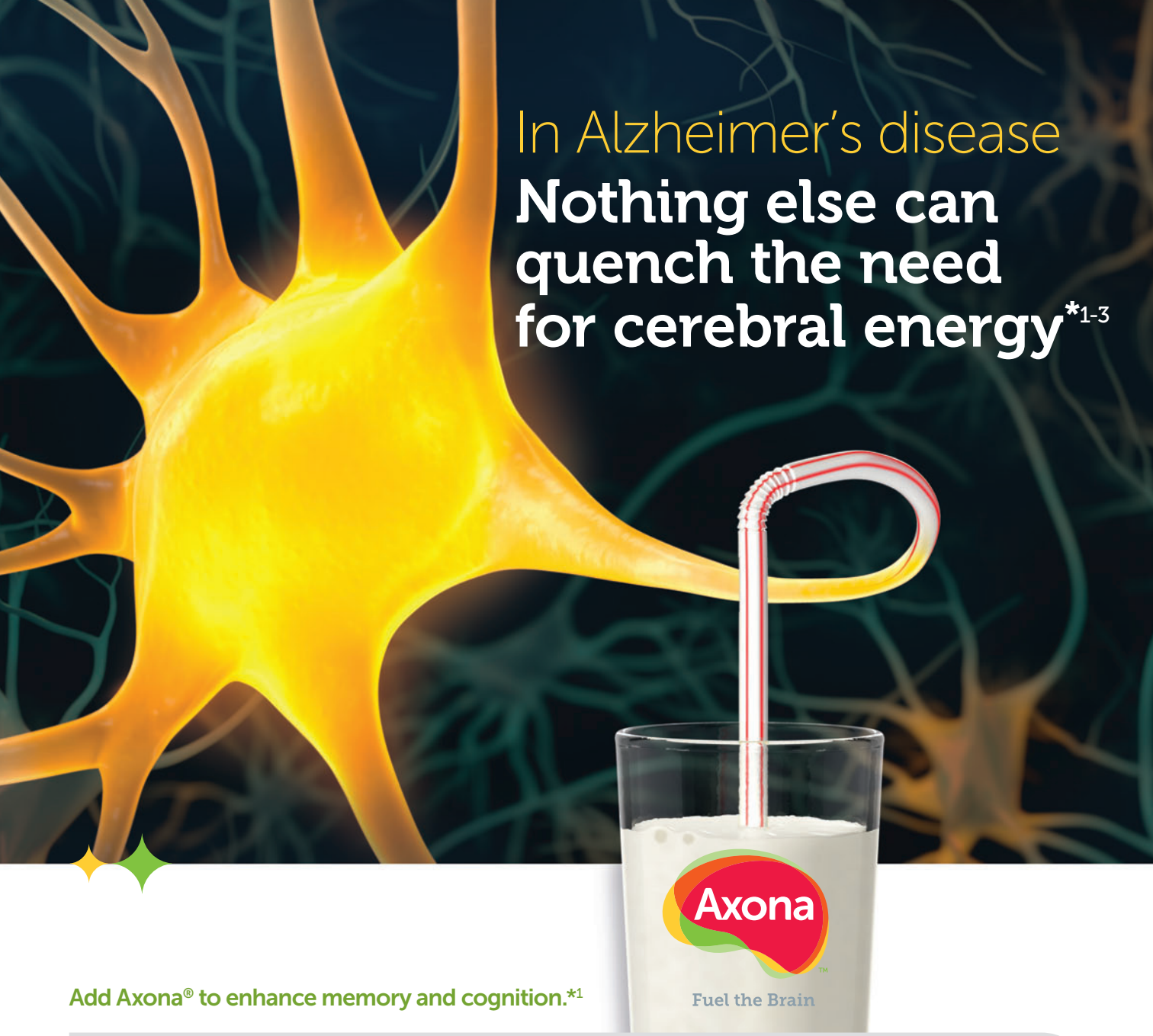

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References: 1. Henderson ST, Vogel JL, Barr LJ, et al. Study of the ketogenic agent AC-1202 in mild to moderate Alzheimer's disease: a randomized, double-blind, placebo-controlled, multicenter trial. *Nutr Metab (Lond).* 2009;6:31. **2.** Cunnane S, Nugent S, Roy M, et al. Brain fuel metabolism, aging, and Alzheimer's disease. *Nutrition.* 2011;27(1):3-20. **3.** National Institute on Aging. Alzheimer's disease [fact sheet]. http://www.nia.nih.gov/sites/default/files/alzheimers_disease_fact_sheet_0.pdf. Reprinted September 2012. Accessed June 4, 2013.

Accera

➔22 practice claims using the National Practitioner Data Bank.

The researchers examined more than 77,600 claims paid between 2004 and 2010 and found that catastrophic claims (those for more than $1 million) comprised only 7.9% of the total. Over the 7-year period, such claims totaled $9.8 billion, out of a total of $27 billion in claims paid.

"The notion that frivolous claims are routinely resulting in $100 million payouts is not true," Makary says in a statement. "The real problem is that far too many tests and procedures are being performed in the name of defensive medicine, as physicians fear they could be sued if they don't order them. That costs upwards of $60 billion a year. It is not the payouts that are bankrupting the system—it's the fear of them."

The data suggest, he continues, that the focus of legal reform efforts should be on doctor protections intended to reduce defensive medicine, rather than on enacting malpractice caps.

Makary advocates for more research to determine what interventions might prevent the types of errors that result in catastrophic payouts, because that would both improve patient safety and reduce costs. But even greater cost reductions, he contends, will come from reducing the overuse of diagnostic tests and procedures.

MORE THAN JUST MONEY

If some progress has been made in tort reform by limiting non-economic damages to patients, and perceptions of risk can greatly differ from reality, perhaps further progress can come from looking at the non-economic costs to physicians of liability litigation.

"Physicians can insure against the payment of damages, but they cannot insure against the emotional, reputational and work-related costs of litigation," wrote Seabury, Chandra, and Jena in *The Wall Street Journal.*

Physicians speak out

Marvin Den, MD, Norwalk, Connecticut

Building trust and the doctor-patient relationship is key

With all the information on the Web—good and bad—it is sometimes hard to convince the patient that the test is not needed. There is also the human factor. How do you relieve the patient's concerns without the test?

The answer is multifaceted. There is the litigation as one part, and the patient's expectations as another. Then, there is always the profit motive. The system is set up so that the doctor is on the short end no matter what. We can and should practice good medicine. I believe most do.

It would be nice if we were always right, but we are not. This can lead to bad comments, the patient seeking help elsewhere and potentially a lawsuit. It is really a fine line sometimes.

There is no simple answer. The most important thing is to establish a very good doctor-patient relationship where this will not happen. Trust will avoid this situation. If you do not have that, the doctor has a choice to make. It may or may not be the right one depending on your perspective.

Jean-Paul Bonnet, DO, Lake Hopatcong, New Jersey

Practice medicine, and don't get pulled into the fear of the legal system

To answer the question directly: No, I will not practice defensive medicine.

I will always practice to the best of my ability to serve the patient first. My decision making in 30 years of practice has never been suckered into the fear world of the legal system. It is a vulturous relationship that has no regard for the patients' best interests. The only interest for most lawyers is their pocket book.

The Hippocratic Oath tells us to do no harm and do what is best for our patients. Unnecessary tests that are done to protect ourselves do not serve patients and perhaps that is why the health system is in the mess it is in. Perhaps this is why our society looks askew at our noble profession.

It is time to do what is right and all will be well.

So, do I practice defensive medicine? When I do, it will be time to retire.

I implore all of my colleagues to stop playing into the charade, especially ER docs, and do what is right. Our hearts will guide us.

In healthcare reform, "you want to take away incentives for physicians to do a lot of stuff," by reforming the fee-for-service model, Seabury tells *Medical Economics*. He adds, however, that if fear of litigation keeps pulling doctors back toward wasteful defensive medicine, little will be gained.

One of the factors fueling that fear, Seabury says, is the length of time that a typical physician has a malpractice case hanging over his or her head. Typically, that's about 51 months, or nearly 11% of an assumed 40-year career (or roughly as long as medical school), according to findings by Seabury, Chandra, Jena and Darius Lakdawalla, PhD, published in the January 2013 issue of *Health Affairs*.

The study was based on a national database of nearly 41,000 physicians covered by a large physician-owned liability insurer and examined malpractice claims closed between 1995 and 2005. The authors found that time to resolution of a malpractice claim increased significantly with the severity of the patient injury and that the time to resolution increased modestly but significantly over the period studied. Pediatrics and obstetrics were the specialties with the longest average time to resolution.

"The substantial portion of the average physician's career spent with an outstanding malpractice claim may be as important as the annual probability of facing a malpractice claim in shaping physicians' perceptions of malpractice risk," the researchers wrote, adding, "claims that did not result in payment accounted for more than 70% of the time physicians spent with open claims."

"The fact that physicians spend such a substantial portion of their careers defending—usually successfully—malpractice claims probably contributes to their negative perceptions of the system."

SEEING TORT REFORM IN A DIFFERENT WAY

In the current environment, where the focus is simultaneously on healthcare qual-

Michael Niziol, MD, Dryden, New York

Patients will not tolerate an increase in error rates

There are several issues surrounding this topic. To begin with, we clearly order extra tests to avoid litigation. As I tell my new practitioners, no one can fault you for ordering a test, but they can only fault you for not ordering the test.

I suspect we are talking about this issue secondary to the cost of these practices. I could reduce the cost of medical care by probably over 30% in the outpatient setting by applying the following process. The most cost-effective care is the clinical experience of your family physician. My clinical expertise allows me to be correct 95% of the time. The question then boils down to the fact are our patients willing to accept a 5% error rate for significantly reduced cost of healthcare.

My experience tells me that the answer is no. People expect 100% accuracy when it comes to their healthcare. There is simply diminishing returns in this process as we moved from 95% to 100% cost increase exponentially.

So, in summary, it is the patients themselves who need to decide whether they are willing to accept a certain error rate in exchange for significantly reduced level of healthcare expenditures. Litigation clearly plays a role in this, and to protect ourselves we would have to be released from such threats. Otherwise, we will continue to order the tests as well. The only way to reduce the excessive use of technology is to have both the patient and the legal system on board. Otherwise any such attempts will be fruitless.

ity, safety, and value for money, "tort reform needs to be looked at in a different way," says Gosfield.

Fortunately, many tort reform tools have been tried, or at least proposed, giving the nation a potential arsenal for paring down the waste that defensive medicine inflicts on the healthcare system. A June 2013 CAP issue brief advocates two current-generation malpractice reform measures. First, the document recommends a "safe harbor" that would protect physicians if they could, broadly speaking, document having adhered to evidence-based clinical guidelines, preferably national guidelines.

Using a planning grant from the federal Agency for Healthcare Research and Quality, Oregon officials estimated last year that a safe harbor provision, and physician adherence to practice guidelines, would cut patient injuries by about 5%. In addition, more than 70% of the Oregon providers surveyed said that a safe harbor would probably decrease the practice of defensive medicine.

Second, the CAP brief advocates standards for developing such practice guidelines. It points to the Choosing Wisely initiative (www.choosingwisely.org), under which, by the end of this year, about 45 physician specialty societies will release lists of common tests and procedures that might be overused or unnecessary.

Not that practice guidelines are always an effective tool. A January 2013 report from The Leapfrog Group, a hospital-quality watchdog organization, found that in many states the percentage of early elective deliveries (those performed prior to the 39th completed week of gestation) remains excessive, despite practice guidelines from several national organizations, including the American College of Obstetricians and Gynecologists, that discourage such deliveries. Evidence-based standards are being talked about a lot, says Bernard, but they haven't been enacted yet.

Another proposed type of safe harbor would provide immunity for a physician or other healthcare provider who apologized following a medical error. For example, In June the Pennsylvania state senate unanimously approved a bill that would make any benevolent gesture such as an apology or explanation by a healthcare provider inadmissible as evidence of liability.

Several states have adopted such measures, says Hebeisen, but he warns that some hospitals have been pushing physicians to make apologies without having legal protections or immunities in place.

Related to these are "disclosure-and-offer" programs. Under such programs, Seabury, Chandra, and Jena explain in their editorial, "providers voluntarily disclose adverse events to affected patients and, when appropriate, make offers of restitution prior to the filing of any lawsuit. The goal of these offers, like payments from no-fault compensation funds, is to reduce the frequency of claims and avoid costly litigation."

Certifications of good faith (also called certificates of merit) are a fairly uncontroversial reform measure (Illinois has required them since 1986.) In states that have adopted them, to proceed with a liability suit the plaintiff has to obtain a statement from a healthcare professional that has reviewed the relevant medical records and affirms that there is a meritorious basis for the suit.

This had already been a usual practice among good lawyers, Hebeisen says, so the mandate to get a certificate of merit was not a particular change for them, but he says this is nonetheless a measure that can benefit everyone.

The idea of specialized health courts has existed for several years, but it got a big boost from a February 2010 blog post in *The Atlantic* by attorney and Common Good chair Philip K. Howard, says Gosfield.

Hebeisen says the concept is gaining traction, while Funai sees health courts as "promising but under-explored." Seabury says that both health courts and apology laws are worth more research and pilot projects.

Beyond these measures, Bernard notes that some states, including Florida and Virginia, have set up special funds for cases involving injuries during childbirth (which tend to generate outsized claims). Also being explored, he says, are special protections for emergency physicians, so their actions are judged by standards of care for emergency medicine, not those for other specialties.

If all of these potential approaches to tort reform sound scattershot, that isn't necessarily bad. Remember that the goal is not necessarily a cure, just better therapies.

Trends

Chronic disease: PCPs called on to meet growing health challenge

Team-based care, health coaching and better specialist communication needed as chronic disease cases climb

by **LISA ZAMOSKY** *contributing author*

HIGHLIGHTS

01 Chronic disease affects about 45% of the U.S. population, and it is believed to be growing.

02 Pulling together resources from within your practice and your community can help you with strategies to manage patients with chronic diseases.

Chronic disease is a leading cause of death in this country, accounting for seven out of 10 deaths, according to the U.S. Department of Health and Human Services (HHS). About 45% of the population, 133 million Americans, live with a chronic condition. By the year 2020, it's expected that number will rise to 157 million Americans.

THE INCREASING PREVALENCE of chronic disease is felt acutely in the primary care physician's (PCP) office. "The work of primary care over the last 20 to 30 years has shifted considerably," says Michael L. Parchman, MD, MPH, director of the MacColl Center for Health Care Innovation with the GroupHealth Research Institute in Seattle, Washington.

According to the Centers for Disease Control, 326 million, or almost 38%, of doctors visits in 2009 were made by adults with multiple chronic conditions. HHS projects that by the year 2020 81 million Americans will have multiple chronic health conditions.

These numbers, along with other changes to the healthcare system, make the practice of medicine far more challenging today for PCPs, particularly those operating independently or in small groups.

At the same time, physicians today have more tools and knowledge available to effectively treat chronic illness, says Thomas Bodenheimer, MD, MPH, adjunct professor of family and community medicine at the University of California, San Francisco School of Medicine. However, they also have less time to treat each chronic health condition. Bodenheimer says that even though the length of the primary care visit has increased slightly to roughly 18 minutes, there are an average of 7.1 issues that have to be dealt with during the patient's time with his or her physician. "Those are the issues that the patient brings up, or things that the physician feels need to be dealt with. That means it's about 2-1/2 to 3 minutes per issue, which is almost impossible to deal with," he says.

Still, experts say small practices can put systems and resources in place to better manage the chronic health conditions of a patient population, while also helping their practices.

"I think the first, most important thing to communicate is that there are resources for the private physician who does chronic care," says Jay Shubrook, DO, associate director of clinical care at the Diabetes Institute at Ohio University in Athens.

TEAM-BASED CARE

Some practices around the country are putting team-based care into action by training practice staff to help with low-complexity work, such as making sure patients receive preventive services including immunizations and colon cancer screenings, Parchman says.

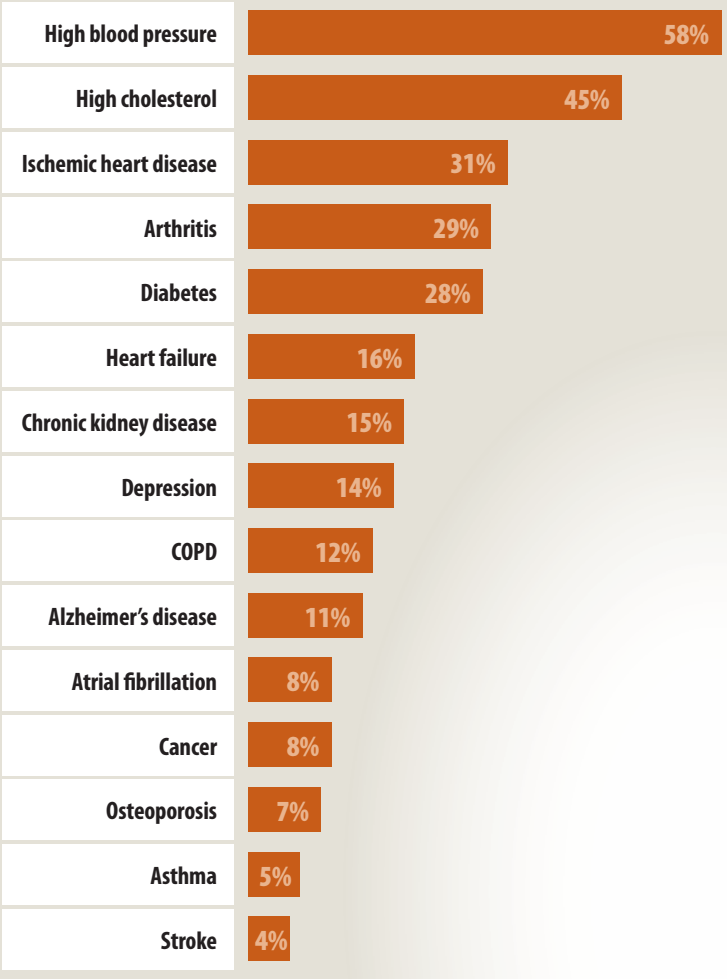
Another commonality among practices taking full advantage of the team-based approach is that staff have clearly defined roles with a lot of task flexibility.

"[If] I'm the RN, I do the triage, I do the care coordination, and case management of complex patients, and I'm here for emergencies. But I can do almost any task in the clinic if need be, and I have my radar scope on all the time, monitoring everybody in the clinic to see who is falling behind, how can I pitch in and help them catch up," Parchman says.

WORKING WITH SPECIALISTS

Another trend Parchman sees is small- to medium-sized practices reaching out to spe-

15 of the most common chronic conditions *for Medicare beneficiaries, 2010*



Source: Centers for Medicare and Medicaid Services, 2012

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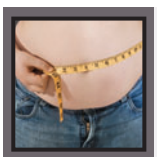

OBESITY

More than 78 million U.S. adults and 12 million children and adolescents are obese, and those numbers are growing every day. Visit the resource center shown below to help you adapt your practice to confront this epidemic.

MedicalEconomics.com/Obesity

> Even though the length of the primary care visit has increased slightly to roughly 18 minutes, there are an average of 7.1 issues that have to be dealt with during a typical encounter."
>
> THOMAS BODENHEIMER, MD, MPH, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

cialists and developing written agreements about referrals and referral management. The goal is to make sure that as the PCP you maintain full knowledge of the care your patient receives elsewhere. These agreements should require, as a condition of continued referral, that specialists forward a written report following a visit, and address no more than the specific problem the patient was referred for.

Parchman says that the message to the specialist is, "Your responsibility is to not take over the management of my patient, but to send my patient back to me. Your responsibility is not to make multiple secondary referrals to other specialists that I don't know about, without coming back to me as the PCP."

HEALTH COACHING

A significant part of adherence and lifestyle modification for improved management of chronic conditions involves educating patients. "Studies have shown that if people know their numbers and know their goals, they do better than people who don't, and most people don't know," Bodenheimer says.

Incorporating motivational interview techniques, putting action plans in place, and working with patients on medication adherence, while time consuming, have been proven to improve care. This is an area where training medical assistants to prepare the patient for the physician visit, conduct motivational interviewing, check and preload medications that require refills, and then link patients to community resources or make other referrals can go a long way toward improving care while freeing up a physician's time.

In addition, Bodenheimer says, patients can be trained as health coaches. "We did a randomized control trial of training patients with diabetes to be health coaches for other patients, and the patients who had coaches did better than the patients with usual care," he says.

An important component of health coaching is that staff work with patients to set small and achievable goals. "Any time they make improvements, you can give credit for that. I think those small pieces, not just chiding your patient, recognizing the small achievements, helping them to reach their goals, take a lot less time than you think, and they have a huge impact on adherence," Bodenheimer says.

GROUP VISITS

The group visit is not a new concept and it can be effective. But there are barriers to putting group visits into effect. "The problem is that the administrative work required to actually make group visits happen is considerable, so it's tough to do in a small practice," Bodenheimer says.

As an alternative, he suggests small practices consider something called a mini-group visit. "Instead of seeing one patient with diabetes for 15 minutes, you see two patients with diabetes for half an hour, or three patients with diabetes for 45 minutes, all at the same time," he says.

This model offers the advantages of the group visit with the physician spending more time with patients, and with patients able to interact with each other. This is very effective in encouraging patients to better manage their illness. "Those are very easy to set up," Bodenheimer says. "You just ask the patient if it's okay if they come in together with another patient who has the same problem. The patient says okay, you do it, and if they like it, you keep doing it."

Each patient can be billed, giving this model the potential of increasing productivity, according to Bodenheimer. Instead of the 15-minute visit, "You could see two patients in 20 minutes, which would probably be doable. That would save you 10 minutes of time that you could use for other patients, for recovering, or doing your paperwork."

DEVELOPING NEW PROGRAMS

In his own practice, Shubrook set up a diabetes "boot camp" that involves patients attending several educational sessions. Instead of relying on insurance reimbursement, his practice approached employers interested in helping workers better manage their health.

"It required a little bit of work, but less than you might think, to go to these employers," Shubrook says. "They actually pay our center the whole fee for the participant, with the hope that they're going to get downstream reduction in costs."

USE LOCAL RESOURCES

If incorporating a new program into a practice is difficult, ex-

➔35

Chronic disease facts

7 OUT OF 10

DEATHS AMONG AMERICANS

each year are from chronic diseases. Heart disease, cancer and stroke account for more than 50% of all deaths each year.

133

MILLION AMERICANS

In 2005—almost one in two adults—had at least one chronic illness.

OBESITY

has become a major health concern. One in every three adults is obese, and almost 1 in 5 youth between the ages of 6 and 19 is obese (BMI ≥ 95th percentile of the CDC growth chart).

About one-fourth of people with chronic conditions have one or more daily activity limitations.

ARTHRITIS

is the most common cause of disability, with nearly 19 million Americans reporting activity limitations.

DIABETES

continues to be the leading cause of kidney failure, nontraumatic lower-extremity amputations, and blindness among adults aged 20 to 74.

EXCESSIVE ALCOHOL CONSUMPTION

is the third-highest preventable cause of death in the United States behind diet and physical activity, and tobacco.

Source: Centers for Disease Control and Prevention

➔32

perts say there are numerous community resources available. For example, most hospitals have educators who can offer health coaching for a variety of chronic illnesses, as well as other resources.

Bodenheimer also points to the National Diabetes Prevention Program, a public-private partnership of community organizations, private insurers, employers, healthcare organizations and government agencies. The National Diabetes Prevention Program is available in 42 states, mainly provided by the YMCA.

Religious and other nonprofit healthcare organizations may offer services that practices can use to help patients gain the knowledge, resources, and support they need to better manage their health.

ELECTRONIC HEALTH RECORDS AND REGISTRIES

"The electronic health record (EHR) is indispensable," Shubrook says. "You can't do good managing without it." It helps to highlight the quality of care, and hold all the information needed to make adjustments.

"Universally, physicians, including myself, overestimate the quality of care we provide," Shubrook says.

> "THE ELECTRONIC HEALTH RECORD (EHR) IS INDISPENSIBLE. YOU CAN'T DO GOOD MANAGING WITHOUT IT."
>
> JAY SHUBROOK, DO, OHIO UNIVERSITY, ATHENS

EHRs allow physicians to address issues that arise, including specialists not informing PCPs about the tests they are referring patients for, such as diabetic eye exams.

In addition, registries of patients with diabetes, asthma or other chronic illnesses are critical to managing patient care. "Having an electronic disease registry is very helpful for looking at your whole population and really trying to work on everyone in your panel of patients being in reasonable control and getting the periodic tests that they should have on time," Bodenheimer says.

Parchman points to several ways in which practices around the country are using registries to better manage chronic illness in their patient population. First, they often assign one person—such as an RN or a medical assistant—to be the registry lead. This person spends a few hours a week reviewing the registry and determining which patients are behind on tests or other needed services. Then they contact the patient.

"The second thing we see them doing is figuring out ways to use health information technology (IT) that improves their workflow and their work processes during the day," Parchman says. For example, it's a good idea to ask the practice IT support to join morning huddles. The idea is that by hearing the workflow challenges staff is facing, they may be able to recommend an IT-based solution.

Finally, many practices are using their IT systems to incorporate care coordination for patients who are at high risk for emergency department visits, hospitalization, falls at home, and adverse reactions to medications. "What they're doing is risk stratifying their patient population—identifying those high-risk, complex patients," Parchman says. He adds that having resources in the practice, or working with regional health plans to identify a resource that can do proactive monitoring of patients improves quality of care.

GROWING DEMAND

The demand for primary care will grow given our aging population, the implementation of the Affordable Care Act, and the increases in chronic illnesses such as diabetes and other conditions related to obesity. And though this adds to the pressure, it also presents opportunities, Shubrook says.

"I do think it's important to highlight, particularly to PCPs, that there's real hope that things are about to get a lot better," he says, "because chronic disease management is killing the healthcare system. At least there are attempts to sort of change the incentives around it."

@ BUSINESS OF HEALTH

HYPERTENSION

Hypertension affects one in three adults in the United States, according to the Centers for Disease Control and Prevention. Though nearly half of people with hypertension have it maintained, if left untreated, it can lead to more serious health problems.

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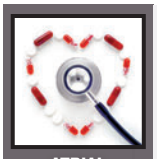
DIABETES



ATRIAL FIBRILATION

Go to MedicalEconomics.com/ResourceCenterIndex to access an indepth collection of information about key chronic health conditions.

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AN APP A DAY
Top apps physicians recommend to patients [42]

Operations

HIPAA: How to protect yourself and your practice

New rules make it more important than ever to be proactive in ensuring compliance

by **JEFFREY BENDIX,** *MA*

HIGHLIGHTS

01 Encrypting patient data, guarding mobile devices, installing firewalls, and adopting written policies and procedures for responding to data breaches are steps practices should take to comply with HIPAA rules governing protected health information.

02 Cyber insurance policies are available at relatively low cost to provide a degree of financial protection in the event of a data breach.

The final "Omnibus" Health Insurance Portability and Accountability Act (HIPAA) rule announced earlier this year includes numerous provisions that, if violated, could result in a medical practice being fined thousands of dollars. Fortunately, there are steps doctors can take to ensure both that they are compliant with HIPAA and to protect themselves financially if they are not.

ALTHOUGH THE ORIGINAL HIPAA legislation affects many aspects of medical practices, the primary focus of the Omnibus rule is on strengthening HIPAA's privacy and security protections for patients' protected health information (PHI). That's because the Omnibus rule revisions stem from the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act, explains Robert Tennant, MA, senior policy adviser for the Medical Group Management Association-American College of Medical Practice Executives (MGMA-ACMPE.)

"The HITECH Act was the same legislation that included the billions of dollars of incentives to providers to adopt electronic health records (EHRs)," Tennant says. "The argument at the time was, if we're going to be storing and transmitting patients' data electronically, we need to ensure to a greater extent the privacy and security of that data."

➔40

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BAYER

"Electronic health data is fundamentally different from paper [data] both because there's more of it, and because it's easier to lose and to alter inadvertently. That's why HHS (the U.S. Department of Health and Human Services) is so adamant about enforcement," adds Kenneth Rashbaum, JD, a health law attorney with Rashbaum Associates in New York, New York.

The Office for Civil Rights (OCR) is responsible for enforcing the HIPAA privacy and security rules, which it does by investigating complaints and conducting compliance reviews—audits—of businesses and organizations covered by the rules. OCR has posted case examples and resolution agreements on its Web site. OCR also posts cases involving breaches of unsecured PHI affecting 500 or more individuals. (See "HIPAA resources and additional information," pages 40-41.) The latter is sometimes referred to as the "wall of shame" by practice consultants and information technology (IT) security experts, Tennant says.

AVOIDING THE 'WALL OF SHAME'

So what can you do to keep your practice off the "wall of shame"? The short answer is, be proactive. "As they say in sports, the best defense is a good offense," Tennant says. "That's why we are encouraging our members to be really aggressive in taking the necessary steps to prevent that breach from occurring in the first place."

Although it is possible to hire a security expert to conduct a "soup to nuts" security risk assessment, the cost is usually prohibitive for a small medical practice. Tennant recommends instead that physicians use the wide variety of resources—many of them free—available through the government and professional societies and organizations to identify the steps they need to take to make their practices HIPAA-compliant. (See "HIPAA resources and additional information.")

SAFEGUARDING PHI

Broadly speaking, those steps fall into two categories. The first is safeguarding patients' PHI so that it is not lost, stolen, or otherwise subject to unauthorized access. In this, the biggest vulnerability most practices face comes from mobile devices such as smartphones, laptop computers, and tablets ("anything that can store electronic information and is easily picked up and carried," Tennant says) because they are so easily lost or stolen.

Fortunately, a solution to the problem is readily available in the form of encryption software. In fact, Tennant says, under the HIPAA rules a lost or stolen mobile device is not treated as a breach as long as the PHI on it is encrypted. The software is relatively inexpensive and available at most places computers are sold. "It's a very reasonable step for a practice to take. There's really no excuse not to do this," Tennant says.

Beyond encryption software and other electronic protections such as firewalls, practices need to establish written policies and procedures describing how it safeguards PHI what remedial steps it will take if a breach occurs. Auditors look for results of HIPAA security assessments and concrete steps such as the appointment of an information security officer. In addition, "they've been looking for proof of implementation of policies and procedures. So it's not enough just to have the written documents, you have to prove that you've actually put them into practice," Rashbaum says.

A key element in the implementation process is making sure that staff members are trained in security measures. Angela Dinh Rose, director of health information management for the American Health Information Management Association, suggests ending HIPAA training sessions with a quiz, and putting the results in employees' files as proof that they've received the training.

Staff training may have the additional benefit of defusing patient concern over a privacy issue before it goes any further. A patient with such a concern likely will first speak to the practice receptionist or other front-office staff person. The staff member needs to treat the complaint seriously, Tennant says, and have the patient speak with the office manager or privacy officer.

HIPAA RESOURCES & additional information

Here are links to resources and additional information doctors and practice managers can use to ensure they are in compliance with Health Insurance Portability and Accountability Act (HIPAA) rules:

- **The complete text of the HIPAA Omnibus Rule is available at: 1.usa.gov/Wl60lE**
- **The Office for Civil Rights' (OCR) sample provisions for a HIPAA-compliant business associate's agreement can be viewed at: 1.usa.gov/2Sk29L**

"Patients who feel they have not had their grievance addressed are the ones most likely to lodge a complaint with the government," Tennant says. "It's better to deal with the issue internally, and maybe issue an apology if appropriate, and of course identify and correct the problem."

BUSINESS ASSOCIATE AGREEMENTS

The second major area of vulnerability for many practices lies in relations with business associates—vendors and service providers—with access to patient PHI. These can range from billers and coders, to document shredders, and now health information exchanges. Under the new HIPAA rules such business associates are considered covered entities, meaning they are responsible for securing and guarding PHI in the same way that practices are—and are subject to the same penalties for violations.

The extent of a medical practice's liability in case of a breach caused by a business associate has not yet been established, but Rashbaum recommends reviewing contracts with vendors that have PHI access to ensure it has all the elements HIPAA requires. (For sample business associate contract provisions, see "HIPAA resources and further information.")

Vendors that service multiple physician practices may have standard agreements that they ask their customers to sign. An attorney should review any agreement to ensure HIPAA compliance before signing, Tennant says. Better yet, he adds, try to have the vendor sign your agreement and let them incur the cost of a lawyer's time.

CYBER INSURANCE POLICIES

Of course, even putting all the right safeguards in place can't guarantee that a breach won't occur or that a practice won't be fined after an audit. For such cases, insurance companies have recently started offering cyber insurance policies. Coverage under such policies varies depending on the type of business says Dean Sorensen, chief executive officer of Sorensen Informatics, Inc. in Lombard, Illinois, and a licensed insurance agent. For small medical practices, he adds, the coverage areas to look for are:

- business interruption (if your practice has to cease or curtail operations while investigating the cause of the breach);
- breach remediation, such as notifying patients and the news media that a breach has occurred;
- fines or other monetary penalties; and
- legal expenses

Policies currently are offered through the Beazley Group, The Hartford, The Travelers Insurance Group, and Zurich Insurance Group. Costs generally range from about $400 to $1000 annually, Sorensen says, depending on the size of the practice and what is covered.

As with most other forms of insurance, obtaining a cyber insurance policy requires underwriting, usually in the form of a data security checklist. "Basically it's saying 'I've done the following things to make my data secure. I have these procedures in place, I have these applications in place,'" Sorensen explains.

Even though the underwriting process is time-consuming, it also benefits the practice by forcing it to look at all its security measures. "They might see they're focusing on the wrong kinds of things, or overlooking something as simple as not locking the door at night," Sorensen says. It also helps ensure that the practice's security measures are HIPAA-compliant, since there is considerable overlap between commercial underwriting and HIPAA security requirements.

Although it's not covered by HIPAA, Sorensen also recommends practices take steps to ensure they are following payment card industry-data security standard (PCI-DSS) when storing, processing, or transmitting patient credit/debit card information. "The actual breach of the credit card information is not PHI, but if there's a breach on the PCI-DSS side, it shows someone can get into my system, which means I have exposure on the HIPAA side as well," Sorensen says.

OCR's guide to conducting a risk analysis is at: 1.usa.gov/biwwnZ

The definition of what is considered a "covered entity" under HIPAA can be found at: 1.usa.gov/5Novuz

A comprehensive "HIPAA Security Rule Toolkit" prepared by the National Institute of Standards and Technologies (NIST) is available at: 1.usa.gov/11lP9C6

The NIST "Guide for conducting risk assessments" is available at: 1.usa.gov/11lP9C6

OCR's list of breaches affecting 500 or more individuals can be viewed at: 1.usa.gov/a2UGEG

A detailed description of OCR's HIPAA enforcement policy, along with enforcement-related data, enforcement highlights, and case examples and resolution agreements can be found at: 1.usa.gov/Np0psP

Practical Matters

10 APPS PHYSICIANS RECOMMEND TO THEIR PATIENTS

by **ALISON RITCHIE**

More physicians than ever are relying on mobile devices to access information and communicate with patients. A recent survey by Wolters Kluwer Health showed that nearly 80% of primary care physicians are using smartphones in their practices. *Medical Economics* recently asked members of its editorial board to share which health apps they recommend most frequently to their patients.

1. iTriage offers patients decision support tools to help them research health problems and take action. This app allows patients to check their symptoms and easily locate a physician or hospital in the event of an emergency.

2. Diabetes App, *by BHI Technologies, helps patients* control blood sugar, track glucose and count carbs. Outside of the physician's office, patients with diabetes often struggle to monitor their condition. This app provides a food database for patients to track their consumption. It also allows physicians to monitor fluctuations. The price is $6.99, but a "lite" version is available for free.

3. iCookbook Diabetic features recipes and nutritional information plus health articles for people with diabetes. When it comes to cooking healthy, patients may need some inspiration. Developed by dietitians, this app provides diabetic-friendly recipes, as well as tools for meal planning and grocery shopping.

4. Diabetes in Check: With digital coaching from certified diabetes educators, patients can eat better, get active, and lower their blood sugar. This app provides constructive feedback as well as tools such as barcode scanners and meal planners, that will help patients control their Type 2 diabetes.

5. Glucose Companion: This app is a handy blood sugar and weight tracker. It offers comprehensive monitoring of a patient's diabetes, and it allows patients to present a complete log to their physician at their next appointment.

6. Blood Pressure Monitor – Family Lite: This app allows patients to monitor their blood pressure and weight on the go. It comes with a lifetime data visualization and statistics reporting. It also displays medication correlations.

7. HeartWise Blood Pressure Tracker *helps patients* monitor their blood pressure at home. This is said to be one of the easiest applications to use for recording blood pressure, resting heart rate, and weight. It also allows patients to import their existing records.

8. Mayo Clinic Health Community: This app provides access to an online health community, where patients can connect with and learn from other patients experiencing similar health issues. It offers a members-only discussion forum, as well as medical news and information from the Mayo Clinic.

9. Tummy Trends lets patients track their irritable bowel syndrome symptoms, exercise habits, water intake, fiber intake and stress levels. An interactive graph allows patients to share their reports with their physicians.

10. iCalcRisk encourages patients to adopt healthier lifestyles by calculating their cardiac risk. Physicians can use the visualizations in this app to show patients how they're doing in managing cholesterol, controlling blood pressure, and lowering their risk of heart attack.


Introducing a
NEW approach in
type 2 diabetes
treatment...

INVOKANA™ (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

INVOKANA™ is not recommended in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- History of a serious hypersensitivity reaction to INVOKANA™.
- Severe renal impairment (eGFR <30 mL/min/1.73 m^2), end stage renal disease, or patients on dialysis.

WARNINGS and PRECAUTIONS

- **Hypotension:** INVOKANA™ causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA™, particularly in patients with impaired renal function (eGFR <60 mL/min/1.73 m^2), elderly patients, and patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (eg, angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA™ in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.

NOW AVAILABLE

In adults with type 2 diabetes,

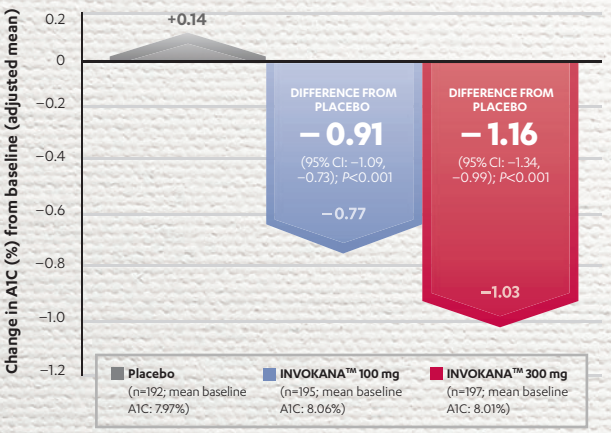
ENVISION NEW POSSIBILITIES

Introducing INVOKANA™—the first and only treatment option approved in the United States that reduces the reabsorption of glucose in the kidneys via sodium glucose co-transporter-2 (SGLT2) inhibition[1]

A1C Reductions as Monotherapy

INVOKANA™ monotherapy provided statistically significant A1C reductions vs placebo at 26 weeks[1]

A1C Change From Baseline With INVOKANA™ Monotherapy[1]



Effect on Weight*

Statistically significant weight reductions vs placebo at 26 weeks (*P*<0.001)[1]

>> Difference from placebo†:
100 mg: −2.2%; 300 mg: −3.3%

Impact on Systolic Blood Pressure (SBP)*

Statistically significant SBP lowering vs placebo at 26 weeks (*P*<0.001)[2]

>> Difference from placebo†:
100 mg: −3.7 mm Hg; 300 mg: −5.4 mm Hg

INVOKANA™ is not indicated for weight loss or as antihypertensive treatment.

***Prespecified secondary endpoint.**

†Adjusted mean.

A1C Reductions vs Sitagliptin

INVOKANA™ 300 mg demonstrated greater A1C reductions vs sitagliptin 100 mg, in combination with metformin + a sulfonylurea, at 52 weeks (*P*<0.05)[1]

>> Difference from sitagliptin†: −0.37%

Incidence of Hypoglycemia

Monotherapy over 26 weeks:
100 mg: 3.6%; 300 mg: 3.0%; placebo: 2.6%[1]

With metformin and a sulfonylurea over 52 weeks:
INVOKANA™ 300 mg: 43.2%; sitagliptin 100 mg: 40.7%[1]

>> Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue

Convenient Once-Daily Dosing[1]

>> Recommended starting dose: INVOKANA™ 100 mg

>> Dose can be increased to 300 mg in patients tolerating 100 mg, who have an eGFR of ≥60 mL/min/1.73 m^2 and require additional glycemic control

The most common (≥5%) adverse reactions were female genital mycotic infection, urinary tract infection, and increased urination.

References: 1. Invokana [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; 2013. **2.** Stenlöf K, Cefalu WT, Kim KA, et al. Efficacy and safety of canagliflozin monotherapy in subjects with type 2 diabetes mellitus inadequately controlled with diet and exercise. *Diabetes Obes Metab*. 2013;15(4):372-382.

Learn more at INVOKANAhcp.com/journal

Invokana™
canagliflozin tablets

IMPORTANT SAFETY INFORMATION *(continued from first page)*

WARNINGS and PRECAUTIONS *(cont'd)*

- **Impairment in Renal Function:** INVOKANA™ (canagliflozin) increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA™. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m^2.
- **Hyperkalemia:** INVOKANA™ can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically after initiating INVOKANA™ in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.
- **Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues:** Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA™.
- **Genital Mycotic Infections:** INVOKANA™ increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections. Monitor and treat appropriately.
- **Hypersensitivity Reactions:** Hypersensitivity reactions (eg, generalized urticaria), some serious, were reported with INVOKANA™ treatment; these reactions generally occurred within hours to days after initiating INVOKANA™. If hypersensitivity reactions occur, discontinue use of INVOKANA™; treat per standard of care and monitor until signs and symptoms resolve.
- **Increases in Low-Density Lipoprotein (LDL-C):** Dose-related increases in LDL-C occur with INVOKANA™. Monitor LDL-C and treat per standard of care after initiating INVOKANA™.
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA™ or any other antidiabetic drug.

DRUG INTERACTIONS

- **UGT Enzyme Inducers:** Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including UGT1A9, UGT2B4, decreased canagliflozin area under the curve (AUC) by 51%. This decrease in exposure to canagliflozin may decrease efficacy. If an inducer of these UGTs (eg, rifampin, phenytoin, phenobarbitol, ritonavir) must be co-administered with INVOKANA™ (canagliflozin), consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA™ 100 mg once daily, have an eGFR greater than 60mL/min/1.73 m^2, and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m^2 receiving concurrent therapy with a UGT inducer and requiring additional glycemic control.
- **Digoxin:** There was an increase in the area AUC and mean peak drug concentration (C_{max}) of digoxin (20% and 36%, respectively) when co-administered with INVOKANA™ 300 mg. Patients taking INVOKANA™ with concomitant digoxin should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

- **Pregnancy Category C:** There are no adequate and well-controlled studies of INVOKANA™ in pregnant women. Based on results from rat studies, canagliflozin may affect renal development and maturation. In a juvenile rat study, increased kidney weights and renal pelvic and tubular dilatation were evident at ≥0.5 times clinical exposure from a 300-mg dose.

  These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- **Nursing Mothers:** It is not known if INVOKANA™ is excreted in human milk. INVOKANA™ is secreted in the milk of lactating rats, reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA™ showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs in utero and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing

human kidney. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from INVOKANA™, a decision should be made whether to discontinue nursing or to discontinue INVOKANA™, taking into account the importance of the drug to the mother.

»**Pediatric Use:** Safety and effectiveness of INVOKANA™ in pediatric patients under 18 years of age have not been established.

»**Geriatric Use:** Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA™ in nine clinical studies of INVOKANA™. Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA™ (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300-mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were ≥75 years of age. Smaller reductions in HbA1C with INVOKANA™ relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA™ 100 mg and -0.74% with INVOKANA™ 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA™ 100 mg and -0.87% with INVOKANA™ 300 mg relative to placebo).

»**Renal Impairment:** The efficacy and safety of INVOKANA™ were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/1.73 m^2). These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR ≥60 mL/min/1.73 m^2); patients treated with INVOKANA™ 300 mg were more likely to experience increases in potassium.

The efficacy and safety of INVOKANA™ have not been established in patients with severe renal impairment (eGFR <30 mL/min/1.73 m^2), with end-stage renal disease (ESRD), or receiving dialysis. INVOKANA™ is not expected to be effective in these patient populations.

»**Hepatic Impairment:** No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA™ has not been studied in patients with severe hepatic impairment and it is therefore not recommended.

OVERDOSAGE

»There were no reports of overdose during the clinical development program of INVOKANA™ (canagliflozin).

In the event of an overdose, contact the Poison Control Center. It is also reasonable to employ the usual supportive measures, eg, remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as dictated by the patient's clinical status. Canagliflozin was negligibly removed during a 4-hour hemodialysis session. Canagliflozin is not expected to be dialyzable by peritoneal dialysis.

ADVERSE REACTIONS

»The most common (≥5%) adverse reactions were female genital mycotic infections, urinary tract infections, and increased urination. Adverse reactions in ≥2% of patients were male genital mycotic infections, vulvovaginal pruritis, thirst, nausea, and constipation.

K02CAN13149

Please see Brief Summary of full Prescribing Information on the following pages.

Invokana™
canagliflozin tablets

Janssen
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Janssen Pharmaceuticals, Inc.

Canagliflozin is licensed from Mitsubishi Tanabe Pharma Corporation.

April 2013 K02CAN13075

INVOKANA™

(canagliflozin) tablets, for oral use

Brief Summary of Prescribing Information.

INDICATIONS AND USAGE

INVOKANA™ (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus *[see Clinical Studies (14) in full Prescribing Information]*.

Limitation of Use: INVOKANA is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

CONTRAINDICATIONS

- History of a serious hypersensitivity reaction to INVOKANA *[see Warnings and Precautions]*.
- Severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), end stage renal disease or patients on dialysis *[see Warnings and Precautions and Use in Specific Populations]*.

WARNINGS AND PRECAUTIONS

Hypotension: INVOKANA causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA *[see Adverse Reactions]* particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m^2), elderly patients, patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (e.g., angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.

Impairment in Renal Function: INVOKANA increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA *[see Adverse Reactions]*. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m^2.

Hyperkalemia: INVOKANA can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia *[see Adverse Reactions]*.

Monitor serum potassium levels periodically after initiating INVOKANA in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.

Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues: Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue *[see Adverse Reactions]*. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA.

Genital Mycotic Infections: INVOKANA increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections *[see Adverse Reactions]*. Monitor and treat appropriately.

Hypersensitivity Reactions: Hypersensitivity reactions (e.g., generalized urticaria), some serious, were reported with INVOKANA treatment; these reactions generally occurred within hours to days after initiating INVOKANA. If hypersensitivity reactions occur, discontinue use of INVOKANA; treat per standard of care and monitor until signs and symptoms resolve *[see Contraindications and Adverse Reactions]*.

Increases in Low-Density Lipoprotein (LDL-C): Dose-related increases in LDL-C occur with INVOKANA *[see Adverse Reactions]*. Monitor LDL-C and treat per standard of care after initiating INVOKANA.

Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA or any other antidiabetic drug.

ADVERSE REACTIONS

The following important adverse reactions are described below and elsewhere in the labeling:

- Hypotension *[see Warnings and Precautions]*
- Impairment in Renal Function *[see Warnings and Precautions]*
- Hyperkalemia *[see Warnings and Precautions]*
- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues *[see Warnings and Precautions]*
- Genital Mycotic Infections *[see Warnings and Precautions]*
- Hypersensitivity Reactions *[see Warnings and Precautions]*
- Increases in Low-Density Lipoprotein (LDL-C) *[see Warnings and Precautions]*

Clinical Studies Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Pool of Placebo-Controlled Trials: The data in Table 1 is derived from four 26-week placebo-controlled trials. In one trial INVOKANA was used as monotherapy and in three trials INVOKANA was used as add-on therapy *[see Clinical Studies (14) in full Prescribing Information]*. These data reflect exposure of 1667 patients to INVOKANA and a mean duration of exposure to INVOKANA of 24 weeks. Patients received INVOKANA 100 mg (N=833), INVOKANA 300 mg (N=834) or placebo (N=646) once daily. The mean age of the population was 56 years and 2% were older than 75 years of age. Fifty percent (50%) of the population was male and 72% were Caucasian, 12% were Asian, and 5% were Black or African American. At baseline the population had diabetes for an average of 7.3 years, had a mean HbA1C of 8.0% and 20% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 88 mL/min/1.73 m^2).

Table 1 shows common adverse reactions associated with the use of INVOKANA. These adverse reactions were not present at baseline, occurred more commonly on INVOKANA than on placebo, and occurred in at least 2% of patients treated with either INVOKANA 100 mg or INVOKANA 300 mg.

Table 1: Adverse Reactions From Pool of Four 26–Week Placebo-Controlled Studies Reported in ≥ 2% of INVOKANA-Treated Patients*

Adverse Reaction	Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Female genital mycotic infections†	3.2%	10.4%	11.4%
Urinary tract infections‡	4.0%	5.9%	4.3%
Increased urination§	0.8%	5.3%	4.6%
Male genital mycotic infections¶	0.6%	4.2%	3.7%
Vulvovaginal pruritus	0.0%	1.6%	3.0%
Thirst#	0.2%	2.8%	2.3%
Constipation	0.9%	1.8%	2.3%
Nausea	1.5%	2.2%	2.3%

* The four placebo-controlled trials included one monotherapy trial and three add-on combination trials with metformin, metformin and sulfonylurea, or metformin and pioglitazone.

† Female genital mycotic infections include the following adverse reactions: Vulvovaginal candidiasis, Vulvovaginal mycotic infection, Vulvovaginitis, Vaginal infection, Vulvitis, and Genital infection fungal. Percentages calculated with the number of female subjects in each group as denominator: placebo (N=312), INVOKANA 100 mg (N=425), and INVOKANA 300 mg (N=430).

‡ Urinary tract infections includes the following adverse reactions: Urinary tract infection, Cystitis, Kidney infection, and Urosepsis.

§ Increased urination includes the following adverse reactions: Polyuria, Pollakiuria, Urine output increased, Micturition urgency, and Nocturia.

¶ Male genital mycotic infections include the following adverse reactions: Balanitis or Balanoposthitis, Balanitis candida, and Genital infection fungal. Percentages calculated with the number of male subjects in each group as denominator: placebo (N=334), INVOKANA 100 mg (N=408), and INVOKANA 300 mg (N=404).

Thirst includes the following adverse reactions: Thirst, Dry mouth, and Polydipsia.

Abdominal pain was also more commonly reported in patients taking INVOKANA 100 mg (1.8%), 300 mg (1.7%) than in patients taking placebo (0.8%).

Pool of Placebo- and Active-Controlled Trials: The occurrence of adverse reactions was also evaluated in a larger pool of patients participating in placebo- and active-controlled trials.

The data combined eight clinical trials *[see Clinical Studies (14) in full Prescribing Information]* and reflect exposure of 6177 patients to INVOKANA. The mean duration of exposure to INVOKANA was 38 weeks with 1832 individuals exposed to INVOKANA for greater than 50 weeks. Patients received INVOKANA 100 mg (N=3092), INVOKANA 300 mg (N=3085) or comparator (N=3262) once daily. The mean age of the population was 60 years and 5% were older than 75 years of age. Fifty-eight percent (58%) of the population was male and 73% were Caucasian, 16% were Asian, and 4% were Black or African American. At baseline, the population had diabetes for an average of 11 years, had a mean HbA1C of 8.0% and 33% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 81 mL/min/1.73 m^2).

The types and frequency of common adverse reactions observed in the pool of eight clinical trials were consistent with those listed in Table 1. In this pool, INVOKANA was also associated with the adverse reactions of fatigue (1.7% with comparator, 2.2% with INVOKANA 100 mg, and 2.0% with INVOKANA 300 mg) and loss of strength or energy (i.e., asthenia) (0.6% with comparator, 0.7% with INVOKANA 100 mg and 1.1% with INVOKANA 300 mg).

In the pool of eight clinical trials, the incidence rate of pancreatitis (acute or chronic) was 0.9, 2.7, and 0.9 per 1000 patient-years of exposure to comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

In the pool of eight clinical trials with a longer mean duration of exposure to INVOKANA (68 weeks), the incidence rate of bone fracture was 14.2, 18.7, and 17.6 per 1000 patient years of exposure to comparator, INVOKANA

100 mg, and INVOKANA 300 mg, respectively. Upper extremity fractures occurred more commonly on INVOKANA than comparator.

In the pool of eight clinical trials, hypersensitivity-related adverse reactions (including erythema, rash, pruritus, urticaria, and angioedema) occurred in 3.0%, 3.8%, and 4.2% of patients receiving comparator, INVOKANA 100 mg and INVOKANA 300 mg, respectively. Five patients experienced serious adverse reactions of hypersensitivity with INVOKANA, which included 4 patients with urticaria and 1 patient with a diffuse rash and urticaria occurring within hours of exposure to INVOKANA. Among these patients, 2 patients discontinued INVOKANA. One patient with urticaria had recurrence when INVOKANA was re-initiated.

Photosensitivity-related adverse reactions (including photosensitivity reaction, polymorphic light eruption, and sunburn) occurred in 0.1%, 0.2%, and 0.2% of patients receiving comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Other adverse reactions occurring more frequently on INVOKANA than on comparator were:

Volume Depletion-Related Adverse Reactions: INVOKANA results in an osmotic diuresis, which may lead to reductions in intravascular volume. In clinical studies, treatment with INVOKANA was associated with a dose-dependent increase in the incidence of volume depletion-related adverse reactions (e.g., hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration). An increased incidence was observed in patients on the 300 mg dose. The three factors associated with the largest increase in volume depletion-related adverse reactions were the use of loop diuretics, moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m^2) and age 75 years and older (Table 2) *[see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Use in Specific Populations]*.

Table 2: Proportion of Patients With at Least one Volume Depletion-Related Adverse Reactions (Pooled Results from 8 Clinical Trials)

Baseline Characteristic	Comparator Group* %	INVOKANA 100 mg %	INVOKANA 300 mg %
Overall population	1.5%	2.3%	3.4%
75 years of age and older†	2.6%	4.9%	8.7%
eGFR less than 60 mL/min/1.73 m^2†	2.5%	4.7%	8.1%
Use of loop diuretic†	4.7%	3.2%	8.8%

***** Includes placebo and active-comparator groups

† Patients could have more than 1of the listed risk factors

Impairment in Renal Function: INVOKANA is associated with a dose-dependent increase in serum creatinine and a concomitant fall in estimated GFR (Table 3). Patients with moderate renal impairment at baseline had larger mean changes.

Table 3: Changes in Serum Creatinine and eGFR Associated with INVOKANA in the Pool of Four Placebo-Controlled Trials and Moderate Renal Impairment Trial

			Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Pool of Four Placebo-Controlled Trials	Baseline	Creatinine (mg/dL)	0.84	0.82	0.82
		eGFR (mL/min/1.73 m^2)	87.0	88.3	88.8
	Week 6 Change	Creatinine (mg/dL)	0.01	0.03	0.05
		eGFR (mL/min/1.73 m^2)	-1.6	-3.8	-5.0
	End of Treatment Change*	Creatinine (mg/dL)	0.01	0.02	0.03
		eGFR (mL/min/1.73 m^2)	-1.6	-2.3	-3.4
			Placebo N=90	**INVOKANA 100 mg N=90**	**INVOKANA 300 mg N=89**
Moderate Renal Impairment Trial	Baseline	Creatinine (mg/dL)	1.61	1.62	1.63
		eGFR (mL/min/1.73 m^2)	40.1	39.7	38.5
	Week 3 Change	Creatinine (mg/dL)	0.03	0.18	0.28
		eGFR (mL/min/1.73 m^2)	-0.7	-4.6	-6.2
	End of Treatment Change*	Creatinine (mg/dL)	0.07	0.16	0.18
		eGFR (mL/min/1.73 m^2)	-1.5	-3.6	-4.0

***** Week 26 in mITT LOCF population

In the pool of four placebo-controlled trials where patients had normal or mildly impaired baseline renal function, the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR below 80 mL/min/1.73 m^2 and 30% lower than baseline, was 2.1% with placebo, 2.0% with INVOKANA 100 mg, and 4.1% with INVOKANA 300 mg. At the end of treatment, 0.5% with placebo, 0.7% with INVOKANA 100 mg, and 1.4% with INVOKANA 300 mg had a significant renal function decline.

INVOKANA™ (canagliflozin) tablets

In a trial carried out in patients with moderate renal impairment with a baseline eGFR of 30 to less than 50 mL/min/1.73 m^2 (mean baseline eGFR 39 mL/min/1.73 m^2) *[see Clinical Studies (14.3) in full Prescribing Information]*, the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR 30% lower than baseline, was 6.9% with placebo, 18% with INVOKANA 100 mg, and 22.5% with INVOKANA 300 mg. At the end of treatment, 4.6% with placebo, 3.4% with INVOKANA 100 mg, and 3.4% with INVOKANA 300 mg had a significant renal function decline.

In a pooled population of patients with moderate renal impairment (N=1085) with baseline eGFR of 30 to less than 60 mL/min/1.73 m^2 (mean baseline eGFR 48 mL/min/1.73 m^2), the overall incidence of these events was lower than in the dedicated trial but a dose-dependent increase in incident episodes of significant renal function decline compared to placebo was still observed.

Use of INVOKANA was associated with an increased incidence of renal-related adverse reactions (e.g., increased blood creatinine, decreased glomerular filtration rate, renal impairment, and acute renal failure), particularly in patients with moderate renal impairment.

In the pooled analysis of patients with moderate renal impairment, the incidence of renal-related adverse reactions was 3.7% with placebo, 8.9% with INVOKANA 100 mg, and 9.3% with INVOKANA 300 mg. Discontinuations due to renal-related adverse events occurred in 1.0% with placebo, 1.2% with INVOKANA 100 mg, and 1.6% with INVOKANA 300 mg *[see Warnings and Precautions]*.

Genital Mycotic Infections: In the pool of four placebo-controlled clinical trials, female genital mycotic infections (e.g., vulvovaginal mycotic infection, vulvovaginal candidiasis, and vulvovaginitis) occurred in 3.2%, 10.4%, and 11.4% of females treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Patients with a history of genital mycotic infections were more likely to develop genital mycotic infections on INVOKANA. Female patients who developed genital mycotic infections on INVOKANA were more likely to experience recurrence and require treatment with oral or topical antifungal agents and anti-microbial agents *[see Warnings and Precautions]*.

In the pool of four placebo-controlled clinical trials, male genital mycotic infections (e.g., candidal balanitis, balanoposthitis) occurred in 0.6%, 4.2%, and 3.7% of males treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Male genital mycotic infections occurred more commonly in uncircumcised males and in males with a prior history of balanitis or balanoposthitis. Male patients who developed genital mycotic infections on INVOKANA were more likely to experience recurrent infections (22% on INVOKANA versus none on placebo), and require treatment with oral or topical antifungal agents and anti-microbial agents than patients on comparators. In the pooled analysis of 8 controlled trials, phimosis was reported in 0.3% of uncircumcised male patients treated with INVOKANA and 0.2% required circumcision to treat the phimosis *[see Warnings and Precautions]*.

Hypoglycemia: In all clinical trials, hypoglycemia was defined as any event regardless of symptoms, where biochemical hypoglycemia was documented (any glucose value below or equal to 70 mg/dL). Severe hypoglycemia was defined as an event consistent with hypoglycemia where the patient required the assistance of another person to recover, lost consciousness, or experienced a seizure (regardless of whether biochemical documentation of a low glucose value was obtained). In individual clinical trials *[see Clinical Studies (14) in full Prescribing Information]*, episodes of hypoglycemia occurred at a higher rate when INVOKANA was co-administered with insulin or sulfonylureas (Table 4) *[see Warnings and Precautions]*.

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies

Monotherapy (26 weeks)	Placebo (N=192)	INVOKANA 100 mg (N=195)	INVOKANA 300 mg (N=197)
Overall [N (%)]	5 (2.6)	7 (3.6)	6 (3.0)
In Combination with Metformin (26 weeks)	**Placebo + Metformin (N=183)**	**INVOKANA 100 mg + Metformin (N=368)**	**INVOKANA 300 mg + Metformin (N=367)**
Overall [N (%)]	3 (1.6)	16 (4.3)	17 (4.6)
Severe [N (%)]†	0 (0)	1 (0.3)	1 (0.3)
In Combination with Metformin (52 weeks)	**Glimepiride + Metformin (N=482)**	**INVOKANA 100 mg + Metformin (N=483)**	**INVOKANA 300 mg + Metformin (N=485)**
Overall [N (%)]	165 (34.2)	27 (5.6)	24 (4.9)
Severe [N (%)]†	15 (3.1)	2 (0.4)	3 (0.6)
In Combination with Sulfonylurea (18 weeks)	**Placebo + Sulfonylurea (N=69)**	**INVOKANA 100 mg + Sulfonylurea (N=74)**	**INVOKANA 300 mg + Sulfonylurea (N=72)**
Overall [N (%)]	4 (5.8)	3 (4.1)	9 (12.5)
In Combination with Metformin + Sulfonylurea (26 weeks)	**Placebo + Metformin + Sulfonylurea (N=156)**	**INVOKANA 100 mg + Metformin + Sulfonylurea (N=157)**	**INVOKANA 300 mg + Metformin + Sulfonylurea (N=156)**
Overall [N (%)]	24 (15.4)	43 (27.4)	47 (30.1)
Severe [N (%)]†	1 (0.6)	1 (0.6)	0

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies (continued)

In Combination with Metformin + Sulfonylurea (52 weeks)	**Sitagliptin + Metformin + Sulfonylurea (N=378)**		**INVOKANA 300 mg + Metformin + Sulfonylurea (N=377)**
Overall [N (%)]	154 (40.7)		163 (43.2)
Severe [N (%)]†	13 (3.4)		15 (4.0)
In Combination with Metformin + Pioglitazone (26 weeks)	**Placebo + Metformin + Pioglitazone (N=115)**	**INVOKANA 100 mg + Metformin + Pioglitazone (N=113)**	**INVOKANA 300 mg + Metformin + Pioglitazone (N=114)**
Overall [N (%)]	3 (2.6)	3 (2.7)	6 (5.3)
In Combination with Insulin (18 weeks)	**Placebo (N=565)**	**INVOKANA 100 mg (N=566)**	**INVOKANA 300 mg (N=587)**
Overall [N (%)]	208 (36.8)	279 (49.3)	285 (48.6)
Severe [N (%)]†	14 (2.5)	10 (1.8)	16 (2.7)

* Number of patients experiencing at least one event of hypoglycemia based on either biochemically documented episodes or severe hypoglycemic events in the intent-to-treat population

† Severe episodes of hypoglycemia were defined as those where the patient required the assistance of another person to recover, lost consciousness, or experienced a seizure (regardless of whether biochemical documentation of a low glucose value was obtained)

Laboratory Tests: *Increases in Serum Potassium:* Dose-related, transient mean increases in serum potassium were observed early after initiation of INVOKANA (i.e., within 3 weeks) in a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*. In this trial, increases in serum potassium of greater than 5.4 mEq/L and 15% above baseline occurred in 16.1%, 12.4%, and 27.0% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. More severe elevations (i.e., equal or greater than 6.5 mEq/L) occurred in 1.1%, 2.2%, and 2.2% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. In patients with moderate renal impairment, increases in potassium were more commonly seen in those with elevated potassium at baseline and in those using medications that reduce potassium excretion, such as potassium-sparing diuretics, angiotensin-converting-enzyme inhibitors, and angiotensin-receptor blockers *[see Warnings and Precautions]*.

Increases in Serum Magnesium: Dose-related increases in serum magnesium were observed early after initiation of INVOKANA (within 6 weeks) and remained elevated throughout treatment. In the pool of four placebo-controlled trials, the mean change in serum magnesium levels was 8.1% and 9.3% with INVOKANA 100 mg and INVOKANA 300 mg, respectively, compared to -0.6% with placebo. In a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*, serum magnesium levels increased by 0.2%, 9.2%, and 14.8% with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Increases in Serum Phosphate: Dose-related increases in serum phosphate levels were observed with INVOKANA. In the pool of four placebo controlled trials, the mean change in serum phosphate levels were 3.6% and 5.1% with INVOKANA 100 mg and INVOKANA 300 mg, respectively, compared to 1.5% with placebo. In a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*, the mean serum phosphate levels increased by 1.2%, 5.0%, and 9.3% with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C) and non-High-Density Lipoprotein Cholesterol (non-HDL-C): In the pool of four placebo-controlled trials, dose-related increases in LDL-C with INVOKANA were observed. Mean changes (percent changes) from baseline in LDL-C relative to placebo were 4.4 mg/dL (4.5%) and 8.2 mg/dL (8.0%) with INVOKANA 100 mg and INVOKANA 300 mg, respectively. The mean baseline LDL-C levels were 104 to 110 mg/dL across treatment groups *[see Warnings and Precautions]*.

Dose-related increases in non-HDL-C with INVOKANA were observed. Mean changes (percent changes) from baseline in non-HDL-C relative to placebo were 2.1 mg/dL (1.5%) and 5.1 mg/dL (3.6%) with INVOKANA 100 mg and 300 mg, respectively. The mean baseline non-HDL-C levels were 140 to 147 mg/dL across treatment groups.

Increases in Hemoglobin: In the pool of four placebo-controlled trials, mean changes (percent changes) from baseline in hemoglobin were -0.18 g/dL (-1.1%) with placebo, 0.47 g/dL (3.5%) with INVOKANA 100 mg, and 0.51 g/dL (3.8%) with INVOKANA 300 mg. The mean baseline hemoglobin value was approximately 14.1 g/dL across treatment groups. At the end of treatment, 0.8%, 4.0%, and 2.7% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively, had hemoglobin above the upper limit of normal.

DRUG INTERACTIONS

UGT Enzyme Inducers: Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including UGT1A9, UGT2B4, decreased canagliflozin area under the curve (AUC) by 51%. This decrease in exposure to canagliflozin may decrease efficacy. If an inducer of these UGTs (e.g., rifampin, phenytoin, phenobarbital, ritonavir) must be co-administered with INVOKANA (canagliflozin), consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA 100 mg once daily, have an eGFR greater than 60 mL/min/1.73 m^2, and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m^2 receiving concurrent therapy with a UGT inducer and require additional glycemic control *[see Dosage and Administration (2.3) and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Digoxin: There was an increase in the area AUC and mean peak drug concentration (C_{max}) of digoxin (20% and 36%, respectively) when co-administered with INVOKANA 300 mg *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Patients taking INVOKANA with concomitant digoxin should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

Pregnancy: Teratogenic Effects: Pregnancy Category C: There are no adequate and well-controlled studies of INVOKANA in pregnant women. Based on results from rat studies, canagliflozin may affect renal development and maturation. In a juvenile rat study, increased kidney weights and renal pelvic and tubular dilatation were evident at greater than or equal to 0.5 times clinical exposure from a 300 mg dose *[see Nonclinical Toxicology (13.2) in full Prescribing Information]*.

These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known if INVOKANA is excreted in human milk. INVOKANA is secreted in the milk of lactating rats reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs *in utero* and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from INVOKANA, a decision should be made whether to discontinue nursing or to discontinue INVOKANA, taking into account the importance of the drug to the mother *[see Nonclinical Toxicology (13.2) in full Prescribing Information]*.

Pediatric Use: Safety and effectiveness of INVOKANA in pediatric patients under 18 years of age have not been established.

Geriatric Use: Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA in nine clinical studies of INVOKANA *[see Clinical Studies (14.3) in full Prescribing Information]*.

Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300 mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were 75 years and older *[see Dosage and Administration (2.1) in full Prescribing Information and Adverse Reactions]*. Smaller reductions in HbA1C with INVOKANA relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA 100 mg and -0.74% with INVOKANA 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA 100 mg and -0.87% with INVOKANA 300 mg relative to placebo).

Renal Impairment: The efficacy and safety of INVOKANA were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to less than 50 mL/min/1.73 m^2) *[see Clinical Studies (14.3) in full Prescribing Information]*. These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR greater than or equal to 60 mL/min/1.73 m^2); patients treated with INVOKANA 300 mg were more likely to experience increases in potassium *[see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Adverse Reactions]*.

The efficacy and safety of INVOKANA have not been established in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), with ESRD, or receiving dialysis. INVOKANA is not expected to be effective in these patient populations *[see Contraindications and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Hepatic Impairment: No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA has not been studied in patients with severe hepatic impairment and is therefore not recommended *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

(Even) more MedEc

SEE WHAT YOU MAY HAVE BEEN MISSING IN OUR ENEWSLETTER

New app helps track Sunshine Law reports

DOCTORS concerned about the Physician Payments Sunshine Act can download a new app to see how the reporting process will work before results are made public next year.

The Centers for Medicare and Medicaid Services (CMS) has released two new mobile apps called Open Payments—one for physicians, and one for healthcare industry users—to raise awareness among healthcare providers regarding transactions reported under the Sunshine Act.

The app for physicians will allow them to track payments and other value transfers to drug and device manufacturers. Physicians will be able to create a profile and track any discrepancies in reporting. The app for industry users, including hospitals and institutions, will have the same features as the physicians' app, but will also be able to store physician profiles.

The Sunshine Act mandates that pharmaceutical and medical device companies report financial relationships with physicians, hospitals, and other healthcare businesses totalling more than $100 per year. Companies began reporting financial data on August 1. The entire list will be published annually beginning in September 2014.

SHARED/SPLIT VISITS
How to code/document shared/split visits [50]

TELEHEALTH CODES
New preventive, telehealth codes proposed for 2014 [54]

ANCILLARY INCOME
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Money

Understanding the new payment models

Alternatives to fee-for-service reimbursement may benefit your practice—if you know how they work

by **ALICE G. GOSFIELD,** *JD*

HIGHLIGHTS

01 Before going to an alternative payment model, be sure to understand all the qualifying conditions and details of how your practice will be paid for the care it provides.

02 Unlike the capitation payment model, today's episode rate models take into account the services patients require for defined clinical conditions, thereby lessening the financial risk to physicians.

As if attempting to qualify for meaningful use payments and Physician Quality Reporting System bonuses weren't enough, the proliferation of new payment models is leaving many primary care physicians (PCPs) confused.

THIS ARTICLE seeks to clarify concepts about which there is considerable misunderstanding among doctors and other medical professionals. It will also touch on some of the contractual issues that these models can generate—from the least complex model, the Patient-Centered Medical Home (PCMH), to the most complex, accountable care organizations (ACOs).

PCMH is a care delivery concept that is intended to produce greater engagement between the physician practice and its patients, particularly around chronic diseases. PCMH seeks to meet the goal of increased value by keeping patients out of the hospital through better management of their chronic conditions. Most PCMH programs sponsored by commercial insurers pay an enhanced per-member, per-month payment to PCPs. Some pay a care management fee per patient. It is important to bear in mind, however, that PCMH is a care delivery model rather than a payment concept.

Where payers make enhanced payments available to PCMH practices, they typically do so on a "take it or leave it" basis. Sometimes there is not even a contract amendment. The health plan merely says, "If you are National Council for Quality Assurance-certified, you are eligible for additional payments."

The issues to pay attention to in such a contract are the qualifying conditions for

payment and ensuring that failure to meet the conditions does not affect your basic right to participate with a plan without PCMH payments.

BUNDLED PAYMENTS

"Bundled payment" is a term describing payments that put multiple providers together in the same financial risk pool. Typically, the term describes payments where disparate providers who are paid under different payment methodologies—e.g., hospitals paid on diagnostic-related groups and physicians paid fee-for-service—are at risk together for the same budget or pool of funds.

Some bundled payment programs make one payment to a single entity, traditionally a hospital, which then allocates the money among the participants. In Medicare's Bundled Payment for Care Initiative (BPCI), however, many of the more than 450 participants are physician entities. Payment may be bundled around a single admission, which was the model for the Medicare coronary artery bypass graft demonstration in the late 1990s.

Today, references to bundled payment usually also entail "episode rates." Episode rates are budgets designed around a continuum of care for a specific patient for a specific condition. Episode payments are also referred to as "case rates." To establish the payment amount, boundaries in terms of time and the range of services to be included must be defined. For example, an episode of care around an acute myocardial infarction would include the admission and subsequent cardiac rehabilitation and other services until 30 or even 180 days after discharge. Some episode rates reach back and include the diagnostic services that established the condition. Episodes in chronic care, such as diabetes, congestive heart failure, or asthma typically extend for a full year to coincide with annual health insurance premiums.

Episode payments or case rates need not entail bundling. A physician group by itself could be paid for its services on a case rate. In today's parlance, however, episode rates are often combined with bundled payments so that the in-

AT A GLANCE

New payment models

Patient-Centered Medical Homes

While it is a care delivery model designed to increase greater engagement by practices and patients and improve the coordination of care among specialists, most programs sponsored by commercial payers make an enhanced per-member, per-month payment to primary care physicians. Some also pay a care management fee per patient.

ISSUES TO WATCH: Monitor closely qualifying conditions for payment. Make certain it does not impact participation with plans without PCMH payments.

Bundled payments

This models puts multiple providers together in a shared risk pool. A budgeted amount is paid for the care of the patient. Typically one entity, traditionally a hospital, allocates the money among the participants. Bundled payments also include episode rates, which are budgets designed around a continuum of care.

ISSUES TO WATCH: Look closely at what services are bundled, what triggers a bundle and when do bundled payments end.

Accountable Care Organizations (ACO)

The term is really about organizational structure and includes a wide array of payment arrangements. Most commercial ACOs use some form of bundled payments, others use a form of retrospective payment reconciliation. Payment measures typically include quality of performance, efficiency, and patient satisfaction.

ISSUES TO WATCH: Closely evaluate language around bundled contracts, governance of the ACO, payment appeal rights, and dispute resolution.

Capitation

An actuarially assigned payment to provider per covered person regardless of whether or not that person actually uses healthcare serivces.

ISSUES TO WATCH: If the actuarial predictions for healthcare coverage are too conservative, physicians are at risk for inadequate funding.

ISSUES TO WATCH

12 Recommendations on payment reform

1. Over time, payers should largely eliminate stand-alone fee-for-service payment to medical practices because of its inherent inefficiencies and problematic financial incentives.
2. The transition to an approach based on quality and value should start with the testing of new models of care over a 5-year time period, incorporating them into increasing numbers of practices, with the goal of broad adoption by the end of the decade.
3. Because fee-for-service will remain an important mode of payment into the future, even as the nation shifts toward fixed-payment models, it will be necessary to continue recalibrating fee-for-service payments to encourage behavior that improves quality and cost-effectiveness and penalize behavior that misuses or overuses care.
4. For both Medicare and private insurers, annual updates should be increased for evaluation and management codes, which are currently undervalued. Updates for procedural diagnosis codes should be frozen for a period of 3 years, except for those that are demonstrated to be currently undervalued.
5. Higher payment for facility-based services that can be performed in a lower-cost setting should be eliminated.
6. Fee-for-service contracts should always incorporate quality metrics into the negotiated reimbursement rates.
7. Fee-for-service reimbursement should encourage small practices (those having fewer than five providers) to form virtual relationships and thereby share resources to achieve higher quality care.
8. Fixed payments should initially focus on areas where significant potential exists for cost savings and higher quality, such as care for people with multiple chronic conditions and in-hospital procedures and their follow-up.
9. Measures to safeguard access to high-quality care, assess the adequacy of risk-adjustment indicators, and promote strong physician commitment to patients should be put into place for fixed payment models.
10. The Sustainable Growth Rate (SGR) should be eliminated.
11. Repeal of the SGR should be paid for with cost-savings from the Medicare program as a whole, including both cuts to physician payments and reductions in inappropriate utilization of Medicare services.
12. The Relative Value Scale Update Committee (RUC) should make decision-making more transparent and diversify its membership so that it is more representative of the medical profession as a whole. At the same time, CMS should develop alternative open, evidence-based, and expert processes to validate the data and methods it uses to establish and update relative values.

Source: National Commission on Physician Payment Reform

centives of the participants are aligned with the goals of improved quality and efficiency. Most bundled payment programs today are focused on procedures such as hip and knee replacements. This is primarily because these are relatively delimited conditions and therefore easier to use as a starting point to learn how to manage these new payment and delivery approaches.

Most experts on episode rates and bundled payments agree, however, that the real potential for improved value will be found in chronic care. Episode-based payments and bundled payments will be increasingly important to PCPs and specialists such as cardiologists, endocrinologists, pulmonologists, and allergy and asthma specialists who treat a high volume of chronic care patients.

Bundled payment or episode rates often come with numerous potential contracting pitfalls. The most critical issues for physicians are clarity regarding what services are included in the bundle, what triggers a bundle (usually a service identified by a current procedural terminology or an international classification of diseases code) and when the bundle ends. When the bundle includes disparate providers, such as hospitals and physicians, or physicians with home health agencies and rehabilitation, the contractual concerns include how disputes will be handled, which payment decisions are subject to challenge, and which are not.

ACCOUNTABLE CARE ORGANIZATIONS

Probably the most confusing term used today is "ACO." People use this term to describe a wide range of payment arrangements, yet the term really pertains to organizational structures. The Medicare Shared Savings ACO program has very specific features. Foremost among them is that any entity that chooses to be a Medicare ACO must be able to accept Medicare Part A and Part B payments to the extent that any dollars will be available at the end of the 3 years of the program to pay the participating providers. In the Medicare program, physicians and other participating providers are paid in the ordinary course of business with a reconciliation

➔49

➔46 and payout if savings are available to be shared at the end of 3 years.

Commercial ACOs are quite variable. Most use some form of retrospective payment reconciliation after paying physicians in the ordinary course. Virtually all ACOs entail some form of bundled payment, and measurement of results, in terms of quality, performance, efficiency, and patient satisfaction. The form of payment from the health plan to the provider entity—the ACO itself—can vary from a percent of premium to global capitation, episode of care payments, or payment in the ordinary course with bonuses for meeting targets. Some commercial ACOs encompass all patients insured by the health plan treated by the participating providers. Others use the term ACO to describe a specific service line, bundled payment, or quality performance bonused mechanism.

PCMH can be part of an ACO, as can bundled payments and episode rates. The ACO is the organizational structure with processes deployed in it to enhance quality, improve value and score well. The payer enters into an agreement with the ACO to pay the amount they negotiate.

Below the level of that agreement, however, a web of contractual arrangements must be created when the participants are not part of a single entity. There are contracts with physicians if the ACO is hospital-owned, with hospitals if it is physician-owned, among the hospitals and physicians if it is jointly operated, and with all the other providers rendering the full continuum of care for which the ACO is accountable. Without detailing all of the contractual issues in these arrangements, they include all of the issues associated with bundled payment as well as issues in the governance of the ACO, appeal rights regarding payment issues, and dispute resolution.[1]

CONTRAST WITH CAPITATION

Some people confuse bundled payment with capitation. Capitation is not a bundled payment model. Capitation is an actuarially determined payment per assigned covered person who may or may not use the physician's services or any other services. Primary care capitation typically pays only for the physician services.

The distinction between capitation and any of the new models described above is that capitation pays the same amount regardless of what the patient needs clinically or receives as services. There are broader types of capitation which may include services beyond physician services, such as physical rehabilitation or pharmacy.

The calculation of the capitation amount derives from actuarial principles of insurance. The big risk in capitation is incidence risk. The actuaries determine what the payment rate will be based on historical utilization of resources—whether of stellar or mediocre quality of value. They project these utilization patterns and the associated clinical conditions into the future to determine a dollar amount that will cover these services with some profit.

If the population to whom the insurance plan is sold does not conform with the actuarial assumptions, then physicians accepting capitation are at risk for inadequate funding. This risk increases as the physicians become responsible for the costs of other providers, too. For example, where actuaries calculate the rates based on typical assumptions and the health plan sells its health insurance to the local cigarette manufacturer or primary employer in an area of a cancer cluster, the incidence risk is much higher.

By contrast, well-constructed episode rates consider the services patients need for the defined clinical condition and that defines the budget. This is one of the fundamental principles of the PROMETHEUS Payment® model.[2]

Episode rates expose physicians to medical management risk; in other words, the physicians are financially at risk for managing care within the budget.

There are a variety of concepts and programs being implemented to change the cost and quality of healthcare. Physicians are critical to all of them. But many of these concepts and programs are not well understood by most physicians. Many offer promise, depending on how they are implemented. Physicians should be vigilant about understanding what is available and offered to them. ◘

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Coding Insights

ARE YOU DOCUMENTING SHARED/SPLIT VISITS CORRECTLY?

I am one of several specialist physicians who recently joined a large hospital organization. We use our midlevel providers—physician assistants (PAs) and nurse practitioners (NPs)—extensively in our practice, both in the hospital and in the office.

At the hospital, they are typically the first to see our patients. The physicians see patients during rounding, document that they agree with the midlevels' findings, and sign off on the notes. We bill these visits under the physician's provider identification numbers (PIN). Is this correct?

We use our PAs in a similar fashion in the office. They initiate the visits for new and established patients, document the visits, and write the plans of care. A physician then sees the patient and signs off on the plan of care. Can we bill these visits under the physician's PIN?

Our organization's compliance team has told us that we are not billing these visits appropriately. How should we bill these visits?

Non-physician practitioners (NPPs), such as PAs and NPs, are increasingly being relied on in medical practices and hospitals because it is a good utilization of resources. However, you do need to thoroughly understand the intricacies of incident-to and shared/split billing practices in order to bill these visits appropriately.

While there are some similarities in these two billing scenarios, we will address each individually because there are distinct differences that need to be understood.

Shared/split visits

Simply stated, shared/split visits are Evaluation and Management (E/M) visits that are "shared" or "split" between a physician and an NPP, such as an NP, PA, clinical nurse specialist, or certified nurse-midwife. If the documentation meets the requirements, the visit can be billed under the physician's PIN, as opposed to the NPP's PIN.

Why does it make a difference whether you bill a visit under the physician's PIN versus the NPP's PIN? Medicare allows 100% of the Medicare fee schedule amount for coverable services submitted by a physician. When services are submitted under an NPP's PIN, Medicare allows only a percentage of the physician fee schedule amount. (The percentage is 85% for physician assistants, nurse practitioners, and clinical nurse specialists.) If the documentation does not meet the guidelines, the service would need to be billed under the NPP's PIN.

With varying compensation models for physicians and NPPs, correct billing of these services is important so that salaries (and perhaps bonuses) are administered appropriately.

According to the Centers for Medicare and Medicaid Services (CMS), shared/split visits are applicable for services rendered in the following settings:

- **hospital inpatient or outpatient,**
- **emergency department,**
- **hospital observation,**
- **hospital discharge, and**
- **office or clinic (when "incident-to" requirements are met. A future column will address this issue.)**

Shared/split visits are not allowed:

- **in a skilled nursing facility or nursing facility setting,**
- **for consultation services,**
- **for critical care services,**
- **for procedures, or**
- **in a patient's home or domiciliary site.**

A note regarding consultations: Although Medicare does not

reimburse for consultation services, the guidelines apply to those carriers who do. For Medicare, an initial inpatient or outpatient code should be billed instead of a consultation code, and shared/split guidelines would apply.

Shared/split visits are defined by CMS in IOM Publication 100-04, Chapter 12, Section 30.6.1(B) as an E/M service "shared between a physician and a NPP from the same group practice, and the physician provides any face-to-face portion of the E/M encounter with the patient."

The publication further states that, "A split/shared E/M visit is defined by Medicare Part B payment policy as a medically necessary encounter with a patient where the physician and a qualified NPP each personally perform a substantive portion of an E/M visit face-to-face with the same patient on the same date of service. A substantive portion of an E/M visit involves all or some portion of the history, exam or medical decision making key components of an E/M service."

The service must be within the NPP's scope of practice as defined by the state law where he or she practices, and it must be performed in collaboration with a physician.

So, what are the documentation requirements for a shared/split visit? These are the key elements that must be met:

- **A shared/split visit can only be utilized if the NPP and physician are from the same group practice, including the same specialty.**
- **The NPP and physician must both perform and document their face-to-face encounter with the patient.**
- **The portion of the E/M service performed and documented by both the NPP and physician must be substantive, which includes part or all of the history, exam or medical decision making.**

Case in point

Let's apply these guideline requirements to the example in the reader's question which states, "The physicians see the patient during rounding, document that they agree with the midlevel's findings, and sign off on the note."

In this example, the physician is only documenting that he/she agrees with the findings that the NPP has already documented. The documentation does not show that the physician had face-to-face contact with the patient, or that he/she performed any of the history, exam or medical decision making elements.

The guidelines require that there must be documentation of the face-to-face portion of the E/M encounter between the patient and the physician. The medical record should clearly identify the part(s) of the E/M service that were personally provided by the physician and those that were provided by the NPP.

Note: The physician must personally document his/her involvement in the patient's care and cannot leave his/her documentation of the visit to the NPP.

Medicare carrier clarifications

Check with your local Medicare carrier to find out which specific guidelines have been clarified in more detail regarding shared/split documentation. Wisconsin Physician Services (WPS), for example, gives the following examples, based on the IOM publication, that would not adequately meet the shared/split visit requirements:

- **"I have personally seen and examined the patient independently, reviewed the PAs history, exam and medical decision making and agree with the assessment and plan as written" signed by the physician,**
- **"Patient seen" signed by the physician,**
- **"Seen and examined" signed by the physician,**
- **"Seen and examined and agree with above (or agree with plan)" signed by the physician,**
- **"As above" signed by the physician,**
- **Documentation by the NPP stating "The patient was seen and examined by myself and Dr. X, who agrees with the plan" with a co-sign of the note by Dr. X,**
- **No comment at all by the physician or only a physician signature at the end of the note.**

Commercial payers

Check with your commercial carriers to confirm that they recognize the shared/split visit guidelines, specifically those carriers who credential NPPs. For carriers who do not credential NPPs, the shared/split visit guidelines would not apply, and all NPP visits would need to be billed under the physician's PIN.

In a future article, incident-to guidelines will be addressed that are applicable to physician office visits. ◻

Answers to readers' questions were provided by ***Renee Stantz,*** *a billing and coding consultant for VEI Consulting Services, in Indianapolis, Indiana. Send your coding questions to* ***medec@advanstar.com****.*

Medicare codes coming for telehealth, preventive care

Primary care physicians could be closer to receiving Medicare payment for managed care of chronic illnesses

by **DONNA MARBURY, MS**

HIGHLIGHTS

01 Medicare plans to add codes in 2015 for non-face-to-face visits with patients for chronic disease management for the first time.

02 Other fee schedule changes include modifications to more than 200 misvalued codes, and changes to the Physician Quality Reporting System and Electronic Health Records incentives.

New Medicare codes to pay for non-face-to-face visits for patients could go into effect in 2015. A proposal released by the Centers for Medicare and Medicaid Services (CMS) in July details two G-codes for primary care physicians (PCPs) for wellness and preventive care services and an expansion of telehealth services.

One code would allow PCPs to bill Medicare for regular physician development and revision of plan of care, communication with other health professionals and medical management over 90-day periods for patients with two or more chronic conditions. Patients would have to qualify through either an annual wellness visit or a preventive physical exam.

Another code would expand billable telehealth services to include designated rural areas near urban areas with a shortage of physicians. Transitional care management via telehealth services would also be billable to Medicare.

These Medicare codes are the first for non-face-to-face visits for PCPs. Medicare is taking a big step by placing more value on wellness and preventive services says Rene Y. Quashie, senior counsel in the health and life sciences practice at Epstein Becker & Green, P.C. in Washington D.C.

"ACP EXPECTS TO WORK WITH CMS TO ASSURE THAT NO UNNECESSARY ADMINISTRATIVE BURDENS ARE PLACED ON PHYSICIANS AND THEIR PRACTICES."

MOLLY COOKE, MD, FACP, PRESIDENT OF THE AMERICAN COLLEGE OF PHYSICIANS

"Many policymakers have concluded that (PCPs) will play a critical role of changing how healthcare will be delivered in the future in this country—especially as we transition from a fee-for-service environment to one re-

> IN LIGHT OF THE SGR'S MANDATE THAT CMS SLASH MEDICARE PHYSICIAN PAYMENT BY 24.4%, THESE INCREMENTAL INCREASES DO NOTHING TO SUSTAIN PRIMARY MEDICAL CARE, MUCH LESS BUILD THE PRIMARY CARE PHYSICIAN WORKFORCE."
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> JEFFREY CAIN, MD, FAAFP, PRESIDENT, AMERICAN ACADEMY OF FAMILY PHYSICIANS

warding quality and patient outcomes. This is especially true in the management and treatment of chronic conditions," Quashie says, adding that expanding telehealth eligibility also shows Medicare's progression.

"This is a response to increasing pressure by providers, patient groups, and other stakeholders to improve access to care in certain rural areas. And telehealth is a great way to bridge access," Quashie says.

THE VALUE OF MANAGED CARE

Molly Cooke, MD, FACP, president of the American College of Physicians (ACP), says that the new codes are in step with Medicare's efforts to put more emphasis on complex chronic disease management through primary care.

"It follows the path of the agency's other initiatives for primary care, including the Medicare Shared Savings Program, the Pioneer ACO (accountable care organization) model, the Advance Payment ACO model, the Comprehensive Primary Care Initiative, Medicaid primary care pay parity, and the Medicare Primary Care Incentive Payment Program," she says.

Cooke also says that ACP has been working, through the Current Procedural Terminology Panel and the Relative Value Update Committee (RUC) of the American Medical Association to develop billing codes and relative values that would account for the non-face-to-face care that internists provide to their patients.

"ACP expects to work with CMS to assure that no unnecessary administrative burdens are placed on physicians and their practices," Cooke says.

EQUITABLE PAY

Jeffrey Cain, MD, FAAFP, American Academy of Family Physicians (AAFP) president, says the codes would help create a more equitable payment system for PCPs.

"Such changes demonstrate CMS's intent to support primary care through policies that promote comprehensive and continuous care," Cain says, while also denouncing the Medicare sustainable rate growth (SGR) formula that will reduce the physician payment rate starting in January 2014. Cain adds that the AAFP is preparing comments on the 2014 Medicare Physician Fee Schedule to submit to CMS by the September 6 deadline.

"In light of the SGR's mandate that CMS slash Medicare physician payment by 24.4%, these incremental increases do nothing to sustain primary medical care, much less build the primary care physician workforce," Cain says.

CMS issued a statement asking that Congress intervene and "address the flaws in the SGR that would provide more stability for Medicare beneficiaries and providers while promoting efficient, high quality care."

Cain says that without intervention by Congress, "family physicians once again will be forced to choose between caring for Medicare beneficiaries at a significant financial loss or ending their participation in Medicare."

OTHER FEE SCHEDULE CHANGES

The fee schedule proposal also states changes to be made to the Physician Quality Reporting System, the Medicare Electronic Health Record Incentive program and the Physician Compare tool on the Medicare.gov Web site.

CMS is also continuing to phase in the Value Modifier mandated by the Affordable Care Act. CMS has identified more than 200 misvalued codes. According to the AAFP, those codes add up to a 3% payment increase for evaluation and management services, and a 1% increase for family practitioners.

The final schedule is slated to be released by November.

Doctor's Bag

APP IDENTIFIES PRESCRIPTIONS USING COMPUTER VISION

MedSnap ID uses computer vision technology allowing physicians to use an iPhone to quickly identify an entire set of patient pills and screen them for safety. It allows patients to demonstrate what prescriptions they're taking and quickly generates an accurate list with drug-drug and drug-disease interactions.

With its patent-pending technology and precision Snap Surface, MedSnap ID provides a subscription-based service that identifies prescription medications.

Using an iPhone camera, the app identifies the medications—including generics—by name and strength, and provides detailed clinical information in a professional database. The app can also export reports through print and email.

Additionally, MedSnap ID Enterprise can securely import the MedSnap regimen into a patient's electronic health record (EHR). Its Visual Pill Library has more than 3,000 medications, and user submissions—verified by a quality assurance team—allow it to grow. MedSnap ID is available for iPhones 4S and 5. Poor medication use costs $200 billion each year in the United States, according to a recent IMS Health study.

MedSnap, LLC. (205) 307-6680 | www.medsnap.com

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Surescripts is offering four additional health technology vendors access to its clinical messaging capabilities. Users of Inofile, Greenway, SCI Solutions, and SOAPware will all have access to its messaging product for clinical interoperability. Epic, GE Medical, NewCrop, NextGen, and several other health technology vendors are also connected to the Surescripts network.

Enhanced capabilities will allow providers to share clinical information through a secure and integrated messaging service. The network allows local and national transmissions between peers, practices, and health systems across all technology platforms.

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The HIE integrates patient records and data from multiple sources into a single patient view, providing real-time access to patient information and eHealth applications. The web platform enables a far larger number of physicans to access the Care360 Solution, which can help provide critical care information at the point of care. Technologies allow data sharing between providers managing the same patients, and therefore greater peer collaboration.

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Diminished cerebral glucose metabolism: A key pathology in Alzheimer's disease

More than three decades of research have revealed that diminished cerebral glucose metabolism (DCGM), also known as glucose hypometabolism, is a key underlying pathological change in the Alzheimer's brain.[1] DCGM leaves a large portion of the brain's energy needs unfulfilled and correlates with cell death and cognitive dysfunction.[2] DCGM occurs years before clinical symptoms of cognitive decline become evident.[1] Targeting DCGM represents a promising new therapeutic strategy for patients with Alzheimer's disease (AD).

The brain depends on glucose for cognitive function

The human brain is one of the most metabolically active organs in the body and metabolizes a large amount of glucose to produce adenosine triphosphate (ATP).[1] Despite its high energy demands, the brain is relatively inflexible in its ability to utilize substrates for energy production and relies almost entirely on circulating glucose for its energy needs.[1,2] This dependence on glucose puts the brain at risk if the supply of glucose is interrupted, or if its ability to metabolize glucose becomes defective.[2] If the brain is not able to produce ATP, synapses cannot be maintained and cells cannot function, ultimately leading to impaired cognition.[2]

DCGM is a well-characterized feature of AD

DCGM was an early observation in AD. Studies from almost 30 years ago found a 17%-24% decline in cerebral glucose metabolism in patients with AD, compared with age-matched controls.[3] Numerous imaging studies have since confirmed this observation.[1]

Abnormally low rates of cerebral glucose metabolism are found in a characteristic pattern in the AD brain, particularly in the posterior cingulate, parietal, temporal, and prefrontal cortices. This pattern is reproducible and has even been proposed as a diagnostic tool for AD.[1]

DCGM occurs early in the disease process

In a pivotal study, Reiman and colleagues demonstrated how early the pathology can begin. The study compared cerebral glucose metabolism in patients with probable AD and young adults (mean age 30.7 years) at high genetic risk of AD (APOE4 carriers). The young adult APOE4 carriers showed no signs of cognitive impairment or plaque deposition, yet DCGM was detected in the same areas of the brain as subjects with AD.[4]

DCGM is not exclusive to APOE4 carriers. By the time Alzheimer's has been diagnosed, DCGM occurs across genotypes APOE3/E4, APOE3/E3, and APOE4/E4.[5]

Given that DCGM occurs before other clinical changes occur, it is unlikely to be due to the gross cell loss observed in AD.[2]

Targeting DCGM in AD

Improving memory performance by chronically raising glucose levels has had some success in animal models and humans. However, this approach is impractical and may not address the problem of DCGM, particularly as glucose levels generally remain normal in AD. This has led to the exploration of alternative fuel sources, such as ketones, to help fuel the brain.[2]

Fueling the brain with ketones in neurodegenerative diseases

During times of diminished cerebral glucose metabolism, the brain is able to use ketones as a back-up fuel source. When glucose levels are low, for example when food is scarce, the liver is naturally triggered to generate ketones as a survival mechanism.[1]

In AD, this natural ketone back-up system can be harnessed to address DCGM. Research has shown that exogenously raising ketone levels is neuroprotective *in vitro* and can enhance memory and cognition *in vivo*.[6-8,10] Indeed, ketogenic diets have a long and successful clinical history. However, they can be impractical, particularly in patients with AD.[2]

Safe elevation of ketone levels

Inducing ketosis through the administration of medium-chain triglycerides (MCTs) has produced promising results in AD. MCTs have unique ketogenic properties due to their medium fatty acid chain lengths. Importantly, MCTs are converted to ketones regardless of other macronutrients consumed; therefore, no dietary restrictions are required.[1]

Now, there is a prescription **medical food** available that safely increases the concentration of ketones. Axona® contains MCTs that are converted to ketones in the liver and then transported to the brain to be used as fuel along with glucose.[9]

Fuel memory and cognition by targeting DCGM in AD

In a phase IIb, 90-day clinical trial, Axona enhanced memory and cognition in APOE4(-) patients with mild to moderate AD. Approximately 80% of trial patients took Axona in combination with one or more approved medications for AD. At the end of the trial period, patients continued with their existing medication, but stopped taking Axona. During this time, the significant effects of Axona ceased.[10]

Axona is the only available prescription therapy that addresses diminished cerebral glucose metabolism, an underlying pathology of AD. Current treatments only target symptoms of the disease.[1] Adding Axona to traditional therapies addresses different aspects of AD at the same time and can help make the biggest impact in enhancing memory and cognition.[10]

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For more information on DCGM in Alzheimer's disease, visit **www.dcgm.com**.

Ancillary services: the prescription for a difficult business climate

by **TRICIA KRIZNER,** *contributing author*

HIGHLIGHTS

01 Before adding a new service to your practice, assess the needs of your patient population, and conduct a thorough cost analysis.

02 For an ancillary service to achieve success, it needs to have the right mix of patient interest, ease of access, practice expertise, service, and revenue generation.

Pressed by rising costs, lagging reimbursements, and growing regulatory pressures, many primary care physicians (PCPs) are searching for ways to boost their practice incomes. The method they often try is to offer an ancillary service, such as laboratory or imaging, or selling weight-loss supplements or vitamins.

Adding an ancillary service can help a practice's bottom line, say consultants and practice management experts. But it requires some research and preparation—along with the willingness to spend the money and effort needed to market the service.

The first step is to assess your patient population to determine if there is a need for a particular product or service and how many patients might benefit from it, says Rosemarie Nelson, principal at MGMA Healthcare Consulting Group in Syracuse, New York, and a *Medical Economics* editorial consultant.

Once you estimate the number of potential patients and the fee for the service, you need to factor in the additional costs to your practice, such as hiring more staff or leasing or purchasing equipment.

KNOW THE MARKET'S NEEDS

The most important consideration in extending a practice's scope of services is to be attuned to the needs of the marketplace, says Michael D. Brown, president of Health Care Economics, Inc. in Fishers, Indiana, and a *Medical Economics* editorial consultant.

"You've got to have the right hours, the right doctor combination and the right equipment combination. You've got to be able to accommodate the market as opposed to the market accommodating the doctors," he says. "One of the key criteria of the market today is one-stop shopping. People don't want to drive all over town. They want you to offer everything you can."

The ultimate goal, he says, is to retain established patients and bring new ones in the door. Before you spend one dollar on adding a service, buying equipment, or hiring additional staff, contact your major insurance carriers and ask what they cover, the amount of the typical reimbursement, and what they don't cover.

"I'd never buy any equipment or additional stuff to broaden my scope of services without checking with the carrier first," Brown says.

While imitation is a form of flattery, it's the wrong way to assess an ancillary. What works in one practice or locale doesn't always translate to

another. Do your homework, says Frank Cohen, principal and senior analyst of The Frank Cohen Group in Clearwater, Florida, and a *Medical Economics* editorial consultant.

What they should do is a feasibility study, he adds. "You do some research and find out how the ancillary works, make sure there are no compliance issues, talk to other doctors who have done it and find out what their experience has been. I don't believe you should do anything until you can quantify it," he says.

Physicians also have to feel comfortable with the services they are providing, says Judy Bee, a practice management consultant with Practice Performance Group, in La Jolla, California, and a *Medical Economics* editorial consultant.

"When I ask primary care providers, 'What kinds of things are you comfortable providing?' one of the first things that comes up is laser hair removal, and that can be pretty dangerous," she says. "You can hurt people with it if you're not good at it. What physicians want to do is train a tech and turn him lose with this thing. So I'll say, 'Let's think this through. Are you willing to take the risk?' "

HOMEWORK PAID OFF

Joseph Ravid, MD, of GulfView Medical Institute in Punta Gorda, Florida, did just that. "I did a lot of homework before I invested in anything, especially big-ticket items," he says. "I spoke to a bunch of colleagues who have been in the market here longer than I have, and they were nice enough to share some of their experiences."

He recommends first determining what services you most often farm out. Ravid, along with his office manager, asked, "How much blood are we sending out? How many stress tests? How many skin procedures?" Then they looked at services that don't take much time to attend to but still provide a good return. "That's the niche I concentrated on."

Ravid and two associates operate GulfView, a full-service family practice that offers balance testing, nuclear stress testing, abdominal aorta aneurysm scans, some dermatology procedures, and cryotherapy.

Some of GulfView's ancillary services, such as nuclear stress testing, are provided by outside companies. Representatives come to GulfView twice a month to perform non-urgent cardiac stress tests. They bring all of their own equipment—treadmills, cardiopulmonary resuscitation trays, and intravenous nuclear medications for those who cannot exercise. They are given two rooms to conduct up to eight tests every two weeks. That is all time will allow because the company travels to a different practice every day. Ravid pays them a set fee per patient. Then he charges the patient for the test and medications.

"It is a very nice ancillary income," he says.

Another company comes in to conduct balance testing every two weeks. The representatives also need two rooms. On the days the companies are coming, GulfView doctors will see new patients. Those visits take longer so there isn't a need to turnover the rooms quickly, thus the practice's flow is not interrupted.

➔62

Fattening the bottom line by helping patients lose weight

Ellyn Levine, MD, of the Center for Family and Health in San Diego, California, has found an ancillary service that addresses a need in the community, has benefited 500 patients in four years, and has added six figures of income per year to her practice. She became a health coach for Take Shape For Life (TSFL).

"We have an obesity crisis in America and I truly believe that TSFL and everything about it is what we (physicians) could be doing, what we should be doing, and can make a huge dent if only people know about it," Levine says. "For the majority of medical conditions I see, weight is often the underlying factor. So it's amazing when you treat the origin how everything falls into place. I don't know how the primary care physician can practice medicine without having a true program to help overweight patients."

Levine heard about the program when a few of her colleagues went on it. Their weight loss was so successful that her physician assistant (PA) asked if they could implement the program with their patients. "My colleagues had lost 30 pounds and started putting patients on the program and my whole office just transformed overnight," Levine says.

Initially, Levine wanted her PA to handle the program. "I thought it was just one more thing to add to my plate and I would have to learn something else," she says. "I told my PA, 'Why don't you handle the weight loss part (of the business)?' "

The first patient lost 80 pounds in 5 months. Another lost 60 pounds. "These are patients I'd seen for a long time and they had made many attempts at weight loss," Levine says. "So I put patients on the program and saw the same type of successes. I never in a million years saw this coming."

About 25% of Levine's patients have tried the program. It uses meal replacement as a tool for weight loss, averaging $11 a day for five meals. But it also has a Web site that gives weight loss tips, recipes and tracking, as well as a wide variety of tools focused on keeping the weight off.

ACHIEVING OPTIMAL HEALTH

"It isn't just a weight loss program," Levine says. "It's a health-coaching program that helps people lose weight, feel better and achieve their optimal health."

Levine's job as a health coach is to introduce all of

➔62

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➔60 "I added these services as I saw the need for the community and for the population where I'm at," says Ravid, whose practice is between Tampa and Fort Myers and is made up of 65% Medicare patients.

He recently added a fully functioning lab where he does an entire panel of chemistry. "I very rarely send a drop of blood out unless it is mandated by the patient's insurance carriers," he says.

Adding the lab was expensive, he says. A good lab can cost upward of $250,000, not including the cost of a full-time lab technician to ensure that the blood is being processed expeditiously, which can be another $55,000 and up a year. However, "just by adding the lab alone, I doubled my income."

Medicine is a business, Ravid says. "Not only do you have to be a very good clinician, but in order for you to survive in today's market and separate yourself from everyone else, you definitely have to be a businessperson as well."

➔60 the tools patients would need to keep the weight off, so in transition, as they are adding more calories, they are developing a maintenance plan. They are also urged to begin a tailored exercise program. TSFL expects Levine to support the patients in their goals by spending time teaching and helping them. "The company pays me for that. I get paid $100 a person for every month that they are on the weight loss phase of the program. I get to go beyond the scope of a 15-minute office visit because I'm being compensated. I call patients on weekends and I email them. I'm working one-on-one with them, and I think it's the direction that physicians need to go with their patients," she says.

Levine is not only involved with helping patients. She also promotes TSFL to other physicians, which adds to her compensation. Based on the prevalence of patients being overweight and obese and in need of a weight loss program, physicians can—without a lot of effort—earn $3,000 a month with this program alone, she says.

One physician she told about TSFL is Jeffrey K. Pearson, DO, of Medicine-in-Motion, in San Marcos, California and a *Medical Economics* editorial board member.

"I got pulled into this kicking and screaming," Pearson says. "I started referring patients to Dr. Levine. The trouble was that she is across town and my patients didn't want to travel that far."

He decided to learn about the program so he could keep his patients happy. But before he recommended it to patients, he wanted to give it a try himself. "I dropped 65 pounds in 4 months," he says, "and I've kept it off for a year and a half."

His first step in implementing TSFL was becoming certified as a health coach at a cost of $200.

"I don't charge patients for being their coach. I spend an hour to an hour and a half coaching a patient, and TSFL reimburses me for my time," Pearson says. "Doctors make a very good living at it. But I didn't do this just to make money. I did this because it was really helping people to lose weight. But it turned out that it was a nice extra income."

Both doctors went outside of their comfort zone and took a chance on the program. It has paid off in added income but most importantly in helping patients.

"So it's made medicine fun because it's not just sick care and disease management all of the time," Levine says. "It's truly healthcare. I'm practicing health, nutrition, wellness and fitness, and it's just been incredible."

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Financial Strategies

HOW TO FIND THE BEST BANK FOR YOUR BUCKS

By **DONNA MARBURY, MS**

Whether you need credit for new equipment or want to simplify daily financial tasks, it is important to find a bank that understands the needs of your practice. Below are some of the most important things to consider when choosing a bank.

Security

For physicians, keeping payer financial information safe is a top priority. Because many physicians still receive paper checks, using a lockbox, which transfer practice mail directly to a bank via a P.O. Box, can make handling checks more secure.

"Using lock box services eliminates a very real opportunity for internal theft as the bank immediately deposit the funds as well as scan explanation of benefits and other documents so that they can be reviewed by administrative or billing staff," says Joe Capko, partner at Capko & Company, a medical practice management consulting firm.

Bank fees

Relationships with your bankers are the most important factor for keeping any bank fees low, says W. Henry Walker, president of Farmers & Merchants (F&M) Bank of Long Beach, California.

"This is based on the fact that a long-term relationship may turn out to be more cost effective. With sufficient funds on deposit, physicians can earn credit through account analysis that would offset the cost of the banking services utilized by their practice," he says.

Credit and interest rates

Physicians have unique credit needs for rent and ownership of facilities and capital equipment. Shopping for rates is a luxury many physicians don't have. Walker says that finding the best rates doesn't always mean the best deal.

"Many community banks may find it difficult to be rate competitive, but can offer better service over the term of the loan. For example, many F&M customers find that the relationship they have with their banker turns out to be more cost effective than 25 to 50 basis points," Walker says.

Mobile and Web services

A growing number of financial institutions are offering mobile and Web banking options, but Capko says it is important for physicians to have final approval on all transactions.

MORE RESOURCES

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"For the most part, online apps are geared toward individuals. The day-to-day operations of a medical practice require the systematic processing of many payments, which doesn't lend itself to well to a mobile phone," he says.

Credit unions versus commercial banks

Credit unions tend to offer more personalized service and favorable interest rates. However, finding networked automatic teller machines (ATMs) can be difficult—about 3,000 of the nation's 7,000 credit unions share ATMs.

Commerical banks usually come with other perks, including more ATMs, mobile apps, and 24-hour customer service. But as a customer, you might feel like there is less one-on-one attention.

"A banker who has experience with physicians can offer targeted advice and products custom-built for their practice. This can provide both a competitive advantage as well as an additional layer of financial security," Walker says. "Patients entrust physicians every day to be an expert in their field. The same should be true of your banking relationship."

Out of Office

Living with numbers

Numbers surround us in business and medicine, and we can use them to find life balance

by **TANYA LEE FEKE, MD** *contributing author*

HIGHLIGHTS

01 Numbers—they are all around us, from values on a diagnostic test to return on investment on medical equipment, but they can also help guide our life.

02 The word "numbers" can be a powerful mnemonic device that helps a physician remember to work in the moment (Now), to uncover or make changes in your life (Uncover), to better manage your work and life (Manage), to find Balance, to Engage others, to Remember, and to Share.

I have never met a physician who went to medical school to become a business person. The unfortunate truth, however, is that physicians are put into business-minded situations everyday, whether hospital-employed or in private practice, and many without proper training. Despite the best intentions of medical schools, graduates have little preparation for the fiscal realities of medicine and the real world of numbers.

SO, HOW HIGH CAN YOU COUNT? Formulas and calculations. Hours and minutes. Dollars and cents. From flashing digits on our alarm clocks to odometers counting the mileage of our daily commutes, numbers keep us moving, pushing us to do more in less time, all in the name of productivity. Though this numeric world may be tantalizing for mathematicians and accountants, for the practicing physician those numbers threaten the foundation of what we do:

- How many hours do you work? Does your professional life compromise your home life?
- How many relative value units do you generate per session? Is this above or below preset expectations?
- Did you use the correct International Classification of Diseases, Ninth Revision (ICD-9) code for billing purposes? How will you adapt to ICD-10 when it kicks into gear in 2014?
- Did you use proper Current Procedural

RECALIBRATING THE NUMBERS

Numbers will continue to surround us, if not by intention then by necessity. How we choose to accommodate them will be a testament to how we succeed in this time of medical reform. We need creative thinking to shift our perspectives when we feel the heavy weight of those changes. Let's use this mnemonic device to find perspective in our work and personal lives.

N OW

Learn to work in the moment. Worrying about the full scope of numbers will only distract you from the task at hand. We may live in a multi-tasking world, but it may be best to take it one step at a time.

U NCOVER

If you are finding dissatisfaction in your current role, look within yourself. What are the triggers? When you become proactive instead of reactive, you can make effective change in your life and practice.

M ANAGE

Learn and understand the details of your current business model, including upcoming regulatory changes. Knowing the hows and whys will remove any sense of victimization and add to your sense of empowerment.

B ALANCE

Medicine is a noble profession but it need not take over your life. Making adequate time for your personal life will lead to increasing fulfillment in the long run. Your family and friends will thank you for it.

E NGAGE

When you are with a patient, really be with the patient. Remove clocks from the exam room walls. Do not flip through your electronic health record to see if you are running behind schedule.

R EMEMBER

Bring back the memories of why you chose medicine as a profession every day. Reigniting that spark will drive your sense of purpose.

S HARE

You need not go it alone. Join a community of medical professionals either in the workplace or via social networking. Providers going through similar situations can be an enriching source of information and fresh ideas.

When we recalibrate the numbers, we remind ourselves why we do what we do. That is what we need in today's healthcare reform, a return to the basics. Only then can we make it count.

— Tanya Lee Feke, MD

Terminology codes to bill your office visits? Are you secure from an audit and the possible fines that could result from one?

- **Have you met percentage thresholds for meaningful use? Pay-for-performance criteria? Certification for a Patient-Centered Medical Home? How will they affect your revenue?**

Every aspect of medical care has become consumed in numeric jargon. While it is important to acknowledge these factors—our financial viability depends on them—focusing too much on these matters in the moment threatens to weaken the stronghold of medical practice, the patient-physician relationship. Distracted from the job at hand, many physicians cannot separate the cacophony of numbers from the person sitting before them.

WHEN IT DOESN'T ADD UP

Physicians practice in different specialties but they all share the same goal—helping people. If only that task were as easy as it sounds. Certain business models prevent a physician from doing what he or she feels will most benefit patients. Add to that the reality that some patients refuse services, while others demand what is unnecessary and you have a real quandary.

Faced with these challenges on a regular basis, medical providers can easily become disheartened. Too often, a fistful of minutes allotted to a patient visit evaporates and an opportunity to improve the lives of everyone in the exam room—the patient, his or her family, and the physician—dissolves into nothingness. The sad results oftentimes are burnout, cynicism, job turnover, and early retirement.

I once had a patient, Joe, complain about a bill he received for services rendered. To have someone challenge my work ethic and accuse me of overcharging insulted me to the core. Review of his chart showed that he was a new patient and his chart documented a detailed history—medical, surgical, family, and social histories, along with a review of medical records from his former primary care provider. His

blood pressure was acutely elevated. As a result, medications had been prescribed and a 1-week follow-up arranged. Coding guidelines showed that I had qualified for the level of visit I had billed, but to him this was still excessive.

Reflection led me to realize that Joe had a different set of numbers guiding his expectations. He had no understanding of ICD-9; he was not faced with 99214 or modifier 25s. For him, the cost of the office visit in relation to paying his other bills took center stage, the unpaid time he took off from work to attend the office visit. His personal experience had given him a unique set of priorities. For him, the numbers simply did not add up.

Similar feelings of frustration erupt when physicians interact with insurance companies and other payers. Government regulations and the ever-controversial sustainable growth rate formula have kept us up in arms for years. We are no different than Joe. The numbers do not always meet what we deem to be fair, and that is what ignites the need for healthcare reform.

One of the difficulties in modern medicine is its frequent lack of transparency. Patients do not always realize all we are doing and why we are doing it. Likewise, many providers have not been educated on business models beyond a quick briefing on coding. They are being guided in the direction of accountable care organizations, not necessarily knowing if these organizations will generate long-term success for their practices. Meaningful use and the Patient-Centered Medical Home model are changing the fundamental dynamics of practice, adding to the already demanding numbers crunch. Many providers simply jump through hoops now so they do not risk financial penalty later.

No one can understand the reasons until the process is explained to them. As providers, we need to be more transparent with our patients to improve medical outcomes and patient satisfaction. As professionals, we need to seek information that justifies our business models and exemplifies best practices. As gatekeepers for healthcare in America, we need to be advocates on both ends. Unfortunately, we often feel too rushed and pressured to do just that. We are so exhausted we sometimes feel like we are drowning in the numbers. The distraction leads to more patient encounters that heighten anxiety levels for both providers and patients.

FINDING THE ONE

We are only human. Naturally, there will be times when we are overwhelmed by our patients and the external pressures that we face not only in medicine but in every aspect of our lives. What we need to learn is how to spin those unsavory situations in ways that bring us back to our origins, our altruism.

My inspiration first came to me by way of a 14-year-old girl, a sparkly teenager who bubbled with the kind of energy you wish you could bottle and share with the world. Her name was Jenny. When we met as freshmen in high school, we had no idea her adolescent years would be tarnished by the cruel diagnosis of leukemia 6 months later. While the teenagers around her worried about the latest fashion trends or who would be taking them to junior prom, she struggled through the turmoil of cancer.

> “SHE WAS NOT A NUMBER. SHE WAS *THE* NUMBER, THE ONLY NUMBER THAT MATTERS—ONE OF A KIND.

I watched her bravely face chemotherapy, watched her lose her flowing locks of hair, watched her oncologist support the family through each stage of treatment, and watched her victory into remission after a bone marrow transplant. I still remember her walking the hallways of our high school to show everyone she was back in the game, strutting as if to the Bee Gee's "Staying Alive." Unfortunately, her dream of graduating high school never came to fruition. On December 1, 1992, Jenny passed away.

Many physicians have a story that inspired them to pursue the long years of medical school, the rigors of residency, and beyond. For me, Jenny, provoked that instinct to be more than I thought I could be. She brought that out in people. She was not a number. She was the number, the only number that matters—one of a kind. If I could find a way to focus on the one, to release the other numbers when I was with a patient, I knew I could make a world of difference.

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Perspective

ACA PROVISION OFFERS NO 'GRACE' TO PRACTICES

BY DONNA MARBURY, MS

Starting in January, practices will have the extra burden of collecting on denied claims from patients due to a 90-day grace period provision of the Affordable Care Act (ACA). The Medical Group Management Association (MGMA) says this grace period makes practices more like collection agencies. The association also offers a solution: insurers must notify practices that a patient has entered the grace period during eligibility verification requests.

Here's how it works: insurers must give patients in exchanges 90 days to pay premiums. Insurers will pay any claims made in the first 30 days, and will hold claims in the last 60 days. If the patient hasn't paid premiums for services in the last 60 days, they can be dropped from their plans and must pay the practice full price.

This provision is supposed to help patients who are not used to being in the healthcare system with more time to make payments. The problem is, some patients are unaware of the stipulation, and could end up owing practices a great deal of money.

"If patients don't realize they are in the grace period, they will be financially responsible for a bill much bigger than it needs to be," says Allison Brennan, senior advocacy adviser for MGMA. "Practices are in business to provide care and don't want to be focused on collecting debt."

On July 3, MGMA President Susan Turney, MD, wrote a to the U.S. Department of Health and Human Services (HHS), decrying the 90-day grace period, and calling for insurance companies to provide real-time eligibility verification to practices.

The MGMA, which represents 22,500 members who lead 13,200 medical practices or serve as professional administrators, believes that insurers should have to follow the same Health Insurance Portability and Accountabilty Act (HIPAA) law that requires them to provide patient eligibility information within 20 seconds (or overnight for large requests) to practices.

As of now, insurers are required to tell practices of coverage eligibility within a "practicable" amount of time for exchange patients, according to the Centers for Medicare and Medicaid Services.

Because exchange patients are receiving coverage directly from insurance companies and not from an employer, there should be no wait to know whether their accounts are current. Real-time verification would at least allow practices to inform patients of their status. This could help patients avoid a costly payment, and practices dodge a cumbersome collection process. "One of the key things we want to see is that insurers are required to provide information about the grace period when the practice calls, or requests it electronically. It is already common for a practice to do this to make sure the patient has insurance. Our concerns are that insurers won't provide the information," Brennan says.

The MGMA has yet to receive a response from government officials, according to Brennan. "There has been a lot of focus on ACA implementation, and we are already seeing changes. We hope the HHS revisits this particular issue because it will ease the fears of practitioners and help patients be more aware of their financial situation," Brennan says.

In the meantime, Brennan suggests that small practices consider aligning with a collection agency to handle what may be an influx of unpaid bills. "We also encourage practices to do an eligibility verification request on every patient every time they come in for services," she says.

@ Want to weigh in on the debate about the 90-day grace period provision of the ACA? Write us at medec@advanstar.com. Your comments could be included in the next issue of *Medical Economics*.