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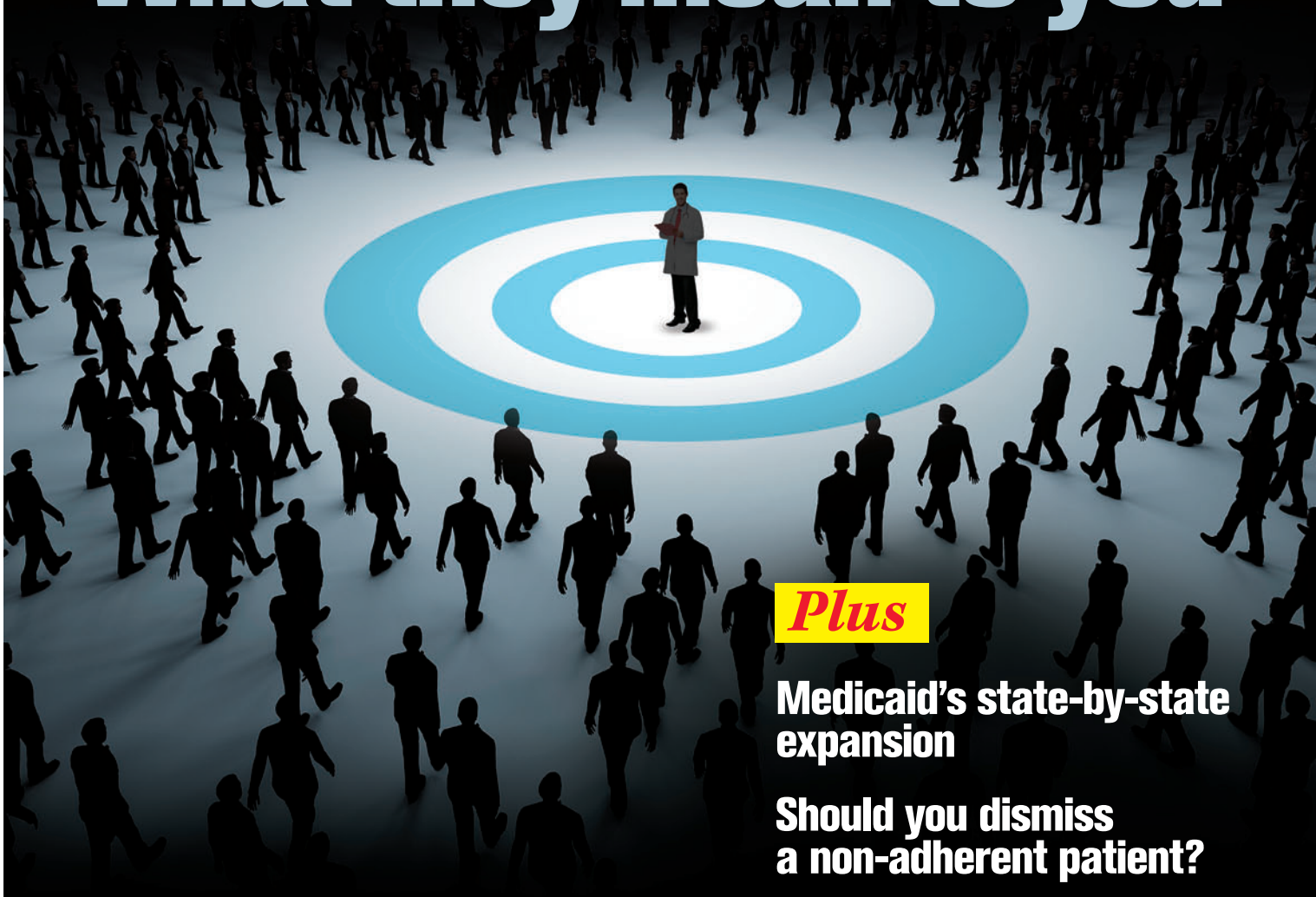

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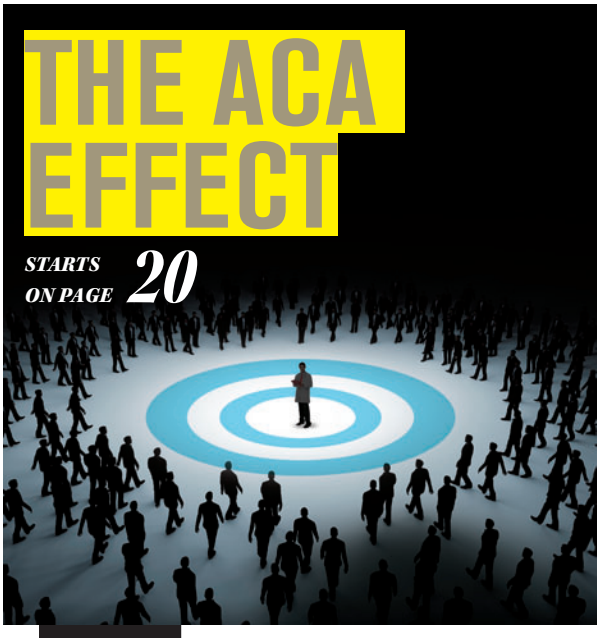

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As the health insurance exchanges ready for open enrollment, experts examine ACA's impact, potential economic gains and liabilities for physicians

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COULD ACOs INCREASE MALPRACTICE LIABILITY?

Accountable care organizations (ACOs) are intended to improve health outcomes and lower costs by bundling payments for episodes of care. But the authors of a recent article in the *Journal of the American Medical Association* argue that the cost containment element of ACOs may leave providers at greater risk for becoming targets of medical malpractice lawsuits.

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"Leasing or financing are usually the best options when acquiring equipment for home sleep studies."

—Keith Borglum, CHBC

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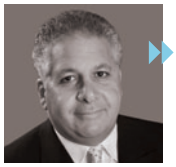

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from the Trenches

IS MOC WORTH THE TIME AND EFFORT IT REQUIRES?

In response to your excellent article on Maintenance of Certification ("MOC: Debate intensifies as Medicare penalties loom," *Medical Economics*, June 25, 2013) I would like to ask Eric Holmboe, MD, if any evidence exists to show that all the work expected of diplomates achieves better outcomes for patients and physicians. Perhaps Holmboe can consider that the American Board of Internal Medicine Foundation has written that physicians should be skeptical of studies funded by the pharmaceutical industry. Does it follow that diplomates should be skeptical of studies funded by the American Board of Internal Medicine attempting to demonstrate any value to maintenance of certification? And if there is no conclusive evidence of MOC efficacy, should all the effort, time, and money spent on pursuing MOC continue?

Also, thanks to Mark Malangoni, MD, for advising us to consider MOC as "a fact of life." Perhaps he can answer whether the lack of diplomate representation on specialty boards mandating MOC participation is not a form of taxation without representation. And perhaps he could comment on forcing diplomates to participate in this expensive, onerous, procedure of uncertain value. How would he advise diplomates who disagree with many ABMS/specialty society MOC policies to proceed?

Marc S. Frager, MD
BOCA RATON, FLORIDA

MOC LEADERS ACT LIKE A LICENSING BODY

In his letter in your June 10 issue ("MOC: We should be held to the same standards") Robert M. Kleinhaus, MD expressed his unhappiness over the fact that physicians who were "grandfathered" into permanent board status do not have to undergo maintenance of certification. But the broader issue is whether the American Board of Medical Specialities (ABMS) is justified to require MOC in the first place.

The world in which the ABMS originated (almost a century ago) and the world in which physicians practice today are vastly different. If the pressures under which physicians practice today had existed at the time when the boards were created, it is doubtful that our medical leadership would have agreed to the over-reaching influence that they exert today. As originally created, the boards were voluntary.

However, now the leaders of the maintenance of certification movement have arrogated to themselves the authority of a licensing body. This is far too much power for them. Their computer-based test, at best can only assess a part of a physician's skills, dedication, and overall capabilities.

Most physicians do participate in personalized, continuing medical education. MOC is redundant and an unnecessary burden.

Edward Volpintesta, MD
BETHEL, CONNECTICUT

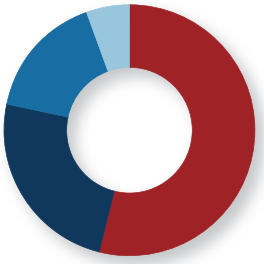
PAYERS AND GOVERNMENT NOW CONTROL PATIENT CARE

I have just read the June 25, 2013 issue of *Medical Economics*. I learned that I will be penalized for not e-prescribing. I will receive another penalty in 2015 and 2016 for not reporting under the Physician Quality Reporting System. I most certainly will never share in electronic health records meaningful use incentives. Converting to ICD-10 will most likely result in financial collapse of my practice. I learned the market value of my practice is insignificant.

It is unbelievable that our profession has allowed it's own demise. The insurance industry and government have taken complete control of the care my patients receive. This is all done with one objective, the pursuit of a dollar. Electronic health records will not help to improve care. They will provide payers and the government with information about every aspect of our practice and our patients health. Whomever controls this information and money controls all of our futures.

Mark R. Harvey, MD
SANDERSVILLE, GEORGIA

Which government regulation will be (or is) the most onerous for physicians to comply with?



- Responses: ICD-10
- Meaningful Use
- Physician Quality Reporting System (PQRS)
- Health Insurance Portability and Accountability Act (HIPAA)

From the ACA to HIPAA to PQRS, the coming months has important deadlines and new mandates affecting your practice. Find a useful guide in our July 10 cover article at http://bit.ly/1bvdadZ

> We created a privileged class of patients, empowered with endless wants. Politicians guaranteed satisfying these wants, abetted by physicians and hospitals that were happy with the easy flow of cash. It was this unbalanced equation…which has put primary care into a death spiral."
>
> **Patrick Conrad, MD,** PORT SAINT JOE, FLORIDA

SENIORS HAVE BECOME A PRIVILEGED CLASS OF PATIENTS

Kristofer Sandlund, MD's letter, "Primary Care fixes come too late" (*Medical Economics*, February 10, 2013) demonstrates precisely, if unintentionally, the greatest flaw in our collapsing system. He notes the widespread lack of interest in primary care and laments that there is no one to "pass the torch to."

Sandlund describes a growing disparity between his office overhead and what Medicare pays, resulting in seniors becoming a money-loser to his practice. He assigns the cause of this to the need to "expand my payroll to meet the ever-growing paperwork and administrative duties."

The article correctly describes the huge bait-and-switch of the 1990's, wherein promises of a stable and satisfying career in primary care actually suckered medical students into a grinding, poorly paid, paperwork, and penalty morass. I know, because I was one of those fooled. But I took away a very different lesson than that which Sandlund would teach.

Sandlund accurately describes the symptoms without acknowledging the root cause of the disease. He precedes his recitation of gloom with the observation: "Our patients over the age of 65 are those with the greatest health needs, *and in my view, they are the most deserving of quality care"* (my emphasis added).

It is that sentiment that unwittingly transformed elderly patients from individual patients to a commodity, and ultimately, to a liability in the author's own words. On what basis do we assume that seniors are the "most" deserving? It is seniors who are able to consume far more from the system then they contribute, handing the difference to the rest of us. It is their demographic that became the political bully which gave government license to force SGRs, EHRs, ICD-10, pay-for-performance, and audits threatening criminal prosecution of physicians, among other items in the rotten cornucopia that is government-sponsored compassion.

We created a privileged class of patients, empowered with endless wants. Politicians guaranteed satisfying these wants, abetted by physicians and hospitals that were happy with the easy flow of cash. It was this unbalanced equation, ignored by Sandlund, which has put primary care into a death spiral.

My solution is to first recognize this cause-and-effect as a way to salvage and rebuild. Please spare me the reflexive accusations of "hating seniors," which are merely a way to dodge the issue. What I hate is being lied to by politicians, bullied by bureaucrats, and taken for granted by those that put them in power.

Like Sandlund, I know the value of primary care as a discipline, and would like to make things better. But until we acknowledge what went wrong, we cannot put it right.

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CMS FEE SCHEDULE PLACES MORE VALUE ON WELLNESS

New Medicare codes to pay for non-face-to-face visits for patients could go into effect in 2015.

A proposal recently released by the Centers for Medicare and Medicaid Services (CMS) details two G-codes for primary care physicians for wellness and preventive care services and an expansion of telehealth services.

One code would allow primary care physicians to bill Medicare for regular physician development and revision of plan care, communication with other health professionals, and medical management over 90-day periods for patients with two or more chronic conditions.

Another code would expand billable telehealth services to include designated rural areas near urban areas with a shortage of physicians.

AAFP FIRES BACK AT THE 'CONVENIENCE CARE REVOLUTION' BEGUN BY RETAILERS

As retail clinics expand their scope of care beyond low-acuity conditions, the threat they pose to existing primary care practices grows, according to an article in the *Journal of the American Medical Association.*

"Primary care practitioners risk a slow but steady decline in their scope of care if they do not offer a viable alternative to these new convenient care options," writes Ateev Mehrotra, MD, a policy analyst with the RAND Corp. and a professor at the University of Pittsburgh School of Medicine.

To some extent, retail clinics' further encroachment into what has traditionally been primary care's territory is already happening. Earlier this year, Walgreen's announced a foray into chronic care management, assessment and treatment, including conditions such as high cholesterol, diabetes, and hypertension.

Walgreen's move didn't please the American Academy of Family Physicians (AAFP). "Our healthcare system is already fragmented, and our concern is that the expansion of retail clinics into chronic care will lower quality, increase costs, and pose a risk to patients' long-term health outcomes," says Jeffrey Cain, MD, AAFP's president.

It's undeniable that what Mehrotra calls "the convenience care revolution" is spreading. Retail clinic visits increased four-fold between 2007 and 2009 and now account for almost 6 million annual visits, he notes.

This popularity of retail clinics—and similar alternatives like urgent-care clinics and employer-based clinics—indicates that these convenient options are filling an unmet need. Previously, patients didn't have many alternatives to seeking basic care from primary care providers aside from the emergency department, Mehrotra writes.

Now, the alternative to traditional primary care providers has become big business, and that hasn't been lost on big business. At least one chain of retail clinics is backed by a venture capital firm. With 50 million annual visits at about $100 each, convenience care potentially represents a $5 billion annual market, Mehrotra notes.

RETAIL CLINIC VISITS
increased four-fold between 2007 and 2009 and now account for almost
6 million visits

And to the extent that retail clinics are able to capture more of that market for low-acuity visits, it could take business away from traditional primary care practices.

"The loss of revenue from treating low-acuity conditions could lead to increased financial pressure on primary care practitioners and emergency departments," Mehrotra says.

So what's a primary care practice to do? In a phone interview, Mehrotra offered three possible measures primary care practices could take to keep pace with the convenience care revolution.

- Offer same-day appointments
- Offer online visits
- Open up a nearby retail clinic and refer low-acuity visits there

"Most patients have a preference of going to a primary care physician, but that appointment has to be timely or they'll go someplace else," Mehrotra adds.

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LIFE EXPECTANCY IMPROVES, BUT U.S. LAGS BEHIND OTHER COUNTRIES

U.S. citizens are living longer, but an analysis of health data from 34 countries shows that the United States still trails other countries as it relates to overall health status.

The study from the American Medical Association found that life-expectancy projections rose from 75.2 years to 78.2 years during the period 1990 to 2010. Healthy life expectancy increased from 65.8 years to 68.1 years.

For life expectancy at birth, the U.S. dropped from 20th to 27th during the time period, while plummeting from 14th to 26th in healthy life expectancy.

Diseases and injuries with the largest number of years of life lost due to premature death were ischemic heart disease, lung cancer, stroke, chronic obstructive pulmonary disease, and road injury.

Also, low back pain, major depressive disorder, musculoskeletal disorders, neck pain, and anxiety disorders are the diseases with the largest number of years lived, according to the study.

Compensation top concern for most physicians, survey says

MORE THAN HALF OF the physicians questioned in the 2013 Physician Practice Preference Survey said compensation is their greatest career concern.

According to the survey conducted by The Medicus Firm, just 32.8% of physicians were satisfied with their 2012 compensation.

The rest of the physician pool reported earnings that did not match the workload, except for the minority (2.6%) that were beyond satisfied with their income.

That's causing nearly one-third (27.8%) of physicians to consider a career change, according to the survey, which accounted for a total of 2,568 physicians representing 19 specialties in 50 states.

The problem isn't just going to disappear, either.

Almost three-fourths of physicians anticipate that their 2013 income will remain about the same, or decrease from their 2012 earnings.

What's the major cause limiting income?

Thirty percent of physicians say its reimbursement; while just over 12% say the main factor limiting income is changes stemming from healthcare reform.

For these reasons, nearly one-third (30.7%) of in-practice physicians say that financial reward is the biggest single factor in making a change in practice status. While 24.2% say the quality of the practice is a viable option for change.

The practice setting that appeals to physicians the most is single-specialty group/partnership. That option accounts for 28.4% of the in-practice physicians surveyed.

Although in-practice physicians favor the single-specialty group, 28.1% of in-training physicians prefer to be hospital employed.

A hospital practice setting does appeal to the in-practice physician, though.

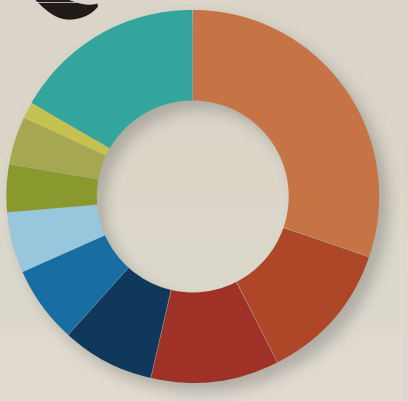
And the statistics backup that theory.

About one in every five physicians say they would prefer a hospital setting, while 24.6% of the physicians surveyed said they closed/left private practice, or plan to in 2013, for employment by hospital or health system.

Other results: 51.6% of physicians will be implementing an electronic health records system, and nearly half (44.6%) will increase working hours.

—Story by Cody Erbacher

Q Which of the following do you feel limits your income the most?



30.3%	Reimbursementd ecreases
12.2%	Changes stemming from healthcare reform
11.1%	Personalc hoice (to work less and earn less)
8.2%	Patient volume/Patient load
6.5%	Payermi x
5.5%	Overheadi ncreases
4.1%	Competition with other physicians
4.1%	Inefficiency
1.5%	Malpractice premium costs
16.4%	Other

Source: The Medicus Firm's *2013 Physician Practice Preference Survey*

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SUBLINGUAL AGENT APPROVED FOR TREATMENT OF OPIOID DEPENDENCE

The FDA approved a once-daily buprenorphine/naloxone (Zubsolv, Orexo) sublingual tablet CIII for use as maintenance treatment for people with opioid dependence. It offers an additional line of therapy to dependents and should be used as part of a complete treatment plan including counseling and psychosocial support.

Compared with other buprenorphine/naloxone treatments, this product is said to have higher bioavailability, faster dissolve time, and smaller tablet size with a new menthol taste.It will be launched in September by the company's subsidiary Orexo US, and partner Publicis Touchpoint Solutions.

Nearly five million Americans are affected by opioid dependence, and only 20% receive treatment. The average healthcare cost per patient with opioid dependence is eight times higher than nondependent patients. Annual spending on opioid dependence is about $56 billion.

For patients who experience difficulty with administration, Zubsolv will offer ease and provide the abuse-deterrent mechanism synonymous with the use of pre-existing formulations of the drug.

Orexo | 1-888-Zubsolv | www.orexo.com

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GlaceEMR v5.0 has achieved 2014 Edition Complete EHR/Ambulatory ONC Health IT Certification, designating that the software is capable of supporting healthcare providers with the Stage 1 and Stage 2 meaningful use measures required to qualify for funding under the American Recovery and Reinvestment Act (ARRA).

It was certified by ICSA Labs, an Office of the National Coordinator-Authorized Certification Body (ONC-ACB) and is compliant in accordance with criteria adopted by HHS. 2014 Edition ONC Health IT Certification is awarded to technologies capable of meeting the more rigorous testing criteria developed to support providers with Stage 2 meaningful use, focusing on the capability of health IT to deliver higher-quality patient care and exchange clinical information securely. The certification is not an endorsement by the U.S. Department of Health and Human Services.

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The ACA effect

As the health insurance exchanges ready for open enrollment, experts examine ACA's impact, economic gains and liabilities for physicians

by **SCOTT BALTIC** *contributing author*

HIGHLIGHTS

01 The theory behind Medicaid-Medicare parity is that it will make it easier for Medicaid patients (including new ones from Medicaid expansion) to get care.

02 The health insurance exchanges will allow (or compel) under the individual mandate millions of currently uninsured Americans to get health insurance for the first time.

03 The ACA will increase access to health insurance for millions of people, but it's not necessarily going to increase access to healthcare.

Ready or not, here they come. As the October 1 open enrollment deadline nears for the Affordable Care Act's (ACA) health insurance exchanges, opening healthcare access to millions of uninsured Americans, there are seemingly just as many unanswered questions about ACA's impact on physician practices in terms of costs, payer rules, quality of reimbursements, increased collections, and other issues associated with an influx of new patients.

WHILE THE INITIAL WAVE of newly insured Americans will enter the healthcare market in January 1, 2014, three ACA provisions are emerging as the most concerning to physician organizations—Medicaid parity, Medicaid expansion, and the opening of the insurance exchanges.

These mandates will allow (or compel, under the individual mandate) millions of currently uninsured Americans to get health insurance, in some cases for the first time.

People without insurance constitute

about 15% of the U.S. population, explains Bob Doherty, senior vice president, governmental affairs and public policy for the American College of Physicians.

According to the Congressional Budget Office, 25 million people will gain healthcare coverage under ACA by 2020.

So it's no surprise that many of the most urgent questions about ACA right now involve the increased patient pool that the act will provide. This report delves into the complexities of Medicaid expansion, Medicaid parity and opening of the insurance exchanges.

And while there is a great deal of attention focused on plan certification for the insurance exchanges, a plethora of unknowns remain.

OPENING ACCESS TO INSURANCE

When it comes to healthcare insurance, it's "the brave new world," Doherty says.

"The vast majority of people will continue to get medical coverage the way they already do, through insurance through their employers," he notes.

The exchanges, however, will be highly variable by state and in how many insurance products insurers participating in the exchanges will offer. For instance, he says, many insurers will take part in California's state exchange, but just two so far will be active in Alaska.

A July 2013 Robert Wood Johnson Foundation report shows that Oregon, for example, expects 11 insurers to participate in its exchange, Colorado is planning on 10, Virginia nine, Maryland six, and Rhode Island, two.

Although insurers are likely to initially stay in markets they're familiar with, there's hope that more insurers will jump into the exchanges over time.

Growth could go either way, he adds. If there are many new insurers, it might add complexity without much benefit, and/or it might break some near-monopolies in certain states.

Another big uncertainty with health insurance exchanges, says healthcare consultant Frank Cohen, principal of the Frank Cohen Group LLC: "We don't know what the rates are going to be."

No fee schedules have yet been released by health insurance exchange-participating insurers. So, as of yet there's no evidence that payments for the new influx of patients will be on par (especially over the long term) with those for the current patient pool.

"Insurance companies aren't worrying about whether physicians are making enough money," Cohen says.

Just as concerning is the economic liability to physicians when it comes to collecting for services. In a letter to the Centers for Medicare and Medicaid Services (CMS), Susan Turney, chief executive officer of the Medical Group Management Association (MGMA), is calling on government regulators to re-evaluate rules around the 3-month grace period for individuals who have not paid their premiums.

"During the first 30 days, insurers must pay for claims, but in the last 60 days they will hold claims," she says. "If the patient's coverage is cancelled after 90 days for failure to pay premiums, issuers are not required to pay any claims for services furnished in the last 60 days of the three-month grace period, which creates a significant burden on physicians who must then collect the full amount directly from the patient."

MGMA argues that as part of a real-time eligibility verification request, "it is essential for practices to have accurate, up-to-date information in order to work with patients and plan accordingly for potential liabilities associated with non-coverage."

SOME OTHER CHALLENGES

In addition, some observers caution physicians that these "new" patients might differ in important respects from their typical, current patients.

The potential clinical issues are obvious, even if, as Doherty surmises, some of these "new" patients have already been seeing primary care physicians (PCPs), at least episodically.

The larger concern, suggests Michael D. Brown, a healthcare consultant based in Indianapolis, Indiana, comes from the facts that many patients who are going into the expanded pool possibly never had insurance before, and that the ACA is perceived by many among the public as "a free ticket to healthcare."

Couple these with the common perception by patients that physicians are very prosperous, he says, and "it's a disaster waiting to happen."

Even more so than usual, Brown con-

"THE FALLOUT IF THIS DOESN'T HAPPEN WILL BE A HIT TO CASH FLOW, WHICH IS ALREADY "THE NUMBER ONE PROBLEM FOR PRIMARY CARE PRACTICES TODAY."

MICHAEL D. BROWN, HEALTH CARE ECONOMICS, INDIANAPOLIS, INDIANA

The right, and the right way, to dismiss a nonadherent patient

As healthcare reform mechanisms that tie physician payments to quality of care and to patient outcomes start to take effect, the potential will arise for patients who aren't adherent to treatment (such as by failing to take prescribed medication), or who don't make needed lifestyle changes, to harm a physician financially.

In a situation like that, a physician might easily be tempted to dismiss the patient, both because of the financial harm and because nonadherence (depending on its extent) might mean that the patient is getting little benefit from the relationship anyway.

So what are the ethics and legalities in such a scenario? It turns out they're pretty straightforward, but first we'll take a quick look at a couple of definitions.

A distinction should be made between noncompliance and nonadherence, says Reid Blackwelder, MD, FAAFP, president-elect of the American Academy of Family Physicians. To him, noncompliance "means [the patient] didn't do what I told them," while nonadherence "means they couldn't do what I told them."

In the moment, Blackwelder says, doctors need to dig into the reasons why a patient is nonadherent. Longer term, a primary care physician needs to cultivate the kind of relationship with the patient that allows him or her to explore any barriers to adherence.

THE LEGALITIES

It's also worth reviewing the difference between dismissing a patient and simply abandoning one.

"Doctors have always been able to dismiss patients, both ethically and legally, for not adhering to medical treatment, for any reason, really," as long as the dismissal follows proper procedure and is nondiscriminatory, says Alan Meisel, JD, director of the Center for Bioethics and Health Law at the University of Pittsburgh.

Healthcare attorney Lee J. Johnson, a *Medical Economics* editorial consultant, agrees that a patient can be dismissed for any reason, or indeed for no stated reason.

Doctors are required only to not abandon patients, Meisel says, but exactly what constitutes abandonment is an unclear and complicated issue: "It's really very fact-sensitive."

"If someone has medical needs, you can't just fire them," he says. For example, "Someone who is acutely ill has much more of a claim on you" than someone with a chronic condition.

What's clearly unethical, Meisel says, is abandoning a patient without making a "reasonable effort" to recommend alternatives for the patient. One aspect of those alternatives would be the geographic availability of other physicians or other appropriate specialists.

The only recent changes to these principles, he says, are those created by nondiscrimination statutes, predominantly state laws, though the Americans with Disabilities Act might provide some protections for patients.

THE PRACTICALITIES

A patient who is being dismissed should be notified in writing, says Johnson, who advises that a physician should never mention financial reasons when terminating a patient.

"If it's noncompliance that you're terminating a patient for," she adds, "document it." Areas of possible nonadherence include failure to show up for appointments, not taking prescribed medications and refusing procedures, which Johnson considers the worst form of nonadherence.

She notes that patients do have the right to refuse treatment, but strongly counsels physicians to get a refusal-of-treatment form signed every time.

cludes, practices have to emphasize educating patients about their payment responsibilities, and that means before they receive service.

The fallout if this doesn't happen will be a hit to cash flow, which Brown says is already "the number one problem for primary care practices today" and which he says has never been worse than it is now. "Doctors these days already don't do a good job of collecting money."

Farther down the road, another potential problem is the collision between patients who aren't necessarily accustomed to getting regular healthcare, and who therefore might not be adherent, and the ACA provisions that will eventually begin to tie payments to quality of care, as measured by various outcomes metrics.

Quality metrics are fine, but it's important to have metrics that work, says Reid Blackwelder, MD, FAAFP, president-elect of the American Academy of Family Physicians (AAFP).

For example, hemoglobin A1C is a good marker for diabetes control, but as Blackwelder notes, "The problem is that we don't treat A1Cs, we treat patients." Aggressive treatment of A1C, he points out, risks low blood sugar, which is dangerous—and potentially fatal—in older patients.

(For a discussion of the ethics and legal issues of dismissing a nonadherent patient, see the related story on this page.)

A CASE FOR PARITY

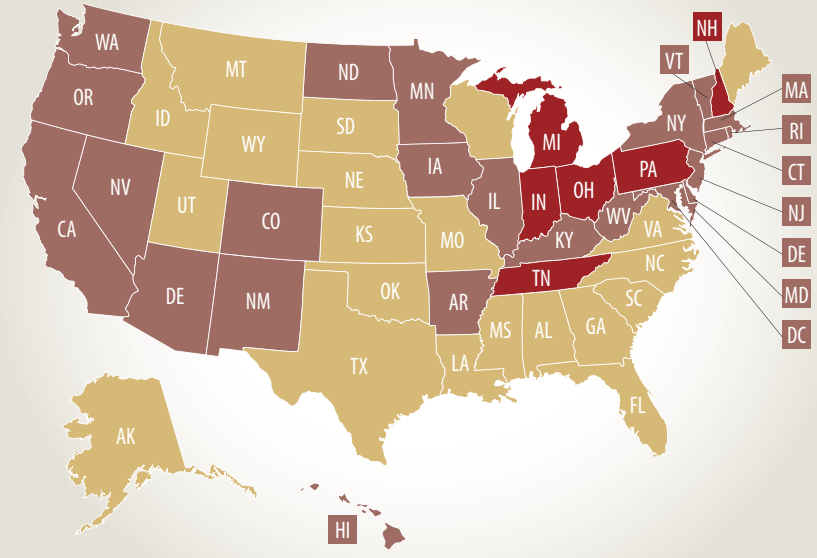
Parity between Medicaid and Medicare payments, for specified primary care services provided by certain PCPs, kicked in last January and will be effective through 2014.

The theory behind Medicaid-Medicare parity was that it would make it easier for Medicaid patients (including new ones from Medicaid expansion) to get care, says Yul Ejnes, MD, MACP, immediate past chair of the board of regents at Coastal Medical in Cranston, Rhode Island.

And he thinks the theory will become reality: "We certainly expect the pool to increase," he says.

Although this ACA provision is already in effect, states had until the end of March to file their needed documentation with CMS, and CMS in turn had 90 days to review and approve these. Only a handful of states have

State-by-state action on Medicaid expansion*



*As of July 1, 2013

Source: The Henry J. Kaiser Family Foundation

been approved so far, but in every state the increased payments will be retroactive to the beginning of 2013.

The parity payment increase is "huge," Doherty says. In California, for example, it will give PCPs a raise of 75%.

The expansion of Medicaid—in those states that approve it—is expected to have a similar effect. As of June, 26 states were on board with Medicaid expansion. (See map, this page.)

Doherty expects "a significant increase in the number of patients" enrolled in Medicaid, at least in the states that enact Medicaid expansion. And he predicts that for internists, a substantial portion of the new patient population will be Medicaid patients, especially adults without children.

MORE MIGHT BE BETTER, OR MAYBE NOT

So a tidal wave of new patients is gradually starting to arrive, and some of them might need more attention or education than a typical practice's current patients. Sounds pretty straightforward.

But all of this begs the question of whether the average primary care practice can even handle significantly more patients.

"Most internists are probably pretty much at full capacity right now," says Doherty.

He also notes that although uncompensated care might decrease, Medicaid patients might start showing up more often, posing a workload issue.

Doherty adds that because the ACA won't address the underlying physician shortage, "You're still going to have this disconnect between supply and demand."

Brown broadly agrees, saying, "Many, many primary care practices can't take on more patients…My typical practice is running in the other direction."

➔25

Cohen is more bullish, pre-

"ACA WON'T ADDRESS THE UNDERLYING PHYSICIAN SHORTAGE, "YOU'RE STILL GOING TO HAVE THIS DISCONNECT BETWEEN SUPPLY AND DEMAND."

BOB DOHERTY, AMERICAN COLLEGE OF PHYSICIANS

ACA provisions for 2014

Insurance mandate
U.S. citizens and legal residents have qualifying health coverage. The Internal Revenue Service (IRS) will enforce this provision.
Implementation: January 1, 2014

Health insurance exchanges
Creates state-based American Health Benefit Exchanges and Small Business Health Options Program (SHOP) Exchanges, administered by a governmental agency or non- profit organization.
Implementation: January 1, 2014

Expanded Medicaid coverage
Expands Medicaid to people not eligible for Medicare under age 65 (children, pregnant women, parents, and adults without dependent children) with incomes up to 133% of the federal poverty line. States may opt out of the increased income levels.
Implementation: January 1, 2014

Presumptive eligibility for Medicaid
Allows hospitals participating in Medicaid to make presumptive eligibility determinations for all Medicaid-eligible populations.
Implementation: January 1, 2014

Health insurance premium, cost-sharing subsidies
Provides tax credits and cost sharing subsidies to eligible individuals.
Implementation: January 1, 2014

Guaranteed availability of insurance
Requires guarantee issue and renewability of health insurance regardless of health status and allows rating variation based only on age (limited to a 3 to 1 ratio), geographic area, family composition, and tobacco use (limited to 1.5 to 1 ratio) in the individual and the small group market and the exchanges.
Implementation: January 1, 2014
No annual limits on coverage
Prohibits annual limits on the dollar value of coverage.
Implementation: January 1, 2014

Essential health benefits
An essential health benefits package outlining a comprehensive set of services, limiting annual cost-sharing to health savings accounts ($5,950/individual and $11,900/family). Creates four categories of plans that will be offered through the exchanges and in the individual and small group markets.
Implementation: January 1, 2014

Multi-state health plans
Requires the Office of Personnel Management to contract with insurers to offer at least two multi-state plans in each exchange. At least one plan must be offered by a non-profit entity and at least one plan must not provide coverage for abortions beyond those permitted by federal law.
Implementation: January 1, 2014

Temporary reinsurance program for health plans
A temporary reinsurance program will collect payments from health insurers in the individual and group markets to provide payments to plans in the individual market that cover high-risk individuals.
Implementation: January 1, 2014 through December 31, 2016

Basic health plan
Allows states to create a basic health plan for uninsured individuals with incomes between 133% and 200% of the federal poverty level.
Implementation: Delayed until 2015

Employer requirements
Assesses a fee of $2,000 per full-time employee, excluding the first 30 employees, on employers with more than 50 employees that do not offer coverage and have at least one full-time employee who receives a premium tax credit. Last year, the Internal Revenue Service issued proposed regulations on the Employer Shared Responsibility provisions.
Implementation: Delayed until January 1, 2015
Medicare Advantage plan loss ratios
Requires Medicare Advantage plans to have medical loss ratios not lower than 85%.
Implementation: January 1, 2014

Wellness programs
Permits employers to offer employees rewards of up to 30%, potentially increasing to 50%, of the cost of coverage for participating in a wellness program and meeting certain health-related standards; establishes 10 state pilot programs to permit participating states to apply similar rewards for participating in wellness programs in the individual market.
Implementation: Changes to employer wellness plans effective January 1, 2014; 10-state pilot programs established by July 1, 2014

Quality of care
Tie physician payments to the quality of care they provide. Physicians will see their payments modified so that those who provide higher-value care will receive higher payments than those who provide lower-quality care.
Implementation: January 2015

Source: Kaiser Family Foundation

➔23 dicting of the ACA that, "it's going to increase access to health insurance for millions of people, but it's not going to increase access to healthcare."

Some people already wait weeks to see a doctor, he notes, and "a lot of physicians are not going to accept those [new] patients."

Other practitioners are more optimistic, however. Ejnes says that although he personally is not taking new patients for a while, except for family members of current patients, Coastal Medical has been planning to grow, if not through additional physicians, then through adding midlevels.

One of the reasons to be cautious about adding capacity, Ejnes says, is that the Medicaid-Medicare parity is temporary.

Coastal Medical is also looking at ways to increase the number of patients "seen" without increasing the actual number of visits, such as through telephone care. The practice has been a Patient-Centered Medical Home (PCMH) for 3 years, Ejnes says, adding that the PCMH model supports payments for patient contact that takes place outside the office.

"'Access' doesn't necessarily mean seeing more patients," he says.

Blackwelder, too, is upbeat about primary care practices' ability to adapt to an increased patient pool.

According to the AAFP's most recent Practice Profile Survey, he says, "Seventy-three percent of our members are available for same-day care," with a significant number available after hours.

"We have to learn how to transform our practices," Blackwelder says, using models like the PCMH; technologies like electronic health records and patient portals, which help reduce the burden of face-to-face time; and team processes like having well-child visits handled by a midlevel.

WHY IT'S WORTH THE EFFORT

There's an old saying that when you're neck-deep in alligators, it's easy to forget that you originally started out to drain the swamp.

This has been a snapshot of where some significant parts of ACA implementation stand as of mid-2013. But it also makes sense to step back for a moment and remember why all of this is happening.

Blackwelder stresses that healthcare reform is "really important for the health of our nation" and that having healthcare coverage lets patients tap into "a routine source of care" and helps minimize "high-cost, poor-outcome care" in emergency departments.

"We're just spending money smarter," he sums up, and that helps the healthcare system work toward the triple goal of improved outcomes, decreased cost, and better coordination of care.

"The purpose of the ACA is to get people health insurance coverage," Doherty says, and that leads to better health outcomes. ■

Will The Delay of the Employer Mandate Affect Your Business?

Some small businesses now have until January 2015 to offer insurance to employees due to a 1-year delay of the employer mandate requirement of the Affordable Care Act (ACA). Employers with 50 or more full-time employees would have faced up to a $3,000 fine for each employee who wasn't offered insurance, starting in January 2014.

The delay stems from efforts to simplify the reporting process and give small business owners a chance to test systems, according to a July 2 blog post on the U.S. Treasury department Web site. "Real-world testing of reporting systems in 2014 will contribute to a smoother transition to implementation in 2015," the blog states. Additional details about the simplified reporting requirements for insurers and employers who already comply with employer mandates will also be released this summer.

Though the employer mandate portion of the ACA has been a hot-button issue, the delay shouldn't cause a big ripple for businesses and patients, says Bob Doherty, senior vice president, governmental affairs and public policy for the American College of Physicians.

"A 1-year delay is not likely to cause larger employers who are currently offering coverage to discontinue it and leave their employees uninsured or shift them to the exchanges," Doherty says. "It will allow employers subject to the mandate another 12 months to make sure that their health plans are up to par with the federal requirements before the mandate kicks in, and for larger employers who do not offer coverage another year to obtain qualified coverage. In the meantime, many smaller employers (50 or fewer) will be eligible for tax credit subsidies to help them afford coverage."

The employer mandate portion of the ACA affects only a sliver of small businesses—about 94% of businesses that have more than 50 full-time employees are already offering them health-care benefits, according to a 2012 survey by the Henry J. Kaiser Family Foundation.

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Collaboration: a key to small practice survival

While uncertainty around ACA is fueling pessimism, sound business strategies can help your practice thrive

by **NANCY GROVES** *Contributing Author*

HIGHLIGHTS

01 Maintaining an independent practice is becoming harder with mounting changes in healthcare.

02 IPAs, ACOs and Patient-Centered Medical Homes are different ways to partner with area healthcare providers.

03 Special attention to practice operations and patients can help maintain a personalized experience, even if you are part of a group.

If there's a word that solo or small practice physicians would choose to describe their future, it would be uncertainty. What will happen when the Affordable Care Act (ACA) is implemented? Will previously uninsured patients flood your office? Can you afford a new or updated electronic health records (EHR) system?

What will be the impact of the International Classification of Diseases-10th revision? Should you find a partner, hire midlevel practitioners, join a larger group or independent practice association (IPA), sell the practice?

Opinions on the survival of small and solo practices are mixed. It's evident, however, that the number of independent practices has been declining. A report on practice characteristics released by the American Academy of Family Physicians (AAFP) showed that as of the end of 2011, 60% of physicians who were active AAFP members were fully employed by hospitals or health systems, physician groups, or university-owned clinics or hospitals, while 35% were sole or partial owners of their practices.

Search firm Merritt Hawkins reported that in 2010-11, 56% of its physician search assignments were for hospital positions, up from 23% in 2005-06, and the percentage may be higher now.

Trends driving this shift in practice models include the top five issues affecting physicians in 2013 identified by the Physicians Foundation: ongoing uncertainty over the ACA, consolidation, the introduction of millions of newly-insured patients, erosion of physician autonomy, and growing administrative burdens.

In less than 6 months, an estimated 30 million Americans could begin obtaining health insurance coverage under the ACA. The details surrounding implementation, including aspects such as the insurance marketplace, accountable care organizations (ACOs), the Medicare physician fee schedule, and the independent payment advisory board, frustrate physicians as they ponder their fate.

HOPE IS NOT A STRATEGY

"Many small practices don't have a great strategy. They're hoping to survive, but the amount of uncertainty out there around the ACA is huge," says Ripley R. Hollister, MD, a family practitioner in Colorado Springs, Colorado and board member of the Physicians Foundation. The organization's 2012 Biennial Physicians Survey of nearly 14,000 doctors found that about 77% were pessimistic or very pessimistic about the future of the medical profession.

You can respond to these challenges with a variety of strategies or models to remain in private practice. For his part, Hollister chose to join an IPA made up of nine small practices with about 22 providers. The practice is not

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alone. In fact, there may be up to 500 IPAs in each state, according to recent reports from the American Medical Association, and the numbers seem to be growing. Why?

"Small practices can't really survive as such," says Hollister. "Small practices are going to have to look bigger at some level, but there are ways of looking bigger like IPAs where you have a larger population of patients to manage, you have a larger pot of money to help with patient education and healthcare management team members, case managers, social workers. It would be hard for a very small practice to hire a social worker, for example, but in an IPA where you have groups of like-minded physicians you could go out and do some of those things that make you look very big."

Further, an IPA is better positioned to enter into financial arrangements with insurance companies that are interested in improving population health and reducing costs and are therefore more willing to help practices offset the cost of data collection, says Hollister. You might get paid, for example, to look at rates of colonoscopies, mammograms, or pap smears.

"There have been some real dollars coming across in contracts from insurance companies to look at those sorts of things," Hollister says.

ANTITRUST CONSIDERATIONS

There are also legal issues to consider.

Many IPAs could face antitrust issues because they include competing healthcare providers, says Peter Pavarini, partner at Squire Sanders LLP in Columbus, Ohio, and president-elect of the American Health Lawyers Association. "There are no fixed limits on IPA size; however, Federal Trade Commission and Department of Justice guidelines and policy statements define safety zones in terms of percentages of competing physicians (by specialty) who are included in an IPA, ACO or other kind of provider networker. Non-exclusive networks can generally be larger than exclusive networks," Pavarini says.

You should check with legal counsel before signing on to an IPA to make sure it abides by antitrust and price fixing laws and management fees are reasonable, says Alan S. Gassman, JD, of Gassman Law Associates P.A. in Clearwater, Florida. "In many states (IPAs) are not regulated and can go belly up, leaving the doctors high and dry and not paid for services rendered," Gassman says. "IPA participation agreements can often be negotiated, so don't just sign these or accept a certain rate of compensation without having someone knowledgeable in the area read, negotiate and explain these. You can't get what you don't ask for."

"I'M A BIG FAN OF THE MEDICAL GROUP BECAUSE I THINK THAT THEY ARE HELPING US."

—LLOYD KURITSKY, DO
SAN DIEGO, CALIFORNIA

San Diego, California internist Lloyd S. Kuritsky, DO, who has been in private practice as a family physician since 1992, has also opted for the IPA model. His practice is aligned with the Sharp Community Medical Group, which in turn is part of an ACO.

"I'm a big fan of the medical group because I think that they are helping us. It would be really hard to be out in private practice these days," Kuritsky says. "The way I think about it is that it would almost be like being out in the middle of the ocean on a raft, whereas I feel like we're on a more solid ship that can help us navigate the waters."

A growing number of IPAs are converting to ACOs, a model that requires a more formal legal, management, and leadership structure. ACOs must have shared savings among participating healthcare professionals and meet Medicaid patient-centerdness criteria. Currently there are more than 250 ACOs, with 106 being approved by the Centers for Medicare & Medicaid Services (CMS) in January 2013.

Despite the IPA's help, survival is constantly on Kuritsky's mind. He and his partner haven't stopped seeking ways to trim expenses. They have relocated their practice several times, looking for a site with lower overhead and rent. He employs a nurse practitioner 2 days a week and will consider increasing her hours next year if the anticipated influx of newly insured patients materializes.

THERE MAY BE UP TO

500 IPAs IN EACH STATE

according to recent reports from the American Medical Association. And the numbers seem to be growing.

> "I'M LIKE AN OLD-TIME DOCTOR. I HAVE THE BEST PRACTICE EVER, AND THIS IS SOMETHING THAT WE SHOULD ASPIRE TO RETAIN."
>
> —MADALYN DAVIDOFF, MD
> MACON, GEORGIA

OTHER FORMS OF COLLABORATION

Less structured collaborations can also help small practices weather transitional times. Jennifer Brull, MD, a family practitioner in rural northwest Kansas, is a member of a group of six small or solo practices that initially collaborated on staffing, billing, and purchasing, and have progressed to jointly purchasing and implementing an EHR system and attesting to meaningful use. They recently submitted documentation for recognition as a Patient-Centered Medical Home.

"We have done things as a group even through we all like to maintain our independence as solo practices," says Brull. The group has three locations in the county, an arrangement that lowers staffing costs since personnel can be shared. The collaborative approach was also beneficial with EHR implementation; the learning curve struck the offices at different times, and those who had gone through it could share what they had learned.

The collaboration offers flexibility in scheduling, Brull says. For example, an individual's decision to take a few days or even a few months off won't adversely affect the finances of the group as a whole. "My time is my own, and I'm the one who has to be worried about my share of the expenses," she says.

To make this model work, she recommends being open and willing to discuss the details, particularly finances. However, she advises partnering on various projects, as her group does, rather than viewing the arrangement strictly in monetary terms. This fosters the feeling of a group with shared interests and goals.

This style works well for Brull, who says she is not facing insurmountable obstacles. "I really don't feel like I'm surviving; I feel like I'm thriving. Sometimes we paint a bleak picture. At least where I am and the culture I'm in, it hasn't been difficult or challenging, it's been good."

Solo cardiologist Madalyn N. Davidoff, MD, who practices in Warner Robins and Macon, Georgia, is enthusiastic about her practice style while acknowledging the stress that comes with it. "I'm like an old-time doctor. I have the best practice ever, and this is something that we should aspire to retain. I proctor students and residents, and they always tell me that I'm one of the only happy doctors they encounter," she says.

Davidoff both participates in efforts to educate legislators about the unintended consequences of prior authorization, limits on the frequency of certain tests, and prescription formularies—which, if changed, could benefit small practices—and takes action at the practice level.

She recommends staying in the forefront of technology and trends, such as EHRs and e-prescribing. Davidoff also emphasizes a "lean and mean" attitude toward practice operations. The electronic receipts are deposited in her account every day, and she reviews them before passing them on for billing. "I watch everything like a hawk," she says.

LOOK AT REVENUE

You also need to have systems in place to make sure you are paid fairly for everything you do. Davidoff has trained her staff to be exceptionally diligent about precertification, asking questions, having patients sign releases, and sending for records from other practices, which pays off in terms of a very low rate of denials.

Another helpful strategy is pursuing the incentives offered for complying with a new mandate, such as meaningful use or quality reporting. "While the healthcare delivery model is being defined, go out for every bit of incentive money that you can use to help you solidify your practice and your income until you know what's going on," Davidoff recommends.

You can also explore relationships with hospitals that could lead to payment for responsibilities that are not currently reimbursed. Hospitals ➔30

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"IT'S A WHOLE NEW PARADIGM, AND ALTHOUGH IT'S NOT EASY TO GET USED TO, ONE CAN SEE THE BENEFITS IN THE ORGANIZATION, SO ONE MUST ADAPT."

REBECCA JAFFE, MD, MPH, FAAFP
WILMINGTON, DELAWARE

➔28 have begun acknowledging the burdens placed on physicians by providing indigent care and quality reporting requirements and are offering to share the load. "There is no real independence for physicians who have any hospital work," Davidoff says. "We have to do this together."

She also copes with the demands of a solo practice by being overbooked by eight to 12 patients a day and is willing to keep up that pace for now. Decisions about a new work environment will wait until there is more clarity on how healthcare will be delivered and the outcomes of innovative pilot projects are known.

If your dream practice model runs in the opposite direction of the trend toward larger groups and employment, solo family practitioner Pamela Wible, MD, in Eugene, Oregon, has adopted a style you might consider. Based largely on community input, she established her own clinic in 2005, operating out of an intimate, homelike setting and working part-time. She spends up to 1 hour with each patient and sees only one at a time rather than have patients "stacked up" in exam rooms.

With no employees, Wimble does all the tasks performed in even the smallest practices by a nurse or medical assistant. She also handles billing and coding. When patients have difficulty with payments, Wible is more likely to ask them to give something back to the community than call a collection agency.

"People want a humanized experience," Wible says, and her patients reward her not only with payment for medical services but "tips." Cash or checks are sometimes tucked into a holiday card, a bonus for her attentive approach.

However, she doesn't accept Medicare and therefore is not bound by its many regulatory requirements.

BE FLEXIBLE, ADAPTABLE

Rebecca Jaffe, MD, MPH, FAAFP, of Wilmington, Delaware, has seen the pendulum of healthcare trends swing in many directions in more than 30 years as a family practitioner. "But this time, especially in the electronic era, I'm not sure the pendulum will swing back again," she says. "It's a whole new paradigm, and although it's not easy to get used to, one can see the benefits in the organization, so one must adapt. But it is a very expensive endeavor to do it correctly, which is probably the biggest struggle as a very small practice, doing it right and not having lots of providers to share the cost involved."

Jaffe and her two colleagues have been talking to other small practices to see if sharing resources might help with managing EHR as well as other complex facets of their work. For example, purchasing immunizations through a consortium might have benefits.

HOLD ONTO AUTONOMY

Like many of her peers, Jaffe is trying to figure out how to manage a larger patient base while not losing the feel of the small, independent practice. "It's daunting to put your trust in other people when you've independently navigated the waters for so long," she says.

As she waits to see how the future unfolds, she recommends keeping communications open with other healthcare providers in your community, including hospitals. In this way, you can learn about new opportunities, gather enough information to make good decisions, and learn strategies for negotiating in a changing environment.

"It's helpful to share best practices and keep up with other physicians' experiences," says Jaffe. "We have to learn from other peoples' mistakes, otherwise we might not survive." ◘

@ MORE RESOURCES

6 steps you can take to remain independent
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Do you have the urge to merge?
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How a manufacturing process transformed healthcare delivery

Adopting new management techniques cut patient wait time, improved physician availability and practice revenue

by **DENNIS P. HAN**, *MD*

HIGHLIGHTS

01 We used 5S workplace efficiency principles to make the practice user-friendly and redefined staff roles to allow multitasking or providing "just in time" value-added service.

02 A physician's willingness to try new things and be flexible is critical for the Lean transformation to occur. This can be the biggest challenge.

Let me tell you how "Lean," also known as the Toyota Production System, transformed my clinical practice from a hectic, stressful, and unpredictable experience to one that runs smoothly and became a paragon of efficiency, safety, and quality.

I used to have both good days and bad days in our clinic. On good days, my patients were seen in a timely fashion, they smiled when I entered the exam room, and the clinics ended on time. On bad days, patients waited a long time, clinic flow was disrupted by unpredictable events, and there were frequent interruptions in my care of patients.

Despite working as quickly and as continuously as possible, I would be greeted with frowning patients to whom I offered numerous apologies for delays that were out of my control. I became good at excuses like, "We've had some emergencies," or "We are down a few staff people today," or "Sorry, that last patient had some serious problems that took some time to sort out." Some were true and others were wishfully so. Either way, it affected the whole physician-patient interaction. Does this sound familiar to you?

For the past 25 years, I have tried to remedy these problems. Despite attempts at adjusting scheduling templates and improving efficiency of various clinic steps, we failed to achieve any breakthrough in changing the patient experience. This, despite my clear understanding of some of the challenges we faced. These included (1) having patients with problems of varying complexity that required different tests and evaluations of various durations, making patient flow problematic; (2) encountering factors outside of my direct control such as scheduling, personnel pay structures, and job descriptions; and (3) the frequent problem of add-on patients for whom I was frequently consulted as to where they should be placed in the clinic schedule. (I was later to find out the physician is probably the worst person to consult for this on a properly functioning clinic team.)

REVELATORY AND TRANSFORMATIVE

I was skeptical when approached by our business administrator with the suggestion that we attempt a "Lean transformation." I had heard of Lean as it applied to manufacturing processes. But I was unaware of its application to healthcare delivery. So began a journey that was a revelation to me and trans-

formative to my medical practice.

What is "Lean?" It is a manufacturing approach that considers the expenditure of resources for any goal other than the creation of value to be wasteful. In healthcare delivery, "value" can be defined as those steps that potentially improve patient health, such as physician-patient face-to-face time, technician time, or image acquisition time. Patient wait times are a key metric in determining how efficiently a practice is run and is an indicator of the amount of "waste" in the process.[1]

> "PATIENT WAIT TIMES ARE A KEY METRIC IN DETERMINING HOW EFFICIENTLY A PRACTICE IS RUN AND IS AN INDICATOR OF THE AMOUNT OF 'WASTE' IN THE PROCESS."

I soon learned that Lean principles do not just apply to manufacturing, but any process that attempts to add value. The Lean "toolbox" includes value stream mapping, the use of 5S principles (sort-stabilize-shine-standardize-sustain), visual cues, spaghetti-diagrams to eliminate wasted movement, and "just-in-time" resource delivery. These tools are critical to taking waste out of a process.

Using these tools, we markedly reduced patient changeover time, characterized in my clinic as wasted physician activity that did not add to healthcare "value." These included activities such as excessive documentation time, completing billing forms, searching for supplies, giving directions on where to get scheduled for tests or the next appointment, etc.

Eliminating these activities maximized my time available for direct interaction with the patient, and relieved the bottleneck effect of unproductive physician activity. We established a team leader position, assumed by a lead technician (notably NOT a physician) who worked with schedulers to ensure that patients were scheduled at appropriate times so that there were no delays predestined from the start. We enhanced visual communication through the use of a clinic whiteboard depicting where each and every patient was located in the process, allowing the team leader to level workflow to the physician and provide him or her a steady menu of tasks but without the backups.

EFFICIENCY PRINCIPLES WORK

We used 5S workplace efficiency principles to make the practice user-friendly, and redefined staff roles to allow multitasking for either technical tasks or providing "just-in-time" value added service. This meant relocating our imaging specialists (ancillary staff) to a workspace closer to patient exam rooms to reduce excessive movement ,and removing two small divider walls in our clinic to enhance our visual cues as to when changeover activity begins.

Despite the same size clinic footprint, each of two doctors in this area now has added space within which his own core team can coordinate his clinic without interference from others. We did all this by engaging the workers in a nonhierarchical "bottom-up" fashion, allowing them to use their own observations and skills to improve flow in ways no physician alone could imagine.

So what happened in my practice after these changes? One patient stated to me that "this is the first time that I was seen so quickly and efficiently in the 20 years that I've been coming here." Just this week, my technicians overheard a patient in the lobby say at 11 a.m., "Now's about the time of day when doctors get behind and we have to wait." My team's sentiment: "Not in Dr. Han's clinic!" My patients are uniformly seen in a timely fashion and our clinics always end on time.

NUMBERS TO BACK IT UP

Are these changes real? We have the numbers to prove it. Our patients have experienced an 85% reduction in non-value added patient wait time, a "top box" patient satisfaction rating in 97% of our responses ("strongly agree to recommend this doctor's office to others"), a 25% year-over-year increase in relative value units production and 41% increase in payments due to increased physician availability.

By eliminating numerous wasted steps, I now have more time to spend face-to-face with my patients, and my technicians are not rushed through important quality procedures. We work deliberately, steadily, and with fewer interruptions or periods of high stress that can lead to missed steps and errors. My patients are happier and I have the opportunity to provide the best care I know how to give.

In an institutional setting, these accomplishments cannot be obtained through the efforts of a single entity or group, nor mandated from upper level management. A Lean transformation requires buy-in from persons at both administrative and operational levels. It requires full administrative support from the authority that holds the purse strings, be it the lead physician practitioner in a private setting, or the head of a major healthcare institution. Why?

In our practice, changes such as redefining workers' roles required authoritative instruction for creativity in the human resources area—it was appropriate to incentivize and reward persons who took on the role of a team leader. Small outlays for minor infrastructure changes yielded major benefits, but they also required support from those in authority to pay for them. It also meant engaging someone familiar with implementation of Lean tools in the healthcare setting. This can be an outside consultant or someone with expertise internally. Finally, at the operational level, a core team of workers (the doctor and his helpers) must be educated in "lean thinking" and must be motivated to search for opportunities for improvement, then implement them and sustain those gains.

THE BIGGEST CHALLENGE

A physician's willingness to try new things and be flexible is critical for Lean transformation to occur. This can be the biggest challenge. I've found that most physicians tend to agree consistently with only one person—themselves. And because the physician has historically been considered an authority figure, his or her mandates can inhibit the process of engaging all workers in a nonthreatening and emotionally safe manner. Nevertheless, the physician should be assured that he or she won't be asked to change medical management without good medical evidence upon which to base such a request. Changes are approached without fanfare, but with a spirit of empiricism, because new ways seem unnatural until they become old.

Though physicians are knowledgeable in the science of patient care, they are largely ignorant of the science of patient care delivery. These concepts are taught at engineering and business schools, but not at medical schools. Yet they contain elements critical for providing excellent healthcare delivery.

Unless you are knowledgeable in terms like value stream mapping, standard work, 5S, "takt" time (available production time per day divided by customer demand per day) and cycle time, percent load, event dependency, and theory of constraints, you are unaware of important concepts in the science of value-added processes, healthcare being the one we as physicians are charged to lead.

In what settings can a Lean transformation occur? It can work in large institutions, small private practices, and everything in between. For institutional practices, a major strength is that it can cross departmental lines to transform delivery from that of being "service-centered," in which patients are shuttled from one service type to another, to being "patient centered," in which the services are centralized spatially or logistically around each patient. For example, we are trialing placement of frequently-used retinal imaging instruments within the physician exam room pod to reduce wasted patient movement.

"Lean" can also help to revamp staffing to match worker skill levels to appropriate tasks. We had some workers who were unmotivated or lacked sufficient organizational skills to be team leaders. We could objectively identify such persons and move them to positions more suited to their abilities.

> "THOUGH PHYSICIANS ARE KNOWLEDGEABLE IN THE SCIENCE OF PATIENT CARE, THEY ARE LARGELY IGNORANT OF THE SCIENCE OF PATIENT CARE DELIVERY."

FAILURE NOT OFF THE TABLE

Attempts at Lean transformation can fail. Usually key steps are omitted, such as value stream mapping to systematically identify waste. Intuition alone is not effective, nor will key players agree on where the waste is occurring. For example, we had not realized how much time our imaging specialists spent walking to process patients until we timed their movements with a stopwatch. Our measurements indicated that they each

walked about 80 hours per year in total—2 work weeks per year of totally wasted time. They had no idea because they were used to it. A cause of failure is attempting to apply efficiency measures too broadly without concentrating on an individual process. It is important to concentrate on one doctor's practice at a time.

Another reason for failure is the absence of high-level institutional support, as mentioned above. Achieving a Lean transformation also will be a distinct challenge unless you choose individuals who are motivated to succeed and provide a shining example to less enthusiastic coworkers who may eventually "see the light." Finally, a Lean consultant with experience in a healthcare setting is essential because no other process in the manufacturing world encompasses the unpredictability of illness and humanistic aspects of patient care.

RETURN ON INVESTMENT

What are the economics of implementing Lean? Its main expense includes the cost of the consultants or internal expertise, and the need to take workers off-line to learn Lean concepts and collaborate on process improvement. In my practice, this was done one-half day twice a month over a period of 10 months, each session of which was quickly followed by a trial of Lean practices in a live clinic.

For a typical medical practice, return on investment (ROI) is estimated to be two to 10 times the expense (100% to 900% ROI), depending upon the operating margin of the practice or process, and market demand. Notably, we have not increased staffing and have, in fact, reduced the number of exam rooms and waiting area needed given our increased efficiency and throughput. But most importantly, Lean processes provide my staff and me the satisfaction of delivering excellent care to patients and hearing their expressions of gratitude.

REFERENCE

1. Suneja A, Suneja C, Lean Doctors, 2010, ASQ Quality Press, Milwaukee. ISBN 978-0-87389-785-3.

The author specializes in ophthalmology in Milwaukee, Wisconsin.

From the Lean Toolbox:
The 5 S's to guide your practice

SORT

Keep only essential items and equipment. Place them in accessible locations. Store or discard everything else.

SHINE

Ensure your office is clean and organized.

STABILIZE

Organize your office staff, work flow, and equipment to maximize value-added tasks.

STANDARDIZE

Ensure and establish uniform procedures throughout your practice.

SUSTAIN

Enforce adherence to office procedures and policies by the staff to prevent backsliding.

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

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

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS and PRECAUTIONS

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

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

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In adults with type 2 diabetes,

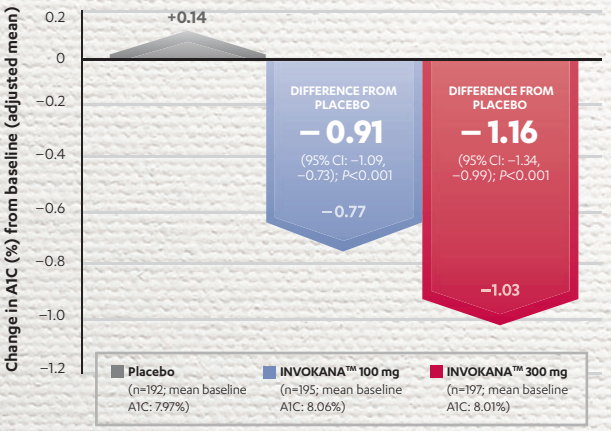
ENVISION NEW POSSIBILITIES

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

A1C Reductions as Monotherapy

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

A1C Change From Baseline With INVOKANA™ Monotherapy[1]



Effect on Weight*

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

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

Impact on Systolic Blood Pressure (SBP)*

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

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

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

***Prespecified secondary endpoint.**

†Adjusted mean.

A1C Reductions vs Sitagliptin

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

» Difference from sitagliptin†: −0.37%

Incidence of Hypoglycemia

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

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

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

Convenient Once-Daily Dosing[1]

» Recommended starting dose: INVOKANA™ 100 mg

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

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

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

Learn more at INVOKANAhcp.com/journal

Invokana™
canagliflozin tablets

WARNINGS and PRECAUTIONS *(cont'd)*

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

DRUG INTERACTIONS

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

USE IN SPECIFIC POPULATIONS

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

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

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

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

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

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

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

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

OVERDOSAGE

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

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

ADVERSE REACTIONS

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

K02CAN13149

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

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canagliflozin tablets

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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 m^2), end stage renal disease or patients on dialysis *[see Warnings and Precautions and Use in Specific Populations]*.

WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

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

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

ADVERSE REACTIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***** Week 26 in mITT LOCF population

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

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

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

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

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

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

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

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

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies

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

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

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

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

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

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

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

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

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

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

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

DRUG INTERACTIONS

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

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

USE IN SPECIFIC POPULATIONS

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

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

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

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

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

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

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

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

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

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

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

PATIENT COUNSELING INFORMATION
See FDA-approved patient labeling (Medication Guide).

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

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

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

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

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

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

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

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

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

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

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

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

Active ingredient made in Belgium

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

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

Licensed from Mitsubishi Tanabe Pharma Corporation

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Networking: a vital part of a job search

WHILE the adage "It's not what you know; it's who you know" doesn't always apply, networking can play a vital role in a physician's career search. But the methodology is changing, says Allan Cacanindin, senior executive vice president of client services for the physician recruitment firm Cejka Search.

Whether physicians network online will likely depend on their age, Cacanindin says it behooves young physicians to meet in person.

"Seasoned physicians seem to have more face-to-face interactions, whereas folks who are just coming into medicine today are more likely to engage online," he says.

LinkedIn remains the leading online network among general business professionals, but Cacanindin recommends that physicians join networks targeted specifically to the healthcare field, such as Sermo and Doximity.

Cacanindin also suggests when networking with other physicians, always ask these questions:

- **Who do you know that best practices your specialty?**
- **Where's the best place you've heard that has…?**
- **What are the best attributes of your current place of practice?**

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RESTRICTIVE COVENANTS
What they cover, how they are enforced [43]

Money

Treating sleep disorders can wake up your bottom line

New diagnostic technologies spell opportunities for improving patient health while bolstering revenue

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

HIGHLIGHTS

01 Obstructive sleep apnea, the most common kind of sleep disorder, has been linked to hypertension and diabetes, among other diseases.

02 Obtaining board certification in sleep medicine enables a primary care physician to bill for the administration and interpretation of home sleep tests, as well as for CPAP initiation and management.

Approximately 20 million American adults are thought to experience symptoms of sleep disorder, primarily obstructive sleep apnea (OSA). That prevalence of sleep problems, combined with a growing array of user-friendly devices for conducting home sleep tests, represents an opportunity for primary care physicians (PCPs) to add a new income stream and improve the quality of life for many of their patients.

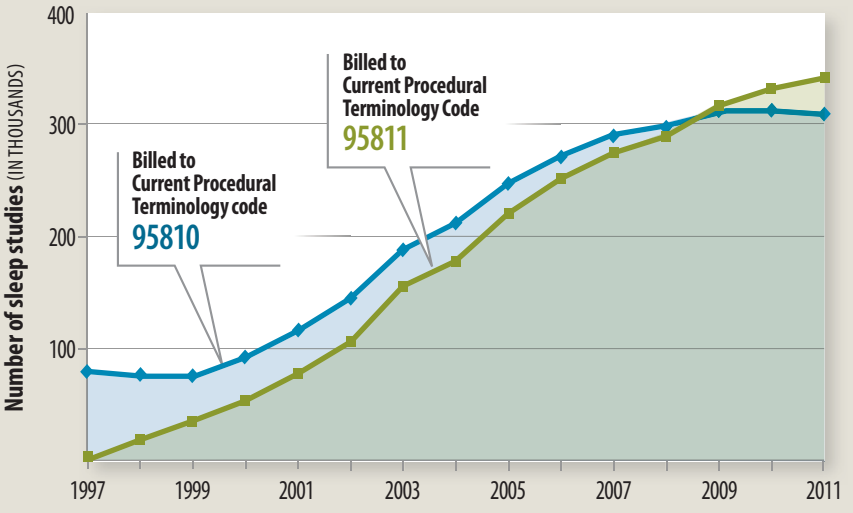
AT THE SAME TIME, experts and physicians with experience in the field warn that it's important to be aware of the pitfalls surrounding sleep testing and treatment. For example, training and licensing requirements for reading the results of sleep tests differ from state to state, and the coding and billing for sleep testing services can be tricky. And as with any ancillary service, you need to be sure you have a sufficiently large patient base to make it profitable.

Nonetheless, the trend—and opportunity—are apparent. The prevalence of sleep disorders has been growing in recent years. According to a National Ambulatory Medical Care survey, physician office visits for sleep apnea rose from 2 million in 2000 to 3.7 million in 2009, an increase of 85%. The percentage increases in visits for insomnia and narcolepsy were even greater—137%

and 133%, respectively. In addition, a growing body of research links OSA to conditions such as hypertension, diabetes, depression, and obesity.

Although no specific data exists regarding the number of PCPs offering diagnosis and treatment for sleep disorders, internal medicine physicians account for about 9%, and family practice physicians about 2% of the in-laboratory diagnostic sleep studies billed to Medicare.

Growth in sleep studies 1997-2011



Source: American Medical Association's RBRVS Data Manager, 2012

BENEFITS OF HOME SLEEP TESTS

PCPs cite a variety of reasons for the decision to offer home sleep testing services to their patients. Jack Maxwell, DO, got interested in sleep disorders about 8 years ago, largely because of their link to chronic conditions such as hypertension, elevated cholesterol, and diabetes. His interest led him to become board-certified in sleep medicine, a relative rarity among family practitioners. Today his eight-provider practice in the Dallas, Texas suburb of Lewisville orders 80 to 100 sleep tests each year.

Because he is board-certified, Maxwell is qualified to interpret the results of home sleep tests, and thus able to bill for all three components of the testing process—test administration, interpretation, and CPAP initiation and management. Consequently, he says, each patient treated for sleep disorders brings about $1,500 in revenue to the practice, compared with approximately $360 for other patients.

Some patients initially resist taking a sleep test or using CPAP, but Maxwell usually is able to persuade them. "A lot of it is salesmanship," he says. "You start talking about how the heart is damaged by long-term obstructive sleep apnea, and they get the picture pretty quickly. And I've been in practice long enough (26 years) that my patients trust me and will go in the direction I try to steer them."

For PCPs thinking of offering sleep disorder diagnosis and treatment as ancillary services, Maxwell advises including sleep-related questions as part of the screening process for routine medical care, partnering with a reputable sleep lab that employs licensed technicians, obtaining continuing medical education credits on sleep diagnosis and treatment, and learning the appropriate billing codes for polysomnograms and CPAP titrations.

Barrett Tilley, MD, began offering home sleep testing in his Fremont, California family practice in 2011. The practice already offered in-house testing for cardiac, lung, and a variety of other diseases and conditions, so when medical device manufacturer Midmark asked to use his practice as a test site for at-home sleep testing equipment, Tilley readily agreed.

Tilley sends test results to a board-certified sleep specialist for interpretation, but his practice is paid for the test administration component of the service and, where needed, for initiation and management of continuous positive airway pressure (CPAP) therapy.

The financial impact of sleep studies has been "significant enough that it's worth having in the office, equal to or better than most other in-office procedures," Tilley says, but declines to provide specific revenue numbers. "I think it's a very beneficial test to offer in a primary care office," he says. "It's simple, it requires little time to discuss with the patient, and the follow-up time is short. I can't think of a reason not to have it."

➔41

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"THE IMPACT HAS BEEN DRAMATIC"

Anne-Marie Feyrer-Melk, MD, a cardiologist and owner of Heart of Arizona Optimal Care in Scottsdale, Arizona, began offering home sleep testing earlier this year, partly in response to patients' resistance to the inconvenience and cost of laboratory sleep studies. Many of the practice's patients have high-deductible insurance plans and were paying up to $700 out-of-pocket for the tests, says Steven Feyrer-Melk, PhD, the practice's director of patient wellness.

"We've only been offering it (home sleep testing) for a few months, but the impact has been dramatic," he says. "The reimbursement's been great, it's been easy to implement into the practice's operations, and the patients love it," he says.

As with any ancillary service, Feyrer-Melk says, the decision to add sleep services was guided by patient service and financial considerations. "They go hand in hand," he notes. "We're always looking for services that can help our patients, but let's face it, we're doing this as well to improve our bottom line. That's part of the business."

George G. Ellis Jr., MD, an internal medicine practitioner in Youngstown, Ohio, and a *Medical Economics* advisory board member, began offering home sleep tests to his patients in 2012. "I can provide better quality care at a more affordable cost this way," he says, noting that an in-facility test can cost as much as $5,800, compared with $200 to $400 for an in-home test.

"The reduced cost will allow more patients to have the study done," Ellis adds. "Also, doing home tests allows me to follow my patients post study, and allows for less referrals and tends to make the patients more compliant with treatment."

Leasing home testing equipment makes sense if a practice can't afford the purchase price, according to Keith Borglum, CHBC, a practice consultant with Professional Management and Marketing in Santa Rosa, California, and a *Medical Economics* editorial consultant. Otherwise, says Borglum, it is usually more financially advantageous for a practice to finance the purchase. "When you do a lease it becomes a cash-flow issue, and there's always that leasing company in the middle that has to make money somehow," he says.

Financing is especially attractive in the current low interest rate environment. "The bankers tell me that money now is the cheapest it's ever been for physicians looking to finance or re-finance something," Borglum says.

REIMBURSEMENT POLICIES DIFFER

When treating patients covered by Medicare, it's important to keep in mind that the reimbursement policies of local Medicare Part B carriers may differ from those of equipment providers, says Marc Raphaelson, MD, a neurologist practicing in Leesburg, Virginia and a member of the health policy committee of the American Academy of Sleep Medicine and a sleep medicine consultant to the National Institutes of Health Clinical Center.

"There are only four DME carriers, and they have uniform criteria for therapy coverage, Raphaelson says. "To the extent that these rules differ, a patient might have a covered sleep test but then might not qualify for treatment coverage. For example, a patient might have a polysomnography (PSG) interpreted where the Part B carrier does not require the interpreting physician to be board certified or eligible in sleep disorders. In that case the test might be covered, but CPAP would not be covered, since the DME carrier requires the PSG to be read by a certified physician."

The prevalence of OSA and its links to the diseases and conditions PCPs often must treat or manage has led some in the sleep field to wonder why more PCPs aren't offering diagnosis and treatment for sleep apnea. Edward Grandi, executive director of the American Sleep Apnea Association, says PCPs should routinely be asking about sleep issues, using validated screening questionnaires, as part of the patient intake process.

"I think the technology for testing has gotten much more user-friendly and PCPs could be doing it more often," Grandi says. "My experience has been that sleep is not an issue on most PCPs' radar. Unless the physician has determined that a significant number of his patients have [OSA] they're not really going to focus on it."

Richard Simon, MD, began researching sleep disorders and offering home sleep testing in his Walla Walla, Washington internal medicine clinic in the early 1990s, becoming board-certified in 1996. He soon found him-

Who specializes in sleep medicine?

BOARD-CERTIFIED SLEEP SPECIALISTS

3,321
The American Board of Internal Medicine

115
the American Board of Family Medicine

AMONG MEMBERS OF THE AMERICAN ACADEMY OF SLEEP MEDICINE

231
list their specialty as family practice

3,285
list internal medicine

Billing for sleep testing

National average anticipated reimbursement range*

Current Procedural Terminology code	National average reasonable and customary billing (non-Medicare)	Medicare/Tricare**	Private payer (in-network)	Private payer (out-of-network)
99211 Test administration	**$30** to **$50**	**$15** to **$25**	**$15** to **$25**	**$15** to **$25**
95806-26 Test interpretation	**$250** to **$350**	**	**$60** to **$100**	**$95** to **$250**
94660 CPAP initiation and management	**$50** to **$100**	**$40** to **$70**	**$30** to **$60**	**$40** to **$70**

*Reimbursement amounts will vary by location
**Requires certification in sleep specialty to interpret test results

Source: SNAP Diagnostics

self getting referrals from all over the region. Eventually he gave up primary care to focus exclusively on treating sleep disorders.

Today Simon is medical director of the Dement Sleep Disorders Center, part of Providence St. Mary Medical Center in Walla Walla. He believes more PCPs would test for sleep apnea if they weren't already so busy. "They have to work so hard, and for such little reimbursement, that these people (PCPs) are just stressed all the time," he says. When he added sleep medicine to his primary care practice his reimbursements went up significantly, "but basically it was because I was adding a whole new service line. I wound up working 7 days a week for about 3 years."

PERSUADING PATIENTS TO GET A FULL NIGHT'S SLEEP

Although he is sympathetic to the barriers PCPs face in offering sleep testing, Simon also thinks many of them overestimate the time and effort involved. "Most of sleep medicine is just about trying to persuade the patient to get 7 to 8 hours sleep each night on a regular schedule, and minimizing caffeine and other stimulants," he says. If the patient snores, ask him or her to take an at-home sleep test for apnea, and if the results are positive, prescribe CPAP. "If the patient does well, you're home free. If he or she doesn't, you refer at that point," he says.

Other PCPs who offer home sleep testing caution that the tests have limitations. "I think home sleep studies are generally sufficient for diagnosing OSA. Where they fall down is if the patient has other sleep disorders," says Susan Wilder, MD, founder and chief executive officer of LifeScape Medical Associates, a five-provider family practice, and LifeScape Premier, a concierge practice, both located in Scottsdale, Arizona. "The tests don't give you more complex monitoring, such as an electroencephalogram. Sometimes the data doesn't jibe with the symptoms the patient describes. So there are times when the patient needs a high-quality sleep lab study to do justice to their needs."

LifeScape stopped offering home sleep tests earlier this year because of problems with the company providing the testing equipment, but Wilder says the practice hopes to resume soon. Before deciding to stop, the tests were producing between $10,000 and $12,000 in revenue annually. "It was a pretty small component (of the practice's total revenues) but we thought we could provide the service better and more conveniently for patients than going to a sleep lab," she says.

Adds Tilley, "With anything we do in primary care, (I feel) it's better to do it in the office so we can have control over it," he says. "I ordered the test; I have the results, and I've got that patient in my office and can say 'this is where you can make a difference in your health.' And any time a primary care office has additional tools for screening and diagnosis that we can get professional fees for, it's beneficial to that office."

Financial Strategies

WHAT YOU NEED TO KNOW ABOUT RESTRICTIVE COVENANTS

By **ROY W. BREITENBACH**

The mention of restrictive covenants provokes an almost visceral reaction among most physicians. But keep in mind these covenants are, for the most part, enforceable.

NON-COMPETITION COVENANTS prevent a physician who leaves a practice from providing services in close proximity to his or her former practice for a set period of time. Non-solicitation covenants preclude a physician who leaves a practice from soliciting patients to join the physician's new practice. These covenants also restrict physicians from soliciting his or her former practice's referral sources or employees.

Restrictive covenants temporarily control how physicians can practice, and how they can obtain new patients. Most courts have recognized that reasonable physician restrictive covenants serve an important purpose and therefore are, for the most part, legally enforceable in most states.

States that are willing to enforce physician non-competition covenants typically will only do so if the covenant is reasonable in scope, duration, and geographic area. The covenant also cannot unduly burden the general public or the individual physician.

A non-competition covenant is considered reasonable in scope if it is limited to the services that the physician actually provided while employed by the practice.

With regard to the reasonableness of duration requirement, the non-competition covenant should last only as long as is needed to ensure that the departing physician is competing on the basis of his or her own skill and efforts, and not on the basis of material that he or she had access to while employed by the former practice. Generally, the covenant should last either the same length of time as the term of the contract containing the covenant or 3 years, whichever is shorter.

Turning to geographic reasonableness, the non-competition covenant should only prohibit a physician from continuing to provide services in the same general area as he or she provided services before leaving the old practice. The restricted area should be no larger than the area from which the old practice draws 80% of its patients. Finally, it must not unduly burden the physician subjected to it.

Enforcement

The enforceability of a non-solicitation covenant primarily depends on the definition of solicitation. Generally, solicitation means purposeful contact with patients in an attempt to convince them to receive services from the physician's new practice. Typically, any contact initiated by the patient does not constitute solicitation, as long as the physician does not disparage his or her former practice. Courts often require, for a non-solicitation covenant to apply, that the physician have treated the patient while working at his or her former practice. Thus, the covenant cannot prevent the physician from soliciting patients he or she never treated at the old practice.

Most courts make a distinction between covenants that prevent a physician from soliciting former patients—which typically are enforceable—and covenants preventing a physician from treating former patients—which typically are not enforceable. Thus, regardless of the existence of a non-solicitation covenant, a physician almost always can treat former patients who come seeking his or her services so long as they are unsolicited. ◻

The author is a partner/director of Garfunkel Wild, PC, in Great Neck, New York. Send your practice finance-related questions to medec@advanstar.com.

Coding Insights

ICD-10 TRAINING: WHAT'S THE COST AND WHO SHOULD RECEIVE IT?

I'm developing a budget for my practice for ICD-10-CM. Who should I train on ICD-10-CM? How much will it cost? Ours is a small practice with two full-time providers and four ancillary staff in addition to the biller and coder.

LET'S START WITH the appointment scheduler. This individual should first determine if this is a new or established patient, While the scheduler does not have to know the exact code number, it is helpful to know what the descriptor requires to properly schedule the appointment. Eligibility must also be addressed at this time.

Physicians and midlevels should be aware of ICD-10-CM coding requirements. If x-rays or surgical procedures are performed in the office, the relevant staff should learn the appropriate ICD-10-CM codes.

This new coding system allows for considerable specificity. Was the problem on the right or left side? Is this an initial visit or a follow-up? Was there sequelae? The documentation in the medical chart must indicate this kind of specificity to properly code a service. The information translated from the chart to the superbill is vital for correct coding and reimbursement, and of course must be substantiated by the documentation. There are still choices of codes with descriptors of "unspecified" but these are to be avoided.

Obviously, coders and billers must be trained to use the new coding system. These personnel will require the most extensive training.

The Medicare National and Local Coverage Determinations and the Medically Unlikely Edits must be reviewed. Many of the measures for Physician Quality Reporting System are based on diagnoses, and coders and billers will need to review these. They will also need to understand the payment guidelines used by commercial third-party payers.

Coders and billers must have an understanding of medical necessity, which is a major determinant of payment for services. These personnel may also be responsible for handling appeals. It's going to be interesting to see how many claims are submitted accurately in the first 6 months after implementation.

Training time

The Medical Group Management Association recommends that medical practices plan for 16 to 24 hours of training for the clinical staff and 40 to 60 hours for coding staff.

Contracts with payers frequently contain "carve outs" and other specified procedures either for additional payment or procedures not covered. Renegotiating contracts will be important for proper reimbursement.

Plan on spending about $2,400 on staff education and training costs. Most importantly, there will be a significant cash-flow reduction with the increased cost going to information technology, changes to business processes and superbills, and increased documentation.

The Centers for Medicare and Medicaid Services has done a fine job in assisting practices—even providing a timeline for compliance. Visit its Web site for details. Even though ICD-10-CM will not go into effect until October 1, 2014, the time to prepare is now. ◘

*The answer to our reader's question was provided by **Maxine Lewis, CMM, CPP, CPC-I, CCS-P,** president of Medical Coding & Reimbursement in Cincinnati, Ohio. Send your coding questions to **medec@advanstar.com**.*

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Technology

The EHR progress report

Physicians address costs, hours worked, and advancement in meaningful use objectives in Medical Economics EHR Best Practices Study

HIGHLIGHTS

01 The 2-year *Medical Economics* EHR Best Practices Study kicked off in January 2012 to document the costs and practices by solo practices when using select electronic health records systems.

02 On average, out-of-pocket expenditures related to the EHR tallied up to $9,116 in July 2013. The 75th percentile reported costs of $15,000.

THE MEDIAN NUMBER of hours worked has finally stabilized, according to 23 physicians reporting as part of the *Medical Economics* EHR Best Practices Study.

In fact, after nearly 17 months since the study began, the median number of hours worked is nearing pre-implementation levels at 43.4 hours per week on average.

Total non-clinical hours worked per week has also been on the decline from an average of 11.4 hours per week during the pre-implementation phase to 9.6 hours per week. In addition, the number of direct patient contact hours per week was 34 and has remained relatively flat throughout the study.

The 2-year *Medical Economics* Best Practices Study began in January 2012 with the first phase of data gathered in March 2012 by 29 solo, office-based physicians. All of the physicians in the study accept new patients and are represented by broad geographic distribution—from New Jersey to California.

The goal of the study has been to document the costs, implementation of best practices, and use of select EHR systems through nine participating companies including ABEL, Aprima, athenahealth, Amazing Charts, CureMD, McKesson, MedNet Medical Solutions, Practice Fusion, and Vitera.

While the study participants did not pay for the systems for the 2-year period, they were asked to document all of the other expenses associated with the implementation and use of the system.

Over the course of the study, those out-of-pocket expenses have been steadily climbing. In fact, on average out-of-pocket expenditures related to the EHR tallied up to $9,116 in July 2013. The 75th percentile noted expenditures of $15,000, while the bottom 25th percentile was closer to $1,250.

A CLOSER LOOK AT THE RESULTS

Here are some salient data points gleaned from the latest survey:

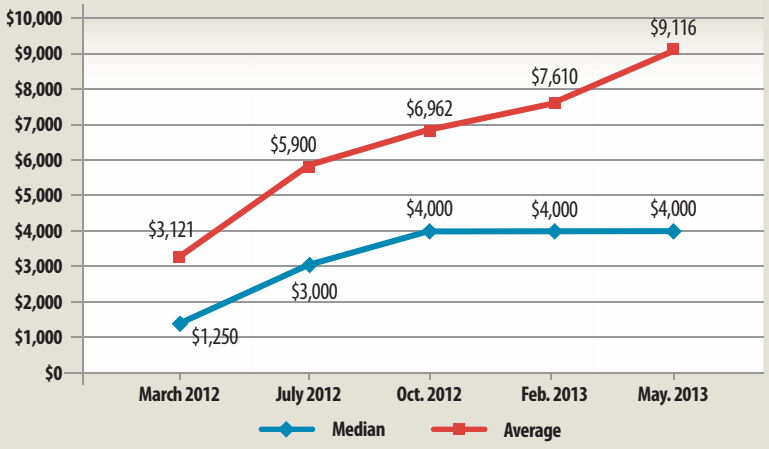
Q: Do you have the ability to determine eligibility prior to a patient's visit?
Yes: **77%**
No: **23%**

Q: What is your average charge per patient?
Median: **$124** (up from a median of $100 nearly 5 months ago)

Q: What was the average reimbursement per patient?
Median: **$75** (the average was $79)

Q: On average what were the practice's denied claims as a percentage of total claims?
Median: **6.2%**.

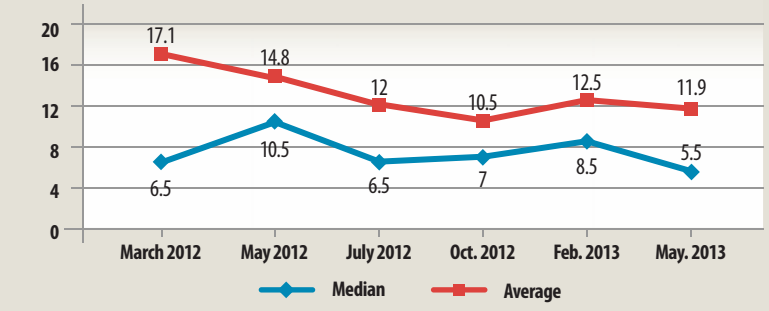
Unanticipated costs related to EHR implementation



*Note: Costs do not reflect expenditures related to EHR software, but for other equipment associated with its implementation, including hardware, peripherals, service, etc.

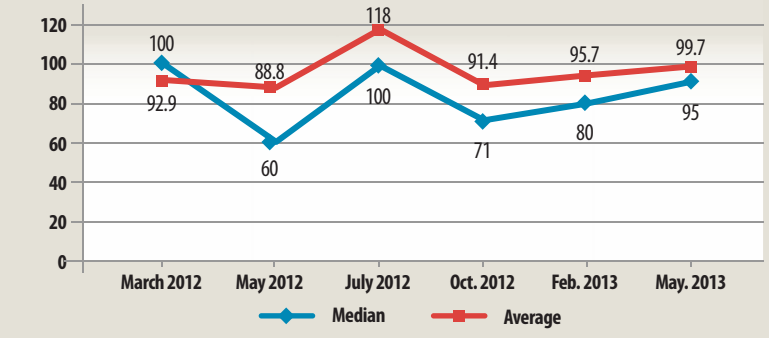
Source: Medical Economics EHR Best Practices Study
Data gathered from 29 physicians participating in 2-year study

New patient office visits per week



Source: Medical Economics EHR Practice Study
Data gathered from 29 physicians participating in 2-year study

Total established-patient office visits per week



Source: Medical Economics EHR Best Practices Study
Data gathered from 29 physicians participating in 2-year study

While many of the participants have attested for meaningful use after more than one year, the field reports making some progress overall with meaningful use 1 objectives:

- Computerized provider order entry: 35%
- Drug-drug and drug-allergy interaction checks: 48%
- Maintain an up-to-date problem list of current and active diagnoses: 65%
- E-prescribing: 61%
- Maintain active medication list: 56%
- Maintain active medication allergy list: 65%
- Record demographics: 56%
- Record and chart changes in vital signs: 65%
- Record smoking status for patients 13 years or older: 65%
- Report ambulatory clinical quality measures to CMS/states: 13%
- Implement one clinical decision support rule: 22%
- Provide patients with an electronic copy of their health information, upon request: 44%
- Capability to exchange key clinical information among providers of care and patient-authorized entities electronically: 13%
- Protect electronic health information: 52%
- Drug formulary checks: 22%
- Incorporate clinical lab test results as structured data: 35%
- Generate lists of patients by specific conditions: 9%
- Send reminders to patients per patient preference for preventive/follow-up care: 9%
- Provide patients with timely electronic access to their health information: 30%
- Use certified EHR technology to identify patient-specific education resources and provide to patient, if appropriate: 35%
- Medication reconciliation: 44%
- Summary of care record for each transition of care/referrals: 26%
- Capability to submit electronic data to immunization registries/systems: 17%
- Capability to provide electronic syndromic surveillance data to public health agencies: 17%.

Older physicians break down technology adoption barriers, study says

by **DONNA MARBURY,** *Content specialist*

HIGHLIGHTS

01 Among the many findings, the survey shows physicians in rural areas are adopting electronic health record (EHR) systems at higher rates than those in urban areas.

02 Overall, 72% of physicians have adopted some type of EHR system and 40% have the capabilities for the basic system.

A boost in electronic health records (EHR) adoption comes from the least likely population of physicians.

Between 2010 and 2012, older physicians, solo practitioners, and community health centers have seen the highest increases of EHR adoption, according to the National Ambulatory Medical Care Survey of EHRs conducted by the Centers for Disease Control and Prevention's National Center for Health Statistics.

Emily Peters, vice president of marketing communications at Web-based EHR provider Practice Fusion, says that the age barriers related to technology adoption have been broken. "People think there are only younger doctors who are leading the trend, but we have an 80-year-old doctor who is doing great with his system," Peters says. "We are starting to see a democratization of healthcare technology, which is making it more affordable... The healthcare technology market is becoming normalized just like the regular technology market, so there are a lot more options."

The survey also found that physicians in rural areas are adopting EHRs at higher rates than those in urban areas. Overall, 72% of physicians have adopted some type of EHR and 40% have the capabilities for a basic EHR system. The survey points to federal financial assistance as a common denominator among the majority of physicians adopting EHR systems.

In 2009, the Health Information Technology for Economic and Clinical Health Act earmarked $30 billion to assist practitioners with EHR adoption. In 2011, the Centers for Medicare and Medicaid Services (CMS) also began providing incentives for practitioners who used EHRs for meaningful use standards, including computerized ordering, e-prescribing, and provider reminders. Survey results show that the year after CMS incentives went into effect, adoption rates of EHR systems rose from 24.9% to 33.9%.

The meaningful use standards attached to EHR legislation have been the biggest motivator to practitioners to embrace healthcare technology, adds Trenor Williams, MD, chief executive officer of Clinovations, a healthcare consulting firm in Washington D.C. "Nothing else has had as big of an impact to healthcare technology. It has showed how big of a role technology plays in healthcare reform," he says.

However, adopting EHR systems continue to be a challenge for smaller practices, according to the study. "Physicians struggle with finding value in these EHR systems from a clinical, financial and operational standpoint," Williams says. "Somewhere in the healthcare community there will have to be value metrics, best practices to show what is really working."

Peters says that practitioners still need more information on how EHRs will make their jobs easier in the long run. "At the root, it is a psychological hurdle. So many of the other hurdles are no longer there. (EHRs) are cheaper and easier to use. The remaining hurdle is a change in workflow. For small practices that are already facing so many other pressures, that can be a scary change," he says.

The next steps will be to see how practices fair once more stages of EHR implementation are required. Williams worries that remote practices without on-staff IT professionals will have issues maintaining and continuing to implement new EHR systems in the future. "Implementation is the preamble to the work," he says.

EHR implementation: training pays dividends

Thoroughly understanding your system before going live will save money and minimize practice disruption later

by **ANDREA DOWNING PECK**

HIGHLIGHTS

01 Before starting EHR training, make sure you are clear on your objectives and that the training is tailored to your practice's needs and your staff's comfort level with technology.

02 Going live with your EHR in stages, rather than all at once, will allow you and your staff to get comfortable with the system and will minimize disruption to the practice's workflow.

Training is a crucial part of successfully implementing an electronic health record (EHR) system. Although you may be tempted to skimp on it to save money, doing so could wind up costing your practice far more in the long run.

"I have not been made aware of any EHR implementation program that failed because of too much training, but I know of a number that have occurred because of too little," says Jason Mitchell, MD, director for the Center for Health Information Technology (IT) at the American Academy of Family Physicians. "We're talking about significant decreases in productivity for months to years, which could have been avoided if training had been appropriate and expectations about what you will be able to do with the EHR were made clear from the beginning."

STARTING A TRAINING PROGRAM

Although no prescription guarantees success, experts agree on steps a primary care practice should follow when developing a training regimen aimed at smoothly transitioning from paper to electronic records.

Bruce Kleaveland, president of Kleaveland Consulting, Inc. in Seattle, Washington, says no "radical new training methodology" is revolutionizing EHR training, but vendors are replacing bootcamp-style training with a more measured approach.

"Most innovation has to do with how you teach a fairly complex application without blowing everybody's mind," he says. "Training in a more incremental fashion," Kleaveland says. "Dealing with a few components and making sure people master them, and using that as an opportunity to develop a comfort level. Also, physicians need to be cognizant that the way a physician uses an application is different than a front-desk person."

Although training continues to evolve as technology becomes more advanced, Lisa Bradshaw, director of training for NextGen Healthcare's ambulatory division, says that successful EHR training "requires a practice's commitment to and dedication of resources for the project. It is essential [that] there is physician and clinical involvement in configuring software to ensure that expectations, requirements, and standards are met."

Margret Amatayakui, president of Margret/A Consulting, LLC says that EHR training should infuse physicians with an understanding of a system's value in clinical decision support rather than simply teach the nuts-and-bolts of screen navigation.

"This is not as simple as taking away

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An EHR training checklist

- ☑ Reasons for EHR conversion explained to staff
- ☑ Training costs budgeted
- ☑ Physician leadership secured
- ☑ Goals of training program understood
- ☑ Variety of trainer options explored
- ☑ In-house "champion(s)" identified, trained
- ☑ Training program tailored to practice's specific needs
- ☑ Timeline for going live with various elements of EHR established
- ☑ "Dress rehearsal" for going live held

the pen and using the keyboard instead," she says. "This is changing how you practice medicine."

Don't underestimate the impact of solid training," adds Michael S. Barr, MD, senior vice president of medical practice for the American College of Physicians, who coauthored the 2011 American EHR Partners' report showing incremental increases in training resulted in measurable increases in clinician satisfaction. "If you think you need 'X' amount of training, you should go 'X' plus."

WHAT WILL IT COST?

Like all other aspects of EHR implementation, the cost of training physicians and staff members to use the system comes with a price tag. The exact amount your practice will pay will vary depending on the type of system you use (SAAS- or server-based), the vendor or consultant providing the training, the extent of the training, and how many people receive training.

A 2010 study of 26 Texas-based, five-physician primary care practices found that the teams responsible for implementing the practices' EHR systems required an average of 52.5 hours of training at a cost of $2,777. The system's physician end-users received an average of 23.9 hours of training at a cost of $1,538 per physician.

Results of the study, which was funded by the Agency for Healthcare Research and Quality, were published in the March 2011 issue of the journal *Health Affairs*.

Here are 14 steps to building an effective EHR training program for your practice:

1/ Get input from staff

Staff members who have a role in selecting the EHR have a better perception of the system after implementation. "Becoming an early stakeholder may make you a little more comfortable, because you know what the EHR should do," Barr says.

2/ Lead by example

Physician leadership is crucial when implementing an EHR. "I've been associated with really successful projects and projects that were train wrecks," Kleaveland says. "The big difference is physician leadership, particularly in a small practice. That very much applies to thinking through how you do training and the training process itself."

3/ Establish an end goal

To create a successful training program, Mitchell says, physicians need to know what they want their EHRs to do for their practices. "Have a vision of your practice using an EHR system," he says. "That helps guide the training process. You have to have some idea of where you are trying to get and what the EHR is going to do differently than a paper-based system."

4/ Uncover technophobes

Staff members who do not have basic computer skills will need extra training to get up to speed before go-live. "If you can't type, that's going to be an issue," Mitchell says. "If using the mouse doesn't make sense to you, if you don't understand key combinations to be able get shortcuts, if using the voice-recognition software takes you 15 minutes, those things are going to destroy you over time."

5/ Investigate training options

Although your EHR vendor is likely to have unmatched knowledge of its product, value-added resellers, consultants, and local regional extension centers (RECs) for health information technology (IT) are worth considering. "Even though vendor representatives should be quite knowledgeable, generally they are the most difficult to schedule and most expensive," Kleaveland says. "If you can find local resources that are knowledgeable, you'd be crazy not to avail yourself of those." (See box, "Regional Extension Centers.")

6/ Customize your training

Because training can cost a small practice nearly as much as the EHR itself, Lou Ann Wiedemann, senior director of health information management practice excellence for the American Health Information Management Association, says that physicians should define in advance their training objectives and ensure training is tailored to their practice.

"There is not a cookie-cutter approach," she says. "Each physician practice is unique in some of the things they are looking for so they need to take that into consideration."

The timing of your training sessions also is key. "You don't want to do training too far in advance or your staff may forget it," Wi-

edemann says. "You do it too close and you may rush it."

7/ Hold a dress rehearsal

Before your go-live date, set up EHR test cases using dummy patient charts to simulate common scenarios, such as a follow-up visit for hypertension.

"If physicians are going to be seeing patients with this software in the room, then simulate that so you are not completely freaking out when the patient shows up and you're trying to examine them and document," Kleaveland says. "The patient wonders, 'Are they examining the computer or examining me?' "

8/ Don't try to learn everything at once

Heather Haugen, Ph.D, senior vice president of research, development, and IT at The Breakaway Group in Greenwood Village, Colorado, says EHR trainers set practices up for failure when they attempt to teach users a vast array of features and functions at once. "If I put you in a classroom for 3 days and I teach you 300 things the EHR does for a physician, you likely won't remember how to log-in when we're done," she says.

Haugen advocates for "scenario-based" learning, which enables users to learn by doing and is modeled after flight simulators in the aviation industry. "Bite-size" training sessions typically are 5 to 7 minutes long and can be done during off hours. This task-based training focuses on physicians and staff first becoming proficient in their primary job tasks.

"Ensuring people can use the application to treat a patient the day of go-live typically means they have to know the key functionality, but they don't know all the bells and whistles and the advanced functionality," Haugen says. "Then overtime they learn that. When the opposite happens, we get in trouble."

9/ Implement in stages

When Jennifer Brull, MD, a solo family physician in Plainville, Kansas began converting her practice to EHRs, she knew flipping a switch all at once would wreck havoc. Instead, the practice implemented the system in stages over 3 months; first by converting to the new electronic billing system, then transitioning to the EHR's scheduling software, before finally rolling out the clinical portion of the system.

"When we went live with clinical, our front office was comfortable with what they were doing," she explains. "They had a couple of months under their belt doing things the new way so when the back office got really stressed, there wasn't stress in both places."

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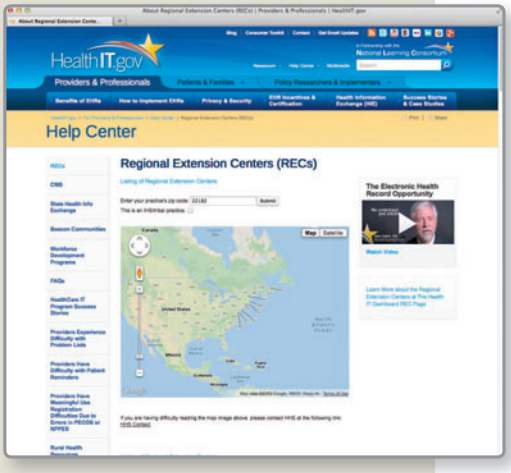

Authorized by the Health Information Technology for Economic and Clinical Health Act, Regional Extension Centers (RECs) have offered primary care physicians EHR education and training services for the past several years.

Although their 4-year federal funding ends this year, some RECs are continuing to sign up providers using remaining grant funds. The availability of training will by location. In Ohio, for example, RECs have provided free EHR education to more than 6,500 primary care providers, and a few of the state's seven RECs have slots remaining. As of 2014, Communications Director Dottie Howe of the Ohio Health Information Partnership says the organization will begin offering physicians a fee-based package of services for EHR selection and ongoing EHR monitoring through meaningful use stage 2.

www.healthit.gov/providers-professionals/regional-extension-centers-recs

10/ Understand the impact on workflow

Practice workflows slow by as much as 50% during implementation, a phenomenon documented by *Medical Economics'* EHR Best Practices Study. Practice management consultant Mary Pat Whaley of Manage My Practice in North Carolina, argues that failing to consider an EHR's impact on workflow can be a major oversight.

"Being trained on the software is totally different from inserting the EHR into the workflow or changing the workflow," she says. "People think, 'We know how to use it. Let's throw it out there and see how it works.' That can be devastating to the practice, to morale, and, of course, devastating financially."

11/ Develop in-house experts

No matter whether your EHR point-person is called a "champion" or "super user," every practice needs one or more staff members who receive extra training and become resident experts who can help others learn the system, assist at go-live, maintain a relationship with the vendor, and stay abreast of system updates.

"The super user is somebody who is going to be able to troubleshoot after the onsite support and training is no longer available," Barr says. "The more super users you have, the easier it is for somebody to turn and find somebody who can help them."

Brull, however, says she made the mistake of failing to remove some of her champions' regular duties during implementation so that they would have time to devote solely to helping others.

"They got through it, but looking back, I would have said 25% of your hours are marked for going around saying, 'Do you need help?' as opposed to letting problems come to them and making them deal with it on top of their regular volume."

12/ Foster teamwork

Knowing that EHR implementation will cause bumps in the road for staff, the implementation team needs to find ways to boost morale. When implementation-related issues stressed a member of Brull's staff, the person was likely to find a row of Hershey Kisses lining his or her desk. "That was a signal to take a deep breath, calm down and eat some chocolate," she says.

13/ Think long term

Your practice needs a long-term commitment to EHR training. For 2 years following implementation, Brull made an EHR question-and-answer session a regular agenda item during bi-monthly staff meetings. Staff could discuss challenges, ask questions, or offer tips to coworkers.

"In the early days we probably took 30 to 60 minutes of our staff meeting just doing things around the EHR implementation," she says. "We never had anybody who had tremendous amounts of frustration build up because they knew every two weeks there was that opportunity to ask questions and get feedback from everyone."

14/ Join user groups

Online user groups and forums are excellent ways to discover shortcuts, discuss solutions or share concerns about your EHR. Some user groups are associated directly with vendors. Others, such as eCWusers.com are independent groups comprised solely of users of a particular EHR—in this case, eClinicalWorks.

Although Brull stops short of describing her EHR implementation as perfect, she says, "We achieved our objective of moving everyone from a paper world to an electronic world in a way we didn't lose staff and we didn't pull our hair out too much."

Brull established a goal of converting at least one patient's records to the EHR each half day. At that pace she was able to convert her 2,000 patients to electronic records in about 5 months, compared with another physician with an older patient population for whom the process took 18 months. She is confident her step-by-step implementation created fewer headaches than if she had tried implementing the system all at once.

Five years after her go-live date, Brull says her patients are benefitting from improved care, with quality metrics rapidly increasing for preventive measures such as colon and breast cancer screenings. She credits her EHR with enabling her to practice better medicine.

"When you really look at patient population numbers instead of a just the chart of the patient in front of you—which is all you can do in a paper world—it's a real wake up call," Brull says. "That's been really good for us." ◻

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SURVEY RANKS TOP EHRs FOR SMALL PRACTICES

Choosing the right electronic health records (EHR) vendor can be one of the most important, difficult, and confusing decisions a physician confronts, particularly because the EHR market today is so fragmented. So knowing the choices that other physicians have made, particularly physicians in small practices, can add valuable context around the decision-making process.

About half of the medical practices in the nation have adopted electronic health records systems, and they've had a dizzying array of electronic health record (EHR) vendors from which to choose.

That's where a report issued earlier this year by health market research firm SK&A comes in handy.

SK&A has contracted with the U.S. Department of Health and Human Services to provide quarterly survey data to the federal government on EHR adoption and usage by physicians around the country.

The company's reports are packed with data that will be of interest to physicians as well as health information technology enthusiasts, The data includes EHR adoption by specialty, region, practice size, and patient volume.

Data from the company's latest report is based on telephone surveys conducted at more than 273,000 U.S. medical sites earlier this year.

What follows is a list of the 10 most popular EHR systems for practices with between one and three physicians, ranked by market share in that category. The information was compiled by and outlined in Brian Ahier's Advanced Health Information Exchange Resources blog.

EHR vendor share for small practices

Rank	Vendor Name	Market Share
1	eClinicalWorks	11%
2	Allscripts	10%
3	Epic Systems	8.1%
4	Practice Fusion	7.1%
5	NextGen Healthcare	5.3%
6	McKesson Provider Technologies	3.8%
7	General Electric Healthcare IT	3.3%
8	AmazingCharts.com	3.2%
9	Cerner	3.1%
10	athenahealth	2.5%

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Epocrates Inc., an athenahealth company, has expanded its collaborations with the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), and the National Comprehensive Cancer Network (NCCN) to deliver content to clinicians on their mobile devices at the point of care.

The CDC will work with Epocrates to provide information on immunization updates, emerging resistant bacteria, and local disease outbreaks. Epocrates can send mobile alerts to clinicians by region or specialty to deliver relevant content in mobile format.

The CDC is also making material available on topics such as weight management and sexually transmitted infections for clinicians to print out or email to patients.

AHRQ will issue comparative effectiveness reports that provide a basis for clinical decision-making. Epocrates has selected more than 35 AHRQ guidelines for its targeted DocAlert messaging system on topics such as drug allergies, cancer screening, and gastroesophageal reflux disease.

Epocrates also recently expanded its iPhone app based on the NCCN Clinical Practice Guidelines in Oncology. The app provides access to NCCN guidelines on prostate, breast, and colon cancers.

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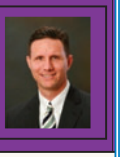

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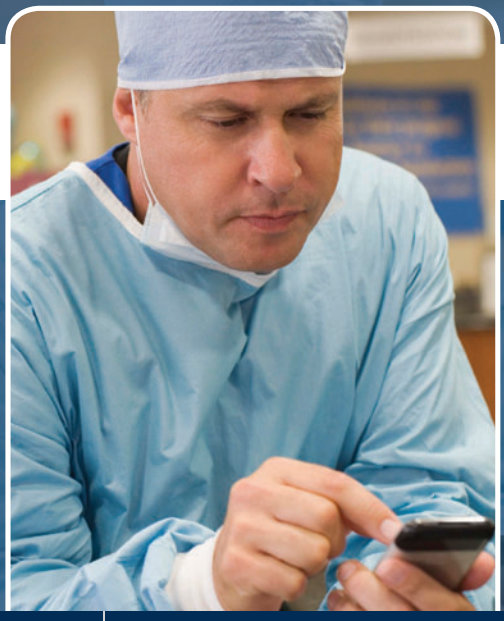

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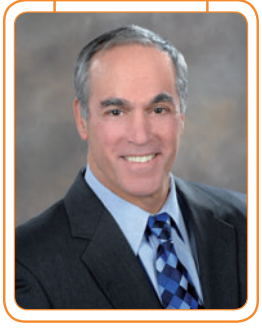

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Perspective

STUDY LOOKS AT STATES MOST LIKELY TO ACCEPT NEW MEDICAID PATIENTS

BY BRANDON GLENN

Primary care physicians (PCPs) are less likely to accept new Medicaid patients than office-based physicians in general, according to a new analysis in *Health Affairs*.

Slightly more than 33% of PCP weren't accepting new Medicaid patients in 2011 and 2012, compared with 30% of all office-based physicians.

But PCPs' acceptance of new Medicaid patients varies widely by state, with only 9% of Minnesota PCPs not accepting new patients, compared with a high of 54% in New Jersey.

With denial rates ranging from 44% to 54%, PCPs in New Jersey, California, Alabama, and Missouri were far less likely than the national average to accept new Medicaid patients, according to the analysis, which was based on data from the National Ambulatory Medical Care Survey Electronic Medical Records Supplement in 2011 and 2012.

Along with Minnesota, there were several other states in which fewer than 20% of PCPs weren't accepting new Medicaid patients. These included Wisconsin, Nebraska, Arkansas, West Virginia, and Iowa.

Among PCPs, internists (44% non-acceptance) were the least likely to take on new Medicaid patients, while pediatricians (21%) were the most likely.

With a number of states choosing to move forward with Medicaid expansion under the Affordable Care Act (ACA), millions of new Medicaid patients could be seeking care from PCPs over the next several years. That's bringing the issue of new Medicaid patient acceptance by PCPs into sharper focus as questions remain as to whether these new patients will have adequate access to care.

Under a provision of the ACA designed to increase PCP acceptance of Medicaid patients, PCPs will be paid higher Medicare reimbursement rates in 2013 and 2014 for some procedures involving Medicaid patients. The provision would increase Medicaid fees approximately 73%, but that number differs by procedure and by state, according to a study by the Kaiser Family Foundation.

Still, even though it's the summer of 2013, PCPs in many states have not yet begun receiving the Medicaid payment boost, in some cases because there have been delays associated with certifying which physicians are eligible for the pay increase.

Prior evidence suggests that physicians' acceptance of Medicaid patients may rise as Medicaid payment rates increase, according to the *Health Affairs* analysis. However, physicians' willingness to accept new Medicaid patients also depends on several other factors, such as delays in payment, the degree of administrative burden involved in getting reimbursed, whether physicians are located in areas near where Medicaid beneficiaries live or work, and the possibility that Medicaid patients may be more likely than other patients to miss appointments.

For those reasons, it's "uncertain" whether the ACA's primary care Medicaid payment boost will achieve its desired results, the analysis says.

PRIOR EVIDENCE SUGGESTS THAT PHYSICIANS' ACCEPTANCE OF MEDICAID PATIENTS MAY RISE AS MEDICAID PAYMENT RATES INCREASE.

Want to weigh in on the debate about ACA, Medicaid expansion and its impact to primary care physicians? We want to know. Write us at medec@advanstar.com. Your comments could be in the next issue of *Medical Economics*.

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