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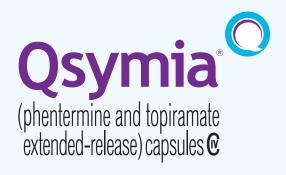
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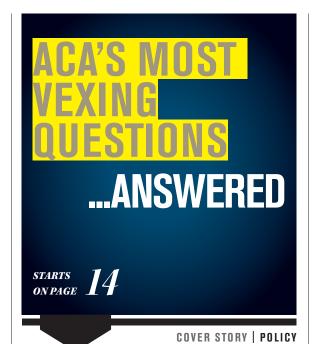
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#### MISSION STATEMENT

Medical Economics is the leading business resource for office-based physicians, providing the expert advice and shared experiences doctors need to successfully meet today's challenges in practice management, patient relations, malpractice, electronic health records, career, and personal finance. Medical Economics provides the nonclinical education doctors didn't get in medical school.

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#### **MAJORITY NOW SUPPORTS LEGALIZING MARIJUANA USE**

CNN medical correspondent Sanjay Gupta's reversal of his long-time opposition to medical marijuana is just the latest sign of marijuana's growing acceptance among the general public and physicians. More than three-fourths of respondents to a recent New England Journal of Medicine poll favored marijuana for medicinal use. Read more at Medical Economics.com/medical marijuana



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A healthcare think tank says three elements are needed. Read more at MedicalEconomics.com/beyond

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#### SCOPE OF PRACTICE

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#### QUALITY METRICS

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Myth busted: The vast, vast majority of #physicians are still accepting new #Medicare patients ow.ly/odg5u

#### BALANCE BILLING

AMA and AOA should push for removal of ban on balance billing, says @drcraigwax ow.ly/oa2ql #physicians #healthcare





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Physicians should only see as many patients as he or she can while maintaining high standards of service and care."

-Judy Bee HEALTHCARE CONSULTANT

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## from the Trenches 99

As doctors, we have to understand that biological systems, including our healthcare system, move in unpredictable and random directions that are often broken by chaos and reformed in order. For American doctors to attempt to take back what we have lost...and to really help our patients, we must adapt to our new environment.

Michael J. Hall, MD, MSC, MIAMI BEACH, FLORIDA

#### DOCTORS MUST BECOME MORE BUSINESS-MINDED

Mark Harvey, MD's letter ("Payers and Government Now Control Patient Care," July 25, 2013) is full of gloom and doom that doctors have lost control and that the insurers and government are up to their old tricks.

Where the heck have you been, doc? This is old hat, and if you go cross-eyed with the alphabet madness of new laws and bills that have been passed over the last 30 years, it's no surprise that you are lost in the wilderness without your shoes.

Look deeper and you will find the future of medicine. In that same issue, Ateev Mehrotra, MD speaks about the "convenience care revolution"—how retail clinics such as Walgreen's

are taking over, and \$5 billion is spent on basic care at \$99 a pop. ("AAFP Fires Back at the 'Convenience Care Revolution' Begun by Retailers," July 25, 2013.)

We all know about the Affordable Care Act and hear scary talk of what will be implemented and how our colleagues are fearful of losing more sleep, getting big fines, and having their Mercedes repossessed. Poppycock! No one really has any idea what will happen, but we know it won't be good. You must stop worrying and reformat you practice.

Now is the time to become more business-minded and less simple-minded. It is extraordinarily important for people to stop participating in the present system and go out on their own. Offer your services for cash, and bypass the system completely. Form alliances with your peers, and stop taking insurance and government dole. Keep only one thing in mind: operate your business from a vantage of truth, honesty, compassion, and integrity. You will fail if you do not. Stop being dependent on the system, become more entrepreneurial and get your financial house in order. Wake up, and stop complaining. Your patients will love you.

There are huge opportunities in medicine. Medicine isn't going retail, it's going back to basics. Medicine is indeed leaving the bloated clinics, the hospitals, the "quickie" cost centers, where we know our patients will encounter smash and grab financing and then bankruptcy. It is moving toward more therapeutic environments where access to good quality healthcare is quick, easy, and affordable.

As doctors, we have to understand that biological systems, including our healthcare system, move in unpredictable and random



directions that are often broken by chaos and reformed in order. For American doctors to attempt to take back what we have lost—our profession and our rights—and to really help our patients (many of who need a kick in the pants and made to become more responsible for their health), we must adapt to our new environment. To form a "more perfect system," we have to go through growing pains, and this is a perfect growing pain event. We have to develop new strategies to survive.

Michael J. Hall, MD, MSc

MIAMI BEACH, FLORIDA

#### DEFENSIVE MEDICINE NOW IS PART OF TRAINING

I found your article on tort reform ("Tort Reform," August 10, 2013) among the best I have read in your publication. There are important elements not considered in the article that your readers may want to consider. First, defensive medicine is being taught in all training centers throughout the United States, thereby assuring that graduates of training programs arrive in practice with a defensive mind-set.

I spent 27 years in an academic career before entering private practice 9 years ago and observed first-hand the evolution of the teaching of defensive medicine. I also see it in the practice patterns of recent graduates of clinical training programs. Thus, if the defensive approach to training young physicians were to be abandoned today, there would still be an entire generation of physicians who have been trained to practice defensively.

Second, defensive medicine has become the standard of practice in the vast majority of communities. Who will reset this standard, especially in light of the above-mentioned training of physicians? The outcome of most malpractice suits is determined by whether or not the physician involved had adhered to the standard of practice. As long as the standard in the community is defensive medicine, the epidemic of litigation will continue.

These two issues are obviously interrelated, but solving them will require a long period of time and a change in the incentives that drive the practice of medicine that you so nicely addressed in your article.

Marc D. Thames, MD

PHOENIX, ARIZONA

The outcome of most malpractice lawsuits is determined by whether or not the physician involved had adhered to the standard of practice. As long as the standard in the community is defensive medicine, the epidemic of litigation will continue.

-MARC D. THAMES MD, PHOENIX, ARIZONA

#### MOC MONOPOLY VIOLATES ANTI-TRUST LAWS

Kudos to Beth Hertz for the fortitude to expose the American Board of Medical Specialties (ABMS) for what they truly are: a greedy, tiny, private corporation out to terrorize and coerce us working physicians to fall under their unregulated control so that we have to pay them forever or will lose our precious board certification status and possibly our insurance contracts. ("MOC: Debate intensifies as Medicare penalties loom," June 25, 2013.) Who installed them as our lords? Who can check and balance their mandates? How can they create this monopoly and stay out of prison?

I joined the American Association of Physicians and Surgeons because of their federal suit against the ABMS and did not renew my American College of Physicians (ACP) membership as it is clear the ACP makes money off fearful internists who feel they must keep their certification.

This maintenance of certification scheme is a violation of federal anti-trust laws and has restrained trade. The lead plaintiff is a physician who was fired from a long-standing hospital job after he "failed" a recertifying exam. Perhaps *Medical Economics* would have the courage to illuminate this lawsuit in greater detail as most physicians are ignorant of the legal system. I am glad to see that at least your editors are not on the payroll of the ABMS , so keep on printing.

Ken Lee, MD

OLYMPIA, WASHINGTON

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## the Vitals Examining the News Affecting the Business of Medicine

#### BARE-BONES HEALTH PLANS MAY STAY UNDER ACA

So-called bare-bones, or "mini-med" health plans, which were supposed to be forbidden under the Affordable Care Act (ACA) may survive after all, Kaiser Health News and the Washington Post are reporting.

The two organizations say that proposed rules governing the ACA don't bar large employers from offering insurance policies that could exclude costly benefits. The law says only that large-employer policies must cover preventive care such as blood pressure tests or vaccines with no copays. So a plan might not cover the hospital care a patient could need for treatment of an illness.

Consumer advocates, employers, and insurers say that unless government regulators move to block them at the last minute, plans with limited benefits may continue to be offered by some large businesses, especially those with lowpaid workers such as retail and restaurant chains.

The new rules prohibit capping the dollar value of annual benefits, but excluding entire categories from coverage, such as hospital stays, is permitted, say benefit consultants.

## PCMH STUDY FINDS BETTER OUTCOMES, LOWER COSTS FOR CHRONIC CARE PATIENTS

Backers of the Patient-Centered Medical Home (PCMH) have claimed that the model can reduce costs while improving health outcomes for certain patient populations. Now additional evidence has emerged to support that claim.

A series of 3-year studies of PCMHs in Pennsylvania conducted by Independence Blue Cross (IBC) found "significant reductions in medical costs for patients with chronic conditions treated in primary care practices that have transformed into medical homes," according to IBC.

The results were especially striking among patients with diabetes, which is one of the nation's most prevalent and costly chronic diseases. These patients saw a 44% reduction in hospital costs and a 21% reduction in overall medical costs. Diabetic patients treated in the studied PCMHs also saw a 60% improvement in getting their low-density lipoprotein levels under adequate control. Overall, the number of patients with poorly controlled diabetes declined by 45% IBC says.

#### PATIENTS TREATED FOR DIABETES IN A MEDICAL HOME



### Young adults are willing to buy health insurance if it's affordable

**A NEW** report from The Commonwealth Fund may dispel the conventional wisdom among healthcare policy makers that young adults think they don't need health insurance.

The survey of approximately 3,400 adults ages 19 to 29 found that when offered health insurance benefits through an employer, two-thirds (67%) took the coverage. Among those who did not enroll in an employer health plan, the main reasons given were that they were covered by a parent, spouse, or partner (54%) or that they couldn't afford the premiums (22%). Only 5% turned down coverage because they felt they didn't need insurance.

"There is a stereotype that young adults believe they are 'invincible' and don't want or need health insurance," says Sara Collins, Commonwealth Fund vice president and the study's lead author. "This survey shows that is a myth—a typical uninsured young adult is from a lowor middle-income family and works a low-wage job. In general, young adults value health insurance but cannot afford it."

The report notes that in the year following enactment of Massachusetts's health reform law, the uninsured rate among the state's 19-to-26-year-olds fell from 21% to 8%.

At the same time, the increase in enrollment nationally among young people due to the ACA's dependent coverage provisions and the resulting decline in uninsured rates since 2010 demonstrates the importance of health insurance to members of this age group, the report states.

The report's findings may provide hope to members of the Obama administration and other backers of the Affordable Care Act (ACA) who have voiced concern that not enough young people will sign up for healthcare insurance to make the legislation viable.

On the other hand, the report also finds that the young adults who would benefit most from the health insurance marketplaces established under the ACA-those without coverage and

those from low- or middleincome households—are the least likely to be aware of them.

Just 27% of those surveyed who were in the 19-to 29-year-old age bracket were award of the marketplaces. Among those in low-income households eligible for subsidized coverage or Medicaid, awareness was only 18%.

In addition, as many as 25 states may not expand Medicaid eligibility, potentially leaving millions of young adults without coverage. The poorest young adults in states that don't expand Medicaid will be especially at risk, because those with incomes under 100% of the federal poverty level will be excluded from both the Medicaid expansion and subsidized private plans.

According to the survey, nearly 30% of young adults who spent a time uninsured during the vear were in families with incomes under 100% of poverty.

#### "This survey shows that...in general, young adults value health insurance but cannot afford it."

-SARA COLLINS, VICE PRESIDENT, COMMONWEALTH FUND

#### **MGMA: EXTEND** MU REPORTING REQUIREMENTS

Citing what it calls a lack of vendor readiness, the Medical Group Management Association (MGMA) is asking the government to extend the reporting requirements for attesting to stage 2 of Medicare's Meaningful Use (MU) program for electronic health records (EHRs). The requirements for physicians take effect January 1, 2014.

In a letter to U.S. Department of Health and Human Services Secretary Kathleen Sebelius, MGMA notes that only 75 products and 21 EHR systems now meet the Stage 2 criteria. Physicians and other eligible professionals who have certified for Stage 1 may be forced to "rip and replace" their systems to avoid Medicare payment adjustments, MGMA adds.

The letter asks HHS to extend the reporting periods for both Stage 1 and Stage 2 MU incentives, to survey vendors certified under Stage 1 criteria to find out which products they expect to recertify for Stage 2 and when, and to provide more flexibility in the Stage 2 requirements.

The Health Information Management Systems Society made a similar request to HHS earlier in August.

## Doctor's Bag

The latest in drugs, devices, technology, and more

#### THERMAL PATIENT ID WRISTBANDS **DESIGNED FOR SENSITIVE SKIN**

PDC Healthcare has released the Comfort Collection, its softest line of thermal patient identification wristbands, including Scanband Plus and ComfortBand Plus.



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IN DEPTH

#### **SOCIAL MEDIA**

The last word on creating social media policies? [62]



Cover Story

# ACA's most vexing questions

Physicians should brace for patients' confusion about the rules, reimbursements, and protocols regarding insurance

by LISA ZAMOSKY contributing author

#### HIGHLIGHTS

O1 While many physicians are pessimistic about the impact of the Affordable Care Act on their practice, some are looking to the law to reimburse for uncompensated care.

**02** Call volumes will increase, some predict, as millions of newly insured patients gain access to insurance.

s October 1 marks the start of open enrollment under the Affordable Care Act (ACA), primary care physicians will need to prepare for the possibility of increasing call volume, patient questions, and greater administrative complexities.

**YET JUST AS** the public struggles to understand the new health insurance market-places that are a central feature of the law, so too do physicians.

A recent survey conducted by Deloitte Center for Health Solutions found that most primary care physicians are either pessimistic about the law or don't know enough to make a determination. Nearly 32% believe it is a step in the wrong direction. And more than half of the physician respondents don't

believe the insurance exchanges will even be ready. The physician staffing firm LocumTenens.com found that 57% say they are not at all familiar with the impact health plans purchased through the marketplaces will have on their business. About 35% of physician say they don't plan to make any changes to their practices in response to the law.

But taking the time to understand the health plans newly available to consumers and how patients can tap into benefits un-



#### That puts an unfair burden on providers, especially if they don't know that a patient is in this grace period. So, we would like to see Congress or CMS change this grace period provision to protect providers..."

ALLISON BRENNAN, MEDICAL GROUP MANAGEMENT ASSOCIATION

der the law is well worth physicians' time, experts say. Among other reasons, it has much to offer those practicing primary care.

"For doctors like myself, internists who practice primary care, there have been a lot of benefits to the plan," says David Cutler, MD, chair of the Board of Regents of the American College of Physicians. "Screening, for instance, is much more prominent, much more accepted now, not only by Medicare, but by the commercial payers. So it's much easier for me now to screen patients, and to provide vaccinations, which historically were never covered, or weakly covered," Cutler says.

And then there's the potential to gain income on previously uncompensated care. Reid Blackwelder, MD, president-elect of the American Academy of Family Physicians (AAFP), says that among the nearly 110,000 AAFP members, on average, physicians provide eight visits a week for people without insurance. "So ideally, that number should drop pretty dramatically. I may have patients who are getting care that haven't before. I'm going to see patients now that have insurance coverage, which means it should help my payment structure."

#### **PUBLIC'S KNOWLEDGE** OF THE LAW IS WEAK

The LocumTenens.com survey also found that 90% of doctors believe that the public has not been adequately educated about how marketplace health plans will function under the ACA. And no doubt, Americans are still very much in the dark. According to a Kaiser Family Foundation poll taken earlier this summer, fewer than one in four Americans knew that the marketplaces existed; nearly one in five were unaware that the ACA was even the law of the land.

In addition, Kaiser found that 43% of those surveyed had an unfavorable view of the law, compared with just 35% who viewed the law in a positive light. This is despite the fact that many consumers have much to gain from many provisions of the ACA. For example, nearly half of those under the age of 65 surveyed believe that they or someone they live with has what would be considered a pre-existing condition, and one in four have either been denied insurance or had their premium increased as a result of an illness-two practices the law prohibits starting in 2014.

Often, however, details of what's actually contained in the law have been lost in the political battle. "People get ideas in their head that are influenced by something other than logic or reason, and I think it's the nature of 24/7 news, and a lot of people who legitimately don't like the Affordable Care Act," Cutler says.

Once they understand what's actually in the law and how they and their families can benefit, he says, perceptions often change.

"My patients very much appreciate, and have for several years now, the fact that their children can be on their plan up to the age of 26. They can't be dropped because (their care) costs too much. Pre-existing conditions are starting to go away as a reason to be turned down for insurance," Cutler says.

Estimates are that anywhere from 7 million to 8.5 million Americans will access the marketplaces in 2014 to obtain a health plan. Most people will have very little or no experience with insurance and will need guidance, experts say, and many will turn to doctors for information. A recent nationwide survey conducted by Healthpocket.com, a nonpartisan Web site that compares and ranks health plans, found that 14% of respondents

All private health insurance plans in ACA's health insurance exchanges will offer the same set of essential health benefits, including;

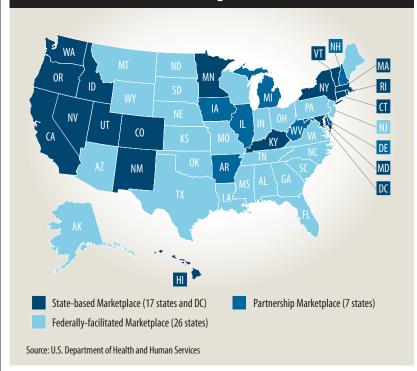
- Ambulatory patient services
- Emergency services
- ☐ Hospitalization
- Maternity and newborn
- Mental health and substance use disorder services, including behavioral health treatment (including counseling and psychotherapy)
- □ Prescription drugs
- Rehabilitative and habilitative services and devices (services and devices to help people with injuries, disabilities, or chronic conditions gain or recover mental and physical skills)
- Laboratory services
- Preventive and wellness services and chronic disease management
- Pediatric services

Source: U.S. Department of Health and Human Services





#### **Health Insurance Exchanges**



#### Resource for states operating in the Federal Exchange or Partnership Marketplace:

Web site: Healthcare.gov

#### Resources for state/district insurance exchanges:

**California:** Covered California Web site: coveredca.com

**Colorado:** Connect for Health Colorado

Web site: connectforhealthco.com

**Connecticut:** Access Health CT Web site: accesshealthct.com

Washington, D.C.: DC Health Link Web site: healthreform.dc.gov

**Hawaii:** Hawaii Health Connector

Web site: hawaiihealthconnector.com

Idaho: Your Health Idaho
Web site: yourhealthidaho.org

**Kentucky:** Kentucky Health Benefit Exchange

Web site: kynect.ky.gov

**Maryland:** Maryland Health Connection Web site: marylandhealthconnection.gov

**Massachusetts:** Health Connector Web site: mahealthconnector.org

Minnesota: MN Sure
Web site: mn.gov/hix

Nevada: Nevada Health Link website: nevadahealthlink.com

New Mexico: New Mexico Health Insurance

**Exchange**Web site: nmhix.com

**New York:** New York State of Health Web site: healthbenefitexchange.ny.gov

**Oregon: Cover Oregon** *Web site:* coveroregon.com

Rhode Island: HealthSourceRl Web site: healthsourceri.com

Utah: Avenue H (for small businesses; healthcare.gov for individuals) Web site: avenueh.com

**Vermont:** Vermont Health Connect Web site: <u>healthconnect.vermont.gov</u>

**Washington:** Washington Health Plan *Web site:* wahealthplanfinder.org

who intended to seek advice on health plans preferred to get it from their doctor or pharmacist.

Family practitioners and internists are, therefore, in a unique position to educate patients about the law. What's more, Blackwelder says, they have a responsibility to do so.

According to Blackwelder, when a physician sees a sick patient not currently covered by insurance it is his or her role—or that of someone on the team—to direct the patient toward state resources. "I think we must do that. And we have to be able to do that regardless of our personal opinion, because it is law, and it is designed to increase the healthcare coverage of Americans," he says. "How people move forward after October 1 really depends a lot on making sure they understand their responsibilities," he says.

Still, physicians often report being overwhelmed by the growing demands of running a practice. Taking the time to understand the health reform law and help patients navigate the new marketplaces and select the right health plan is for many another burdensome task they simply don't have time for. But there are fairly simple systems that medical practices can put in place to reduce the burden, say both Cutler and Blackwelder.

#### **USE A TEAM-BASED APPROACH**

Implementing a team-based approach to patient care can go a long way toward reducing the burden primary care doctors are likely to continue facing because of new pressures brought on by the law.

"It would help to have someone in your practice specifically for this role," Blackwelder says. "It would really make sense to have somebody who... knows the resources. When a patient came in, if someone was identified as a new enrollee or potentially someone who could benefit from the exchange, then there would be an opportunity for someone in the front office to have that conversation."

Starting a dialogue with patients, rather than jump-



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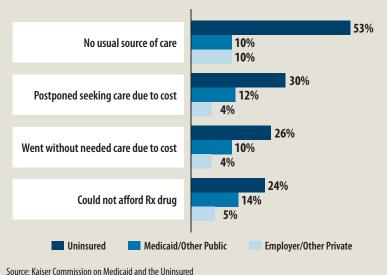
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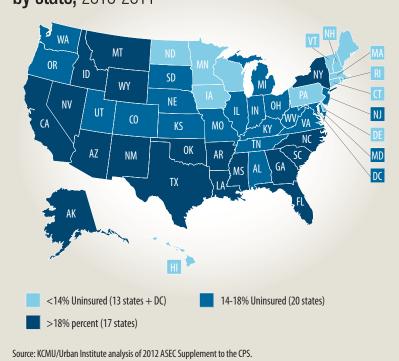




#### Barriers to healthcare among non-elderly adults by insurance status, 2011



Uninsured rates among the nonelderly by state, 2010-2011



ing in with facts about the ACA, can make it easier to provide useful information. "You can't just give facts to overcome fear," Blackwelder says. He suggests asking open-ended questions, directly identifying patients' emotional state and giving them a chance to express their position before explaining details of the law and how it might affect them.

Don't re-create the wheel. So much of this, in general, is "how you work smarter and not harder," Blackwelder says. There are a host of resources available to explain details of ACA provisions for both physicians and consumers.

The government-created health reform Web site Healthcare.gov explains the law and provides tools and information about each of the state marketplaces including Web sites and phone numbers. (See "ACA Resources" on page 18.)

FamilyDoctor.org offers a page addressing common consumer questions about the ACA.

The American College of Physicians offers "An Internist's Practical Guide to Understanding Health System Reform" on its Web site (acponline.org), as well as a physician and practice timeline that outlines which provisions of the law are taking effect and when.

Creating a printed handout with state-based resources where consumers can go for personalized assistance to learn about their health insurance options provides an important service for patients that may ultimately serve the interests of a medical practice.

#### IMPORTANT CONTRACTING CONSIDERATIONS

Physicians also have numerous administrative issues to deal with under the law. One of the more immediate concerns is whether or not to participate in the networks of the new health plans being sold through the state-based marketplaces. And despite the late date, many of the networks have yet to be solidified.

"There is a lot of variability across the states in terms of where practices are with



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Primary care visit copay	\$60 (3 a year)	\$45	\$30	\$20
Specialty care visit copay	\$70	\$65	\$50	\$40
Urgent care visit copay	\$120	\$90	\$60	\$40
Lab testing copay	30%	\$45	\$30	\$20
Generic medication copay	\$19	\$19	\$19	\$5
X-ray copay	30%	\$65	\$50	\$40
Emergency room copay	\$300	\$250	\$250	\$150
Hospital care, outpatient surgery	30% of plan's negotiated rate	20% of plan's negotiated rate	HMO*	HMO**
Imaging (MRI, CT, PET Scans)	30%	\$250	\$250	\$150
<b>Brand medications</b> (may be subject to annual drug deductible)	\$50-\$75 after deductible	meet \$250 deductible	no deductible	no deductible
Preferred brand copay After drug deductible (if any)	\$50	\$50	\$50	\$15
Maximum out-of-pocket for individual	\$6,350	\$6,350	\$6,350	\$4,000
Maximum out-of-pocket for family	\$12,700	\$12,700	\$12,700	\$8,000

<sup>\*</sup>Outpatient surgery: \$600; hospital, \$600/day up to 5 days

Source: Covered California

their contracting with payers and making decisions about how to or whether or not to participate with these exchange products," says Allison Brennan, senior advocacy advisor with the Medical Group Management Association.

Among the questions she hears from physicians many concern payment rates, the size of the patient population insurers expect to serve, and which insurers are offering products through the marketplace.

In many markets around the country, newer payers with whom many physicians may not have experience have entered the market. "One of the things that we've been hearing is just the uncertainty and the variation across states in terms of where practices and payers are in that contract negotiating process," Brennan says.

As practices consider the contracts before them, Brennan advises watching for several items when deciding whether to participate in marketplace plans

1. Look at payer mix. "We recommend our members evaluate their practice's payer mix and determine how much capacity they would have to accept new patients," Brennan says.

<sup>\*\*</sup> Outpatient surgery: \$250; hospital, \$250/day up to 5 days





2. Reach out to payers you want to work with. "If the payers have already been identified in your exchange, and you want to participate, you can reach out to them and try to initiate that discussion and start to have those contract negotiations," Brennan says.

Watch for communication from insurers. According to Brennan, some insurers are requiring practices with whom they have already contracted to actively opt out of contracting for the exchange plans if they wish not to participate.

"So, rather than the plan calling them up and saying, 'hey, do you want to contract for this exchange product,' what they're doing is sending them a letter that says unless you respond to this within seven days, we'll assume that you'll be participating in this new plan," he says

3. Pay close attention to contract details. One major concern for physician practices is contract language that allows for a 90-day grace period for a patient who has an exchange plan and stops paying his or her premium. During the first 30 days of that period, the insurer is required to continue to pay claims. But in the last 60 days, payment can be withheld. If the patient fails to pay all of his or her premiums, they'll lose the coverage at the end of the 90 days, and physicians will be required to collect any withheld payments directly from the patient.

"That puts an unfair burden on providers, especially if they don't know that a patient is in this grace period," Brennan says. "So we would like to see Congress or [the Center for Medicare and Medicid Services] change this grace period provision to protect providers, and at the very least, they should make some specific changes requiring insurers to provide up-to-date information when a patient enters the grace period," Brennan says.

As a matter of protection, she says, practices need to conduct eligibility verification requests for every visit. And, it's worth requesting that some of that liability shift back to the insurer or requiring contract language that says the insurer will notify the practice when the patient has entered the grace period.

4. Evaluate and revamp payment and collections policies and procedures. This is especially important if your practice treats many patients with high-deductible health plans, which will be common among those

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THAT MORE THAN ONE
IN FOUR UNINSURED
AMERICANS
ELIGIBLE FOR THE
NEW ACA PREMIUM
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HAVE A CHECKING
ACCOUNT

purchasing coverage through the exchanges.

An alarming study from Jackson Hewitt concludes that more than one in four uninsured Americans (approximately 8.5 million people) eligible for the new ACA premium assistance tax credits do not have a checking account, the vehicle through which insurance companies plan to require customers to pay healthcare premiums.

**5. Know your state.** While the health reform law seeks to create uniformity in health plan offerings, there are still wide variations among the states. Brennan suggests doctors stay abreast of what's happening in their area. "They have to make sure they're really tracking how this is evolving in their state, and in their local market," she says.

#### A NEW WORLD AWAITS

The true impact of the ACA and whether the marketplaces will operate as promised, whether enough consumers will buy insurance policies, and how heavily affected primary care practices will be all remain to be seen.

Will we end up with a healthcare system that works better for consumers and physicians alike in the long run? "I'm an optimist," Blackwelder says. "I'm not going to say I'm sure it will work. Then again, the flip side of that is, it would be hard pressed to do worse than some of the systems we've already suffered through."

IN DEPTH

#### **TEAM-CENTERED CARE**

New models will require shifting roles [33]

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How technology is changing job functions [39]

#### **TIPS FOR FLU SEASON**

Preparing for flu season challenges [42]



## Scope of practice debate

Many organizations are seeking solutions to the impending primary care physician shortage, but should nurse practitioners fill the void?

by DONNA MARBURY, MS Content Specialist

#### HIGHLIGHTS

- **01** Several states are considering expanding the scope of practice for nurse practitioners in order to fill the shortage of primary care physicians.
- **02** Nurse practitioners may be abandoning primary care and moving into subspecialties that pay more.
- **03** A team-based, collaborative apporach, in many forms, will help physicians best utilize the skills of nurse practitioners.

As the individual mandate requirement of the Affordable Care Act (ACA) draws closer, healthcare professionals are scrambling to figure out how a tsunami of new patients will be serviced by a dwindling number of primary care physicians (PCPs).»

the **NUMBERS** point to a perfect storm of overwhelmed physicians and underserved patients. More than 830,000 physicians are over 50 years old, nearing retirement, and are seeing fewer patients, according to a 2012 Physicians Foundation survey. By 2025, there will be 15 million more patients eligible for Medicare, and more than 30 million Americans in the healthcare system due to the ACA. The country would need an additional 51,880 PCPs by 2025 in

order to keep up with this influx of patients, with the majority of these new physicians needed by 2015, according to an Annals of Family Medicine study.

One solution—broadening the responsibilities of non-physician practitioners (NPPs) including nurse practitioners (NPs) and physician assistants (PAs)—has sparked a debate across the healthcare community. Since the ACA passed in 2010, California, Massachusetts, Michigan, Pennsylvania,

and New Jersey have considered legislation that would allow NPs the ability to practice without a physician's oversight.

California's scope of practice bill is currently advancing through its legislature, despite opposition from the California Medical Association. Both the AARP and the American Association of Nurse Practitioners withdrew their support of the bill due to the removal of a provision allowing NPs (with 3 years of experience with a physician) permission to practice outside of confined settings without supervision, and would mandate that NPs carry medical liability insurance. California is facing a shortage of up to 17,000 PCPs, with up to 4 million new patients expected in its healthcare system

"When we talk about scope of practice, that's not defined by me or any state, it is defined by your license," says Reid Blackwelder, MD, president-elect of the American Academy of Family Physicians (AAFP). "People believe NPs, PAs, and PCPs are the same and they aren't. There's a huge difference in education and training, and that information needs to be clear."

#### **GAPS ON BOTH SIDES**

Blackwelder says the limited clinical experience of NPs make them unable to, "come out of training ready to hit the ground running. Family physicians train a total of 21,000 hours, while NPs train between 3,500 to 6.000 hours, and some schools are 100% online."

That difference in training, with more emphasis on patient's needs, is actually what the healthcare system needs to combat increases in chronic disease management, says Judy Bee, president of Practice Performance Group in La Jolla, California, and editorial consultant for Medical Eco-

"NPs are seen as more patient-centric than physicians, and don't necessarily subscribe to the 'treat'em and street'em philosophy' that could quickly overwhelm the healthcare system," Bee says, adding that NPs can assist patients with managing chronic disease and alert physicians when they need additional care. "NPs are the entry point," she says.

Relying on NPs to fill the shortage of PCPs may not be an option, based on reports that the number of NPs in primary care has fallen from 51% in 1996 to 31% in 2010. The shortage of clinicians entering careers in primary care may even be extending into NPs and PAs, according to a recent study by AAFP's Graham Center.

"NPs and PAs are going into subspecialties just like medical school students," Blackwelder says. An increase in college debt and lower pay models in primary care cause many to continue their education to pursue careers in oncology, cardiology or dermatology, that can pay up to 16% more.

#### FINDING MODELS THAT WORK

Bee is puzzled by the debate over NPs and their role in the expanding healthcare system-she always recommends them as a solution to practice-volume problems.

"When doctors tell me they are looking to hire another doctor, nine times out of 10 they should hire a good NP first," Bee says. "It's less risky, less expensive, and a good interim step. The fact is, some doctors need to be solo."

Bee says NPs can treat patients with less clinical care, and refer those who need additional care to the PCP. Though half of patients say they prefer PCPs, almost 60% would see an NP rather than wait a day for their doctor, according to a Health Affairs study.

"There are a myriad of ways that physician extension works," Bee says, adding that communications between physicians and NPs needs to become more transparent. "The doctor has to invest time with his staff, training them on his or her approach."

Blackwelder agrees that there is a place for NPs under team-based models. The AAFP has collaborated with the Centers for Medicare and Medicaid Services, developing seven models in different states and communities that address better access, patient experience and lower costs with PCPs as the leader.

"Our doctors still have the capacity for same-day visits, and after-hour care that is not being utilized. We challenge our members to fully utilize electronic health records and other technology. A lot of patients don't need face-to-face visits, and those are models we have looked into," Blackwelder says.

#### PATIENTS ARE IN THE MIDDLE

There also needs to be more effort toward educating patients old and new about col-



#### Why more NPs, PAs may not save us from the primary care shortage

By BRANDON GLENN, Digital Content Manager

here's been plenty of worry about the impending primary care shortage, but the solution has always seemed fairly obvious - get more nurse practitioners (NPs) and physician assistants (PAs) delivering routine primary care services while allowing physicians to work at the top of their training.

Except maybe it's not that easy.

A new policy paper from a research group affiliated with the American Academy of Family Physicians (AAFP) suggests that more NPs and PAs may not be ready to step in for primary care physicians to relieve the shortage.

The reason? Just like doctors, NPs and PAs may increasingly be seeking subspecialty careers that come with better pay and less hassle.

Just 43% of the nation's 70,000 PAs, and 52% of the nation's 106,000 NPs practice in primary care, according to data cited by the AAFP's Robert Graham Center for Policy Studies in Family Medicine and Primary Care.

Somewhat similarly, a study earlier this year in the Annals of Family Medicine found that the percentage of PAs working in primary care fell to 31% in 2010 from 51% in 1996.

Unlike that study, he Graham Center's policy paper doesn't address whether the numbers have been trending up or down in recent years, but the researchers suggest that simply depending on more NPs and PAs to assume more primary care duties isn't wise policy. (It's probably fair to note here that the AAFP is generally opposed to expanding NPs' scope of practice.)

"Relying on NPs and PAs to solve the problem of a growing shortage of primary care physicians may not be an option, and policy makers should not abandon policy solutions designed to increase the number of primary care physicians, NPs, and PAs," the researchers write.

Pronouncements like that aren't likely to greeted warmly by some legislators in California, home to what's currently the nation's most high-profile scope-of-practice debate. Earlier this month, the bill's sponsor watered down the legislation pertaining to NPs' scope of practice after it failed to get enough votes in committee.

The latest version of the bill allow NPs to operate independently from physicians only if they practice at a hospital, clinic or other medical facilities. A prior version of the bill would've allowed NPs to operate completely independent of physician oversight after completing 6,420 hours of supervised work.

As is typical in scope-of-practice tussles, the state's most prominent lobbying group for physicians fiercely opposes bill - even the watered-down version, arguing that it could compromise patient safety.

But California is just the tip of the iceberg in the national scope-of-practice debate. Last year 827 scope-of-practice bills were proposed nationwide, with 124 of them passing in 29 states, California Healthline reported. (Some of those bills apply to occupations other than PAs and NPs, such as pharmacists and optometrists.)

While nurses' and physicians' groups are likely to battle over scope of practice across the nation for years to come, each side can certainly agree that they need each other for the often-touted team-based care concept to fully achieve its potential.

"In order for America to realize the promise of team-based care, we all have to come to a better and shared understanding of what it means for medical providers to work together," AAFP President-Elect Reid Blackwelder, MD, recently said. "As with any team structure, we must define roles. Each team member is critical but they're not interchangeable."

laborative care models, says Laura Palmer, FACMPE, senior industry analyst at the Medical Group Management Association (MGMA).

According to a *Health Affairs* study published in June, almost half of patients interviewed preferred a physician as their PCP, but would opt to see an NP instead of waiting for an appointment.

"A lot of people have not accessed healthcare except in emergency situations. The first issue will be that pent up demand for access," Palmer says, adding that the NP's role of following up with patients with chronic conditions will be critical.

A survey released by the AAFP in 2012 states that 26% of patients thought NPs were doctors. And NPs who have a doctor in nurse practice degree, and are sometimes referred to as doctors, confused 35% of patients. Palmer says that patients need to know the differences between the roles of the physicians and NPsnow patients are unclear, she says.

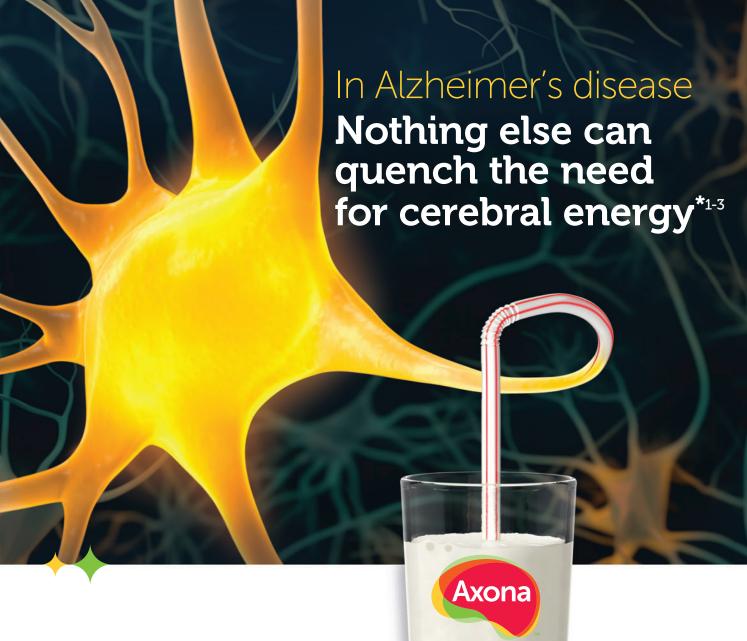
"NPs will have the time and capacity to spend more time with patients, so the doctor needs to introduce them as part of the care team," Palmer says.

#### **NO FAST AND EASY** SOLUTIONS

The politics of the increased scope of practice for NPs ignores the increase demand for chronic care management that will be a major part of patient care, says Keith Borglum, healthcare business consultant in Santa Rosa, California, and Medical Economics editorial consultant.

"Some doctors are anti-NPs, politically they want to protect their turf. But the forecast for available medical professionals in the future is so bleak," Borglum says. "The argument about quality of care is a fair argument. But much of the healthcare demanded doesn't need anywhere near a physician's expertise," Borglum says.

Borglum says that even though collaborative and team-based models are on the rise, more healthcare workers will



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References: 1. Henderson ST, Vogel JL, Barr LJ, et al. Study of the ketogenic agent AC-1202 in mild to moderate Alzheimer's disease: a randomized, double-blind, placebo-controlled, multicenter trial. Nutr Metab (Lond). 2009-63:1. 2. Cunnane S. Nugent S. Roy M, et al. Brain fuel metabolism, aging, and Alzheimer's disease. Nutrition. 2011;27(1):3-20. 3. National Institute on Aging. Alzheimer's disease fact sheet]. http://www.nia.nin.gov/sites/default/files/alzheimers\_disease\_fact\_sheet\_opdr. Reprinted September 2012. Accessed June 4, 2013.

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Fuel the Brain





#### SCOPE OF PRACTICE ACROSS THE COUNTRY

#### States that allow NPs to practice with no physician oversight

Alaska Arizona Colorado Hawaii Idaho Iowa Maine Montana Nevada

New Hampshire New Mexico North Dakota Oregon Rhode Island Vermont Washington Wyoming

District of Columbia

#### States that require that NPs collaborate with physicians

Alabama Arkansas Connecticut Delaware Illinois Indiana Kansas Kentucky Louisiana Maryland Minnesota Mississippi Nebraska New Jersey New York Ohio Pennsylvania South Dakota

Utah Wisconsin West Virginia

#### States that require physician supervision

California Florida Georgia Massachusetts Michigan Missouri North Carolina Oklahoma South Carolina Tennessee Texas Virginia

not be able to manage the mil-**→** 2.8 lions of patients who are en route

"There's tougher competition from retail clinics. We need to think about patient self-triage through insurance companies, and other technological solutions as well. "Our society's demand upon a finite and shrinking pool of providers needs every possible solution we can throw at it," Borglum says. "We can't just solve the problem with more bodies."

Palmer says the biggest hurdles in the scope of practice debate are mental ones concerning physicians' views on NPPs. "Some physicians may have had bad experiences or weren't comfortable with the training of NPs before," says Palmer, who adds that collaborative care utilizing NPPs is MGMA's most searched topic. "Trust comes with repeated exposure with good people.

Doctors need to understand the competency requirements and experience they go through. Then a lot of resistance will be broken down."

Ultimately, Bee says that with increases in telemedicine and other non-face-to-face appointments being reimbursed by payers, well-trained and informed NPPs are essential. She adds that reports of a huge rift between physicians and NPs are over-statedmany agree that some form of team-based primary care is the solution.

"I have reports from happy doctors that have long and fruitful relationships with NPs," Bee says. "There are some doctors who are dead set against it, but I think those are the ones who don't have a NP. Strong and proactive NPs and PAs in small practices truly are physician extenders. They are used best when they have a conscious and organized role in a practice."



## Building a team-based medical practice

New models for care delivery require shifting roles for employees and greater sharing of responsibilities

by JEFFREY BENDIX, MA, Senior Editor

#### HIGHLIGHTS

- **01** Team-based care is characterized by being ongoing and proactive, and allowing each provider to practice at the top of his or her license.
- **02** A comprehensive electronic health record system is a vital part of team-based practice, because it facilitates information sharing, data gathering, and patient communication.

rimary care practices are being urged to adopt "patient-centric" practice models, such as the Patient-Centered Medical Home (PCMH) or accountable care organization, as a way of improving the quality of care they provide. But implementing these models requires a team-based approach to patient care. And although most practices would say they operate as a team now, they quickly find that the term means something quite different in the context of patient-centric care delivery.

So what is a team-based primary care practice? And how does a practice owner or administrator go about building one?

#### TEAM-BASED VERSUS 'HERO' MODEL OF CARE DELIVERY

To answer those questions, it helps to understand how the team concept differs from the way most primary care practices now operate. Although somewhat oversimplified, the current paradigm is largely episodic and reactive, while a team-based approach is characterized as ongoing and proactive. Under the current model, patient care comes almost exclusively from the

physician, whereas in a team-based practice virtually everyone has responsibility for some aspect of patient care.

"I call what we have now the 'hero' model, where the physician is the only source of knowledge, education, and decision-making, and everyone else is basically there to support the physician," says Bruce Bagley, MD, interim president and chief executive officer of TransforMed, a branch of the American Academy of Family Physicians that seeks to help practices transition to the PCMH model.

By contrast, under a team model "we look at all the resources we have available, in particular the human resources, and determine who are the best people to help monitor or manage different parts of the patient's care based on those individuals' qualifications, rather than on the initials after their name," says Mark Greenawald, MD, FAAFP, associate professor and vice chair of family and community medicine at the Virginia Tech Carilion School of Medicine. Greenawald also sees patients part-time in a Carilion facility.

"Part of the attraction of the PCMH and other new models of care is that they allow providers to practice closer to the level of their license," Green-

#### "TODAY, THE PERSON IN THAT (FRONT OFFICE) POSITION IS MUCH MORE TUNED IN TO THEIR ROLE AND HOW IT MATTERS IN THE

PRACTCE." MARK GREENAWALD, MD, FAAFP, VIRGINIA TECH CARILION SCHOOL OF MEDICINE

awald adds. "They provide the opportunity for professionals to be stretched and challenges at whatever level they operate. For us, it meant defining staff roles in ways that really looked at training and skill levels and ask are we really using them that way?"

#### USING STAFF TO FULL EXTENT OF THEIR TRAINING

Charles Cutler, MD, FACP, an internist in Norristown, Pennsylvania and chair of the American College of Physician's Board of Regents, notes that under the current system he would be called on to perform tasks that don't require his level of training, such as filling out a school physical, or for which others have better training, such as providing dietary instruction.

But a patient-centered, team-based system, "uses a variety of different medical professionals to the full extent of their training. Maybe a nurse practitioner is the best person to fill out a school form. Maybe a trained dietician is the best person for the specifics of dietary care. But if you're experiencing symptoms of pneumonia, you should be seeing me," he says.

The expansion of roles under a teambased model isn't limited to providers. Greenawald cites the changing role of a front-office staff person in his practice. Five years ago, he says, the person's responsibilities were to answer the phone, take messages, and make appointments. "It could have been a secretarial position anywhere. There was nothing unique to medicine about it," he says.

"Today, the person in that position is much more tuned in to their role in the practice and how it matters. So if the patient's chart says they are due for a mammography the receptionist will say, 'as long as I've got you on the phone let's find a time you can come in for a mammogram.' That's a huge paradigm shift."

#### FOSTERING A GREATER SENSE OF OWNERSHIP

Moreover, as staff members and providers other than the physician expand their roles, they begin to feel a greater sense of ownership and responsibility for patients' well-being. "They start to see how what they do make a real difference to a patient, even on the back end of a visit, so they feel a real sense of ownership in ensuring the follow-up visit," Greenawald notes.

"In the past, if a patient didn't show for an appointment the response was 'maybe they'll make another appointment," he says. Now it's really following up with the patient, saying 'we see you missed your appointment. Is something wrong, can we get you re-scheduled"?

Bertha Safford, MD, is part of a multilocation family practice in northwestern Washington State that started to make the transition to team-based care in the late 1990's, after she and some colleagues attended a seminar on treating patients with diabetes. While there they were introduced to the chronic care model developed by Edward Wagner, MD, which emphasizes the importance of proactive team care.

"At that point we started engaging our whole team in the care of our diabetes patients, and then we slowly expanded into other areas," she says. The practice established standing orders and protocols for midlevels and medical assistants so that immunizations have been administered if indicated, mammograms have been scheduled, and medications have been reconciled before the patient sees the doctor.

#### THE ROLE OF THE EHR

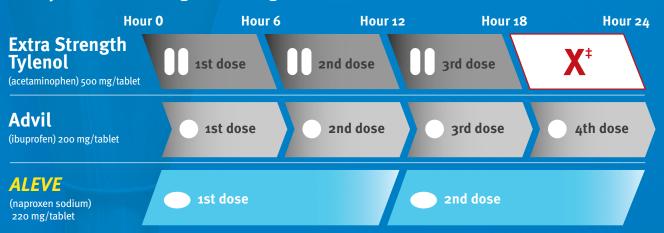
A comprehensive electronic health record (EHR) system is virtually a must for teambased care to function effectively, experts say. That's because



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#### Accountability-based primary care workforce model



#### **Attributions** of team

- Role clarity
- Role training
- Working to top of practice
- Team communication
- Subject experts for patient population

Driven by patient needs

Source: American Hospital Association

the team approach relies heavily on being proactive in patient care, which in turn means being able to identify specific patient populations, such as those with diabetes, so that team members can schedule needed appointments and monitor patients' progress.

"I can go into my EHR and in 2 minutes pull up a list of patients with, say, hemoglobin A1C levels greater than eight," says Greenawald. "Then we can start asking the people on that list to come see us because their diabetes isn't under control."

Carilion uses its EHR system to identify "high-risk, high-utilizer" patients, Greenawald says, based on factors such the number of emergency department visits and the number of chronic diseases a patient has. "We decided these are patients we really want to go after, both because they're at risk

for having something bad happen to them, and from a cost perspective."

"An EHR is basically a platform that allows us to build better care processes," says Bagley. "For example, if a patient calls and gets transferred to the population health manager, then that person can get the patient's information in front of them immediately and begin addressing the patient's needs."

#### PERSUADING EMPLOYEES TO BUY IN

As with any significant organizational change, getting buy-in from employees is key. Practices who have made the transition say they rely on training, and the promise of a more rewarding work environment to persuade employees to go along. "I think we appealed to their (staff members) hearts, by saying this is how we're going to be able to



#### () Operations

provide better care," says Safford. "And then training is a key piece. You can't change your practice to a team approach where everyone has a role unless you specifically train them to those roles."

New physicians and clinical assistants undergo a series of training sessions in the practice's methods, and the physician's charts are reviewed to ensure they are adhering to them. "Otherwise you couldn't sustain a model like this," Safford says.

#### OVERCOMING PATIENT RESISTANCE

Of course, staff members and physicians aren't the only ones who need to be persuaded of the benefits of team-based care. Longtime patients accustomed to seeing only the physician may balk at the idea of receiving even routine or follow-up care from a midlevel or medical assistant.

A key to easing that transition is the "handoff" of the patient from the physician to another team member, says Paul Grundy, MD, MPH, president of the Patient-Centered Medical Home Collaborative, and global director of healthcare transformation at IBM. He recalls seeing a medical assistant in a practice call a patient about following up on some test results.

"The assistant started out by saying 'I'm calling on behalf of Dr. Gonzales because she cares about you, and she wants you to know that. Then the MA provided the details about what needed to be done, and finished by saying, 'Any time you want to get in touch with Dr. Gonzales she's available to you.' And the patient was fine with that.

"If this (handoff) is done right, no matter when or how it occurs, the patient knows the doctor cares about them, and that is crucial, Grundy says.

Does the team-based approach work? Evidence so far is sketchy, but promising, at least in terms of provider satisfaction. A 2011 study published in the *Annals of Family* Medicine looked at how 23 "high-performing" family practices had reduced physician burnout and brought joy to the practice of medicine.

Much of what researchers found in these practices mirrored the characteristics of team-based medicine, including "proactive planned care, with pre-visit planning and laboratory tests, sharing clinical practice among a team, with expanded rooming protocols, standing orders, and panel manTEAM-BASED **RESOURCES** 

Here are links to resources to help you develop a team-based practice:

- The Patient-Centered Medical Home **Collaborative:** www.pcpcc.org
- **▶** American College of Physicians **Practice Advisor:** www.practiceadvisor.org/home
- TransforMed: www.transformed.com/
- Comprehensive Primary Care **Initiative:** 1.usa.gov/Ls7uRe

agement, and improving team functioning through co-location, team meetings, and work flow mapping."

#### IMPROVED QUALITY OUTCOMES

Safford says her practice has seen results in terms of better quality outcomes. Among patients with diabetes for example, blood sugar levels, blood pressure, and several other American Diabetes Association recommended guidelines have been stable for 6 years.

Among other benefits, improved quality data has enabled the practice to negotiate higher reimbursement rates from insurance companies. The practice consistently ranks highly in third-party payer surveys of patient satisfaction, and employee turnover is down. "I think our desirability as a place to work has been helped by the fact that we try to use everyone to their maximum ability," Safford says.



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## EHRs and audits mean new roles for doctors, staff

One practice's experience illustrates the shifts in responsibilities brought on by payers' requirements for more quality data

by LORI E. ROUSCHE, MD

#### HIGHLIGHTS

**01** Nurses and front-office staff are increasingly taking on additional tasks due to payers' quality reporting requirements, which can sometimes lead to stress and friction among employees.

**02** Practices will need to rewrite job descriptions to reflect the ongoing evolution of responsibilities in the EHR era.

ith the introduction of electronic health records (EHRs), and the increasing use of audit results and quality measures for payment, it is clear that the traditional nurse and front-office staff job descriptions have to be revamped. As doctors have to meet more and more requirements to get paid, they need to rely heavily on their staff to collect and enter data that insurers will review and use to determine payments.

The traditional nurse position is no longer just rooming patients, taking

blood pressures and triaging health concerns from patients over the phone. And the standard front-office worker isn't just pulling charts and scheduling appointments.

In our group practice of 30 providers in seven offices, we had to reassign tasks to staff that hadn't changed their daily routine in many years and didn't want to have their job descriptions rewritten.

It is human nature to resist change, so the easy acceptance of EHRs in general was not always easy for either doctors or staff. However, it was necessary to make the change, and so we did.

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Of course there was a lot of grumbling and some difficult days. But the harder part now is figuring out how we shift our staff from their pre-EHR roles to the new ones required in the post-EHR era.

#### ADDED RESPONSIBILITIES FOR NURSES

Let's start with the nurses. They are now required to do much more than just rooming a patient and taking and entering vital signs. In order to reach meaningful use goals, they must enter whether or not the patient smokes. They have to reconcile the current medications and click the appropriate box. They have to review the allergies and click the box.

In the fall, they need to ask a patient if he or she has had a flu shot, and enter the answer in the computer with the proper current procedural terminology (CPT) code for the doctor. This is far more time-consuming than the old way, and the nurses feel stressed about it. They can no longer make patient phone calls between bringing patients back for the doctor, because they don't have enough time. Nurses on the phone are also struggling. Every encounter now is more time-consuming, because the EHR system is inherently slower than paper charts.

It is not as easy for the nurses to multitask, because they can only have one chart open at a time. At the end of the day, they don't feel as accomplished as they normally would because the 'jelly-beans' (phone messages) are no longer always empty.

For data entry, we originally tasked the nurses with trying to enter the patient's mammogram, colonoscopy, and Tetanus, Diphtheria, and Pertussis vaccination information from the paper chart into the computer while rooming the patient. This just bogged the nurses down, and was simply too time-consuming. Digging through paper charts to find the exact date of a colonoscopy performed 7 years previously was not cost-efficient, nor did it allow for a reasonable workflow that kept the doctor on time. We decided, therefore, to have our front-office staff enter some of this data.

#### ASKING MORE OF FRONT-OFFICE STAFF

Traditionally, the front-office staff abhors anything clinical. They don't even like delivering a stool specimen in a brown bag from "AS MEDICINE
EVOLVES IN THE NEW
EHR ERA, IT WILL BE
CRUCIAL FOR OFFICE
STAFFS TO ACCEPT
THE CHANGES. JOB
DESCRIPTIONS
WILL NEED TO BE
REWRITTEN, AND
HOPEFULLY THIS
WILL CONTRIBUTE TO
IMPROVED PATIENT
CARE"

the patient to the nurse. The very idea of holding a full cup of warm urine was vile to them. Also, having to be responsible for adding data other than just demographics to a chart was foreign to them. The front-office staff wasn't comfortable notating mammograms and hemoglobin A1c levels. However, because they were less busy with the billing, thanks to the computer system, they were the obvious choice to enter data the insurance companies crave.

With a little encouragement, the front-office staff took over the majority of the audits. Now they diligently look up the data in the paper charts, and enter it into the EHR. If no mammogram results are in the paper chart, they check the EHR. They know to look under "alerts," and if it hasn't populated there, to check in the "diagnostic imaging" results, and if not there, then in "patient documents."

If they don't find a record of the required test, the front-office staff now sends the patient a letter from the doctors explaining the importance of the test for the patient's health. Included in the envelope is a requisition for the test, and a letter to sign and return if the patient refuses to get the test. Some insurance companies now accept a refusal as a completed test. The front-office staff will scan the refusal letter into the EHR, so the doctor gets

credit for asking.

A high school student also helps to enter data. He was hired initially to help the front-office staff enter problem lists and medications when we were first implementing the EHR system. After a year, when most patients' basic information had been entered in the EHR, his job evolved to entering immunization records for patients under age 18. Recently his responsibilities changed yet again to entering results of mammograms, colonoscopies, and dual X-ray absorptiometry scans performed pre-EHR. We did this because it is now crucial for the practice to have all of the audit data in place so that we aren't penalized at year's end and lose money.

#### QUESTIONS CHANGE WITH NEW DATA REQUIREMENTS

As staff members become more comfortable with the EHR, everyone is getting a little faster. The nurses are now required to ask patients aged 65 and over about falls and enter the answers under preventative measures before they bring the patients back for the doctor. As the audits and quality measures change year to year, the questions the nurses ask will change as well. In the future they may assess alcohol intake and urinary incontinence issues before the provider even enters the room.

The doctors' role has changed too. When reports come in and need review, the doctor tries to populate the alerts to make information easier to find during audits. Physicians also need to enter the International Classification of Diseases-9th Revision and CPT codes, and check off the evaluation and management code before the patient returns to the front desk to check out.

This may sound no different than when we used paper bills, but it is. It requires finding the proper code, and opening and closing many boxes to get all the information entered properly. However, it makes the biller's job easier, leaving him or her more time for audit work.

Doctors are also performing more data entry than ever before while still trying to make eye contact with patients. Doctors are entering their own referrals during the office visit rather than requesting their nurse to do so. This frees up some time for the nurse to do her other new tasks. So the shifting of responsibilities is an unremitting challenge with the EHR system, and will continue to transform our practice well into the future.

Our office continues to strive to provide the highest quality of care possible to our patients. It is sometimes difficult to do so while trying to enter so much data for the insurance companies. Unfortunately, without the data, reimbursements go down. Without adequate payments, there will be no practice to provide care for our patients.

Fortunately, our staff understands this dynamic and is quite cooperative with the process of transforming traditional job roles and responsibilities into new ones. As medicine evolves in the new EHR era, it will be crucial for office staffs to accept the changes. Job descriptions will need to be rewritten, and hopefully this will contribute to improved patient care.

Lori E. Rousche, MD is a diplomate of the American Board of Family Physicians and practices family medicine at TriValley Primary Care in Souderton, PA



MORE RESOURCES

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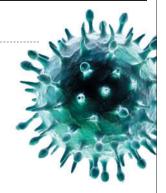


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# Same-day care, capacity key to managing flu season

Last year's flu season brought chills to some providers; experts say planning, education are even more critical now

by DONNA MARBURY, MS Content Specialist

## HIGHLIGHTS

O1 Schedule early and effective communication with patients about vaccination clinics and exteneded services through cold and flu season.

**02** Carving out time in your schedule specifically for cold and flu patients will cater to the needs of patients and be a marketing tool for your practice.



Fortunately, physicians can prepare in advance for an onslaught of patients who want advance or same-day care surrounding their cold and flu symptoms. Going into the season without a plan does a disservice to your patients, which could be an invitation for them to go to retail and urgent-care clinics for services you could provide. Last year, Walgreens administed 5.5 million flu shots and made millions more selling other cold and flu treatments.

"A low level appointment might be \$60. Missing 10 of those a day over two and a half months is a lot of money," says Gray Tuttle, principal in healthcare management for Rehmann in Lansing, Michigan. "The key opportunity is having the capacity when flu season hits." Preparation is the key to managing this hectic season.

## PREPPING FOR FLUIMMUNIZATIONS

An advantage your practice has over retail clinics is education. Make sure you and your staff are communicating with patients about the right time to get flu shots, and set up times for them to get them. "Ask patients to refrain from obtaining the annual flu immunization until the appropriate time so that it provides maximum protection," says Robin Diamond, MSN, JD, RN, senior vice president for The Doctors Company. "Many drug stores and other retail outlets offer the flu immunization too early, and its protection wanes by the height of flu season."

Check to see what payers fully cover flu vaccinations, and consider having clinics that cater to those patients at convenient times. If not fully covered, make sure to let patients know in advance how much flu shots would cost them out of pocket, so that they are prepared.





# High risk, low priority

ew mothers and people who are morbidly obese have a higher chance of dying from the flu, but are not prioritized for flu shots, according by a study released by the **British Medical Association.** 

Though pregnant women with the flu go to the hospital more, the study finds that women in postpartum had a higher risk of severe outcomes from the flu. Women within four weeks of having a baby had "a significantly increased risk of death," according to the study.

People with a body mass index of more than 30 also show an increased risk of death and complications from the flu. The authors note that many chronic illnesses, including diabetes, present a higher flu mortality rate, but "morbid obesity was

identified as a potential independent risk factor after adjustment for these comorbidities."

The study, co-sponsored by the World Health Organization, suggests that obesity and the postpartum period be added to the list of high-risk factors that should allow for priority flu vaccinations. Also noted was the "poor quality of evidence" that determines which demographics and



The World Health Organization states that data for populations with a high-risk of flu complications should be reevaluated.

factors lead to higher complications and mortality from flu

"Despite the widely accepted public health policy of recommending vaccination to groups believed to be at high risk for complications of influenza, a comprehensive and systematic review of the evidence defining these groups is lacking," the study found.

Setting up flu vaccination clinics after hours or on weekends, and allowing for walk-in vaccinations will certainly capture patients who might go to retail clinics, Tuttle says. "If patients can come in unannounced for flu shots that are fair and competitively priced, pharmacies won't be able to compete," Tuttle says.

Consider partnering with area businesses to offer flu clinics to their employees. This also provides an opportunity to offer tutorials about standard precautions against colds and flu, and market your business to new clients.

There are certain factors that are out of your control, like vaccine shortages. The Centers for Disease Control and Prevention

(CDC) projects that manufacturers are producing between 135 million and 139 million doses of flu vaccinations for this upcoming flu season. Early communication with patients is key to making sure they look to your practice for information regarding changes in the flu season, vaccination availability, and dates and times of clinics, especialy for immuno-compromised patients.

## **USING EHRS TO MARKET** SEASONAL CARE

Depending on the type of electronic health record (EHR) system you have, you may be able to look across several date points to aggregate your most vulnerable patients for flu vaccinations, says Tim A. Sayed, MD, a member of the Healthcare Information and Management Systems Society EHR Association executive committee.

"You can create alerts based off of diagnoses entered by the doctor. So if a patient has a high risk of pneumonia based on age or had the flu before, the EHR system can alert them a month before flu vaccinations are available," Sayed says. "It will be important to get the word out in compliance with privacy laws, but in digestible ways patients can use it."

Sayed says eventually with stage 2 of meaningful use, there will be opportunities for practices to look at patterns across geographic and other demographic patient populations to see what trends there are in flu outbreaks and what treatments are and aren't working.

## SAME-DAY CARE IS ESSENTIAL

Tuttle says that by not providing opportunities for same-day appointments, practices are pushing their patients into urgent care and retail clinics.

For solo practices, Tuttle suggests that practices should leave an hour in the morning and in the afternoon for patients with flu symptoms. "Providing the promise for same-day service is a huge practice builder," Tuttle says.

With small practices, he has seen success when physicians rotate being the "duty doctor" for a day during the height of cold and flu season. This doctor schedules minimal appointments, and is primarily open for walk ins. Tuttle says that he has witnessed one doctor seeing 80 walk-in patients in a day under this model.

"For no or little additional costs, there's a lot of added revenue to this model," Tuttle says. "Use this as a marketing tool. Quick visits are great for the patient and yield good economic results."

Keep a light schedule on Monday mornings when patients who were sick over the weekend are most likely to call in. Consider opening early on Mondays, not only to call patients who left messages and schedule appointments, but to see patients or their children before work or school.

## SPECIAL STAFFING CONSIDERATIONS

The cold and flu season runs next to many winter holidays, another difficult time for

## An ounce of prevention

## Listen to your doctor

Only 63% percent of healthcare workers receive flu shots, according to the Centers for Disease Control. Making sure you and your staff are vaccinated first will help keep the team providing care rather than receiving it.

## Give masks to patients

Offer masks to patients exhibiting any respiratory issues, and make sure they know how to use them properly. Hang posters close to the entry area (in languages that reflect your patients' ethnicity) and near elevators and waiting areas that show how to wear masks, proper hygiene, and cough etiquette.



staffing. Your staff may be scheduling vacation time or may even get sick themselves.

"You shouldn't have to hire seasonal help if your nurse practitioners and physician assistants are well trained," Tuttle says. "You may need additional front-desk support if you are already short staffed and considering longer hours."

Consider tapping a temp agency early in the season to identify candidates who can fill in early mornings, evenings and weekends. Also consider temporary workers who are willing to work the days before and after holidays, if your staff members have vacation scheduled and your office is open.

## REPURPOSING SPACE AND RESOURCES

The Centers for Disease Control and Prevention suggest that a portion of your wait-

## COLD & FLU STATISTICS

2,452

The number of flu viruses that the CDC has characterized since October 2012.

200,000

The number of flu-related hospitalizations each year

There will be between

135 MILLION and 139 MILLION

flu vaccines produced for this flu season

# 75,000 to 125,000

The number of children under 1 year old that are hospitalized each year due to RSV infection

## \$40 BILLION

The cost of the common cold to the U.S. economy in lost workdays and treatments annually.

Florida had the longest respiratory syncytial virus (RSV) season last year, 30 weeks

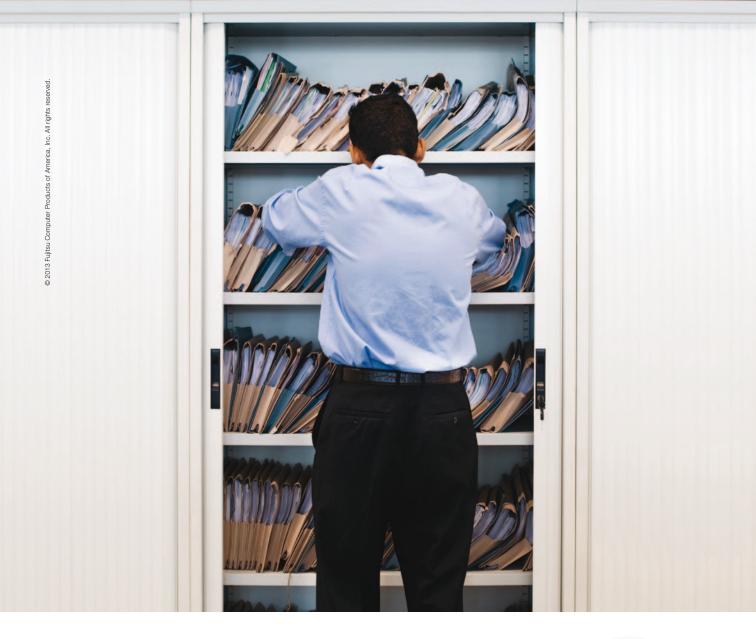
This season's flu vaccination protects against Influenza A (H1N1) viruses, influenza A (H3N2) viruses, and influenza B viruses

Sources: Centers for Disease Control and Prevention, University of Michigan

ing area be sectioned off for patients with respiratory infections. If this isn't possible, consider a station that processes cold and flu patients so they can move through the waiting area quickly.

"Isolate patients who are sneezing or coughing by immediately having staff escort them to a treatment room where the patient should be asked to wash their hands for at least 20 seconds," Diamond says, adding that tissues, masks, and hand sanitizer should be available at your check-in station.

Ralph E. Holsworth, DO, medical director of Southeast Colorado Hospital in Springfield, Colorado, suggests that doctors keep bottled water in waiting areas during flu season for both patients and staff. "It only takes a 1% to 2% drop in body fluid to experience mild signs of dehydration. Staying hydrated can help individuals avoid a trip to the doctor or emergency room for dehydration, and help physicians reduce the number of office staff sick," Holsworth says.



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## IN DEPTH



# Cloud-based EHR helps practice connect in new ways

A look at how an EHR system made e-prescribing, charting, and reading a doctor's handwriting easier

by DARIN PAINTER, contributing author

## HIGHLIGHTS

- O1 Columbus Health
  Professionals quickly
  converted its e-prescribing
  and medical charting
  functions from paper to
  electronic using an EHR
  system.
- O2 The practice looks forward to adding other functions to its EHR system including scheduling, laboratory results and imaging.

At a time when healthcare providers seem to be dwelling on the idea of collecting—more patients, more billings, more cost savings, and more meaningful use incentives—Kevin Olson, DO, and his practice, Columbus Health Professionals in Columbus, Ohio, is focused instead on connecting.

**DISON, A FAMILY PRACTITIONER,** is charged with suppressing costs with improved efficiency, and impressing patients with improved care. Like many of his peers, he realizes that today's healthcare system is under the gun and under the microscope, and that is why he's sticking with an approach that has worked for 25 years.

"I see kids from the womb to the tomb — little tykes, adolescents, middle-aged folks, and geriatrics," he says. "More than anything,

we value our relationships with those people and always want to provide optimal care, no matter what they need." Columbus Health Professionals offers a wide range of services, including orthopedics; ear, nose, and throat care; obstetrics; and wellness checkups. The practice has about 10,000 active charts, Olson says, and he sees from 30 to 60 patients a day.

The self-effacing Olson is a self-proclaimed "man of the







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

INVOKANA  $^{\text{TM}}$  is not recommended in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

## IMPORTANT SAFETY INFORMATION

#### **CONTRAINDICATIONS**

- >> History of a serious hypersensitivity reaction to INVOKANA™.
- >> Severe renal impairment (eGFR <30 mL/min/1.73 m²), end stage renal disease, or patients on dialysis.

## **WARNINGS and PRECAUTIONS**

**>>Hypotension:** INVOKANA™ causes intravascular volume contraction. Symptomatic hypotension can occur after

initiating INVOKANA<sup>TM</sup>, particularly in patients with impaired renal function (eGFR <60 mL/min/1.73 m²), elderly patients, and patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (eg, angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA<sup>TM</sup> in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages. In adults with type 2 diabetes,

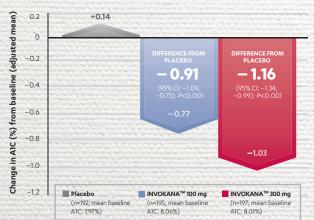
# ENVISION NEW POSSIBILITIES

Introducing INVOKANA<sup>™</sup>—the first and only treatment option approved in the United States that reduces the reabsorption of glucose in the kidneys via sodium glucose co-transporter-2 (SGLT2) inhibition¹

#### A1C Reductions as Monotherapy

INVOKANA<sup>™</sup> monotherapy provided statistically significant A1C reductions vs placebo at 26 weeks<sup>1</sup>

A1C Change From Baseline With INVOKANA™ Monotherapy¹



#### Effect on Weight\*

Statistically significant weight reductions vs placebo at 26 weeks (P<0.001)<sup>1</sup>

➤ Difference from placebo†: 100 mg: -2.2%; 300 mg: -3.3%

#### Impact on Systolic Blood Pressure (SBP)\*

Statistically significant SBP lowering vs placebo at 26 weeks (P<0.001)<sup>2</sup>

➤ Difference from placebo†: 100 mg: -3.7 mm Hg; 300 mg: -5.4 mm Hg

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

\*Prespecified secondary endpoint.

†Adjusted mean.

#### A1C Reductions vs Sitagliptin

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

➤ Difference from sitagliptin<sup>†</sup>: -0.37%

## Incidence of Hypoglycemia

Monotherapy over 26 weeks: 100 mg: 3.6%; 300 mg: 3.0%; placebo: 2.6%<sup>1</sup>

With metformin and a sulfonylurea over 52 weeks:

INVOKANA<sup>™</sup> 300 mg: 43.2%; sitagliptin 100 mg: 40.7%<sup>1</sup>

>> Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA<sup>™</sup> can increase the risk of

hypoglycemia when combined with insulin or an insulin

secretagogue

Convenient Once-Daily Dosing<sup>1</sup>

- >> Recommended starting dose: INVOKANA™ 100 mg
- Dose can be increased to 300 mg in patients tolerating 100 mg, who have an eGFR of ≥60 mL/min/1.73 m² and require additional glycemic control

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

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

Learn more at INVOKANAhcp.com/journal



#### WARNINGS and PRECAUTIONS (cont'd)

- Impairment in Renal Function: INVOKANA™ (canagliflozin) increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA™. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m².
- ➤Hyperkalemia: INVOKANA™ can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically after initiating INVOKANA™ in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.
- \*\*Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues: Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA™.
- **>>Genital Mycotic Infections:** INVOKANA™ increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections. Monitor and treat appropriately.
- ➤Hypersensitivity Reactions: Hypersensitivity reactions (eg, generalized urticaria), some serious, were reported with INVOKANA™ treatment; these reactions generally occurred within hours to days after initiating INVOKANA™. If hypersensitivity reactions occur, discontinue use of INVOKANA™; treat per standard of care and monitor until signs and symptoms resolve.
- ➤Increases in Low-Density Lipoprotein (LDL-C): Doserelated increases in LDL-C occur with INVOKANA™. Monitor LDL-C and treat per standard of care after initiating INVOKANA™.
- **»Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA™ or any other antidiabetic drug.

### **DRUG INTERACTIONS**

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

#### **USE IN SPECIFIC POPULATIONS**

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

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

Nursing Mothers: It is not known if INVOKANA™ is excreted in human milk. INVOKANA™ is secreted in the milk of lactating rats, reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA™ showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs in utero and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing



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

- »Pediatric Use: Safety and effectiveness of INVOKANA™ in pediatric patients under 18 years of age have not been established.
- **>> Geriatric Use:** Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA™ in nine clinical studies of INVOKANA™. Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA™ (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300-mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were ≥75 years of age. Smaller reductions in HbA1C with INVOKANA™ relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA™ 100 mg and -0.74% with INVOKANA™ 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA™ 100 mg and -0.87% with INVOKANA™ 300 mg relative to placebo).
- >> Renal Impairment: The efficacy and safety of INVOKANA™ were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/ 1.73 m<sup>2</sup>). These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR ≥60 mL/min/1.73 m<sup>2</sup>); patients treated with INVOKANA™ 300 mg were more likely to experience increases in potassium.

The efficacy and safety of INVOKANA™ have not been established in patients with severe renal impairment (eGFR <30 mL/min/1.73 m²), with end-stage renal disease (ESRD), or receiving dialysis. INVOKANA™ is not expected to be effective in these patient populations.

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

#### **OVERDOSAGE**

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

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

#### **ADVERSE REACTIONS**

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

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



## Janssen Pharmaceuticals, Inc.

Canagliflozin is licensed from Mitsubishi Tanabe Pharma Corporation.



## **INVOKANA™**

(canagliflozin) tablets, for oral use

Brief Summary of Prescribing Information.

#### INDICATIONS AND USAGE

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

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

#### CONTRAINDICATIONS

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

#### WARNINGS AND PRECAUTIONS

Hypotension: INVOKANA causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA [see Adverse Reactions] particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²), elderly patients, patients on either diuretics or medications that interfere with the renin-angiotensinaldosterone system (e.g., angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.

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

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

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

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

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

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

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

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

#### ADVERSE REACTIONS

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

- Hypotension [see Warnings and Precautions]
- Impairment in Renal Function Isee Warnings and Precautions!
- Hyperkalemia [see Warnings and Precautions]
- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues Isee Warnings and Precautions
- Genital Mycotic Infections [see Warnings and Precautions]
- Hypersensitivity Reactions [see Warnings and Precautions]
   Increases in Low-Density Lipoprotein (LDL-C) [see Warnings and **Precautions**1

Clinical Studies Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. Pool of Placebo-Controlled Trials: The data in Table 1 is derived from four 26-week placebo-controlled trials. In one trial INVOKANA was used as monotherapy and in three trials INVOKANA was used as add-on therapy [see Clinical Studies (14) in full Prescribing Information]. These data reflect exposure of 1667 patients to INVOKANA and a mean duration of exposure to

#### INVOKANA™ (canagliflozin) tablets

INVOKANA of 24 weeks. Patients received INVOKANA 100 mg (N=833), INVOKANA 300 mg (N=834) or placebo (N=646) once daily. The mean age of the population was 56 years and 2% were older than 75 years of age. Fifty percent (50%) of the population was male and 72% were Caucasian, 12% were Asian, and 5% were Black or African American. At baseline the population had diabetes for an average of 7.3 years, had a mean HbA1C of 8.0% and 20% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 88 mL/min/1.73 m<sup>2</sup>).

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

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

Adverse Reaction	Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Female genital mycotic infections <sup>†</sup>	3.2%	10.4%	11.4%
Urinary tract infections <sup>‡</sup>	4.0%	5.9%	4.3%
Increased urination§	0.8%	5.3%	4.6%
Male genital mycotic infections <sup>1</sup>	0.6%	4.2%	3.7%
Vulvovaginal pruritus	0.0%	1.6%	3.0%
Thirst#	0.2%	2.8%	2.3%
Constipation	0.9%	1.8%	2.3%
Nausea	1.5%	2.2%	2.3%

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

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

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

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

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

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

Abdominal pain was also more commonly reported in patients taking INVOKANA 100 mg (1.8%), 300 mg (1.7%) than in patients taking placebo (0.8%). Pool of Placebo- and Active-Controlled Trials: The occurrence of adverse reactions was also evaluated in a larger pool of patients participating in placebo- and active-controlled trials.

The data combined eight clinical trials *[see Clinical Studies (14) in full* Prescribing Information and reflect exposure of 6177 patients to INVOKANA. The mean duration of exposure to INVOKANA was 38 weeks with 1832 individuals exposed to INVOKANA for greater than 50 weeks. Patients received INVOKANA 100 mg (N=3092), INVOKANA 300 mg (N=3085) or comparator (N=3262) once daily. The mean age of the population was 60 years and 5% were older than 75 years of age. Fifty-eight percent (58%) of the population was male and 73% were Caucasian, 16% were Asian, and 4% were Black or African American. At baseline, the population had diabetes for an average of 11 years, had a mean HbA1C of 8.0% and 33% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 81 mL/min/1.73 m²).

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

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

In the pool of eight clinical trials with a longer mean duration of exposure to INVOKANA (68 weeks), the incidence rate of bone fracture was 14.2, 18.7, and 17.6 per 1000 patient years of exposure to comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Upper extremity fractures occurred more commonly on INVOKANA than comparator.

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

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

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

<u>Volume Depletion-Related Adverse Reactions:</u> 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 Reactions (Pooled Results from 8 Clinical Trials)

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

<sup>\*</sup> Includes placebo and active-comparator groups

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

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

			Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
	Baseline	Creatinine (mg/dL)	0.84	0.82	0.82
Pool of		eGFR (mL/min/1.73 m²)	87.0	88.3	88.8
Four	Week 6	Creatinine (mg/dL)	0.01	0.03	0.05
Placebo- Controlled	Change	eGFR (mL/min/1.73 m²)	-1.6	-3.8	-5.0
Trials	End of	Creatinine (mg/dL)	0.01	0.02	0.03
	Treatment Change*	eGFR (mL/min/1.73 m²)	-1.6	-2.3	-3.4
			Placebo N=90	INVOKANA 100 mg N=90	INVOKANA 300 mg N=89
	Baseline	Creatinine (mg/dL)	1.61	1.62	1.63
	baseline	eGFR (mL/min/1.73 m²)	40.1	39.7	38.5
Moderate Renal Impairment Trial	Week 3	Creatinine (mg/dL)	0.03	0.18	0.28
	Change	eGFR (mL/min/1.73 m²)	-0.7	-4.6	-6.2
	End of Treatment Change*	Creatinine (mg/dL)	0.07	0.16	0.18
		eGFR (mL/min/1.73 m²)	-1.5	-3.6	-4.0

<sup>\*</sup> Week 26 in mITT LOCF population

In the pool of four placebo-controlled trials where patients had normal or mildly impaired baseline renal function, the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR below 80 mL/min/1.73 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 (14.3) in full Prescribing Information], the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR 30% lower than baseline, was 6.9% with placebo, 18% with INVOKANA 100 mg, and 22.5% with INVOKANA 300 mg. At the end of treatment, 4.6% with placebo, 3.4% with INVOKANA 100 mg, and 3.4% with INVOKANA 300 mg had a significant renal function decline.

In a pooled population of patients with moderate renal impairment (N=1085) with baseline eGFR of 30 to less than 60 mL/min/1.73 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 was associated with an increased incidence of renalrelated adverse reactions (e.g., increased blood creatinine, decreased glomerular filtration rate, renal impairment, and acute renal failure), particularly in patients with moderate renal impairment.

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

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

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

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

Table 4: Incidence of Hypoglycemia\* in Controlled Clinical Studies

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

<sup>†</sup> Patients could have more than 1of the listed risk factors

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

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

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

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

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

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

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

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

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

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

#### **DRUG INTERACTIONS**

UGT Enzyme Inducers: Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including

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

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

#### **USE IN SPECIFIC POPULATIONS**

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

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

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

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

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

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

Renal Impairment: The efficacy and safety of INVOKANA were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to less than 50 mL/min/1.73 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); patients treated with INVOKANA 300 mg were more likely to experience increases in potassium [see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Adverse Reactions].

The efficacy and safety of INVOKANA have not been established in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 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 Inform patients of the potential risks and benefits of INVUKANA and of alternative modes of therapy. Also inform patients about the importance of adherence to dietary instructions, regular physical activity, periodic blood glucose monitoring and HbA1C testing, recognition and management of hypoglycemia and hyperglycemia, and assessment for diabetes complications. Advise patients to seek medical advice promptly during periods of stress such as fever, trauma, infection, or surgery, as medication requirements may change.

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

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

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

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

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

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

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

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

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

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

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SEE WHAT YOU MAY HAVE BEEN MISSING IN OUR ENEWSLETTER

## AMA pushes back on **Medicare fees**

>> THE American Medical Association (AMA), in its summary of the proposed 2014 Medicare Physician Fee Schedule, is critical of several elements of the schedule.

The Centers for Medicare and Medicaid Services is calling for large payment reductions for more than 200 services, which it claims are misvalued because physician offices receive larger reimbursements than ambulatory surgical centers or outpatient departments at hospitals would receive for the same

The 2014 proposal

would cap physician payments for those services at the same amount the hospitals receive.

The AMA calls this policy "arbitrary" and defends the higher payment for services in physician offices.

"For hospitals, payments above and below the cost of service are assumed to average out over time," the summary says. "But physicians...cannot offset their losses this way. The AMA will ... seek to delay implementation until the [Relative Value Scale Update Committee ] can review these codes."

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Stone Age," but last winter he wondered if Columbus Health Professionals could benefit from punching more keystrokes and using less paper. He wanted to know how he could speed up medical charting, receive lab test results faster, and begin to prescribe medications electronically.

Olson certainly isn't alone. When health-care consumer demands grow and internal resources seem to be stretched thin, even many old-school physicians are considering new ways to achieve optimal results. To that end, Columbus Health Professionals became one of 29 participants in the 2-year *Medical Economics* Electronic Health Records (EHRs) Best Practices Study, an ongoing project intended to draw out valuable, real-world insight for healthcare leaders.

The study paired Olson and other physicians with nine EHR vendors. He and his staff used Practice Fusion, a free, customizable, cloud-based service founded in 2005 that now has more than 150,000 users. The software platform is comprehensive—it includes charting, scheduling, billing, e-prescribing, lab integrations, and secure messaging—and it is geared mostly to small practices that can get started with EHRs using just a computer and an Internet connection.

"I had heard and read about electronic medical record war stories," Olson says, knowing that the transition and training might be painful. But he also envisioned potential long-term benefits including improved efficiency, information management, and patient education and care. "Just having immediate access to each patient's information," including his or her panel, health status, prescription history and other data, "can help any practice," he says.

Olson wanted Practice Fusion to enable his team to access real-time information needed to make data-driven decisions. He wanted to improve operational efficiency, yet maintain patient volume. He wanted his staff to quit mentioning his hard-to-read





Medical Economics EHR Best Practices Study

http://www.modernmedicine.com/ EHRbestpractices handwriting and instead read prescription information clearly on a computer. And he wanted to still make it home by 5:30 p.m.

## PREPARATION, TRAINING, AND EARLY REACTION

While many organizations view charting, scheduling, and billing as integral, Olson and his team believe those procedures are integrated—part of a single system that can help the practice centralize its information.

As part of his evaluation, Olson wanted a vendor with low upfront costs, a growing base of users, and features that would fit the workflow of his practice. "We chose Practice Fusion because it looked like a reasonable program at a reasonable cost," he says. "But we were cautious from the get-go. I talked to some peers, and most have tried two or three systems before settling on one that worked best for them. So I wanted ours to be affordable, in case we needed to change, and to look like something that would fit our practice."

Emily Peters, vice president of marketing communications for Practice Fusion, says the price point is a big plus with doctors. The support from advertising allows for the system to be free. "We hope everything else makes them stay with us," she says.

It only takes seconds to sign up for an account, but "it doesn't take seconds to learn," says Tina Huther, office manager at Columbus Health Professionals. She and several other staff members spent weeks learning the new electronic means of data capture and rethinking multiple processes in the practice, including patient data entry, coding, and prescribing.

"I don't think anyone here began as a big fan of EHRs," Olson says. "I was pretty much computer-illiterate, so for me, it was a real pain. I could see the information was going to be there at my fingertips, but our learning curve has been slow. One reality is that people learn in different ways, and even if the system is supposed to be intuitive, not everyone is going to learn at the same pace, or in the same way."

Huther says she is a visual learner, and would have preferred in-person training, instead of an online support system, even with unlimited access. "The first day, I would have thrown it away if I could have. I mean, I could tell it definitely had possibilities for improving the practice, but the early frustration level was through the roof," Huther says.





Olson says he and his staff are now learning more about the system's customizable forms and templates. "One thing we learned early on is that it's important for what I write down to enter the system in the way I had intended," Olson says. "That can be a challenge, because computers do what they're told, not necessarily what we want them to do."

## IMPROVED MEDICAL CHARTING AND E-PRESCRIBING

Designed by doctors and medical associations, the system boasts more than 220 medical-chart templates designed to serve the needs of dozens of specialties, Peters says. Although Columbus Health Professionals hasn't delved deeply into the system's customizable features, "we're getting value from the charting module," Huther says. "It's compatible with our processes, and we like that we can edit them. We think we'll get quicker with time."

Convenience has been the biggest advantage of online medical charts, Huther says. She and others at the practice can see an instant list of diagnoses, prescriptions, drug allergies, and past medical history. From one dashboard, they can manage medication lists, immunization records, and Centers for Disease Control and Prevention growth charts. Also, referrals are accessible directly from the charting workflow, so Olson could send a patient referral as he is finishing a chart note.

Aside from medical charting, e-prescribing is where the practice is reporting EHR success. "A few years ago, there might have been five medications for common conditions. Now, there might be 50, and that complexity isn't easy to handle," Huther says. Once Columbus Health Professionals' credentials were verified, the practice could begin e-prescribing to more than 70,000 U.S. pharmacies through its EHR account with just a few clicks. The practice is also integrated to labs such as Quest, LabCorp, and BioReference, as well as some regional facilities.

"The absolute biggest pro for our office is that we can read Dr. Olson's handwriting, because there isn't any to read. We won't have a problem with transcribing prescriptions incorrectly, which happened from time to time in the paper-based system," Huther says. "Also, the fact that doctors can share information with one another right away is a huge benefit."

Huther also looks forward to using the EHR for scheduling, and integrating laboratory and imaging results. "We know we're not taking advantage of everything the system has to offer, but charting and e-prescribing have given us a start," she

#### RESULTS AND EXPECTATIONS

Before adopting the EHR, Olson would write down medication lists for older patients. Invariably, some of those paper sheets would literally get lost (patients would misplace them) or metaphorically lost (in translation when patients struggled to decipher the handwriting). "That part of patient care is better already because of the electronic system-my ability to educate the patient with these medical records has improved, and hopefully will keep improving," he says.

Despite the practice's struggles, Olson says, he believes in the carrot that some medical technology proponents hold as cardinal truth—that implementing an EHR system will negatively affect productivity at first, but the increased access to data ultimately will improve patient engagement and billing.

"In general, I now believe EHRs mostly help with volume," Olson says. "If you're used to spending 45 minutes with one patient, as some specialists admirably do, then EHRs probably won't change any productivity. But if you're structured like us, and you might see 60 patients a day, and you're switching from paper to digital, then in time you'll probably see your volume rise without too many problems."

For meaningful use attestation, Columbus Health Professionals has access to a dashboard that updates daily and tracks goals. According to Peters, Practice Fusion has helped users receive more than \$100 million through meaningful use 1 and 2 stimulus incentives.

When it comes to metrics, Olson says the practice is less concerned about tangible benefits and more concerned about continuing to foster a positive connection with patients. "I do look forward to a time when more physicians will be able to share medical information easily and securely," he says. "We're learning more about what we can do with the system. It started out painful, but I like the potential."

IN DEPTH

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# The negotiating table

Experts identify the top considerations when discussing a practice sale or merger

by DEBRA BEAULIEU, contributing author

## HIGHLIGHTS

- **01** Identify what goals you want to accomplish by merging before you begin conversations with potential partners.
- **02** Be ready to discuss ways to merge staffing, EHRs, facilities, and other duplicate services.

Among the major challenges posed by the Affordable Care Act, there's an undeniable trend: Practice owners are looking to sell or merge with other organizations as a means to adapt and thrive in today's healthcare environment. However, it can take years to identify the partners and circumstances that best meet your practice's needs. >>

Wolters Kluwer Health, 34% of primary care, family medicine, and internal medicine physicians said that over the next 3 to 5 years they would be "exploring different business models," which could include "mergers [or] becoming part of a hospital system."

For practitioners who are part of this statistic, there is far more work involved beyond deciding if alignment or consolidation is the right choice.

"This is not the kind of thing you can do on the fly," says Kenneth T. Hertz, FACMPE, a principal consultant with the Medical Group Management Association. "There are so many details and so much complexity involved that unless you take the time to put together a comprehensive checklist and check it twice, you're going to run into problems. It's virtually guaranteed," he says.





# THE ONE THING YOU DON'T WANT TO HAVE HAPPEN, ESPECIALLY IF YOU'RE A PRACTICE THAT IS LOOKING TO SELL OR MERGE WITH A BIGGER GROUP, HOSPITAL, OR HOSPITAL SYSTEM, IS THAT YOU DON'T WANT THEM TO TAKE ADVANTAGE OF WHAT THEY LEARNED ABOUT YOUR PRACTICE."

-BILL KALOGREDIS, JD, CHBC, KALOGREDIS, SANSWEET, DEARDEN AND BURKE, LTD., WAYNE, PENNSYLVANIA

## START PLANNING BEFORE TALKING TO PARTNERS

With so much legwork to be done, practices can put themselves at an advantage by thinking about their alignment strategy even before finding a specific partner, Hertz says.

To start with, your practice needs to identify what its goals are in joining another, potentially larger, organization. "This means deciding what you're trying to achieve, what the deal breakers are to you, and understanding your practice and what you're looking for in a partner," he says.

In addition, you can use this preplanning phase to prepare for the due diligence process that will start once you begin discussions with a potential buyer or partner. For example, how current is your list of assets? Do you have documentation for your software and hardware? Can you easily access information about malpractice suits and insurance coverage?

## GAIN TRUST WITH FULL TRANSPARENCY

Once you identify a potential partner and begin talks, one of the keys to gaining the other party's trust is to be as open and transparent with information about your organization as possible says Tejas Mehta, MD, who took over his father's primary care practice, Mehta Medical Group in Humble, Texas, 15 months ago.

As part of his growth strategy for the business, Mehta merged with a nearby solo physician in March 2013. However, prior to the actual merger both practices engaged in talks for more than 4 years, Mehta says.

The biggest challenge to making the deal finally happen, according to Mehta, was gaining the other physician's trust. "This guy was an independent physician, but even groups are leery of joining somebody else,"

he says. "There are a lot of docs out there, unfortunately, who sort of gloss over the numbers. There's a lot of opacity in the structure of the company and the finances of the company, so at the end of the day, there's very little faith to push the company or those working for him."

To prove that he would make a trustworthy and valuable partner, Mehta promised the other practitioner upfront full transparency of numbers and operations, as well as assuring him that he would be treated the same as the other primary care physicians in the group.

"And I think that helped sell him," Mehta says, adding that the materials he provided also proved to the other doctor that he would be coming into an organization that was professional and well-run.

"I've got the appropriate managers in place and we pay attention to our finances; we watch every single penny," he says. "At the end of the day, they [potential partners] need to know that they're coming to an organization that's accountable to them as the group moves forward."

While also advocating for honesty and transparency, healthcare attorney Bill Kalogredis, JD, CHBC, of Kalogredis, Sansweet, Dearden and Burke, Ltd., in Wayne, Pennsylvania, warns that both parties should sign confidentiality agreements before opening their books to each other (which Mehta did).

Kalogredis recommends that the parties agree not to tell anyone that they are talking, and that they will return all documentation to each other should the deal not go through. "The one thing you don't want to have happen, especially if you're a practice that is looking to sell or merge with a bigger group, hospital, or hospital system, is that you don't want them to take advantage of what they learned about your practice," he says.

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## COMMON DISCUSSION POINTS

Once both parties' information is on the table and there is a shared interest in moving forward, there are still numerous potential sticking points the buyer and seller or merging entities will need to work through.

This is the current task before Richard Morgan, administrator of Augusta GYN, P.C., in Augusta, Georgia, whose group is in the early stages of exploring a merger with a nearby practice.

At this point, he is confident that, "the personalities and blending of the practices really shouldn't be a problem," Morgan says. "It's just some of the hot topic items we have to work out." These topics will vary by practice, but some common discussion points may include:

- Governance—Who will have decisionmaking authority? What will be the new group's track to partnership?
- Distribution of earnings and expenses—Will previous arrangements made for one group's part-time doctors be honored? How will fixed and variable expenses be allocated? How might physicians' compensation formulas change?
- Electronic health records—If the two entities are using different systems, will one migrate to the other, or will they adopt another system altogether?
- Staffing—Will each practice's administrator still have a role? How will absences, such as maternity leave, be handled? Will employees with overlapping responsibilities be let go or transferred to different positions? How will employees' benefits, payroll, and policies be affected? What information about the transaction will be shared with staff and when?
- Physical location—Will either or both parties be moving locations? Will a new owner have the right to move physicians to practice in another location after the sale?

Primary care practices in particular should discuss with potential partners their concerns and expectations regarding patient access, volume, and physician workloads, says Hertz. "Those are going to be the big issues because there's going to be this

kind of tsunami [with healthcare reform]. The question is whether there is a thoughtful plan for the practice in terms of how to address that."

## MAKE AGREEMENTS AS CLEAR AS POSSIBLE

Even when the parties are extremely careful to address the myriad implications of a sale or merger, practitioners should be sure to read over their final contract or employment agreement thoroughly before signing, warns Owen Dahl, MBA, FACHE, a consultant based in The Woodlands, Texas.

"More often than not I find a few changes in that final agreement," he says. "So I would suggest that with the last final agreement, don't assume that all the terms are the same as you discussed. Make sure you read with a fine tooth comb because that's where the surprises are."

When it comes to negotiating contracts in general, be especially mindful of avoiding provisions that are vague or subject to later interpretation, Kalogredis adds.

"The biggest advice I can give is to clearly define what the deal is," Kalogredis says. "I don't like vagueness from either side if I can help it. Nobody's going to come up with the perfect document every time, but you try to at least address the issues. And by addressing the issues, you're at least saying, 'Yes, I agree' or 'No, I don't."

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## Financial Strategies

# HOW TO MAKE PAYMENT PLANS WORK FOR PATIENTS

By KEITH BORGLUM, CHBC, CBB Contributing Author

Should you offer financing of your medical services to your patients? Keep in mind that medical bills are reportedly the number one reason for personal bankruptcies in the United States.

## **MANY MORE PATIENTS**

are now uninsured due to the recession, layoffs, and working part-time jobs without health insurance. Others are underinsured or have high-deductible plans such as Health Saving Accounts.

The Affordable Care
Act (ACA) is suffering
delays, and even when
ready, many people and
companies are expected to
opt out and pay the minor
penalties instead. The ACA
plans may have deductibles
in the thousands of dollars,
an amount well beyond the
means of many people.

Providing financing through your office is one way of enabling your patients to move forward in getting the medical care they need. More patients can afford small monthly payments, than can afford a single large payment. Providing financing lets the patient get medical care, and lets the providers get paid; a win-win, at least as far as getting and delivering care is concerned. What you don't want to create are patient debts for which you won't ever get paid.

There are two major ways to provide financing for patients. The first is to be a conduit for a finance company, and the second is to offer your own financing, direct to patients, out of your own pocket.

Finance companies are eager to install lending programs in your practice. These operate similar to financing through purveyors of appliances, furniture,

automobiles, etc. The finance companies provide loans to patients, just like a credit card, but limited to medical care. These loans can often be obtained by patients whose credit cards are maxed-out or patients who are less credit-worthy, but often at the price of much higher interest rates than regular credit cards. The patient can be qualified for the loan on the spot in your office, and you get paid right away.

Within these financing company plans, two flavors exist: recourse and nonrecourse. In recourse loans, the patient pays lower interest, but if they don't pay, you will be required to repay the money the finance company paid you. In non-recourse loans, the interest is higher, but if the patient doesn't pay, you don't need to pay the money back. Research popular finance companies, which may include some of the world's biggest banks, but be aware that many won't finance primary care. They will provide you glossy posters and brochures and forms for your reception area, and make it easy for you. You can check with your current bank and medical association first to see what they offer.

The second approach is to finance payment plans for patients on your own. This involves more work, including setting

up the protocols, creating financing forms, processing the payments, collecting past-due payments, and training staff. You also need to comply with federal and state Truth in Lending requirements. Some patients might not be as responsible with payments when paying you directly, rather than to a finance company.

The advantage to offering financing yourself is that it can be more profitable than using the finance companies, because you earn the higher interest (sometimes 9% or more). I know of a cosmetic practice that earns almost as much by bundling and selling its consumer loans on the banking secondarymarket as it earns through surgeries.

Another option is using companies such as DocPay. com, which will set up monthly payment plans for patients and deduct payments from patient accounts. Rather than charging interest to the patient, DocPay charges you or the patient a small perpayment fee.

While no one type of financing plan is perfect, every practice can find a plan that fits its needs. Before implementing a plan, check with your accountant or attorney about state and federal compliance requirements in your location.





## Practical Matters

## **IMPROVE PRACTICE EFFICIENCIES** TO WRING OUT **NEW REVENUE**

by JUDY BEE, Contributing author

Fees aren't going up, but many of your medical practice expenses are. Look to greater efficiencies to eke out more from reimbursements.

#### **WORKING LONGER OR**

**FASTER** are not good options and can have deleterious effects. In fact, a physician should only see as many patients as he or she can while maintaining high standards of service and clinical care.

Some physicians think they have to do everything. Not so. Getting the right help, on the other hand, can increase reimbursements and ultimately improve the financial state of the practice.

But to achieve this goal, most physicians need to organize their practice operations and staff.

Rule #1: Physicians should not do work that a lower-cost worker can do.

A physician should work at the highest level of licensure all the time. That

means there must be others working alongside the physician who are working toward the same goal at the same rate.

Using a registered nurse to room patients, take vitals, and clean specula is a waste of training and money. A medical assistant is trained to do those tasks and many more.

In a practice with three physicians and three assistants, it might be wise to hire one credentialed nurse to handle patient education, clinical call backs, and triage to relieve the other two medical assistants and keep traffic moving and physicians on time.

In many practices, everybody does everything. This approach degrades production and squanders much of the strength of the

team as it relates to skills, education, and judgement.

An orthopedist once told us that the perfect patient was "prepped, draped, and anesthetized." Efficient physicians deserve to have a patient ready to be seen—all records available, and instrumentation/ supplies within 30 inches every time. That keeps the physician moving.

In some cases that might mean that one physician needs two medical assistants because the patient's time with the physician is limited. A fracture care patient, for example, needs the cast removed, an x-ray, and the cast reapplied. If one welltrained assistant is doing the cast work, she cannot keep patient traffic moving. The physician visit is brief: evaluate the healing, give directions for the cast, and decide when to see the patient next.

Think about your patient volume and make decisions about whether more duties can be delegated to your assistants.

## A word about education

Patient education is crucial for both treatment compliance and efficient

productivity. To assess your process, ask your front-office staff how many patients come to the desk after the clinical encounter with more questions. If the administrative personnel are trying to answer clinical questions, or if they are fielding numerous calls from confused patients the day after a visit, you know you have a problem.

One successful approach uses a welltrained staff member to reinforce a physician's recommendations and answer other general questions after the physician leaves the examination room.

Use easy-to-understand literature, wall charts, and models. Teach your staff how to communicate with patients too. Let them shadow you to learn.

The intended result is better-educated patients with fewer incoming phone

The use of "well-trained staff" implies an investment of time and patience from the physician to get staff up to speed.

Remember, the work needs to be done, but it doesn't all have to be done by the doctor.



The author is a practice management consultant with Performance Practice Group in La Jolla, California. Send your practice management questions to medec@advanstar.com.





## Coding Insights

## BEHAVIORAL COUNSELING KEY TO REIMBURSEMENTS FOR OBESITY



Many of our patients seem to be gaining weight, and we are seeing more cases of obesity. Our physician is already spending time discussing risk factors with patients. Is there reimbursement specifically for weight management counseling?

IT IS IMPORTANT for physicians to discuss risk factors with patients, and obesity is one of the most important. We are keenly aware that the prevalence of and problems associated with obesity are causing major health problems in the United States.

The Centers for Medicare and Medicaid Services (CMS) started reimbursing for obesity counseling in November 2011, when they introduced Healthcare Common Procedure Coding System (HCPCS) code G0447, face-to-face behavioral counseling for obesity, 15 minutes.

This code reimburses at approximately \$25 and is for patients with a body mass index (BMI) of 30 kg/m2 or greater. While many may argue that this reimbursement amount isn't worth the physician's time, I would suggest that the need for this type of discussion between a physician and patient is

priceless when it comes to a patient's overall health.

The United States
Preventive Services Task
Force (USPSTF) considers
BMI over 30 kg/m2 a good
indication of morbidity
and mortality. Behavioral
counseling and behavior
modification can be an
effective combination
to produce moderate,
sustainable weight loss.

According to CMS' National Coverage determination (NCD) for Intensive Behavioral Therapy, NCD 210.12, the therapy for obesity consists of the following:

- screening for obesity in adults using measurement of body mass index (BMI), calculated by dividing weight in kilograms by the square of height in meters (expressed kg/m2);
- dietary (nutritional) assessment; and
- intensive behavioral counseling and behavioral therapy

to promote sustained weight loss through highintensity interventions on diet and exercise.

Additionally, the NCD states that the intensive behavioral intervention for obesity should be consistent with the 5-A framework (assess, advise, agree on goals, assist, and arrange support) that has been highlighted by the USPSTF.

Medicare will pay for G0447 up to 22 times in a 12-month period, counted from the date of the first claim. The valid ICD-9 codes are V85.30-V85.39, V85.41-V85.45, and the ICD-10 codes will be Z68.30-Z68.39, Z68.41-Z68.45.

Check with your local Medicare administrative

contractor for clarification on the ability to bill more than one unit per visit. Medicare coinsurance and Part B deductible are waived for this service. The patient must be competent and alert at the time of counseling, which may be provided by primary care physicians, advanced practice nurses, and physician assistants.

These services also can be performed by auxiliary personnel when incident-to quidelines are met.

For Medicare beneficiaries with obesity, CMS covers: one face-to-face visit every week for the first month and one face-to-face visit every other week for months 2 through 6. A weight loss reassessment needs to be performed at the 6-month visit, and those patients who have lost at least three kg during that time period will be eligible for one monthly visit for another 6 months.

Keep in mind also that there are BMI quality measures for which you can receive incentive payments from CMS through its Physician Quality Reporting System program.



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

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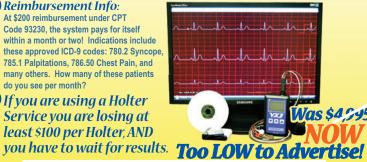
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## The Last Word

## THE PROBLEM WITH SOCIAL MEDIA POLICIES FOR PHYSICIANS

by BRANDON GLENN, Digital Content Manager

Social media guidelines for physicians frequently focus on the need for doctors to separate their personal from their professional identities, but those types of policies get social media all wrong, according to a viewpoint recently published in *JAMA*.

**INSTEAD,** the viewpoint's authors suggest a simpler, more straightforward means for physicians to assess potential social media activity: Is what you're about to say appropriate for a doctor to talk about in public?

"When a physician asks, 'Should I post this on social media?' the answer does not depend on whether the content is professional or personal but instead depends on whether it is appropriate for a physician in a public space," write the authors - Matthew DeCamp, MD, PhD; Thomas Koenig, MD; and Margaret Chisolm, MD - from Johns Hopkins University.

But for those who remain unconvinced, the authors offer these four reasons why, for physicians, it simply isn't feasible to separate personal and professional identities:

## It's operationally impossible

With minimal effort and information, anyone can do a Web search that quickly connects a physician's personal content to her professional content - assuming both types of content exist. And if both types of content do exist, there's no way to keep them separated, when a connection between the two is just a Google search away.

## Lack of user consensus

Despite recommendations from groups such as the American College of Physicians and the Federation of State Medical Boards, some physicians remain unconvinced of the need to maintain separation between personal and professional content. For some, blurring the lines

between the two is part of the reason to use social media in the first place, as doing so can level hierarchies and increase transparency, the authors say.

## They're often the same thing

Separating personal and professional identities is inconsistent with the concept of professional identity. In other words, professional identify is determined to at least some extent by personal identity. For example, medical students undergo identity changes from student to professional and from consumer of medical services to provider.

Those personal identity transitions help shape who they are as professionals. "When recommendations fail to acknowledge the complex, mutable nature

of professional identity and its connection to personal identity, the recommendations fail to offer the unambiguous, practical guidance that is needed," the authors write.

## It could be harmful

Doctors aren't required to avoid personal contact with patients offline, so why should they be required to do so when they're using social media? In small or rural communities in particular, such encounters can be unavoidable, and they can even be beneficial to both doctor and patient. The unrealistic expectation that physicians need to maintain two separate identities can carry with it a "psychological or physical burden," the authors write.

The authors stress that they aren't proposing that doctors should "eliminate boundaries," or that "anything goes" on social media. Rather, the key to resolving physicians' "online identity crisis" lies in recognizing that social media exist in primarily public spaces, not in exclusively professional or exclusively personal ones.

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