Rethinking Quality Care

Hidden key to better outcomes, lower costs

PLUS

PHYSICIANS GRILL DR. GOOGLE
DOCS TEST SYMPTOM SEARCHES

MEET PATIENT EXPECTATIONS
A GAME PLAN FOR SUCCESS
Physicians can’t serve patients alone

In recent analysis of 1,500 U.S. physicians and 1,750 patients, HRI found that both consumers and clinicians are ready to embrace broader care teams to improve patient care. And since Medicare and private payers are basing more reimbursement on outcomes, the healthier your patients, the healthier your practice will be financially.

...it’s what your patients want these days: someone to treat all their needs on their schedule.

In fact, HRI found that a primary care dream team designed around the needs of complex chronic patients—whose improvement is crucial to providing quality care—could result in $1.2 million in savings for every 10,000 patients treated. Now you can tweak those numbers for your own practice to see that savings are possible.

From discussions I’ve had with physicians, I know they do see value in adding new team members to their practices, but cost is often a concern. HRI found that while few practices today employ them, dieticians, mental health professionals, clinical educators and social workers were tops on the dream team wish list for primary care docs. (For more on integrating behavioral health into primary care, see our cover story on page 18).

Any primary care dream team should take into account patient preferences regarding who they are comfortable seeing and their complex health needs when drafting team members, HRI says. So take a hard look at your patient panel and determine who would best aid you in caring for your patients. Is it a dietician to help your patients with diabetes? Do you need a nurse practitioner to help with routine checks of elderly and/or frail patients? Would a mental health expert help you knock down barriers to better treatment compliance?

Primary care is changing, driven by patient demand and reimbursement based on quality outcomes. To succeed, physicians can no longer go it alone. By building a team of your choosing around you—either of employees or community partners — the end goal is still the same: better patient care.

Keith L. Martin is editorial director of Medical Economics. Who would you add to your primary care dream team? Tell us at medec@ubm.com.
Addressing mental health

The hidden key to better outcome, lower costs

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Doctors can be paid to put patient care on backburner

n regards to the *JAMA* article (“Irresponsible to say physicians can be bought to put patient care second,” June 25, 2016) alleging physicians can be influenced by drug representative incentives/meals, I have to agree with their points.

I closed my practice about five years ago. During my 25 years in solo practice, I was bombarded with representative offers of meals, golf and early on, even trips. I would accept meals provided only to me, in conjunction with a detail of the product.

I did accept golf, if a conference was included. I found the representatives to be extremely pushy at every visit. When I decided to become a freelance provider, I worked in numerous offices. What I found, in regards to other representative-doctor relationships, shocked me.

I witnessed representatives providing meals to 15 to 20 staff members (nurses, clerks, medical assistants ... even bookkeepers!) Sometimes, the doctor(s) didn’t even appear for the meal or details.

I also was often told by individual representatives (when asked), that they couldn’t even “get in to see the doctor” unless the whole staff was fed, and some said certain days were set apart for each company.

The most damming statement I heard from one representative, years ago, was that a local clinic even offered employees free meals—if they took a positive position. I’m glad the industry has had to cut back [on incentives] and I am certain as Congress continues to crack down on these so-called doctor-representative “partnerships,” our profession is going to see even stricter rules, mainly because of the abuses of the above mentioned offices.

Craig Freyer MD
COLLEYVILLE, TEXAS

No doubt about it, EHRs are terrible

As a primary care physician, I’m just going to say it, all electronic health records (EHRs) suck. They suck the life out of physicians, they suck the time out of relationships in human interactions and they suck at any utility other than being a glorified digital file cabinet and a clunky digital cash register.

If we remember one thing, medicine is about patients and patients require time to process new diseases, new treatment plans and new ways of having to cope, then we should all come to the requisite conclusion that patients arguably need more time than EHRs need data. That said, data is important—trying to solve this problem for myself, I built some software in my office years ago that connects doctors and patients, in between visits that took no extra work from doctors and empowered and engaged patients to connect so their doctor knew how they were doing.

It’s a tool that, surprisingly, is now the tool of choice for many large healthcare systems around bundles and value. If you care about patients and not metrics, you win.

Anonymous
ONLINE COMMENT

“We should all come to the requisite conclusion that patients arguably need more time than EHRs need data.”
We must stay on the Obamacare course

In the article, written by Craig Wax, DO (“Healthcare reform is still possible, but Obamacare must go”, Sept. 25, 2016), the following statements are particularly worthy of attention: “The ACA is perhaps the largest tax ever levied upon the citizens and the most expensive failure in our nation’s history...Now we are faced with politicians who promise to ‘fix’ it or double down with government single-payer healthcare. I vote instead for full repeal.”

The following is my reply to this article: I want my voice to be heard, as another DO, but with a different view from that of Craig Wax, who espouses a free market for health insurance.

We had a free market prior to Obamacare, but the poor ... did not have any insurance. Now 20 million people are covered by Obamacare. Some people might want to return to the former system, but not my patients, who are grateful that they can be treated for their illnesses under Obamacare.

Obamacare is not a perfect health system, but it is an improvement over what we had before; it can be improved further. Ditching it completely would be a giant step backwards.

Yes, we need to continue Obamacare for those 20 million people and more, because the poor will always be with us, and yes, we are our brother’s keeper. Especially doctors.

V. Heemstra, DO
WHITE PLAINS, NEW YORK

Concern for Medicare patients grows

I read your article, “Obamacare Report Card (July 25, 2016)” and the editorial by Dr. Chandler “Obamacare hasn’t solved the challenge of uninsured patients (July 25, 2016)” with great interest.

I am a solo practitioner in California and would like to point out some of our problems with the ACA expansion of Medi-Cal (Medicaid run by the state of California). When the federal government passed the Medicaid-Medicare parity rule, highlighted in the Report Card article, the state of California took them to court saying that since the state runs the program the federal government cannot tell them what to pay doctors.

The state won and an average office visit still pays a pitiful $16 which does not cover office/billing expenses for most doctors. Currently, California has the highest number of Medicaid (Medi-Cal) patients of any state and 30% of our population is on Medicaid (Medi-Cal). Since 2013, the Medi-Cal enrollment increased by 39% but the number of participating doctors fell from 69% to 63% and continues to decline.

Only 69% of participation physicians are accepting new patients.

So, the ACA has increased the number of people with Medi-Cal but reduced the number of doctors treating them. And yes, in order to get care many patients still have to go to the emergency room. As the federal Medicaid subsidies to states decrease and eventually are gone, state governments will have some very tough choices to make. I cannot see how Medicaid patients will be able to get adequate care in the coming years.

Gary Peer, MD
LIVERMORE, CALIFORNIA

Repeal, don’t repair, Medicare pay reform

In response to “GOP Doctor’s Caucus: We’ll fix MACRA if CMS won’t (November 25, 2016),” MACRA must be ended, not mended.

MACRA is based on the false assumption that central planners are capable of assessing a patient better than that patient’s physician.

MACRA reduces the role of the physician to data entry and implementation of a checklist of approved “quality” measures. Money which is needed to pay for physician services is diverted to pay for quality bonuses.

But no “quality bonus” ever admitted a sick patient to the hospital at 3 a.m.

Anonymous
ONLINE COMMENT

In reply to “7 tips to stop technology from damaging the patient experience”

Good tips. Remember #HealthIsPrimary and make the patient the center of your attention, not the computer.

@aafpprez
VIA TWITTER
Extended practice hours may reduce emergency department visits

However, the question remains: Are longer hours practical for most primary care practices? Nitin Damle, MD, MS, FACP, president of the American College of Physicians and a practicing internist, says they are indeed worth it.

“We have had after-hours and Saturday morning hours for 15 years,” he says. “We find it helpful to patients, and it seems to decrease ER use modestly along with providing continuity of care.”

Turning to the familiar primary care practice instead of the emergency department provides patients with the benefit of professionals who already know their medical history.

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BLOGGERS

“Medicare and Medicaid have problems that far exceed those of Social Security. Although besieged by demographic issues, Social Security pays out a fixed amount per person according to a known formula.”

— Ken Fisher, MD, internist/nephrologist in Kalamazoo, Michigan

“With tons of vendors offering this that and the other, it can be overwhelming for providers who are new to telehealth. Often, technical jargon gets thrown around when it comes to telehealth, leaving providers in a haze.”

— Jake DiBattista, a territory manager at SimpleVisit, a video service provider for physicians

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TOP HEADLINES NOW

16 spooky Halloween-themed ICD-10 codes

ICD-10 has some very specific codes doctors may need this fall

Avoid financial disaster when collecting patient debt

As deductibles rise, the ability for physicians to avoid financial ruin gets to be tougher if patient balances aren’t taken seriously

5 tips for tactfully combatting negative patient reviews

Review sites like Yelp and Healthgrades often attract patients who are likely to air grievances
PREVENTION IS REALITY

While traditional HIV prevention methods remain essential and effective, the epidemic continues.1 We have entered an era of HIV prevention in which the National HIV/AIDS Strategy, clinical studies, and the latest federal and global health guidelines (including those from the CDC and WHO) recognize the importance of a comprehensive prevention approach.2-6 Be part of this prevention movement.

You can help protect your patients by utilizing a comprehensive approach. Be proactive. Combine routine HIV and STI testing with sexual history conversations and education on the importance of condoms. For HIV-positive patients, initiating and adhering to treatment helps prevent HIV transmission to negative partners. For HIV-negative patients at risk of HIV infection, consider additional prevention methods such as behavioral counseling, PrEP (pre-exposure prophylaxis), and PEP (post-exposure prophylaxis).3 Learn more about using a comprehensive prevention approach, and help end the HIV epidemic.1

Visit PreventHIV.com for more information.

hopping for healthcare may be a hassle, but patients are beginning to look around with the help of savings and incentives, according to a recent report.

The report, conducted by Vitals (a healthcare website that provides tools to access affordable care), analyzed the activity of more than one million of its members from January to July 2016. Women accounted for 70% of the shoppers. Forty-two percent of their members age 46 or older accounted for 70% of the shopping.

Because large price variations exist between medical facilities for the same procedure regardless of quality, the healthcare website’s program rewards people who shop for high-quality, lower-cost care. The program shares a portion of the savings generated with members, giving them up to $500 in cash, although more than half of the incentive amounts members earned were $50 or less. Less than 6% were $200 or more.

The top five procedures people shopped for on Vitals included lab work, mammograms, MRIs, colonoscopies and CT scans.

"People don’t have an emotional attachment to the radiologist tech who performs their imaging scan or the phlebotomist who draws their blood," Mitch Rothschild, chairman and founder of Vitals, said in a press release. "People are willing to shop for these type of routine procedures because it doesn’t disrupt the traditional doctor-patient relationship."

With loyalty no longer a factor, patients head online to shop for healthcare

**PERSONAL SHOPPING ADVOCATES**
While 66% of people search online for a physician, two-thirds of those who actually switch — and therefore create savings — come in through Vitals’ call center where consumers can talk to personal shopping advocates.

**CLOSE TO HOME**
Members were also more willing to switch when they didn’t have to travel far for a better-value facility. Over 80% of the people who switched drove less than 20 miles. In comparison, 4% percent were willing to drive 40 miles or more.
Introducing MiraFIBER—from the trusted makers of MiraLAX®

- A nonfermentable fiber less likely to cause uncomfortable gas
- Adds bulk to stool to help support regularity* 
- 100% soluble fiber for nongritty taste
- Also available in convenient caplets

Recommend MiraFIBER. Help keep your patients going.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.
Scrambling to make a meaningful connection

It’s more difficult than ever to connect with patients. One physician explains why its worth the effort.

by STEPHEN WALSTON, MD Contributing author

Practicing medicine in the 21st century is hard. Demands on doctors are nothing new, but inevitably the expectations of every player in healthcare continues to evolve.

My clinic expects me to meet my productivity threshold, earn high patient satisfaction scores, be available for coverage on weekends and evenings, and put forth a collegial and positive presence in the office.

Insurance companies expect me to document thoroughly and bill accurately for each clinical encounter using the most current version of the ICD, justify the medical decisions I make and represent the disease burden of my patient panel with HCC coding and RAF scoring and meet current quality measures for complex diseases like high blood pressure and diabetes.

But today’s specific topic (not unlike a good physician) focuses on patients. What do they expect?

An appointment at their preferred time with minimal waiting. Free parking. They expect to be able to talk about each of their concerns in the allotted time, and expect to leave with adequate diagnostic and prognostic information. They expect to be guided on a path to feeling and living better. And the only way I can adequately rise to that challenge is by creating a real connection within the doctor-patient relationship.

As a primary care doctor, connecting with patients is my most important job. And that connection is where the joy of medicine is really found. It’s a feeling of genuine trust and mutual respect. It requires patience, active listening, clear and useful information, and providing real emotional support.

Take a second and imagine the satisfaction a quarterback must feel when he completes a perfect throw to a wide-open receiver in the end zone. It’s a great feeling when things come together that way—that’s why he chose to play football.

In this healthcare environment, the act of making that type of successful connection sometimes feels less like an easy perfect spiral and more like a wild hail Mary—while running sideways full-speed, away from a swarm of 300-pound linebackers.

Don’t understand football? I know how you feel: sometimes I don’t understand the healthcare system.

In any case, I don’t want to make it seem like connecting...
The cure for physician burnout:

LET DOCTORS BE DOCTORS™

The average doctor spends 49.2% of their day on the EHR. It’s not hard to see why more than half of all physicians are burned out.

At athenahealth®, we organize the moment of care, provide built-in clinical guidelines, and allow doctors to delegate non-clinical tasks. So you can get back to the job you do best: caring for patients.

athenahealth.com/burnout
As a primary care doctor, connecting with patients is my most important job. And that connection is where the joy of medicine is really found.

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Operations

2016 Physician Writing Contest

As a primary care doctor, connecting with patients is my most important job. And that connection is where the joy of medicine is really found.

with patients is a lost cause. In fact, here are two strategies that have helped me get better at this.

CREATE A GAME PLAN

I've found the habit of "agenda-setting" right at the start of the visit is an effective tool to optimize the use of time. Before I even get into the details of a single problem, I want to know everything that's on my patient's list of issues to discuss. I'll often encourage them to write that list down before the visit. Some items may be very simple and addressed with a very quick answer to their satisfaction.

To my occasional mild shock, I've been able to address issues numbering into the double-digits in one visit using this technique, and patients undoubtedly appreciate it. Sometimes one of these issues could be potentially serious and buried at the bottom of a long list of fairly benign and non-urgent items. Agenda-setting right from the start helps me quickly identify what needs to be addressed today, not tomorrow.

When we arrive at the end of the agenda I read the entire thing back to my patient, line by line. Sometimes I actually notice a subtle change in their demeanor as I do this, almost as if they're thinking to themselves, "Gosh, that actually sounds like more stuff to discuss than I realized." And when the list proves to be too long for a 15-minute visit, it's time to work together so the final agenda can be set.

"OK great, Mr. Thompson, I see we have nine issues on our list, and unfortunately we won't be able to do adequate justice to each of these things during our time today. I feel it's really important to discuss your chest pain, as this could be the most serious. Let's choose an additional two issues that are most important to you..."

This gives patients a more active role in planning the visit, and they leave knowing their other concerns were at least briefly heard. And if we need to schedule more time in the near future to address issues four through nine, we can plan for that as well.

MAKE SURE EVERYONE UNDERSTANDS THE PLAY

The other crucial time for making connections often comes at the end of the visit when communicating my assessment and plan. This is important for both patients and the family members involved in their care. While health systems often act as if every patient fits neatly into a 15-minute box, some most certainly do not. In order to give the best counseling possible, I need to know what my patient knows. So I ask them:

"Based on the injury you described to me and my findings on your shoulder exam, your pain strongly suggests a rotator cuff injury, Ms. Greene. Before we go further, however, tell me this: What do you know about rotator cuff injuries?"

The response may be, "My sister had a rotator cuff injury and she had to have surgery, and I definitely don't want to have surgery." Or they may know more about rotator cuff injuries than I do. But now that I have a better idea of where my patient is coming from on this specific problem, I can start from their place of knowledge, address their specific concerns and ultimately recommend a treatment plan that is safe, effective and consistent with their values.

Making these connections is hard work, but it's critical to being an effective physician and reaching a therapeutic goal. When I use the two techniques described above, one at the beginning of a visit and another at the end, by the time a patient leaves my clinic, we're much more likely to be working together as a team.

MORE ONLINE Read the winners of the 2016 Physician Writing Contest at: MedicalEconomics.com
In the treatment of type 2 diabetes, along with diet and exercise, INVOKANA® can
AWAKEN A TRANSFORMATION

INVOKANA® 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®, such as anaphylaxis or angioedema
- Severe renal impairment (eGFR <30 mL/min/1.73 m²), 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.
In the treatment of type 2 diabetes, along with diet and exercise, INVOKANA® can

**AWAKEN A TRANSFORMATION**

INVOKANA® 300 mg demonstrated superior reductions in A1C, body weight,* and systolic blood pressure (BP)* vs Januvia® 100 mg²-⁴

- In a prespecified analysis, superiority was determined once noninferiority was confirmed

### Adjusted Mean Change in A1C From Baseline at 52 Weeks (%)²

<table>
<thead>
<tr>
<th></th>
<th>Mean baseline:</th>
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<tbody>
<tr>
<td>Januvia® (sitagliptin) 100 mg + metformin and a sulfonylurea (n=378)</td>
<td>8.13%</td>
<td>8.12%</td>
<td></td>
</tr>
<tr>
<td>INVOKANA® 300 mg + metformin and a sulfonylurea (n=377)</td>
<td>-0.66</td>
<td>-1.03</td>
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**Prespecified secondary endpoints:**

<table>
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<tr>
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<th>Adjusted mean change in body weight from baseline at 52 weeks²:</th>
<th>Adjusted mean change in systolic BP from baseline at 52 weeks:³</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>&gt;&gt; Difference from Januvia®*: −2.8% (−5.3 lb) (95% CI: −3.3, −2.2; P&lt;0.001)</td>
<td>&gt;&gt; Difference from Januvia®*: −5.9 mm Hg (95% CI: −7.6, −4.2; P&lt;0.001)</td>
</tr>
</tbody>
</table>

INVOKANA® starting dose: 100 mg once daily. In patients tolerating the starting dose who have an eGFR ≥60 mL/min/1.73 m² and require additional glycemic control, the dose can be increased to 300 mg once daily.²

Indicated trademarks are registered trademarks of their respective owners.

**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 m²), elderly patients, patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system, or patients with low systolic blood pressure. Before initiating in patients with ≥1 of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating.
Similar overall incidence of AEs vs Januvia

Incidence of any AE, Januvia® 100 mg: 77.5%; INVOKANA® 300 mg: 76.7%
Incidences of specific AEs were similar between groups, except for:
Male/female genital mycotic infection, Januvia® 100 mg: 0.5%/4.3%; INVOKANA® 300 mg: 9.2%/15.3%

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

Ketoacidosis: Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, have been identified in patients with type 1 and 2 diabetes mellitus receiving SGLT2 inhibitors, including INVOKANA®. Fatal cases of ketoacidosis have been reported in patients taking INVOKANA®. Before initiating INVOKANA®, consider factors in patient history that may predispose to ketoacidosis, including pancreatic insulin deficiency, caloric restriction disorders, and alcohol abuse. In patients treated with INVOKANA®, consider monitoring for ketoacidosis and temporarily discontinuing in clinical situations known to predispose to ketoacidosis (eg, prolonged fasting due to acute illness or surgery).

Acute Kidney Injury and Impairment in Renal Function: INVOKANA® causes intravascular volume contraction and can cause renal impairment. Postmarketing reports of acute kidney injury, some requiring hospitalization and dialysis, were reported; some reports involved patients younger than 65 years of age. Before initiation, consider factors that may predispose patients to acute kidney injury including hypovolemia, chronic renal insufficiency, congestive heart failure and concomitant medications. Consider temporarily discontinuing INVOKANA® in any setting of reduced oral intake or fluid losses; monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue promptly and institute treatment.

INVOKANA® increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiation. Renal function should be evaluated prior to initiation and periodically thereafter. Dose adjustment and more frequent renal function monitoring are recommended in patients with an eGFR <60 mL/min/1.73 m².

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.
**IMPORTANT SAFETY INFORMATION (cont’d)**

**Hyperkalemia:** INVOKE\textregistered A® can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.

**Uroepithelial and Pyelonephritis:** There have been reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors, including INVOKE\textregistered A®. Treatment with SGLT2 inhibitors increases this risk. Evaluate patients for signs and symptoms and treat promptly.

**Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues:** INVOKE\textregistered A® can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKE\textregistered A®.

**Genital Mycotic Infections:** INVOKE\textregistered A® increases risk of genital mycotic infections. Patients with history of these infections and uncircumcised males were more likely to develop these infections. Monitor and treat appropriately.

**Hypersensitivity Reactions:** Hypersensitivity reactions, including angioedema and anaphylaxis, were reported with INVOKE\textregistered A®; these reactions generally occurred within hours to days after initiation. If reactions occur, discontinue INVOKE\textregistered A®, treat per standard of care, and monitor until signs and symptoms resolve.

**Bone Fracture:** Increased risk of bone fracture, occurring as early as 12 weeks after treatment initiation, was observed in patients using INVOKE\textregistered A®. Consider factors that contribute to fracture risk prior to initiating INVOKE\textregistered A®.

**Increases in Low-Density Lipoprotein (LDL-C):** Dose-related increases in LDL-C can occur with INVOKE\textregistered A®. Monitor LDL-C and treat per standard of care after initiating.

**Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKE\textregistered A® or any other antidiabetic drug.

**DRUG INTERACTIONS**

**UGT Enzyme Inducers:** Rifampin: Co-administration of INVOKE\textregistered A® with rifampin decreased INVOKE\textregistered A® area under the curve (AUC) by 51% and therefore may decrease efficacy. If an inducer of UGT enzymes must be co-administered with INVOKE\textregistered A®, consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKE\textregistered A® 100 mg once daily, have an eGFR ≥60 mL/min/1.73 m², and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR <60 mL/min/1.73 m² who require additional glycemic control.

**Digoxin:** There was an increase in the AUC and mean peak drug concentration of digoxin (20% and 36%, respectively) when co-administered with INVOKE\textregistered A® 300 mg. Monitor appropriately.

**Positive Urine Glucose Test:** Monitoring glycosuria control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose test results. Use alternative methods to monitor glycosuria control.

**Interference With 1,5-Anhydroglucitol (1,5-AG) Assay:** Monitoring glycosuria control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycosuria control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycosuria control.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy:** Based on animal data showing adverse renal effects, INVOKE\textregistered A® is not recommended during the second and third trimesters of pregnancy. Limited data with INVOKE\textregistered A® in pregnant women are not sufficient to determine a drug-associated risk for major birth defects or miscarriage. There are risks to mother and fetus associated with poorly controlled diabetes in pregnancy.

**Nursing Mothers:** There is no information regarding the presence of INVOKE\textregistered A® in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed infant, advise women that use of INVOKE\textregistered A® is not recommended while breastfeeding.

**Pediatric Use:** Safety and effectiveness in patients <18 years of age have not been established.

**Geriatric Use:** 2034 patients ≥65 years and 345 patients ≥75 years were exposed to INVOKE\textregistered A® in 9 clinical studies. Patients ≥65 years had a higher incidence of adverse reactions related to reduced intravascular volume (eg, hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300-mg dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were ≥75 years. Smaller reductions in HbA1c relative to placebo were seen in patients ≥65 years (‒0.61% with INVOKE\textregistered A® 100 mg and –0.74% with INVOKE\textregistered A® 300 mg) compared to younger patients (‒0.72% with INVOKE\textregistered A® 100 mg and –0.87% with INVOKE\textregistered A® 300 mg).

**Renal Impairment:** Efficacy and safety were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/1.73 m²). These patients had less overall glycemic efficacy and 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 m²); patients treated with 300 mg were more likely to experience increases in potassium. INVOKE\textregistered A® is not recommended in patients with severe renal impairment (eGFR <30 mL/min/1.73 m²), with end-stage renal disease, or receiving dialysis.

**Hepatic Impairment:** INVOKE\textregistered A® has not been studied in patients with severe hepatic impairment and is not recommended in this population.

**OVERDOSAGE**

In the event of an overdose, contact the Poison Control Center and employ the usual supportive measures, eg, remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as needed.

**ADVERSE REACTIONS**

The most common adverse reactions associated with INVOKE\textregistered A® (5% or greater incidence) were female genital mycotic infections, urinary tract infections, and increased urination.

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

**References:**


**Invokana® canagliflozin tablets**

Janssen Pharmaceuticals, Inc.

Canagliflozin is licensed from Mitsubishi Tanabe Pharma Corporation.
Studies (14) in full Prescribing Information]

Acute Kidney Injury and Impairment in Renal Function:

Ketoacidosis:

INVOKANA® (canagliflozin) is indicated as an adjunct to diet and exercise to

INDICATIONS AND USAGE

Brief Summary of Prescribing Information.

...contribute to ketoacidosis, including dehydration, hyperglycemia, hypercalciemia, chronic renal insufficiency, and hyperkalemia due to medications or other medical conditions.

Urosepsis and Pyelonephritis: There have been postmarketing reports of serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization in patients receiving SGLT2 inhibitors, including INVOKANA. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated [see Adverse Reactions].

Hyperglycemia 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 secretagogues 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, including angioedema and anaphylaxis, have been reported with INVOKANA. These reactions generally occurred within hours to days after initiating INVOKANA. If hypersensitivity reactions occur, discontinue use of INVOKANA; treat and monitor until signs and symptoms resolve [see Contraindications and Adverse Reactions].

Bone Fracture: An increased risk of bone fracture, occurring as early as 12 weeks after treatment initiation, was observed in patients using INVOKANA. Consider factors that contribute to fracture risk prior to initiating INVOKANA [see 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 if appropriate 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]
• Ketoacidosis [see Warnings and Precautions]
• Acute Kidney Injury and Impairment in Renal Function [see Warnings and Precautions]
• Hyperkalemia [see Warnings and Precautions]
• Urosepsis and Pyelonephritis [see Warnings and Precautions]
• Genital Mycotic Infections [see Warnings and Precautions]
• Hypersensitivity Reactions [see Warnings and Precautions]
• Bone Fracture [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 randomized placebo-controlled trials [see Warnings and Precautions]. One of these trials 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®** (canagliflozin) tablets

INVOKANA® of 24 weeks. Patients received INVOKANA 100 mg (N=833), INVOKANA 300 mg (N=834) or placebo (N=846) 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 m²).

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>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo (N=846)</th>
<th>INVOKANA 100 mg (N=833)</th>
<th>INVOKANA 300 mg (N=834)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary tract infections</td>
<td>0.7%</td>
<td>5.5%</td>
<td>4.4%</td>
</tr>
<tr>
<td>Increased urination</td>
<td>0.1%</td>
<td>5.1%</td>
<td>4.6%</td>
</tr>
<tr>
<td>Constipation</td>
<td>0.9%</td>
<td>1.8%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Nausea</td>
<td>1.3%</td>
<td>2.1%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Male genital mycotic infections</td>
<td>0.2%</td>
<td>10.6%</td>
<td>11.6%</td>
</tr>
<tr>
<td>Vulvovaginal pruritus</td>
<td>0.0%</td>
<td>1.6%</td>
<td>3.2%</td>
</tr>
<tr>
<td>Male genital mycotic infections</td>
<td>0.7%</td>
<td>4.2%</td>
<td>3.8%</td>
</tr>
</tbody>
</table>

* 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.

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

† Increase in adverse reactions (including pruritus) was observed within the first few weeks of treatment.

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

**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 m²), 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 Reaction (Pooled Results from 8 Clinical Trials)**

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Comparator Group*</th>
<th>INVOKANA 100 mg</th>
<th>INVOKANA 300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall population</td>
<td>1.5%</td>
<td>2.3%</td>
<td>3.4%</td>
</tr>
<tr>
<td>75 years of age and older†</td>
<td>2.6%</td>
<td>4.9%</td>
<td>8.7%</td>
</tr>
<tr>
<td>eGFR less than 60 mL/min/1.73 m²†</td>
<td>2.5%</td>
<td>4.7%</td>
<td>8.1%</td>
</tr>
<tr>
<td>Use of loop diuretic†</td>
<td>4.7%</td>
<td>3.2%</td>
<td>8.8%</td>
</tr>
</tbody>
</table>

* Includes placebo and active-comparator groups

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

**Falls:** In a pool of nine clinical trials with mean duration of exposure to INVOKANA of 85 weeks, the proportion of patients who experienced falls was 1.3%, 1.5%, and 2.1% with comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. The higher risk of falls for patients treated with INVOKANA was observed within the first few weeks of treatment.

**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**

<table>
<thead>
<tr>
<th>Pool of Four Placebo-Controlled Trials</th>
<th>Baseline Creatinine (mg/dL)</th>
<th>eGFR (mL/min/1.73 m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo (N=646)</td>
<td>0.84</td>
<td>87.0</td>
</tr>
<tr>
<td>INVOKANA 100 mg (N=833)</td>
<td>0.82</td>
<td>88.3</td>
</tr>
<tr>
<td>INVOKANA 300 mg (N=834)</td>
<td>0.82</td>
<td>88.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Week 6 Change</th>
<th>eGFR (mL/min/1.73 m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo (N=646)</td>
<td>-1.8</td>
</tr>
<tr>
<td>INVOKANA 100 mg (N=833)</td>
<td>-3.8</td>
</tr>
<tr>
<td>INVOKANA 300 mg (N=834)</td>
<td>-5.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>End of Treatment Change*</th>
<th>eGFR (mL/min/1.73 m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo (N=646)</td>
<td>-1.6</td>
</tr>
<tr>
<td>INVOKANA 100 mg (N=833)</td>
<td>-2.3</td>
</tr>
<tr>
<td>INVOKANA 300 mg (N=834)</td>
<td>-3.4</td>
</tr>
</tbody>
</table>

**Week 26 in mITT LOCF population

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In the pool of eight clinical trials, hyperglycemia-related adverse reactions (including asthma, 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 hyperglycemia 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:

**Table 1:** Adverse Reactions From Pool of Four 26-Week Placebo-Controlled Studies Reported in ≥ 2% of INVOKANA-Treated Patients*
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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 m² 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 m² (mean baseline eGFR 39 mL/min/1.73 m²) [See Clinical Studies (14) 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 2.2% 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 m² (mean baseline eGFR 48 mL/min/1.73 m²), 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 has been 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, 8.5% 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 2.6%, 10.6%, and 11.6% 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. In females, discontinuation due to genital mycotic infections occurred in 0% and 0.7% of patients treated with placebo and INVOKANA, respectively [see Warnings and Precautions].

In the pool of four placebo-controlled clinical trials, male genital mycotic infections (e.g., candidal balanitis, balanoposthitis) occurred in 0.7%, 4.2%, and 4.6% 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 males, discontinuations due to genital mycotic infections occurred in 0% and 0.5% of patients treated with placebo and INVOKANA, respectively. In the pooled analysis of 8 controlled trials, phimosis was reported in 0.3% of uncircumcised males 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).

Bone Fracture: The occurrence of bone fractures was evaluated in a pool of nine clinical trials with a mean duration of exposure to INVOKANA of 85 weeks. The incidence rates of adjudicated bone fractures were 1.1, 1.4, and 1.5 per 100 patient-years of exposure in the comparator, INVOKANA 100 mg, and INVOKANA 300 mg groups, respectively. Fractures were observed as early as 12 weeks after treatment initiation and were more likely to be low trauma (e.g., fall from no more than standing height), and affect the upper extremities [see Warnings and Precautions].

Laboratory and Imaging Tests: Increases in Serum Potassium In a pooled population of patients (N=723) with moderate renal impairment (eGFR 45 to less than 60 mL/min/1.73 m²), increases in serum potassium to greater than 5.4 mEq/L and 15% above baseline occurred in 5.3%, 5.0%, and 8.8% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Severe elevations (greater than or equal to 6.5 mEq/L) occurred in 0.4% of patients treated with placebo, no patients treated with INVOKANA 100 mg, and 1.3% of patients treated with INVOKANA 300 mg.

In these patients, increases in potassium were more commonly seen in those with elevated potassium at baseline. Among patients with moderate renal impairment, approximately 84% were taking medications that interfere with potassium excretion, such as potassium-sparring diuretics, angiotensin-converting enzyme inhibitors, and angiotensin-receptor blockers [see Warnings and Precautions and Use in Specific Populations].

| 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) |
| Severe (N [%]) | 1 (0.5) | 3 (1.5) | 7 (3.6) |
| Overall (N [%]) | 208 (34.8) | 279 (48.3) | 285 (48.8) |
| 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)
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**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 percent 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, 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 (3.8%) with INVOKANA 100 mg and INVOKANA 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.

**Decreases in Bone Mineral Density:** Bone mineral density (BMD) was measured by dual-energy X-ray absorptiometry in a clinical trial of 714 older adults (mean age 64 years) [see Clinical Studies (14.3) in full Prescribing Information]. At 2 years, patients randomized to INVOKANA 100 mg and INVOKANA 300 mg had placebo-corrected declines in BMD at the total hip of 0.9% and 1.2%, respectively, and at the lumbar spine of 0.3% and 0.7%, respectively. Additionally, placebo-adjusted BMD declines were 0.1% at the femoral neck for both INVOKANA doses, and 0.4% at the distal forearm for patients randomized to INVOKANA 300 mg. The placebo-adj usted change at the distal forearm for patients randomized to INVOKANA 100 mg was 0%.

**Postmarketing Experience:** Additional adverse reactions have been identified during postapproval use of INVOKANA. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**Ketoacidosis [see Warnings and Precautions]**

**Acute Kidney Injury and Impairment in Renal Function [see Warnings and Precautions]**

**Anaphylaxis, Angioedema [see Warnings and Precautions]**

**Urosepsis and Pyelonephritis [see Warnings and Precautions]**

**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 m², and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m² receiving concurrent treatment with a UGT inducer and require additional glycem ic control [see Dosage and Administration (2.3) and Clinical Pharmacology (12.3) in full Prescribing Information].

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Dioxicin: There was an increase in the AUC and mean drug concent ration (Cmax) of digoxin (15% and 38%, 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.

**Positive Urine Glucose Test:** Monitoring glycemic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests. Use alternative methods to monitor glycemic control.

**Interference with 1,5-anhydroglucitol (1,5-AG) Assay:** Monitoring glycemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycemic control.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy:**

**Risk Summary:** Based on animal data showing adverse renal effects, INVOKANA is not recommended during the second and third trimesters of pregnancy.

Limited data with INVOKANA in pregnant women are not sufficient to determine a drug-associated risk for major birth defects or miscarriage. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy [see Clinical Considerations].

In animal studies, adverse renal pelvic and tubule dilatations that were not reversible were observed in rats when canagliflozin was administered during a period of renal development corresponding to the late second and third trimesters of human pregnancy, at an exposure 0.5-times the 300 mg clinical dose, based on AUC.

The estimated background risk of major birth defects is 6-10% in women with pre-gestational diabetes with a HbA1c >7 and has been reported to be as high as 20-25% in women with a HbA1c >10. The estimated background risk of miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

**Clinical Considerations:** Disease-associated maternal and/or embryo/fetal risk: Poorly controlled diabetes in pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, preterm delivery, stillbirth and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia related mortality.

**Animal Data:** Canagliflozin dosed directly to juvenile rats from postnatal day (PND) 21 until PND 90 at doses of 4, 20, 65, or 100 mg/kg increased kidney weights and dose dependently increased the incidence and severity of renal pelvic and tubular dilatation at all doses tested. Exposure at the lowest dose was greater than or equal to 0.5-times the 300 mg clinical dose, based on the ratio of AUC. These outcomes occurred with drug exposure during periods of renal development in rats that correspond to the late second and third trimester of human renal development. The renal pelvic dilatations observed in juvenile animals did not fully reverse within a 1 month recovery period.

In embryo-fetal development studies in rats and rabbits, canagliflozin was administered for intervals coinciding with the first trimester period of organogenesis in humans. No developmental toxicities independent of maternal toxicity were observed when canagliflozin was administered at doses up to 100 mg/kg in pregnant rats and 160 mg/kg in pregnant rabbits during embryonic organogenesis or during a study in which maternal rats were dosed from gestation day (GD) 6 through PND 21, yielding exposures up to approximately 19-times the 300 mg clinical dose, based on AUC.

**Lactation:**

**Risk Summary:** There is no information regarding the presence of INVOKANA in human milk, the effects on the breastfed infant, or the effects on milk production. Canagliflozin is present in the milk of lactating rats [see Data]. 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 of the potential for serious adverse reactions in a breastfed infant, advise women that use of INVOKANA is not recommended while breastfeeding.

**Data:** Animal Data: Radiolabeled canagliflozin administered to lactating rats on day 13 post-partum was present at a milk/plasma ratio of 1.40, indicating that canagliflozin and its metabolites are transferred into milk at a concentration comparable to that in plasma. Juvenile rats directly exposed to canagliflozin showed a risk to the developing kidney (renal pelvic and tubular dilatations) during maturation.

**Pediatric Use:** Safety and effectiveness of INVOKANA in pediatric patients under 18 years of age have not been established.
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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; a 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 60 mL/min/1.73 m²) [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 m²). Dose-related, transient mean increases in serum potassium were observed early after initiation of INVOKANA (i.e., within 3 weeks) in this trial. Increases in serum potassium of greater than or equal to 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. Severe elevations (greater than or equal to 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 [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 m²), 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].

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 the case of vomiting, 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.

INVOKANA® (canagliflozin) tablets

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.

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

Ketoacidosis: Instruct patients that ketoacidosis is a serious life-threatening condition. Cases of ketoacidosis have been reported during use of INVOKANA. Instruct patients to check ketones (when possible) if symptoms consistent with ketoacidosis occur even if blood glucose is not elevated. If symptoms of ketoacidosis (including nausea, vomiting, abdominal pain, tiredness, and labored breathing) occur, instruct patients to discontinue INVOKANA and seek medical advice immediately [see Warnings and Precautions].

Acute Kidney Injury: Instruct patients that acute kidney injury has been reported during use of INVOKANA. Advise patients to seek medical advice immediately if they have reduced oral intake (such as due to acute illness or fasting) or increased fluid losses (such as due to vomiting, diarrhea, or excessive heat exposure), as it may be appropriate to temporarily discontinue INVOKANA use in those settings [see Warnings and Precautions].

Serious Urinary Tract Infections: Instruct patients of the potential for urinary tract infections, which may be serious. Provide them with information on the symptoms of urinary tract infections. Advise them to seek medical advice if such symptoms occur [see Warnings and Precautions].

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 if such symptoms occur [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, rash, anaphylaxis, and angioedema, have been reported with INVOKANA. Advise patients to report immediately any signs or symptoms suggesting allergic reaction, and to discontinue drug until they have consulted prescribing physicians.

Bone Fracture: Inform patients that bone fractures have been reported in patients taking INVOKANA. Provide them with information on the signs and symptoms of bone fractures, and of risk factors that contribute to fracture risk.

Pregnancy: Advise pregnant women, and females of reproductive potential of the potential risk to a fetus with treatment with INVOKANA [see Use in Specific Populations]. Instruct females of reproductive potential to report pregnancies to their physicians as soon as possible.

Lactation: Advise women that breastfeeding is not recommended during treatment with INVOKANA [see Use in Specific Populations].

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BEHAVIORAL HEALTH:
The new frontier in primary care

Adjusting to value-based models, practices seek ways of integrating mental health providers

by KEN TERRY Contributing author

HIGHLIGHTS

Primary care physicians write about 80% of the prescriptions for psychotropic medications. However, most doctors are not adequately trained to deal with patient mental health issues.

WHILE PRIMARY CARE physicians provide most mental healthcare, few of those in private practice are integrating behavioral health providers into their groups, due largely to the lack of financial support for it in the fee-for-service world.

But that situation is likely to change.

As value-based pay replaces fee-for-service, mental health integration is becoming more commonplace and expected.

Behavioral health conversations regarding a patient’s well-being—asking about their mental state, about substance abuse, and whether there’s a gun in the house—“is going to become part of the standard of medical care,” predicts Michael Caudle, MD, an ob/gyn at Cherokee Health Systems, which operates a network of federally qualified health centers in Tennessee. “You’re not going to be able to avoid asking these questions in practice, or you’re not going to have proper reimbursement. And when you find answers to those questions, you’ll need some way to deal with it.”

Furthermore, as a recent editorial in the Journal of the American Medical Association noted, “Integrated [team-based care] is clearly superior to [traditional management] for patients with complex mental illness and chronic medical disease...It would be unethical...to randomize this type of high-risk patient to usual care when integrated care has been shown in many studies and many types of health systems to be superior to traditional care.”

With this kind of endorsement, it’s likely that integrated care will continue to gain ground. So whether a primary care doctor is employed by a hospital or is in private practice, he or she will probably work in an integrated setting in the future.

POOR TRAINING, POOR CARE

About a third of U.S. adults who have medical conditions also have mental health disorders, according to 2011 research by the Robert Wood Johnson Foundation, and 68% of adults with mental illnesses also have
Patients with behavioral health problems—which include both mental illness and substance abuse disorders—cost two to three times as much to care for as those without them, the Commonwealth Fund discovered in 2014. A prime reason is that they often don’t take care of themselves.

Parinda Khatri, Ph.D., chief clinical officer at Cherokee Health Systems, notes that 40% of patients with diabetes are depressed, and that many of them won’t get their blood sugar under control unless clinicians address their depression.

“If you give someone a prescription and ask them to take it regularly, you’ve asked them to change about seven health behaviors,” she points out. “They have to fill the prescription, they have to take it home, they have to build it into their regimen. They may or may not have to modify their diet. All of that requires significant health behavior change.”

Primary care physicians write about 80% of the prescriptions for psychotropic medications. However, most of them don’t treat mental illness very well, says Marci Nielsen, Ph.D., president and chief executive officer of the Patient-Centered Primary Care Collaborative, an advocacy group for medical homes. They’re not trained adequately to deal with these issues, she observes, because they’re compelled to see a certain number of patients each day.

Primary care doctors “treat people all the time [for mental illness], but in suboptimal ways,” agrees David Woodlock, president and chief executive officer of ICL, a non-profit firm that operates a network of mental health clinics in New York City. “They’re writing a prescription for Prozac when the evidence is quite clear that anti-depressant medication and psychotherapy are the optimal treatments for depression.”

Woodlock partly blames lack of access to behavioral health specialists for the overreliance on primary care physicians. Low insurance reimbursement means patients often can’t afford mental health care, and some health plans make it difficult for doctors to refer patients, he says.

“There’s also a stigma attached to seeing a counselor, he notes. Even when patients are referred to a psychologist or a licensed clinical social worker (LCSW), they keep their appointments only about half the time.

Some healthcare systems and community health centers try to overcome these barriers by co-locating behavioral health providers in primary care practices. But while this approach can avoid the stigma of seeking help for mental conditions, merely placing different kinds of providers near medical conditions.

TAKING STOCK The Three C’s of behavioral health

Today there is a need to provide behavioral healthcare for many patients beyond basic physical treatment.

The first step is to honestly assess practice needs by reviewing patient records for diagnosis, discussing with staff to identify patients by types of behavioral needs, and then to determine if there is a need that is not being met in your practice. This also includes an honest assessment of each provider in the office as to their skills and interest in directly dealing with a behavioral health issue.

Once this honest assessment is complete, primary care physicians have three options:

- **CONTRACT**
  Work with outside entities that provide behavioral health services in a more direct, cross referral model.

- **CO-LOCATE**
  In other words, provide space in the office for a behavioral health professional.

- **COLLABORATE**
  Hire a behavioral health professional into the practice

Editor’s note: This article was first published in our partner publication, Physician’s Practice.
Trends  

Mental health and primary care

each other doesn't necessarily improve care.

To make a significant difference in outcomes, experts say, primary care providers and behavioral health professionals must act as a single care team, communicate through electronic health records and collaborate in developing care plans. They must also have access to psychiatrists as a backup resource.

COUNSELING IN THE EXAM ROOM

Cherokee Health Systems, which includes 23 community clinics in 14 Tennessee counties, has been integrating primary care and behavioral health care for 30 years. "Integration is a core aspect of our clinical approach, primarily because we've found that we cannot pro-
vide good primary care without addressing the behavioral health issues," notes Khatri.

The ratio of PCPs to behavioral health providers at Cherokee is about four to one (three to one in pediatric practices), she says. The clinical psychologists and LCSWs are embedded in the primary care teams, and the physicians use screening tools to determine which patients might benefit from counseling. If a patient consents to see a therapist, his or her doctor will have the therapist meet with that patient in the exam room.

"We do the assessment right there," Khatri says. "Our experience is that if people have to come back for that, you've added a barrier.

Cherokee’s PCPs and behavioral health professionals work off the same electronic health record (EHR) system and create patient care plans together. Any provider who pulls up the record sees a dashboard that includes a snapshot of the patient’s care, including care gaps. If Khatri, a psychologist, notices that a patient hasn’t had a test for asthma or another chronic disease, she’ll tell the patient she needs to get one and will set it up.

If a patient has a serious mental health condition, he or she can be referred to one of the psychiatrists who regularly work with Cherokee. Primary care doctors also can consult with these psychiatrists about medication management. But the primary care teams handle 90% of behavioral health problems, Khatri says.

Cherokee’s Caudle observes that some patients’ physical symptoms may be related to mental health conditions. Frequently, he sees patients who present with generalized pelvic pain or who fake pregnancy because the physical symptom is more acceptable than admitting that they have other problems. Sometimes, when women come in with unspecified pelvic pain, “It’s a sign that they’re depressed or have a history of some kind [unrelated to their medical conditions]. I’ll say, ‘Would you like to talk to somebody about this?’ And often they say yes.”

The initial assessment of the person’s problem may lead to later visits with a mental health professional, he says. In that case, the patient can see the psychologist or LCSW when she returns for ob/gyn follow-up or can see the therapist on her own. In some cases, he adds, the counselors notice care gaps and follow up on their own.

“That’s one of the big values

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Behavioral health codes for primary care

Starting January 1, 2017, Medicare proposes to cover several behavioral health-related services under temporary “G” codes, including one specifically for primary care:

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CMS may still change the duration for this visit or create an add-on code for an additional 20 minutes.

There are three new codes for collaborative behavioral health management where mental health providers work in consultation with a primary care team:

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<td>Subsequent psychiatric collaborative care management First 60 minutes</td>
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References:
Integration is a core aspect of our clinical approach ... we cannot provide good primary care without addressing the behavioral health issues.”

— PARINDA KHATRI, PHD, CHIEF CLINICAL OFFICER, CHEROKEE HEALTH SYSTEMS, TENNESSEE

Integration

Integration is a core aspect of our clinical approach ... we cannot provide good primary care without addressing the behavioral health issues.”

— PARINDA KHATRI, PHD, CHIEF CLINICAL OFFICER, CHEROKEE HEALTH SYSTEMS, TENNESSEE

20 of this approach,” Caudle says. “As we eliminate the barriers between the doctors and the mental health professionals, I learn some psychology, and they learn about medicine. And they become better at it, so they can advocate for things like birth control.”

LARGE GROUP APPROACH

Even more than Cherokee, Intermountain Healthcare, based in Salt Lake City, stresses primary care in its 15-year-old approach to behavioral health care integration. All of Intermountain’s 62 primary care clinics are integrated. They are also patient-centered medical homes, which requires them to emphasize behavioral health. Primary care physicians work with mental health specialists on care teams that provide essential support to the doctors.

Intermountain’s care teams screen for depression, anxiety and other mental health conditions during annual visits and on every visit by a patient with a chronic disease. But the integrated approach has been flexible from the start, says Brenda Reiss-Brennan, Ph.D., APRN, the healthcare system’s mental health integration director.

“If you were there for a sore throat and you weren’t sleeping and weren’t working and couldn’t get out of bed, it became a normal routine thing to check for depression or anything else that was going on,” she says.

When a screening questionnaire indicates that a patient may have a mental health issue, the doctor offers him or her the options of medication, education and/or psychotherapy. “In any of those categories, the primary care physician would provide the care,” Reiss-Brennan notes, in the form of light mental health counseling.

If the patient needs more extensive counseling, they’re referred to a behavioral health provider in the clinic. But that isn’t routine, as it is in some other groups that have co-located mental health professionals, she points out. “In our system, 80% of the mental health care is provided by the primary care doc.”

To compensate for deficiencies in the doctors’ training, she adds, mental health experts coach them on such topics as anxiety, depression, motivational interviewing and cognitive behavioral therapy. For further guidance, they can follow mental health protocols similar to those for diabetes and asthma. If a patient’s condition is of moderate complexity, he or she is referred to a counselor. Complex or urgent cases are sent to a psychiatrist.

During a study period from 2010-2013, Reiss-Brennan notes, the cost of the program to the Intermountain Healthcare system was $22 per member per year, and the Intermountain health plan saved $115 per member per year. This return on investment makes it easy to justify the additional expense of integrating behavioral care.

FINANCIAL SUSTAINABILITY

Cherokee adopted integration because of its mission, which includes providing superior primary care and filling the need for mental healthcare in rural areas, which might otherwise go unmet. While the network is starting to get value-based-reimbursement contracts from health plans, its population is heavily skewed toward Medicaid and self-pay patients. That means Cherokee has to limit costs so it can afford to serve those who can’t pay.

“It would have been more profitable for us if we hadn’t gone this route,” Khatri says. “But we didn’t want to do that, because we see ourselves as stewards of limited health-care resources.”

Private practitioners also find it difficult to get financing for integration, notes Ben Miller, PsyD, director of the health policy center and associate professor in the department of family medicine at the University of Colorado School of Medicine. “There’s very little incentive
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for small and medium-sized primary care practices to onboard or integrate a behavioral clinician, because the payment structure doesn’t support that,” he points out.

One group that has made it work is the Westminster Medical Clinic, a primary care practice in Westminster, Colorado, that includes three physicians, two physician assistants and a nurse practitioner.

Led by Robert Scott Hammond, MD, the practice finally hit upon the right formula to help patients by partnering with a community mental health center five years ago. That center now pays the salaries of the psychologist and the LCSW who are embedded in the practice. Without that financial support, Hammond says, the practice could not afford these professionals.

Over the years, he says, the practice has had to make financial sacrifices to continue providing mental health services. The partners took cuts in pay, and staff salaries were frozen for a long time. Yet the group is still united in its vision.

“We don’t feel we can provide quality primary care without addressing mental health issues, which impact 40%-50% of our patient visits,” he explains. “It’s like going in to see a patient without a stethoscope.

Hammond and his colleagues screen patients at every visit for depression, anxiety, substance abuse and other issues. If the brief initial screen is positive, patients are asked to complete a longer questionnaire that helps the doctors diagnose them. The patients are then divided into two groups according to the severity of their conditions. If they are in moderate distress, doctors can address it.

In high-acuity cases, the physicians can make a referral to an onsite therapist through their EHR, to which the mental health professionals have access. Although the behavioral health providers use a different EHR than the PCPs, they can enter notes from their counseling sessions into the doctors’ EHR, following an agreed-upon template.

“We don’t get every bit of information, but we’ve developed a nice bidirectional information flow that’s useful,” Hammond says. “So when we make a referral, they get the information they need and we get the information we need.”

Severe cases are referred to a psychiatrist whom the doctors access through the community mental health center. The physicians can also consult with a psychiatrist about psychotropic medications before prescribing them.

A study of the group’s outcomes showed that the integrated approach reduced the prevalence of depression and anxiety by about 50%, Hammond says. The researchers also found a positive trend in the HbA1c results of diabetic patients, but the sample was too small for statistical significance. Provider and patient satisfaction are also up, he adds.

But Hammond is realistic that absent grant funding or an initiative that provides support, primary care practices will encounter obstacles in following his practice’s footsteps. Nonetheless, as more opportunities emerge, he stresses that integration is a crucial element of healthcare reform.

“We cannot move forward without mental health integration,” Hammond says. “It’s such a critical part of our care delivery. It’s unimaginable that we don’t have it.”

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**BEHAVIORAL HEALTH FOR PRIVATE PRACTICE PHYSICIANS**

Team-based care, not just co-location, is the key to effective behavioral health integration. Ben Miller, PsyD, director of the health policy center and associate professor in the department of family medicine at the University of Colorado School of Medicine, says that private practice doctors can take 3 steps to improve the mental healthcare they provide:

**1/ Seek help from payers** in building the requisite care teams so they can deliver better, more cost-effective care.

**2/ Establish relationships with behavioral health providers** in their communities. “Start with providers within five miles of your practice, because there’s a good chance they’re touching some of the patients you’re touching.” Talking to these people will help lay the groundwork for later collaboration, he says.

**3/ Physicians should try to calculate** what percentage of their patients with a chronic disease have a comorbid behavioral health condition, Miller says. Understanding the prevalence of these conditions can help the practice figure out how to meet the need.
new bill in Congress is designed to help overcome one of the most challenging barriers patients face when accessing care: out-of-pocket cost. But it’s unclear if it can get through Congress this year.

In July, Representatives Diane Black (R-Tennessee) and Earl Blumenauer (D-Oregon) introduced HR 5652, the Better Access to Care Act of 2016, to make some types of coverage more affordable for the growing numbers of Americans with high-deductible health plans (HDHPs) paired with health savings accounts (HSAs).

The legislation would address the IRS rule that says HDHPs with HSAs can’t be used to cover services for patients with pre-existing conditions unless the patient has covered the single-visit or annual deductible. A patient with diabetes, for example, must pay for an annual eye exam out-of-pocket unless she has already paid her deductible in full.

This provision forces some patients with HDHPs and HSAs to forego such care, explains A. Mark Fendrick, MD, an internist and professor in the department of internal medicine at the University of Michigan in Ann Arbor. “This bill is the most common sense healthcare reform idea that no one has heard about,” Fendrick says.

In 2005, only 2% of employers offering health benefits had these kinds of plans. By 2015, it had risen to 20%. As of January 2015, 19.7 million Americans had an HDHP and HSA, an increase of 13.2% from a year earlier. The average deductible for individuals enrolled in these plans last year was $2,196 and for families it was $4,347, the Kaiser Family Foundation reported.

“Why would you make it harder for my patients to do the things that I beg my patients to do?” asks Fendrick, director of the university’s Center for Value-Based Insurance Design. He argues that high deductibles should be reserved for low-value services such as those identified by the American Board of Internal Medicine Foundation’s “Choosing Wisely” campaign, and eliminated for high-value care such as the services and medications recommended in clinical care guidelines.

Black has experience with patients who have HDHPs with HSAs and who struggle to pay for care. Before being elected to Congress in 2010 from Tennessee’s Sixth Congressional District, she worked as a nurse for 40 years. “I saw this issue present itself over and over again, particularly in my work as a long-term care nurse,” she tells Medical Economics. “Typically it wasn’t an intentional decision at the outset not to take a prescribed medication, it was simply a matter of life happening and other costs getting in the way.”

When forced to choose between buying groceries and filling a prescription, a patient will make healthcare a lower priority every time, she says. Federal regulations already allow patients to get certain types of preventive care without paying a deductible first, Black says. “It only makes sense to create a separate exception for medications and services people depend on to manage a chronic condition,” she adds.

The IRS regulation not only makes it difficult for patients to afford the care they need, but could make it challenging for physicians to take full advantage of quality-driven payment models that base bonuses on the use of specified clinical services, Fendrick says.

Black is unsure if Congress will pass the bill before year end, but she remains hopeful.

Joseph Burns is an journalist in Falmouth, Massachusetts. Do you think this bill would help your patients? Tell us at medec@ubm.com

A new bill in Congress is designed to help overcome one of the most challenging barriers patients face when accessing care: out-of-pocket cost. But it’s unclear if it can get through Congress this year.

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“Why would you make it harder for my patients to do the things that I beg my patients to do?” asks Fendrick, director of the university’s Center for Value-Based Insurance Design. He argues that high deductibles should be reserved for low-value services such as those identified by the American Board of Internal Medicine Foundation’s “Choosing Wisely” campaign, and eliminated for high-value care such as the services and medications recommended in clinical care guidelines.

Black has experience with patients who have HDHPs with HSAs and who struggle to pay for care. Before being elected to Congress in 2010 from Tennessee’s Sixth Congressional District, she worked as a nurse for 40 years. “I saw this issue present itself over and over again, particularly in my work as a long-term care nurse,” she tells Medical Economics. “Typically it wasn’t an intentional decision at the outset not to take a prescribed medication, it was simply a matter of life happening and other costs getting in the way.”

When forced to choose between buying groceries and filling a prescription, a patient will make healthcare a lower priority every time, she says. Federal regulations already allow patients to get certain types of preventive care without paying a deductible first, Black says. “It only makes sense to create a separate exception for medications and services people depend on to manage a chronic condition,” she adds.

The IRS regulation not only makes it difficult for patients to afford the care they need, but could make it challenging for physicians to take full advantage of quality-driven payment models that base bonuses on the use of specified clinical services, Fendrick says.

Black is unsure if Congress will pass the bill before year end, but she remains hopeful.

Joseph Burns is an journalist in Falmouth, Massachusetts. Do you think this bill would help your patients? Tell us at medec@ubm.com
Sharing performance pay with practice staff

With value-based reimbursement coming, it’s time to consider how and when to share the rewards with employees.

by LISA A. ERAMO Contributing author

HIGHLIGHTS

Deciding whether to share incentive payments is not easy in times of decreased reimbursements, but it can actually increase revenue if done right.

WHEN IT WAS TIME to distribute the $15 million earned from payers through shared savings, physicians at Coastal Medical had a decision to make: Should they give employees a portion of those earnings?

The question is a difficult one since many practices struggle to keep their doors open thanks to increased overhead and the costs of meeting regulatory requirements. There are many other ways physicians could use the additional revenue, such as purchasing new equipment or perhaps even pocketing it themselves.

G. Alan Kurose, MD, chief executive officer of Rhode Island-based Coastal Medical, says the board of directors for the physician-owned accountable care organization (ACO) decided in 2015 to distribute a percentage of the shared-savings payments among employees as a reward for their hard work.

“We wanted to demonstrate to every employee that if we are all in this together when there is new and challenging work to be done, the same should be true when that extra work generates a profit,” says Kurose.

High-quality, low-cost care is generally the formula for success when it comes to pay-for-performance and other financial incentive payments. Everyone in the practice plays a role in making this work, so shouldn’t everyone also benefit from the shared savings that are generated as a result? This is a question that physicians must be ready to answer when incentive bonuses are generated.

SHARING THE WEALTH

For some physicians, the answer is “yes.”

Coastal Medical uses some of its incentive funds from the Centers for Medicare & Medicaid Services and commercial payers to cover the incremental costs related to population health management (e.g., hiring nurse care managers, clinical pharmacists, data analysts, and a team of quality assistants.) It generally uses the remainder to fund new clinical initiatives as well as to distribute financial bonuses to practice employees.

Physicians at Coastal Medical set a goal of providing front-line staff members (medical assistants, medical secretaries, quality assistants and clerical staff) with an annual shared-savings bonus equal to at least one week’s pay. They exceeded the goal in 2015—the first year the bonuses were distributed—and were able to again in 2016.

When it comes time to distribute the shared-savings bonuses, Kurose, along with the chief oper-
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Getting so many people to row in the same direction with a sense of purpose is a challenge. ... I think this has been the greatest benefit of our decision to distribute shared savings to every employee.”

—G. ALAN KUROSE, MD, CHIEF EXECUTIVE OFFICER, COASTAL MEDICAL, RHODE ISLAND

Once it has met this threshold, the physician retains 50% of any profits beyond the $2,000 and shares the remaining 50% with staff. One LPN and one medical assistant each receive 15% of the balance because they contribute most significantly to CCM by drafting care plans and calling patients. Merrifield and one of the other medical assistants, who are less involved with CCM, receive 10% each.

“We want to provide a great environment for our patients, but we also have to provide a great environment for our employees. Everybody here knows that if the business makes a profit, it’s going to trickle down,” says Sue Zumwalt, CMM, CPEDCS. Zumwalt is office manager at a California-based, physician-owned pediatric practice that distributes a portion of its ACO shared-savings among staff members.

Zumwalt says the practice’s four physicians generate about $80,000 and $100,000 each in quarterly incentives. The doctors share some of these funds as follows:

- Nurse practitioners receive a bonus twice annually based on a formula that takes into consideration their average cost per visit and their ability to meet certain internal performance measures.
- Zumwalt receives a quarterly bonus based on her ability to help the practice meet national benchmarks for immunizations and physicals.
- Other staff members receive a seniority-based bonus derived from revenue that exceeds projected amounts—not necessarily from shared-savings payments. Physicians set aside a portion of this amount for staff profit-sharing bonus payments.
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**What to consider when sharing incentive pay with staff**

- **Determine what percentage of your practice’s revenue is derived from incentive or shared-savings payments.**

  What is the average dollar amount by month, quarter and annually? Has this amount remained fairly consistent over time?

- **Identify how much (if any) of that money you would be willing—and able—to share with staff.**

  Consider overhead expenses, electronic health record (EHR) maintenance costs and other financial obligations. Also identify future goals, such as hiring an additional medical assistant, switching EHR vendors, etc., and how those might affect your ability to provide bonus payments or increase salaries using these additional funds.

- **Determine how you will divide that money among staff.**

  Will you provide each staff member with the same amount across the board? Will you base it on job descriptions/titles? Number of years spent working at the practice? Assumed contribution to the shared-savings effort?

- **Decide whether you’ll pay a one-time bonus, several scheduled bonuses throughout the year or a salary increase.**

  Remember that salary increases could be difficult to maintain over time if incentive payments lessen or cease entirely, says Damle. Bonus payments may offer greater flexibility.

- **Require employees to meet internal performance goals.**

  For example, require medical coders to maintain a denial rate of 5% or lower, or require secretaries to perform eligibility verification on 100% of patients.

- **Inform employees of the performance-based payments.**

  Include language in personnel policies stating that bonuses are paid only when performance goals are met. Take the time to talk with employees about how they can personally make the practice successful—and what this would mean in terms of additional compensation.

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“Even an extra $100 is huge,” says Zumwalt. “You start doing that a few times, and the employee’s attitude toward the other things you’re asking them to do will change.”

**REWARD OR REINVEST?**

Rhode Island-based internal medicine physician Nitin Damle, MD, FACP, says he’s cautious about sharing incentive payments with staff members. “We would need to see a pretty steady stream of funds over a longer period of time before we could commit to a program like that,” he says.

Damle, president of the American College of Physicians, is one of eight internists in the practice that also has 25 non-clinical staff members. The practice receives supplemental payments by participating in a patient-centered medical home initiative as well as the PQRS and Meaningful Use programs. It also receives enhanced payments for quality improvement and cost containment through several managed-care contracts, and it recently joined an ACO.

The practice has used these additional funds to hire clinical nurse managers who help patients manage chronic conditions, measure and report on quality, and perform transitional care management. It is also hiring a chief operating officer who will be responsible for streamlining operations. After covering these costs, there isn’t a lot of money left for salary increase or bonuses, says Damle.

“We want to see that we’ve made a significant leap in terms of quality and cost containment—and that we’re being adequately compensated for that,” he says. “Then we’d be in a position to share some of those benefits.”

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INDICATIONS

• RELISTOR is an opioid antagonist. RELISTOR tablets and RELISTOR injection are indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain.

• RELISTOR injection is also indicated for the treatment of OIC in adults with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. Limitations of Use: Use beyond four months has not been studied in the advanced illness population.

IMPORTANT SAFETY INFORMATION - RELISTOR (methylnaltrexone bromide) tablets, for oral use and RELISTOR (methylnaltrexone bromide) injection, for subcutaneous use

• RELISTOR tablets and injection are contraindicated in patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation.

• Cases of gastrointestinal perforation have been reported in adult patients with opioid-induced constipation and advanced illness with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the gastrointestinal tract (e.g., peptic ulcer disease, Ogilvie's syndrome, diverticular disease, infiltrative gastrointestinal tract malignancies or peritoneal metastases). Take into account the overall risk-benefit profile when using RELISTOR in patients with these conditions or other conditions which might result in impaired integrity of the gastrointestinal tract wall (e.g., Crohn's disease). Monitor for the development of severe, persistent, or worsening abdominal pain; discontinue RELISTOR in patients who develop this symptom.

• If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their healthcare provider.

• Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, and yawning have occurred in patients treated with RELISTOR. Patients having disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal and/or reduced analgesia and should be monitored for adequacy of analgesia and symptoms of opioid withdrawal.

• Avoid concomitant use of RELISTOR with other opioid antagonists because of the potential for additive effects of opioid receptor antagonism and increased risk of opioid withdrawal.

The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the immature fetal blood brain barrier and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because of the potential for serious adverse reactions, including opioid withdrawal, in breastfed infants, advise women that breastfeeding is not recommended during treatment with RELISTOR. In nursing mothers, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

A dosage reduction of RELISTOR tablets and RELISTOR injection is recommended in patients with moderate and severe renal impairment (creatinine clearance less than 60 mL/minute as estimated by Cockcroft-Gault). No dosage adjustment of RELISTOR tablets or RELISTOR injection is needed in patients with mild renal impairment.

A dosage reduction of RELISTOR tablets is recommended in patients with moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment. No dosage adjustment of RELISTOR tablets is needed in patients with mild hepatic impairment (Child-Pugh Class A). No dosage adjustment of RELISTOR injection is needed for patients with mild or moderate hepatic impairment. In patients with severe hepatic impairment, monitor for methylnaltrexone-related adverse reactions.

In the clinical studies, the most common adverse reactions were:

OIC in adult patients with chronic non-cancer pain

• RELISTOR tablets (≥ 2% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (14%), diarrhea (5%), headache (4%), abdominal distention (4%), vomiting (3%), hyperhidrosis (3%), anxiety (2%), muscle spasms (2%), rhinorrhea (2%), and chills (2%).

• RELISTOR injection (≥ 1% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (21%), nausea (9%), diarrhea (6%), hyperhidrosis (6%), hot flush (3%), tremor (1%), and chills (1%).

OIC in adult patients with advanced illness

• RELISTOR injection (≥ 5% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (29%) flatulence (13%), nausea (12%), dizziness (7%), and diarrhea (6%).

Please see Brief Summary for RELISTOR tablets and RELISTOR injection on adjacent page and full Prescribing Information at relistor.com.

The safety of RELISTOR injection was evaluated in a double-blind, placebo-controlled trial in adult patients with OIC and chronic non-cancer pain receiving opioid analgesia. This study (Study 2) included a 4-week, double-blind, placebo-controlled period in which adult patients were randomized to receive RELISTOR injection 12 mg subcutaneously once daily (150 patients) or placebo once daily (152 patients). In the double-blind period, patients began an 8-week open-label treatment period during which RELISTOR injection 12 mg subcutaneously was administered less frequently than the recommended dosage regimen.

The most common adverse reactions in adult patients with OIC and chronic non-cancer pain receiving RELISTOR injection are shown in Table 5. The adverse reactions in the table below may reflect symptoms of opioid withdrawal.

**Table 5: Adverse Reactions* in 4-Week Double-Blind, Placebo-Controlled Period of Clinical Study of RELISTOR Injection in Adult Patients with OIC and Chronic Non-Cancer Pain (Study 2)**

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>RELISTOR Injection n = 150</th>
<th>Placebo n = 162</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal Pain**</td>
<td>14% (6)</td>
<td>10% (6)</td>
</tr>
<tr>
<td>Nausea</td>
<td>9% (6)</td>
<td>6% (10)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>6% (1)</td>
<td>6% (1)</td>
</tr>
<tr>
<td>Hyperhidrosis</td>
<td>6% (1)</td>
<td>6% (1)</td>
</tr>
<tr>
<td>Hot Flash</td>
<td>3% (1)</td>
<td>3% (1)</td>
</tr>
<tr>
<td>Chills</td>
<td>3% (1)</td>
<td>3% (1)</td>
</tr>
<tr>
<td>Abdominal distention</td>
<td>4% (1)</td>
<td>2% (1)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>3% (1)</td>
<td>2% (1)</td>
</tr>
<tr>
<td>Hyperthermia</td>
<td>3% (1)</td>
<td>2% (1)</td>
</tr>
<tr>
<td>Flatulence</td>
<td>2% (1)</td>
<td>1% (1)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>1% (1)</td>
<td>1% (1)</td>
</tr>
<tr>
<td>Musclespare</td>
<td>2% (1)</td>
<td>2% (1)</td>
</tr>
<tr>
<td>Rhinorrhea</td>
<td>2% (1)</td>
<td>2% (1)</td>
</tr>
<tr>
<td>Nervousness</td>
<td>2% (1)</td>
<td>2% (1)</td>
</tr>
<tr>
<td>Chills</td>
<td>2% (1)</td>
<td>2% (1)</td>
</tr>
</tbody>
</table>

**Adverse reactions occurring in at least 2% of patients receiving RELISTOR tablets 450 mg once daily and at an incidence greater than placebo.

**Includes: abdominal pain, upper abdominal pain, lower abdominal pain, abdominal discomfort and abdominal tenderness.**
THE VALUE OF A PENSION

Many individuals are employed in occupations that come with a pension in retirement. Here, I define pension as an income for life, usually based on years of work and salary. Pensions can differ in a number of ways. There are three ways to consider the value of a pension.

1. The value of cash flow

The first is to consider the value of the cash flow.

Take, for example, a retired executive with a pension of $80,000 a year. It may be that this amount, along with Social Security, allows the executive and his or her spouse to meet their lifestyle expenses. Having money in a retirement portfolio is just icing on the cake. Whether the pension is inflation-adjusted becomes important in this assessment, because decades of inflation might markedly reduce its worth.

2. The value of the portfolio

A second way to value a pension is to consider what you would need to have in a retirement portfolio in order to generate the pension income.

For example, you might say that at a 4% distribution rate, a $40,000 annual pension would require a portfolio of $1 million. This is acceptable for valuing the pension for the retirees, but the portfolio assets are potentially worth more than this because they may remain after death, whereas pensions stop. In addition, most portfolio distribution plans include adjustments for inflation, but a pension may not.

3. The value of comparison

The final and perhaps most accurate way to value a pension is to compare what it would cost to buy an immediate annuity that would pay the same income starting at the same age.

Take the retired couple with the $80,000 annual pension mentioned previously. To receive the same joint lifetime guaranteed income from an insurance company would cost just over $1.5 million.

One important variable to consider is the safety of the pension. Many corporate, and some municipal payers of pensions have defaulted on their promises due to financial distress (see the recent case of Detroit). A promise to pay an income for decades is serious business. I’d consider only the U.S. government itself as a totally safe source of pension income, because it can always print money to pay you.

Steven Podnos, MD, CFP, is the principal of Wealth Care, LLC in Merritt Island, Florida. Send your financial questions to medec@ubm.com.
Pitfalls in terminating a patient relationship

Physicians sometimes face the prospect of dismissing patients from their practice. It’s not easy, but there is a right way and a wrong way to do it.

- **Termination guidelines**
  A physician is generally permitted to terminate his or her relationship with a patient, but must comply with certain ethical and legal guidelines in doing so. The termination cannot be based on age, color, disability, gender, national origin, religion, sexual orientation or any other discriminatory reason. A physician cannot terminate a patient relationship in a manner that would be deemed an abandonment of the patient or neglect of patient care. There needs to be some assurance of continuity of care.

- **What to do before terminating**
  Prior to terminating the relationship, a physician may want to consider speaking with the patient to the extent that the issue involved can be resolved (e.g., failure to pay a bill.) It would be prudent to conduct any such discussion with a member of the physician’s staff present and to contemporaneously document the discussions by a memo to the files of the practice.

- **Assuring continuity of care**
  With respect to continuity of care issues, the physician first needs to determine whether the treatment has reached a stage where the physician can safely end his or her oversight of the patient. For example, if a patient recently had been operated by the physician, or if the patient is pregnant with a due date that is near, the physician needs to consider whether terminating the relationship at that time would be in the best interests of the patient.

- **Check the payer contract**
  Read payer fine print. If the patient is covered by a plan in which the physician participates, the physician needs to review the agreement to confirm that the plan does not restrict his or her ability to end the patient relationship, or that the plan does not include additional requirements prior to taking such a step.

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**Termination letter essentials**

**Advance notice**
Assuming the patient is not in a sensitive phase of treatment, the physician needs to provide sufficient advance written notice to allow the patient time to find another healthcare provider. Generally, 30 to 60 days is recommended, though a shorter period or immediate termination may be necessary where the reason for the termination is for grounds such as threats to the staff or illegal activity.

**What to include**
The letter should establish the date of termination, provide the patient with alternative healthcare providers and include information concerning how the patient can obtain his or her medical records. The letter does not need to specify the reasons for termination. In many cases, this may be the most appropriate course to take in order to avoid any allegations that the physician has defamed the patient.

**Certified mail**
It is generally recommended that the letter be sent to the patient’s address as set forth in the patient’s record and that it be sent by a form of certified mail.

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John Peter Kraljic, JD, is a partner at Garfunkel Wild, P.C., in Great Neck, New York. Send your legal questions to: medec@ubm.com.
Billing drug reconciliation

I spend a tremendous amount of time reconciling medications with and for my patients. I don’t see a specific “data” indicator for this in the decision-making tables. How do I account for this?

A: Great question, and you are right, there is no mention of this specifically as medication reconciliation anywhere in the guidelines. That said, the website of the Centers for Medicare & Medicaid Services’ Evaluation and Management (E/M) Services Guide contains some language that pertains to Table 1:

“Some important points that should be kept in mind when documenting the number of diagnoses or management options are:

- The initiation of, or changes in, treatment should be documented.
- Treatment includes a wide range of management options including patient instructions, nursing instructions, therapies and medications.”

How this will help you account for the time spent on this task is not so clear, though. If you were to document “medications reviewed and updated for (diagnosis 1, 2, 3, 4, etc.),” you should get the points associated with each stable or worsening problem. This would be best in the assessment and plan (A/P).

An alternative might be to use an indicator from Table 2—review and summary of old records. If you labeled a section of your chart “Med Reconciliation,” either around the A/P or in the Medication area—Review and Summary of Old Records, then you could list the conditions and changes made. This is probably the long way around.

You mentioned the time this takes, and we hear this a lot. Is the patient present, and do you go over the meds with him or her? This could be characterized as counseling, depending on the circumstances.

Q: I have a transitional care management (TCM) question.

The patient is seen by the primary care physician eight days after hospitalization. There was a phone call within two days of discharge. The TCM code was billed. The patient returns a week later with continued issues related to the problem he was hospitalized for. Can that second visit be billed?

A: Absolutely, as a regular E/M visit, either a 99213 or 99214 code. The TCM code includes only the first visit following the hospitalization discharge. Others can be billed in the same 30-day period and are separately payable.

Those are the likely options as regards the guidelines. But this important and ever-more time-consuming task for primary care has always been somewhat treated just as a cost of doing business. Following the suggestions above can help to change that.

Q: For an established patient, does medical decision-making [MDM] have to be one of the “two out of three” components used to choose the E/M code? The Current Procedural Terminology book doesn’t specify that.

A: Many practices adopt this policy to be certain that all notes are anchored in medical necessity, not just a lot of electronic health record history and exam.

One Medicare medical director has said “if not using the MDM, how are you showing medical necessity for the service?” That person went on to say: “If you can answer that question through your medical record documentation by using the other two components; history and exam, then the MDM would not be required.” The use of decision-making as a required element is a measure of prudence and responsible coding.

Bill Dacey, CPC, MBA, MHA, is a principal in the Dacey Group and an AAPC-certified instructor. Send your coding and billing questions to medec@ubm.com.
Many factors determine where a physician might want to set up shop. Here’s help to figure out where that could be. by ERICA SPREY Contributing author

Each year, Physicians Practice assesses conditions across the United States in search of the best states for physicians to practice. We reach out to both public and private organizations to assemble objective data sets that we think indicate favorable practice conditions for physicians. Then we whittle our list down to the top five states.

TEXAS
The Lone Star State
STATE MOTTO: FRIENDSHIP
Lloyd Van Winkle, MD, has practiced primary care medicine in Castroville, Texas—a town of 3,800, 25 miles from San Antonio—for more than 30 years. Van Winkle, who grew up in the state, did his undergraduate training, medical school and residency in Texas. He says the small-town camaraderie was one of the key draws that kept him in Texas.

“Well, I know everybody,” he says. “So I know when they have diabetes and buy an ice cream at the grocery store, I know it. It’s a nice experience to be in a small town. To have that kind of connection with your patients.”

Van Winkle also appreciates the climate in Texas, noting, “In December when we are on the back porch barbecuing my brother says, ‘You know what people in Minnesota are thinking about right now? Doing this next summer.’”

Because of a low physician density, low cost of living, reasonable tax burden, and high residency retention rate, Texas made the top of our list for the best states to practice. The only sour note was malpractice payouts, which ranked in the bottom third of our analysis.

Since it is a large state, patients can sometimes have trouble finding a physician, especially in rural areas. Van Winkle says he practices in an underserved area federally designated as a Health Professional Shortage Area (HPSA). However, that can be a bonus for family physicians who are interested in a well-rounded scope of practice.
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IDAHO

the Gem State

STATE MOTTO: LET IT BE PERPETUAL

Idaho is known for its unspoiled wilderness and varied topography that encompasses mountain ranges, numerous lakes and rivers, waterfalls, and canyons. It is also a great place to raise a family, according to Zachary Warnock, MD, a primary care physician with Intermountain Medical Clinic, based in Pocatello, Idaho.

“My wife and I were looking for a place where we felt comfortable raising our children and where we could get out and go camping and hiking and skiing. Just spend time outdoors, because that’s a big part of what we love to do,” he says.

Warnock, who is originally from a small town in Utah, says he and his wife decided to settle in Idaho not just for the environment, but also for the freedom to practice medicine the way he wished.

Idaho made our list because it has the second-lowest physician density in our analysis, a low tax burden and cost of living, and very low malpractice payouts. Warnock acknowledges that while the dearth of physicians can have a negative effect on patient care, there is an advantage in that it opens up a larger scope of practice for physicians practicing there.

For Warnock, that means caring for patients of all ages—which involves pediatrics, adult medicine and geriatrics “including and up to taking care of people as they die.” He says he strives to have a well-rounded practice and make the time to interact with his patients, including in their homes if that is where they need treatment.

MISSISSIPPI

the Magnolia State

STATE MOTTO: BY VALOR AND ARMS

Mississippi has once again made our list of top states, holding the top ranking for lowest physician density and lowest cost of living. It also scores well in post-residency retention rates.

Family practitioner Carlos A. Latorre, MD, can attest to that. He says that after completing his residency at the University of Mississippi Medical Center, nine of out 11 residents in his cycle stayed to set up practice in the state. Latorre works for Merit Health River Region in the Mississippi River city of Vicksburg, in the southwestern part of the state.

Situated in a metropolitan area of about 50,000 residents, Vicksburg itself is not considered rural. But Latorre says many of the surrounding towns are more rustic. “When you cross into Louisiana, as soon as you cross the river, it is also rural because there’s nothing for another 70 miles,” he says.

It is that small-town hominess that Latorre finds most satisfying. He says he is well-known in his community, having lived there before attending medical school. Patients feel comfortable entrusting their care to him and tell him, “We are glad you are here.”

Latorre is also president of a local physician foundation that promotes public health educational initiatives such as tobacco ces...
sation programs. In addition to a supportive medical association, Latorre notes "the cost of living is low, the salaries are very decent, there is a lot of work in terms of patients to be seen, and good collaboration between physicians. It is a very harmonious place to work."

UTAH
the Beehive State
STATE MOTTO: INDUSTRY
Anesthesiologist Paul N. Clayton, MD, president of the Utah Medical Association, started his medical internship in Detroit, but soon realized that he wanted to return to his home state of Utah.

"Considering all of the things that go into the equation of where do we want to practice [and] where do we want to raise a family, we just felt drawn back to Salt Lake City," he says. He and his wife both had extended families in Salt Lake and appreciated the natural environment in Utah, with its changing weather and diverse geography.

Our analysis placed Utah in the top quartile for low physician density, low cost of living, low tax burden, and low malpractice payouts. It also does well in residency retention rates.

Utah enjoys a spirit of collegiality among its physicians and has a strong relationship with its medical associations and government, according to Clayton. "I think in general, in Utah, physicians are well thought of, are respected. We have a very effective state medical association that is effective in lobbying for us with the legislature," he says.

But there are some tradeoffs. As the most populous city in Utah, Salt Lake draws many physicians looking to set up practice. In Clayton’s experience, however, that competition can limit opportunities for physicians to become part of narrow payer panels, effectively curtailing referrals and practice growth.

But that doesn’t mean there aren’t opportunities in other areas of the state, Clayton adds. There is a great need for primary care physicians in the rural areas of the state.

GEORGIA
the Peach State
STATE MOTTO: WISDOM, JUSTICE, MODERATION
With a low cost of living, low physician density and very low tax burden, Georgia is a great place to settle down. It scored well on five of our six metrics, with high malpractice payouts being the only exception.

Mitzi Rubin, MD, a primary care physician employed by WellStar Health System in Marietta, Georgia, agrees. "The nice thing about practicing in Georgia is that we are fairly close to everything. We are a few hours from the beach, you have the lakes [and] you have the mountains," she says.

Rubin attended medical school in Chicago, and while she says both she and her husband enjoyed living there, there was never a doubt about returning to Georgia. "The lower cost of living and the many opportunities to get out and enjoy nature convinced them to come back.

As a primary care physician, Rubin says she can treat 95% of patient complaints, at least in the initial phase. And her patients know that, she says, which means they come to her directly, rather than asking to see a specialist first. That willingness to entrust patient care to the home-town doc allows physicians the freedom to define their own practice.

Erin Sprey is associate editor for Physicians Practice. She may be reached at erica.sprey@ubm.com.
or Harry L. Greenberg, MD, a dermatologist based in Las Vegas, Sin City had long represented the ultimate location, due both to its quirky character and its opportunities for practicing his specialty.

After finishing his residency in Temple, Texas, Greenberg joined a large single-specialty practice in Las Vegas in 2006. One year later, Greenberg created his dream practice, Las Vegas Dermatology.

“I've always wanted to live in Las Vegas and have my own practice,” he says. “Vegas represented an underserved area with plenty of opportunity to do medical and cosmetic dermatology.”

While some physicians relocate to pursue new markets or employment opportunities, others move for personal reasons. Deciding where to relocate is the first of many challenges, according to Keith Borglum, CHBC, a Santa Rosa, California-based healthcare business consultant who assisted Greenberg with opening his practice. “Most are focused on a particular city because they are relocating to be near family or the spouse's family, or sometimes for a personal avocation, like surfing or mountain biking,” Borglum says.

Once location is no longer a variable in the equation, the physician can take the next steps. These may vary, depending on whether he or she is considering a job offer, buying a practice, or starting from scratch. If starting from scratch, setting business objectives and creating a marketing plan are essential steps.

Regardless of the scenario, the physician should start developing the blueprints of her new professional life before relocation, says Neville M. Bilimoria, JD, a partner in the Chicago office of the Health Law Practice Group for law firm Duane Morris. “Many physicians realize [after moving] that the grass is not always greener in a new location,” Bilimoria says. “It takes sometimes years to establish a practice in a particular locale. I counsel my clients all the time on developing a good business plan and marketing strategy.”

For physicians who do not plan to join an existing practice, “mystery shopping” is the best initial strategy, Borglum says. In other words, physicians should test out healthcare providers in their new area to see what the needs are in that market. “The longer the wait time for non-emergency new patients in the community, the easier it is to start from scratch,” he says. “Your wait time will equal the community [wait time] within the first year. I've had physicians have full practices within two or three weeks of opening. Others lag for months.”

Selecting an underserved market, such as locations 30 minutes or more outside a core urban area, is the best way to jump-start a new practice, Borglum says. When starting out, Greenberg put a lot of effort into attracting new patients. “I joined the Las Vegas Chamber of Commerce, went door to door introducing myself to other physicians, asking them for their business, and gave multiple lectures at the medical school and various community organizations,” he explains. “Whenever you move to a new city, no one knows who you are and no one cares, so it does take time to get established.”

Stephen Hirshorn, a retired general
surgeon and anesthesiologist, moved from Michigan to Florida in 1982 to be near his elderly parents. He says establishing a successful practice as a newcomer starts with the three “A’s: availability, affability and ability. “You must be available when needed, nice to patients, and, of course, reasonably talented.”

Borglum advises clients to “hammer the marketplace with appropriate marketing during the first month to jumpstart patient acquisition, which then increases patient referrals.” Physicians can use internet search engine optimization and direct mail to familiarize the community with the new practice. “Plan to spend half your annual marketing budget during the first week,” he says.

**BUYING A PRACTICE**

In well-served markets, buying an established practice may be the better choice. However, Borglum cautions that practices are often over-valued, which could cause the buying physician to lose money for the first few years. Physicians should retain an appraiser who specializes in medical practices to avoid overpaying, he says.

Physicians joining an existing practice have the advantage of an established patient base and business infrastructure. “Plan to not change operations for at least 60 to 90 days, to learn everything they are doing,” Borglum says. He advises clients in this situation to keep the existing staff, who can help familiarize the new physician with the practice and its patients.

The former owner of the practice can also help ease the transition by sending a notice to all patients introducing the new physician. “Have a photo in the letter with the smiling seller’s arm around the buyer, demonstrating acceptance, with wording such as ‘I’ve finally found a physician that I am confident that can take care of you as well as I have,’” Borglum says.

**RELOCATION TASKS**

Whether joining an established practice or starting from scratch, physicians must tackle the administrative aspects of relocation, such as meeting the licensure requirements for their new state. “This can be done by going to each state’s board of medicine and understanding the licensure requirements, applications and registration requirements,” says Bilimoria. “Some states offer reciprocal-
Google health search goes back to medical school

Two physicians test out what the tech giant says is an improved search function for responding to patient inquiries

**Google announced** earlier this year it would try to help both doctors and patients by reducing the anxiety and stress that often accompany symptom-related searches on its search engine app.

To do so, Google recruited consulting physicians and experts from Harvard Medical School and the Mayo Clinic to evaluate the medical conditions that appear in patient searches. The tech giant admits that patients looking up symptoms in the past often found the most extreme and rare medical cases rather than those most likely to be causing their ailment.

Through a new algorithm, it will cross-reference symptoms with what Google deems “high quality medical information” to present a more balanced search result.

Google hopes its efforts result in better search results that provide patients with a starting point for more in-depth research and consultation with a local health professional.

But is it working? We asked two doctors to test it out and tell us what they learned.

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**What you get depends on how you ask**

*By Melissa Lucarelli, MD*

Initially, when trying out the new health algorithm in the Google app, I was pleased with the well-illustrated and easy-to-understand explanations of common health conditions. Using my iPhone to search for “high blood pressure” resulted in a colorful graphic explaining how to measure blood pressure and an informative summary with clickable tabs about symptoms and treatments and related health conditions. Further down the page were other reference sources that mostly seemed to be from reputable websites (including the American Heart Association and Mayo Clinic).

The Google app also performed better than its competitors when searching the same topics, resulting in less advertising than Bing and fewer off-topic websites than Yahoo. So after this initial success, I decided to enlist the opinions of a team of experts: my family.
What a difference it makes to change the question you ask!

Test subject #1: My tech-savvy 40-year-old brother. He downloaded the iPhone app and found absolutely no difference in the quality or reliability of the search results compared to using the Google search engine on his home computer. His search topics were “Enbrel vs. Humira,” “headache from air freshener” and “Prozac for anxiety.” To demonstrate the improvements on the app, I suggested that he search instead for more general topics such as psoriasis, migraine or anxiety. After all these queries returned helpful but very basic patient education information, he commented that perhaps the Google app is not intended for people who already know how to use a computer.

Test subject #2: My 17-year-old son. His first search (using his Android phone) was for “rash on legs,” and I was pleased to see that a pop-up appeared with a quote from an article suggesting that atopic dermatitis or contact dermatitis are common causes. Below that were other articles with related conditions like shingles and stasis dermatitis.

Next, he searched “herpes from a toilet.” Initially, a reassuring pop-up read, “It’s very unlikely that you would get genital herpes from a toilet seat. Genital herpes is a sexually transmitted infection (STI) spread by skin–to–skin contact.”

Under this were a few helpful websites which my son scrolled over. He clicked on a link to a YouTube video that played an infomercial featuring someone wearing a white coat selling herbal products that supposedly treat herpes.

The good news is that Google seems to be continuing to improve its health algorithm. When I repeated the herpes search in the app two weeks later, the medically questionable video had been taken down.

Test subject #3: My 12-year-old daughter. I wasn’t too surprised when the first thing she typed into her Chromebook was “my butt itches.” For this search, the Google app performed wonderfully. It gave a clear definition of pruritis ani (anal itching) along with useful suggestions about hygiene and reasons to call a doctor.

However, her search for “why am I fat” was—as my kids say—an epic fail. What followed was a series of juvenile self-quizzes and blog sites propagating misinformation and reinforcing many negative stereotypes about obesity.

Is the Google app’s new health algorithm an improvement over other internet search tools? I think it certainly has potential. The patient education information about common health conditions such as hypertension and asthma was well-written and clear, and higher quality medical sites seem to have been prioritized in health-related searches.

After comparing the health topic search results with those of other general search tools, I am much more likely to use the Google app in the exam room to illustrate common health conditions at the point of care.

Melissa Lucarelli, MD, is a primary care physician practicing in Randolph, Wisconsin, and a member of the Medical Economics editorial advisory board.
Providing more sense than sleepless nights

By David A. Galli, MD

Picture a middle-aged man, slouching in a chair in your office, looking exhausted.

“Doc, I looked up my symptoms online,” he says before nervously letting out a weak laugh, “and I really think I’ve got cancer.”

Usually a detailed history and physical exam, along with some extra compassion and reassurance, can spare poor souls like him from further anxiety, needless testing and making premature funeral plans. The internet is an absolute treasure trove of valuable information, available in seconds for any seeker. Unfortunately, it is also home to outright falsehoods, medical quackery and products promising to give any man the virility of a 22-year-old.

Tragic anecdotes posted on online forums make rare diseases seem like certainties to patients whose nature is to project a worst-case scenario from a common symptom. Trying to sort the wheat from the chaff leaves many patients bewildered.

Google has introduced a new format to streamline the process for people seeking information on causes and treatments of common symptoms. Type in “headache,” for example, and among the diagnoses that pop up are migraine and tension headache, not frightening and rare ones like glioblastoma or brain-eating amoeba.

You want to dig deeper? Tap on “tension headache” and additional information appears, including a more detailed definition of the condition and the ages most commonly affected. Treatments are suggested, along with additional links for drugs and their side-effects and interactions.

Other warnings are given as to when to seek further care. Pithy bullet-points of advice appear next to easily-identifiable icons, such as a cartoon clock used to give the reader a time course to expect before they get better. For those really interested, links connect to the reputable National Center for Biotechnology Information and Mayo Clinic websites.

I tried a search on the app for another common symptom, “back pain.” Immediately, in bold letters, I found the words “very common,” along with the comforting truth that back pain is usually self-treatable and lab testing and imaging studies are rarely required. A conservative course of time, physical therapy and pain medications are recommended as ways to help.

A search on “acid reflux” gives a concise and easy-to-understand definition, along with various levels of treatment, from dietary modifications, elevating the head of the bed, and weight loss to drug therapy with H2 blockers and proton pump inhibitors.

My major criticism here and on the search for back pain is the lack of mention of alarm symptoms. Symptoms such as dysphagia and unplanned weight loss with acid reflux or back pain in connection with persistent fever or history of cancer, are reasons to seek treatment sooner, and not evident on a cursory scan of the results.

Overall, however, the explanations flow in smooth fashion, are completely easy to navigate, and relay common-sense results backed up with the caveat to “consult a doctor for medical advice.”

The explanations flow in smooth fashion, are completely easy to navigate, and relay common-sense results backed up with the caveat to ‘consult a doctor for medical advice.’

David Galli, MD is a board-certified internist in Chesterfield, Missouri.
“As a primary care doctor, connecting with patients is my most important job.”

STEPHEN WALSTON, MD, INTERNIST, SEATTLE, WASHINGTON

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“Getting so many people to row in the same direction with a sense of purpose is a challenge.”

G. ALLAN KUROSE, MD, CHIEF EXECUTIVE OFFICER, COASTAL MEDICAL, RHODE ISLAND

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80% of prescriptions for psychotropic medications are written by primary care physicians.

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Top Challenges for 2017

For the fourth consecutive year, Medical Economics reveals the list of obstacles physicians will face in the coming year and, more importantly, how to overcome them. This year, readers voted on their top issues seeking solutions.

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