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NOVEMBER 25, 2013
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Flat, declining salaries inflate physician worries

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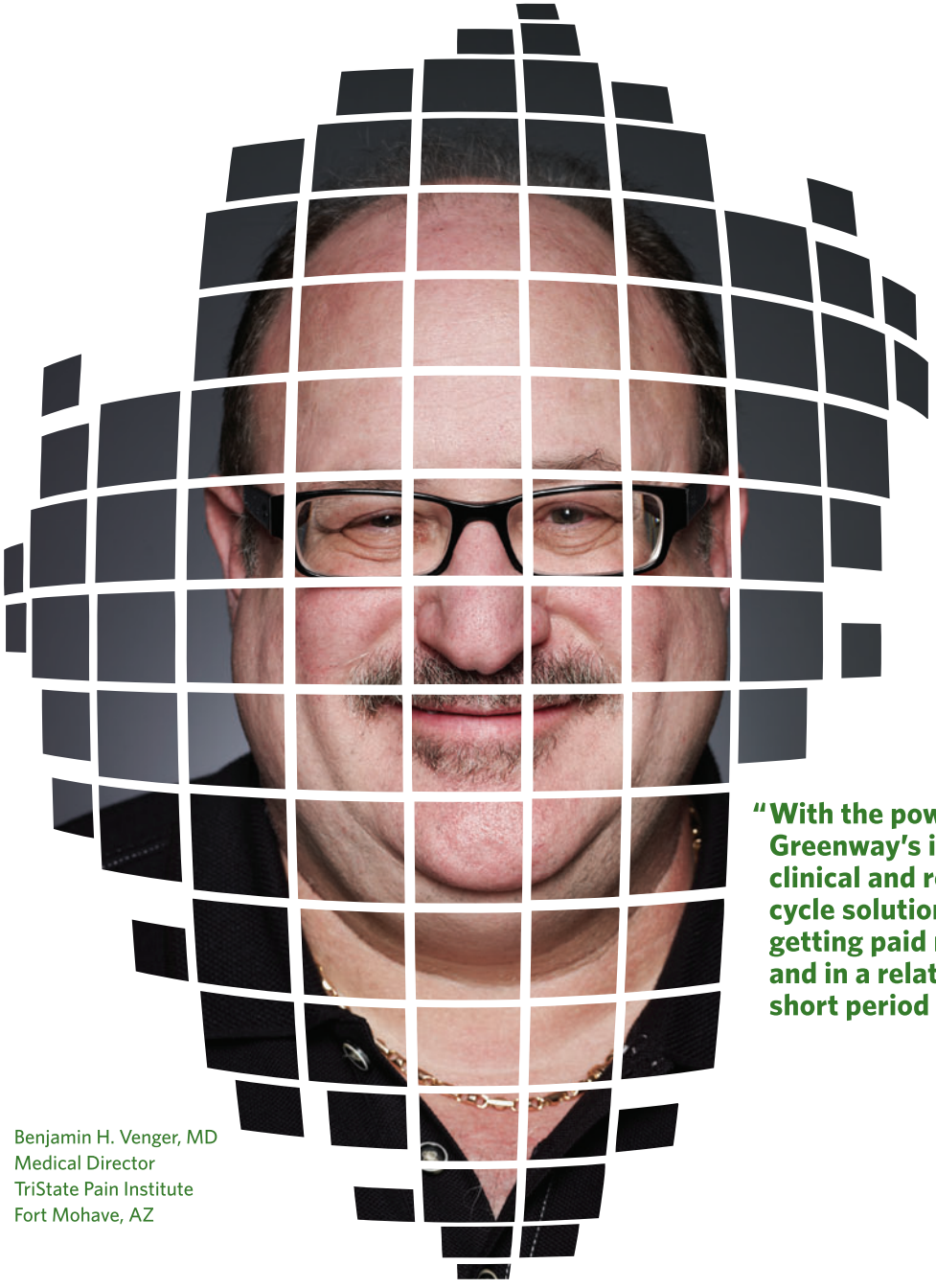

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"Most practices change systems because the software is too difficult to use."

—Derek Kosiorek PRINCIPAL CONSULTANT, MGMA HEALTHCARE CONSULTING GROUP

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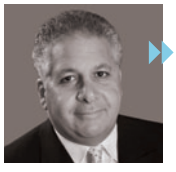

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thoughts from **K.J. LEE, MD, FACS**

NEW PAYMENT MODELS SHOULD REWARD QUALITY

The business side of healthcare, in its current iteration, is broken. There are so many stakeholders with competing economic interests that maintaining a cost/quality/access to care equilibrium is nearly impossible. Specifically, the current payer/provider dynamic is fundamentally flawed and unsustainable.

Beth Thomas Hertz's September 25th article, "Sorting through the new reimbursement models," highlights a variety of new and reinvented payment models while emphasizing some of the most pressing reimbursement issues. Hertz quotes Marci Nielsen for perspective on what should be the guiding principles of healthcare payment reform. Nielsen states, "The broadest goal is to incentivize the right care for the right cost. But it cannot only be cost—the quality has to be there."

Nielsen succinctly sums up the need for appropriate and quality care for all patients, at an appropriate cost. Stripping away some of the unnecessary hurdles in the current payment structure can surely facilitate this goal if the stakeholders can agree on a mutually beneficial system.

Overlooked in Hertz's review of payment types is a hybrid payment model incorporating both pay-for-performance and fee-for-service. There is an allusion to the underpinnings of a hybrid model in the article's quote from Jill Rubin Hummel: "There are some very real barriers to fee-for-service going away entirely, but gradually more compensation will ultimately be value-based, not volume-based, where payments are based on outcomes, quality, and cost."

This salient point acknowledges the economic flaw of the current compensation model, where high-volume patient loads are practically encouraged so as to maximize reimbursement. Unraveling the business interests in the current healthcare payer model requires a multi-modal approach. Healthcare, and its associated compensation models, are not one-size-fits-all propositions.

The current reimbursement structure contains many issues relating to the submission and payment of claims. Many providers feel they need to up-code to maximize revenue or down-code for fear of having a claim denied. Contradictory business goals have twisted this system into a payer versus provider tug-of-war, with patient care sometimes leveraged as a bargaining chip.

Instituting quality metrics is a must to ensure that the patient remains at the center of this equation. This hybrid reimbursement model might be the most viable option for easily modifying the existing payment system while integrating quality care metrics and reducing costs.

Modifying the existing fee-for-service infrastructure by incorporating a performance-based reimbursement metric could benefit all stakeholders. This hybrid reimbursement system would use a two-payment structure. For the first payment all claims would be paid at a rate of, hypothetically, 60% of the maximum allowable fee within 1 week of the date of submission.

The second payment, consisting of the remaining zero to 40% of the claim's total maximum allowable fee, would be paid quarterly, with the payment amount based on the provider's scores on metrics such as outcome measures, complication measures, patient satisfaction, and stewardship of healthcare resources. These performance metrics would be assessed by analyzing a statistically valid sample of the provider's patient encounters taken from the provider's electronic health records.

This hybrid system would remove unnecessary steps, such as payers rejecting claims and providers re-submitting claims, and would lower the operational and administrative costs of claims processing. These changes alone should drastically decrease many of healthcare's operational costs. The second payment would drive quality and appropriateness of care, and measure the doctor's stewardship of the healthcare dollar.

This hybrid model's upfront 60% payment will naturally incentivize providers to be readily accessible for patient care and the subsequent payment would cultivate good stewardship of the healthcare dollar and raise the bar for quality of care. Any meaningful reform of healthcare reimbursement must focus on quality patient care first and foremost, then equitable reimbursement in a rational model.

Changes to the healthcare reimbursement system are needed to prevent financial interests from affecting patient care. Stakeholders on all sides would be well served by reminding themselves that at some point, we are all patients.

ABOUT THE AUTHOR

Lee is associate clinical professor of surgery at Yale University School of Medicine, New Haven, Connecticut.

> Several alternatives exist to the adversarial system that prevails, including early payment, apologizing, workers type of insurance, and health courts. All are humane methods and can be used to reasonably and fairly deal with patients and physicians.
>
> **Edward Volpintesta, MD,** BETHEL, CONNECTICUT

PRIOR AUTHORIZATION ARTICLE WAS INCOMPLETE

Your article on prior authorizations ("Curing the prior authorization headache," October 10, 2013) leaves out a few issues. I completed Drug Addiction Training Act 2000 training years ago. My DEA number was altered to a special number to prove this. The only indication for the buprenorphine I can prescribe is opiate dependency. Since this is a maintenance drug, the people are on it indefinitely.

I write prescriptions confirming that they need it. Now, I get a call from the pharmacy that I need to call for preauthorization. I call and go through the phone tree. Then I get someone demanding the group policy number. I then have to go to the Internet to fill out the form. This requires my calling for an ID number, etc. My DEA number has the X code showing I completed the course. So why do I have to reanswer questions when the prescription has the DEA number confirming the information?

Lastly, no one in your articles commented upon the case *Gibson vs. Medco.* The judge ruled that Dr. Gibson was to be reimbursed for time spent in prior authorizations for medications when the argument was over the economic issues and not patient safety.

When I cite the decision to pharmaceutical companies, I have been told that they do not accept the judge's ruling. I ask if the purpose of the [preauthorization] call is to control costs. When they say yes, I ask if I am paid for my time. When told no, I ask if they are being paid for their time. They say they are. So I say, 'then you want me to work for free to save the pharmaceutical management company money?'

I often get told that I have an attitude problem and am a bad doctor.

Aaron Levine, MD
HOUSTON, TEXAS

WE NEED ALTERNATIVES TO MALPRACTICE SYSTEM

The story on reforming the malpractice system ("Tort reform," August 10, 2013) focused on physicians' fear about undergoing the stress of a malpractice suit.

Whether a suit is baseless, and whether the physician wins or not, waiting on tenterhooks while attorneys argue over the merits of a suit is an ordeal that causes dread in most physicians.

Malpractice suits often take years to resolve. Worrying over how the outcome will affect their reputations and their livelihoods can force some physicians to quit practice. And who would want to be operated on by a surgeon who is disturbed and distracted because he/she is awaiting the settlement of a suit?

Several alternatives exist to the adversarial system, including early payment, apologizing, workers type of insurance, and health courts. All are humane methods and can be used to reasonably and fairly deal with patients and physicians.

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NEW FEDERAL STANDARDS WILL HELP STREAMLINE PAYMENTS

New federal standards required by the Affordable Care Act are expected to help streamline payments to physicians, reports AMA Wire.

The new rules will make it possible for physicians to "automate the time-consuming process of manually matching payments from insurers with claims that have been submitted," reads the AMA Wire report.

"The new rules can benefit physicians by eliminating many mundane and costly manual tasks like depositing checks, while cutting red tape and speeding payments," said American Medical Association President Ardis Dee Hoven, MD, in a news release. "This is a great opportunity for physicians."

The Centers for Medicare and Medicaid Services estimates that about one-third of claim payments are now being transferred electronically. Payers reliance on such electronic transfers is expected to increase.

The new standards begin January 1, 2014.

WILL NEW CARE MODELS SOLVE THE PHYSICIAN SHORTAGE?

New models of primary care delivery could help alleviate the expected shortage of primary care physicians (PCPs), a new study concludes.

The study, published in the November issue of *Health Affairs*, focuses on the Patient-Centered Medical Home (PCMH) and the nurse-managed health center, both of which rely more on nonphysician providers (NPPs) such as nurse practitioners and physician assistants.

Lead researcher David Auerbach and his colleagues begin by forecasting the demand in 2025 for PCPs and NPPs. Then they develop demand forecasts using varying degrees of increased prevalence of PCMHs and nurse-managed centers. They found that increasing the prevalence of these emerging models and increasing panel size of the average PCMH could reduce the PCP shortage from 45,000 PCPs under the status quo to 7,000 PCPs in their best-case forecast.

The authors caution that these forecasts depend on liberalizing scope-of-practice laws and payment methods that reward providers for population management and large panel sizes.

Provider Type	2010		2025	
	Number	Percent of total	Number	Percent of total
Physicians	210,000	71%	216,000	60%
Nurse Practitioners	56,000	19%	103,000	29%
Physician Assistants	30,000	10%	42,000	12%

Source: *Health Affairs*

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OK TO SAY SORRY UNDER NEW PA APOLOGY LAW

A new medical liability law in Pennsylvania will allow physicians to apologize for medical mistakes or other unfavorable patient outcomes without worrying about the threat of a lawsuit.

The law was signed in late October and will protect physician apologies that are made to patients prior to any lawsuits. They generally will not be allowed as evidence against physicians except if the apology is an admission of negligence, fault, or error.

The bill was championed by the American Medical Association (AMA) and the Pennsylvania Medical Society.

"Open communication between patients and healthcare providers is essential to ensuring optimal healthcare outcomes," the AMA wrote in a letter to the Pennsylvania State Senate. "Protecting statements by healthcare providers ... that express sympathy, condolence ... or a general sense of benevolence to a patient after an unanticipated outcome fosters open communication between the healthcare provider and the patient."

At least 38 states have physician apology laws on the books.

SGR reform proposal calls for 10-year pay freeze, new incentive program

A NEW PROPOSAL to reform the broken Sustainable Growth Rate (SGR) formula has emerged from Congress. It calls for a repeal of the SGR, a 10-year payment freeze and a new performance-based incentive program.

The plan calls for freezing payment levels through 2023 and creates a value-based performance (VBP) payment program in 2017. Creation of the VBP also would kill reimbursement penalties under the Physician Quality Reporting System, Value-Based Payment Modifier and Meaningful Use penalties at the end of 2016, according to a discussion draft prepared by the House Ways and Means Committee and the Senate Finance Committee, Democratic and Republican leaders in both committees are preparing the plan, dubbed the "SGR Repeal and Reform Proposal."

The SGR has been a headache for physicians for years. The formula was originally created to help contain the growth in healthcare spending, but instead has called for drastic cuts in physician payments each year, requiring Congress to step in at the last moment and override the cuts. In the last 10 years, Congress has spent almost $150 billion on short-term SGR fixes.

"A decade of short-term 'patches' has frustrated providers, threatened access for beneficiaries, and created a budgetary dilemma from which Congress has struggled to emerge," reads the discussion draft.

Unless Congress acts by January 1, physician payments will be cut by approximately 24.4% in 2014.

Congressional leaders say their proposal would reform the traditional fee-for-service payment model and focus on "value over volume" by encouraging physicians to participate in emerging payment models, including Patient Centered Medical Homes and Accountable Care Organizations.

Groups such as the American Medical Association (AMA), the American College of Physicians (ACP), and the American Academy of Family Physicians (AAFP) all said they were encouraged by the latest proposal.

"The framework released [last month] is an encouraging development, and represents a pivotal step toward stabilizing and improving the Medicare program on behalf of America's seniors and physicians," says Ardis Dee Hoven, MD, the AMA president, in a prepared statement.

"A decade of short-term [SGR] 'patches' has frustrated providers, threatened access for beneficiaries, and created a budgetary dilemma from which Congress has struggled to emerge."

Charles Cutler, MD, FACP, the chairman of the ACP's Board of Regents, says he is confident Congress this year can "achieve a historic bipartisan consensus" on repealing the SGR.

AAFP President Reid Blackwelder, MD, FAAFP, said in a statement that the 10-year payment freeze is "disappointing" but that repealing the SGR will allow everyone to concentrate on "better payments for primary care physicians."

Doctor's Bag

The latest in drugs, devices, technology, and more

ABI SYSTEMS FOR THE DIAGNOSIS OF PERIPHERAL ARTERIAL DISEASE

Summit Doppler Systems offers two different models of fast-efficient ankle-brachial index exam (ABI) systems for the diagnosis of Peripheral Arterial Disease (PAD). The Vista AVS (L500VA) is a full-featured ABI/Segmental system designed to make ABI and other arterial exams faster and easier to conduct, interpret, and document. Clinicians can navigate through the system using an on-screen guide and hand-held controller.

The Vista ABI (L450VA) was designed to accommodate single-level exams and can be ordered with optional PC software and a PPG probe. The Vista ABI does not accommodate segmental exams, however, the Vista AVS was designed for segmental procedures.

These are just two systems out of a complete line from Summit Doppler that perform the ABI Exam to assist in the diagnosis of PAD. Other ABI systems include the LifeDop 300 ABI (L300AC) and LifeDop 250 ABI (L250AC/AB), portable bi-directional Dopplers with compact printers.

The systems are affordable and enable clinicians to perform fast and efficient peripheral arterial exams. In-office demonstrations for both Vista AVS and Vista ABI are available and practices are encouraged to schedule a demonstration.

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ADP ADVANCEDMD OFFERS IPHONE APP FOR DOCTORS

ADP AdvancedMD has released an iPhone app for physician that provides additional mobility and efficiency, allowing users to access files on the go, when desktop or iPad access is not convenient.

The app features secure patient and office messaging, access to patient data, and immediate scheduling, as well as access to appointments and visit type, reason for visit, demographics; and access to patient charts. Physicians can also search patients by name, DOB or phone; view memos, referring providers, insurance, allergies and medications; and e-mail patients.

No data is stored on the device so doctors can maintain HIPAA compliance. The AdvancedMD cloud platform allows for anytime, anywhere access, ideal for commuting, on call, or multiple site physicians. The app is available from the App Store and is free with an AdvancedMD subscription.

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- The effect of BELVIQ on cardiovascular morbidity and mortality has not been established.

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- BELVIQ should not be taken during pregnancy or by women who are planning to become pregnant.

Warnings and Precautions

- BELVIQ is a serotonergic drug. The development of potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions have been reported during use of serotonergic drugs, including, but not limited to, selective serotonin-norepinephrine reuptake inhibitors, and selective serotonin reuptake inhibitors, tricyclic antidepressants, bupropion, triptans, dietary supplements such as St. John's Wort and tryptophan, drugs that impair metabolism of serotonin (including monoamine oxidase inhibitors), dextromethorphan, lithium, tramadol, antipsychotics or other dopamine antagonists,

particularly when used in combination. Patients should be monitored for the emergence of serotonin syndrome symptoms or NMS-like reactions, including agitation, hallucinations, coma, tachycardia, labile blood pressure, hyperthermia, hyperreflexia, incoordination, nausea, vomiting, diarrhea, and muscle rigidity. Treatment with BELVIQ and any concomitant serotonergic or antidopaminergic agents should be discontinued immediately if the above events occur, and supportive symptomatic treatment should be initiated.

- Patients should not take BELVIQ in combination with drugs that have been associated with valvular heart disease (eg, cabergoline). In clinical trials, 2.4% of patients taking BELVIQ and 2.0% of patients taking placebo developed valvular regurgitation: none of these patients were symptomatic. BELVIQ should be used with caution in patients with congestive heart failure (CHF). Patients who develop signs and symptoms of valvular heart disease, including dyspnea, dependent edema, CHF, or a new cardiac murmur, should be evaluated and discontinuation of BELVIQ should be considered.
- Impairment in attention, memory, somnolence, confusion, and fatigue, have been reported in patients taking BELVIQ. Patients should not drive a car or operate heavy machinery until they know how BELVIQ affects them.
- The recommended dose of 10 mg twice daily should not be exceeded, as higher doses may cause euphoria, hallucination, and dissociation. Monitor patients for the development or worsening of depression, suicidal thoughts or behaviors, and/or any changes in mood. Discontinue BELVIQ in patients who develop suicidal thoughts or behaviors.
- Weight loss may increase the risk of hypoglycemia in patients with type 2 diabetes mellitus who are being treated with antidiabetic medications, so measurement of blood sugar levels before and during treatment with BELVIQ is recommended. Decreases in doses of antidiabetic medications or changes in medication regimen should be considered.
- Men who experience priapism should immediately discontinue BELVIQ and seek emergency medical attention. BELVIQ should be used with caution with erectile dysfunction medications. BELVIQ should be used with caution in men who have conditions that might predispose them to priapism (eg, sickle cell anemia, multiple myeloma, or leukemia), or in men with anatomical deformation of the penis (eg, angulation, cavernosal fibrosis, or Peyronie's disease).
- Because BELVIQ may cause a slow heartbeat, it should be used with caution in patients with a history of bradycardia or heart block greater than first degree.
- Consider monitoring for CBC changes, prolactin excess, and pulmonary hypertension.

Most Common Adverse Reactions

- In patients without diabetes: headache (17%), dizziness (9%), fatigue (7%), nausea (8%), dry mouth (5%), and constipation (6%).
- In patients with diabetes: hypoglycemia (29%), headache (15%), back pain (12%), cough (8%), and fatigue (7%).

Nursing Mothers

- BELVIQ should not be taken by women who are nursing.

BELVIQ is a federally controlled substance (CIV) because it may be abused or lead to dependence.

Please see Brief Summary of Prescribing Information and references on adjacent pages.

BELVIQ® (lorcaserin HCl) CIV

BELVIQ®
(lorcaserin HCl) CIV

BRIEF SUMMARY:
For prescribing information, see package insert.

INDICATIONS AND USAGE
BELVIQ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:
- 30 kg/m^2 or greater (obese), or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes)

Limitations of Use:
- The safety and efficacy of coadministration of BELVIQ with other products intended for weight loss including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations have not been established
- The effect of BELVIQ on cardiovascular morbidity and mortality has not been established

DOSAGE AND ADMINISTRATION
The recommended dose of BELVIQ is 10 mg administered orally twice daily. Do not exceed recommended dose. BELVIQ can be taken with or without food. Response to therapy should be evaluated by week 12. If a patient has not lost at least 5% of baseline body weight, discontinue BELVIQ, as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment.

CONTRAINDICATION
- Pregnancy

WARNINGS AND PRECAUTIONS
Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)-like Reactions. BELVIQ is a serotonergic drug. The development of a potentially life-threatening serotonin syndrome or Neuroleptic Malignant Syndrome (NMS)-like reactions have been reported during use of serotonergic drugs, including, but not limited to, selective serotonin-norepinephrine reuptake inhibitors (SNRIs) and selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), bupropion, triptans, dietary supplements such as St. John's Wort and tryptophan, drugs that impair metabolism of serotonin (including monoamine oxidase inhibitors [MAOIs]), dextromethorphan, lithium, tramadol, antipsychotics or other dopamine antagonists, particularly when used in combination.
Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Serotonin syndrome, in its most severe form, can resemble neuroleptic malignant syndrome, which includes hyperthermia, muscle rigidity, autonomic instability with possible rapid fluctuation of vital signs, and mental status changes. Patients should be monitored for the emergence of serotonin syndrome or NMS-like signs and symptoms.
The safety of BELVIQ when coadministered with other serotonergic or antidopaminergic agents, including antipsychotics, or drugs that impair metabolism of serotonin, including MAOIs, has not been systematically evaluated and has not been established.
If concomitant administration of BELVIQ with an agent that affects the serotonergic neurotransmitter system is clinically warranted, extreme caution and careful observation of the patient is advised, particularly during treatment initiation and dose increases. Treatment with BELVIQ and any concomitant serotonergic or antidopaminergic agents, including antipsychotics, should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated.
Valvular Heart Disease. Regurgitant cardiac valvular disease, primarily affecting the mitral and/or aortic valves, has been reported in patients who took serotonergic drugs with 5-HT$_{2B}$ receptor agonist activity. The etiology of the regurgitant valvular disease is thought to be activation of 5-HT$_{2B}$ receptors on cardiac interstitial cells. At therapeutic concentrations, BELVIQ is selective for 5-HT$_{2C}$ receptors as compared to 5-HT$_{2B}$ receptors. In clinical trials of 1-year duration, 2.4% of patients receiving BELVIQ and 2.0% of patients receiving placebo developed echocardiographic criteria for valvular regurgitation at one year (mild or greater aortic regurgitation and/or moderate or greater mitral regurgitation): none of these patients was symptomatic.
BELVIQ has not been studied in patients with congestive heart failure or hemodynamically-significant valvular heart disease. Preliminary data suggest that 5HT$_{2B}$ receptors may be overexpressed in congestive heart failure. Therefore, BELVIQ should be used with caution in patients with congestive heart failure.
BELVIQ should not be used in combination with serotonergic and dopaminergic drugs that are potent 5-HT$_{2B}$ receptor agonists and are known to increase the risk for cardiac valvulopathy (e.g., cabergoline).
Patients who develop signs or symptoms of valvular heart disease, including dyspnea, dependent edema, congestive heart failure, or a new cardiac murmur while being treated with BELVIQ should be evaluated and discontinuation of BELVIQ should be considered.
Cognitive Impairment. In clinical trials of at least one year in duration, impairments in attention and memory were reported adverse reactions associated with 1.9% of patients treated with BELVIQ and 0.5% of patients treated with placebo, and led to discontinuation in 0.3% and 0.1% of these patients, respectively. Other reported adverse reactions associated with BELVIQ in clinical trials included confusion, somnolence, and fatigue.
Since BELVIQ has the potential to impair cognitive function, patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that BELVIQ therapy does not affect them adversely.
Psychiatric Disorders. Events of euphoria, hallucination, and dissociation were seen with BELVIQ at supratherapeutic doses in short-term studies. In clinical trials of at least 1-year in duration, 6 patients (0.2%) treated with BELVIQ developed euphoria, as compared with 1 patient (<0.1%) treated with placebo. Doses of BELVIQ should not exceed 10 mg twice a day.
Some drugs that target the central nervous system have been associated with depression or suicidal ideation. Patients treated with BELVIQ should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue BELVIQ in patients who experience suicidal thoughts or behaviors.
Potential Risk of Hypoglycemia in Patients with Type 2 Diabetes Mellitus on Anti-diabetic Therapy. Weight loss may increase the risk of hypoglycemia in patients with type 2 diabetes mellitus treated with insulin and/or insulin secretagogues (e.g., sulfonylureas); hypoglycemia was observed in clinical trials with BELVIQ. BELVIQ has not been studied in combination with insulin. Measurement of blood glucose levels prior to starting BELVIQ and during BELVIQ treatment is recommended in patients with type 2 diabetes. Decreases in medication doses for anti-diabetic medications which are non-glucose-dependent should be considered to mitigate the risk of hypoglycemia. If a patient develops hypoglycemia after starting BELVIQ, appropriate changes should be made to the anti-diabetic drug regimen.
Priapism. Priapism (painful erections greater than 6 hours in duration) is a potential effect of 5-HT$_{2C}$ receptor agonism.
If not treated promptly, priapism can result in irreversible damage to the erectile tissue. Men who have an erection lasting greater than 4 hours, whether painful or not, should immediately discontinue the drug and seek emergency medical attention.
BELVIQ should be used with caution in men who have conditions that might predispose them to priapism (e.g., sickle cell anemia, multiple myeloma, or leukemia), or in men with anatomical deformation of the penis (e.g., angulation, cavernosal fibrosis, or Peyronie's disease). There is limited experience with the combination of BELVIQ and medication indicated for erectile dysfunction (e.g., phosphodiesterase type 5 inhibitors). Therefore, the combination of BELVIQ and these medications should be used with caution.
Heart Rate Decreases. In clinical trials of at least 1-year in duration, the mean change in heart rate (HR) was -1.2 beats per minute (bpm) in BELVIQ and -0.4 bpm in placebo-treated patients without diabetes and -2.0 beats per minute (bpm) in BELVIQ and -0.4 bpm in placebo-treated patients with type 2 diabetes. The incidence of HR less than 50 bpm was 5.3% in BELVIQ and 3.2% in placebo-treated patients without diabetes and 3.6% in BELVIQ and 2.0% in placebo-treated patients with type 2 diabetes. In the combined population, adverse reactions of bradycardia occurred in 0.3% of BELVIQ and 0.1% of placebo-treated patients. Use with caution in patients with bradycardia or a history of heart block greater than first degree.
Hematological Changes. In clinical trials of at least one year in duration, adverse reactions of decreases in white blood cell count (including leukopenia, lymphopenia, neutropenia, and decreased white cell count) were reported in 0.4% of patients treated with BELVIQ as compared to 0.2% of patients treated with placebo. Adverse reactions of decreases in red blood cell count (including anemia and decreases in hemoglobin and hematocrit) were reported by 1.3% of patients treated with BELVIQ as compared to 1.2% treated with placebo. Consider periodic monitoring of complete blood count during treatment with BELVIQ.
Prolactin Elevation. Lorcaserin moderately elevates prolactin levels. In a subset of placebo-controlled clinical trials of at least one year in duration, elevations of prolactin greater than the upper limit of normal, two times the upper limit of normal, and five times the upper limit of normal, measured both before and 2 hours after dosing, occurred in 6.7%, 1.7%, and 0.1% of BELVIQ-treated patients and 4.8%, 0.8%, and 0.0% of placebo-treated patients, respectively. Prolactin should be measured when symptoms and signs of prolactin excess are suspected (e.g., galactorrhea, gynecomastia). There was one patient treated with BELVIQ who developed a prolactinoma during the trial. The relationship of BELVIQ to the prolactinoma in this patient is unknown.
Pulmonary Hypertension. Certain centrally-acting weight loss agents that act on the serotonin system have been associated with pulmonary hypertension, a rare but lethal disease. Because of the low incidence of this disease, the clinical trial experience with BELVIQ is inadequate to determine if BELVIQ increases the risk for pulmonary hypertension.

ADVERSE REACTIONS
Clinical Trials Experience. In the BELVIQ placebo-controlled clinical database of trials of at least one year in duration, of 6888 patients (3451 BELVIQ vs. 3437 placebo; age range 18-66 years, 79.3% women, 66.6% Caucasians, 19.2% Blacks, 11.8% Hispanics, 2.4% other, 7.4% type 2 diabetics), a total of 1969 patients were exposed to BELVIQ 10 mg twice daily for 1 year and 426 patients were exposed for 2 years.
In clinical trials of at least one year in duration, 8.6% of patients treated with BELVIQ prematurely discontinued treatment due to adverse reactions, compared with 6.7% of placebo-treated patients. The most common adverse reactions leading to discontinuation more often among BELVIQ treated patients than placebo were headache (1.3% vs. 0.8%), depression (0.9% vs. 0.5%) and dizziness (0.7% vs. 0.2%).

Most Common Adverse Reactions

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 rates in the clinical trials of another drug and may not reflect the rates observed in practice.
The most common adverse reactions for non-diabetic patients (greater than 5% and more commonly than placebo) treated with BELVIQ compared to placebo were headache, dizziness, fatigue, nausea, dry mouth, and constipation. The most common adverse reactions for diabetic patients were hypoglycemia, headache, back pain, cough, and fatigue. Adverse reactions that were reported by greater than or equal to 2% of patients and were more frequently reported by patients taking BELVIQ compared to placebo are summarized in Table 1 (non-diabetic subjects) and Table 2 (subjects with type 2 diabetes mellitus).

Table 1. Adverse Reactions Reported by Greater Than or Equal to 2% of BELVIQ Patients and More Commonly than with Placebo in Patients without Diabetes Mellitus

	Number of Patients (%)	
Adverse Reaction	**BELVIQ 10 mg BID N=3195**	**Placebo N=3185**
Gastrointestinal Disorders		
Nausea	264 (8.3)	170 (5.3)
Diarrhea	207 (6.5)	179 (5.6)
Constipation	186 (5.8)	125 (3.9)
Dry mouth	169 (5.3)	74 (2.3)
Vomiting	122 (3.8)	83 (2.6)
General Disorders And Administration Site Conditions		
Fatigue	229 (7.2)	114 (3.6)
Infections And Infestations		
Upper respiratory tract infection	439 (13.7)	391 (12.3)
Nasopharyngitis	414 (13.0)	381 (12.0)
Urinary tract infection	207 (6.5)	171 (5.4)
Musculoskeletal And Connective Tissue Disorders		
Back pain	201 (6.3)	178 (5.6)
Musculoskeletal pain	65 (2.0)	43 (1.4)
Nervous System Disorders		
Headache	537 (16.8)	321 (10.1)
Dizziness	270 (8.5)	122 (3.8)
Respiratory, Thoracic And Mediastinal Disorders		
Cough	136 (4.3)	109 (3.4)
Oropharyngeal pain	111 (3.5)	80 (2.5)
Sinus congestion	93 (2.9)	78 (2.4)
Skin And Subcutaneous Tissue Disorders		
Rash	67 (2.1)	58 (1.8)

Table 2. Adverse Reactions Reported by Greater Than or Equal to 2% of BELVIQ Patients and More Commonly than with Placebo in Patients with Type 2 Diabetes Mellitus

	Number of Patients (%)	
Adverse Reaction	**BELVIQ 10 mg BID N=256**	**Placebo N=252**
Gastrointestinal Disorders		
Nausea	24 (9.4)	20 (7.9)
Toothache	7 (2.7)	0

(Table continues)

Table 2. (cont'd.)

Adverse Reaction	Number of Patients (%)	
	BELVIQ 10 mg BID N=256	Placebo N=252
General Disorders And Administration Site Conditions		
Fatigue	19 (7.4)	10 (4.0)
Peripheral edema	12 (4.7)	6 (2.4)
Immune System Disorders		
Seasonal allergy	8 (3.1)	2 (0.8)
Infections And Infestations		
Nasopharyngitis	29 (11.3)	25 (9.9)
Urinary tract infection	23 (9.0)	15 (6.0)
Gastroenteritis	8 (3.1)	5 (2.0)
Metabolism And Nutrition Disorders		
Hypoglycemia	75 (29.3)	53 (21.0)
Worsening of diabetes mellitus	7 (2.7)	2 (0.8)
Decreased appetite	6 (2.3)	1 (0.4)
Musculoskeletal And Connective Tissue Disorders		
Back pain	30 (11.7)	20 (7.9)
Muscle spasms	12 (4.7)	9 (3.6)
Nervous System Disorders		
Headache	37 (14.5)	18 (7.1)
Dizziness	18 (7.0)	16 (6.3)
Psychiatric Disorders		
Anxiety	9 (3.5)	8 (3.2)
Insomnia	9 (3.5)	6 (2.4)
Stress	7 (2.7)	3 (1.2)
Depression	6 (2.3)	5 (2.0)
Respiratory, Thoracic And Mediastinal Disorders		
Cough	21 (8.2)	11 (4.4)
Vascular Disorders		
Hypertension	13 (5.1)	8 (3.2)

Other Adverse Reactions

Serotonin-associated Adverse Reactions. SSRIs, SNRIs, bupropion, tricyclic antidepressants, and MAOIs were excluded from the BELVIQ trials. Triptans and dextromethorphan were permitted: 2% and 15%, respectively, of patients without diabetes and 1% and 12%, respectively, of patients with type 2 diabetes experienced concomitant use at some point during the trials. Two patients treated with BELVIQ in the clinical program experienced a constellation of symptoms and signs consistent with serotonergic excess, including one patient on concomitant dextromethorphan who reported an event of serotonin syndrome. Some symptoms of possible serotonergic etiology that are included in the criteria for serotonin syndrome were reported by patients treated with BELVIQ and placebo during clinical trials of at least 1 year in duration. In both groups, chills were the most frequent of these events (1.0% vs. 0.2%, respectively), followed by tremor (0.3% vs. 0.2%), confusional state (0.2% vs. less than 0.1%), disorientation (0.1% vs. 0.1%) and hyperhidrosis (0.1% vs. 0.2%). Because serotonin syndrome has a very low incidence, an association between BELVIQ and serotonin syndrome cannot be excluded on the basis of clinical trial results.

Hypoglycemia in Patients with Type 2 Diabetes. In a clinical trial of patients with type 2 diabetes mellitus, hypoglycemia requiring the assistance of another person occurred in 4 (1.6%) of BELVIQ-treated patients and in 1 (0.4%) placebo-treated patient. Of these 4 BELVIQ-treated patients, all were concomitantly using a sulfonylurea (with or without metformin). BELVIQ has not been studied in patients taking insulin. Hypoglycemia defined as blood sugar less than or equal to 65 mg/dL and with symptoms occurred in 19 (7.4%) BELVIQ-treated patients and 16 (6.3%) placebo-treated patients.

Cognitive Impairment. In clinical trials of at least 1-year duration, adverse reactions related to cognitive impairment (e.g., difficulty with concentration/attention, difficulty with memory, and confusion) occurred in 2.3% of patients taking BELVIQ and 0.7% of patients taking placebo.

Psychiatric Disorders. Psychiatric disorders leading to hospitalization or drug withdrawal occurred more frequently in patients treated with BELVIQ (2.2%) as compared to placebo (1.1%) in non-diabetic patients.

Euphoria. In short-term studies with healthy individuals, the incidence of euphoric mood following supratherapeutic doses of BELVIQ (40 and 60 mg) was increased as compared to placebo. In clinical trials of at least 1-year duration in obese patients, euphoria was observed in 0.17% of patients taking BELVIQ and 0.03% taking placebo.

Depression and Suicidality. In trials of at least one year in duration, reports of depression/mood problems occurred in 2.6% BELVIQ-treated vs. 2.4% placebo-treated and suicidal ideation occurred in 0.6% BELVIQ-treated vs. 0.4% placebo-treated patients. 1.3% of BELVIQ patients vs. 0.6% of placebo patients discontinued drug due to depression-, mood-, or suicidal ideation-related events.

Laboratory Abnormalities. *Lymphocyte and Neutrophil Counts.* In clinical trials of at least 1-year duration, lymphocyte counts were below the lower limit of normal in 12.2% of patients taking BELVIQ and 9.0% taking placebo, and neutrophil counts were low in 5.6% and 4.3%, respectively. *Hemoglobin.* In clinical trials of at least 1-year duration, 10.4% of patients taking BELVIQ and 9.3% taking placebo had hemoglobin below the lower limit of normal at some point during the trials.

Prolactin. In clinical trials, elevations of prolactin greater than the upper limit of normal, two times the upper limit of normal, and five times the upper limit of normal, occurred in 6.7%, 1.7%, and 0.1% of BELVIQ-treated patients and 4.8%, 0.8%, and 0.0% of placebo-treated patients, respectively.

Eye Disorders. More patients on BELVIQ reported an eye disorder than patients on placebo in clinical trials of patients without diabetes (4.5% vs. 3.0%) and with type 2 diabetes (6.3% vs. 1.6%). In the population without diabetes, events of blurred vision, dry eye, and visual impairment occurred in BELVIQ-treated patients at an incidence greater than that of placebo. In the population with type 2 diabetes, visual disorders, conjunctival infections, irritations, and inflammations, ocular sensation disorders, and cataract conditions occurred in BELVIQ-treated patients at an incidence greater than placebo.

Echocardiographic Safety Assessments

The possible occurrence of regurgitant cardiac valve disease was prospectively evaluated in 7794 patients in three clinical trials of at least one year in duration, 3451 of whom took BELVIQ 10 mg twice daily. The primary echocardiographic safety parameter was the proportion of patients who developed echocardiographic criteria of mild or greater aortic insufficiency and/or moderate or greater mitral insufficiency from baseline to 1 year. At 1 year, 2.4% of patients who received BELVIQ and 2.0% of patients who received placebo developed valvular regurgitation. The relative risk for valvulopathy with BELVIQ is summarized in Table 3. BELVIQ was not studied in patients with congestive heart failure or hemodynamically-significant valvular heart disease.

Table 3. Incidence of FDA-Defined Valvulopathy at Week 52 by Treatment Group[1]

	Study 1		Study 2		Study 3	
	BELVIQ N=1278	Placebo N=1191	BELVIQ N=1208	Placebo N=1153	BELVIQ N=210	Placebo N=209
FDA-defined Valvulopathy, n (%)	34 (2.7)	28 (2.4)	24 (2.0)	23 (2.0)	6 (2.9)	1 (0.5)
Relative Risk (95% CI)	1.13 (0.69, 1.85)		1.00 (0.57, 1.75)		5.97 (0.73, 49.17)	
Pooled RR (95% CI)	**1.16 (0.81, 1.67)**					

[1] Patients without valvulopathy at baseline who received study medication and had a post-baseline echocardiogram; ITT-intention-to-treat; LOCF-last observation carried forward.

DRUG INTERACTIONS

Use with Other Agents that Affect Serotonin Pathways. Based on the mechanism of action of BELVIQ and the theoretical potential for serotonin syndrome, use with extreme caution in combination with other drugs that may affect the serotonergic neurotransmitter systems, including, but not limited to, triptans, monoamine oxidase inhibitors (MAOIs, including linezolid, an antibiotic which is a reversible non-selective MAOI), selective serotonin reuptake inhibitors (SSRIs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), dextromethorphan, tricyclic antidepressants (TCAs), bupropion, lithium, tramadol, tryptophan, and St. John's Wort.

Cytochrome P450 (2D6) substrates. Use caution when administering BELVIQ together with drugs that are CYP 2D6 substrates, as BELVIQ can increase exposure of these drugs.

USE IN SPECIFIC POPULATIONS

Pregnancy. Pregnancy Category X.

Risk Summary. BELVIQ is contraindicated during pregnancy, because weight loss offers no potential benefit to a pregnant woman and may result in fetal harm. Maternal exposure to lorcaserin in late pregnancy in rats resulted in lower body weight in offspring which persisted to adulthood. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard of maternal weight loss to the fetus.

Clinical Considerations. A minimum weight gain, and no weight loss, is currently recommended for all pregnant women, including those who are already overweight or obese, due to the obligatory weight gain that occurs in maternal tissues during pregnancy.

Animal Data. Reproduction studies were performed in pregnant rats and rabbits that were administered lorcaserin during the period of embryofetal organogenesis. Plasma exposures up to 44 and 19 times human exposure in rats and rabbits, respectively, did not reveal evidence of teratogenicity or embryolethality with lorcaserin hydrochloride.

In a pre- and postnatal development study, maternal rats were dosed from gestation through post-natal day 21 at 5, 15, and 50mg/kg lorcaserin; pups were indirectly exposed in utero and throughout lactation. The highest dose (~44 times human exposure) resulted in stillborns and lower pup viability. All doses lowered pup body weight similarly at birth which persisted to adulthood; however, no developmental abnormalities were observed and reproductive performance was not affected at any dose.

Nursing Mothers. It is not known whether BELVIQ is excreted in human milk. Because many drugs are excreted in human milk, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use. The safety and effectiveness of BELVIQ in pediatric patients below the age of 18 have not been established and the use of BELVIQ is not recommended in pediatric patients.

Geriatric Use. In the BELVIQ clinical trials, a total of 135 (2.5%) of the patients were 65 years of age and older. Clinical studies of BELVIQ did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

Since elderly patients have a higher incidence of renal impairment, use of BELVIQ in the elderly should be made on the basis of renal function. Elderly patients with normal renal function should require no dose adjustment.

Renal Impairment. No dose adjustment of BELVIQ is required in patients with mild renal impairment. Use BELVIQ with caution in patients with moderate renal impairment. Use of BELVIQ in patients with severe renal impairment or end stage renal disease is not recommended.

Hepatic Impairment. Dose adjustment is not required for patients with mild hepatic impairment (Child-Pugh score 5-6) to moderate hepatic impairment (Child-Pugh score 7-9). The effect of severe hepatic impairment on lorcaserin was not evaluated. Use lorcaserin with caution in patients with severe hepatic impairment.

DRUG ABUSE AND DEPENDENCE

Controlled Substance. BELVIQ is listed in Schedule IV of the Controlled Substances Act.

Abuse. In a human abuse potential study in recreational drug abusers, supratherapeutic oral doses of lorcaserin (40 and 60 mg) produced up to two- to six-fold increases on measures of "High", "Good Drug Effects", "Hallucinations" and "Sedation" compared to placebo. These responses were similar to those produced by oral administration of the positive control drugs, zolpidem (15 and 30 mg) and ketamine (100 mg). In this study, the incidence of the adverse reaction of euphoria following lorcaserin administration (40 and 60 mg; 19%) is similar to the incidence following zolpidem administration (13-16%), but less than the incidence following ketamine administration (50%). The duration of euphoria following lorcaserin administration persisted longer (> 9 hours) than that following zolpidem (1.5 hours) or ketamine (2.5 hours) administration.

Overall, in short-term studies with healthy individuals, the rate of euphoria following oral administration of lorcaserin was 16% following 40 mg (n = 11 of 70) and 19% following 60 mg (n = 6 of 31). However, in clinical studies with obese patients with durations of 4 weeks to 2 years, the incidence of euphoria and hallucinations following oral doses of lorcaserin up to 40 mg was low (< 1.0%).

Dependence. There are no data from well-conducted animal or human studies that evaluate whether lorcaserin can induce physical dependence, as evidenced by a withdrawal syndrome. However, the ability of lorcaserin to produce hallucinations, euphoria, and positive subjective responses at supratherapeutic doses suggests that lorcaserin may produce psychic dependence.

OVERDOSAGE

No experience with overdose of BELVIQ is available. In clinical studies that used doses that were higher than the recommended dose, the most frequent adverse reactions associated with BELVIQ were headache, nausea, abdominal discomfort, and dizziness. Single 40- and 60-mg doses of BELVIQ caused euphoria, altered mood, and hallucination in some subjects. Treatment of overdose should consist of BELVIQ discontinuation and general supportive measures in the management of overdosage. BELVIQ is not eliminated to a therapeutically significant degree by hemodialysis.

References: 1. BELVIQ [package insert]. Woodcliff Lake, NJ: Eisai Inc; 2012. **2.** Thomsen WJ, Grottick AJ, Menzaghi F, et al. Lorcaserin, a novel selective human 5-hydroxytryptamine$_{2C}$ agonist: in vitro and in vivo pharmacological characterization. *J Pharmacol Exp Ther.* 2008;325(2):577-587.

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2013 Continuing Study

Flat, declining salaries inflate physician worries over payments, red tape

by **DANIEL R. VERDON** *Group Content Director*

Most primary care physicians love their work, but they are clearly frustrated about their income and the increasing compliance challenges associated with payers and government initiatives, according to results from the 85th annual *Medical Economics* 2013 Exclusive Continuing Study, which collected responses from physicians about their professional life.

ALTHOUGH THE INCOME DATA show slight gains for internal medicine and declines for physicians with an ownership stake in practice and family medicine, nearly 33% of those physicians surveyed are moonlighting in secondary roles as a way to boost their earnings.

Also, consider that the majority of the 4,934 responding physicians fear the impact of declining reimbursements and note that frustrations with their practice have less to do with patient visits, and a lot more to do with hassles associated with payers, prior authorizations, and government red tape. These sentiments are so strong that they are actually changing attitudes about the profession. When asked about the future of practice, one physician simply stated: "Sometimes, the grass is greener."

Nearly 45% of internists responding to this survey said that if they could go back in time, they would change either their specialty or their career. The same sentiment was expressed by 43% of the family physicians who responded.

In this Special Report, *Medical Economics*

REALITY CHECK

Excerpts of comments submitted by physicians to *Medical Economics* in gathering data for this report.

"In spite of its imperfections, a career in family medicine has great rewards. I just hope it stays that way."

"Still love the practice of medicine, because I do it on my terms."

"Family medicine is all guts, no glory."

"We can still change the world."

"Family practice carries the responsibilities of providing most of the care, yet the reimbursements are the lowest."

Mean salary comparison for both employed physicians and practice owners

	2012 Median income = $188,000		
	2011	2012	Difference
Family practice/general practice	$198,000	$195,000	-2%
Internal medicine	$206,000	$208,000	+1%
Pediatrics	$184,000	$195,000	+6%
Cardiology	$383,000	$381,000	-0.5%
Hospitalists	$248,000	$246,000	-0.8%
Emergency/acute care	$242,000	$229,000	-5%
Psychiatry	$151,000	$190,000	+21%
OB/GYN	$257,000	$263,000	+2%
Dermatology	$368,000	$368,000	0
Ophthalmology	$296,000	$281,000	-5%
Urology	$355,000	$388,000	+9%

Source: 2013 *Medical Economics* Physicians Earnings Survey

showcases the results of its 2013 Physician Earnings Survey and takes a closer look at compensation trends, secondary incomes, malpractice, technology frustrations, work/life balance, and attitudes about the future of healthcare.

Here are the most frequently cited professional concerns:

- Fees and reimbursement (68%)
- Burden of paperwork (56%)
- Healthcare reform (54%)
- Value of primary care vs. specialty care and use of midlevels (43%)
- Third-party interference (43%)
- Malpractice/tort reform (39%)
- Doctor shortage (29%)
- EHRs (28%)
- Accountable care organizations (17%)

Some of the top themes emerging from the data set include:

FEAR AND UNCERTAINTY

As healthcare remains in the throes of rapid change as it relates to insured patient populations, volume and reimbursement during reforms from the Affordable Care Act (ACA), nearly 84% of the physicians surveyed told *Medical Economics* that the financial state of practice compared to 1 year ago is either worse or the same. Only 15% of those respondents on average say the economic conditions have improved.

PAYER PERSPECTIVES

Insurance coverage was investigated from two perspectives, percentage of patients covered by public or private payers, and the percentage of revenues derived from each. About 44% of surveyed physicians' patients have private health plans, representing about 47% of revenue. Medicare accounts for about 23% of patients and about 22% of revenue; Medicaid represents about 20%

HIGHLIGHTS

01 Fees/reimbursements, paperwork burden and healthcare reform rank as the top 3 professional concerns for physicians.

02 Nearly half of practice revenue is generated by private health plans.

"Family medicine services pay so little that I have no time for vacation, time away from my office, and often no money to pay overdue bills. We are required to cram multiple patients into our day just to make ends meet, which reduces the quality of care."

"Still enjoy the patient interaction, and diagnostic challenge."

"It's too much regulation, paperwork, compliance, insurance, and not enough patient time. Also, the reimbursement inequity is glaring."

"Primary care is not valued in the United States. Priority is given for population and chronic disease management. No financial incentive for time and commitment."

of patients and 17% of revenue. Private pay or uninsured accounts for 8% and 6% of patients and 9% and 4.5% of revenue, respectively.

PRODUCTIVITY

While most physicians are still posting an average of 50 hours per week in the practice, numbers of patients seen have remained consistent in primary care. The ACA may be a game changer, though. In fact, ACA provisions, increased patient populations, and a renewed vigor to reduce healthcare costs in the United States likely will force physicians to work more efficiently. (See story on p. 32.)

OWNERSHIP TRENDS

So, who is going to purchase your practice? This survey asked those without an ownership stake whether they wanted one. Interestingly, physicians in smaller practices had more of an interest in an ownership position than physicians in large practices. Just as interesting, those physicians seeing more patients each week may be more likely to seek an ownership position.

FRUSTRATED BY TECHNOLOGY

The vast majority of primary care physicians use electronic health records (EHRs). Still, a significant minority of physicians are balking at going digital. Also, the survey examines costs related to EHR implementation and use. (See story on p. 42.)

MALPRACTICE PREMIUMS

Most primary care practices are seeing malpractice premiums hold steady or decline, but the ACA could reverse the trend. (See story on p. 38.)

@ MORE ONLINE!

To see more details about this study and access more of the results, go to

medicaleconomics.com/salarysurvey

ABOUT THE SURVEY

The 2013 Exclusive Physician Earnings Survey was part of the 85th annual Continuing Study conducted by *Medical Economics*. The survey sample consisted of all 104,570 physicians in Advanstar Communications' database of doctors with working email addresses. This database was compiled from the circulations (print and digital) of publications produced by Advanstar including *Medical Economics, Contemporary Pediatrics, Contemporary Ob/Gyn, Cosmetic Surgery Times, Dermatology Times, Ophthalmology Times,* and *Urology Times*.

Data collection took place via the Internet in June. Readex Research broadcast initial email requests to all sample members, inviting them to participate in the survey by visiting the access-controlled website hosted by Readex.

A total of 4,934 responses were received. Qualifying for the final tabulation were the 4,604 respondents who indicated that they are actively practicing (that is, not retired) and that their primary field of practice is not academic/research or a field other than the 15 listed on the survey. From these, 4,200 respondents were randomly selected for the final tabulation.

Percentages are subject to a margin of error of ±1.5% at the 95% confidence level. Percentages calculated on smaller tabulation bases—for example, primary field or age—are subject to more statistical variability.

WHO PARTICIPATED

The survey found that, overall, practicing physicians are highly experienced. Nearly 84% of the participants have been in practice more than 10 years, including nearly half (57%) who have been in practice for more than 20 years. Correspondingly, 67% are aged more than 50 years, including 34% who are at least 60 years old. Only 3% are aged fewer than 35 years. The median respondent has 24 years of experience and is 56 years old.

Two-thirds of responding physicians are male (66%), and one-third are female (33%). Representation of women increases substantially among younger age cohorts: 40 to 49 (46% female), 35 to 39 (49%), and under 35 (62%).

The respondent base offer wide national representation. When asked in which state they primarily practice, the highest response came from physicians in the South (35%), with about equal proportions saying Northeast (21%), Midwest (19%), and West (21%). By individual state, the greatest representation came from California (10%), New York (8%), Texas (8%), and Florida (6%).

By community type, about half of participating physicians are located in suburban areas (52%). About one-third are in either urban communities (27%) or the inner city (8%). About one in eight are located in rural areas (12%).

Half of the physician respondents have an ownership interest in their practices.

Thirty percent are in solo practice. Among those in group practices, the most common ownership group size is three to 10 physicians (26%). Sixteen percent are in groups of 11 to 50, and 13% are with groups of more than 50 physicians.

Most participating physicians are in single-specialty practices (73%). This proportion remains about the same across all fields of practice. Highest percentages are among those in dermatology (85%) and plastic surgery (84%).

"Cognitive services will never be compensated as well as procedural services."

"Dealings with third-party payers have destroyed the patient-doctor bond… The new attitude is do whatever is covered, and the ones determining whether or not you are doing the right thing are desk jockeys that only know numbers."

"The yearly (SGR) threat of a 30% cut overnight, would bankrupt me overnight. Expenses only go up."

"Doctors are squeezed between legal risk, required paperwork, and increasing overhead. The goal of patient care and time with patients is lost."

Physician owners take a 6% pay cut in 2012; other incomes relatively flat, survey says

by **DANIEL R. VERDON,** *Group Content Director*

Physician practice owners took a pay cut last year, according to the results of the 85th exclusive Medical Economics Continuing Study, an annual survey that examines physician earnings.

Average incomes for physicians with an ownership stake in practice dropped nearly 6% to $244,000 in 2012 from $260,000 in 2011, according to the data. The mean incomes for employed physicians (including some specialties) climbed to $216,000 this year, up from $211,000 last year (2% increase).

While internal medicine posted a slight increase over last, those gains were not experienced by family physician who noted a 2% decline overall (Table, p. 23). The most significant income gains were noted for pediatrics, urologists, psychiatrists, and gynecologists. Conversely, declines were posted by physicians working in emergency and acute care, ophthalmologists, hospitalists, and cardiologists.

Financial state of progress

	2010	2011	2012
Better than a year ago	14%	16%	15%
About the same	43%	44%	47%
Worse than a year ago	39%	37%	37%
No answer	4%	3%	1%

Source: 2013 Exclusive Physician Earnings Survey

Some of the other survey results include:

- Male physicians made significantly more on average (34%) than female physicians regardless of whether they were employed in a group practice or maintained an ownership position within the practice.
- For employed physicians, the annual mean income for female physicians was $179,000 and their male colleagues brought in $240,000. For those physicians with an ownership interest in practice, female physicians earned $195,000 compared to $263,000 for male respondents.
- As might be expected, numbers of patient visits had a significant impact on annual income for physicians. In fact, those physicians seeing fewer than 25 patients a week made $158,000 while those seeing 150-174 patients a week pulled down $287,000 a year.
- The survey denotes some regional differences in income (Table, p. 31), but not substantially as might be expected based on factors like cost of living, cost of care, reimbursement rates, etc.
- One-third of physicians gained income from secondary sources. The average amount for all physicians was $53,900 with a median of $20,000.
- The three most common sources of secondary incomes included hospitals, healthcare consulting and conducting clinical trials.
- Men were more likely than women to gain income from secondary sources (36% compared to 27%, respectively).
- Working more than 50 hours a week doesn't always translate into proportionately higher wages for physicians. According to the data, median incomes for those physicians working 51-60 hours a week hovered around $213,000 ($83.50 per hour, based on 51 hours a week for 50 weeks). For physicians working 61-70 hours a week, the total median rose 11% ($25,000 a year) to $238,000 ($78 per hour, based on 61 hours per week over 50 weeks). Those physicians working 71-80 hours a week increased incomes to $263,000 at a rate of $74 per hour (71 hours a week for 50 weeks). Interestingly enough, incomes plateaued for those physicians working more than 80 hours a week and declined for those working 90 or more a week. ■

➔ 30

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To access more of these results, go to

medicaleconomics.com/salarysurvey

How much do physicians earn?

Field	Average salary	Median salary
Family practice / General physician	$195,000	$188,000
Internal medicine	$208,000	$188,000
pediatrics	$195,000	$163,000
cardiology	$381,000	$363,000
gastroenterology	$297,000	$250,000
hospitalists	$246,000	$238,000
emergency / acute care	$229,000	$213,000
psychiatry	$190,000	$188,000
OB/GYN	$263,000	$238,000
dermatology	$368,000	$313,000
ophthalmology	$281,000	$263,000
surgery	$374,000	$338,000
urology	$388,000	$363,000
plastic surgery	$345,000	$288,000
neurology / neurosurgery	$253,000	$238,000
All physicians	$231,000	$188,000

Source: 2013 Exclusive Physician Earnings Survey

Earnings by Gender

MEN

Median: 2012 Earnings: **$213,000** Median age: **58**

	Under $120,000	$120,000 – $149,999	$150,000 – $174,999	$175,000 – $199,999	$200,000 – $249,999	$250,000 – $299,999	$300,000 – $349,999	$350,000 – $399,999	$400,000 or more
2009	15%	10%	11%	11%	17%	10%	8%	5%	13%
2010	17%	10%	9%	10%	16%	10%	9%	5%	14%
2011	15%	8%	11%	9%	16%	12%	8%	5%	15%
2012	15%	9%	8%	10%	17%	11%	9%	6%	14%

WOMEN

Median: 2012 Earnings: **$163,000** Median age: **50**

2009	32%	16%	14%	10%	12%	5%	4%	3%	2%
2010	30%	16%	12%	10%	12%	6%	6%	2%	4%
2011	28%	16%	13%	9%	13%	7%	6%	2%	6%
2012	26%	16%	13%	11%	13%	8%	5%	3%	4%

Source: 2013 Exclusive Physician Earnings Survey

What Primary Care Physicians Earn: A 5-year Review

FAMILY/GENERAL PHYSICIANS

2012 Median income = **$188,000**

	Under $120,000	$120,000 – $149,999	$150,000 – $174,999	$175,000 – $199,999	$200,000 – $249,999	$250,000 – $299,999	$300,000 – $349,999	$350,000 – $399,999	$400,000 or more
2007	31%	18%	12%	9%	12%	9%	4%	2%	3%
2008	29%	13%	11%	11%	19%	7%	4%	2%	4%
2009	24%	18%	16%	12%	13%	7%	3%	2%	2%
2010	24%	17%	15%	13%	15%	5%	5%	2%	4%
2011	20%	12%	16%	12%	15%	9%	4%	2%	5%
2012	21%	13%	13%	14%	18%	7%	6%	2%	4%

INTERNAL MEDICINE PHYSICIANS

2012 Median income = **$188,000**

2007	22%	19%	12%	10%	17%	9%	4%	2%	3%
2008	28%	13%	10%	16%	15%	5%	4%	1%	4%
2009	21%	12%	20%	14%	13%	6%	12%	8%	13%
2010	21%	13%	12%	15%	16%	7%	6%	4%	3%
2011	17%	13%	13%	12%	17%	11%	6%	3%	6%
2012	18%	10%	10%	12%	17%	11%	6%	4%	6%

OB/GYNs

2012 Median income = **$238,000**

2007	20%	8%	6%	5%	15%	14%	10%	6%	16%
2008	21%	4%	3%	9%	18%	12%	12%	8%	13%
2009	19%	6%	8%	9%	21%	13%	10%	6%	12%
2010	19%	8%	5%	7%	16%	13%	13%	6%	13%
2011	16%	6%	7%	8%	17%	13%	10%	6%	14%
2012	15%	7%	7%	7%	13%	15%	11%	7%	15%

PEDIATRICIANS

2012 Median income = **$163,000**

2007	23%	15%	11%	12%	16%	9%	6%	4%	4%
2008	24%	11%	13%	9%	18%	7%	8%	6%	4%
2009	23%	17%	13%	12%	15%	8%	5%	2%	3%
2010	27%	18%	12%	11%	15%	7%	4%	2%	4%
2011	25%	17%	15%	9%	14%	7%	5%	2%	6%
2012	22%	17%	12%	12%	14%	7%	7%	2%	5%

Source: 2013 Exclusive Physician Earnings Survey

Earnings by Community

INNER CITY

2012 Median income = $188,000

	Under $120,000	$120,000 – $149,999	$150,000 – $174,999	$175,000 – $199,999	$200,000 – $249,999	$250,000 – $299,999	$300,000 – $349,999	$350,000 – $399,999	$400,000 or more
2008	26%	4%	8%	11%	10%	11%	7%	6%	17%
2009	25%	14%	15%	9%	14%	8%	4%	2%	6%
2010	28%	14%	12%	10%	11%	9%	6%	4%	5%
2011	27%	14%	10%	10%	12%	9%	4%	5%	9%
2012	21%	15%	9%	10%	13%	11%	9%	2%	7%

URBAN

2012 Median income = $188,000

2008	24%	8%	5%	9%	18%	9%	8%	5%	16%
2009	21%	12%	11%	11%	14%	8%	7%	4%	11%
2010	22%	11%	9%	9%	14%	9%	8%	5%	12%
2011	19%	12%	12%	9%	15%	10%	7%	4%	11%
2012	19%	11%	11%	11%	15%	8%	8%	5%	9%

SUBURBAN

2012 Median income = $213,000

2008	22%	8%	8%	10%	16%	8%	9%	6%	14%
2009	19%	11%	11%	10%	16%	8%	8%	4%	10%
2010	20%	12%	9%	10%	15%	9%	7%	4%	11%
2011	20%	10%	11%	9%	15%	9%	7%	4%	13%
2012	18%	11%	9%	10%	15%	10%	8%	4%	12%

RURAL

2012 Median income = $213,000

2008	20%	13%	10%	7%	17%	10%	7%	4%	12%
2009	20%	12%	12%	11%	20%	8%	8%	3%	9%
2010	18%	13%	12%	12%	18%	9%	7%	3%	7%
2011	16%	11%	11%	10%	18%	12%	7%	3%	10%
2012	13%	9%	12%	12%	18%	12%	8%	5%	9%

Source: 2013 Exclusive Physician Earnings Survey

Earnings by Region

NORTHEAST

2012 Median income = $188,000

	Under $120,000	$120,000 – $149,999	$150,000 – $174,999	$175,000 – $199,999	$200,000 – $249,999	$250,000 – $299,999	$300,000 – $349,999	$350,000 – $399,999	$400,000 or more
2008	26%	9%	8%	10%	15%	7%	8%	4%	14%
2009	21%	11%	12%	11%	15%	6%	7%	5%	10%
2010	23%	13%	10%	10%	13%	8%	8%	5%	10%
2011	19%	13%	13%	10%	13%	9%	6%	3%	12%
2012	20%	14%	9%	10%	14%	8%	8%	4%	11%

MIDWEST

2012 Median income = $213,000

2008	19%	11%	8%	9%	16%	10%	9%	6%	12%
2009	16%	11%	12%	11%	17%	9%	9%	3%	9%
2010	18%	12%	12%	9%	17%	11%	6%	3%	11%
2011	17%	10%	10%	8%	18%	12%	8%	5%	11%
2012	17%	10%	10%	10%	18%	12%	8%	4%	10%

SOUTH

2012 Median income = $188,000

2008	20%	8%	8%	10%	17%	8%	8%	5%	16%
2009	19%	12%	12%	9%	15%	10%	7%	4%	9%
2010	20%	12%	9%	11%	16%	7%	8%	3%	10%
2011	18%	11%	12%	9%	14%	10%	7%	4%	12%
2012	17%	11%	10%	11%	14%	11%	8%	5%	11%

WEST

2012 Median income = $188,000

2008	22%	8%	6%	8%	17%	10%	8%	5%	16%
2009	23%	13%	10%	12%	15%	7%	7%	3%	8%
2010	23%	12%	9%	10%	16%	9%	7%	5%	10%
2011	20%	10%	11%	11%	14%	11%	5%	4%	12%
2012	18%	11%	11%	11%	16%	9%	8%	3%	11%

Source: 2013 Exclusive Physician Earnings Survey

Productivity in primary care is geared for a revival

Though some physicians are facing a decrease in patient volume, experts say the boom is coming

by **DONNA MARBURY, MS** *Content Specialist*

HIGHLIGHTS

01 Young doctors saw fewer patients and worked more hours last year.

02 Urban physicians are reporting that they worked the same amount of hours, while seeing more patients in 2012.

03 Paperwork and added technology mandates have affected productivity, especially with solo practitioners.

Though visits to primary care physicians (PCPs) have slumped compared with previous years, experts say that productivity in the primary care field is ready for resurgence in the next few years. The 85th annual *Medical Economics* 2013 Physician Profile Study found that the average doctor worked 50 hours a week in 2012, while 27% worked 40 hours or fewer per week.

Median hours per week remained unchanged from 2011 to 2012 for family/general practitioners at 50 hours, though visits per week increased slightly from 98 in 2011 to 99 in 2012.

Internists worked fewer median hours—54 hours per week in 2011 compared with 52 in 2012. They also reported seeing fewer patients, going from 98 per week in 2011 to 93 a week in 2012.

Both groups of primary care professionals have yet to recoup their patient load from 2009, when family/general practitioners reported seeing 102 patients a week while working 51 hours, and internists saw 101 patients while working 54 hours a week.

Enhancing PCP productivity will be important because millions of patients are expected to flood the healthcare system in the next few years due to the Affordable Care Act (ACA), Medicare expansion, and an aging Baby Boomer population, while practitioners continue to feel added practice management pressures such as more documentation and prior authorization.

YOUNG PHYSICIANS WORKING HARD TO KEEP UP

Younger doctors are working more hours per week compared with earlier years. In 2012, doctors younger than 35 reported working 59 hours week, compared with working about 56 hours a week the previous year. Those doctors also report seeing significantly fewer patients. In 2012, doctors under 35 saw 81 patients a week, compared with 83 patients a week in 2011.

"Longer hours and fewer patient encounters in the younger band of physicians might be explained by a couple things. First, younger physicians haven't yet mastered the means of efficiency that often come from hard experience," says Gray Tuttle Jr., CHBC, principal healthcare adviser with The Rehmann Group in Lansing, Michigan and a *Medical Economics* editorial consultant. "Next, could more of [these physicians] be under hospital employment models? I see fewer encounters in that setting than independent, private practice."

Though some older doctors aren't seeing much change in the hours they have worked over the past few years, they too are seeing fewer patients a week. Doctors ages 50 to 54

→35

Productivity by region – overall

	MEDIAN HOURS PER WEEK						MEAN VISITS PER WEEK					
	2007	2008	2009	2010	2011	2012	2007	2008	2009	2010	2011	2012
Northeast*	46	46	52	50	50	49	94	92	96	93	91	90
South	46	46	52	51	50	51	106	97	101	99	99	98
Midwest	46	46	51	52	51	51	87	95	95	91	93	92
West	56	46	50	49	49	49	100	88	88	85	89	89

*Called East in 2007 to 2009 survey

Source: 2013 Exclusive Physician Earnings Survey

Productivity by community – overall

	MEDIAN HOURS PER WEEK						MEAN VISITS PER WEEK					
	2007	2008	2009	2010	2011	2012	2007	2008	2009	2010	2011	2012
Inner city	46	46	52	51	50	50	68	72	95	92	93	85
Urban	46	46	52	51	50	50	87	87	88	88	87	89
Suburban	46	46	51	50	49	49	106	97	98	95	98	96
Rural	56	46	52	53	52	52	106	98	104	99	99	96

Source: 2013 Exclusive Physician Earnings Survey

➔32 reported seeing 99 patients a week in 2012, compared with more than 100 patients a week in the three previous years.

Even doctors a little older, ages 55 to 59, reported seeing 96 patients a week in 2012, compared with 101 patients a week in 2011. That trend is reversed in older doctors, as doctors 60 to 64 saw slightly more patients in 2012 (97) compared with 2011 (95). Doctors closest to retirement—ages 65 and older—saw 79 patients a week in 2012, more than they have in the past four years.

"Older doctors shorten their work day or week because they don't have debt and they do have retirement money, which is exactly what younger doctors need to establish," Tuttle says.

PATIENT INCREASES PREDICTED IN ALL COMMUNITIES

Rural, inner city, and suburban physicians are working the same amount of hours, while seeing slightly fewer patients.

Rural physicians reported working 52 hours a week for the past two years, while seeing 96 patients a week in 2012, compared with seeing 99 patients a week in 2011.

Inner-city doctors saw the fewest patients in 2012 (85 patients in 2012 versus 93 patients in 2011). They reported working 50 hours a week in 2011 and 2012.

MORE HOURS DON'T MEAN MORE DOLLARS

DOCTORS WHO work more than 60 hours a week don't necessarily contribute more money to their practices. Only 5% of doctors who worked 61-70 hours, and only 9% of those worked more than 90 hours a week contributed between $350,000 to $399,999 last year.

Overall in 2012, 18% of physicians reported that they contributed more than $250,000 to the practice they have an ownership interest in.

It's no surprise that doctors who worked the fewest hours contributed less money to their practices bottom line.

According to the survey, 23% of doctors who worked less than 30 hours a week contributed less than $100,000 to their practice. Forty-four percent of doctors who made less than $60,000 last year reported contributing less than $100,000 to their practice.

Productivity by gender – overall

	MEDIAN HOURS PER WEEK						MEAN VISITS PER WEEK					
	2007	2008	2009	2010	2011	2012	2007	2008	2009	2010	2011	2012
Men	56	46	53	52	51	52	100	102	100	98	100	99
Women	46	46	47	47	47	46	87	78	86	84	82	82

Source: 2013 Exclusive Physician Earnings Survey

Productivity by age – overall

	MEDIAN HOURS PER WEEK					MEAN VISITS PER WEEK				
	2008	2009	2010	2011	2012	2008	2009	2010	2011	2012
Younger than 30	46	61	57	52	71	56	82	82	84	75
30 to 34	46	52	49	49	47	87	86	88	83	87
35 to 39	46	50	51	48	49	88	93	90	93	94
40 to 44	46	52	50	50	51	97	96	95	95	93
45 to 49	56	51	52	52	51	97	102	97	98	98
50 to 54	56	54	53	53	53	97	102	100	103	99
55 to 59	46	54	53	52	52	103	101	98	101	96
60 to 64	46	50	49	50	51	97	96	94	95	97
65 and older	36	43	43	42	43	72	73	76	77	79

Source: 2013 Exclusive Physician Earnings Survey

Patients visits – by speciality

	MEAN NUMBER OF PATIENTS SEEN IN LAST FULL WORKWEEK								
	Less than 25	25 to 49	50 to 74	75 to 99	100 to 124	125 to 149	150 to 174	175 to 199	200 or more
Family/ general	5%	11%	16%	26%	17%	10%	5%	3%	5%
Internists	6%	16%	20%	21%	15%	10%	3%	2%	6%

Source: 2013 Exclusive Physician Earnings Survey

Urban doctors were the only ones who reported seeing more patients. In 2012, doctors in urban communities reported working 50 hours a week, and saw 89 patients a week in 2012 compared with 87 patients a week in 2011.

In the next few years, doctors from all communities will see an increase in patients, according to Judy Bee, a healthcare consultant in La Jolla, California, and *Medical Economics* editorial consultant.

"It depends on the socio-economics of the practice, but I think all practices will start seeing people who haven't had coverage before," Bee says. "It might be a culture shock. If your practice currently sees a high volume of patients with no insurance, you might see a groundswell. But geography has nothing to do with it."

DOCUMENTATION'S DRAIN ON PRODUCTIVITY

Time management in a physician's office is more than just patients divided by hours. Other factors, including increased paperwork and integrating technology into practice management, also eat away at a physician's productivity.

Anita Sabharwal, MD, a 10-year solo practitioner from Peoria, Illinois, says that her hours have remained steady from 2011 to 2012, and her patient volume may have dipped slightly over the past year. However, the biggest drains on her time are the bureaucratic functions of her job—and she thinks it will only get worse.

Median hours worked per week – by speciality

	2006	2007	2008	2009	2010	2011	2012
Family/general	50/45*	46/46*	46	51	50	50	50
Internists	50	56	46	54	53	54	52

* family and general physician hours tabulated seperately these years

Source: 2013 Exclusive Physician Earnings Survey

Mean patient visits per week – by speciality

	2006	2007	2008	2009	2010	2011	2012
Family/general	100/80*	112/81*	107	102	96	98	99
Internists	98	94	97	101	92	98	93

* family and general physician hours tabulated seperately these years

Source: 2013 Exclusive Physician Earnings Survey

"The time spent on documentation and prior authorizations has certainly increased this year," Sabharwal says. "The ACA will certainly increase the work load and need for more documentation. Productivity at the practice was better prior to the electronic health records, as documentation was more relevant and easier."

Sabharwal says she is worried that the costs and time involved in implementing Meaningful Use 2 (MU2) will also eat away at the time she needs to run an efficient practice.

"MU2 next year will be more demanding and expensive for a solo practitioner. I have been delaying the patient portal purchase for last several months because of the cost," she says, adding that the increased documentation coupled with lower reimbursements have caused her to expand her business in ways besides adding more patients and hours.

"The reimbursements have not improved for last several years and the only reason I have been able to stay independent is because of the ancillary services I offer," Sabharwal says.

HOW PRODUCTIVITY WILL CHANGE IN THE NEXT FEW YEARS

PCPs should start prepping for an increase in patients, in spite of the current numbers, practice management experts say.

"Some say there will be a rushing demand for primary care physicians. Physicians will have to either learn to be more efficient or work longer hours," Tuttle says. "The first challenge is to not add more hours in the week. The last resort is extended hours. One benefit of the ACA, PCPs will be able to see more patients with insurance, so it should be a boon for them."

Tuttle points to the rise in urgent care and retail clinics as one reason why patient visits have remained constant in primary care. According to RAND Health, Americans made almost 6 million visits to retail clinics in 2009, the same point that patient visits began slumping in primary care.

"Urgent cares are positioned nicely, but they are threats to PCPs. Many practices are happy for patients to go to urgent care, but that's money they could capture for themselves," Tuttle says.

Ultimately, Bee says that though no one can predict what the actual growth will be, physicians should start thinking of ways to incorporate non-physician practitioners in their practices and to anticipate and solicit new patients. She says that a shift toward practice models incorporating midlevel providers such as nurse practitioners and physician assistants will be one way that PCPs will be able to accommodate more patients without increasing hours.

"If a doctor wants to grow [by] a finite number of patients, he [or she] has to decide how to use midlevel providers," Bee says. "There's a drastic shortage of doctors, and an acute need. It makes all the sense in the world."

Competition driving malpractice premiums down

Doctors benefit from more companies entering the malpractice market, but the Affordable Care Act could end the slide

by **JEFFREY BENDIX, MA** *Senior Editor*

HIGHLIGHTS

01 Family/general practitioners saw their medical malpractice premiums hold steady in 2012, while premiums for internists were down slightly.

02 More insurance carriers have begun offering malpractice coverage or expanded their coverage regions in recent years, which has helped keep premiums down.

Medical malpractice premiums continue to hold steady or decline for primary care physicians (PCPs), helped by more insurance carriers entering the field and the ongoing consolidation of primary care practices.

Medical Economics' 2013 Exclusive Malpractice Survey found that median (midpoint) annual premiums for family/general practitioners in 2012 were $11,900, the same as 2011. Internal medicine practitioners saw their premiums decline by 0.7%, from $12,900 to $12,800. Since 2009, median annual premiums for family/general physicians have dropped by 5.8%, and premiums for internal medicine practitioners have come down by 11.7%.

Overall, 58% of family/general practitioners and 62% of internists reported an increase or no change in their premiums, while 10% of family practitioners and 11% of internists reported a decrease. The remainder either did not know or didn't respond. The median amount of reported increases among family practitioners was $980, while the median reported increase for internists was $1,200.

Data for the survey—part of the 85th Continuing Study conducted by *Medical Economics*—was collected from physicians in June via the Internet. Fifteen percent of survey respondents said their malpractice premiums went up in 2012, 41% said they remained the same, and 10% reported a decrease. The remaining 35% either didn't know or didn't answer.

Among family practitioners, the median reported increase and decrease in premiums were $980 and $890, respectively. For internists, the reported amounts were $1,200 and $780.

SWITCHING CARRIERS, MANAGING RISK

For Jeffrey Kagan, MD, an internist in Newington, Connecticut, and *Medical Economics* editorial board member, the drop in premiums has been dramatic. His practice—which consists of himself, another physician, and a nurse practitioner—has seen its premiums go from $144,000 in 2007 to $81,000 in 2012 to $44,000 in 2013.

The past year's decrease was mostly due to switching coverage from CMIC to Coverys, a move that came about when the practice joined an accountable care organization.

Beyond that, Kagan says, his practice has been taking steps to lower their risk profile, such as deciding not to take the certification course required to prescribe buprenorphine and naloxone, (a drug used to treat opioid dependence), so as not to attract opioid addicts.

"We view them as a potentially high risk for mal-

➔40

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Median annual premiums by geographic region

	2007	2008	2009	2010	2011	2012
Northeast	$17,500	$17,500	$19,900	$20,100	$18,500	$18,100
South	$12,500	$12,500	$14,600	$13,600	$12,800	$12,600
Midwest	$17,500	$12,500	$16,400	$14,500	$14,700	$14,200
West	$12,500	$12,500	$14,000	$13,600	$14,300	$12,800

Median annual premiums by age

	2007	2008	2009	2010	2011	2012
Under 30	$17,500	$12,500	$10,000	$7,500	$1,500	N/A
30 to 34	$12,500	$12,500	$12,800	$11,200	$13,300	$12,500
35 to 39	$12,500	$12,500	$14,400	$14,400	$13,400	$13,200
40 to 44	$17,500	$17,500	$17,400	$15,500	$14,000	$14,500
45 to 49	$17,500	$17,500	$18,200	$16,700	$15,500	$14,400
50 to 54	$17,500	$17,500	$16,500	$15,700	$14,400	$14,400
55 to 59	$17,500	$12,500	$15,700	$15,200	$14,000	$14,000
60 to 64	$17,500	$12,500	$15,500	$14,100	$14,900	$13,900
65 and over	$12,500	$12,500	$13,300	$12,200	$12,900	$12,600

Median annual premiums by years in practice

	2007	2008	2009	2010	2011	2012
2 or fewer	$12,500	$10,000	$13,600	$10,000	$14,200	$15,000
3 to 5	$12,500	$12,500	$14,100	$14,300	$13,900	$15,600
6 to 10	$17,500	$12,500	$17,000	$15,900	$13,700	$12,900
11 to 20	$17,500	$17,500	$17,800	$16,500	$14,500	$14,500
21 to 30	$17,500	$17,500	$15,900	$14,900	$14,700	$14,200
more than 30	$17,500	$12,500	$13,600	$12,900	$13,100	$12,900

Median annual premiums by practice size

	2007	2008	2009	2010	2011	2012
Solo	$17,500	$12,500	$14,500	$13,600	$13,400	$12,900
Expense sharing	$35,000	$17,500	$15,000	$14,700	$14,900	$13,800
2 physicians	$17,500	$17,500	$17,800	$15,900	$14,600	$13,900
3 to 10 physicians	$17,500	$17,500	$17,400	$17,200	$15,600	$16,000
11 to 25 physicians	$12,500	$17,500	$16,900	$18,000	$13,500	$14,700
26 to 50 physicians	$17,500	$17,500	$15,900	$16,900	$13,000	$15,000
More than 50 physicians	$12,500	$17,500	$14,100	$13,800	$14,100	$14,300

Source: 2013 Exclusive Physician Earnings Survey

➔38 practice," he says. The practice has also been more closely monitoring patients who have recently been discharged from a hospital.

Kagan says his practice may also be benefitting from Connecticut's "Certificate of Merit" law. Passed in 2005, the law requires that a malpractice suit be reviewed by a physician in the same specialty and obtain a Certificate of Merit before being allowed to move forward.

SMALL PRACTICES SEE BIGGEST DECLINES

Survey results were broken down among several categories, including geographic region, type of community, physician age, number of years in practice, number of hours worked per week, and number of patient visits.

In general, smaller practices were the most likely to experience declines. For example, median premiums for practices with fewer than 25 patient visits per week saw an 18% drop in their annual premiums, from $10,000 to $8,200.

Similarly, the three smallest categories as measured by number of physicians in the practice (solo, expense sharing, and two physicians) all had declines in their median premium amounts. By contrast, the four largest categories (three to 10 physicians, 11 to 25, 26 to 50, and more than 50) saw increases.

At a median premium amount of $18,100, doctors in the Northeast continued to pay the most for malpractice coverage, followed by the Midwest $14,200), West ($12,800), and South ($12,400). Premiums in all four regions were down from 2011, however.

PCPs practicing in the inner city saw their malpractice premiums jump by nearly 11% to $16,300 (following a 19% decline the previous year). PCPs with urban, suburban, or rural practices had declines of 4.8%, 4.1%, and 6.9%, respectively.

COMPETITION GROWING AMONG CARRIERS

Rob Francis, MBA, chief operating officer for The Doctors Company, a medical malpractice insurance provider based in Napa, California, attributes the downward trend in the malpractice market to

a flurry of state laws enacted a decade ago aimed at discouraging malpractice lawsuits.

More recently, he says, carriers that once served only one or two states or one part of the country have been expanding into new regions, while companies that did not previously offer medical malpractice coverage are starting to do so.

"Companies are seeing that the physicians are consolidating into larger groups or joining with hospital systems, and in order to maintain market share there's a lot more competition for these accounts, which pushes prices down," Francis says. The Doctors Company's rates were down 4% in 2012 from the previous year, Francis adds, and have fallen by 33% since 2005.

Francis notes that primary care doctors benefit from having a lower risk profile than specialists such as cardiologists or obstetricians. "Their malpractice premium rates are going to reflect that," he says.

Looking ahead, however, Francis says the Affordable Care Act, with its encouragement of bundled payment models, has the potential to slow or even reverse the downward trend in malpractice rates. "We think those more managed care-like payment structures will lead to some renewed liability claims of economically motivated care versus care that's strictly for the benefit of the patient," he says.

"When those kinds of allegations are made they tend to inflame juries and drive up award amounts," Francis adds. "We saw it happen during the managed care movement of the 1990s, and we believe it will happen again."

@ MORE ONLINE!

To view a debate on the impact of medical malpractice lawsuits on the healthcare system go to

http://bit.ly/1hjflBA

Median annual premiums for primary care physicians

	2007	2008	2009	2010	2011	2012
FP/GP	$12,500	$12,500	$12,600	$12,100	$11,900	$11,900
Internal medicine	$12,500	$12,500	$14,500	$13,100	$12,900	$12,800

Median annual premiums by type of community

	2007	2008	2009	2010	2011	2012
Inner city	$12,500	$12,500	$15,000	$18,200	$14,700	$16,300
Urban	$17,500	$17,500	$15,300	$14,500	$14,500	$13,800
Suburban	$17,500	$17,500	$16,500	$15,400	$14,500	$13,900
Rural	$12,500	$12,500	$14,800	$13,000	$12,900	$12,000

Median annual premiums by hours worked

	2007	2008	2009	2010	2011	2012
30 or fewer	$12,500	$7,500	$10,000	$8,600	$8,400	$9,200
31 to 40	$12,500	$12,500	$13,400	$12,200	$12,300	$12,100
41 to 50	$12,500	$12,500	$14,100	$13,900	$13,100	$12,400
51 to 60	$17,500	$17,500	$17,300	$17,100	$15,300	$14,900
61 to 70	$17,500	$17,500	$22,800	$17,800	$17,700	$16,300
71 to 80	$35,000	$25,000	$24,000	$26,400	$23,200	$18,800
81 to 90	$25,000	$35,000	$20,000	$21,400	$19,100	$19,300
More than 90	$35,000	$17,500	$27,300	$22,000	$20,000	$29,000

Median annual premiums by patient visits

	2007	2008	2009	2010	2011	2012
Fewer than 25	$12,500	$7,500	$10,400	$9,000	$10,000	$8,200
25 to 49	$17,500	$12,500	$14,100	$12,500	$12,800	$12,900
50 to 74	$17,500	$12,500	$16,700	$14,900	$12,700	$13,600
75 to 99	$12,500	$17,500	$16,200	$15,100	$ 9,200	$14,300
100 to 124	$17,500	$17,500	$16,800	$15,300	$13,000	$13,800
125 to 149	$17,500	$17,500	$14,700	$15,600	$ 9,800	$15,200
150 to 174	$25,000	$12,500	$18,600	$16,700	$10,000	$14,800
175 to 199	$17,500	$15,000	$17,500	$17,500	$16,200	$15,000
200 or more	$25,000	$17,500	$17,400	$16,400	$10,500	$15,400

Source: 2013 Exclusive Physician Earnings Survey

EHR holdouts: Why some physicians refuse to plug in

Most primary care physicians use electronic health records, but others say they are opting out for good

by **CHRIS MAZZOLINI, MS** *Content Manager*

HIGHLIGHTS

01 Older physicians in smaller, lower income practices are less likely to use EHRs because of issues associated with cost, training, and technical support.

02 Physicians who do not adopt EHRs and meet meaningful use will face reimbursement penalties starting in 2015, but some physicians say the lower income will hurt their practice less than installing an EHR system.

Nearly 79% of primary care physicians (PCPs) are using electronic health record (EHR) systems, an 8% rise when compared to the previous year. At the same time, a growing minority of PCPs say they will never use EHR at their practice, despite losing out on incentive payments and facing future reimbursement penalties. *Medical Economics* 2013 Continuing Survey helps explain why they resist.

MORE PCPS are using EHRs than ever before, and that growth is expected to continue as the government's meaningful use incentive period moves into its second phase next year.

But the survey results also show that the number of EHR holdouts is growing. Nearly half of the PCPs surveyed who do not have an EHR system told *Medical Economics* they have no plans to ever use EHR at their practice, 10% more than last year. For the purposes of the survey, PCPs include family practice and internal medicine physicians.

In 2011, 27% of surveyed PCPs said they did not have an EHR system at their practice. In this year's survey, that number dropped to 20%.

But the number of PCPs without EHR systems who said they did not plan to purchase a system rose in 2012 to 48%, from 32% the year before. And it's not just PCPs who are holding out. The survey data for all physician specialties follows the same trend. Last year, about 34% of all physicians without an EHR said they had no plans to get one. This year that number rose to 46%.

WHO ARE THE EHR HOLDOUTS?

Going without an EHR system means foregoing meaningful ➔43

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*Data on file. Based on NBRx data sourced from IMS NPA Market Dynamics Database, weekly data through 9/20/13.

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

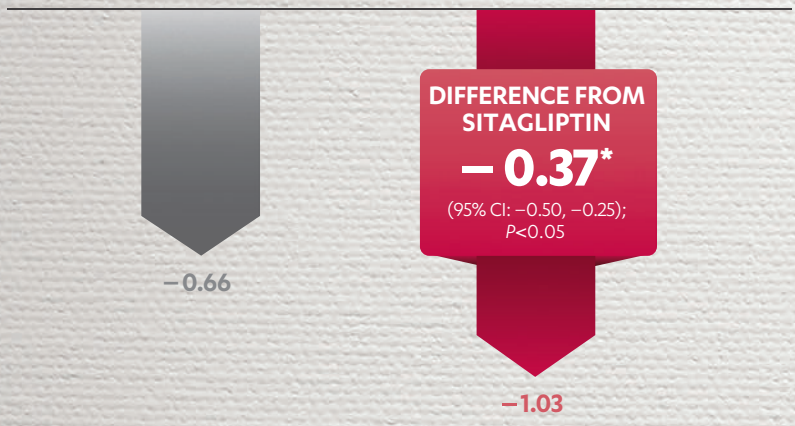
CONTRAINDICATIONS

- 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.

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.

INVOKANA™ 300 mg demonstrated greater reductions in A1C vs sitagliptin 100 mg at 52 weeks...

Adjusted Mean Change in A1C From Baseline (%): INVOKANA™ 300 mg vs Sitagliptin 100 mg, Each in Combination With Metformin + a Sulfonylurea[1]



Sitagliptin 100 mg + metformin and a sulfonylurea
(n=378; mean baseline A1C: 8.13%)

INVOKANA™ 300 mg + metformin and a sulfonylurea
(n=377; mean baseline A1C: 8.12%)

Incidence of Hypoglycemia

With metformin + a sulfonylurea over 52 weeks: INVOKANA™ (canagliflozin) 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[1]

Convenient Once-Daily Oral Dosing[1]

- Recommended starting dose: INVOKANA™ 100 mg
- Dose can be increased to 300 mg in patients tolerating 100 mg who have an eGFR ≥60 mL/min/1.73 m^2 and require additional glycemic control

*INVOKANA™ + metformin is considered noninferior to sitagliptin + metformin because the upper limit of the 95% confidence interval is less than the prespecified noninferiority margin of 0.3%.

IMPORTANT SAFETY INFORMATION (cont'd)

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.
- **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™. 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.

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...as well as greater reductions in body weight† and systolic blood pressure (SBP)†

Change in Body Weight†

Significant reductions in body weight at 52 weeks, each in combination with metformin + a sulfonylurea (*P*<0.001)[1]

- Difference from sitagliptin‡:
  300 mg: **–2.8%**

Change in SBP†

Significant lowering of SBP at 52 weeks, each in combination with metformin + a sulfonylurea (*P*<0.001)[2]

- Difference from sitagliptin‡:
  300 mg: **–5.9 mm Hg**

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

†Prespecified secondary endpoint.

‡Adjusted mean.

INVOKANA™ provides SGLT2 inhibition, reducing renal glucose reabsorption and increasing urinary glucose excretion.[1]

Adverse Reactions

In 4 pooled placebo-controlled trials, the most common (≥5%) adverse reactions were female genital mycotic infection, urinary tract infection, and increased urination.[1§]

References: 1. INVOKANA™ [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; 2013. **2.** Schernthaner G, Gross JL, Rosenstock J, et al. Canagliflozin compared with sitagliptin for patients with type 2 diabetes who do not have adequate glycemic control with metformin plus sulfonylurea: a 52-week randomized trial. *Diabetes Care*. 2013;36(9):2508-2515. **3.** Data on file. Janssen Pharmaceuticals, Inc., Titusville, NJ. Data as of 9/17/13.

SGLT2 = sodium glucose co-transporter-2.

§Included 1 monotherapy and 3 add-on combination trials with metformin, metformin + a sulfonylurea, or metformin + pioglitazone.

Learn more at **INVOKANAhcp.com/journal**

- **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.

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.

ENVISION NEW
POSSIBILITIES

Invokana™
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IMPORTANT SAFETY INFORMATION (cont'd)

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, 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 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.

Janssen Pharmaceuticals, Inc.

Canagliflozin is licensed from Mitsubishi Tanabe Pharma Corporation.

October 2013 002060-130903

»**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 pruritus, 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

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.

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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.

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

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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]*.

INVOKANA™ (canagliflozin) tablets

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, e.g., 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.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

Instructions: Instruct patients to read the Medication Guide before starting INVOKANA (canagliflozin) therapy and to reread it each time the prescription is renewed.

Inform patients of the potential risks and benefits of INVOKANA and of alternative modes of therapy. Also inform patients about the importance of adherence to dietary instructions, regular physical activity, periodic blood glucose monitoring and HbA1C testing, recognition and management of hypoglycemia and hyperglycemia, and assessment for diabetes complications. Advise patients to seek medical advice promptly during periods of stress such as fever, trauma, infection, or surgery, as medication requirements may change.

Instruct patients to take INVOKANA only as prescribed. If a dose is missed, advise patients to take it as soon as it is remembered unless it is almost time for the next dose, in which case patients should skip the missed dose and take the medicine at the next regularly scheduled time. Advise patients not to take two doses of INVOKANA at the same time.

Inform patients that the most common adverse reactions associated with INVOKANA are genital mycotic infection, urinary tract infection, and increased urination.

Inform female patients of child bearing age that the use of INVOKANA during pregnancy has not been studied in humans, and that INVOKANA should only be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Instruct patients to report pregnancies to their physicians as soon as possible.

Inform nursing mothers to discontinue INVOKANA or nursing, taking into account the importance of drug to the mother.

Laboratory Tests: Due to its mechanism of action, patients taking INVOKANA will test positive for glucose in their urine.

Hypotension: Inform patients that symptomatic hypotension may occur with INVOKANA and advise them to contact their doctor if they experience such symptoms *[see Warnings and Precautions]*. Inform patients that dehydration may increase the risk for hypotension, and to have adequate fluid intake.

Genital Mycotic Infections in Females (e.g., Vulvovaginitis): Inform female patients that vaginal yeast infection may occur and provide them with information on the signs and symptoms of vaginal yeast infection. Advise them of treatment options and when to seek medical advice *[see Warnings and Precautions]*.

Genital Mycotic Infections in Males (e.g., Balanitis or Balanoposthitis): Inform male patients that yeast infection of penis (e.g., balanitis or balanoposthitis) may occur, especially in uncircumcised males and patients with prior history. Provide them with information on the signs and symptoms of balanitis and balanoposthitis (rash or redness of the glans or foreskin of the penis). Advise them of treatment options and when to seek medical advice *[see Warnings and Precautions]*.

Hypersensitivity Reactions: Inform patients that serious hypersensitivity reactions such as urticaria and rash have been reported with INVOKANA. Advise patients to report immediately any signs or symptoms suggesting allergic reaction or angioedema, and to take no more drug until they have consulted prescribing physicians.

Urinary Tract Infections: Inform patients of the potential for urinary tract infections. Provide them with information on the symptoms of urinary tract infections. Advise them to seek medical advice if such symptoms occur.

Active ingredient made in Belgium

Finished product manufactured by:
Janssen Ortho, LLC
Gurabo, PR 00778

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

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➔42 use incentives today and facing reimbursement penalties starting in 2015. That is a sacrifice many physicians seem willing to make if it means avoiding the hassles that come with an EHR, says Gray Tuttle Jr., CHBC, principal healthcare adviser with The Rehmann Group in Lansing, Michigan, and a *Medical Economics* editorial consultant.

Survey data shows that EHR holdouts work in smaller, lower-income practices. But the key variable appears to be age: The older the physician the lower the likelihood that he or she use an EHR system. While 81% of physicians younger than 50 use an EHR, only about 70% of physicians older than 50 use an EHR system.

Given the amount of change coming to how medicine will be practiced beyond this year, retirement may be the only option for many of these holdouts. Besides Meaningful Use penalties, physicians in 2014 will also be forced to navigate the complexities of changing to the ICD-10 coding system in October 2014. That's a daunting and perhaps impossible task without an EHR system.

Tuttle says he recently spoke with one of his clients, a physician in her 60s, who said she wants to retire and that avoiding the pressure to use EHR was "contributory to her decision to hang it up." And that is a common sentiment among his older clients, Tuttle says.

"I've heard them say: 'I will probably never install an EHR.' They have accepted the fact that it will trigger retirement or accepted the fact that they will be paid less," Tuttle says.

Michael D. Brown, CHBC, president of Health Care Economics, Inc., in Fishers, Indiana, and a *Medical Economics* editorial consultant, says he sees clear age break among his clients when it comes to EHR adoption. Younger physicians seem better able to adapt to EHRs while older physicians are more resistant. "They say 'I went to medical school to treat patients, not to fiddle around on a computer,'" Brown says.

"I think you have to look at our physician populations out there. The ones that are learned and comfortable with

EHR system use

While the majority of practices have an EHR system, many of those that do not are resisting pressure to obtain one.

Does your practice use an EHR system?

	Yes	No	No answer
Family / General physicians *N=959*	80%	19%	1%
Internal medicine physicians *N=597*	77%	22%	1%

If your practice does not use an EHR system, do you plan to purchase one?

	Yes	No	No answer
Family / General physicians *N=195*	43%	49%	8%
Internal medicine physicians *N=135*	54%	42%	4%

Meaningful use

A majority of physicians say their practices have achieved meaningful use (MU) within the last year. Most practices with an EHR that have not achieved MU plan to do so.

Have you achieved meaningful use (MU) in the past 12 months?

	Yes	No	Don't know	Do not use an EHR	No answer
Family Practice / General Physicians *N=959*	58%	20%	-	19%	3%
Internal medicine physicians *N=597*	60%	15%	-	22%	3%

If your practice has not achieved MU yet, do you expect to do so within the next year?

	Yes	No	Don't know	Do not use an EHR	No answer
Family Practice / General Physicians *N=407*	21%	9%	17%	46%	7%
Internal medicine physicians *N=240*	17%	8%	15%	55%	5%

EHR costs

While physicians surveyed who do not own their practice understandably have less knowledge about EHR costs and fees, many practice owners surveyed were not clear on how long it would take to recoup their initial investment. Owners did have a solid grasp of EHR monthly fees

How long will it take your practice to recoup its initial EHR investment?

	Within 1 year	Within 3 years	Within 5 years	Don't know	Do not use an EHR
Practice owners *N=2241*	10%	14%	13%	28%	33%
Non-practice owners *N=1959*	2%	8%	9%	61%	17%

How much does your practice spend per month in ongoing EHR fees?

	More than $1,000	$500-$1000	Under $500	Don't know	Do not use an EHR
Practice owners *N=2241*	23%	16%	16%	10%	33%
Non-practice owners *N=1959*	10%	4%	2%	64%	17%

Source: 2013 Exclusive Physicians Earnings Survey

computers, they blend in and go to EHR much easier. The ones that are over, say, the age 45, think it is nothing but a mess," Brown says.

"They are scared," Brown adds. "They are really fearful. Many of them haven't even worked with a practice management system, and they are scared they are not going to be able to adapt themselves."

The other important factors are practice size and income. The survey data shows that the smaller the practice size and lower the income, the greater chance a physician will be without an EHR and have no intentions of purchasing a system in the future.

These smaller practices with fewer resources have a harder time affording the upfront costs and regular fees associated with an EHR and more difficulty absorbing any revenue losses from the paper-to-EHR transition. Another on-

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What kind of practices don't use EHR systems?

Physicians who do not use EHR systems typically are older, and tend to work in solo or smaller practices.

Does your practice use an electronic health record system? (By age)

	Yes	No	No answer
34 and under *N=132*	82%	17%	1%
35-39 *N=297*	84%	16%	0%
40-44 *N=466*	80%	19%	1%
45-49 *N=487*	81%	18%	1%
50-54 *N=614*	78%	22%	1%
55-59 *N=764*	73%	25%	2%
60-64 *N=698*	70%	29%	1%
65 and up *N=724*	60%	38%	1%

Does your practice use an electronic health record system? (By practice size)

	Yes	No	No answer
Solo Practice *N=1258*	59%	40%	1%
Expense sharing *N=203*	65%	35%	0%
group of 2 *N=356*	65%	35%	0%
group of 3-10 *N=1119*	76%	23%	1%
group of 11-25 *N=453*	89%	9%	1%
group of 26-50 *N=192*	88%	11%	1%
group more than 50 *N=556*	94%	6%	1%

Does your practice use an electronic health record system? (By salary)

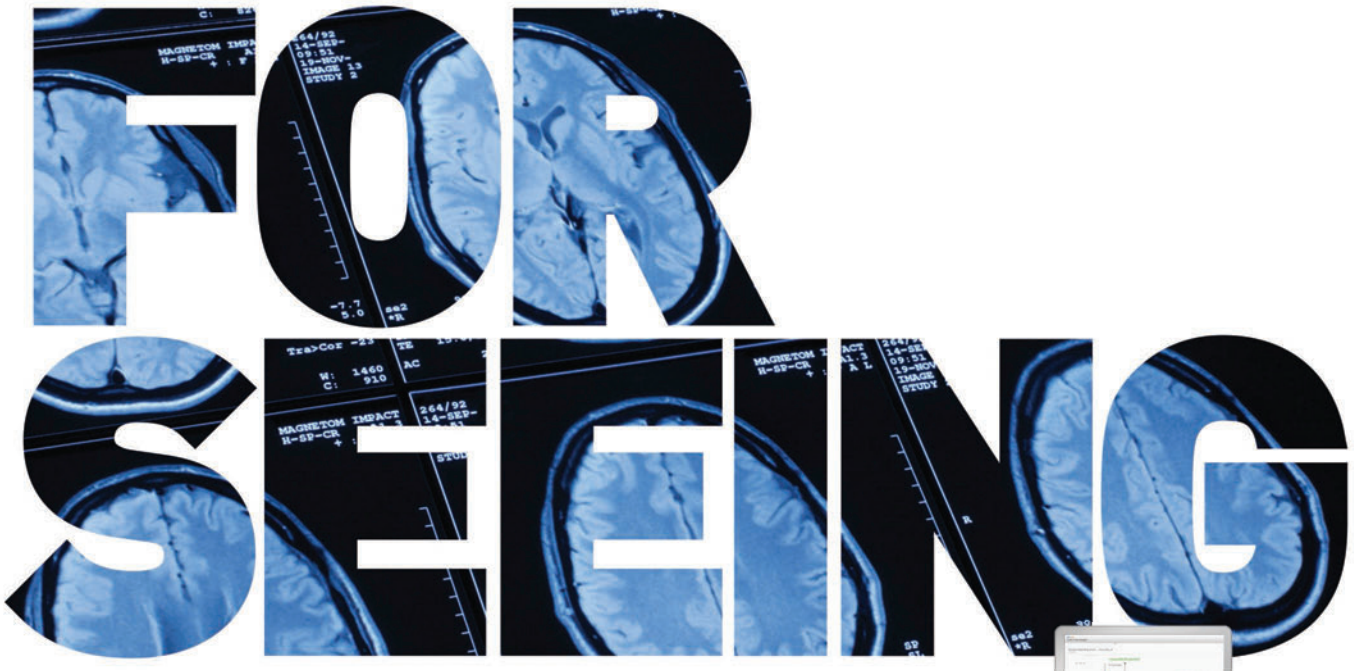
	Yes	No	No answer
Less than $60,000 *N=227*	52%	47%	1%
$60,000-$99,000 *N=292*	65%	34%	1%
$100,000-$149,000 *N=716*	73%	26%	1%
$150,000-$199,000 *N=852*	77%	22%	1%
$200,000-$299,000 *N=1062*	78%	21%	1%
$300,000-$399,000 *N=508*	79%	21%	1%
$400,000-$499,000 *N=211*	68%	30%	2%
$500,000 and up *N=241*	73%	27%	1%

Source: 2013 Exclusive Physicians Earnings Survey

These resources make EHRs easier

Complaints about what EHRs have done to physicians' practices are common, and such horror stories likely lead many physicians who remain without an EHR system to develop cold feet. Many physicians surveyed listed EHR systems as one of the factors contributing to dissatisfaction with their careers. These resources can help physicians make better decisions concerning their EHR systems:

- **The *Medical Economics* Top 100 EHR List: An exclusive ranking highlighting the top EHR vendors, including company revenue, system capabilities, and Meaningful Use readiness.** http://medicaleconomics.modernmedicine.com/top-100-EHRs
- **Certified Health IT Product List: This database provides a comprehensive list of EHR systems that have been tested and certified byThe Office of the National Coordinator for Health Information Technology (ONC):** http://oncchpl.force.com/ehrcert?q=chpl
- **Healthcare Information and Management Systems Society (HIMSS): The nonprofit focused on health IT provides pages of online resources about EHR, from adoption to usability:** http://www.himss.org/library/ehr/



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Do you plan to switch EHRs?

Most physicians surveyed said they do not plan to switch EHR vendors, or discontinue use of an EHR system after meaningful use incentives come to an end.

Do you plan to switch EHR vendors in the next year?

	Yes	No	Don't know	Do not use an EHR	No answer
Family / General physicians *N=959*	9%	54%	15%	19%	3%
Internal medicine physicians *N=597*	9%	54%	13%	22%	2%

Do you plan to continue using EHR after the incentive period?

	Yes	No	Don't know	Do not use an EHR	No answer
Family / General physicians *N=959*	63%	1%	13%	19%	4%
Internal medicine physicians *N=597*	65%	1%	10%	22%	2%

Source: 2013 Exclusive Physicians Earnings Survey

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going issue is that they often can't afford to hire staff members with the technical expertise to help them manage any technical problems.

"They don't want to make the expenditure," Brown says. "And many of these practices don't have the right people on staff to be able to adhere, understand and soak-in the EHR."

'I DON'T EVEN THINK' ABOUT EHR

Gigi Lefebvre, MD, who is in her 23rd year running a solo practice in St. Petersburg, Florida, says she will never use EHRs. Lefebvre says her decision to avoid EHRs is about running her practice the way she wants to, and being able to devote enough time to her patients' needs rather than wrangling with a potentially clunky software system.

As a small practice—Lefebvre has a two-employee staff and sees about 13 patients per day—she worries that she will not receive the technical support she needs if she ever went to an EHR system.

"If I had an EHR and had difficulties, I am so small that no one is going to come to help me," she says.

Instead of using an EHR system, Lefebvre says she spends at least 30 minutes with each of her patients during visits and concentrates on providing good care with strong preventative medicine services. She says obtaining an EHR system as only getting in the way of an effective physician-patient relationship and as a needless cash drain on her already struggling bottom line.

"There is nothing worth it to me," Lefebvre says. "Doctors get thousands of dollars from the government for EHR but I don't even think about it. I can even lose more than that by being inefficient in my practice."

STILL, EHRs REMAIN THE FUTURE OF MEDICINE

That is a common sentiment among physicians, who see themselves as increasingly beset on all sides and EHR as just another barrier to treating patients. When asked what are the biggest issues facing primary care, most said declining reimbursements, paperwork burdens, and healthcare reform. But 28% of survey respondents said EHRs. In write-in comments collected by the survey, physicians' anonymously disparaged their EHR systems, saying they only add aggravation.

"Most physicians have enough worries about shrinking reimbursement and growing expenses," Brown says. "They consider EHR as a total mess and another headache."

Despite these complaints, a comfortable majority of physicians use EHR at their practice, and the adoption rates increase every year, even for older physicians. Between 2010 and 2012, older physicians contributed to the biggest increases in EHR adoption, according to the National Ambulatory Medical Care Survey of EHRs, which was conducted by the Centers for Disease Control and Prevention's National Center for Health Statistics.

And acceptance of EHRs is much higher among younger physicians who grew up with computers in their midst, Tuttle says. As the EHR holdouts retire, younger physicians who are comfortable using computers and the cloud to store and process medical records will replace them.

"Eventually, it's safe to say that all physicians will use EHRs, but that's still a bit away," Tuttle says. "These people eventually are going to retire and they are being replaced with people who grew up using computers. I lecture residents, and they love EHR. You know why? They never knew it any other way." ◻

@ MORE ONLINE!

To see more details about this study and access more of the results, go to

medicaleconomics.com/salarysurvey.

CODING INSIGHTS
Can you combine 1995 and 1997 E/M Guidelines? [54]

Operations

Building compensation plans in a pay-for-performance era

New compensation models will be key as payers look to reward quality vs. volume

BY DEBRA BEAULIEU, *Contributing author*

HIGHLIGHTS

01 Medical groups should look at ways to align their compensation models with the way revenue flows into the practice, which may now include incentives for patient satisfaction, quality of care, and cost containment.

02 Avoid compensation layering, or having too many "add on" systems to a group's compensation formula.

03 Start by looking at where payers already offer incentives or plan to in the near future.

It is becoming more common for physician groups to reward certain **quality metrics** as part of their internal reimbursement structure. The trend is affecting **a small but increasing portion of physicians' pay.**

BY NOW, pay for performance is an established concept in the world of third-party reimbursement. Primary care physicians (PCPs) derived 3% of their total compensation last year based on quality measures, while performance-based data was linked to 2% of total compensation for specialists, according to the Medical Group Management Association— American College of Medical Practice Executives' (MGMA-ACMPE) *Physician Compensation and Production Survey*.

"Quality and patient satisfaction metrics are not yet dominant components of physician compensation plans right now, however, as reimbursement models continue to shift, the small changes we've observed recently will gain momentum," Susan L. Turney, MD, MGMA-ACMPE president and chief executive officer (CEO), explained in an announcement.

Recruiting firm Merritt Hawkins has seen even stronger evidence of the growing trend, as 39% of its 2013 search assignments that offered physicians a production bonus also included payments based on quality metrics. This figure was up from fewer than 7% in 2011, according to a report released in August.

ALIGN COMPENSATION WITH REIMBURSEMENT

This shift in payment structures is an inevitable result of the healthcare marketplace transitioning away from paying for volume in favor of rewarding quality, says Deborah Walker Keegan, PhD, FACMPE, president of

Medical Practice Dimensions, Inc., and principal of Woodcock & Walker Consulting in Asheville/Arden, North Carolina.

Thus, medical groups should look at ways to align their compensation models with the way revenue flows into the practice, which may now include incentives for patient satisfaction, quality of care, and cost containment.

> "MIXED-MODEL REIMBURSEMENT IS ONE OF THE TOUGHEST MODELS TO BE IN, AND WE'RE GOING TO BE IN IT FOR SOME TIME AS WE TRY TO FIGURE OUT WHAT THIS END-STATE REIMBURSEMENT REFORM IS ALL ABOUT."
>
> –DEBORAH WALKER KEEGAN, PHD, FACMPE, PRESIDENT OF MEDICAL PRACTICE DIMENSIONS, INC., AND PRINCIPAL OF WOODCOCK & WALKER CONSULTING, ASHEVILLE/ARDEN, NORTH CAROLINA

"Talking about productivity alone is inconsistent with the changes in the delivery system," Walker Keegan says. "It's been inconsistent with value-based reimbursement and inconsistent with alignment with the fund-flow model. If you're going to get paid on value, it's time to think about compensation with some of those value components in it because you need to focus attention on physicians and clinicians meeting certain goals related to federal programs and payer changes."

CHOOSE THE RIGHT METRICS

Where many practices struggle, however, is in selecting the right metrics to reward, says Craig Samitt, MD, executive vice president of HealthCare Partners in Torrance, California. Samitt is also a commissioner of the Medicare Payment Advisory Council and former president and chief executive officer of Dean Health System in Wisconsin.

"The measures need to be reliable, reproducible, measurable, and valid—and that can often be the hardest challenge because there aren't many proven quality measures that apply to each and every physician," Samitt says.

Start by looking at where payers are already offering incentives or plan to in the near future. For example, if you have a primary care practice that is part of a larger group, you are already being evaluated on Medicare's value-based modifier, although it hasn't impacted your reimbursement yet, notes Bruce A. Johnson, JD, a Denver, Colorado-based physician compensation expert.

In addition, with reimbursements based on patient satisfaction around the corner, it makes sense to start tracking and rewarding your scores internally, Johnson says. Quality measures dealing with chronic conditions, as many current government and private-payer programs do, are also important for groups to get a handle on.

Some payers may allow practices to pick from a list of metrics, including obesity, diabetes, hypertension, or congestive heart failure, says Gail Levy of The Levy Advantage consulting firm in Baltimore, Maryland. "Depending on the deal, a physician might agree to receive 90% of his salary, but I wouldn't advise going any lower," she says.

AVOID 'COMPENSATION LAYERING'

But putting this puzzle together isn't easy, Samitt warns. Groups need to consider which measures to use, what percent of an incentive to apply to each measure, and how difficult the targets will be to achieve. "There are many elements of the transition that are complex that take some degree of finesse to do it successfully," he says.

What you want to avoid, according to Walker Keegan, is a phenomenon she calls compensation layering, or having too many "add on" systems to a group's compensation formula. For example, groups might attempt to give physicians a cut of the additional money they earn from participating in Meaningful Use, e-prescribing, the Physician Quality Reporting System (PQRS), bundled payments, performance payments, and more. "That is unwieldy," she says. "Then you're focusing attention on too many variables and you're trying to micromanage the compensation plan."

Rather, Walker Keegan advises groups to take a step back and determine what portion of physicians' compensation should be related to quality, additional production beyond the norm, service, access, and so on. "We weight those additional categories and identify either flat dollar amounts, percent to total points, and percent of base compensation that may be at risk, and move that way rather than trying to take every dollar that comes into a practice and filter it to the

physicians through compensation layering," Walker Keegan says.

CONSIDER ADDITIONAL COSTS

Another factor in determining the worth of your pay for performance plan is the extra work you and your staff will have to do to maintain the program. Many programs require significantly more administrative work—even with electronic health record systems, a program that only helps a sliver of your patient population may cause you to hire another employee.

"You might end up retooling your practice for 20% or 30% of your practice and getting no added income," she says.

However, Levy says that some plans offer the help of a nurse or administrator. In this case, there may be certain compensations added just for participating in the program.

"Some of these plans require added personnel, sometimes you don't need to add new staff, you just need to train them," Levy says. "There are additional costs in the extra tracking and reporting you have to do. Some plans provide a nurse or a navigator, but if you have to hire an additional nurse, that's a big risk."

DIVIDING THE PIE

Another complexity in creating a performance-based compensation plan is determining how bonus dollars should be allocated. Specifically, you need to decide for every metric whether you'll apply the incentive to individuals, to one or more departments, or to all of the physicians in the group, Samitt says. "The most effective measures are the ones that reward all three, so you really want a blend," he says. For instance, he recommends that patient satisfaction measures be applied at the individual level, quality and accessibility measures applied by department or specialty, and cost measures applied at the overall organization level. That way no individual physician feels conflicted about a cost decision.

When this transition is done well, practices stand to benefit from improvements in quality, service, and cost, Samitt says. However, a critical component to success is involving physicians in the process.

"My experience in healthcare organizations is that change happens most effectively when we involve physicians in the change process, not when we make changes around the physician or to the physician," he says. "[Compensation redesign] can't be done by a group of executives in a room that rework the incentives and then roll them out to the physicians." Samitt adds that physicians can be charged to lead their own compensation redesign within defined parameters.

LIGHT AT THE END OF THE TUNNEL

Nonetheless, expect the transition period to be difficult, warns Walker Keegan. "It's very hard for practices to manage in a mixed-model reimbursement and to manage a compensation plan that's aligned with mixed-model reimbursement," she says. "Mixed-model reimbursement is one of the toughest models to be in, and we're going to be in it for some time as we try to figure out what this end-state reimbursement reform is all about."

> "CHANGE HAPPENS MOST EFFECTIVELY WHEN WE INVOLVE PHYSICIANS IN THE CHANGE PROCESS, NOT WHEN WE MAKE CHANGES AROUND THE PHYSICIAN."
>
> –CRAIG SAMITT, MD, EXECUTIVE VICE PRESIDENT, HEALTHCARE PARTNERS, TORRANCE, CALIFORNIA AND COMMISSIONER, MEDICARE PAYMENT ADVISORY COUNCIL

In the meantime, it's important to emphasize to physicians the upsides to joining the movement toward value-based compensation, Johnson says. "Those that do it well can actually increase their reimbursement because they're going to be focusing their attention on the things that matter to their payment," he says.

Being an active participant in these changes, Johnson adds, can help offset some of physicians' anxiety about the sustainable growth rate, for example, and the mounting pressure to become hospital employees.

"If a physician is interested in trying to retain [his or her] independence and their autonomy, it behooves them to begin to focus their attention on these things because internal and external reimbursement will hinge on these quality measures down the road," he says. "It puts them more in the driver's seat to try and control their own destiny." ◻

This activity is supported by an unrestricted educational grant from the Western Pain Society.

Release Date: November 1, 2013
Expiration Date: November 1, 2014

LEARNING OBJECTIVE

Identify monitoring parameters for the safe use of nonsteroidal anti-inflammatory drugs (NSAIDs) in patients on chronic low dose aspirin

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Activity Type: Knowledge-based
ACPE ID# 0781-0000-13-006-H05-P

Concomitant Use of NSAIDs and Aspirin: Is it Ever a Safe Combination?

There is a wide variety of over-the-counter (OTC) medications available, allowing patients to self-medicate with herbal supplements, cold and flu remedies, and a variety of pain relievers. Many patients—by some estimates, more than 40 million—take low-dose daily aspirin for cardioprotection,[1] some on the recommendation of their healthcare provider and others on their own without mentioning anything to their provider.

Occasional use of an OTC nonsteroidal anti-inflammatory drug (NSAID) is safe for most individuals, even those taking daily aspirin. However, use of an NSAID with daily aspirin can lead to gastrointestinal (GI) problems as well as diminish the cardioprotective value of a daily aspirin if the NSAID is used frequently or at high doses.[2] In addition, inappropriate NSAID use may also increase blood pressure and adversely affect hypertension control. For these reasons, patient counseling about the safe and appropriate use of NSAIDs is critical.

A recent roundtable discussion among a multi-disciplianary team of healthcare providers highlighted the need to question patients about medications they are taking and to educate patients about how to diminish potential adverse interactions from the concurrent use of NSAIDs and aspirin, or NSAIDs and antihypertensive medications.

Moderator: Many patients take daily low-dose aspirin for cardioprotection and will self-medicate with another OTC drug, such as an NSAID, for pain relief. What are some of the potential issues with this combination?

Anthony Dalpiaz, PharmD: That situation does come up quite a bit. When I encounter it, I first ask patients why they are taking low-dose aspirin since many don't have a true indication for its use. They just think that aspirin is good for them. If they do have a true indication, I then have the conversation about what pain medications they have already tried, if any. I also inquire about whether they intend to use an NSAID, and if so, how long they intend to use it—short term (ie, for a day or two) or long term.

Brett Snodgrass, NP: You need to figure out whether or not the patient is using aspirin because a healthcare provider recommended it for the prevention of a myocardial infarction or stroke. It's not uncommon for patients to decide on their own to take daily aspirin.

Bill McCarberg, MD: Many patients self-medicate with aspirin because they've heard from reading the lay press or from their uncle or a friend who has told them that they should take a baby aspirin every day. Providers should talk with this sort of patient about whether he or she should be taking aspirin. Daily low-dose aspirin is recommended by the U.S. Preventive Services Task Force (USPSTF) for men age 45 to 79 years when the potential benefit in reduction of risk for myocardial infarction outweighs the potential harm due to an increase in GI hemorrhage. Daily low-dose aspirin is also recommended for women age 55 to 79 years when the potential benefit of reduction in risk for ischemic stroke outweighs the potential harm of an increase in GI hemorrhage. The USPSTF does not recommend daily low-dose aspirin for prevention of a cardiac event in men younger than 45 and women younger than age 55.[3]

The American College of Cardiology/American Heart Association guidelines recommend aspirin at a dose of 75 mg to 325 mg once daily for patients of any age with a history of heart attack or stroke, patients who have a coronary artery stent or have had coronary artery bypass graft surgery, or patients who are undergoing surgery for hip fracture. A daily 75 mg to 162 mg daily dose of aspirin is also

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recommended for patients with diabetes or peripheral artery disease, even though there is no conclusive evidence that it is beneficial.[4]

In addition to daily aspirin, patients also often self-medicate with OTC NSAIDs for acute as well as chronic conditions. With or without concomitant aspirin use, serious GI adverse events can occur with high doses of NSAIDs used over the long term,[5] although we know from upper endoscopy studies that a low dose of an NSAID in a susceptible patient can cause gastric problems, including dyspepsia, peptic ulceration, hemorrhage, intestinal bleeding, and perforation. It is important for patients to be aware of these possible GI side effects and to contact their doctor if they occur while on NSAIDs. In addition, the patient who is on long-term NSAID therapy should titrate to the lowest effective dose when treating a chronic condition.

Taking both aspirin and ibuprofen together comes with risk. For patients taking this combination for a short duration, I would probably not advise them to take a proton pump inhibitor (PPI), as research has indicated that the combination of an NSAID with both a PPI and low-dose aspirin may result in extensive damage and bleeding in the small intestine.[6,7]

Patients on chronic low-dose aspirin who are looking for pain relief should try something else before choosing an NSAID, particularly if they will need long-term pain relief. My point to patients is that if they do have a headache or a sports injury, try acetaminophen or a non-pharmacologic treatment, such as ice or heat therapy, as a first option.

AD: Although patients will take enteric-coated aspirin thinking it's better for the GI tract than nonenteric-coated aspirin, that is not the case when it is taken with an NSAID. Enteric-coated aspirin with an NSAID could potentially cause further GI damage because the damage would be a little bit lower down in the GI tract. The other downside of enteric-coated aspirin, whether or not an NSAID is also being taken, is that the enteric coating makes it less effective as an inhibitor of platelet aggregation and therefore gives the patient potentially less cardioprotection.[7]

Moderator: How do you monitor patients for NSAID-induced damage in the small intestine?

BS: I monitor by asking questions. I ask patients who are on aspirin and NSAIDs whether they ever experience bloody stools or any fatigue that might indicate some type of blood loss throughout the GI tract. If they speak of an increasing fatigue, of just not feeling well, or, if they say they have had dark, tarry stools or bright red blood in their stool, then of course I would take action.

I ask patients taking NSAIDs about any abdominal pain or upset stomach. I tell them to take NSAIDs with food and to be on the lookout for stomach irritation, and to let me know if they experience stomach issues.

For most people, if they're going to have an issue with an NSAID, it will begin with abdominal pain or nausea.

Doing labs periodically is also important. I typically request a complete blood count (CBC) for my patients on NSAIDs and aspirin. The caveat, however, is that insurance often will not pay for the CBC alone and will require presence of another symptom, such as a dark, tarry stool or fatigue.

BM: I ask patients about any upset stomach, any kind of reflux symptoms, or dark-colored stools. Those things would all be mentioned if people are taking long-term NSAIDs. I don't say anything about kidney issues because patients wouldn't know whether or not that is a problem. Possibly, I would mention to them that their mean blood pressure could go up with regular NSAID use (as much as 5 mm Hg),[8] but that is something that we would see through regular monitoring.

Moderator: We know that NSAIDs may diminish the cardioprotective effect of aspirin. How can these issues be avoided?

BM: Research published in the *New England Journal of Medicine* by Catella-Lawson et al explained that ibuprofen antagonizes the platelet inhibition effect of aspirin; however, rofecoxib, acetaminophen, and diclofenac do not have that effect. The authors found that a clinical dosing regimen of ibuprofen may competitively inhibit the sustained inhibitory effect on platelets, which is the cardioprotective property of aspirin. In other words, there could be an increased risk of heart attack and stroke if a patient who needs aspirin for its cardioprotective effects uses ibuprofen on a prolonged basis. The researchers went on to say that this effect of ibuprofen may be bypassed by taking aspirin two hours before a single daily dose of ibuprofen.[2]

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A second study looked at a more clinically relevant dosing regimen of ibuprofen where it was administered three times per day, along with a once-daily enteric-coated aspirin. Taking aspirin before the morning dose of ibuprofen did not prevent the platelet-inhibition effect. The authors observed that the inhibitory effects of daily low-dose aspirin on platelets are competitively inhibited by the prolonged use of multiple daily doses of ibuprofen, even when aspirin is administered before the first dose of the NSAID. Prolonged administration of a typical regimen of delayed-release diclofenac did not, however, inhibit the antiplatelet effect of enteric-coated aspirin.[2]

Fortunately, occasional use of an NSAID concomitant with aspirin is unlikely to be a problem.[9] U.S. Food and Drug Administration (FDA) recommendations state that occasional use of ibuprofen presents minimal risk for any attenuation of the antiplatelet effect of low-dose aspirin because of aspirin's long-lasting effect on platelets.[10]

"Fortunately, occasional use of an NSAID concomitant with aspirin is unlikely to be a problem.[9]"

–Bill McCarberg, MD

Moderator: FDA recommendations state that patients should separate low-dose aspirin and ibuprofen by at least 30 minutes and delay taking aspirin for at least 8 hours after taking ibuprofen. What are your thoughts?

BM: As the FDA states, taking aspirin and ibuprofen together can diminish the antiplatelet activity of aspirin, and patients should be alerted to this effect. Occasional use of ibuprofen with aspirin would have minimal effect on the aspirin's efficacy.[9,10]

Moderator: What about patients at risk for a cardiovascular event, such as a patient being treated for hypertension?

BS: If a selective or nonselective NSAID is required, the patient should use it for the shortest period of time at the lowest dose possible that provides them with relief.[11]

BM: It is not recommended that a patient on an antihypertensive take an NSAID because it can raise blood pressure, and use of both a selective and nonselective NSAID can adversely affect

control of treated hypertension.[11] It is important to keep in mind that the FDA recommendations are all based upon long-term studies where researchers monitored compliance, which may not represent a real-world situation involving possible irregular use. We don't know the effect that an NSAID taken short term (ie, 2 to 3 days) for a muscle sprain or headache has on a patient's blood pressure. We know that not every patient's blood pressure will increase when they take an NSAID, so it's difficult to make an absolute judgment on whether all patients with cardiovascular risk factors should stop using NSAIDs. We know that NSAIDs are commonly used in patients with hypertension, but it's probably not the safest thing to do without patient education and blood pressure monitoring.

AD: Patients being treated for hypertension should have adequate follow-up and regular contact with their healthcare provider, who can monitor their blood pressure. The provider should also educate the patient about the potential risk of higher blood pressure and explain that long-term use of an NSAID can reduce the effectiveness of antihypertensive agents and could result in the need for an additional treatment or agent to counteract the side effect of the NSAID. Patients should be informed that they may end up taking more medications if they continue to take NSAIDs for a long period of time.

Moderator: Are there any specific types of antihypertensive medications that are particularly affected by NSAID use?

AD: The efficacy of angiotensin-receptor blockers (ARBs), angiotensin-converting enzyme (ACE) inhibitors, beta-blockers, and diuretics can be affected by NSAID use. NSAIDs can partially reverse the effect of these drugs, whose mechanisms depend on modulating prostaglandins, renin, or sodium and water balance. Calcium-channel blockers and centrally acting antihypertensives are among the least affected antihypertensive agents. The dose and duration of NSAID therapy often determine the extent of this effect. In a study by Horn et al, both higher doses of NSAIDs and chronic therapy that extended beyond a week were risk factors tied to an increase in blood pressure.[12]

Researchers also reported that co-administration of an NSAID with some antihypertensive agents can result in a 50% reduction in the efficacy of the antihypertensive, thus decreasing the beneficial cardiovascular effects of blood pressure reduction. They recommended monitoring the patient who takes an NSAID for several weeks for signs of fluid retention, such as weight gain or peripheral edema.[12]

Moderator: Is NSAID use safe for people who have experienced a cardiovascular event, such as a stroke or myocardial infarction?

BS: I do not recommend NSAIDs for patients who have had a cardiovascular event. I typically advise them to use acetaminophen or even a short-term opioid, which is safer, in fact, than an NSAID in patients with known cardiovascular events. Research published in the *American Journal of Medicine* in 2013 concluded that older adult patients who have cardiovascular disease, diabetes, or those who take low-dose aspirin should be taking opioid therapy instead of NSAID therapy for chronic pain. The American

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Geriatric Society also recommends opioids as an option for patients at higher risk for NSAID-related adverse effects.[13]

BM: An NSAID can increase the risk of another cardiovascular event, but that risk is variable. The higher the dose, the higher the risk, and the longer period of time that you take the NSAID, the higher the risk. That's why the FDA has come out with recommendations about using the lowest dose for the shortest amount of time. One of the things that I try to emphasize to patients is that instead of choosing the highest dose possible, start with a lower dose and see if that is effective. Patients, especially those with a past cardiovascular event, should certainly be informed about the risks of NSAIDs.

AD: A recent study in *Anesthesia & Analgesia* showed that a combination of an NSAID and acetaminophen could be more effective than either drug alone.[14]

Moderator: Could patients try a combination of the two and maybe use a lower dose of each?

BM: Results of that systematic review of 21 studies suggested that the combination of acetaminophen and an NSAID may offer superior analgesia. Ibuprofen was the NSAID that was the most widely evaluated in those studies.

"An NSAID can increase the risk of another cardiovascular event, but that risk is variable. The higher the dose, the higher the risk, and the longer period of time that you take the NSAID, the higher the risk. That's why the FDA has come out with recommendations about using the lowest dose for the shortest amount of time."

–Bill McCarberg, MD

The researchers found no evidence of increased incidence of side effects with the combination of acetaminophen and ibuprofen, and no difference in side effects with combination therapy versus single-drug therapy. However, it is important to note that this study looked at combination therapy among patients with acute postoperative pain, not patients who have suffered a cardiovascular event.[14]

In that study, the researchers also said that the combination of an NSAID and acetaminophen would not be suitable for patients who have a contraindication to either drug. For example, patients with liver disease should not take or should minimize their use of acetaminophen, while patients with a history of GI ulcers or renal impairment should not use an NSAID. The FDA is looking now at whether acetaminophen may also have GI effects, so it's important to advise patients to use a low dose of any NSAID. There could be a whole patient-doctor discussion around the wisdom of combining the use of these two drugs and/or possibly taking a lower dose of each.

AD: I am also concerned about patients with a history of cardiovascular events that may not only be taking aspirin but also another antiplatelet inhibitor, such as clopidogrel. That is a combination that patients should be aware could present an increased risk. Patients should be counseled about which drugs they should avoid, such as NSAIDs, as well as how to take them safely.

Moderator: What are some practice pearls that could help providers who are treating patients who may be taking a combination of drugs, such as aspirin and NSAIDs?

BM: An important thing to remember is that many patients are taking aspirin even though their providers may not know about it. They're taking aspirin because they think it will be cardioprotective, even though you, as their provider, don't know about it or don't think they should be taking it.

People also frequently take OTC NSAIDs and may not report that to their provider. They may even be sharing opioids with a family member. I had a patient who said that she felt some chest pain, so she took her mother's digoxin because she thought that would be good for her chest pain. We know that people share medicines all the time, so don't be afraid to ask your patients if they are taking other medicines or supplements.

If a patient's blood pressure has been difficult to control, look at what other medicines the patient may be taking that could be affecting their blood pressure control. Know what the risk factors are for different types of drugs so that you can educate your patients.

BS: The most important practice pearl for me is the need to educate staff about the risks of NSAIDs and aspirin, and the importance of taking a thorough patient history and asking questions about any medicines the patient is taking. When you prescribe a medication, you have to ask patients whether they are taking any herbal medications, any OTC NSAIDs, any aspirin, etc. You have to get very explicit when you talk to your patients because they often will give you only the information you ask for. They don't always give you all the information that you need.

BM: It's almost as though you have to really pull some of that information out of them because they don't think they are taking a drug if they are taking herbals or naturopathic drugs or some other type of OTC medication. However, they may be at risk and not know it. I have been surprised over and over again, especially when I see an adverse event or begin having trouble controlling blood pressure in somebody that was doing well, and then I discover that the patient had some pain and had started taking an NSAID that they hadn't reported to me. They may have started taking an herbal supplement and not realized that some of the ingredients may include an NSAID or aspirin.

AD: When I worked in an internal medicine and later in a GI clinic, I saw patients with inflammatory bowel disease who were unknowingly taking multiple NSAIDs, medication for their migraine headaches that contained aspirin, additional medications for a sinus infection that contained ibuprofen, as well as taking OTC ibuprofen for their joint pain. You have to tease out what exactly they are taking and provide thorough patient education.

Talking to patients about their use of OTC medications and supplements is vital to patient care. Many patients may not reveal their use of these medications unless their provider specifically asks, and they may not understand the health risks of combined use of certain types of drugs. Providers should educate their patients about the potential health risks of taking an NSAID and daily low-dose aspirin, including the adverse effect of the NSAID on the cardioprotective value of daily low-dose aspirin and blood pressure-lowering effect of some antihypertensive medications.

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Coding Insights

CAN 1995 AND 1997 E/M GUIDELINES BE COMBINED?

Our office is starting to do a monthly audit of our physician charts. We're going to be looking at documentation and coding to make sure they are on the right track. When we're conducting these audits, do we have to use either 1995 or 1997 guidelines or can we combine the two?

HISTORICALLY, the Center for Medicare and Medicaid Services (CMS) has instructed that one of the Evaluation and Management (E/M) Guidelines had to be used—either 1995 or 1997—when charts were reviewed, internally or externally.

Recently, however, they have changed (and I believe advanced) their instruction to state that, "… beginning for services performed on or after September 10, 2013, physicians may use the 1997 documentation guidelines for an extended history of present illness (HPI) along with other elements from the 1995 guidelines to document an evaluation and management service."

The full article, "Medicare E/M FAQs," can be found at: http://go.cms.gov/16F3HBY.

Let's discuss what this means exactly and how it will benefit your physicians and non-physician practitioners (NPPs) in their reviews.

First, let's review the differences and similarities between the two guidelines.

1995 versus 1997 E/M Guidelines

There are not too many differences between the 1995 and the 1997 guidelines and there are some similarities. Let's discuss both of the guidelines now.

Two major differences exist between the 1995 and 1997 E/M guidelines: HPI and the exam element.

The following criteria are the same for the 1995 and 1997 E/M guidelines, including: The Review of Systems; Past, Family and Social History; and Medical Decision Making.

Now, let's delve into the two major differences: HPI and the exam.

History of present illness

The HPI is arguably one of the most important pieces of E/M visit documentation because it, in conjunction with the chief complaint, supports medical necessity for the visit. It is described in the Current Procedural Terminology (CPT) guidelines as "a chronological description of the development of the patient's illness from the first sign and/or symptom or from the previous

1995 E/M exam guidelines

Body Areas	Organ Systems
Head, including the face	Constitutional (e.g., vital signs, general appearance)
Neck	Eyes
Chest, including breasts and axillae	Ears, nose, mouth and throat
Abdomen	Cardiovascular
Genitalia, groin, buttocks	Respiratory
Back, including spine	Gastrointestinal
Each extremity	Genitourinary
	Musculoskeletal
	Skin
	Neurologic
	Psychiatric
	Hematologic/lymphatic/ immunologic

The 1995 guidelines include a one-size-fits-all, multi-system exam that recognizes body areas and organ systems.

encounter to the present. It includes the following elements:

- location,
- quality,
- severity,
- duration,
- timing,
- context,
- modifying factors; and
- associated signs and symptoms.

For an extended HPI, the 1997 E/M Guidelines also allow for "the status of at least three chronic or inactive conditions."

Until September 10, 2013, CMS had strictly interpreted the guidelines and only allowed the status of at least three chronic or inactive conditions when utilizing the 1997 E/M Guidelines. However, physicians/NPPs and reviewers now can "mix" the guidelines in so far as credit can be given in the HPI for the elements listed above or the status of three chronic or inactive conditions regardless of which set of guidelines being utilized.

For years, reviewers have thought that credit should be given to physicians/NPPs for the status of chronic conditions for either set of guidelines. This is because it takes the provider's time and medical knowledge to review the patient's chronic conditions, and this type of thoroughness is simply good patient care.

WITHOUT QUESTION, THE 1995 GUIDELINES ARE MUCH MORE STRAIGHT-FORWARD AND ARE EASIER FOR PROVIDERS, NPPS, AND REVIEWERS.

The guidelines state that reviews should be conducted so that the physician/NPP obtains the most favorable outcome, and allowing for the review and status of chronic conditions in the HPI further advances this goal.

Exam Element: 1995 guidelines

While most of the guidelines remain the same between the two versions, the exam component is very different. The 1995 guidelines include a one-size-fits-all multi-system exam that recognizes body areas and organ systems.

In contrast, the 1997 guidelines not only offer a general multi-system exam, but also single organ system examinations for:

- cardiovascular,
- ear, nose and throat,
- eye,
- genitourinary,
- hematologic/lymphatic/immunologic,
- musculoskeletal,
- neurological,
- psychiatric,
- respiratory, and
- skin.

Without question, the 1995 guidelines are much more straight forward and are easier to use for physicians/NPPs and reviewers alike.

However, specialty physicians and NPPs sometimes find that single organ system exams are better suited to document their specific specialty elements, while general practitioners tend to lean toward the 1995 general multi-system exam because they don't normally need the specificity that the single organ system exams offer. Physicians/NPPs and reviewers can—and should—choose the examination that most benefits the physician or NPP.

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*The answer to our reader's question was provided by **Renee Stantz**, a billing and coding consultant with VEI Consulting Services in Indianapolis, Indiana. Send your practice management questions to **medec@advanstar.com**.*

Legally Speaking

BREAKING UP IS HARD TO DO: HOW TO LEAVE A HEALTH PLAN

by **ROBERT E. SCHILLER, JD**

Is your health plan cheating on you? Is it leaving you out while inviting others to participate in new products? Is it steering business away to other providers, either with patient cost-share differentials, or "transparency" programs purporting to identify cost-effective providers? Does it fail to return your calls? Does it woo you with sweet-nothings about collaboration or quality bonuses, while lowering your fees?

YOU PROBABLY don't need a lawyer to tell you this, but these could all be signs that the relationship is over, and it is time to move on.

Unfortunately, the decision is often still a difficult one, especially with the dominant health plans in your market. However, if you do decide you are through, here is how you can get out of your agreement and start your new life as a non-participating provider.

Review your contract

Contract termination is governed by the terms of your participation agreement with the health plan and by applicable law. You must always carefully review the terms of the participation agreement and all subsequent amendments, as well as any relevant statutory or regulatory requirements.

In this rapidly changing healthcare environment, it is becoming increasingly important to think strategically and critically in terms of your health plan participation. Whether you are actively considering dropping participation with a health plan, it would be a worthwhile exercise to review your current contracts and chart what your relevant rights are.

If you cannot locate a copy of your contract or are not sure you have all of the amendments, contact the health plan and request a copy of the full agreement, as amended. They should provide it without objection.

Find out when you can cancel

All contracts require a reasonable notice period prior to the effective date of a termination. Many may limit your ability to get out of the agreement to one date per year. If you miss the notice period, you could be stuck in the agreement for another year.

Often, provider participation agreements are set up as "evergreen" contracts that automatically renew each year on the anniversary date of execution, or some other date established in the agreement, unless either party provides written notice of non-renewal a specified number of days in advance of the renewal date. You do not need to provide a reason to the health plan for your decision.

However, this right is only exercisable once a year, so once you have decided to quit, you could still be stuck in a bad relationship for the better part of a year before you are able to extricate yourself by this method. And if you fail to identify and meet the advance notice requirements, you could be stuck until the next anniversary date.

Some participating provider agreements have a "termination without cause" provision, meaning you can notify the health plan that you would like to end the contract as of a certain date, but you are not required to provide a reason. In some cases, this right may be exercised at any time. In others, it might be linked to the anniversary date of the agreement (in which case, it is really nothing more than a non-renewal clause in different words).

Breach of contract

All contracts will have a provision permitting you to terminate the agreement if you believe the health plan has breached a material term, and the health plan fails to cure the breach within a specified period of time.

The problem with relying on this provision is that you have to identify a breach and give the health plan an opportunity to cure. The health plan may avail itself of the opportunity to cure

the alleged breach, or may choose to dispute that it is, in fact, in breach. As a result, you may not be able to terminate the agreement on this basis or you may be subject to lengthy and perhaps costly delays. There also may be dispute resolution provisions in your agreement, requiring you to exhaust internal (or even external) processes before you can terminate the agreement for a breach.

In the end, it is a much more cumbersome process than a non-renewal or termination without cause. This may be ok when there are clear issues, and you are ready to pick a fight (and bear the cost of that fight, including legal fees) but most providers would prefer to avoid having to rely on this type of provision.

On the other hand, it is not limited to a particular date each year. There will be circumstances where it may be the only alternative.

Additional termination rights

Many agreements may contain one or more provisions triggering an additional right to terminate.

These may be grounded in a statute or regulation or simply be the result of a negotiation between the parties. For example, a contract provision may provide that a regulatory change or a unilateral amendment to the provider's participation agreement that has an adverse effect on the provider may give rise to an additional right to terminate the agreement.

For example, if the health plan unilaterally reduced its fees by 2%, the provider might have a right to terminate the agreement in the middle of a contract year in response to that reduction. However, you should be aware that some of these types of terminations may require some serious calculation on the provider's behalf to determine, for example, that the change had a "material" adverse impact, however that term is defined in the agreement.

Terminating one line of business

In some cases, the agreement may permit the provider to terminate participation with one or more of the health plan's lines of business, while remaining a participant with all other lines.

As with all of the other non-renewal and termination rights discussed above, it is important to know the terms of the provision and to identify any notice requirements or other pre-conditions early on, so you do not lose the benefit of the provision.

You should also determine whether the health plan is permitted to terminate you from the remaining lines of business in response, and whether your practice is positioned to weather that consequence as well.

> "HEALTH PLANS ARE NOTORIOUS STICKLERS WHEN IT SUITS THEIR OWN PURPOSES."

Mistakes can be costly

Of course, having an appropriate basis to terminate or non-renew an agreement is not helpful if you get the mechanics wrong, so make sure you also consult the terms of your agreement that govern the provision of "notices."

Make sure notices are sent to the right contact and address and by the proper method of delivery. Health plans are notorious sticklers when it suits their own purposes. If they believe it is in their best interest to keep you in the network, they are not above refusing to accept a termination notice that is defective in any way.

Don't put yourself in that position. If it is unclear where the notice should be sent, contact the health plan and request the answer, preferably in an email so you can maintain a record.

Typically, the provision will indicate that notices may be delivered in person, by overnight courier or by certified mail, return receipt requested. Don't settle for first class mail, even if the agreement says it is acceptable. You will have no proof it was received.

Notices should be sent far enough in advance so that they are received at the health plan prior to the deadline for notices. If the contract calls for 180 days prior written notice, make sure you have provided enough time for it to be received at the health plan at least 180 days in advance of the proposed termination or non-renewal date.

Unless the contract expressly states otherwise, it is not sufficient that it was postmarked by that date. It must be in hand at the health plan by that date. ◻

Robert E. Schiller *is a Partner at Garfunkel Wild, P.C., in Great Neck, New York. Send your practice management questions to* ***medec@advanstar.com****.*

Financial Strategies

THE PROS AND CONS OF EXPANDING INTO URGENT CARE

by **MARISA MANLEY, JD**

The number of urgent care centers in the United States is growing, and many physicians see expansion into urgent care services as an opportunity to grow their practices. These tips explore what medical practices need to consider when expanding into urgent care, including real estate needs, gauging the market and competition, and how to conduct market research.

MANY MEDICAL PRACTICES—from family care and pediatricians to orthopedic specialists— are looking into adding urgent care to the roster of services they offer.

With the growth in urgent care centers from 8,000 locations nationwide in 2008 to 9,300 in 2013, many physicians see such an expansion as an opportunity to grow their practices and increase their revenue.

What do practices need to consider when expanding into urgent care? Does it take more than just hanging out a new sign?

Here are several questions and tips practices should consider when exploring whether expansion into urgent care is the right move.

Determine if urgent care fits your practice

Decide whether you can and should devote space to providing urgent care service or convert the practice entirely into an urgent care practice.

All in all, you need to be very clear about how the urgent care facility fits into the overall practice strategy before you commit and spend funds.

A primary care physician (PCP), pediatrician, or orthopedic surgical practice, for example, may elect to set up an urgent care service as an adjunct to the regular practice. Emergency situations, such as an animal bite, can create a need for pediatric services on an urgent basis — waiting two weeks for an appointment is not an option during a medical emergency.

Get ready for new business costs

Plan for all costs of adding urgent care to an existing practice and facility. These may include adding space.

Consider what marketing efforts will be needed to inform the community of your new services. For instance, you'll need to attract walk-in patients. All of these changes and others imply additional costs.

Be realistic when assessing your facility needs

Assess facilities needs realistically, and understand how you expect to meet those needs. If you decide to expand within an existing facility, you will likely need a separate entrance and waiting area.

Patients waiting for a scheduled appointment will not be happy to see arriving patients receiving service before they do. As you expand, be aware of regulatory requirements that affect your build-out like permits or licenses for x-ray equipment.

Parking needs to be ample, convenient, and visible. If patients seeking urgent care must circle your parking lot to find a space, they will go elsewhere. A covered drop-off point may help.

Conduct thorough market research, study competition

Know and understand your market and the size of the area you will serve. Gauge the public's need for urgent care services in your area and the reasonable travel radius for patients to reach your practice.

You may have a built-in market as patients seek to avoid waiting in emergency rooms, but be aware that with the recent rapid growth in urgent care, some markets may

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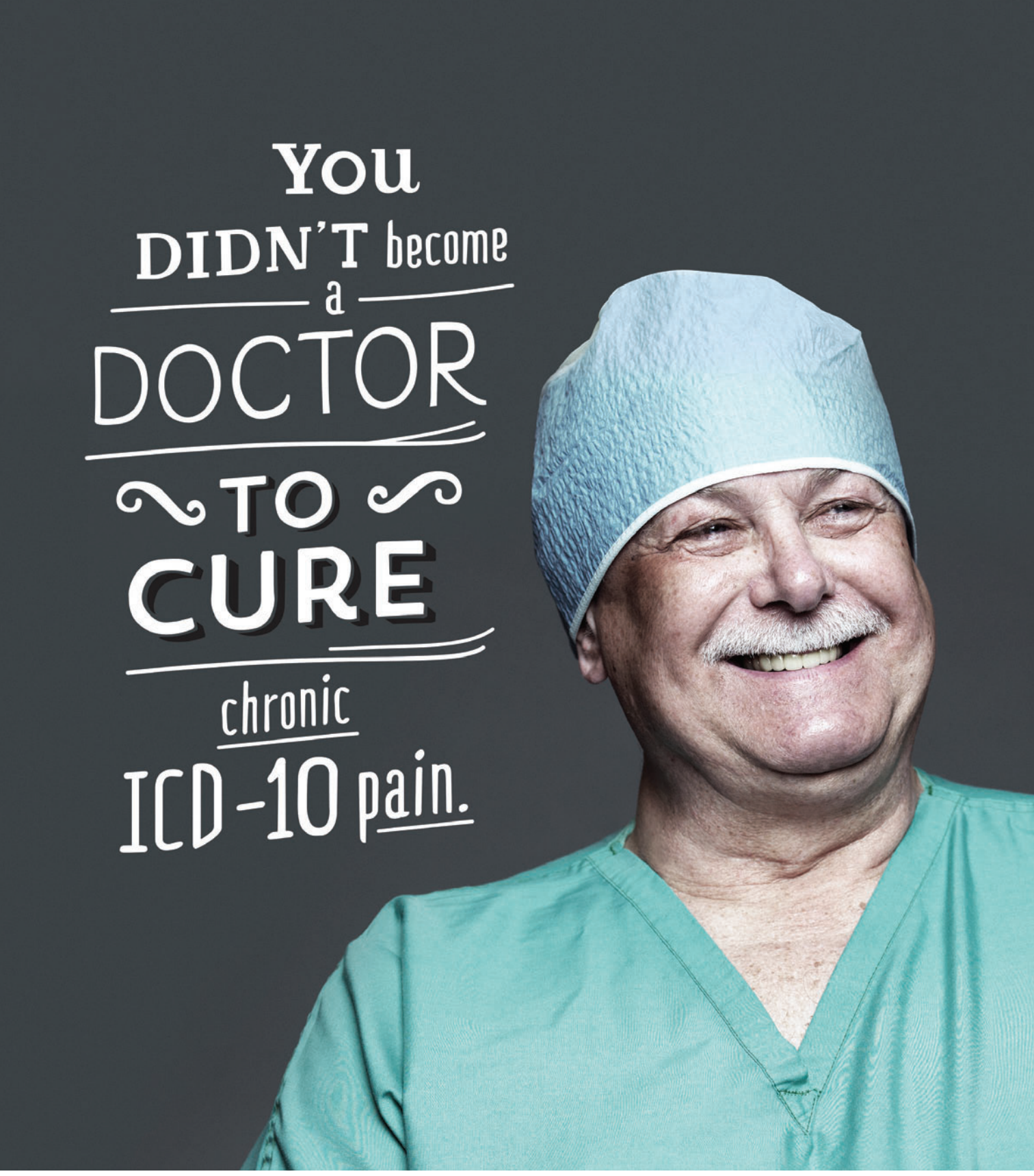

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➔58 be saturated. A new facility that opens on a major shopping strip may be the third or fourth urgent care operator in a four-mile stretch. It's a great location but could be doomed before it opens because of the competition.

Has a hospital established an urgent care center that will compete with you? Will establishing your own urgent care center diminish the referrals you receive from pediatric, internal medicine, and family practices?

Existing practices should see that you are not just a competitor but offer something different. Review the hours your competitors operate and when you can offer supplemental coverage.

So carefully research the local market conditions first. Determine the location of other urgent care centers through a market survey using professional real estate databases.

Study local laws and regulations

How will local laws and regulations affect your plans?

An urgent care practice needs walk-in traffic. This requires a highly visible location with instantly recognizable signage. Be aware of local signage ordinances and other restrictions that will limit your visibility.

DECIDE WHETHER YOU CAN AND SHOULD DEVOTE SPACE TO PROVIDING URGENT CARE SERVICE OR CONVERT THE PRACTICE ENTIRELY INTO AN URGENT CARE PRACTICE.

Other restrictions, laws, and regulations, such as parking restrictions, may be unfriendly to establishing new medical practices and services. So always check with your local planning department or other government agencies before beginning.

Consider your real estate your brand

Many patients seeking urgent care want an alternative to hospital emergency rooms. Others may have no primary care doctor and just want a quick way to treat a cold, fever, or sprain.

Here are some questions to consider when evaluating your facility:

- **Is your facility welcoming, clean and contemporary?**
- **Is the waiting area attractive with a soothing ambience?**
- **Do your patients feel comfortable—not too hot or too cold— in the exam room?**
- **Is the front office designed to help your patients register quickly and easily and then leave your practice without needless complication?**

Remember, your patients having positive experiences in your space will be key to your future success.

Use caution before entering market

Not every physician or group should jump on the urgent care bandwagon. Following these steps will help you determine if it is the right move for your practice.

A successful urgent care facility must have the correct real estate platform in terms of size, location, functionality, visibility, and accessibility.

If you've assessed the needs for urgent care in your market, gauged the competition, staffed with the best practitioners available and created a welcoming facility, urgent care can be a viable strategy for a new, independent practice or an expansion of your existing medical facility. ■

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Marisa Manley *is president of Healthcare Real Estate Advisors (HCREA) in New York, New York. Send your practice management questions to* ***medec@advanstar.com****.*

Tech Talk

ENSURING A SMOOTH TRANSITION TO YOUR NEW EHR SYSTEM

by **DEREK KOSIOREK,** *CPEHR, CPHIT*

Entering into a relationship with an electronic health records (EHR) vendor is like entering into a marriage. You need to select a partner with whom you can get along and trust, communicate openly, and who will have your back when times get tough. You want a partner who will share your long-term interests.

ENDING A MARRIAGE can be painful, but is it possible that separating from an EHR vendor can be just as bad?

There are many reasons to switch EHR vendors. Mergers or acquisitions often require reduced support of existing software. A practice's growth can render a product unusable. Organizational relationships with a new group or hospital may make a change beneficial. Often the main reason why practices change systems is because the current software is too difficult or impractical to use.

Technology is nothing more than a tool to manage information. If the tool doesn't do its job, it shouldn't be used. Many practices are beginning the process of changing EHR systems, and every one of them wants the next system to be better than the one they currently have.

You may think installing an EHR the second time will be tough. Believe it or not, it won't be. Your staff is now used to the changes that go with EHR, so that hurdle has already been overcome.

Here are some steps that can go a long way to ensure a smooth and successful second EHR implementation.

Set some goals

Many groups go into an EHR implementation without having clear expectations for what the EHR will do for them. If you were building a house, you wouldn't start just throwing bricks on the ground and hoping a functional house is the result. So why do it for software that may cost just as much as a house?

Instead, set specific goals for what you want to be happening with your software in the coming 12 to 18 months. Do you want reduced patient wait times? Do you want improved physician satisfaction? How about fewer errors? It may even be that you want staff and patients complaining less. The point is to set measurable goals, so you can revisit them and determine success after the project is finished.

Lesson learned

What could be improved from the last install? Did your staff receive enough training? Were the right computers and equipment purchased? Were the alerts set to trigger at the right times and frequency?

Remember, it is as important to keep in mind what went right as remembering what went wrong. What functionalities must you keep in the next generation of your EHR?

New technologies

By its nature, technology is an industry that evolves quickly. When looking at making major changes to your practice, it's important to consider the new ways of doing things.

The cloud is offering benefits that were inconceivable just a few years ago. Do your doctors or nurses want touchscreen tablets to carry around the office? It's possible now.

What method of remote access will you need to gain access to the system? Do the research, and find the most efficient methods.

Portals: your new front door

Whatever system you select, make sure that you plan to open your Internet portal for the patients to access EHR information.

There are many reasons to do this, but it's easy to predict that not having a portal will be a detriment to your practice in the coming years. If you don't have one, you can be sure your competitors will. ◘

The author is a principal consultant for MGMA Health Care Consulting Group. Send your practice management questions to ***medec@advanstar.com****.*

Trends

Genetic testing's brave new world

Why primary care physicians should be ready to address a wave of options poised to enter market

by **MARK CRANE,** *Contributing author*

HIGHLIGHTS

01 When discussing genetics with patients, physicians must dispel myths about genetics and what test results mean.

02 While some private insurers and Medicaid programs may balk at covering genetic tests, most are considered preventative services covered under the Affordable Care Act.

Actress Angelina Jolie made headlines around the world last May when she wrote an op-ed in *The New York Times* describing how she elected to have a preventive double mastectomy based on the results of genetic tests. Her decision cast genetic and genomic testing into the spotlight, and widescale product development may soon fuel new patient inquiries—a lot of them.

TODAY, THERE ARE MORE than 2,500 genetic tests available to aid in the diagnosis of more than 1,000 diseases and conditions. The number of tests is growing and becoming more commonly used to predict, diagnose, and aid in treatment decisions.

While primary care physicians (PCPs) say that only a tiny percentage of patients inquire about genetic testing and counseling, that is likely to change—and soon—for several reasons:

- The number of tests is expanding rapidly, enabling physicians to target how patients will respond to chemotherapy and radiation therapy. "By looking at genetic predispositions, the benefit in the therapeutic realm is just tremendous," says David Fleming, MD, chair of the department of internal medicine at the University of Missouri School of Medicine and president-elect of the American College of Physicians.

"IF YOU ASK PRIMARY CARE DOCTORS IF THEY KNOW ENOUGH ABOUT GENETICS, MOST WILL ANSWER 'NO.' THERE JUST AREN'T ENOUGH GENETIC COUNSELORS."

–FREDERICK CHEN, MD, MPH, ASSOCIATE PROFESSOR OF FAMILY MEDICINE, THE UNIVERSITY OF WASHINGTON

- **While some private insurers and Medicaid programs may balk at providing coverage, more genetic tests, including BRCA 1 and 2, are considered preventive services covered under the Affordable Care Act without a copay.**
- **Direct-to-consumer genetic testing, such as 23andMe, is being widely advertised. For $99, patients can receive reports on more than 240 medical conditions and traits. They are seeking advice from their family physicians about how to interpret the test results.**
- **There are only 1,400 physician geneticists and 3,000 certified genetic counselors, according to the American College of Medical Geneticists. Primary care physicians will need to be better prepared on the subject to meet increasing patient demand.**

Jolie's mother died of ovarian cancer at age 56. Genetic testing revealed Jolie has the BRCA 1 mutation and an 87% risk of breast cancer and a 50% risk of ovarian cancer. Jolie's message was to encourage every woman to seek out "information and medical experts who can help you through this aspect of your life, and to make your own informed choices."

1/ What PCPs need to know about genetics

According to Frederick Chen, MD, MPH, associate professor of family medicine at the University of Washington, a lot more dialogue about genetics and genomics testing will occur in primary care examination rooms around the country. And there is a need for education of physicians and patients.

"If you ask primary care doctors if they know enough about genetics, most will answer no," says Chen, who worked on the website geneticsinprimarycare.org, representing the American Academy of Family Physicians. "There just aren't enough genetic counselors. Family doctors are a trusted source for

"We need to make sure we have as much information as possible about the tests we're recommending before we have substantive discussion with patients."

—DAVID FLEMING, MD, CHAIR OF THE DEPARTMENT OF INTERNAL MEDICINE, THE UNIVERSITY OF MISSOURI SCHOOL OF MEDICINE AND PRESIDENT-ELECT, THE AMERICAN COLLEGE OF PHYSICIANS

GENETICS versus GENOMICS

There is a difference between **genetics** and **genomics**. The National Human Genome Research Institute, a division of the National Institutes of Health (NIH), provides these definitions and descriptions for genetics and genomics.

Genetics refers to the study of genes and their roles in inheritance—in other words, the way that certain traits or conditions are passed down from one generation to another. Genetics involves scientific studies of genes and their effects. Genes, the units of heredity, carry the instructions for making proteins, which direct the activities of cells and functions of the body. Examples of genetic or inherited disorders include cystic fibrosis, Huntington's disease, and phenylketonuria.

Genetics helps individuals and families learn about how conditions such as sickle cell anemia and cystic fibrosis are inherited in families, what screening and testing options are available, and, for some genetic conditions, what treatments are available.

VS

Genomics is a more recent term that describes the study of all of a person's genes (the genome), including interactions of those genes with each other and with the person's environment. Genomics includes the scientific study of complex diseases such as heart disease, asthma, diabetes, and cancer because these diseases are typically caused more by a combination of genetic and environmental factors than by individual genes. Genomics is offering new possibilities for therapies and treatments for some complex diseases, as well as new diagnostic methods.

Genomics is helping researchers discover why some people get sick from certain infections, environmental factors, and behaviors, while others do not.

patients and their families. We should know who to call to refer for testing and how to help patients get counseling they need. We must be that conduit and bridge."

Fleming agrees. "I have the luxury of being able to refer patients to a large genetics group at the university medical center but most physicians don't have that available," he says. "By default, much of the discussion about genetics falls to primary care doctors who aren't trained as counselors. We need to make sure we have as much information as possible about the test we're recommending before we have substantive discussion with patients. We really need to revamp the curriculum in medical school and training to provide those skills."

Fear is a main reason patients won't ask about genetic tests. Some may not want to know the results, presuming a positive result means there's nothing they can do.

"Patients also are uncertain about whether test results will truly be confidential," says Gregory Hood, MD, an internist in Lexington, Kentucky, and a *Medical Economics* editorial adviser. "They worry that their employers may find out, their insurance will be dropped, or they'll have to pay a higher premium."

That concern is real despite the Genetic Information Nondiscrimination Act of 2008 that protects patients from being treated unfairly because of DNA information.

"We try to use a genetics clinic that does a lot of discussion and counseling before the test is even ordered," Hood says. "It's important to demonstrate to patients that you've thought one or two steps beyond just ordering the test, that you're looking for the best approach to benefit the patient. Taking a good history is still the most important step. Just as we were taught in medical school, when resolving issues with patients, it's 70% history, 20% examination and 10% testing. The growth in genetic testing doesn't change that dynamic."

Genetic testing may be underutilized because it's expensive. For example, the BRCA test can cost more than $3,000. "The cost is a

huge issue," says W. Gregory Feero, MD, PhD, a family physician and genetics specialist in Fairfield, Maine. "In Maine, 25% of the population is on Medicaid. It's very difficult to get the state to pay for genetic testing. Large private insurers usually pay for it, realizing that testing could save lives and resources.

"Some physicians won't always inform patients about testing if they think the individual can't afford it," says Feero, who also was chief of the Genomic Healthcare Branch of the National Human Genome Research Institute at the National Institutes of Health. "That's an ethical dilemma. If I know Medicaid won't pay, should I recommend it anyway? I always tell patients about the risk and offer them options. You'd hate to have a patient come back and say, 'I'd have paid for that out of my own pocket if only you'd told me about it.'"

With close to 50 million uninsured people in the United States, Fleming says those without the means don't have the option to get testing that can positively influence treatment and inform decision-making.

"If you can't pay for it, you can't have it. That's a real issue," he says.

2/ Talking with patients about genetic testing

There is no approved dialogue or template for discussing genetic testing with patients, although there may be soon as the field grows and approaches become more standardized.

Typically, the issue is raised when talking about family history. "I may see a red flag, such as someone in the family affected by cancer at an early age, multiple cancers in the family, or an unusual presentation such as male breast cancer," Feero says. "Then you try to flush out more family history.

"I'll talk to the patient about what the red flag could mean, and if appropriate, make a referral to a genetic specialist for more formalized counseling and potential testing," he adds. "I've never ordered a test myself. I tell the patient that counseling can be lengthy. It's wise to bring a relative with them who knows the family history or may also be affected by the disease."

It's important for the patient to inform family members about their testing, and PCPs can often be the conduit for that disclosure. "The doctor can't reveal it without the patient's permission. His [or her] information must be confidential," Chen says. "But we can certainly encourage the patient to reveal it. A good example is with colon cancer. If the patient tests positive for the trait, he [or she] should let family members also at risk know about it. So I've said, 'This is a risk for you but also for other family members.' If the patient is positive for the gene, you can recommend earlier screening such as a colonoscopy at age 30 for him and family members."

Fleming agrees. "It's the patient's genetic information, and he has the right to withhold it even from family members who might benefit from knowing. We can encourage disclosure but can't force it. For example, a parent may have a marker for Huntington's disease which can't be treated. He may opt against informing his children."

3/ Myths to dispel about genetic testing

Patients have myths about testing that need to be debunked.

"Many patients believe that a positive genetic test means they will definitely develop the disease," Feero says. That's true in some cases like Huntington's. But for many conditions, especially cancer, the test shows that the risk is elevated but it doesn't mean they will develop cancer."

Another myth is that the test tells the patient everything he or she needs to know about a prognosis, Chen says.

"What we've learned is that the interface between genes and environment is complicated. You can't just say you have a 50% chance of getting diabetes, for example. What you eat, how much you exercise, etc., has an important impact.

"I also worry about patients who get their own gene testing done with a direct to consumer kit," Chen says. "They think it will give them the answer for all diseases. It's much more complex than that."

Feero agrees. "I've had only one patient who had a direct-to-consumer test. But I'd tell patients that these panels aren't very useful for making healthcare decisions."

The American Medical Association (AMA) has called for greater oversight of these tests as has the U.S. Food and Drug Administration and American Society of Human Genetics.

"Without the benefit of proper medical counseling, patients may spend money on direct-to-consumer genetic tests needlessly

"Some physicians won't always inform patients about testing if they think the individual can't afford it. That's an ethical dilemma. I always tell patients about the risk and offer them options."

—W. GREGORY FEERO, MD, PHD, FAMILY PHYSICIAN AND GENETICS SPECIALIST, FAIRFIELD, MAINE, AND FORMER CHIEF OF THE GENOMIC HEALTHCARE BRANCH OF THE NATIONAL HUMAN GENOME RESEARCH INSTITUTE

WHAT ARE THE TYPES OF GENETIC TESTS?

This listing describes some of the most common. The information and descriptions below are from the U.S. National Library of Medicine.

NEWBORN SCREENING

Newborn screening is used just after birth to identify genetic disorders that can be treated early in life. Millions of babies are tested each year in the United States. All states currently test infants for phenylketonuria (a genetic disorder that causes mental retardation if left untreated) and congenital hypothyroidism (a disorder of the thyroid gland). Most states also test for other genetic disorders.

DIAGNOSTIC TESTING

Diagnostic testing is used to identify or rule out a specific genetic or chromosomal condition. In many cases, genetic testing is used to confirm a diagnosis when a particular condition is suspected based on physical signs and symptoms. Diagnostic testing can be performed before birth or at any time during a person's life, but is not available for all genes or all genetic conditions. The results of a diagnostic test can influence a person's choices about health care and the management of the disorder.

CARRIER TESTING

Carrier testing is used to identify people who carry one copy of a gene mutation that, when present in two copies, causes a genetic disorder. This type of testing is offered to individuals who have a family history of a genetic disorder and to people in certain ethnic groups with an increased risk of specific genetic conditions. If both parents are tested, the test can provide information about a couple's risk of having a child with a genetic condition.

PRENATAL TESTING

Prenatal testing is used to detect changes in a fetus's genes or chromosomes before birth. This type of testing is offered during pregnancy if there is an increased risk that the baby will have a genetic or chromosomal disorder. In some cases, prenatal testing can lessen a couple's uncertainty or help them make decisions about a pregnancy. It cannot identify all possible inherited disorders and birth defects, however.

PRE-IMPLANTATION TESTING

Preimplantation testing, also called preimplantation genetic diagnosis, is a specialized technique that can reduce the risk of having a child with a particular genetic or chromosomal disorder. It is used to detect genetic changes in embryos that were created using assisted reproductive techniques such as in-vitro fertilization. In-vitro fertilization involves removing egg cells from a woman's ovaries and fertilizing them with sperm cells outside the body. To perform preimplantation testing, a small number of cells are taken from these embryos and tested for certain genetic changes. Only embryos without these changes are implanted in the uterus to initiate a pregnancy.

PREDICTIVE AND PRESYMPTOMATIC TESTING

Predictive and presymptomatic types of testing are used to detect gene mutations associated with disorders that appear after birth, often later in life. These tests can be helpful to people who have a family member with a genetic disorder, but who have no features of the disorder themselves at the time of testing. Predictive testing can identify mutations that increase a person's risk of developing disorders with a genetic basis, such as certain types of cancer. Presymptomatic testing can determine whether a person will develop a genetic disorder, such as hemochromatosis (an iron overload disorder), before any signs or symptoms appear. The results of predictive and presymptomatic testing can provide information about a person's risk of developing a specific disorder and help with making decisions about medical care.

or misinterpret the results of the tests, causing them to make unnecessary or unhealthy lifestyle changes," says AMA President Ardis Dee Hoven, MD.

As demand for genetic testing grows, the healthcare system will need a more effective electronic health record infrastructure.

"It needs to not only store medical information but provide point of care education about the tests primary care doctors will encounter," Feero says. "It should be set up so that patient handouts can be printed out so the burden isn't on the physician to keep it all in his head. We're a long way from doing that right now."

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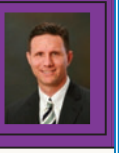

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The Last Word

RUC COMMITTEE TAKES STEPS TOWARD TRANSPARENCY

by **DONNA MARBURY, MS** *Content Specialist*

After a series of negative media reports, the American Medical Association (AMA) is finally taking measures to make its Specialty Society Relative Value Scale Update Committee (RUC) less opaque.The 31-member RUC committee will begin publishing minutes, dates and locations of meetings, and votes for individual current procedural (CP) codes, though individual votes will not be revealed.

THE COMMITTEE will also revamp the way it gathers information from physicians, which determines how the committee sets values for services. Now, the committee will require more surveys for the most frequently-performed procedures. Any procedure performed more than 100,000 times annually will require at least 50 surveys, and procedures performed more than 1 million times will require more than 75 surveys.

Information about RUC meetings will be posted on the AMA website after the Centers for Medicare and Medicaid Services (CMS) releases its annual fee schedule. The RUC committee has been accused of overvaluing certain procedures—sometimes by up to 100%.

Some doctors have reported working more than 24 hours a day on procedures that were recommended by RUC as taking longer—and costing more—than they should. For example, an investigation by the *Washington Post* last summer found that Medicare pays for colonoscopies that are valued at 75 minutes, yet actually take 15 minutes.

Though RUC is an independent body, for the past 22 years CMS has used about 90% to 95% of RUC's recommendations. Some organizations believe that disparities in valuing procedures have caused a reimbursement divide between specialists and primary care physicians. Though CMS usually publishes its Medicare fee schedule on November 1, due to the 16-day government shutdown in October, the schedule will be released on November 27.

The American Academy of Family Physicians' (AAFP) criticism of RUC's lack of primary care representation led to the committee adding a rotating primary care chair and suggesting CP codes for chronic care management this year.

"Only time will tell whether these changes lead to a fair evaluation of all physician services, particularly primary care," says Glen Stream, MD, MBI, immediate past board chair of AAFP.

"The recent actions the RUC has taken regarding transparency are positive steps in the right direction. They are consistent with AAFP's efforts to push for greater transparency in the RUC process along with more representation of primary care physicians on the RUC," Stream says.

"I am very interested to see the vote tallies. Even the people sitting around the table don't know the final vote tally," says Shari Erickson, vice president of governmental and regulatory affairs for the American College of Physicians (ACP), adding that the ACP will wait and see if any other recommendations from the organization could make the RUC process more open.

"The concern would be that releasing individual votes could lead to the industry lobbying individuals who vote in a certain pattern. If it turns out that there are people voting in a bloc, then maybe there should be a call for the release of individual votes. But this initial step is very positive and we want to see what things look like," Erickson says.

According to the AMA website, RUC meetings are not closed, but they do require prior registration for attendance. The RUC committee meets three times a year, with its next meeting scheduled for January 30, 2014, in Phoenix, Arizona.

@ Do you think transparency at RUC meetings will help or hurt healthcare? Write us at medec@advanstar.com. Your comments could be included in the next issue of *Medical Economics*.