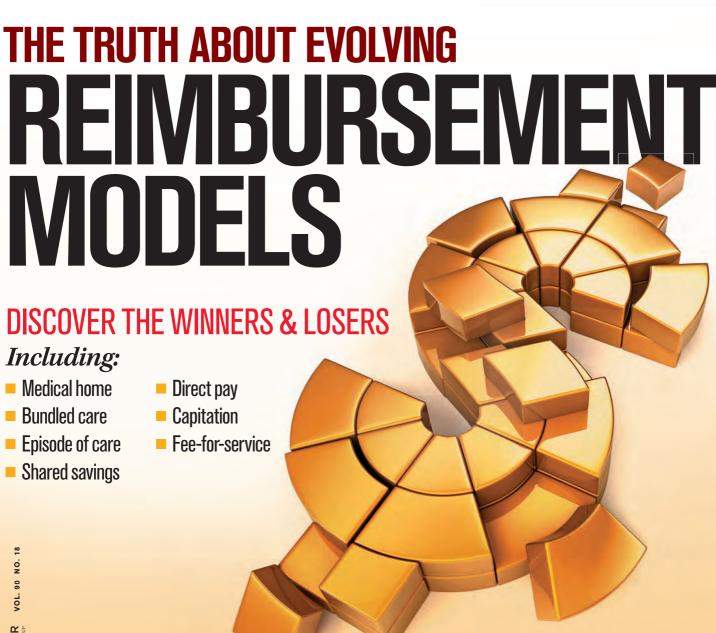
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FNITORIAL

DANIEL R. VERDON

GROUP EDITOR, PRIMARY CARE 440-891-2614 / dverdon@advanstar.com

SENIOR EDITOR JEFFREY BENDIX, MA 440-891-2684 / jbendix@advanstar.com

CONTENT SPECIALIST DONNA MARBURY, MS 440-891-2607 / dmarbury@advanstar.com

BRANDON GLENN

DIGITAL & INTERACTIVE CONTENT MANAGER 440-891-2638 / bglenn@advanstar.com

> CONTENT ASSOCIATE ALISON RITCHIE 440-891-2601 / aritchie@advanstar.com

> > CONTRIBUTINGED ITORS **GAIL GARFINKEL WEISS**

GROUP ART DIRECTOR ROBERT MCGARR 440-891-2628 / rmcgarr@advanstar.com

> NICOLE DAVIS-SLOCUM SENIOR GRAPHIC DESIGNER

PRODUCTION

SENIOR PRODUCTION MANAGER KAREN LENZEN

AUDIENCE DEVELOPMENT

CORPORATE DIRECTOR JOY PUZZO

DIRECTOR CHRISTINE SHAPPELL

MANAGER JOE MARTIN

PHRIISHING & SALES

GEORGIANN DECENZO

EXECUTIVE VICE PRESIDENT 440-891-2778 / gdecenzo@advanstar.com

VICE PRESIDENT, GROUP PUBLISHER 732-346-3017 / ksylvia@advanstar.com

DEBBY SAVAGE ASSOCIATE PUBLISHER 732-346-3053 / dsavage@advanstar.com

ANA SANTISO NATIONAL ACCOUNT MANAGER 732-346-3032 / asantiso@advanstar.com

JOANNA SHIPPOLI ACCOUNT MANAGER, RECRUITMENT ADVERTISING 440-891-2615 / jshippoli@advanstar.com

DARLENE BALZANO ACCOUNT MANAGER, CLASSIFIED/DISPLAY ADVERTISING 440-891-2779 / dbalzano@advanstar.com

PATRICK CARMODY ACCOUNT MANAGER, CLASSIFIED/DISPLAY ADVERTISING 440-891-2621 / pcarmody@advanstar.com

DON BERMAN BUSINESS DIRECTOR, EMEDIA 212-951-6745 / dberman@advanstar.com

GAIL KAYE DIRECTOR, SALES DATA HANNAH CURIS SALES SUPPORT

REPRINTS

877-652-5295 ext. 121 / bkolb@wrightsmedia.com Outside US, UK, direct dial: 281-419-5725. Ext. 121

RENÉE SCHUSTER LIST ACCOUNT EXECUTIVE 440-891-2613 / rschuster@advanstar.com

MAUREEN CANNON PERMISSIONS 440-891-2742 / mcannon@advanstar.com

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- * Ambulatory EHR (1-10 physicians), as reported in the 2012 Best in KLAS Awards report

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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.

-COMING NEXT MONTH

Medical Economics to celebrate its 90th birthday, and offer a sneak peak at medicine's economic future

Few media brands have weathered the test of time. And in October, *Medical Economics* celebrates nearly a century as the leading business publication for physicians. As part of coverage, we will take a look back at medicine's achievements, and fast forward to the opportunities and challenges facing physicians.

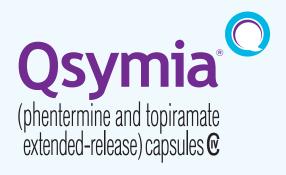
COMING NEXT MONTH

Here are some of the other stories in the works for the October issues of *Medical Economics*:

- Treating the prior authorization headache
- An inside look at the RUC debate
- The top 100 EHR systems
- Why mobile technology will transform patient communication, education
- 5 reasons to keep an eye on the health of your EHR vendors
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GENDER PAY GAP WIDENING AMONG DOCTORS

The gap between what men and women earn may be narrowing overall, but among physicians it's actually widening. A new study reveals that the median annual income of male physicians between 2006 and 2010 was 25% higher than women, compared with a 20% difference during the years 1996-2000. Learn more at

MedicalEconomics.com/earningsgap



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One #physician says other #doctors can learn lessons from Jay Z about marketing http://ow.ly/oLGJq via @KevinMD."

PRIMARY CARE SHORTAGE

Could tapping retired #physicians be a key to reversing the #PrimaryCare shortage? http://ow.ly/oJHma via @HealthLeaders

RURAL HEALTHCARE

Are rural health clinics being unfairly excluded from #EHR incentive payments? http://ow.ly/oLFLv via @modrnhealthcr #HealthIT

MIDLEVELS

Will Obama admin. require insurers to designate NPs as #PrimaryCare providers? http://ow.ly/oJqc3 via @KHNews #nurse

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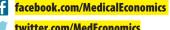
FACILITY FEES

Is #Medicare finally getting tough on #hospitals' facility fees? Maybe a little. http://ow.ly/ol4LT via @modrnhealthcr

ELECTRONIC HEALTH RECORDS

A look inside a \$1 billion Epic #EHR system's (temporary) failure ow.ly/oK29D #HealthIT via @hitnewstweet





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Taking the time to train and incentivize your staff can pay dividends in the form of better performance.

-H. Christopher Zaenger, CHBC

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EDITORIAL CONSULTANTS

PRACTICE MANAGEMENT

Judy Bee

www.ppgconsulting.com La Jolla, CA

Keith Borglum, CHBC

Professional Management and Marketing Santa Rosa, CA

Kenneth Bowden, CHBC

Berkshire Professional Management Pittsfield, MA

Michael D. Brown, CHBC

Health Care Economics Indianapolis, IN

Frank Cohen, MPA

www.frankcohengroup.com Clearwater, FL

Virginia Martin, CMA, CPC, CHCO, CHBC

Healthcare Consulting Associates of N.W. Ohio Inc. Waterville, OH

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TAXES & PERSONAL FINANCE

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Altfest Personal Wealth Management New York City

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from the Trenches 99

I am not saying the ideas of improving patient care are wrong. I am saying that holding payment based upon not meeting "quality measures" is wrong. I would hope that

physicians care enough about their patients to do these measures without the stimulus of payment bonuses or penalties."

Lawrence Voesack, MD, ODESSA, TEXAS

REIMBURSEMENTS ARE HEADING THE WRONG WAY, FAST

In the August 10, 2013 issue of *Medical Economics* there are various articles
—"Understanding New Payment Models,"
"Medicare's 2014 Fee Schedule," and
"Measuring The ACA Impact"—concerning reimbursement for the services provided by physicians.

It appears that physicians are operating in a fear mode to get justly paid for the services rendered.

When was the last time you were at the store and someone tried to negotiate the price of a gallon of milk?

I am saddened by the pathway reimbursement for services is moving in. This is not something new, it is just expanding in its scope and speed. When I was a medical student and laparoscopic procedures were in their infancy, I

heard surgeons complaining that the reimbursement for doing a laparoscopic chole-cystectomy was half of what an open procedure paid. It saved payers money because of the shorter length of stay in the hospital, but to the surgeon it made no sense they would be paid less.

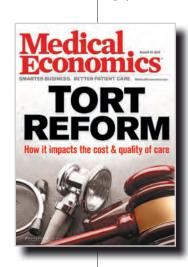
Reimbursement has become more complex and burdensome for the work we do. When Medicare first came into being, physicians were told that Medicare would not negatively impact reimbursements for services. Now, the Centers for Medicare and Medicaid Services (CMS) is the driving force behind the rules for reimbursements. Contract reimbursements are based on a percentage of what Medicare pays.

I am not saying the ideas of improving patient care are wrong. I am saying that holding payment based on not meeting "quality measures" is wrong. I would hope that physicians care enough about their patients to do these measures without the stimulus of payment bonuses or penalties.

One sure way of payment protection is to return to payment plans popular in the 1960s:

- Payment for services are due at the time of appointment.
- We do not file with insurance companies for payment.
- We will give the patient a receipt so he or she can file for reimbursement.

Unfortunately, whether physicians want to admit it or not, we have placed ourselves in the wrong area of the triangle when it comes to payment—from between the physician and patient to between the physician and payer. Once this has been corrected, I will no longer have to worry about my payments constantly being negotiated down by



Even if figures show that many seniors get more in healthcare benefits than they put in terms of premiums, those numbers do not take into account the time value of money, inflation, and premiums paid into private insurances until they turned 65 while also paying into FICA."



Gerard Freisinger, MD, WARWICK, NEW YORK

insurance payers or dictated by CMS.

What other service or industry has their payments so regulated?

Lawrence Voesack, MD ODESSA, TEXAS

MOC DOESN'T CREATE BETTER PHYSICIANS

Thank you for publishing a well-written article by Beth Thomas Hertz regarding Maintenance of Certification. ("MOC: Debate intensifies as Medicare penalties loom," June 25, 2013.)

MOC has evolved into a costly burden to physicians, patients, and the healthcare system. I would like to point out that Drs. Malangoni, Holmboe, and Phillips, whom Hertz quotes, all work for one of the boards that have become a profiteering juggernaut without any reasonable proof of benefit, efficacy, or patient protection. As she points out, certification is being tied to the privilege of practicing medicine.

As physicians, we should demand evidence-based analysis of strategies proposed to improve our ability to practice, just as we do our research. We should not give in to potential threats of government mandates. For two centuries, the medical profession has evaluated the proper use of techniques, procedures, and therapies that have proved to be of important benefit.

Most practicing physicians find MOC to be clinically irrelevant, and it has not been found to correlate with creating better physicians. Yet with an ever-increasing physician shortage, the self-serving boards are creating systems that potentially will decrease access to healthcare for many Americans.

Perhaps the American Board of Medical Specialties or any of the individual subspecialties can spend their resources on studying why camaraderie, collegiality, and membership in local organized medicine has plummeted since the introduction of recertification.

> Howard C. Mandel, MD, FACOG LOS ANGELES, CALIFORNIA

SENIORS DESERVE THE CARE THEY RECEIVE

Patrick Conrad's letter ("Seniors have become a privileged class of patients," July 25, 2013) makes me ashamed to be called a professional colleague.

First: seniors are more vulnerable to chronic disease than any other age group. Many have paid into insurances and FICA (Social Security) for much of their adult life. Even if figures show that many seniors get more in healthcare benefits than they put in terms of premiums, those numbers do not take into account the time value of money, inflation, and premiums paid into private insurances until they turned 65 while also paying into FICA.

Second: The additional regulations, fee adjustments, and other bureaucratic demands stem from a system of cottage industry feefor-service, not from the American Association of Retired Persons. This has led to providers becoming members of large groups or hospitals as employees with a staff doing the paper work from a pool of providers' billables.

Gerard Freisinger, MD

WARWICK, NEW YORK

TELL US medec@advanstar.com

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the Itals Examining the News Affecting the Business of Medicine

MEDIGAP PLANS COULD **ENCOURAGE** ACO LOYALTY

Members of the Medicare Payment Advisory Committee (MedPAC) recently told Medicare commissioners that a supplemental plan for patients could encourage them to be more loyal to single accountable care organizations (ACOs)

At a September meeting, MedPAC said that a MediGap plan would encourage patients to stay within an ACO for treatment and overall managed care. Recent criticisms of ACOs include that patients receive care outside the organization, though the ACO is still financially responsible.

The ACO model has received criticism as nine of Medicare's 32 Pioneer ACOs dropped out of the program earlier this year. Problems the failed ACOs had included difficulties saving money due to patients receiving care outside of the program and a lack of affordable patient education options.

Experts believe the Centers for Medicare and Medicaid Services will rule on the policy to be included in next year's ACO rules, though they have yet to make a public statement.

PHYSICIANS PAYING MORE FOR TECHNOLOGY TRAINING, **STAFF SURVEY SAYS**

It may be no surprise that physicians are reporting spending more on operations and technology. According to the Medical Group Management Association (MGMA) Cost Survey Report, medical practices annual expenses per full-time employee for technology have increased almost 30% from a median of \$15,211 in 2008 to \$19.439 in 2012.

Purchasing electronic health records systems (EHRs) and training staff to use them to meet

THE INCREASE IN MEDIAN ANNUAL **TECHNOLOGY EXPENSES**

PER FULL-TIME EMPLOYEE FROM 2008-2012

meaningful use standards have contributed to a much of the cost increase. "Implementing and optimizing information technology is a significant investment for physician practices," says Derek Kosiorek, principal of the MGMA Health Care Consulting Group.

"Although EHRs can be costly, it's admirable that physician practices are leveraging sophisticated

tools that produce higher efficiencies and impact patient care."

Overall, the report found that practices are spending 8.7% more in staffing costs due to additional business operations, and clinical and ancillary support professionals.



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RATE REVIEW SAVED PATIENTS OVER \$1 BILLION LAST YEAR

Requiring health insurance companies to justify premium increases saved 6.8 million Americans \$1.2 billion in 2012, according to the Department of Health and Human Services (HHS.)

The rate review provision is a part of the Affordable Care Act (ACA) and was implemented in September 2011. Since then, any rate increase of more than 10% has to be submitted for review and justified by state governments.

So far, the ACA made grants to 46 states, Washington D.C., and five territories to help them create review programs.

"Thanks to the health care law, we are seeing that holding insurance companies accountable is leading to increased competition and saving billions of dollars for consumers across the country," says Kathleen Sebelius, secretary of HHS.

"This type of competition and transparency will continue in the health insurance marketplace, or Exchanges, where Americans will be able to shop for and compare plans side-by-side to find the one that fits their needs and budget," she says.

Mergers, high-cost drugs could inflate healthcare costs in 2014

HEALTHCARE

PRACTICE consolidation could raise healthcare costs by as much as 20% in 2014, according to a report by PricewaterhouseCoopers Health Research Institute.

"These price increases are especially acute in markets with one dominant system," the report states.

Consolidation of healthcare practices has increased by more than 50% since 2009, according to the report.

The report also identifies the rise "expensive complex biologics" for treatment of cancer and other complex illnesses as another cost inflater in the upcoming year. The higher costs for

these drugs are cancelling out the influx of lowercost, generic drugs that have entered the market in recent years, bringing prescription drug costs down.

Four factors were identified as potentially lowering healthcare costs in the upcoming year. These include:

- more access to convenient care,
- high performance care networks,
- lower readmission rates and
- higher insurance deductibles.

Increases in "alternative venues," including telehealth services and lower-cost retail clinics, are making care more efficient. Also, a push for public awareness about the high costs of hospital readmissions is credited for a 94% increase in coverage of the topic in publications in the past year. Penalties for hospital readmission will continue to rise through 2015.

Overall, the report projects that healthcare costs will rise by 6.5% in 2014. Factoring in higher costs and cost-saving initiatives, such as higher deductibles, the report predicts that healthcare costs will increase by 4.5%. The institute estimated cost growth at 7.5% for 2013.

INDUSTRY CONSOLIDATION CAN LEAD TO HIGHER PRICES Hospital deals on the rise 58 58 59 51 57 58 60 52 72 90 94 94 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012

Source: PricewaterhouseCoopers Health Research Institute

Doctor's Bag

The latest in drugs, devices, technology, and more

FDA APPROVES BOTOX COSMETIC TO IMPROVE CROW'S FEET LINES



The FDA has approved a new use for Botox Cosmetic (onabotulinumtoxinA) for the temporary improvement in the appearance of moderate to severe lateral canthal lines, or crow's feet, in adults. It's currently the only FDA approved drug treatment option for lateral canthal lines. FDA approved Botox Cosmetic in 2002 for temporarily minimizing glabellar lines, or frown lines, in adults.

Administered via intramuscular injections, it works by keeping muscles from tightening so wrinkles are less prominent. Treatment for both frown lines and crow's feet can be administered at the same time

Safety and effectiveness were established in two clinical efficacy and safety studies. The most common adverse reaction for the treatment of lateral canthal lines is Evelid edema. Both Botox and Botox Cosmetic

have a boxed warning about the effects of the botulinum toxin spreading from the area of injection to other areas of the body, which could cause potentially life-threatening symptoms similar to botulism.

No serious case of toxin spread has been confirmed when the products were used at the recommended doses. Adverse reactions can be reported to the FDA's MedWatch Adverse Event Reporting program.

(714) 246-4500 800-FDA-1088

www.allergan.com | www.fda.gov/MedWatch

MANAGE YOUR PRACTICE'S ONLINE REPUTATION

Demandforce automated marketing, communication, and reputation building software will now be available through the athenahealth Marketplace, a one-stop shop for providers to

browse and select health care IT (HIT) solutions. Providers currently using athenaCommunicatorSM, a cloud-based patient engagement and communications platform, will gain access to Demandforce's suite of online marketing tools.

With the communication platform, Demandforce will allow providers to better manage the reputation of their

practice online using social media content, patient reviews, and email marketing promotions.

Solutions featured in the Marketplace have been pilot-tested as part of the athenahealth workflow by More Disruption Please (MDP), athenahealth's business development program aimed at launching innovation in health care.

athenahealth, Inc.

(800) 981-5084 | www.athenahealth.com/marketplace

COMPREHENSIVE ICD-10 TRAINING

ZirMed is helping providers prepare for ICD-10 with educational resources, mapping tools, and training solutions. The strategy helps providers identify appropriate ICD-10 codes and back-code from ICD-10 to ICD-9. Invalid codes are flagged and guidance is provided on payer edits, showing providers how to fix errors prior to submission.

Rejected claims information is analyzed and payer feedback is translated into easy-to-understand guidance. Analytics and reporting technology help providers identify incorrect coding procedures and adjust processes for optimal reimbursement.

ZirMed works directly with pavers to conduct ongoing testing for implementing improvements. ZirMed will also accept 5010 files with ICD-10 codes from providers in the self-test area. It has partnered with ICD-10 expert Precyse to provide online training as well.

ZirMed

(877) 494-7633 public.zirmed.com

Do you have a favorite new product?

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Cover Story

Sorting through new reimbursement models

An assortment of new payment models are available in attempts to fix the fee-for-service imbalance

by **BETH THOMAS HERTZ,** contributing author

he entire healthcare community is looking for ways to reduce costs and confusion, while yielding better patient outcomes. New reimbursement models being tested by Medicare, private payers and think tanks aim to consider all the entities in the payment process

—and they all have their advantages and their drawbacks.



O1 New reimbursement models address different aspects of patient care including managed, acute, and episodic care. **02** Revised versions of the fee-for-service payment model will most likely continue to be a part of the reimbursement system.

WHILE MANY primary care physicians (PCPs) welcome the change, Jill Rubin Hummel, vice president of payment innovation at WellPoint, Inc., says she is often asked for advice on how to sort through the many new reimbursement models that are emerging.

"I always tell them that the days of fee-for-service medicine as they know it are really numbered," she says. "The movement to value-based payment can take many forms, but the concept of not just paying for value but for the qual-





ity of the care delivered will, over time, become the new normal."

Marci Nielsen, PhD, MPH, chief executive officer of the Patient-Centered Primary Care Collaborative, says that for any new model to work, it is important that physicians not have to carry all the risk. Risk needs to be shared and adjusted; otherwise, it will be like the dreaded capitation of the past.

"This is so different than the 1990s. We have much better access to information to improve risk adjustment," Nielsen says. Moreover, she adds, many of the models now being considered have arisen from providers themselves, rather than being forced on them by payers.

So which options are winners and which are losers for PCPs? Medical Economics recently posed that question to a variety of experts.

ADVANCED MEDICAL HOMES

The medical home model gives a physician some form of upfront payment in anticipation that the money will be used to achieve savings down the road. What varies is the payment amount and the expectations attached to it.

"If it's a very small payment and you are expected to achieve very significant changes in quality, it won't be enough to put really aggressive improvements in place," says Harold Miller, director of the Center for Healthcare Ouality and Payment Reform.

Also, although Medicare may give a physician money upfront, the amount may decrease in subsequent years, he says. So if a practice hires a nurse manager to work with chronic disease patients now, it may not be earning enough to sustain that salary when the funding goes down. Fear of this dynamic may prevent many practices from investing enough to be successful in achieving qualitybased improvements.

Currently, much of the medical home funding is coming through pilot programs that are not guaranteed to last. When the pilot ends, physicians may have to lay off an employee.

"You are making a bet on whether this is the way of the world," Miller says. "The good news is that even though some of these are demonstration projects, they are where people are going. But you can end up with potential gaps."

For example, he says, there could be a gap

of 9 months before it resumes, which can leave a small practice with a real cash flow problem.

BUNDLED PAYMENTS

The value of bundling payments depends on their content. Putting two things together that you would have already coupled does not mean a whole lot, Miller says.

Another use for bundling is paying two providers who were previously paid separately, for example, making a single payment to the hospital and physician. The question becomes, how do you divide it up? In some cases, Medicare has required that the payments be made to a physician-hospital organization that is jointly controlled.

Nielsen says some specialties lend themselves more to bundling, such as orthopedic and cardiac procedures, or maternity care. But others do not, such as the management of patients with multiple comorbidities where several caregivers are involved. Primary care is probably not the market for this model.

"How do you carve up all those payments?" Nielsen asks. "It is not as easy to do as if the patient was only being seen in the hospital. Hospitals are where we know how to do this."

EPISODE OF CARE

The episode-of-care model is a version of bundled payments, in that providers are paid for treating a specific condition over a period of time. It is also like fee-for-service in that doctors are paid for providing a specific service. What needs to be differentiated in the future is that it is not just an isolated visit, Nielsen says.

For example, when Nielsen recently broke her arm, treating it required an urgent care visit, an orthopedics specialist, and a radiologist, as well as multiple X-rays. The episode-of-care model would have made one payment that covers all of the work that needs to go into healing her arm.

Currently these doctors have no incentive for limiting how often they see her, she says, but if there was one payment across the system for treating her injury, it would incentivize them to possibly order fewer Xrays, for example. This would lower costs, save her time, and reduce her lifetime exposure to radiation.

"The broadest goal is to incentivize the



right care for the right cost," Nielsen says.

But it cannot only be cost—the quality has to be there, Nielsen emphasizes. If her arm is not treated properly and she needs surgery to fix it, the cost goes up.

Miller says that episode-of-care models tend to have some costs for preventable events built in, such as hospital readmission costs. Physicians need to determine what the rates of readmissions, infections, or complication are for the conditions they are covering before they agree to an episodic fee.

"It assumes that they can figure out how to reduce readmission rates or other costs down the line," Miller says. "If the physician can do that, it's a win-win."

He says one of the big problems in this type of model is getting the information needed to make good decisions.

"You have to have data to be able to analyze whether or not it is a good deal for you. This has been a challenge in the commercial sector and Medicare market," Miller says. "They tend not to have current data or accurate data to give you and may ask you to sign a contract based on data from 2 years ago, but the numbers today may not look anything like they did 2 years ago."

Physicians can protect themselves against this by creating risk corridors: if actual costs turn out to be significantly higher than expected, the physician may only be responsible for a small amount of the total risk, Miller says.

SHARED SAVINGS

The shared savings model says, "we are all in this together," starting with the insurer and the physician. Physicians split savings on patient care with the insurer. However, if care costs go over budget, physicians could be responsible for a percentage of the difference. Nielsen says the savings needs to be enough to motivate the providers to change their behaviors.

"If we make it significant and they really have some skin in the game, and they know how to do it because they have the right tools and infrastructure to do it, we are seeing there is really some potential for the physician to be in better alignment with health plans," she says.

However, Miller says the shared savings models could be the worst option for providers because they are structured with no change in fee-for-service payments, yet they offer the possibility of a bonus payment in a year or more if providers can save money.

For example, PCPs claim that hiring a nurse care manager can help reduce chronic disease hospitalizations. But the physician has to find the money to pay the nurse the first year, with the hope that the expense will lead to overall savings for the practice. Numerous factors, some beyond the physician's control, can prevent that from happening, and the physician would take the loss. But the physician has to find the money to pay the nurse the first year and hope that the expense leads to overall savings for the practice. A variety of factors can prevent that from happening, some beyond the physician's control, and he or she would not get any money back.

"Moreover, these are often based on minimum savings percentages, so you cannot stick your toe into the water a little bit," he says. "You either have to dive into it significantly or there is no opportunity to benefit."

Miller says the minimum savings percentages are higher for smaller practices because they might have more opportunities for random variations in cost, and Medicare doesn't want to risk making payments that are not deserved.

"This makes it more difficult for small practices to do enough to hit that threshold to get money back to cover their costs," he says.

Tracking shared savings works on a several-year cycle and the clock resets every 3 years, he says.

"(Shared savings) are portrayed as an easy starting point for practices, but in fact they can be the worst to get into," Miller says. "A payment model that has a shared savings component in it can be good but it needs to have other features, such as getting enough money up front and the savings being based on costs the physician can control."

Nielsen has speculated that the shared savings model would be more effective if it went beyond just insurers and providers to include patients as well. The need for patients to improve their health-related behaviors is critical, yet many lack the motivation to sustain changes, once initiated. What about letting patients in on them? Incentivizing them to improve their behaviors is so important and yet some lack the motivation to follow through.

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> Michelle Hershberger, RN, CCRN, BSN Wichita Nephrology Group, Wichita. KS





→ 22 than just chastised," she says. "Humans need incentives to change."

And do not forget employers, she adds. Many large ones are self-insured and they would love some savings to come to them, and not just to the health plan managing the benefits.

Involvement could grow to non-clinical entities that help lower costs, like YMCAs and other programs. "We focus a lot of the medicine side of the ledger. We don't often focus on everything else, and all those non-clinical factors can be so important," Nielsen says.

DIRECT PAY

Erika Bliss, MD, FAAFP, is chief executive officer of Qliance, a Seattle-area company that was an early pioneer of direct primary care movement. Bliss says that patients of Qliance's five clinics in the Puget Sound area pay a flat monthly fee in exchange for comprehensive primary care. "There is no billing insurance, and no per-visit fees. It is a true membership model," she says.

She says this model removes the barriers to accessing primary care that many people face. Since patients have unlimited access to their physician or a colleague in an urgent situation, they do not allow small problems

Insurers Can Help You Navigate the Transition

ill Rubin Hummel, vice president of payment innovation at WellPoint, Inc., strongly advises physicians to think about how they can change the way they practice so they can deliver value-based care.

This can require re-engineering a practice, but she says the changes can be incremental. Start by finding payers who want to partner with you as you make the transition

She says Wellpoint tries to follow a strategy it affectionately calls "No PCP left behind." In other words, while it certainly works with large providers, it also is committed to helping small, independent practices engage in value-based contracts.

"We provide them with tools and support and contribute the assets that we have while the small practitioner contributes his or her assets, which is direct point-of-care contacts and relationship with the patients," she says. "Both sides contribute what they can."

Wellpoint provides support tools for population health management,

"We engage small independent practices because in many of our communities that is where our members receive their care."

-- JILL RUBIN HUMMEL, VICE PRESIDENT OF PAYMENT INNOVATION. WELLPOINT. INC.

hot-spot reports to help identify patients who are at high risk for needing hospital admission, and evidence-based guideline data on which patients have gaps in their care.

The company also offers access to its longitudinal patient records. "These let physicians see what is going on in their practice and across the continuum,"

Hummel says.

With some providers,
Wellpoint pays a per-member,
per-month, small extra payment that
provides a predictable cash flow to help
the practice offer coordination-of-care
services and care via phone calls. About
20% of PCP practices in its patientcentered medical home model get a
subsidy of this type, with small practices
being most likely to receive it. After a
sucessful pilot, this program was rolled
out in January.

Wellpoint also offers a shared-savings model designed to offer providers a chance to obtain a portion of savings if quality measures are met.

She says Wellpoint hopes to have 75% or more of its PCP practices participating in these incentives in the next 3 to 4 years.

"We need to reach PCPs where they work and how they practice," she says.
"We engage small independent practices because in many of our communities, that is where our members receive their care ...and we want them to succeed in the value-based payment system."





escalate. They are not deterred by the possibility of facing co-payments, and they do not have to limit their visits to 15 minutes. Many are for 30 to 60 minutes.

The patient and physician are able to create a strong relationship from which they both benefit. "We are restoring primary care physicians to the role they are supposed to play," Bliss says.

NEW ACCESS METHODS

In addition to office visits, Qliance patients can access their physician via phone and email, and, soon, video chats. Bliss says some physicians worry they will be overrun by their patients' demands if they adopt such a method, but she has not found that to be the case.

"Once you make yourself available to patients, they are quite respectful of your time and sometimes you have to bug them to call you. It's not overwhelming at all," she says.

Bliss adds that patients enjoy having a predictable monthly cost and physicians enjoy earning a steady income in an environment that allows them focus on the patient, free from billing concerns. It is especially liberating for PCPs, she says, because they rarely bill for complex, costly procedures, so they spend a lot of time and money pursuing small claims.

Of every dollar paid to a PCP today, she estimates, about 40 cents goes to pay for the billing process. "That is a huge waste of an already small dollar," Bliss says.

She says the direct-pay model changes the way physicians think by making them accountable to their patients directly. "It frees you up to think about wholistic care and encourages you to treat them better with nothing getting in the way," she says. "You are not just cranking through enough visits to pay your bills."

In order for direct pay to work, however, it is important to limit the number of patients each physician has. She and her colleagues cap their practice at about 800 patients each, as opposed to the several thousand that many PCPs carry.

Patients pay \$54 to \$94 per month, based on their age, with the average being about \$70. The fees are paid by individual patients or employers/unions. Recently, a Medicaid managed care company also has contracted Qliance services.

Most PCPs have only about \$20 per

month in resources per patient, and billing costs usually have to be deducted from that. "Seventy dollar per person per month can enable physicians do so much more for their patients," she says.

"We find patients join for many reasons but once they engage with us, they all stay for the personal relationship they build with someone who really cares about their health," Bliss says.

Direct-pay patients are advised to have some type of catastrophic insurance coverage if possible, but Bliss says that Qliance sees a lot of variety in the coverage its patients have, from having no insurance to high-end plans.

Nielsen notes that one problem with direct pay is that there are still a lot of administrative tasks associated with it. Practices must be willing to fill that gap if the "middle man" of insurance companies are eliminated.

CAPITATION

When coupled with risk adjustment and consistent quality metrics, capitation, once a dirty word in healthcare, can still work, Nielsen believes. She calls Kaiser Permanente a great example—its physicians are paid salaries with performance bonuses available.

"When you own all of the pieces in the care spectrum and all of those folks are on your team, capitation can absolutely work," she says.

It will not work if all the onus is on the providers, if quality is not incentivized, and if patients are unhappy, she adds.

FEE FOR SERVICE

Many experts think a revised version of the fee-for-service model will remain part of the healthcare system for a long time to come. In fact, fee-for-service payments are the underpinning of shared-savings models.

"There are some very real barriers to feefor-service going away entirely, but gradually more compensation will ultimately be value-based, not volume-based, where payments are based on outcomes, quality, and cost," says Hummel of Wellpoint.

Nielsen also sees some room for fee-forservice to continue in the new quality arena: Since it incentivizes providers to offer more of whatever type of care they offer, using it to reimburse for preventive services can make a lot of sense.



Coding Insights

DEMYSTIFYING MEDICARE'S 'INCIDENT TO' BILLING BY NPs, PAs

I am one of several specialist physicians who recently joined a large hospital organization. We use our midlevels extensively, both in the hospital and the office. Some are on staff at the hospital and are normally the first to see our patients. Our physicians then see the patients

during rounding, document that they agree with the midlevel's findings, and sign off on the note. We bill these visits under the physician's Provider Identification Number (PIN). Is this correct? We utilize our PAs in a similar fashion in the office. They initiate the visits for new and established patients, document the visits and write the plans of care. The physician then sees the patient and signs off on the plan of care. We have been told by our new organization's compliance team that we are not billing these visits appropriately. How should we bill them?

LET'S DELVE INTO incidentto guidelines first. Incidentto billing is a way of billing outpatient services (rendered in a physician's office located in a separate office or in an institution, or in a patient's home) provided by a non-physician practitioner (NPP) such as a nurse practitioner (NP), physician assistant (PA), clinical nurse specialist, certified nurse midwife, clinical psychologist, clinical social worker, physical therapist, or occupational therapist.

NPPs have their own

benefit category and may provide services without direct physician supervision. They can bill directly for services and incident-to a physician's services, if they are licensed by their state to assist perform the services.

Billing under a physician's PIN

According to the Center for Medicare and Medicaid Services (CMS) National Coverage Provision for incident-to services, when NPPs provide services that are incident-to a physician or other practitioner's service, they may bill under the physician's PIN when the service or supply is:

- An integral, although incidental, part of the physician's professional service;
- Commonly rendered without charge or included in the physician's bill;
- Of the type that is commonly furnished in physician offices or clinics;
- Furnished by the physician or auxiliary personnel under the physician's direct supervision.

Medicare defines these services as those performed by a NPP or auxiliary staff member who is acting under the supervision of a physician and who is employed by or contracted with the physician or the legal entity that employs or contracts with the physician.

There must have been a direct, professional service furnished by the physician to initiate the course of treatment of which the service being performed by the non-physician is an incidental part.

This means that the physician must see the patient first, in order to initiate the plan of care for that patient, and the NPP follows that plan of care during subsequent visits.

It also means that if a patient mentions a new problem during a follow-up visit for a problem with an established plan of care, the visit cannot be billed incident-to. For example:

Dr. A is treating a patient for diabetes.
The patient's evaluation and management (E/M) encounter in the office is with a PA of the same group for an upper respiratory infection. Can the PA bill the service incident-to Dr. A and bill under Dr. A's PIN?

In this situation, the upper-respiratory infection is not part of the treatment for diabetes and, therefore, is not an "integral, although incidental" part of Dr. A's



"professional service." The PA should not bill incident-to under Dr. A's provider number, but should bill the appropriate level of new or established E/M service provided under his or her own provider number. The physician must have performed the initial service for the diagnosis or condition, and must remain actively involved in the course of treatment.

Finally, the physician must perform subsequent services that reflect his or her continued active management of the patient's care.

Direct physician supervision

To understand this billing scenario, we need to explore further what CMS means by "physician's direct supervision."

According to CMS,
"Direct supervision in the
office setting means the
physician must be present
in the office suite and
immediately available
and able to provide
assistance and direction
throughout the time the
service is performed. Direct
supervision does not mean
that the physician must be
present in the same room
with his or her aide."

Additionally, CMS states, "If auxiliary personnel perform services outside the office setting, e.g., in a patient's home or an institution (other than a

THE ONLY TIME
WHEN A NPP
OR AUXILIARY
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A PHYSICIAN'S
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AND DIRECTLY
AVAILABLE TO
HEIP

hospital or Skilled Nursing Facility,) their services are covered incident to a physician's service only if there is direct personal supervision by the physician."

Therefore, the only time when a NPP or auxiliary staff member can bill a service under a physician's PIN is when a physician is in the office suite and directly available to help, if needed. The physician merely being available by phone does not constitute direct supervision.

Keep in mind that the physician providing the direct supervision (or who is in the office) does not need to be the physician

who established the plan of care for the patient. Check with your Medicare carrier for where the physician name(s) (i.e., the supervising physician and the physician who established the patient's plan of care) should be placed on the claim form.

Exception to direct supervision

Services to homebound patients in underserved areas, CMS says, are not subject to direct supervision, but rather general supervision requirements.

CMS defines general supervision as "The physician needs to be physically present at the patient's place of residence when the service is performed. But the service must be ordered by the physician and performed under his overall supervision and control. The physician retains professional liability for the service." A patient is considered homebound when his ability to leave his home is restricted and requires considerable effort.

Closer look at your choices

While auxiliary personnel

must bill their services incident-to (because insurance carriers do not credential them), NPPs have a choice whether to bill their services incident-to to Medicare. The incentive to bill incident-to services is reimbursement. Medicare allows 100% of the Medicare fee schedule amount for coverable services submitted by a physician.

Medicare allows a percentage of the physician fee schedule amount when services are submitted under a NPP provider number. The percentage is 85% for physician assistants, nurse practitioners, and clinical nurse specialists.

The drawback to incident-to billing is the administrative burden of coordinating physicians and NPPs schedules in order to have a supervising physician on-site.

If your NPP or auxiliary staff is going to bill incident-to a physician's services, be sure to follow the guidelines because this is an area under scrutiny by payers who recognize this type of billing. For that reason and because of the complexity of the guidelines, some offices have chosen to avoid incident-to billing.



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



Financial Strategies

BUNDLING SERVICES SAVES TIME, MONEY

by DEREK KOSIOREK, CPEHR, CPHIT

Very few things will frustrate a medical practice owner or administrator more than the sight of outside vendors blaming each other for a technical problem the practice is experiencing.

FOR EXAMPLE, say one of your remote locations loses access to the practice's electronic health record (EHR) system. You call the EHR vendor. The vendor blames the server and tell you there's nothing they can do. So you call the server support people and they blame the data lines; there's nothing they can do. And you know what's coming next - a call to the data line people. Nope, it's not their problem either, because they blame the server. And so the circle of blame begins.

Not that you care whose problem it is, of course. You just need it fixed.

One way to reduce the problem of buck passing to reduce the number of vendors you use. Consolidating vendor contracts can save time and headaches when you need a problem solved quickly, because you need call only one person to solve it.

To achieve vendor reduction, medical practices are adopting the bundled services concept, under which a vendor sells multiple products or services in a package for a single, reduced price. Bundling services is often used by cable companies to persuade consumers to purchase Internet, cable television, and telephone services together.

To a medical practice, however, bundled services can come in many forms. The most common is using one company for data and phone lines. In fact, most phone service is now run over data lines anyway. Voice Over Internet Protocol (VOIP) is very common in practices of every size.

As an additional

incentive, it is common for telecom companies to offer a favorable introductory rate for their services. This can be for up to 1 year, but with a commitment of multiple years after that. Before signing this type of agreement, however, look at the total cost over the term of the contract and consider where you will be in 2 to 3 years. Your practice's growth, or lack of it, will affect the telecom contract and may trigger additional fees.

Most EHR vendors package their practice management (PM) systems into the EHR and offer it at a greatly reduced rate if you bundle them together, often pricing the PM at half off or even offering it free. It is in their interest to sell you multiple products that need their support. However, it's in your interest to have an integrated system, because of the interfaces, training complexity, and limited functionality that come with patched together software.

Vendors like bundling services because it makes them more money. But higher profits also creates competition, which can benefit your practice. For every company that will bundle a service or product, there are usually three more that do the same thing and willing to negotiate on pricing. Make sure you do an "apples-to-apples" comparison when deciding among vendors.

Paying a company to keep your servers in a secure offsite location allows your information technology staff to focus on improving how your practice uses technology, rather than spending time on maintaining the systems. Many such companies also partner with local or national businesses to sell server and networking equipment at a discount.

Of course, bundling services and consolidating vendors can cause problems as well. Relying too much on a single vendor is a risk that some practices prefer to avoid. Severing a relationship with a vendor that supports mission-critical data and equipment can be quite painful, and involve significant money, time, and resources.

Make sure that your contract details the steps involved in recovering your equipment and your data if you ever decide to change vendors.



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





INVOKANA $^{\text{TM}}$ (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™, 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™ 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,

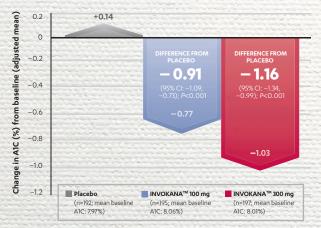
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Introducing INVOKANA[™]—the first and only treatment option approved in the United States that reduces the reabsorption of glucose in the kidneys via sodium glucose co-transporter-2 (SGLT2) inhibition¹

A1C Reductions as Monotherapy

INVOKANA[™] monotherapy provided statistically significant A1C reductions vs placebo at 26 weeks¹

A1C Change From Baseline With INVOKANA™ Monotherapy¹



Effect on Weight*

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

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

Impact on Systolic Blood Pressure (SBP)*

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

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

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

*Prespecified secondary endpoint.

†Adjusted mean.

A1C Reductions vs Sitagliptin

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

➤ Difference from sitagliptin[†]: -0.37%

Incidence of Hypoglycemia

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

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

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

Convenient Once-Daily Dosing¹

- >>> 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.

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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 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 requiring additional alycemic control.
- »Digoxin: There was an increase in the area AUC and mean peak drug concentration (C_{max}) of digoxin (20% and 36%, respectively) when co-administered with INVOKANA™ 300 mg. Patients taking INVOKANA™ with concomitant digoxin should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

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

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

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



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

- »Pediatric Use: Safety and effectiveness of INVOKANA™ in pediatric patients under 18 years of age have not been established.
- **>>Geriatric Use:** Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA™ in nine clinical studies of INVOKANA™. Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA™ (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300-mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were ≥75 years of age. Smaller reductions in HbA1C with INVOKANA™ relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA™ 100 mg and -0.74% with INVOKANA™ 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA™ 100 mg and -0.87% with INVOKANA™ 300 mg relative to placebo).
- >> Renal Impairment: The efficacy and safety of INVOKANA™ were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/ 1.73 m²). 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 m²); 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.

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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 m²), 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 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 [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 m²).

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

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

Adverse Reaction	Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Female genital mycotic infections [†]	3.2%	10.4%	11.4%
Urinary tract infections [‡]	4.0%	5.9%	4.3%
Increased urination§	0.8%	5.3%	4.6%
Male genital mycotic infections ¹	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:

Volume Depletion-Related Adverse Reactions: INVOKANA results in an osmotic diuresis, which may lead to reductions in intravascular volume. In clinical studies, treatment with INVOKANA was associated with a dose-dependent increase in the incidence of volume depletion-related adverse reactions (e.g., hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration). An increased incidence was observed in patients on the 300 mg dose. The three factors associated with the largest increase in volume depletion-related adverse reactions were the use of loop diuretics, moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²) and age 75 years and older (Table 2) [see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Use in Specific Populations].

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

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

^{*} Includes placebo and active-comparator groups

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	Daseille	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	INVOKANA 100 mg	INVOKANA 300 mg
			N=90	N=90	N=89
	Pagalina	Creatinine (mg/dL)	N=90 1.61	N=90 1.62	N=89 1.63
	Baseline	Creatinine (mg/dL) eGFR (mL/min/1.73 m²)			
Moderate Renal	Baseline Week 3	. 0	1.61	1.62	1.63
Renal Impairment		eGFR (mL/min/1.73 m²)	1.61	1.62	1.63
Renal	Week 3	eGFR (mL/min/1.73 m²) Creatinine (mg/dL)	1.61 40.1 0.03	1.62 39.7 0.18	1.63 38.5 0.28

^{*} 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 (%)] [†]	0 (0)	1 (0.3)	1 (0.3)
In Combination with Metformin (52 weeks)	Glimepiride + Metformin (N=482)	INVOKANA 100 mg + Metformin (N=483)	INVOKANA 300 mg + Metformin (N=485)
Overall [N (%)]	165 (34.2)	27 (5.6)	24 (4.9)
Severe [N (%)] [†]	15 (3.1)	2 (0.4)	3 (0.6)
In Combination with Sulfonylurea (18 weeks)	Placebo + Sulfonylurea (N=69)	INVOKANA 100 mg + Sulfonylurea (N=74)	INVOKANA 300 mg + Sulfonylurea (N=72)
Overall [N (%)]	4 (5.8)	3 (4.1)	9 (12.5)
In Combination with Metformin + Sulfonylurea (26 weeks)	Placebo + Metformin + Sulfonylurea (N=156)	INVOKANA 100 mg + Metformin + Sulfonylurea (N=157)	INVOKANA 300 mg + Metformin + Sulfonylurea (N=156)
Overall [N (%)]	24 (15.4)	43 (27.4)	47 (30.1)
Severe [N (%)] [†]	1 (0.6)	1 (0.6)	0

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

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

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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_{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].

INVOKANA™ (canagliflozin) tablets

OVERDOSAGE

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

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

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

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

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

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

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

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

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

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

<u>Hypotension:</u> 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.

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

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Moving up the job ladder in healthcare

NOT EVERY HOSPITAL

or medical practice is looking to move physicians up into leadership roles, but the good ones are, according to Gibb Wingate, a senior recruiting consultant for The Delta Companies.

"It's important to a lot of doctors to have a physician's perspective in administration," he says. "Sadly, sometimes it can seem like two opposing sides."

Fortunately, more hospitals are acknowledging the role physicians can play in management. Wingate says he has worked with a level two trauma center that is administered entirely by physicians.

"The only thing those guys did to key themselves up for that is they have the experience and the business mind that was needed for the role," he says.

But that doesn't mean executive positions are for everyone. Wingate says only certain physicians are willing to take on the added responsibility of running a business.

"They actively pursued that career path," he says. "In those positions, you have to give up patients or work extra hours."

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Is it the right time for you to buy another practice?

The increased need for primary care practices could be an opportunity to purchase another business

by DONNA MARBURY, MS Content Specialist

HIGHLIGHTS

O1 The availability and cost of a medical practice varies widely depending on the market and specialty.

02 Evaluating costs, but also performance, compatibility and possible antitrust violations are important when buying a practice.

ith all of the changes facing healthcare, including the increased bureaucracy and frustration, buying a medical practice may seem like more trouble than it's worth. However, many experts agree that now is a good time to consider buying.

"I spend a lot of time dispelling the myth that there is no value in buying a medical practice," says Chris Majdi, medical practice broker at Transition Consultants in Los Alamitos, California. "Some physicians are good at running a practice, and might consider buying another."

It is no secret that the acquisition of medical practices is a big players game. Hospitals and large physicians groups have increased as solo and small practices have started to shrink. The consulting firm Accenture predicts that only 33% of physicians remain independent this year, versus 43% in 2009 and 57% in 2000.

Though the solo and small practice market is getting smaller, there has been a rise in medium-sized groups with six to 50 physicians. In 1997 only 13% of practices were medium-sized. That number jumped to almost 18% by 2005.

And then there's the issue of afford-

ability. The prices of medical practices are wide spread, with most practices selling between 1 times to 4 times their annual net earnings, and 20% to 80% of their annual gross collections, according to Medical Practice Brokers. If you are in the market for an internal medicine practice, on average they sell for about 35% of their annual collections.

Though it is hard to count exactly how many smaller practices are merging or buying each other, it is clear that the opportunity could be a lucrative one.

"There's no one size fits all approach to buying a practice," says Kenneth T. Hertz, FACMPE, principal with the MGMA Healthcare Consulting Group in Alexandria, Louisiana. "I've seen practices buy charts for \$1 or \$2 per chart from another practice, or if a doctor wants to retire, he can sell everything for \$25,000. It's such a volatile market, so purchases must be based on strategic decisions."

HOT MARKETS AND SPECIALTIES

Majdi says California, Florida, and New York continue to be major markets to purchase a medical practice. "Some are concerned about the Affordable





Care Act (ACA) and other health reform. But there are going to be more beneficiaries in the system, which means more money," he says, adding that the lack of primary care providers in larger areas have made them the most sought after practices. Other specialties that are seeing a lot of attention include pain management and optometry, Majdi says.

"In California, there is a lot of money in pediatrics and primary care. Five or six years ago, we couldn't give away a pediatrics practice, but now we have sold nine in the past 18 months."

With the current shift in healthcare toward managed care for chronic illnesses, with Patient-Centered Medical Homes and Accountable Care Organizations being closely monitored models, primary care practices are being becoming hot properties.

"The primary care market will be important because of the strategies in keeping patients at a lower level of care to bend the healthcare cost curve. This makes primary care a critical piece of the future," says Hertz.

THE VALUE OF A PRACTICE

There is a lot more to consider when it comes to putting a value on a medical practice beside money. "The decision is not just financial, but should be based on the strategic value to you and your organization," Hertz says.

Practice owners need a solid checklist and a thoughtful and thorough approach to evaluating a medical practice. When trying to quantify a practice's value, make sure you look at:

- The growth rate of new patients
- Reimbursements and fee schedules for private payer and Medicare contracts
- The physicians' reputations in the practice and the community
- How long have other employees been with the practice
- Debt, accounts payable and receivable, collections, and the revenue cycle
- Tangibles like furniture, fixtures, and equipment
- The age and usability of technology, including computer software and electronic health records (EHRs)

Be clear on what you are trying to gain, and that makes valuing a little easier. "Do

THE DECISION IS NOT JUST FINANCIAL, BUT SHOULD BE BASED ON THE STRATEGIC VALUE TO YOU AND YOUR ORGANIZATION."

KENNETH T. HERTZ, FACMPE, PRINCIPAL, MGMA HEALTHCARE CONSULTING GROUP, ALEXANDRIA, LOUISIANA

you want to gain market share or patients? Do you want to solidify your place in the market or mark your presence next to a competitor?" Hertz says.

If you are looking to combine two practices, evaluating how they will be compatible is essential. Both practices might have different work philosophies and strategic goals, and this is important to predict how they will operate together in the future. Make sure buyers and sellers agree on how physician and staff payment and bonuses will operate, what operating hours will be and which technology systems will be used.

"One practice may have a vision of being profitable, balancing work and personal time, while taking on all patients. Another group might only want to take 10 patients a day and work three days a week. They may not be compatible," Hertz says.

A DIAMOND IN THE ROUGH?

Trying to determine the value of a practice may lead to discovering an undervalued or underperforming practice that may be available at a price that's hard to pass up. "Understand why it is underperforming and what needs to be done to turn it around. That depends on the situation," says David

Greene, president of Medical Practice Brokers, located in Colorado Spring, Colorado.

There are some elements of a practice that cannot be easily fixed, such as older equipment and furniture, hard to use EHRs and other technology, bad location and a lot of competition, Greene says. "However, if the practice is underperforming because of excess expense in a couple of areas, a competent practice manager can turn a practice around by changing staff or by improving collections," he says.

The underperforming practice should still fit into your overall goals. On top of the challenges involved with buying a practice, trying to fix a broken one is added pressure. "Anytime a practice is going to merge with another, you have to make sure the entities are compatible. If there have been no new patients in the past five years, that's a problem," Hertz says.

DIFFERENT WAYS TO PURCHASE

Determining whether you want to buy a practice's assets, or the entire corporation is the first thing to decide when negotiating. "Most buyers of a medical practice want to buy the assets, not the stock. If you buy the selected assets you don't assume the liabilities—the debts associated with the practice," says Ronald Finkelstein, ABV, CPA, principal-in-charge and leader of the Healthcare Services Group of Morrison, Brown, Argiz & Farra, in Fort Lauderdale, Florida.

Small-practice owners often have less capital to buy out a practice all at once. There are many types of buying models including an outright sell, bank financing, or paying the seller in installments based on the cash flow of the practice, called an earn out.

Though rare, some buyer negotiations may involve paying "good will," or additional money based on the perceived value of the practice over the tangible assets.

Physicians can also buy a practice with "sweat equity," according to Finkelstein, by working for a physician who is looking to retire and transition his business to another physician. "The buying doctor will be able to retain as many patients as possible by learning the practice and gaining the trust of patients and the community," he says, adding that with this type of transition plan, the buying doctor can negotiate payment over 6 to 24 months while the retiring doctor leaves the practice.

ANTITRUST ISSUES FOR SMALL PRACTICES

Even small practice owners who are looking to buy another small practice must consider antitrust issues. Consequently, the smaller the practice and community, the more at-risk practices may be for violating antitrust laws.

"Doctors with small practices might think that antitrust laws don't apply to them, but anytime there used to be two businesses and now there are one, there is a loss of competition," says Steve Cernak, of counsel at Schiff Hardin in Ann Arbor, Michigan.

Government agencies are looking closer at healthcare businesses to deter antitrust violations because of the rising costs and public attention attached to the industry. Though it is rare for a small practice to be audited by the Federal Trade Commission, the U.S. Justice Department, or their own state for violating antitrust laws, a violation could be costly. Officials can block medical practices from merging or break them apart, which could cost thousands of dollars in legal fees.

Cernak says that in rural communities where healthcare services may already be scarce, there is a risk of raising antitrust flags because a merger might eliminate services. "Even if there is some concern about loss of competition, there could be issues. Think about how big the market is—that's the denominator. Then what place in the market is your business and another business is the numerator," Cernak says.

He also stresses the importance of being able to quantify the value of the merger for patients, so that if there is an audit, a practice owner can show how it benefits the community. "You have to be clear on what are the benefits for the patient. If there are cost savings, will it be passed on to the patients? Will it be an easier commute?" Cernak says.



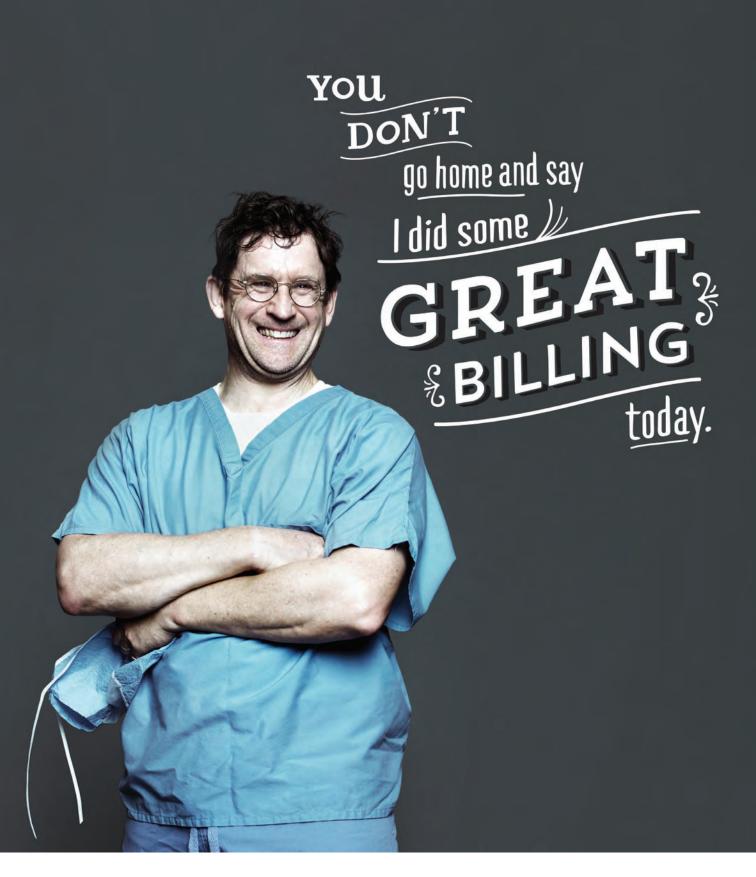
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BUSINESS OF HEALTH SERIES

Helping your patients kick the smoking habit

Medication and counseling can ease the difficult process of ending tobacco use.

by JEFFREY BENDIX, MA, Senior Editor

HIGHLIGHTS

- O1 Flag patients who are smokers in your records, and ask them during every visit if they are ready to quit, even if they have never shown interest in quitting.
- **02** Let patients know what they are likely to experience in their first days without tobacco, and discuss strategies for overcoming the temptation to relapse.
- O3 Don't allow yourself or the patient to get discouraged if the patient's first quit attempt fails. Keep in mind that the average patient makes six attempts to quit before succeeding.

Primary care physicians (PCPs) often think of themselves as being on the front lines of the battle to keep Americans healthy, and nowhere is that more true than in combatting smoking and other forms of tobacco use.

**HELPING PATIENTS* quit smoking is one of the most effective things that family doctors can do both in terms of outcome and cost-benefits for activities in an office," says Jeffrey Cain, MD, FAAFP, president of the American Academy of Family Physicians. Even a 30-second discussion of the benefits of tobacco cessation doubles the successful quit rate, Cain says.

Moreover, the range of behavioral and pharmacological tools available to PCPs to help their patients stop smoking continues to expand, thanks to ongoing research into the addictive properties of nicotine and best practices for cessation counseling. Tobacco cessation counseling has also gotten a boost

from the Affordable Care Act, which requires employer-sponsored insurance plans to cover all preventive services given an 'A' or 'B' rating by the U.S. Preventive Services Task Force, including tobacco cessation. Medicare also will pay for a limited number of cessation counseling sessions.

Although smoking cessation will rarely be a major source of revenue for a practice, PCPs can and should bill for the time spent on it, experts say. Counseling can be billed under Current Procedural Terminology codes 99406 or 99407. (See "Billing for tobacco cessation counseling, page 39.) Many commercial insurers will also reimburse for the service.

A PUBLIC HEALTH SUCCESS

By virtually any measure, the nation's ongoing effort to reduce smoking has been a major public health success story. In the mid-1960s, when the first Surgeon General report on the harmful effects of smoking was published, about 40% of adults smoked. By 2010, the smoking rate among adults had fallen to just over 19%, according to the Centers for Disease Control and Prevention (CDC). To-bacco advertising now is severely restricted, smoking is prohibited virtually everywhere indoors, and smoking is no longer considered socially acceptable among large segments of the public.

On the other hand, the CDC estimates that tobacco use still is responsible for 443,000 deaths annually, making it the nation's number one cause of preventable mortality. And although about 70% of the estimated 46 million adult smokers say they would like to quit, that still leaves a core group of some 13.8 million adults who aren't interested in quitting.

THE FIRST STEP: ROUTINE SCREENING

So how do you help patients stop smoking? The first step is to include tobacco use status as part of routine patient screening, making sure the information gets entered in the patient's chart, and flagging those patients who do smoke. Charles Cutler, ACP, an internist in Norristown, Pennsylvania, and chairman of the American College of Physicians' Board of Regents, enters smoking status under "social history" in a patient's electronic health record (EHR). The practice's EHR system is configured so that social history can be accessed with a single click.

"Before I even go into the reason for the patient's visit, I'll open the conversation by reviewing the social history, which includes smoking status. The 'OK, Mr. Jones, what brings you in today?' follows that routine screen," he says.

THE 5A'S INTERVENTION

William Blazey, DO, a family practitioner in Old Westbury and Central Islip, New York, uses the "5 A's Intervention" developed by the U.S. Public Health Service to begin a conversation with patients about tobacco cessation (See "The 5A's Intervention," page 40.) "We found that by making templates

[for the intervention] on our EHR system we can do a brief, focused clinical intervention. Most of the time we can get it done in 3 to 5 minutes," he says.

Another advantage of using the 5 As is that it precludes spending too much time counseling patients who aren't interested in quitting, while ensuring that practitioners at least raise the cessation question at each visit. "Hopefully sooner or later they'll see the light and when they do, they'll come to you," Blazey says.

Assessing a patient's readiness to quit is a crucial element in cessation counseling, says Sarah Mullins, MD, a family practitioner in the suburbs of Wilmington, Delaware, and a member of the American Academy of Family Practitioner's (AAFP) tobacco cessation advisory committee.

"When we teach tobacco cessation counseling, we often talk about how you have to roll with the resistance you may get from the patient," Mullins says. "If the patient has no interest in quitting, it doesn't mean you don't counsel, it means saying I'm here for you when you're ready. That has been shown to be statistically significant to improving their chances of quitting eventually, even if they weren't ready that particular day."

For those who are ready to quit, counseling can take place either individually or in group sessions. Mullins uses a cognitive behavioral therapy approach to her individual counseling sessions with patients. She talks to patients about specific steps they can take to prepare for "the quit," such as removing ashtrays from the home, vacuuming rugs, and removing the lighter from the car. She also advises smokers to switch brands the week before their quit date. "It tastes bad, they don't like it, and it becomes easier to give up than their usual brand," she says.

PREPARING THE PATIENT FOR THE OUIT

From there, Mullins segues into a discussion of what the patient can expect on quit day, especially the side effects of nicotine withdrawal and strategies for coping with them. Among her suggestions: keeping lozenges or gum handy for nicotine cravings, deepbreathing exercises, and drinking water while on the phone as a substitute for smoking.

"You troubleshoot the very practical issues, then think about what are the bigger triggers," Mullins says. "For most smokers

BILLING FOR SMOKING CESSATION COUNSELING

Two Current Procedural Terminology (CPT) codes are available to bill for smoking cessation counseling:

99406: smoking and tobacco-use cessation counseling visit, intermediate, greater than 3 minutes, up to 10 minutes, and

99407: smoking and tobacco-use cessation counseling visit, intensive, greater than 10 minutes.

Medicare defines an "attempt" as a maximum of four intermediate or intensive counseling sessions. The total annual benefit covers up to eight cessation counseling sessions in a 12-month period, says Maxine Lewis, CMM, CPC, a medical coding specialist in Cincinnati, Ohio.

Beneficiaries are eligible to receive an additional eight counseling sessions during a second or subsequent year provided that at least 11 months have passed since the first Medicarecovered cessation counseling session took place, Lewis savs. Beneficiaries must be competent and alert at the time that counseling services are provided and counseling must be provided by a qualified physician or other Medicare-recognized practitioner.

THE 5 A'S INTERVENTION

The 5A's intervention, developed by the U.S. Public Health Service, is a fast and easy-to-remember way to identify patients who may be ready to guit smoking and to begin a smoking cessation dialogue with them.

SK

Identify and document the tobacco use state of every patient at every visit.

DVISE

In a clear, strong, and personalized manner, urge every tobacco user to quit.

If the patient uses tobacco, is he or she willing to make a quit attempt? If the patient is an ex-tobacco user, how recently did he or she quit, and is the patient facing any challenges to remaining abstinent?

SSIST

For the patient willing to make a quit attempt, offer medication and provide or refer for counseling or additional behavioral treatment. For patients uninterested in quitting at this time, provide interventions designed to increase future quit attempts. For the recent quitter, provide release prevention.

A RRANGE

For the patient willing to make a quit attempt, arrange for follow-up contacts, starting with the first week after the quit date. For patients unwilling to attempt quitting at this time, address tobacco dependence and willingness to guit at next visit.

Source: Treating Tobacco Use and Dependence: 2008 Update, U.S. Public Health Service

quitting smoking relapse occurs when they're around other smokers, or when they're drinking alcohol. So we look at ways to minimize being in those situations."

Involving a spouse or partner in the quit process also is key, says Cutler, especially if that person smokes too. That's because the chances of a successful quit diminish significantly with another smoker in the home. "In that case you need to ask the patient, 'Can you and your spouse work together on this? Can you at least get your smoking spouse not to smoke in the house?' says Cutler.

GROUP SESSIONS

Another approach to helping patients quit is through group sessions. The procedure is similar to those used for patients with diabetes, hypertension, and other chronic diseases: Pick dates and times, invite patients who are ready to quit, and prepare a meeting space in your practice's offices.

Mullins has her patients check in as they would for a regular office visit, after which a nurse takes the patient's vital signs and brings the patient to the group meeting room. Mullins then talks about the health risks of smoking and has patients do some exercises in a workbook and talk about their experiences with using tobacco. Then she takes each patient to an exam room to prescribe pharmacotherapy.

(Detailed instructions for conducting group sessions are available in the AAFP's "Guide to Tobacco Cessation Group Visits," available for download www.aafp.org/dam/AAFP/documents/patient_care/tobacco/GrpVisit-Guide2012.pdf).

"The patients were really glad to have the opportunity to spend an hour with their doctor working on this 3 weeks in a row," Mullins says. "And we know that the more intense the intervention—the longer the duration, the more involved the activities-the more likely they are to have a successful quit."

MAKE IT A TEAM EFFORT

Cain emphasizes that others in a practice besides the physician should be involved in cessation efforts. "It's important for doctors to remember they don't have to do everything, in fact, cessation is a good example of where a Patient-Centered Medical Home's team-based model works," he says.

As part of its "Ask and Act" program, the AAFP encourages medical practices to identify an "office champion," with the authority to recommend and implement ways of integrating tobacco cessation into the practice's routine.

Yet another option for helping patients, says Mullins, is to inform them of the dangers of smoking and the importance of quitting, then referrin them to the universal telephone quitline number, 1-800-784-8669 (1-800-QUITNOW.) The patient will be connected to a counselor in his



ASSESS YOUR PRACTICE'S COMMITMENT TO SMOKING CESSATION

Your practice's environment can demonstrate your commitment to helping patients stop smoking and using other tobacco products. Conduct a brief assessment by answering these questions:

- How does your practice identify and document patients who are tobacco users? Who is responsible for doing so?
- How does your practice communicate to patients the importance of quitting and your ability to assist them?

Self-help materials in exam rooms Lapel pins Other How does your practice help patients quit smoking? Distributes educational materials Refers patients to a quitline Refers patients to outside support groups or counseling options Conducts tobacco cessation group visits Counsels patients at visits Prescribes medications at visits Prescribes medications at visits Provides follow-up for patients trying to quit What systems do you have in place to ensure that tobacco use is addressed during patient visits? Prompts in electronic health records system Flags or stickers on paper charts Tobacco use status as part of vital signs Registry of patients who use tobacco Feedback to clinicians on adherence with guidelines Regular staff training Other		Tobacco-free signs at entrances Posters in waiting areas Posters in examination rooms Self-help materials in waiting areas
How does your practice help patients quit smoking? Distributes educational materials Refers patients to a quitline Refers patients to outside support groups or counseling options Conducts tobacco cessation group visits Counsels patients at visits Prescribes medications at visits Provides follow-up for patients trying to quit What systems do you have in place to ensure that tobacco use is addressed during patient visits? Prompts in electronic health records system Flags or stickers on paper charts Tobacco use status as part of vital signs Registry of patients who use tobacco Feedback to clinicians on adherence with guidelines Regular staff training		Self-help materials in exam rooms Lapel pins
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		Flags or stickers on paper charts Tobacco use status as part of vital signs Registry of patients who use tobacco Feedback to clinicians on adherence with guidelines Regular staff training

What resources are available in your community that your patients

or her state who will help the patient through the quit process.

Mullins says some of her colleagues will have the patient call the quitline from the doctor's office. Another option is to fax a referral sheet with the patient's contact information, and a quitline counselor will contact the patient. Some quitlines will provide a free 1-month supply of nicotine patches or medication to help the patient get started.

ADDING PHARMACOTHERAPY

Combining counseling or behavior modification with some form of pharmacotherapy often can improve a patient's chance of quitting successfully. The U.S. Public Health Service recommends seven first-line medications that it says have been found to reliably increase long-term smoking abstinence rates:

- Bupropion SR
- Nicotine gum
- Nicotine inhaler
- Nicotine lozenge
- Nicotine nasal spray
- Nicotine patch
- Varenicline

The medications can be tried in various combinations, says Cain. "The trick is to figure out what the patient has tried before, and help them find a more effective combination," he says.

Even with the widespread knowledge of smoking's dangers and advances in pharmacotherapy, quitting is almost always difficult. (The average smoker makes six attempts before he or she succeeds, according to the CDC.) That can be frustrating for PCPs, notes Cain, but doctors can overcome those feelings by thinking of smoking as a chronic disease, rather than an acute issue.

"If you think of smoking like a condition where you give an antibiotic and the patient is fine, you're going to fail," he says. "But if you change your mindset to one of helping someone with a chronic disease to live a longer and better life, both you and the patient are much more likely to succeed."

could use to help with their guit attempts?

Source: Treating Tobacco Dependence Practice Manual, American Academy of Family Physicians

HIPAA:

Training critical to protect patients, practice

Here's what you need to know about safeguarding your patients' health information under the new rules

by TERRY SALZ, Contributing writer

HIGHLIGHTS

- **01** To remain HIPAA compliant, conduct a thorough assessment of risks and vulnerabilities to confidentiality
- **02** Appoint one person in the practice to understand, monitor, document and train staff on the rules and auidelines.
- **03** The goal of a successful compliance program is to limit potential unauthorized access without compromising healthcare delivery.

mployees who violate the rules because they don't know them make inviting targets for new enforcement initiatives under the Health Information Technology for Economic and Clinical Health (HITECH) Act.

The lesson for all offices is to train employees on HITECH and on new and existing Health Insurance Portability and Accountability Act (HIPAA) rules. It is imperative to understand the penalties for workforce mistakes and the effects it could have on your practice and your staff.

Training in privacy, security, unsecured breaches, and regulations and how these rules and regulations affect your practice is critical.

As a proactive approach, you should conduct an accurate and thorough assessment of the risks and vulnerabilities to the confidentiality, integrity, and availability of sensitive information held by your practice. All your employees need to understand how this affects them and their part in structuring a level of protocol and not avoiding their responsibility. These changes affect everyone, so your staff needs to be aware that this is a part of your practice's structure and that you do not have the option of not enforcing it.

There are many different levels to the changes and modifications and therefore you should take a methodical approach to understanding, implementing, and training as the changes occur. As with any standards and laws, someone must be in a position to monitor, update, document, and train staff on the rules and guidelines. Employees also need to understand their roles and responsibilities under the protocols. More importantly, they need to know who is responsible for updating staff members on any changes to the rules and standards and who to go to should an issue arise.

To start with, it is important to understand each of the terms used in connection with HITECH and HIPAA and why they are in effect.

HIPAA: The Health Insurance Portability and Accountability act (HIPAA) sets the standard for protecting sensitive patient data. HIPAA was enacted in 1996 to protect individual patients' private medical information. The law prohibited healthcare practitioners and institutions from releasing protected health information (PHI) to anyone, including health insurers, without the patient's consent. Employers must train any employee who has contact with medical records in appropriate HIPAA compliance.

Notifications to employees are critical

every time there is a substantive change in protocol that may affect medical privacy and how it is handled. It is important to remember that not all employees have been trained in the guidelines and protocols, even if they have worked for a long time in the medical field. It is your responsibility to see that your employees are aware of the rules, laws, and standards to follow in your practice.

Of course, as with any rule, there are some exceptions. Here are some examples:

LAWSUITS AND DISPUTES

If you are involved in a lawsuit or a dispute, you may disclose PHI in response to a court or administrative order. You also may disclose in response to a subpoena, discovery request, or other lawful process by another party involved in the dispute, but only if efforts have been made to tell you about the request or to obtain an order protecting the information requested.

LAW ENFORCEMENT

You may release PHI if asked by a law enforcement official for the following reasons:

- In response to a court order, subpoena, warrant, summons, or similar process;
- To identify or locate a suspect, fugitive, material witness or missing person;
- Information bout the victim of a crime if, under certain limited circumstances, you are unable to obtain the person's agreement;
- A death suspected of being the result of criminal conduct;
- Regarding criminal conduct on the premises;
- In emergency circumstances or to report a crime, the location of the crime or victims, or the identity, description, or location of the person who committed the crime.

MEDICAL EXAMINERS AND FUNERAL DIRECTORS

You may release PHI to a coroner or medical examiner. This may be necessary, for example, to identify a deceased person or to determine the cause of death. Health information may also be released to funeral directors as necessary for them to perform their duties.

INMATES, INDIVIDUALS IN CUSTODY

In the case of inmates of a correctional institution or those who are under the custody of

a law enforcement official, you may release PHI information under the following circumstances:

- for the institution to provide the patient with healthcare;
- to protect the patients' health and safety or the health and safety of others; or
- for the safety and security of the correctional institution

An important part of HIPAA is the requirement to comply with a patient's request not to disclose PHI to a patient's health insurance provider, so long as the patient has paid for the medical product or service out of his or her own pocket. Flagging such requests in the patient's record will be problematic unless all members of your staff are aware of this requirement and the appropriate protocols are in place. Everyone in the office and related to access to this information will need to be involved and have a complete understanding of the rule.

The HIPAA final rule states explicitly that all disclosures required by law supersede the patient's request for non-disclosure. Otherwise, a provider who discloses PHI to the insurer is violating HIPAA and the HITECH Act, and is subject to possible criminal or civil penalties or other corrective action spelled out in the rule.

It is also important to understand who is now subject to penalties under HIPAA. Prior to enactment of the final rule in January of this year, HIPAA directly affected healthcare providers and insurance companies. Now "business associates"—any organization associated with these providers that has access to PHI—must also comply or face fines.

The patient has the following rights regarding their health information:

PHI: To understand PHI, you have to examine two definitions that were included in the original HIPAA legislation of 1996. These contain the statutory definitions of health information and individually identifiable health information.

Medical practices must evaluate and enhance protections needed to prevent unnecessary or inappropriate access to PHI. Any suggestions as to how you can better limit access to and disclosure of your patient information should be brought to your practice's HIPAA compliance officer.

The minimum necessary stan-

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ways to protect health information when using a mobile device

Use a password or other authentication

Configure your mobile devices to require passwords, personal identification numbers (PINs), or passcodes. Activate the automatic screen locking function for a predetermined time period to prevent unauthorized use.

- 2. Install and enable encryption Mobile devices can have built-in encryption capabilities, or you can buy and install an encryption tool on your device.
- Install and activate remote wiping and/or remote disabling

These functions enable you to erase data on a mobile device remotely. If you enable the remote wipe feature, you can permanently delete data stored on a lost or stolen mobile device. Features that allow remote disabling enable you to lock or completely erase data stored on a mobile device if it is lost or stolen. If the mobile device is recovered, you can unlock it.

▲ Disable, and do not install or use file-sharing applications File sharing is software or a system that allows Internet users to connect to each other and trade computer files. The feature can also enable unauthorized users to access your laptop without your knowledge. By disabling or not

Source: Office of Civil Rights, Health and Human Services

using file-sharing applications, you reduce a known risk to data on your mobile device.

- Install and enable a firewall A personal firewall on a mobile device can protect against unauthorized connections.
 - Firewalls intercept incoming and outgoing connection attempts and block or permit them based on a set of rules.
- 6. Install and enable security software

Security software can be installed to protect against malicious applications, viruses, spyware, and malware-based attacks.

Keep your security software up to date

> When you regularly update your security software, you have the latest tools to prevent unauthorized access to health information on or through your mobile device.

Research mobile applications (apps) before downloading

> A mobile app is a software program that performs one or more specific functions. Before you download and install an app on your mobile device, verify that the app will perform only functions you approve of. Use known websites or other trusted sources

that you know will give reputable reviews of the app.

Maintain physical control

The benefits of mobile devices - portability, small size, and convenience - are also their challenges for protecting and securing health information. Mobile devices are easily lost or stolen. There is also a risk of unauthorized use and disclosure of patient health information. You can limit an unauthorized users' access, tampering or theft of your mobile device when you physically secure the device.

10. Use adequate security to send or receive health information over public Wi-Fi networks

> Public Wi-Fi networks can be an easy way for unauthorized users to intercept information. You can protect and secure health information by not sending or receiving it when connected to a public Wi-Fi network, unless you use secure, encrypted connections.

Delete all stored health information before discarding or reusing the mobile device

> When you use software tools that wipe data stored on a mobile device before discarding or reusing the device, you can protect and secure health information from unauthorized access.



dard is intended to reflect and be consistent with, not override, professional judgment and standards. Your goal is to limit access to PHI with the caveat that it have no impact on the quality of healthcare that you offer.

The recent release of the final HIPAA Omnibus Rule will be one of the most significant changes to the HIPAA regulations, one that will have far-reaching implications for PHI disclosure management. Penalties for violations have increased to a maximum of \$1.5 million per calendar year, and the definition of what constitutes a breach has changed. Being proactive should always be your rule because you don't want to be in a position of having to react should a PHI breach occur.

HITECH: The Health Information Technology for Economic and Clinical Health (HITECH) Act supports the enforcement of HIPAA requirements by increasing the penalties for healthcare organizations that violate HIPAA privacy and security rules. The HITECH Act is in response to developments in health technology and the increased use, storage, and transmittal of electronic health information.

The 2013 HITECH Final Rules, which went into effect March 26, 2013, impose significant new obligations on covered entities, business associates, and subcontractors. A "business associate" is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity.

The rules governing business associates take effect September 22, 2014. You need to ensure that independent contractors and/or agents who furnish services to your practice are aware of the requirements of the compliance program with respect to HIPAA and the protection of PHI.

These key dates for implementation of programs to remain in compliance with HIPAA/HITECH rules:

- March 26, 2013: The Rules became effective.
- September 23, 2013: Covered entities must comply with most of the new Rules' provisions.
- September 25, 2013: Disclosures of PHI become subject to the new restrictions on sale of PHI
- September 22, 2014: Covered entities must bring all of their Business Associate agreements ("BAAs") into compliance

YOU SHOULD CONDUCT
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BY YOUR PRACTICE."

with the rules; the new rules also apply this requirement to business associates agreements with their covered subcontractors.

With all the changes that are taking place, you should conduct a risk assessment in your practice. It is important to know what you would do in the event of a breach involving PHI. It is even more important to verify that the correct measures are taken. I would recommend bringing an outside party to do an onsite review of the security practice that is in place. A thorough risk assessment will help your practice comply with the rules and this will identify and facilitate an efficient and secure process in protecting your Practice.

Being proactive means taking timely, effective action. This is what these changes call for. Proactive people foresee potential obstacles and exert their power to find ways to overcome them before those obstacles turn into roadblocks. Which road are you taking?

Terry Salz is chief executive officer of International Medical Billing Management and Consulting, Inc., in Punta Gorda, Florida.

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Practical Matters

FINDING THE VALUE OF EMPLOYEE SATISFACTION

by H. CHRISTOPHER ZAENGER, CHBC

Contributing Author

Keeping your staff happy while pushing them to be better takes time and work outside of your busy schedule. By properly training and incentivizing your staff, you will see a return in better performance.

THE AVERAGE payroll cost so far this year for Major League Baseball is 45% of the combined team revenue. The range is from as little as 13% for the Houston Astros to as high as 88% for the Los Angeles Dodgers. This is a service business. According to the National Society of Certified Healthcare **Business Consultants**, roughly half of a practice's operating costs are spent on staff. Player-personnel focus is major league.

Physicians are highly trained and skilled individuals. Yet, when I asked the head of a pediatric group how his staff was performing, seconds passed in silence, broken by his not uncommon whisper: "I do not know, but it's a mess."

Physicians are often ill-prepared, and sometimes reticent, to hire, train, manage, or fire staff. So how do you best manage your most costly and most required asset? More importantly, how do you take the underperformers and turn them into superstars?

It may surprise you to know, and delight you at the same time, that studies done in the last 15 years indicate that money is not even in the top 50 things that employees care about at work.

Employees need to know how what they do adds value to the business and helps both the patient and the physician succeed. They also

Additional contributions to the article made by members of the National Society of Certified Healthcare Business Consultants

Judy Aburmishan, CPA, CHBC (Illinois),

Mike DeVries, CFP, CHBC, EA (Michigan),

Gail Levy (Maryland),

Marc Lion, CPA, CFP (New York),

Kathy Moghadas, RN, CLRM, CHBC (Florida),

Steven Pelz, CHBC (New York), Debra Phairas, MBA (California),

Tessie Quattlebaum, CHBC, FACHE (Georgia), Christopher Zaenger, CHBC (editor-Illinois)

want to succeed and need to know how to do it.

Managing and improving staff performance is a learned skill. Below is a list of ways to create an environment that motivates your staff.

Know what you need

Make sure you provide written personnel policies and procedures, position list and job descriptions, clean furnishings, working phones and other systems, and flow and function so your staff can do their jobs.

Know how to hire

Michael Douglas said it in the movie, "The American President:" it's all about character. Hiring skills alone does little if the person cannot get along with others or cannot prioritize tasks due to poor judgment.

Behavioral interviewing is key. So although asking "what did you like most about your last job" may be a good question to warm up a

candidate, a better question is "do you remember a situation where you solved a problem at work? Describe what happened. Was your input recognized? How did you feel? What was the outcome?"

Many times future behavior is predicted by past behavior. Asking questions that get at actual experiences and highlight how the person acted in actual situations is significantly more telling.

Train for results

So many practices fail to train. They simply show new hires to the desk and put them to work, thinking that their previous experience will get them through. Rarely do I see two practices that operate exactly the same, say the same things to patients, have the same phone system, computer software, or forms, and the same locations for storage.

Good orientation and training requires hand-on experience with a skilled



() Operations

staffer showing the way and coaching the new hire. In addition, the new employee will need time to do and learn the task well before adding another task with high expectations.

Create performance expectations

Such items as dress code, work schedule adherence, and Health Insurance Portability and Accountability Act (HIPAA) compliance are requirements of the job where failure to adhere results in termination.

Other factors demonstrate superior performance. It is also important to demonstrate expected results while the work is being done each day, to address issues as they surface, and to reinforce the positive outcomes. Ongoing specific feedback is critical to success.

Conduct purposeful reviews

Have you ever chastised a medical assistant because she did not do the vitals, enter the chief complaint, or ask that diabetic patient to take her shoes off? That's a "contemporaneous" review. Address problems as they occur with the goal of helping the employee succeed, not as a complaint. Regular annual reviews

(we like them based on hire anniversary date to spread the love and avoid comparison shopping) are not motivators. Employees expect a raise. So consider separating the performance review from the wage review.

Performance reviews are best conducted with previous targets having been established, employees giving their own impressions of their performance, notations taken, and the employee knowing how they are performing before they enter the session. Reviews should conclude with new being targets set.

Be consistent

Once a policy is established or a procedure created. do not alter it daily or for special circumstances. We cannot tell you how many times two physicians each instruct staff to perform a task differently and then change their minds repeatedly. The result is that employees are confused and embarrassed to ask, and the physicians are at odds with each other. So, they do what they think is best and neither physician is satisfied.

Praise publicly, give private feedback

The physician screaming at a staffer in the hallway for all to hear and in front of

patients does little to solve a problem and less to build the image of the practice or respect of the physician.

Pull the employee aside and let them know you care about their success. Then tell them what you expect and why it matters.

Saying, "you need to take vitals correctly and enter them in the chart" has less impact than saying, "a misread blood pressure can cause me to inaccurately alter her medication and put her in the hospital" or "if each medical assistant failed to enter the vitals for us we would lose 2 hours per day of time and fall behind with patients, and some patients may not get in today who need to be seen. So please help me keep our patients happy and healthy."

Motivate

When it came time to give my executive assistant a review, she requested additional days off in lieu of a salary increase. What a concept!

You will note as you develop an understanding of your staff that employees are motivated by different things. What works well for one may fall flat for another. Do you have one employee that when she takes the desk it seems more cash is collected that day? Give him or her a \$50 Visa gift card in front of other employees (and tell them why). They just got

reviewed, and praised and motivating reinforcement in less than 2 minutes--and other staff members just got educated.

Here are 10 incentives that can work for your practice:

- 1. Gas and restaurant gift cards
- 2. Fresh flowers
- 3. Share your incentive dollars with everyone it is a team effort after all and you may find targets will be easier to hit.
- 4. New computers (larger monitors) or better task chairs
- 5. Scheduled in-house and professional training
- 6. Certification support in time and reimbursement
- 7. Flex hours or work from home
- 8. Clinical in-service for non-clinical staff
- 9. Time off
- 10. Saying, "thank you"

When all else fails, fire

Consultants agree: Hanging on to a sub-par employee is demotivating to the other employees and pulls down team performance.

The practice owners set the tone, create or resolve confusion, mold staff behavior, and foster a spirit of fairness and mutual respect, all to build an efficient, vibrant motivated, creative and pleasant work environment from which the physicians, staff and patients enjoy and benefit.

IN DEPTH

TECHNOLOGY NEWS

Most doctors think EHRs improve patient care [54]



Making the EHR your partner in patient care

Computers in the examining room need not be a barrier to good communication with your patients

by ANDREA DOWNING PECK, Contributing Writer

HIGHLIGHTS

- O1 Begin an office visit by explaining to the patient why you are using the computer and how it can improve the quality of care you provide.
- O2 Allowing the patient to view the EHR screen during the examination and see the information you are entering builds trust and strengthens your connection with the patient.

No longer a rarity in patient examination rooms, electronic health records (EHRs) now are found in nearly 72% of office-based physicians' practices, a 400% increase from a decade earlier, according to the National Center for Health Statistics. For many doctors, however, leveraging the EHR to enhance patient-doctor engagement during an office visit remains an elusive goal.

MOST PRIMARY care physicians receive no instruction on best practices for using the EHR in an exam room. Instead, EHR training typically focuses on teaching providers to navigate data entry tasks and introduces them to a system's features. Yet there are ways physicians can help ensure that their EHR enhances the doctor-patient relationship rather than creating a barrier to patient communication.

Jason Mitchell, MD, director of the Cen-

ter for Health Information Technology at the American Academy of Family Physicians (AAFP), says the first step is recognizing the computer is "a third party in the room."

"Acknowledging the computer can be a significant distraction from interaction with the patient is absolutely essential," Mitchell says. "You have to find ways to mitigate that and draw the patient into the interaction you are having with the computer."

"As you gain comfort using any kind of





system, whether it is a piece of paper and pen or a computer keyboard, it becomes more of a tool and less of a concern," says Jennifer Brull, MD, a solo family practitioner in Plainville, Kansas. Brull now considers her EHR an invaluable partner in patient care, but she admits she did not initially view it that way.

"The discussion around the EHR and computers is because so many physicians of my generation and older generations felt uncomfortable using the computer," Brull says. "We wound up directing so much attention to the computer that it took attention away from the patient."

LET PATIENTS SEE WHAT YOU'RE DOING ON THE EHR

In the exam room, Brull allows patients to view the computer screen at all times, which enables patients to easily view charts and graphs as well as double-check that Brull's note-taking accurately reflects the patient's words. "I love the tools our EHR gives us," she says. "I can talk to a patient about weight gain but when I show them a graph of their weight over several years, they can see it. A picture does mean a thousand words."

William Ventres, MD, a family physician who in 2006 coauthored one of the first tip sheets on doctor-patient communication using EHRs, is not convinced much progress has been made in overcoming the barriers to patient engagement posed by computers.

"The good news, apparently, is that my coauthors and I got to look at these issues early on after EHRs were first introduced," Ventres says. "The bad news is that it is still common for healthcare systems to plop down computers in front of their clinicians without any training or instruction about how to use them to enhance, and not detract from, the therapeutic relationships between doctors and patients."

Ventres' original advice to physicians on how to use an EHR to enhance in-office communication continues to hold true. Those recommendations range from the obvious—learn how to type and master basic computer skills-to overlooked details such as:

- listening to a patient's concerns before opening the computer screen;
- telling patients what you are doing at the computer when entering information;

- pointing to the computer screen when sharing data or results with patients;
- understanding when it is important to push the computer screen away; and
- encouraging patient participation in building

FILLING THE KNOWLEDGE VOID

Though physicians continue to receive little formal instruction on using EHRs in the presence of their patients, there are signs that the knowledge void may be starting to fill. At its 2013 annual meeting, the American Medical Association (AMA) approved a policy pledging to develop resources for members on effectively using computers and EHRs in patient-physician interactions and to encourage physicians to incorporate questions regarding use of computers and EHRs in patient-satisfaction surveys.

The AMA Board of Trustees' report calling for the policy change outlined recommendations from Ventres' 2006 Family Practice Management article and Kaiser Permanente's tips to its clinicians. Kaiser Permanente uses the acronym LEVEL to foster integration of computers into patientdoctor encounters:

- Let the patient look on: Move the computer screen so the patient can see it, invite the patient to view information, ask the patient to verify information as entered.
- Eye contact: Greet the patient, maintain eye
- Value the computer as a tool: Acknowledge the computer; let the patient know how it improves care.
- Explain what you are doing: Inform the patient about actions and decisions, tell the patient what you are doing, such as ordering labs.
- Log off and say that you are doing so: Tell the patient you are logging off to safeguard his or her information.

Medical schools also are recognizing the need to teach physicians how to maximize the EHR in patient interactions. At the University of Arizona (UA) College of Medicine-Phoenix, first-semester students are receiving a 20-minute training session on how to use the EHR in a "relationship enhancing

Howard Silverman, MD, associate dean for information resources and educational technology at the UA College of Medicine-



Phoenix, says the college's observational studies showed today's computer-savvy students make the same missteps as older generations when using an EHR in an exam room such as turning their backs to patients while using the computer, and apologizing for having to use the computer.

"There's an assumption the new generation of medical students are computer literate so they will [engage patients] naturally," Silverman says. "We have very good data [showing that] that is not the case."

STUDENTS NEED TRAINING TOO

Accordingly, the school developed a training intervention that teaches students to begin an office visit by explaining to patients why the computer is important to the visit, has them reassure patients about confidentiality, and directs them to position the computer screen so that the patient can see the screen to review information such as medication lists, laboratory values, and X-rays.

Students are also told to recognize cues to close their laptops and focus solely on the patient, such as when the patient starts discussing sensitive information or before beginning a physical exam. Another tip involves alerting patients that the doctor's attention temporarily will be focused on the computer screen before beginning computer-intensive tasks such as recording a pa-

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--JASON MITCHELL, MD, DIRECTOR, CENTER FOR HEALTH INFORMATION TECHNOLOGY, AMERICAN ACADEMY OF FAMILY PHYSICIANS

tient's medical history.

"When you shift into that mode, say 'I am going to ask you some rapid-fire questions. I want to record your answers in the computer because I want to make sure I get this down accurately so I can give you the best possible care," Silverman explains. "Now the clickety-clack has been reframed as a positive thing as opposed to 'I am playing video poker and you don't know what I'm doing."

Silverman is confident that practicing

physicians would benefit from EHR training similar to that developed for UA College of Medicine-Phoenix students, which aims to elevate the doctor-patient relationship.

"The issue with EHR ergonomics is not to make the EHR tolerable," he says. "It is to make the encounter better than it would have been without the EHR. Everybody's assumption is that the interaction degrades because the computer is there. It could be the same or it could be better. We prefer the better alternative. The question is, how do we get people there?"

THE EHR IS 'NO LONGER AN ALIEN OBJECT'

In his seventh year using an EHR, Salvatore Volpe, MD, a Staten Island, New York-based internal medicine physician, says the computer is "no longer an alien object" in the room for him or his patients.

"Once I learned where everything was on the screen and I got past the gee-whiz-thisis-such-a-great-toy phase, I was able to get back to my old routine, which is listen for a little while, ask questions, digest it and then play court stenographer," says Volpe, a member of the *Medical Economics* editorial

Patients now expect Volpe to bring a laptop into the exam room and understand how it will be used. "I have many patients who will talk to me for a while and then as I am typing, they will say, 'Just let me know when I should continue talking,' which I think is beautiful," he says. "It means we know the routine. You know I need this machine to keep track of everything but I don't want to handicap your talking. You also realize I can only type so quickly, and I am paying attention to you and not just robotically writing things down."

Volpe also believes EHR templates for preoperative exams and other tasks enhance his ability to connect with patients. "I have some predefined data points I have to collect," he says. "The EHR is a great way to let me do that efficiently. Because I have become more efficient, I can spend more time talking to the patient."

THE BENEFITS OF JUST LISTENING

For Boston internist Chloeanne Georgia, MD, using an EHR effectively in the exam room is an ever-evolving process. While she used to immediately begin taking notes at

the start of a patient visit, she now sets the keyboard aside and listens to the patient's story.

"I've found that sitting and listening works better for me because sometimes when I type as the patient is talking, I can't make sense of the notes I'm taking because they are incomplete sentences or phrases that may mean something or not. I end up going back to rewrite the whole note anyway," she says.

The AAFP's Mitchell says the growth of medical devices that automatically transfer data into electronic records also will help strengthen the doctor-patient relationship.

"If you have device integration with the EHR, it helps the interaction with the patient," he says. "The information is immediately available and can be shown to the patient. To be able to show blood pressure trends over time, to be able to look at lab results together helps tremendously in validating a treatment plan with a patient or showing what is going wrong."

THE ROLE OF PATIENT PORTALS

Mitchell also believes that patient portals, which enable physicians and staff to easily communicate with patients and give patients access to appointment scheduling, prescription refills, and their medical history will play an important role in improving patient engagement.

"That after-visit follow-up is now much easier," he says. "It really strengthens the provider-patient relationship when the patient knows they are cared about. It is not, 'we have your copay and now we're done,' but we care that the treatment regimen we decided on is sustainable for you, is working for you and that you're not having any other problems."

Kenneth Hertz, a principal with the MGMA Healthcare Consulting Group, thinks that EHRs ultimately will fulfill their promise to transform healthcare, though there are hurdles to overcome before that happens.

"I see practices making progress," Hertz says. "Physicians are working hard at this. Staffs are working hard. A lot of people are working to make this happen. It could be five years before we start to see major transformational change, but I have to believe it is going to happen because it has to happen."

Tech News

EHRS ARE GOOD FOR PATIENT CARE, DOCTORS SAY

The majority of physicians believe that using electronic health records (EHRs) has a positive impact on patient care, according to a recent survey.

ATHENAHEALTH'S 2013

Physician Sentiment Index showed that 68% of physicians believe EHRs somewhat or significantly improve patient care, while 17% believe that they worsen care. The survey, conducted in March 2013, used athenahealth's Epocrates physician member base.

The 1,200 respondents to the survey included independent and hospitalemployed primary care physicians and specialists.

The findings support what patients have said in similar surveys. In Aeffect Inc.'s EMR Patient Impact Study, the majority of patients using EHRs reported feeling more satisfied with their quality of care and access to their health information.

But despite the positive impact on patient care, EHRs still pose ongoing challenges to physicians' workdays. In fact, the dissatisfaction is so prominent that multiple market surveys show one in five physicians may switch from his or her current EHR system to another vendor. Physicians report frustration over their EHR's inability to decrease their workload and their system's difficulty of use.

The athenahealth survey may lend additional insight as to why some physicians are unhappy. Nearly half of those surveyed said they feel EHR systems were not designed with physicians in mind. It also revealed that more than half (51%) of physicians do not believe that the financial benefits of EHRs outweigh the costs.

But the good news for patients is of those physicians, 55% feel that the benefits to the patient outweigh the expense.

MORE PERSONAL TWEETS COULD AID HEALTH DEPARTMENTS

If your local heath department (LHD) is on Twitter, does it engage followers or just serve as a 140-character encyclopedia? A recent study finds that more LHDs are using Twitter, but mostly in one-way communication with followers.

The study conducted by the *Journal of Medical Internet Research* (JMIR) researched Twitter use in the public health field. It included more than 200 LHDs nationwide, from large to small, urban to rural.

Social media use is still in its early stages, with more urban and highdensity-populated LHDs being more Twitter-savvy than rural ones.

Most tweets from LHDs focused on personal health (56.1%) or information about the organization (39.5%). Of those Tweets about personal health, the majority focused on factual information (58.5%), while about 40% encouraged some sort of action. When LHDs tweeted about their organizations, a majority talked about events and services (51.9%), while only 35% tried to engage followers in a conversation.

One-way communication is important for public health organizations during disease outbreaks and emergency situations, but the JMIR study finds that these organizations have an opportunity to engage followers at a higher level.

"Limiting social media use to one-way communication decreases its interactive capacity to engage its audience. While social media can be used to disseminate health information, it should also be used to create dialogue and engage audiences," the study states. At least one-third of LHDs used Twitter to engage their followers by using personal pronouns and other more conversational language.

The study offers tips to public health groups on how to increase Twitter engagement, including developing relationships with both organizations and individuals; increasing information about participating in programs and services; and using more original content with less tweets directing followers to other Web sites.

"LHDs may know nothing or very little about their followers unless they engage in a dialogic communication to establish relationships. To indiscriminately post information on Twitter is inefficient," JMIR states.

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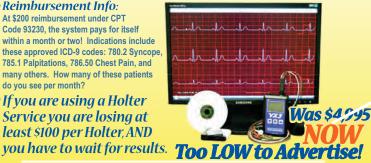
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The Last Word

THREE REASONS TO ADD BEHAVIORAL HEALTH

by ALISON RITCHIE Content Associate

More than 70% of primary care visits are related to psychosocial issues, including anxiety and depression. Although few primary care physicians currently have the resources to help patients address those issues, a new program at the Harvard Medical School Center for Primary Care may show that investing in those services is worthwhile both for the provider and the patient.

AS PART OF the Center's Academic Innovations Collaborative, six of the 18 medical practices under the center will integrate behavioral health services into their primary care facilities. The initiative is funded through a 2-year grant, and the remaining 12 sites can apply next year.

Russ Phillips, MD, director of the Center for Primary Care at Harvard Medical School, says it's not that primary care physicians don't want to screen for mental health disorders, but that they aren't equipped to deal with the findings.

"Screening is only worth doing if you have the resources within your practice to actually treat problems that you detect," he says. "Traditionally, behavioral health has been sort of marginalized, and patients have been treated separately from those with physical health concerns. But we know mental health issues present commonly in primary care and complicate the care of patients with other medical conditions. So trying to integrate those services into primary care practices makes sense."

The program creates a network of staff within the practice to actively connect with patients and to evaluate their status. It will also provide practices with social workers who can counsel patients, and mental health specialists who physicians can consult if their patients don't respond to initial treatment.

Phillips says primary care practices may benefit from offering behavioral health services in three different ways:

1. Improved patient health:

By addressing mental health issues with their primary care physician, Phillips says patients will likely see better outcomes. "Mental health disorders complicate the care of patients with any chronic medical condition, such as diabetes or heart failure," he says.

2. Reduced physician burnout:

"I have been a primary care physician for 35 years and for many of us it can feel very lonely because often we're working by ourselves," Phillips says. "We don't have resources. We have patients come to us with problems that we may not feel prepared

to address. A way that this new program will be particularly helpful is we'll also be providing trainings for teams within primary care practices to increase their level of expertise in caring for mental health disorders."

3. Reduced costs of care:

"We know treating depression can improve outcomes, which will reduce emergency room visits and hospitalizations," Phillips adds. "Oftentimes costs for patients with diabetes who also have depression are increased by about 20%. If you treat that depression, you can save that amount in addition to making patients healthier and feel better."

Even though this program is grant-funded, Phillips predicts that it will be financially sustainable over time, and he hopes that the results will encourage other primary care practices to consider offering these services.

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