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DECEMBER 25, 2013

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TOP 10 CHALLENGES FACING PHYSICIANS IN 2014

- Changing patient populations
- Government mandates
- Payment trends
- ACA
- Staff turnover
- Control over medical decisions
- Technology costs
- The future of family practice
- Time
- Work-life balance

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DECEMBER 25, 2013

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Issue 24

IN DEPTH

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COVER STORY | TRENDS

Why the major challenges of 2014 are also opportunities for primary care

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- Government mandates
- Payer headaches
- Plus: Physician poll results

COLUMNS

MISSION STATEMENT

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

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ONLINE EXCLUSIVE

DOCTORS RESIST UNITED HEALTHCARE NETWORK CUTS

Two Connecticut county medical associations are jointly seeking a temporary restraining order to prevent insurance giant United Healthcare from moving ahead with plans to drop 2,200 of the state's physicians from its Medicare Advantage program. The associations are also appealing to Connecticut lawmakers to help them in their fight against United Healthcare. Find the latest at **MedicalEonomics.com/Unitedhealthcare**

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#1 FAMILY PHYSICIANS STAY NEAR WHERE THEY TRAIN
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#3 SENIORS WANT ONLINE HEALTHCARE OPTIONS
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The board members and consultants contribute expertise and analysis that help shape the content of Medical Economics.

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"Work with your vendor now to ensure that your system updates are done in time."

—Renee Stantz
VEI CONSULTING SERVICES, INDIANAPOLIS, INDIANA

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from the **Trenches**

> ICD-10 is about money, data, and power—all being stripped from physicians and surrendered to payers who will beat us even more with what we willingly surrender. It has nothing to do with improving patient care. This is simply the spin from those who stand to gain fortunes as it goes forward.
>
> **Paul G. Brown, MD,** MARION, VIRGINIA

DOCTORS SHOULD SUPPORT REPEAL OF ICD-10 MANDATE

Your article "Countdown to ICD-10" (November 10, 2013) does a great disservice to your readers. I did not see a single discussion of the ongoing attempts to rescind this bureaucratic boondoggle. The American Medical Association continues to call for the delay or elimination of the program, as do over 40 other specialty physician organizations. It would better serve physicians if they would devote their efforts to informing their elected representatives about ICD-10 and encouraging them to support it's repeal.

The tone of your article reflects a self-fulfilling prophecy—that there is no choice but to capitulate. You quote only one physician who is currently preparing to implement ICD-10. Every other individual referenced stands to directly profit as this proceeds and they all ring the alarm bells with increasing fervor.

The time for meekness in medicine is passing. Those of us who have devoted our life to caring for patients as a full-time calling need to stand up for our patients and ourselves. ICD-10 is about money, data, and power—all being stripped from physicians and surrendered to payers who will beat us even more with what we willingly surrender. It has nothing to do with improving patient care. This is simply the spin from those who stand to gain fortunes as it goes forward.

Documentation does not improve care and there are no valid studies proving that it does. My family physician's records were kept on 5x8-inch index cards, and I received excellent care from him. Imagine a one-line note such as this today: Paul: Acute appendicitis. Dr. Smith at St. Marys." That type of charting was, however, the standard for decades and no one indicted physicians because of it.

Physicians need to say "enough." It is time that we demand our altruism no longer be used against us. Demand that your elected representative support repeal of ICD-10. Step back from patient care for a time if it is implemented. The effect of that will be much less damaging than the quiet loss of thousands of physicians for whom this is the last straw.

Paul G. Brown, MD
MARION, VIRGINIA

PATIENT CARE IS AT RISK

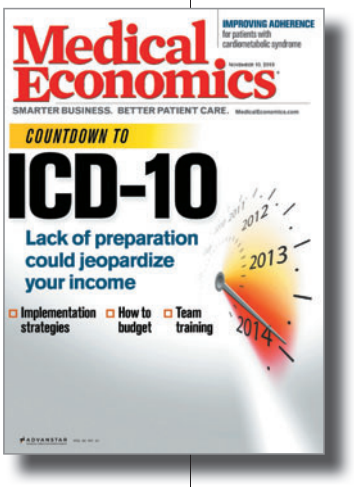
Absolutely, doctors are being marginalized. ("Physicians are no longer the stars of healthcare," November 10, 2013.) I think we should organize a national strike. It dismays me to see a Humana logo at the top of my medical association's email newsletter as well. Is that not a conflict of interest? I worry about the future of patient care.

Rolando Hinojosa, MD
MISSION, TEXAS

> We have a lot of good evidence now that we can make a difference in the lives of our patients by providing broad and deep coordinated care with a doctor at the helm but not necessarily the star. I have accepted my inability to provide the care a team can provide and I have seen the results that are also shown in evidence-based approaches.
>
> **John Giannone, MD,** DEPOSIT, NEW YORK

BEING A STAR ISN'T NEEDED TO HELP PATIENTS

I started as a family physician in 1985. By today's standards, I guess it was the wild west. I admitted to the intensive care unit, did obstetrics, sigmoidoscopies, and colposcopies, and served on more committees and boards than one can imagine.



I never really thought about being a star. I always saw myself as being the hands of a much greater force that had nurtured and trained me for the moment I was to make others feel important, healthy and cared for.

As Richard Waltman, MD so well described my current role, I am a "provider." ("Physicians are no longer the stars of healthcare," November 10, 2013.)

We have a lot of good evidence now that we can make a difference in the lives of our patients by providing broad and deep coordinated care with a doctor at the helm but not necessarily the star or the holder of all knowledge. I have accepted my inability to provide the care a team can provide and I have seen the results that are also shown in evidence-based approaches.

As a young doctor I admitted many, many patients with diabetic amputations, strokes, and more. In my 30-year career, I have seen a remarkable decrease in these ailments.

I have finally come to center, knowing that as a provider with a medical degree, I am making a difference. And guess what? I still get a good seat in a restaurant and some other expressions of respect for being the doctor in a small town.

Yes, being the star was fun, but keeping patients alive longer and happier is more fun.

John Giannone, MD
DEPOSIT, NEW YORK

LET DOCTORS PRACTICE AS THEY SEE FIT

Last decade, the U.S. government decided to force electronic health records (EHRs) on all physicians. The promise was, "Begin participating in 2011 and 2012 to earn the maximum incentive—up to $44,000 for Medicare and up to $63,750 for Medicaid" and "certified EHR technology can help improve the quality of health outcomes and the efficiency of healthcare, while providing privacy and security safeguards."

The reality is that physicians and healthcare facilities paid up to $70,000 per physician per year to establish and maintain EHRs. Physicians have had to deal with constant work disruption, steep learning curves, and loss of productivity ➔14

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IT SEEMS BEST TO ASSERT OUR RIGHT TO PRACTICE MEDICINE IN THE WAY WE SEE FIT THAT BEST SUITS OUR PATIENTS. THIS CAN ONLY BE ACCOMPLISHED BY OPTING OUT OF ALL INSURANCE AND GOVERNMENT PROGRAMS.

—CRAIG M. WAX, DO, MULLICA HILL, NEW JERSEY

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➔12 costing even more money. The U.S. Department of Health and Human Services demands that physicians meet the criteria for Meaningful Use (MU) to get the promised reimbursement.

In reality, the government is asserting that EHR is not optional, but is mandatory, via the "carrot and stick" threat. Consequently EHR MU audits have begun to assess compliance and recover government investment.

The government promised that Obamacare would provide all citizens with "free health insurance." But in 2013, we saw efficient discount health insurance plans dropped from the market, while insurers scrambled to meet the government edict with bloated plans that cost up to 200% more.

The government had 3 years to develop an infrastructure for the Obamacare website registration system for the health insurance all taxpaying citizens must buy. They outsourced the information technology work (read that "jobs") to Canada. We watched in disbelief as Obamacare rolled out in October and no one could sign up due to errors and nonexistent customer support. This is typical of most government programs in general and all entitlement programs; radical idea, poor planning, massive budget overruns, and dreadful execution.

Our time-honored medical tradition is to respect a patient's privacy. Now, under the Health Insurance Portability and Accountability Act, the government can audit us without notice and play the roles of judge, jury and executioner. Physicians must hire an attorney, deal with practice disruption and lost income, and defend themselves against government-sponsored bounty hunters with seemingly unlimited time and money.

Physicians are damned if we do and damned if we don't comply with expensive, arbitrary, and patient-physician privacy -conflicted government edicts. It seems best to assert our right to practice medicine in the way we see fit and that best suits our patients. This can only be accomplished by opting out of ALL insurance and government programs. Patients pay physicians and facilities directly at competitive prices on the free market; quality and service go up while prices go down. Everyone wins.

Craig M. Wax, DO
MULLICA HILL, NEW JERSEY

TOP 100 EHR LIST NEEDED DIFFERENT SURVEY METHOD

I received my copy of *Medical Economics* containing the Top 100 electronic health records (EHR) systems ("The Top 100 EHRs," October 25, 2013) and was surprised to not see the ChartMaker EHR as well as other vendors missing from the list. Although I agree with what you were attempting to accomplish with this issue, I take exception to your survey methods. Allowing privately-held companies to self-report their annual sales revenue is very subjective and at best nonverifiable.

A more objective and verifiable method to achieve the Top 100 EHR list would be to go to the healthdata.gov website and download the list of physicians who have achieved Meaningful Use certification. This list is in XLS format and with a little knowledge of Microsoft Excel, you could total and sort the list by vendors with the most Meaningful Users. On that list, ChartMaker and STI Computer Services would be the 29th largest vendor in the country.

Joseph M. Cerra
EAGLEVILLE, PENNSYLVANIA

the Vitals

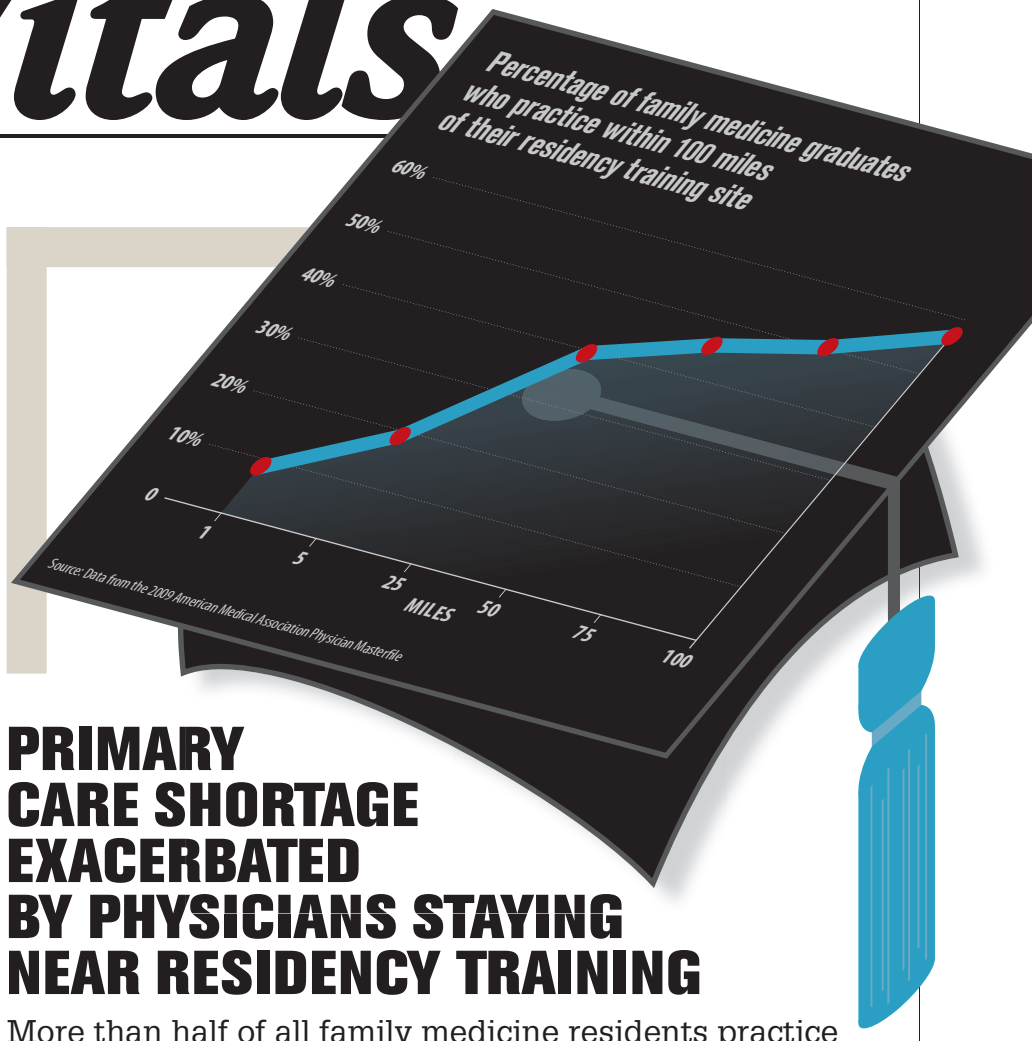
MGMA: HIGH PERFORMING DOCTORS USE PATIENT SATISFACTION SURVEYS

A new report from the Medical Group Management Association (MGMA) found that high performing physicians have something in common: They use patient-satisfaction surveys to evaluate how they are doing.

The report found that nearly 80% of physicians rated as "better performers" by the MGMA use such surveys. Almost 10% of better-performing practices used patient surveys as part of their physician compensation formula.

"Successful groups actively and regularly solicit feedback from their patients," said Kenneth T. Hertz, FACMPE, Principal, MGMA Health Care Consulting Group. "Patient satisfaction surveys give practices an immense amount of detail on their patients' experience, and that feedback is particularly useful as medical groups seek to improve and elevate the care they provide."

The report was compiled using data in the MGMA 2013 Cost Survey.



PRIMARY CARE SHORTAGE EXACERBATED BY PHYSICIANS STAYING NEAR RESIDENCY TRAINING

More than half of all family medicine residents practice near where they trained. These individual decisions have far-reaching implications for U.S. primary care. Researchers with the Robert Graham Center examined data from the 2009 American Medical Association Physician Masterfile and found that 56% of family medicine residents stay within 100 miles of where they graduated from residency. The authors found that 19% of these graduates stay within 5 miles of their residency program, and 39% remain within 25 miles. The findings were published in the November issue of American Family Physician.

"The distribution of physicians continues to compromise access to primary care, a problem compounded by limited volume of training outside of major metropolitan areas and large academic health centers," the authors say, adding the results show a need to support efforts to decentralize medical training.

WILL HEALTH EXCHANGE PLANS PAY DOCS LESS?

Physicians in multiple states are concerned that health plans in the new insurance exchanges will pay them less.

Physicians in New York, California, Connecticut, Texas and Georgia have complained to their state medical associations about low payment rates from the exchange plans, reports *Kaiser Health News*.

The report says insurance officials have acknowledged reducing reimbursement rates in some of the exchange health plans because they are "under enormous pressure to keep premiums affordable."

ONLINE SMALL BUSINESS EXCHANGE DELAYED

The Affordable Care Act has had another delay. The online federal SHOP Exchange for small businesses has been delayed a year, until the open enrollment period in late 2014.

State-run exchanges will still offer online enrollment, and small business will still be able to purchase coverage for their employees through a broker or insurers.

@ Do you think the Affordable Care Act will cause more problems for physicians? Tell us at medec@advanstar.com

WITH REIMBURSEMENT CUT LOOMING, PHYSICIANS URGE SGR REPEAL

A REAL PUSH is underway in Congress to repeal the flawed Sustainable Growth Rate (SGR) formula, but whether Congress can get a permanent fix done before leaving on December recess is not likely.

If a permanent repeal can't be worked out before recess, Congressional leaders are considering a temporary SGR fix with intentions of revisiting this issue in early 2014.

A recent letter from 259 Congressional members to Speaker of the House Rep. John Boehner and Minority Leader Rep. Nancy Pelosi says the time is now to do away with SGR.

"We should not pass up this chance to repeal the SGR—with fiscally responsible offsets—and enact a permanent solution," the letter reads. "This year represents a great opportunity to repeal the flawed SGR formula, reform healthcare delivery to drive quality and efficiency, and set Medicare on a more stable and predictable course for current and future generations of patients and physicians."

The SGR formula was created in the 1990s to help contain the growth in healthcare spending, but instead has called for drastic cuts in physician payments each year, requiring Congress to step in at the last moment and override the cuts. The proposal would cost about $116.5 billion, according to the latest estimates from the Congressional Budget Office. In the last 10 years, Congress has spent $146 billion on short-term SGR fixes.

Without a repeal of the SGR, Medicare reimbursements will be cut by 24.4% starting on January 1, 2014.

The latest reform efforts calls for freezing payment levels through 2023 and creating a value-based performance (VBP) payment program in 2017. Creation of the VBP also would end reimbursement penalties under the Physician Quality Reporting System, Value-Based Payment Modifier and Meaningful Use penalties at the end of 2016, according to a draft proposal.

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

Without a repeal of the SGR formula, Medicare reimbursements will be cut by 24.4% starting on January 1, 2014.

> "There is truly a sense that in a bipartisan, bicameral fashion, we can move this off the table and finally repeal the SGR."
>
> – AAFP PRESIDENT REID BLACKWELDER, MD, FAAFP

"There is truly a sense that in a bipartisan, bicameral fashion, we can move this off the table and finally repeal the SGR," says AAFP President Reid Blackwelder, MD, FAAFP, according to *AAFP News Now*. "We can't get anything else done; all other areas of advocacy depend upon that finally being resolved."

The AMA also released a statement urging repeal of the SGR: "Congress should act decisively this year to pass the SGR repeal, provide positive updates and improve the performance programs. Repealing the SGR this year will give Medicare a firm and stable foundation so physicians can pursue delivery innovations that help improve care and reduce costs."

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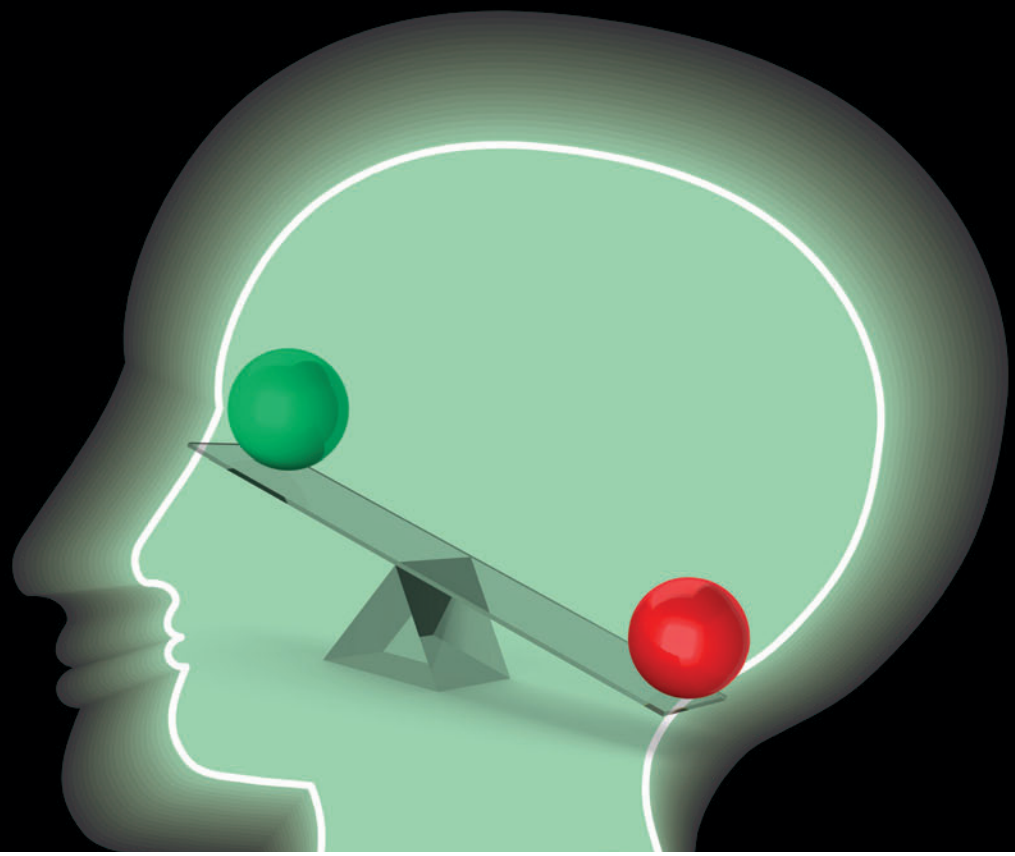

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Medical Economics

An estimated 40 to 70 million Americans are affected by insomnia, however the true prevalence of insomnia is unknown because it is underdiagnosed and underreported. Recent updates in the nosology and diagnostic criteria for insomnia as well as advances in the understanding of its pathophysiology has led to the development of potential new treatments.

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40% of payers on exchanges also offer Medicaid plans

CLOSE to four of 10 issuers participating in health insurance marketplaces also offer coverage through a Medicaid managed care plan, according to new analysis from the Association for Community Affiliated Plans (ACAP)..

There are 290 Qualified Health Plan (QHP) issuers in the 50 states and the District of Columbia, counting issuers once for each state in which they participate in a marketplace. Of those 290 issuers, four in 10—113 overall—also offer coverage through a Medicaid MCO in the same state.

This suggests that there is significant overlap between marketplace plan offerings and Medicaid managed care in many states, which would help to limit the impact of "churn," or enrollees entering and exiting Medicaid because of unforeseen loss of coverage. It can be caused by minor fluctuations in income, clerical errors, or failure to renew enrollment on a timely basis, among other factors.

"Plans whose mission includes providing coverage to lower-income families have a real opportunity, through offering coverage in marketplaces, to cover entire families. This study highlights that opportunity," says ACAP CEO Margaret A. Murray. "This also holds true for individuals in the workforce with low incomes who may move between coverage through Medicaid and the marketplace. The issue of 'churn' in Medicaid is very real—the average enrollee is in the program for less than 10 months of the year."

The issue of churn can not only lead to negative health outcomes for patients but also poses significant challenges for health plans.

According to the analyses, 33 states and the District of Columbia were found to have issuers that offered both a marketplace plan and a Medicaid managed care plan. The analysis showed 17 states with no overlap between issuers participating in Medicaid and the marketplaces.

FEWDOC TORS USE GENETIC TESTING

Just over half (51%) of primary care pediatricians (PCPs) do not feel competent to provide adequate healthcare to children with genetic conditions.

The finding comes from an online survey, which also revealed that few general practitioners order genetic tests or discuss the risks and benefits associated with them, and that most do not take the recommended amount of family history.

Researchers from a number of children's hospitals and research institutions across the United States queried 88 PCPs associated with the American Academy of Pediatrics' Quality Improvement Innovation Networks.

The investigators found that not quite half (49%) of the respondents agreed or strongly agreed that they feel competent to provide care related to genetics or genomics. Not counting mandatory newborn screening, only 14% reported ordering genetic-based tests more than 3 times per year. Only 13% strongly agreed that they discuss with patients the potential risks, benefits, and limitations of genetic tests.

Researchers say the results show the need for education and training about genetic conditions.

Doctor's Bag

The latest in drugs, devices, technology, and more

FDA APPROVES NSAID TO ADDRESS DOSE-RELATED SAFETY CONCERNS

FDA has approved diclofenac (Zorvolex) capsules, a nonsteroidal anti-inflammatory drug (NSAID), for the treatment of mild-to-moderate acute pain in adults. Zorvolex was approved at dosage strengths that are 20% lower than currently available diclofenac products. The approval was supported by data from a phase 3 multicenter, randomized study.

Patients treated with diclofenac reported significant pain relief compared with patients receiving placebo.

The treatment was developed to align with recommendations that NSAIDs be used at the lowest effective dose for the shortest possible duration of time consistent with individual patient treatment goals. The risk of serious adverse events, including cardiovascular thrombotic events associated with NSAIDs is higher among patients receiving higher doses of NSAIDs.

Zorvolex was developed using proprietary SoluMatrix Fine Particle Technology and contains diclofenac as submicron particles that are approximately 20 times smaller than their original size. The reduction in particle size provides an increased surface area, leading to faster dissolution.

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EHR/ANALYTICS INTEGRATION AIDS PAYERS, PROVIDERS

Allscripts and Inovalon have entered a multi-year agreement that enables Inovalon's advanced healthcare data analytics for payers to leverage Allscripts Electronic Health Record (EHR) Platform to improve clinical and quality outcomes as well as financial performance.

With the agreement, Inovalon will be able to apply its advanced quality improvement and risk score accuracy analytics to the Allscripts EHR Platform, improving the speed and workflow efficiency of data exchanges within the medical record process between payers and providers.

Through the integration of analytics and electronic medical record data abstraction, the integration of Inovalon's toolsets within the Allscripts environment decreases the burden for both payers and providers while increasing quality outcomes and risk score data accuracy.

Allscripts and Inovalon www.allscripts.com | www.inovalon.com/

DRUG APPROVED TO TREAT PULMONARY HYPERTENSION

FDA approved riociguat (Adempas) tablets for the treatment of adults with chronic thromboembolic pulmonary hypertension (CTEPH) after surgical treatment or inoperable CTEPH as well as adults with pulmonary arterial hypertension (PAH).

Prior its approval, there were no approved non-surgical therapies for CTEPH. Riociguat represents a new drug class and has the potential to overcome limitations of other approved PAH therapies, like nitric oxide (NO) dependence.

It is contraindicated in pregnancy as well as with coadministration of nitrates or nitric oxide donors and with concomitant administration with PDE inhibitors. For female patients, riociguat is available only through the Adempas REMS Program. The drug is priced at $7,500 for 30 days of treatment, which consists of 1 oral tablet taken 3 times a day.

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TOP 10 CHALLENGES FACING PHYSICIANS IN 2014

WHILE EXPERTS PREDICT CONTINUED COST PRESSURE IN 2014,

PRIMARY CARE COULD BENEFIT FROM WIDESCALE CHANGE

by **JEFFREY BENDIX, DONNA MARBURY, CHRIS MAZZOLINI, ALISON RITCHIE,** *and* **DANIEL. R. VERDON,** *editors*

Every challenge is an opportunity.

And while this list of 10 challenges facing physicians seems daunting and nearly insurmountable for smaller office-based practices, many believe there is tremendous upside for primary care physicians in leading healthcare delivery in the United States in 2014 and beyond. The result could mean more autonomy; it could mean better quality of life for you and your patients, and hopefully result in less interference with the doctor-patient relationship.

But it's going to take work, management experts say. Physicians will need to reinvent their operations to create efficiencies and thoroughly evaluate the revenue cycle to maximize cash flow. That means you will need to review payer contracts, and look at adopting technology to improve patient care. You may have to re-engineer workloads, workflows and staff responsibilities.

It is exactly this premise that *Medical Economics* is showcasing with this list of 10 challenges and opportunities facing physicians next year. We believe that understanding the dynamics of a changing market will ultimately help physicians shape it, adapt to it and succeed.

Over the course of this past year, we have learned through interviews and surveys that you find tremendous professional satisfaction from helping patients improve their lives. In fact, it continues to be the reason you entered medicine, and the reason you will stay. At the same time there are trends outside of this relationship that are interfering with your time with patients and continually threatening the economic viability of your practice.

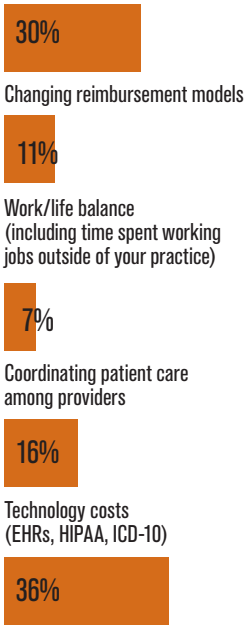
Healthcare is in the throes of great change. And history has shown that large-scale disruption incubates innovation. Our collective opportunity as a healthcare profession is to build a stronger healthcare delivery system rightfully led by primary care that seeks to remain cost conscious, efficient in its delivery, and fairly compensated for helping people attain the most precious commodity of all—a healthy life.

—Daniel R. Verdon

Physicians weigh in on challenges facing primary care

Medical Economics **conducted a web survey asking our readers to tell us what they believe are the major challenges facing primary care in 2014. We received responses from 279 readers. The poll was conducted in late November.**

What do you feel is the biggest challenge facing primary care physicians in 2014?



Source: *Medical Economics* online poll

@ **To participate in future reader polls and get news important to physicians in your email inbox, sign up for** ***Medical Economics*****' eConsult newsletter. Sign up at: MedicalEconomics.com/enewssignup**

Challenge #1 Payment for medical services

ACA AND CHANGING PAYMENT TRENDS

Healthcare's ailing reimbursement system will likely take a turn for the worse in 2014, before it recovers.

And while 2013's payment structure seems dehydrated to many physicians because of tighter negotiated payments by health insurers, escalating costs of doing business, and the seemingly endless cascade of bureaucracy tied to payments, some believe relief won't be felt for the cadre of U.S. physicians in office-based practices for some time.

Why? Healthcare is in the midst of transformational change in the way it is financed. Fifteen of the 16 key provisions of the Affordable Care Act (ACA) will take effect in 2014, and they will most definitely impact the numbers of patients you see and the way you are paid for medical services.

Despite the flawed rollout of the insurance exchanges this fall, coverage for new health insurance enrollees begins on January 1. The new law stipulates that insurance companies cannot drop coverage based on pre-existing conditions. For states that have opted to expand Medicaid, that coverage also begins in January.

While more people are reportedly enrolling in the exchanges, U.S. residents will be required to have qualifying health coverage or face financial penalties. Wellness programs allow 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. The ACA also creates a 10-state pilot program (by July 1, 2014) to track and monitor successes.

On March 31, the insurance exchanges close for 2014 enrollment, and we will have a barometer to gauge how many newly insured Americans entered the market. Data related to physician payments for services by health insurers will also offer another indicator.

Here are some of the keys to watch for next year.

THE NARROW NETWORKS SQUEEZE

Payers are consolidating networks and repositioning in markets as a result of the ACA. We saw the results play out from October through December as physicians received termination notices from key health insurers in more than 10 states regarding network consolidation for Medicare Advantage. (See related story, p. 37.) These moves have impacted thousands of physicians and patients, and this trend may not go away anytime soon.

Narrow networks are believed to offer payers more bargaining power in negotiating contracts with providers and lowering costs of care. Narrow networks also limit choice for patients with a smaller pool of providers and hospitals.

QUALITY AND QUANTITY

The year 2014 will be about cost control, says a recent report from consulting giant pricewaterhousecoopers (PwC) titled "Medical Cost Trend: Behind the Numbers 2014" despite one of the greatest healthcare insurance expansions in history. "For an industry that until recently had consistently seen double-digit growth, the ongoing slowdown poses immediate financial challenges. At the same time, the imperative to do more with less has paved the way for a true transformation of the health ecosystem, from fee-for-service medicine to consumer-centered care that rewards quality outcomes," PwC says.

Traditional fee-for-service is moving toward a payment structured leaning toward compensation based on outcomes. And many variations will likely surface. Models that will be further developed include:

- **bundled payments for services, (and in some cases bundled payments for multiple providers),**
- **episode of care,**

Alternate care venues cost less for routine and minor care*

Source: PwC Health Research Institute
*Minor illnesses include sinusitis, urinary tract infections, common cold, or flu.

(providers paid to treat a specific condition over a period of time),
- Physician Quality Reporting System (incorporating quality metrics),
- shared savings programs (physicians split savings with the insurer), and
- Patient-Centered Medical Home

High-deductible health plans will also pose business challenges for most practices and will require a more aggressive collection policy at the time of visit. PwC estimates that employers offering high-deductible plans as their only option has grown 31% since 2012.

OPPORTUNITIES ABOUND

And while the predictions sound dire, there are plenty of opportunities for primary care to assert its leadership, showcase its status as a relative bargain among healthcare providers, and advance its mission to experiment with direct pay, ancillary services, and team up with employers and insurers to capitalize on innovative wellness programs to improve the health of your patient population and the practice's bottom line. Primary care will need to reinvent its services to patients, reassess its use of technology to better monitor population health and engage patients in new ways.

Challenge #2 Government mandates

2014: THE YEAR OF THE GOVERNMENT MANDATE

When primary care physicians (PCPs) of the future look back on 2014, they may well recall it as the "year of the mandate." That's because PCPs will see their practices affected by four major government-sponsored requirements:

- the use of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) coding system for billing, effective October 1;
- the second stage of the Meaningful Use incentive program (MU2) for electronic health records (EHRs);
- updated rules for the Health Insurance Portability and Accountability Act (HIPAA) and;
- the Physician Quality Reporting System (PQRS).

ICD-10: CONVERT OR DON'T GET PAID

Of these, the requirement to use the ICD-10-CM coding system will probably have the greatest impact, for the simple reason that practices not using the new code set will no longer be reimbursed by third-party payers.

The ICD-10-CM codes require a far greater level of specificity than the current ICD-9-CM code set, and thus require training for coders, billers, and providers, as well as extensive changes to—and testing of—billing software. A 2008 study estimated that conversion costs will range from $83,000 to $2.7 million, depending on the size of the practice.

MEANINGFUL USE: ATTEST NEXT YEAR OR FACE PENALTIES

The coming year will also be important for doctors taking part in the government's Meaningful Use (MU) incentive program to adopt electronic health record (EHR) systems. Those who successfully attested to MU1 in 2011 or 2012 can choose any 90-day period in 2014 to meet their MU2 objectives and qualify for the next round of incentive payments.

In addition, 2014 is the last year in which doctors who have not previously participated in MU can do so and avoid financial penalties beginning in 2015.

HIPAA rule violation categories and penalty amounts

The Health Insurance Portability and Accountability Act (HIPAA) omnibus rule establishes four "tiers" of violations, based on "increasing levels of culpability," with a range of fines for each tier.

Category	Fine range
Did not know of breach	$100 to $50,000
Had reasonable cause to know	$1,000 to $50,000
Willful neglect, corrected	$10,000 to $50,000
Willful neglect, not corrected	$50,000

"As a solo doc, it's almost impossible to do all the requirements. Too expensive if we do and the penalties can put us out of business. Small group practice is dead or dying."

—PHYSICIAN SURVEYED BY *MEDICAL ECONOMICS*

The biggest challenge many doctors will face in attesting to MU2 is meeting the requirements for electronically exchanging patients' health information with other providers, especially those using a different EHR system. EHR vendors are working to include information exchange capabilities in their systems. Participating in a health information exchange network will also enable doctors to meet the interoperability requirements, although the networks are not available everywhere.

HIPAA: RISK ANALYSIS REQUIRED THIS YEAR, PLUS MORE STRINGENT PENALTIES

HIPAA's more comprehensive rule for guarding patients' protected health information (PHI)—and more stringent penalties for failing to do so—began in September, but 2014 will be the first full year in which medical practices feel their effect.

Among other things, HIPAA rules require a practice to conduct and document a risk analysis for their PHI, review its practices and procedures for when PHI is lost or stolen, having the ability to send health information to patients electronically, and update its notice of privacy and ensure its availability to patients. The HIPAA rule also sets and describes the four categories of penalties for rule violations and the dollar amounts for each.

PQRS: REWARD NEXT YEAR, PENALTIES IN 2015

The final mandate requiring PCPs' attention in 2014 is PQRS, the federal program that rewards physicians and practices for successfully reporting on 138 outcome quality measures. That's because 2014 is the last year in which the financial rewards—equal to 0.5% of covered Medicare Part B Physician Fee Schedule (PFS) services—are available. Beginning in 2015, the incentive turns into a penalty equal to 1.5% of covered Part B PFS services. The penalty rises to 2% in 2016.

To-date, physicians' participation in PQRS has been fairly low. It remains to be seen whether the threat of a penalty will cause more doctors to report.

Challenge #3 Payer headaches, and the fine print

NAVIGATING A CONVOLUTED PAYMENT MAZE

The health insurance landscape is more uncertain now than it has ever been. Many physicians are feeling they are on uneven ground, with insurance companies having the upper hand when it comes to how and if they can properly treat the patients who choose to see them.

The Affordable Care Act has caused many insurance companies to make drastic changes—dropping physicians from panels, causing patients to scramble for new plans and new doctors, and making the whole process of finding quality healthcare even more confusing and tedious.

Medical Economics recently polled physicians on their concerns for 2014, and dealing with payers was one of the top issues cited. "Getting done what patients need will be very difficult if we have to call for everything including for medications," one doctor told *Medical Economics* anonymously. "Paymentwise, MDs have no say. Take it or leave it. Like UnitedHealthcare thinks now patients are theirs and not doctors'."

"Insurance companies dictate which doctor, which medicine, which test, how long in the hospital," said another surveyed physician. "Insurance companies have planted themselves between the patient and doctors and on top of the money pile."

> "Payment wise, MDs have no say. Take it or leave it."
>
> "Insurance companies have planted themselves between the patient and doctors and on top of the money pile."
>
> —PHYSICIAN COMMENTS FROM *MEDICAL ECONOMICS* ONLINE SURVEY, NOVEMBER 2013

UNITEDHEALTHCARE DROPS PHYSICIANS

In a developing story, UnitedHealthcare cut physicians from its Medicare Advantage program, with plans to reduce its 350,000-nationwide physician panel by up to 52,500 in 2014.

Doctors in at least 10 states have already received letters

from multiple payers telling them they are no longer part of certain networks, according to the American Medical Association. Aside from class-action lawsuits, restraining orders, and appealing, which could take months or years, there isn't much a physician can do to fight back against being dropped.

Experts believe that the uncertainty surrounding health insurance will continue to fall on physicians—and that patients will ultimately be the ones to suffer as a result. UnitedHealthcare is said to be the first of many payers who will start dropping Medicare Advantage physicians, and any other physicians who can't adhere to strict metrics that don't fully consider quality of care.

$3,430

THE COST OF PRIOR AUTHORIZATION ACTIVITIES PER FULL-TIME PHYSICIAN.

—2013 STUDY BY THE *JOURNAL OF THE AMERICAN BOARD OF FAMILY MEDICINE*

PRIOR AUTHORIZATIONS CONSUME TIME, MONEY

In the office, prior authorizations continue to sap time and money from practices.

With more time and staff dedicated to communicating with payers, prior authorization activities can cost a practice up to $3,430 per full-time physician, according to a 2013 study published by the *Journal of the American Board of Family Medicine.*

"This all wastes a lot of our time, and it's not reimbursed," says Jeffrey Kagan, MD, an internal medicine practitioner in Newington, Connecticut, and *Medical Economics* editorial adviser. "I feel that if an authorization has to be done the insurance company should allow a higher level of billing for the visit or a surcharge. I'm sure attorneys don't bring motions before a judge for free."

With more patients entering the healthcare system and more payers involved with more physicians, the pressure from insurance companies is not likely to yield in 2014 or in the near future.

Challenge #4 Time

FINDING TIME FOR PATIENTS DESPITE ESCALATING ADMINISTRATIVE NOISE

Primary care physicians (PCPs) pursued medicine because they want to help patients. But every year, physicians complain they are spending less time with patients and more time dealing with the noise that surrounds the business of medicine.

In 2014, it may be deafening.

So, what is the noise? It's all the requirements that pull physicians away from seeing patients and helping them become or remain healthy. It's the government regulations and private payer requirements they must meet; it's the day-to-day difficulty of trying to a run a business, not have enough time.

Next year may be a perfect storm that forces physicians to spend even less time with their patients. The rollout of the Affordable Care Act means business uncertainty, new requirements, and possibly floods of newly-insured patients crowding already busy patient panels. October 1 has been set as the date for the switchover to International Classification of Diseases, 10th Revision, Clinical Management (ICD-10-CM) coding language. Practices that don't successfully make that switch will simply not get paid.

In addition, practices will either be playing catch-up to meet Meaningful Use 1 or embarking on the much more challenges stage 2 requirements.

Medical Economics provided physicians with an opportunity to make anonymous comments about the challenges facing primary care. Many were concerned that the onslaught of requirements are drowning out the joy of why they chose medicine in the first place.

"I think both the patient and the physicians are fearful about the future of medicine."

—PHYSICIAN COMMENT FROM *MEDICAL ECONOMICS*' ONLINE SURVEY, NOVEMBER 2013

"I love the patient interaction as much as ever but it is being slowly eroded by so many factors which are beyond our control," a physician told *Medical Economics*. "I think both the patient and the physicians are fearful about the future of medicine."

➔30

Indication

BELVIQ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obese), or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, dyslipidemia, type 2 diabetes).

Limitations of Use

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

Important Safety Information

Contraindication

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

Warnings and Precautions

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

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

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

Most Common Adverse Reactions

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

Nursing Mothers

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

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

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

BELVIQ® (lorcaserin HCl) CIV

BELVIQ®
(lorcaserin HCl) CIV

BRIEF SUMMARY:
For prescribing information, see package insert.

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

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

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

CONTRAINDICATION
- Pregnancy

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

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

Most Common Adverse Reactions

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

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

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

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

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

(Table continues)

Table 2. (cont'd.)

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

Other Adverse Reactions

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

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

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

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

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

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

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

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

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

Echocardiographic Safety Assessments

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

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

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

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

DRUG INTERACTIONS

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

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

USE IN SPECIFIC POPULATIONS

Pregnancy. Pregnancy Category X.

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

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

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

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

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

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

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

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

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

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

DRUG ABUSE AND DEPENDENCE

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

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

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

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

OVERDOSAGE

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

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

Challenge #5 Technology costs

STICKER SHOCK: THE COST OF TECHNOLOGY

Practice owners can expect some big health information technology expenses in 2014, as ICD-10 goes live in October, and continuing costs of electronic health records (EHR) systems and Health Insurance Portability and Accountability Act (HIPAA) compliance continue to be significant.

"We are still slowed down 2-plus years after switching to an EHR, and there seems to be a never-ending stream of updates and other expenses, not to mention the costs of the IT guys when something goes wrong," Rebecca Preston, MD, a family physician at Preston Family Practice in Western Springs, Illinois, told *Medical Economics* in a recent poll. "I dread the thought of ICD-10, especially when a lot of it does not have anything to offer me as a primary care doctor."

This is even more of a challenge when physicians see much of the technology they must purchase as a hindrance, not a benefit, to their practice.

"Many practice-based physicians will be challenged to find time and resources to fully understand all of these programs and associated operational implications, and implement new and updated supporting technologies while focusing on their primary role—patient care," says Mickey McGlynn, Health Information and Management Systems Society EHR Association chair.

Though there are EHR holdouts—20% of primary care physicians still don't have them, and 34% say they don't plan on ever getting an EHR system, according to *Medical Economics* 2013 Continuing Survey—the reality is that technology upgrades could make or break your business in the next year.

"Our industry is in a period of rapid transformation. Physician practices are doing more and more to innovate and respond to our rapidly changing environment to meet the needs of their patients, but with fewer resources," says Susan L. Turney, MD, MS, FACMPE, FACP, president and chief executive officer of the Medical Group Management Association.

Cost of average EHR system

IN-OFFICE

$33,000	$4,000
UPFRONT COST	YEARLY COST

SAAS

$26,000	$8,000
UPFRONT COST	YEARLY COST

http://www.healthit.gov/providers-professionals/faqs/how-much-going-cost-me

Source: HealthIT.gov

"Our industry is in a period of rapid transformation. Physician practices are doing more and more to innovate and respond to our rapidly changing environment to meet the needs of their patients, but with fewer resources."

—SUSAN L. TURNEY, MD, MS, FACMPE, FACP, PRESIDENT AND CEO OF THE MEDICAL GROUP MANAGEMENT ASSOCIATION.

COST OF IMPLEMENTING ICD-10 FOR A SMALL PRACTICE

+ $2,405 STAFF TRAINING

+ $6,900 BUSINESS-PROCESS ANALYSIS OF HEALTH PLAN CONTRACTS, COVERAGE DETERMINATIONS AND DOCUMENTATION

+ $2,895 CLAIM FORM (SUPERBILLS) SOFTWARE

+ $7,500 IT SYSTEM CHANGES

+ $44,000 INCREASED DOCUMENTATION COSTS

+ $19,500 CASH-FLOW DISRUPTION

= **$83,200**

Total estimated cost for a practice with three physicians and two administrative staff

http://www.mgma.com/press/default.aspx?id=22586

Source: MGMA, Nachimson Advisors

Challenge #6 Staffing and training

HIGHER STAFF TURNOVER MEANS NEW PRACTICE COSTS

flexibility and efficiency—those two qualities will be crucial for staff recruitment and training in 2014. For many medical practices, survival in the changing healthcare landscape will require staff members to embrace a team-oriented culture and take on new roles within the practice.

As reimbursements become increasingly tied to performance and patient outcomes, success will depend on practices functioning as a team, and more will likely implement the Patient-Centered Medical Home (PCMH) or Accountable Care Organization (ACO) models.

"[These changes] will place increasing pressure on primary care physicians (PCPs) to partner with other providers who share their concept of quality medical care. This may be very difficult due to the independent thinking and personalities of PCPs, specialists, and other providers, who may have the 'what's in it for me' bias," one physician wrote in a *Medical Economics* survey.

But finding support staff that meets the necessary criteria is easier said than done. Another survey respondent shared their practice's ongoing struggle: "We can't find primary care doctors, and the midlevels we are coming across don't give us much confidence. Our growth is severely handicapped by the difficulty in finding strong employees."

6.8%

PHYSICIAN TURNOVER RATE, A NEW HIGH.

—ANNUAL PHYSICIAN RETENTION SURVEY, THE AMERICAN MEDICAL GROUP ASSOCIATION & CEJKA SEARCH

Coupled with hiring challenges is the difficulty of keeping talented employees once you find them. Earlier this year, the American Medical Group Association (AMGA) and Cejka Search released their annual Physician Retention Survey, which showed that the physician turnover rate hit a new high at 6.8%. The same survey also predicts that the difficulty of hiring and retaining physicians will likely intensify in the coming years, as the primary care physician shortage persists and more aging physicians begin to retire from the workforce.

Training will also be paramount next year for both current and new employees, especially in preparation for the transition to the International Classification of Diseases, 10th Revision, clinical management coding system. Practice owners should anticipate additional hours and costs required for staff training.

Challenge #7 Putting control back in the hands of physicians

STRESS, LACK OF AUTONOMY SOUR ATTITUDES ABOUT MEDICINE'S FUTURE

It's getting harder for solo practitioners to keep their heads above water financially, and their love for practicing medicine seems to be fading. Responses from the *Medical Economics* 2013 Physician Profile Survey regarding job satisfaction seem dismal, to say the least.

About a dozen physicians said there was "too much regulation." More pointed to stress, uncertainty, and workload. One doctor summed up what many feel: "Training is too long and too expensive. Work hours are horrible. Reimbursement continues to fall. Regulation continues to increase."

Physicians feel they are doing a good job when they are providing quality care, and according to a report by the RAND Corporation, productivity quotas and regulations are roadblocks to job satisfaction.

52%

PHYSICIANS WHO ARE PRACTICE OWNERS.

—AMA 2012 PHYSICIAN PRACTICE BENCHMARK SURVEY

Although it is widely believed that better working conditions are leading primary care doctors (PCPs) to flee to hospital employment, in reality most PCPs continue to own their practices. Nearly 62% of internal medicine specialists are practice owners, while almost 56% of obstetricians/gynecologists and 46% of internists are practice owners, according to the American Medical Association's 2012 Physician Practice Benchmark Survey. The numbers decline when it comes to family practice (39.8%) and pediatrics (37.3%).

So in the face of increased regulations, decreased reimbursements, and technology that interferes with the doctor/patient relationship, what is the incentive for physicians to maintain their autonomy? "Many doctors like the lifestyle that goes with owning a private practice. This extends beyond specialty," Charles Cutler, MD, FACP, chair of the Board of Regents of the American College of Physicians said in the October 10, 2013 issue of *Medical Economics*.

One physician from our survey offered this explanation: "I love practicing medicine. I can't imagine anything else that gives me the intellectual challenge, the ability to work with people and teach, and the physical opportunity to act and help people become better."

Challenge #8 Changing patient populations

2014: THE YEAR OF THE NEW PATIENT?

Millions of Americans without health insurance will soon have it because of Medicaid expansion and other provisions of the Affordable Care Act (ACA).

What happens next is the crucial question. How many of those newly-insured individuals will try to see a primary care doctor in 2014? These patients will present new challenges to physicians when it comes to both providing care and anticipating revenue.

The year 2014 is shaping up to be the year of the new patient and, perhaps just as importantly to practice owners, the year of the high-deductible health plan patient.

As *Medical Economics* reported in its December 10, 2013 issue, as many as 80% of these newly-insured patients are at high risk of nonpayment. Medical Group Management Association (MGMA) President and Chief Executive Officer Susan L. Turney, MD, MS, FACMPE, FACP, says that the MGMA has identified collecting from self-pay, high-deductible, or health savings account patients is one of biggest challenges identified by MGMA members.

As a result, more physicians will have conversations with patients that until recently were regarded as taboo. They are going to be talking about money, and the cost of procedures. This has implications for the healthcare system as a whole (evidence shows that simply discussing healthcare prices can push costs down) and for individual physicians, many of whom feel ill-at-ease talking about money with patients or taking actions such as charging for treatments in advance.

That is going to change. "There aren't many industries that the customer pays so far after the service is performed. Physicians need to get out in front of the payment. This is a big change in the mindset for the industry. Providers won't be able to afford to collect payments after service for much longer," Nate Davis, product manager

➔35

➔32 with ZirMed, a healthcare information technology and management solutions company in Louisville, Kentucky, told *Medical Economics* as part of an article about high-deductible health plans.

PAGING DR. GOOGLE

A possible horde of new patients isn't the only change in patient populations that physicians will have to confront. Today's patients are less likely to take what a physician tells them at face value, and often come to appointments armed with a self-diagnosis backed up by information they obtain from WebMD and Google. Nearly 60% of patients are considered "online diagnosers," according to the Pew Internet & American Life Project.

80%

NEWLY-INSURED PATIENTS WHO ARE AT A HIGH RISK OF NONPAYMENT

—MEDICAL ECONOMICS, DECEMBER 10, 2013

Pro-active patients are a generally good thing, but they present new challenges to physicians. "My hope is that patients will come in with questions, having done some reading," Reid Blackwelder, MD, FAAFP, president of the American Academy of Family Physicians, told *Medical Economics* for our Dec. 10, 2013 article on doctor-patient relationships. "It makes my role easier in caring for that patient, but it does sometimes require a different mindset for us physicians, because medicine has for a long time been very patriarchal."

The good news for physicians is that Dr. Google isn't cutting into their business. The Pew project found that more than half of the "online diagnosers" consulted with their doctor or a medical professional about what they found online.

Challenge #9 Primary care's changing role

ARE PCMHs THE FUTURE OF PRIMARY CARE?

Many thought leaders in family and internal medicine believe that the reforms brought on by the Affordable Care Act will ultimately create a more unified, less fragmented healthcare system. The vision is that primary care physicians will lead the delivery of medicine and coordinate care through the maze of specialists.

It's a future that isn't steeped in the chronic bureaucratic headaches that seem so pervasive today, but offers a broad vision of tomorrow that might ultimately transform how patients receive care and follow-up to it.

Much of this vision is focused on the Patient-Centered Medical Home (PCMH). According to the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ), the PCMH performs five functions:

1. Offers comprehensive care for prevention and wellness, acute and chronic care;
2. Treats the whole person based on his or her unique needs, culture, values and preferences;
3. Coordinates care among healthcare system (specialty care, hospitals, home health care, and community services and supports);
4. Offers greater access to services (with shorter waiting times for urgent needs and enhanced in-person hours);
5. Commits to quality care and quality improvement using evidence-based medicine to guide shared decision-making with patients and families.

"AHRQ recognizes the central of health information technology in successfully operationalizing and implementing the key features of the medical home. Additionally, AHRQ notes that building a primary care delivery platform that the nation can rely on for accessible, affordable, and high-quality health care will require significant workforce development and fundamental payment reform."

The challenge for primary care practices will lie in conducting a thorough analysis of its organization, health information technology platform, procedures, and policies related to coordinating care across the medical neighborhood, examining access to the practice, supporting self-managed care, and utilizing risk-stratified care management principles to manage patient populations.

It is a far different approach to medicine, and it will take some work to transform most practices into a highly-efficient PCMH, reports the American Academy of Family Physicians. In fact, Robert L. Wergin, MD, FAAFP, a family physician in Milford, Neb., and president-elect of the AAFP, says that nearly three-quarters of the association's members are working toward some of these PCMH tenets, including expanded office hours.

If you are interested in the PCMH concept, AAFP has compiled a number of resources specifically to help family physicians at www.aafp.org/pcmh.

Here are some of the concepts addressed: ➔36

➔35

Operations:
- Create and refine the organizational structure
- Define the work associated with concepts like care coordination
- Rework job descriptions/duties
- Budget and forecast for the future
- Redefine the cultural based around operating in a high-producing healthcare team

Health information technology:
- Assemble a project team
- Assess the practice's readiness communicate, share data, e-prescribe and analyze trends within patient populations
- Evaluate your EHR's system capabilities
- Establish new workflows where necessary
- Create new policies related to email, use of smart phones, texting, etc.

Quality:
- Define a planned care visit, and identify your team
- Set team goals
- Set up a Plan-Do-Study-Act cycle to measure outcomes
- Collect and analyze data to improve care

Patient-centered care
- Set up same-day appointments
- Develop an online presence for your practice
- Create mechanisms to encourage patient self-management
- Assess patient satisfaction

Challenge #10 Work-life balance

RECONNECTING WITH LIFE OUTSIDE OF THE OFFICE

There is no such thing as a 40-hour workweek for physicians. More than 73% of physicians surveyed by *Medical Economics* work more than 40 hours per week, and about 24% work more than 60 hours per week. The demands of the profession mean that for many physicians the work-life balance is tipped heavily toward work, and that's unlikely to change in 2014.

Next year, physicians will confront uncertainty as the Affordable Care Act takes full effect and emerging care and reimbursement models that put greater focus on patient outcomes and accountability are pushed to the forefront. They will deal with complicated government mandates, including the switchover to ICD-10-CM and more complicated stage 2 Meaningful Use incentive requirements. On top of that, practice owners will continue to face declining reimbursement struggle to keep their businesses viable.

The onslaught of these pressures can lead to the dreaded occupational hazard: burnout. "I am so burned out from complying with regs, adapting to new technology that is less than reliable, juggling an accounts receivable checking account and paying bills that I find myself coming home later and going into office earlier every day," says an anonymous physician responding to a *Medical Economics* survey published in the November 25, 2013, issue. "I would like to have a better work life balance but without an income it's hard to balance!"

So physicians decide they need to work longer hours—and even second jobs—to stay afloat. About 36% of primary care physicians (PCPs) moonlighted on a second job, according to *Medical Economics* survey results. Meanwhile, home lives are sacrificed and career satisfaction declines. More than 30% of PCPs told *Medical Economics* that they would not recommend their child pursue a career in medicine. More than that, burnout is causing many physicians to quit practicing medicine or retire early, which only worsens the primary care shortage.

> "I am so burned out from complying with regs, adapting to new technology that is less than reliable, juggling an accounts receivable checking account and paying bills that I find myself coming home later and going into office earlier every day."
>
> —PHYSICIAN SURVEYED BY *MEDICAL ECONOMICS*

Maintaining a reasonable work-life balance helps safeguard physician wellness which "helps us serve as better role models for our patients and as even more enthusiastic providers of care when we are physically, mentally, and emotionally healthy," says Tim Sayed, MD, a plastic surgeon who serves on the Healthcare Information and Management Systems Society Electronic Health Record Association Executive Committee.

The unavoidable fact is that unhappy physicians make for a poorer healthcare system. Fixing the issues of physician work-life balance is a major component to improving healthcare in the United States. ◘

Physicians fight back against UnitedHealthcare

Connecticut medical groups have won an injunction to temporarily halt the company's plan to drop doctors from its Medicare Advantage panels

by **KEITH GRIFFIN** *Contributing author*

A quickly coordinated, multi-front campaign by two Connecticut medical associations has resulted in a preliminary injunction against UnitedHealthcare and its plan to cut more than 2,200 physicians, or about 20% of its network in Connecticut, from its Medicare Advantage panels.

The Hartford County and Fairfield County medical associations first became aware of UnitedHealthcare's intentions in October when member physicians began receiving notices that they would not have their contracts renewed.

The notices sent a seismic shock through the state's medical community as the realization sank in that approximately one in five doctors were being cut from the company's Medicare Advantage panels and between 20,000 and 30,000 patients were going to be affected.

The primary front in the battle against the company's plan thus far has been the court case. On November 6, the associations filed suit against UnitedHealthcare in U.S. District Court in Bridgeport, Connecticut, before Judge Stefan Underhill.

On December 7, Underhill ruled that the Hartford County Medical and Fairfield County Medical associations "met their burden of demonstrating that they will suffer harm that is imminent and

"We understand this is an uphill battle. It's costly and could take a long time. We're not as rich as UnitedHealthcare but we have the public with us."

—BOLLEPALLI SUBBARAO, MD, PRESIDENT OF THE HARTFORD COUNTY MEDICAL ASSOCIATION

The bigger picture

The struggle in Connecticut may be the opening salvo in an escalating fight between payers and providers. Thousands more physicians in Arkansas, Florida, Indiana, Nebraska, New Jersey, New York, Ohio, Rhode Island, Texas, and Utah are believed to have been impacted by recent network cancellations by health insurance companies, according to the American Medical Association (AMA). Physicians have reported receiving cancellation letters from Blue Cross and Blue Shield plans, Anthem, and Humana.

The Medicare Advantage cancellation notices are coming on the heels of a seriously debilitated rollout of the Affordable Care Act's insurance exchange, and widespread insurance cancellations now estimated at impacting some 7 million U.S. citizens. The AMA, with 81 other medical groups, said the terminations were "without cause" and called on the Centers for Medicare and Medicaid Services to address the issue.

cannot be adequately compensated through damages."

The injunction forces UnitedHealthcare to start proceedings from the beginning and "do it the right way," says Roy Breitenbach, JD, legal counsel for the medical associations.

"[The decision] levels the playing field, and we're prepared to go forward," contends Breitenbach, a partner/director of Garfunkel Wild PC in Great Neck, New York. "If they start from scratch and follow the termination proceedings, there are certain rights to follow the termination."

UnitedHealthcare intends to immediately appeal the decision, the company says in an e-mailed statement.

"We believe the court's ruling will create unnecessary and harmful confusion and disruption to Medicare beneficiaries in Connecticut," says Terry O'Hara, chief communications officer for UnitedHealthcare Group. "We know that these changes can be concerning for some doctors and customers, and supporting our customers is our highest priority. UnitedHealthcare will continue to stay focused on the people we serve."

> "THIS IS GOING TO AFFECT US WITH ALL INSURANCE COMPANIES IF WE DON'T TAKE A STAND."

— LAUREEN RUBINO, MD, GENERAL SURGEON, MANCHESTER, CONNECTICUT

The ruling affects only members of the Hartford County Medical Association and Fairfield County Medical Association. It does not cover the state's other medical associations, including the Connecticut State Medical Society and its members. The majority of the affected 2,200-plus physicians are reported to be in Hartford, New Haven, and New London counties.

WHAT THE RULING MEANS

The judge's ruling boiled down to evidence that UnitedHealthcare appears to have breached its contract with the physicians by removing them without cause or explanation, in apparent violation of Medicare regulations. Underhill wrote: "At oral argument, United suggested that it routinely amends [the contract] without the consent of participating physicians as a way of removing physicians from participation in a particular plan." But the judge noted the insurer provided no evidence of that in follow-up documents and, in fact, only used the amendment "to add physicians to the network, not delete them."

Bollepalli Subbarao, MD, president of the Hartford County Medical Association, characterized those actions by UnitedHealthcare as "pure abuse."

"Both the Fairfield and Hartford County medical associations took this bold step for our patients and for our member physicians. We won't let UnitedHealthcare get away with interfering with the doctor-patient relationship. While this is one huge step in the right direction, the journey is far from over," said Robin Oshman, MD, president of the Fairfield County Medical Association, in a statement following the judge's decision.

Angela Mattie, MPH, JD, chair and associate professor in the Healthcare Management and Organizational Leadership Department in the Quinnipiac University School of Business in Hamden, Connecticut, is a healthcare lawyer who has been following the issue. She said things might change regardless of who prevails in the court case.

"Basically this is a contract issue in its purest form. The contract terms that had existed … may cease to exist between the insurer and provider as far as longevity and length of time on the contract. There's the

> "[The decision to drop physicians] was simply to fatten the bottom line of UnitedHealthcare."
>
> —U.S. SENATOR RICHARD BLUMENTHAL (D-CT)

potential there will become less of a contractual relationship with the insurer and the relationship will become more at-will."

WAGING A MEDIA BATTLE

While the legal case is ongoing, the physicians have been working to make their voices heard among members of the public and in national and state capitals. Federal and state legislators along with member physicians were brought together with affected patients at two town hall meetings in Westport, and West Hartford, Connecticut so all parties could plead their cases before the media.

No punches were pulled at the meetings. At West Hartford's town hall, Michael Saffir, MD, president of the Connecticut State Medical Society and a psychiatrist practicing in Fairfield, termed UnitedHealthcare's actions a "sneak attack" because of its timing at the start of the open enrollment period. He said the insurer's decision not to consult its own medical advisory panel was "idiotic" and prompted doctors' resignations from the panel.

Laureen Forgione-Rubino, MD, a general surgeon from Manchester, Connecticut, warned of dire times ahead if doctors don't win this fight against UnitedHealthcare. "This is going to affect us with all insurance companies if we don't take a stand," she said. "It will spread to other insurance companies if we don't stop this."

Rubino said that most doctors don't vet their contracts with insurers or hire attorneys to review them, usually choosing instead to focus only on key issues.

"Whoever thought they could cut you out of the entire program?" she said, a point driven home when a UnitedHealthcare representative told her office manager the move was taken because it was allowed in her contract.

Rubino said 35 patients in her practice were affected by her being cut from the network before the injunction. "It's difficult because there's no criteria. I don't have malpractice. I don't have any issues. I do the third-most robotic surgeries in Connecticut. The way they did it I can't take care of my patients anymore."

U.S. Senator Richard Blumenthal (D-CT) also spoke at the town hall meeting. He said the entire Connecticut Congressional delegation has been conferring with officials of the Centers for Medicare and Medicaid Services (CMS) to push it to determine the adequacy of UnitedHealthcare's network in the wake of so many doctors being cut.

STATEMENT FROM UNITEDHEALTHCARE ON RULING

"We believe the court's ruling will create unnecessary and harmful confusion and disruption to Medicare beneficiaries in Connecticut. We know that these changes can be concerning for some doctors and customers, and supporting our customers is our highest priority. UnitedHealthcare will continue to stay focused on the people we serve."

—TERRY O'HARA, UNITEDHEALTHCARE GROUP

> "THE INDIVIDUAL ACTIONS OF MANY DOCTORS CAN BRING AN INSURANCE COMPANY TO ITS KNEES AND THREATEN ITS ECONOMIC VITALITY."
>
> —MICHAEL P. CONNAIR, MD, ORTHOPEDIC SURGEON, NORTH HAVEN, CONNECTICUT

"We're determined to use every bit of persuasion available to us," he said, slamming UnitedHealthcare for not being responsive to legislative calls for information regarding its decision, which he said was done "simply to fatten the bottom line of UnitedHealthcare."

PHYSICIANS WEIGH IN

O'Hara, the spokesman for UnitedHealthcare, refuted charges of a lack of communication. "We've worked with multiple parties at the state and local level to help understand the changes we're making and the reasons," he said in a phone conversation.

Blumenthal told *Medical Economics* in an interview after he spoke, "My hope is [CMS] will be responsive. If they're not, I'm not sure what the next step will be. I won't discuss our options beyond that. We're not in the business of making threats but we will consider the alternatives," he said.

One doctor at the meeting took a different tact. He said instead of UnitedHealthcare releasing doctors, physicians should quit the insurer. Michael P. Connair, MD, an orthopedic surgeon from North Haven, Connecticut, called on his medical colleagues—not acting in collusion—to stop working for UnitedHealthcare. "The individual actions of many doctors can bring an insurance company to its knees and threaten its economic vitality," he told the audience of 63, which included legislators, doctors, patients, and association staff members.

Connair, who is a member of the National Union of Hospital and Health Care Employees, as well as the Federation of Physicians and Dentists, cited actions by physicians in Ohio and Rhode Island when insurers sought to cut reimbursement rates. The physicians' departures from the insurance companies left them without enough doctors to provide adequate coverage in their networks. "UnitedHealthcare crumbles pretty quickly if they don't have the services for their patients," he said.

The associations also held a press conference on December 5 at Connecticut's Legislative Office Building in Hartford. Addressing TV news, radio, web, and print journalists, doctors and legislators made impassioned pleas against UnitedHealthcare and proposed at least one legislative solution when the General Assembly convenes in February.

Osham, president of the Fairfield County Medical Association, said states should be able to determine the adequacy of an insurer's coverage network rather than CMS and an insurer. She cited the case of a dialysis patient who was advised to obtain treatment by taking a ferry across Long Island Sound to New York after all the nephrologists were eliminated from UnitedHealthcare's panel in Bridgeport, Connecticut.

Prasad Srinivasan, MD, a Glastonbury, Connecticut allergist and Connecticut state representative, said legislation on network adequacy would be introduced when the General Assembly convenes in February. "A 10-mile radius might be adequate for maintaining coverage, but is it appropriate to send a dialysis patient on a ferry?" he asked.

Subbarao, the Hartford County Medical Association president, said before the court ruling, "We understand this is an uphill battle. It's costly and could take a long time. We're not as rich as UnitedHealthcare but we have the public with us." ■

How the ACA will transform primary care practices

Experts discuss five ways healthcare reform will change how physicians run their businesses

by **DEBRA BEAULIEU** *Contributing author*

HIGHLIGHTS

01 Expect newly insured patients visiting your office to need more of an orientation into how their health plans work.

02 Adopting a team approach will take on even greater importance to providing comprehensive, preventative, whole-person care called for in reform efforts.

The dynamics of primary care will enter a new era as major provisions of the Affordable Care Act (ACA) take effect on January 1, 2014. While the changes are expansive and the impacts are in many ways still unknown, experts who spoke with *Medical Economics* offered predictions falling into five main categories.

1/ Increased demand

As the first stop for many patients who will be newly insured under health reform, primary care physicians (PCPs) can expect to see an uptick in volume and demand. What's more, winter illnesses make January and February high-demand months for PCPs anyway, says notes practice-management consultant, speaker, and author Elizabeth Woodcock, MBA, FACMPE, CPC. "This natural patient demand, combined with the ACA, is really going to be a perfect storm coming as we move into 2014," she says.

Storm or not, Robert L. Wergin, MD, FAAFP, a family physician in Milford, Nebraska, and president-elect of the American Academy of Family Physicians (AAFP) says he welcomes the opportunity to see more insured patients in his office, which is located in a rural community of about 2,000 people.

"In my practice I already see a fair number of uninsured or reduced-cost patients. You often see these people with acute illnesses, so I see [the ACA] as an opportunity to address many of the other issues they may have," he says.

With more financial barriers removed, Wergin also says he's encouraged by the opportunity to provide patients who choose him as their regular physician with more comprehensive care. →42

2/ Growth of Patient-Centered Medical Homes (PCMH)

To truly provide the comprehensive, preventative, whole-person care Wergin and many of his colleagues want to providea team approach to care will take on even greater importance.

"I'm going to call on my physician assistant, nurse practitioner and even staff to utilize their services and hopefully allow physicians to just do what physicians need to do and delegate what we don't," he says.

And given the expected rise in demand, practices will be even more behooved to act on the PCMH tenet of increased access. According to Wergin, 71% of AAFP members have already expanded their daily office hours to accommodate patient needs and 30% have expanded weekend hours.

At his own practice, the physicians take turns providing coverage for Saturday office hours, Wergin says.

3/ Coping with the effects of increased market churning

Although it's not a new phenomenon, plans offered under ACA insurance exchanges may in some cases offer patients narrower provider networks, notes Molly Cooke, MD, FACP, a professor of medicine at the University of California San Francisco and president of the American College of Physicians. So if a patient's longtime physician is excluded from the new network, the patient will have to choose between paying the out-of-network fee and finding a new doctor.

This creates a great deal of churning in the marketplace, Cooke says. "There's a fair amount of cost and waste associated with the general phenomenon of making patients switch doctors," she says.

In her own practice, Cooke explained that she might be able to visit with even a fairly sick established patient for 15 to 20 minutes, but that it might take 45 minutes to get up to speed on an identical new patient. "Anytime you start creating these wholesale shifts in where patients are getting their care, it's burdensome on the system, it's a burden to the individual clinician, and it's a hardship for patients."

> "Anytime you start creating these wholesale shifts in where patients are getting their care, it's burdensome on the system, it's a burden to the individual clinician, and it's a hardship for patients."
>
> —MOLLY COOKE, MD, FACP
> PRESIDENT, AMERICAN COLLEGE OF PHYSICIANS, AND PROFESSOR OF MEDICINE, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

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4/ Managing patients' coverage questions

Although patients already bring many of their questions about insurance, deductibles, and similar issues to the doctor's office, Wergin expects newly insured patients visiting his office to need even more of an orientation into how their health plans work. "We're preparing to handle some of that," he says. "We want to be patient centered and help them with that, and we assume they may have questions in that regard."

But the time required to provide this education is not plentiful in busy practices, nor is it reimbursed, says Cooke. What Woodcock recommends is that all office staff have access to contact information for patient navigators in their communities, and to advise patients to talk to their employers and benefits officers about their coverage. "I advise very pleasantly responding to patient questions, and at the same time making sure the patient has somewhere to go to direct questions, and frankly not asking the physician's practice every which way, because they don't have time to do that," Woodcock says.

> "I advise very pleasantly responding to patient questions, and at the same time making sure the patient has somewhere to go to direct questions."
>
> —ELIZABETH WOODCOCK, MBA, FACMPE, CPC
> PRACTICE MANAGEMENT CONSULTANT

5/ Updating work flows

"Clearly, the old way of doing business, the old traditions about who did what kind of work and how patients interact practices and who they spend time with about which problem—that's all going to need to change," says Cooke.

Nonetheless, according to data from the Medical Group Management Association released in October, more than half (52%) of surveyed practices have no business changes planned as a result of the health exchanges opening.

The reasons for this inertia, according to Cooke, have less to do with nostalgia or avoidance, and much more to do with physicians and practice leaders—especially in generalist and primary care practices—being stretched so thin already. "People are so busy that they don't really have time to take two hours or half a day to even think about who's there in the office and how they might reorganize things," she says.

In making the case to do so, however, Cooke uses a skiing analogy. If a skier takes a lesson, very often an instructor will recommend changes to the athlete's technique that will enhance that person's skill going forward. "But while I try to incorporate those changes, I don't have any muscle memory for the new way of doing things. So I'm better off after my lesson dropping down to some easier slopes and really trying to incorporate the new skills into my practice," she says. "And that's where I think clinicians are very challenged now. Everyone is so busy and their margins are so thin that they don't have time to say we're going to practice at 80% of our normal volume for 6 weeks and learn some new work flows."

But despite 2014 representing an incredibly demanding time for outpatient practice, Cooke says that these are challenges the healthcare community can indeed overcome.

30 MILLION

estimated number of newly insured patients under ACA

Source: Whitehouse.gov

27

States and the District of Columbia have decided to expand Medicaid, as of early December

Source: The Commonwealth Fund

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

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Expiration Date: December 1, 2014

LEARNING OBJECTIVE

- Cite risk factors for NSAID-induced renal failure
- List patient education pearls to prevent NSAID-related gastrointestinal and renal toxicity

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Activity Type: Knowledge-based
ACPE ID# 0781-0000-13-009-H05-P

NSAIDs and Renal Toxicity in the Community Setting: A Practical Guide for Clinicians

Non-steroidal anti-inflammatory drugs (NSAIDs) are a diverse group of medications widely used for controlling pain and inflammation associated with musculoskeletal conditions.[1] NSAIDs have common analgesic, anti-inflammatory, and anti-pyretic properties. They represent approximately 60% of over-the-counter (OTC) analgesic agents (e.g., acetylsalicylic acid, ibuprofen, and naproxen) in the United States.[2,3] A recently published analysis of data from the National Ambulatory Medical Care Survey (NAMCS) representing 690 million individuals found that between 2000 and 2007, NSAIDs were prescribed for pain in 95% of patient visits.[4]

A recent multidisciplinary roundtable discussion among healthcare providers reinforced that, while NSAIDs act rapidly and are generally well tolerated, patients need to be informed about the range of adverse effects that can be associated with NSAID use, such as gastrointestinal (GI), cardiovascular, hepatic, and renal effects.[1,5]

Moderator: We're becoming more aware of adverse renal effects associated with NSAIDs. How do NSAIDs affect the kidneys?

John Devlin, PharmD: NSAIDs exert their analgesic and anti-inflammatory effects by inhibiting prostaglandin production through their ability to block the synthesis of the cyclo-oxygenase (COX)-2 products of arachidonic acid. At the same time, NSAIDs also inhibit COX-1 production that results in the reduced production of renal prostaglandin that has an important vasodilatory, protective effect in the renal vasculature.[5-8] While this effect is unlikely to be clinically significant in healthy patients with normal renal blood flow, it can result in renal impairment in patients with reduced renal blood flow (e.g., congestive heart failure) or in patients with preexisting renal vasoconstriction (e.g., hypertension).[5,7,9] A decrease in renal blood flow reduces the glomerular filtration rate (GFR) and leads to an increase in serum creatinine. Less commonly, NSAIDs can also exert an

PUTTING CONCEPTS INTO CLINICAL PRACTICE

Two new clinically-focused, CME-certified case studies are now available online focusing on the use of NSAIDs in the primary care setting. To access these cases, please go to the initiative homepage at www.iche.edu/nsaids

Figure 1 NSAID-Related Renal Side Effects and Risk Factors for Renal Toxicity

Renal Side Effects[16,26]	Risk Factors
• Salt and water retention	• Age >60 years[16]
• Edema	• Heart failure[41]
• Kidney function	• ACE inhibitors, ARBs, loop diuretics, beta-blockers [23,32]
• Effectiveness of diuretic medication	• Underlying renal insufficiency (GFR <60mL per minute per 1.73m^2)[6]
• Urate excretion	• Intravascular volume depletion[16]
• Hyperkalemia	• Dehydration[33]
• Analgesic nephropathy	
• Chronic interstitial nephritis	
• Acute interstitial nephritis	
• Glomerulonephritis	

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acute toxic effect on the renal parenchyma that may result in interstitial nephritis that will also lead to a reduction in the glomerular filtration rate.[5,7]

Moderator: What are the most common NSAID-related renal complications you see in clinical practice?

C. Mel Wilcox, MD: NSAIDs are known to exert a range of adverse renal effects, including decreased renal perfusion, decreased GFR, edema, and increased blood pressure (Figure 1). These effects occur in approximately 1% to 5% of patients taking NSAIDs.[10,11] Most commonly, I see patients who are on an NSAID chronically. They might not be at high risk for toxicity—such as patients with hypertension or cardiovascular disease—but they might develop some peripheral edema, which is what brings them to my office. The prevalence of symptomatic edema associated with NSAID use is estimated at 3% to 5%,[11] and new onset or exacerbation can precipitate congestive cardiac failure, in which case NSAIDs should be avoided.[12]

The more drastic case would be an elderly patient with known congestive heart failure who is on an angiotensin-converting enzyme (ACE) inhibitor and develops potentially worsening heart failure. The anti-natriuretic and vasoconstrictive properties of NSAIDs can destabilize the blood pressure control exerted by ACE inhibitors and exacerbate heart failure.[13] In fact, a retrospective cohort study of 3,928 patients with hypertension who were prescribed acetaminophen or NSAIDs reported that, compared to patients taking acetaminophen, patients taking NSAIDs had a 2 mm Hg increase in systolic blood pressure. In a subgroup of patients taking ACE inhibitors and calcium-channel blockers, the systolic blood pressure increase among patients taking NSAIDs was 3 mm Hg.[13]

Moderator: What are some of the risk factors for developing renal toxicities among patients taking NSAIDs?

Wilcox: A patient with heart failure or a patient with cirrhosis first comes to mind.[5] In addition, the use of NSAIDs in patients with decreased renal perfusion may lead to hemodynamic decompensation and future renal complications.[2]

In conditions where blood volume is compromised, angiotensin II, norepinephrine, vasopressin, and sympathetic nerve activity all increase and raise renal vascular resistance.[7] American College of Cardiology/American Heart Association practice guidelines tell us to avoid NSAIDs when possible for patients with heart failure.[14] The evidence also suggests that we should avoid NSAIDs in patients with cirrhosis in order to prevent renal impairment.[5,15]

Moderator: Are there any concomitant medications that may put a patient at risk for renal problems if they're taking NSAIDs either on a short-term or long-term basis?

Devlin: Absolutely. Some of the most well-reported, longer-term medications that increase risk for NSAID-related renal toxicity are ACE inhibitors and angiotensin receptor blockers (ARBs),[5] which have anti-angiotensin II activity and can disrupt the kidney's ability to autoregulate GFR.[12,16] Studies have shown that the concurrent use of diuretics, ACE inhibitors, or ARBs taken with NSAIDs can increase the risk for kidney injury.[17-19]

Julia Pallentino, MSN, NP: I also see patients who are on antihypertensives plus loop diuretics, which increase the patient's risk for NSAID-induced renal toxicity.[16] It is wise to be cautious with these patients, since loop diuretics can adversely interact with NSAIDs to impair renal function.[2]

Devlin: There are other nephrotoxins that are used acutely in inpatient or outpatient settings that providers need to be mindful of. For example, a patient who had a computed tomography scan with contrast and was started on an NSAID would certainly increase his risk for contrast-induced nephropathy.[16] This is because NSAIDs inhibit the local vasodilatory effects of prostaglandins and render the kidney more vulnerable to nephrotoxic contrast agents.[20]

It's also been shown that patients who take chronic acetaminophen along with chronic NSAIDs are at a greater risk for chronic renal failure than patients on NSAIDs alone.[16,21]

"Providers should recommend NSAIDs with caution when combining them with agents that potentially decrease renal function, such as ACE inhibitors and beta blockers."

–C. Mel Wilcox, MD

Moderator: We talked about ACE inhibitors, ARBs, and diuretics as being anti-hypertensive agents that can pose potential risk for renal toxicity when used with NSAIDs. What are your thoughts about a patient who is taking an anti-hypertensive agent other than these three along with an NSAID?

Wilcox: My guess would be that they'd be slightly less at risk than they are from ACE inhibitors or ARBs. But if the patient is taking antihypertensives for long-standing hypertension, they still may be at risk for renal toxicity because they already have some renal insufficiency that may be subclinical.[7] Providers should recommend NSAIDs with caution when combining them with agents that potentially decrease renal function, such as ACE inhibitors and beta-blockers.[16]

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Devlin: As the blood pressure goals in the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure guidelines get tighter and tighter, patients—particularly the elderly—are increasingly being managed aggressively for hypertension and often need several medications to achieve adequate blood pressure control.[22] Some patients may be overtreated with antihypertensives, which could lead to decreased renal perfusion and confer risk for NSAID-associated renal toxicity.

A recent observational study using a large British primary care database (N=487,372) reported that adding an NSAID to dual antihypertensive therapy (diuretics with ACE inhibitors or ARBs) was associated with an increased rate of acute kidney injury (rate ratio: 1.31; 95% confidence interval [CI]: 1.12-1.53), especially in the first 30 days of use.[23]

Moderator: In general, does the duration and dose of NSAID treatment play a role in the risk of renal toxicity?

Devlin: In my experience in the hospital setting, if we have a patient with chronic kidney disease, particularly if they are intravascularly volume depleted from, say, diuretic administration, we can see relatively rapid reductions in creatinine clearance even with just a few doses of the NSAID. But I would say that nephrotoxicity is likely to be greatest with chronic NSAID users.

The main thing to look at is how long the patient is on the NSAID and the dose that they are taking (Figure 2). Although adverse events can potentially occur at any time during treatment, a higher dose poses a greater risk for renal toxicity than a lower dose,[18] and the risk for adverse events increases with the duration of treatment.[1,5] A nested, case-control study by Huerta and colleagues used a large primary-care database (N=386,916) to report that NSAID users had a relative risk (RR) for acute renal failure of 3.2 (95% CI: 1.8-5.8), which increased with both short- and long-term therapy, as well as with higher doses.[18] The risk ratio for renal insufficiencies in patients on short-term NSAID therapy (i.e., treatment duration of up to 1 year) was 2.6, and almost doubled as patients got closer to more than 1 year of continuous use (RR: 4.33). As doses increased from low-medium to high, the RR also increased from 2.51 to 3.38.

It's also important to look at the COX-1 specificity of NSAIDs. NSAIDs are ranked according to their anti-inflammatory potency, propensity to cause renal and GI toxicity, and relative selectivity for COX-1 and COX-2,[24] depending on the dose administered.[8] Both COX-1 and COX-2 NSAIDs reduce pain and inflammation in a time- and dose-dependent fashion,[9] but there's a huge variability in the COX-1 specificity between drugs like ketorolac vs. ibuprofen, or indomethacin vs. ibuprofen.[3,25] COX-2 inhibition is not an absolute property; it's a continuous variable.[9]

Wilcox: Dose and duration also depend on the individual patient and the patient's level of risk for renal toxicity. Although there is little difference in the mean efficacy of NSAIDs, patients vary in their responses to different NSAIDs.[26] Someone with a higher risk profile may be less likely to tolerate a higher dose for a short period or a smaller dose for a longer period. Is it an elderly patient with mild renal insufficiency or known heart failure? Would one ibuprofen be safe in that person? Perhaps. But most patients aren't just going to take one dose for a pain syndrome, back pain, or arthritis. They're probably going to take more than just one dose, which clearly would put them at a much higher risk.[5]

Pallentino: For patients with liver disease, I recommend NSAID use for a short duration of time, but certainly not very high doses for long periods.[27] Although the guidelines aren't completely clear, it's generally recommended that patients with chronic liver disease take lower than the usual recommended doses of OTC analgesics, including NSAIDs.[28]

Devlin: Many patients with pain are self-medicating. A lot of households have a bottle of ibuprofen or naproxen at home that is being used here and there on an as-needed basis. Data on national patterns of NSAID use show that 26% to 44% of individuals consume more than the recommended dosage.[29] In addition, chronic use of NSAIDs tends to increase with age.[3] Studies show that adults over the age of 65 are the largest users of OTC medications—20% to 30% of people >65 years of age take NSAIDs for pain relief on a given day.[29,30]

Concomitant medication use also increases with age. A recent community study found that approximately 75% of 357 people >55 years of age who used NSAIDs had more than one medical condition, including hypertension, chronic kidney disease (CKD), or cardiovascular disease.[31] In the same study, approximately 10% of the sample using NSAIDs were also taking ACE inhibitors, diuretics, and anti-hypertensive medications (11.2%, 10.7%, and 9.3%, respectively).[31]

These types of patients can be very hard to monitor. Even if you talk to a patient about the medications they take, they're very focused on their prescribed regimen—their heart-failure medications, diuretics, antihypertensives, or lipid-lowering agents—and they might not even mention that they pop an ibuprofen if they feel a little stiff in the morning or have a headache.

Moderator: What is the renal impact of NSAIDs on the patient who has no risk factors, who doesn't fit the bill for any of the situations discussed earlier?

Figure 2 COX Selectivity and Maximum Recommended Dosing of Commonly Used NSAIDs[3]

NSAID	COX-2 Selectivity	Maximum Daily Dose (mg/d)
Ibuprofen	Non-selective	1200-3200
Naproxen	Non-selective	500-1000
Ketoprofen	Non-selective	200-300
Celecoxib	Selective	200
Diclofenac	Non-selective	100-150

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Wilcox: Most healthy patients who self-medicate with NSAIDs for a limited time can tolerate these drugs without adverse effects, unless perhaps they increase their dose for pain relief and they get dehydrated for some reason.[2,7,25] But in general, NSAIDs are safe in those patients as long as they read the label and make sure they're not taking concomitant medications from the same class, since an increased total dose of NSAIDs is associated with a high risk of adverse reactions.[18,26]

Devlin: The only really dangerous thing that could happen to these patients is acute interstitial nephritis (AIN),[16] but the risk for AIN is very low relative to the huge number of healthy patients who take NSAIDs.

"Most healthy patients who self-medicate with NSAIDs for a limited time can tolerate these drugs without adverse effects, unless perhaps they increase their dose for pain relief and they get dehydrated for some reason." [2,7,26]

–C. Mel Wilcox, MD

Moderator: In general, is dehydration an issue among patients taking NSAIDs? How does it fit into the overall picture?

Wilcox: Yes. For many of the older patients that we see, although dehydration from exercise would be uncommon, dehydration from some other comorbidity can happen quite easily. A patient may have gastroenteritis,[5] get dehydrated, and have a little fever and then take NSAIDs for a couple of days. I've seen this on several occasions. Or someone with known renal insufficiency or known risk factors develops volume depletion from some other problem (e.g., loop diuretics pose a risk of volume depletion),[14] and then takes NSAIDs.

ACE inhibitors or ARBs can alter renal hemodynamics in patients who are volume depleted.[9] Research is ongoing to determine their role as "thirst blockers" by inhibiting the renin-angiotensin system implicated in thirst perception.[32]

Moderator: Let's say renal issues arise in a patient. Would NSAID-induced renal impairment be reversible?

Wilcox: The evidence indicates that acute NSAID-induced renal failure is commonly reversible within 24 hours of discontinuing NSAIDs,[7,33] but it depends on how big a hit the kidneys take. Reversibility might take longer if the patient has multiple kidney comorbidities, like the patient I mentioned with known heart failure and renal insufficiency who develops dehydration and acute tubular necrosis.

Devlin: It's really important to identify patients' baseline renal function when starting NSAID therapy. Although it's unclear whether monitoring improves morbidity or mortality, a recent review of consensus guidelines recommended that clinicians consider monitoring serum creatinine levels in patients taking NSAIDs who are at risk for renal failure, as well as in patients taking ACE inhibitors or ARBs.[5]

An analysis of NSAID use in a cross-section of 12,065 patients (using National Health and Nutrition Examination Survey data from 1999-2004) found that 2.5% to 5% of people with CKD reported using OTC NSAIDs in the previous 30 days, and 66% of patients with moderate to severe CKD had been using an NSAID for at least 1 year.[34] To put that in perspective, a Canadian cohort study of a community of 10,184 older adults reported that, over a 2.75-year period, patients with a baseline mean GFR between 60 to 89 mL/min/1.73m^2 using NSAIDs increased their risk of rapid kidney disease progression by 25% compared with non-NSAID users.[6] The National Kidney Foundation and other consensus guidelines recommend to avoid using NSAIDs in most patients with CKD.[34]

Moderator: What would you say to a patient with risk factors for renal impairment about the safe use of NSAIDs?

Devlin: I'd have a discussion about maybe choosing and maximizing the use of acetaminophen, though obviously not in a patient with end stage liver disease, and then evaluating the patient's pain level, especially if it's an arthritic-type picture where the pain is more chronic. Several clinical guidelines, including those from the American Geriatric Society, recommend acetaminophen as the first option of pain relief for arthritis in older adults,[35] with the caveat that clinicians should educate patients about the maximum safe dose of acetaminophen from all sources (<4 g/24 hours).[24] In elderly patients, patients with cardiac or renal failure, or those who are taking ACE inhibitors or ARBs, clinicians should monitor blood pressure and a serum creatinine concentration (to estimate GFR) 1 to 2 weeks after starting NSAID treatment.[5,12,18]

Pallentino: Patients with mild liver disease can usually tolerate lower doses of both NSAIDs and acetaminophen.[28] However, we should really save those for when they are really needed, caution patients not to use them on any kind of regular basis, and talk to them about the absolute maximum they can take.

Wilcox: I think one of the patient education pearls that I would emphasize is the importance of avoiding OTC NSAIDs if you know you're at risk for renal toxicity. Studies show that patients may be unaware of the risks and of adverse effects associated with NSAIDs.[36] A study summarizing results from two national consumer surveys (9,062 respondents) showed that, among respondents using OTC NSAIDs, 60% were unaware that NSAIDs posed any risks for side effects, and 49% were unconcerned about risk potential.[29]

Pallentino: Many patients, especially older adults, may feel that it is unimportant to disclose information about using NSAIDs. One study reported that only 58% of patients told their physicians about any OTC use, and physicians asked about OTC use in only 37% of patient encounters.[37]

When you ask patients, "Are you taking this?" they will say, "Oh, you mean that's a medicine, too?," especially with regard to OTC agents. Since I treat patients with cirrhosis, I tell them that I want to know everything they're taking, including supplements and anything they're buying at the health food store or ordering over the Internet. This gives me a more complete picture of the medications they're taking so I can appropriately warn them of the risks. We can only counsel patients about appropriate dose and potential adverse effects if we are aware of how much medication is being used.[2] Data are scarce on the prevalence of drug interactions with herbal/dietary supplements (HDS), but 9% to 19% of patients use HDS, and concurrent use with OTC analgesics is common.[38]

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CHRONIC CARE MANAGEMENT SERVICES
Physicians will start receiving payments outside of face-to-face visits in 2015 [77]

Policy

What will exchanges, Medicaid expansion mean to your practice?

The impact will depend on where you are and if you accept new patients, but everyone will be affected

by **JEFFREY BENDIX,MA,** *Senior editor*

HIGHLIGHTS

01 New patients who have obtained coverage through Medicaid or the insurance exchanges are more likely to have chronic conditions that require more care than current patients.

02 Practices expecting an influx of new patients can prepare by maximizing the use of existing space, adding nonphysician providers, and moving towards team-based care.

The saying, "all politics is local" also applies to the impact of the new healthcare insurance exchanges and expanded Medicaid eligibility that are part of the Affordable Care Act (ACA). Depending on where you are and the choices your practice makes, the effects of these developments will range from negligible to profound, although most providers will be affected at least indirectly.

THE EXCHANGES and Medicaid expansion are intended to provide healthcare insurance to a large portion of the approximately 50 million Americans who currently lack it. The exchanges, which started in October, let customers shop for and compare health insurance plans in four broad price ranges. The ACA also includes subsidies, in the form of tax credits, to help make the plans more affordable. Insurance compa-

> "I SEE PATIENTS ALL THE TIME WITH NO INSURANCE WHO ARE PRETTY SICK.... IF THEY'D HAD PRIOR CARE WE MAY HAVE BEEN ABLE TO DECREASE THE LEVEL OF CARE THEY HAVE TO GET NOW."
>
> ROBERT HUNTER, DO, EMERGENCY DEPARTMENT PHYSICIAN, DAYTON, OHIO

nies are not required to participate in the exchanges, and practices are not required to accept patients who obtain insurance under the exchanges.

The ACA originally broadened Medicaid eligibility nationwide to people with income up to 138% of the federal poverty level—about $32,500 for a family of four. The U.S. Supreme Court later ruled, however, that states could decide for themselves whether to expand Medicaid eligibility. As of early December, 26 states and the District of Columbia had chosen to do so, according to the Kaiser Family Foundation.

Given all the uncertainties surrounding the ACA, including the startup problems of healthcare.gov, the federal health exchange website, it's not surprising that medical practices are approaching the exchanges very cautiously. Fewer than half of the 1,000 practices responding to an October survey by the Medical Group Management Association said they were not planning any business changes as a result of the ACA, and fewer than 5% anticipated adding new providers or extending business hours.

WHAT DOES IT MEAN FOR YOU?

So what will Medicaid expansion and the insurance exchanges mean for your practice? If you are in one of the 20 states that have not expanded Medicaid—or if your state has expanded Medicaid eligibility but your practice does not accept Medicaid patients—obviously that part of the legislation will not affect you. The same holds true for practices that choose not to contract with exchange plans or accept patients who enroll through the exchanges, or who already have a large percentage of patients covered by Medicare, Medicaid, or some other public payer.

On the other hand, if you are in a state that has expanded Medicaid eligibility, and/or your practice will accept patients from the insurance exchanges, then you could be in for some significant changes—starting with the makeup of your patient population. Almost by definition, many of these new patients will not have had access to regular healthcare previously. Consequently, they are more likely to have chronic conditions, such as diabetes, hypertension, and hyperlipidemia, for which they have received little or no treatment. (EDs).

"I see patients who come in all the time with no insurance, and they're pretty sick. And of course we spend a lot of money on their care because they're in the critical care phase of their disease, whereas if they'd had some prior care we may have been able to decrease the level of care they have to get now," says Robert Hunter, DO, FACOFP, an emergency department and family physician in Dayton, Ohio.

Adds Thomas Zimmerman, DO, a family physician in Oceanside, New York: "I was hopeful about the ACA and the whole idea of getting more people on insurance, people who would otherwise go untreated or, just as bad, clog up the EDs with non-acute issues. As things stand now, you have people there from both ends of the spectrum, either with bellyaches or full-blown myocardial infarctions because their hypertension has gone untreated for so long."

COMPLIANCE CHALLENGES

In addition, because they have not been accustomed to regular care, many of the new patients are likely to present compliance challenges. "The combination means you're putting a lot of work into patients who will probably have a poor follow-through," says Hunter. "I believe that's why you have primary care doctors and ➔50

➔49 specialists who don't want to treat this population, because they're very labor-intensive and that causes providers to become frustrated."

Rather than refusing to treat these new patients, however, Hunter advocates taking the time to explain to patients the reasons for a course of treatment and why it's important for the patient to stick to it. "I think the best thing we can do as primary care doctors is to engage patients in their care, talk to them about hemoglobin A1C and why it's important to bring that number down and how they can't get better if we don't see them," he says.

"The most important thing for most of us is taking care of our patients," adds Reid Blackwelder, MD, FAAFP, president of the American Academy of Family Physicians. "And the challenge of caring for more of them (as a result of the ACA) will require us as physicians to make sure we do good education, because one of the most important aspects of adherence to treatment plans is making sure you're clear about what you're doing, and why, so you can explain it to the patient."

PREPARING FOR MORE PATIENTS

The multi-specialty group to which Hunter belongs is gearing up for an influx of new patients by looking at ways of maximizing its existing space. "The group is asking, 'how can we make every office, and every room in every office, more profitable?" he says. "Whereas before the attitude was 'see your patients and don't worry if some rooms are empty' now it's 'could we put a lab station in a room that's not being used? Could we have a surgeon use it a few days a week?' We're trying to make use of every inch." The group has also hired additional nurse practitioners to handle the anticipated patient volume.

Of course, even practices not directly affected by the insurance exchanges or Medicaid expansion may feel some indirect impact Probably the most common are patients whose insurance policies are not being renewed because they don't meet the ACA's minimum standards of coverage, or insurance companies dropping physicians from their panels. Insurance giant United Healthcare, for example, announced in November that it planned to cut physicians from its Medicare Advantage plans in 11 states, including 2,200 in Connecticut alone.

In addition, many of the policies on the exchanges are likely to include fairly narrow networks of providers, leading to "churn" in the marketplace. (See "Top 10 issues facing physicians in 2014," page 20.)

For all the challenges new patients may pose, Blackwelder sees them as an opportunity as well. He notes that the average family practitioner now treats nine uninsured patients each week, most of whom are receiving free or greatly discounted care. If even a portion of those patients were to obtain insurance coverage, it would represent a boost to the practice's income.

Blackwelder says a simple step practices can take to accommodate the changes brought on by the ACA is to start asking patients if they've changed their insurance status when they call for appointments. "The more you can identify if there are any insurance-related issues, if they might have to dot some i's or cross some t's before they come in, the better off they will be," he says.

In addition, practices need to find ways to use the physician's time more efficiently. One way to do that is to add a patient portal, so that patients can take care of needs that formerly required a face-to-face visit, such as obtaining lab results or getting prescriptions refilled.

Along the same lines, using a team-based approach to patient care allows non-physician providers to take on some of the tasks traditionally provided by physicians, such as patient education or coordinating care with family members or other providers. "A big part of the challenge of taking care of more patients is seeing what you can do in your own practice to create that team-based care," he says.

@ MORE RESOURCES

Has your state expanded Medicaid eligibility? Find out at:

http://bit.ly/1kjgc6l

View a list of frequently-asked questions from patients about the Affordable Care Act and the answers to them at:

http://1.usa.gov/1ju2sse

Are you too busy to accept new patients?

Why closing your panel is a bad idea, and how to find the time and space to squeeze in new patients

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

HIGHLIGHTS

01 It's almost always a mistake to close your panel to new patients, experts say.

02 Proper use of midlevel providers can both help deal with large panel sizes and bring higher profits to your practice.

03 Physicians should carefully consider which exchange or Medicaid plans they want to participate in to prevent oversaturation of the practice.

Do you have too many patients? Primary care physicians with crowded waiting rooms already feel overburdened. Many physicians are thinking of closing their practices to new patients. Experts say that no matter how busy you are, closing your panel may be a mistake.

AS THE AFFORDABLE CARE ACT (ACA) kicks in, millions of newly insured patients may soon come knocking at your door. Many physicians are already working long hours yet don't have enough time to spend with each patient. They need a breather and want to make sure they aren't spread so thin that they can't provide appropriate and effective care.

If you think the solution is closing your panel to new patients, you may want to think again. It's almost always a mistake to close your panel to new patients, say the physician experts and practice management consultants who spoke to *Medical Economics* on the issue.

"Busy is in the eye of the beholder," says Rosemarie Nelson, a Medical Group Management Association (MGMA) consultant based in Syracuse, NY. "The average panel for a primary care doctor is about 2,500 patients. Some busy practices are simply inefficient. A practice with 2,200 patients may want to close while another with 3,200 pa-

> Medicine is a team effort and physicians need to rely more on their staffs to engage patients with data collection, coaching, and even prescribing. Resistance to change comes from both sides. Doctors have to convince themselves and colleagues that they can let go of some aspects of care and let midlevels handle them.
>
> —WILLIAM MANARD, MD, DIRECTOR OF CLINICAL SERVICES IN THE DEPARTMENT OF FAMILY AND COMMUNITY MEDICINE, ST. LOUIS UNIVERSITY SCHOOL OF MEDICINE, ST. LOUIS, MISSOURI

tients has figured out ways to accommodate new patients without sacrificing quality."

Closing your panel should be a last resort. "Once you turn the faucet off, turning it back on when your situation changes may be a challenge if word gets around the community that you weren't accepting new patients," says William T. Manard, MD, director of clinical services in the Department of Family and Community Medicine at St. Louis University School of Medicine in St. Louis, Missouri.

"Even in mature practices, it's essential to replace patients who leave your care," says Gray Tuttle Jr., a consultant with the Rehmann Group in Lansing, Michigan. "Closing your panel causes misperceptions by patients and other doctors. They may conclude that the doctor is retiring, leaving or is ill. That can accelerate the contraction of your practice beyond what you wanted."

EXPANDING YOUR CAPACITY FOR MORE PATIENTS

It's clear there's a problem when the waiting room is packed, it's difficult for established patients to get an appointment, and sick patients can't be seen soon enough, says Judy Bee, a principal of PPG Consulting in La Jolla, California. "Often unknown to the doctor, staff members are suggesting that patients go to an urgent care center because they're just so jammed."

Tuttle agrees. "If it takes more than a month for a new patient to get an appointment, the practice is probably pushing the limit on what it can accommodate," he says. "Established patients should be able to get in within two weeks. Practices need systems for same-day care or patients will go to urgent care centers instead."

Here are five ways you can adjust your practice management process to accept more patients without substantially increasing your workload.

1/ Scheduling fixes

How many patients did you see today that didn't need to be seen right away? "It's often as much as 40%," Bee says. "Practices often see patients who are stable but chronically ill every three months. Instead of making an appointment that far in advance, you can send reminder cards. When patients call for an appointment, you'll have a better idea of your capacity and can adjust the schedule so that there's room for patients who have more acute needs."

Physicians should save a few slots for sick patients who need to be seen that day, she says. Bee recommends a scheduling model where physicians determine the average number of work-ins for each day of the week. Then look at the average number of no-shows or last minute cancellations. Monitor the urgent patients or appointments made within one week. Note how many return appointments are made for patients seen as an emergency or urgent. This can help the practice best adjust its schedule.

2/ Sharing more responsibility with midlevels

If the practice is still overwhelmed, it's time to make better use of medical assistants and midlevel providers such as nurse practitioners and physician assistants.

"Medicine is a team effort and physicians need to rely more on their staffs to engage patients with data collection, coaching and even prescribing," says Manard. "Resistance

to change comes from both sides. Doctors have to convince themselves and colleagues that they can let go of some aspects of care and let midlevels handle them.

"Many patients expect to be cared for only by the doctor," he says. "We need to educate patients that nurses and assistants can handle many parts of care that don't require our level of training.

"We have also created protocols for preventive tests and common conditions, either by phone or face to face," he adds. "Nurses can call in prescriptions, etc."

Adding providers is a key strategy for any practice going forward. "It's necessary to deal with the anticipated onslaught of demand created by the Affordable Care Act," Tuttle says. "Properly using a midlevel can be a profit center."

3/ Expanding office hours to meet patient demand

Hiring midlevel providers won't help much if there aren't enough exam rooms to handle the patient volume at your practice, Nelson cautions. "If the facility is physically limited, it's time to expand hours and work in shifts," Nelson says. "One provider can work early morning to mid-day, another provider comes in and works until evening. Physical expansion should be addressed if necessary."

Bee agrees. "Expanding hours doesn't give a doctor any more hours to see patients. But it does provide more space so that midlevels can pick up the slack."

4/ Use more virtual care to connect with patients

Not all measures of "availability" require the doctor's immediate or personal attention,

Easing the burden on an over-paneled physician

Despite trying many strategies to continue accepting new patients, some of your practice's providers may still be burdened with a too-large patient panel.

Here are some ways to lessen the burden:

1. **Patients come, but patients also go. Use the natural patient attrition over time to help ease the burden.**
2. **Temporarily close the over-paneled physicians to new patients.**
3. **Help the physician out with more resources, from more midlevel assistance to additional examination rooms.**
4. **If nothing else works, you can move patients away from that physician by shifting them to other providers in your practice. Don't forget to inform patients of the change.**

Source: American Academy of Family Physicians

40%

The average share of patients a physician sees in a day that did not need to be seen that day.

Source: Judy Bee, principal, PPG Consulting, La Jolla, California

2,500

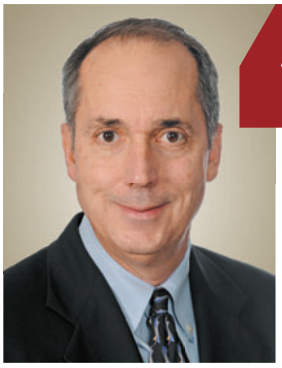
The average patient-panel size for a primary care physician.

Source: Rosemarie Nelson, consultant, Medical Group Management Association, Syracuse, New York

3.19

Average number of visits per patient each year.

Source: Family Practice Management, April 2007



> If it takes more than a month for a new patient to get an appointment, the practice is probably pushing the limit on what it can accommodate. Established patients should be able to get in within two weeks. Practices need systems for same-day care or patients will go to urgent care centers instead."
>
> —GRAY TUTTLE JR., CONSULTANT, REHMANN GROUP, LANSING, MICHIGAN

Manard says. "We can provide more virtual care by telephone, websites, electronic health records (EHRs) and patient portals. I didn't see any patients today but I answered 10 emails. Technology allows us to monitor chronic conditions and notice trends."

Patient portals are integrated into many EHR systems. Standalone options also are available. An up-to-date health record can facilitate directed interventions, Manard says. Advice can be "blasted" to groups of patients as a way to educate them in between visits.

"We can leverage data in electronic records to send out mailings for preventive services," he says. "We can send out reminders for mammograms, etc., with minimal time investment."

5/ Dropping bad insurers

Practices should review their payer lists and determine if there are any they would be better off without. Does a poor paying third party represent more than 10% of the practice? If so, consider dropping it, says Tuttle. "You can't do that if it represents 25%, though. It would take too long to fill in that capacity.

"You don't have to take all payers," he adds. "It's purely a business decision. The key is to follow the rules and provide adequate notice to the plan and patients."

Each insurance contract is different. "I'd seek legal advice before dropping a payer," Manard says. "Most insurers require providers to continue to accept new covered patients, at least to some degree if you want to continue to accept that payer. If you decide to withdraw from participating with an insurer over reimbursement issues or just to help manage panel size, recognize that any patients with that coverage will likely leave your practice as well. Account for this in any objective panel size calculation. Also recognize that it may mean terminating long-term relationships with patients."

THE IMPACT OF HEALTHCARE REFORM

It's still uncertain how the ACA will affect primary care, but most experts believe the demand for care will increase significantly. "There's no question that doctors need to find ways to accommodate larger panels," Tuttle says.

"I see it as an opportunity," he says. "There is big expansion of Medicaid. A provision in the law increases reimbursement rates for primary care doctors to Medicare levels for two years. Medicare is still a good payer."

An addition of up to 30 million newly insured patients will certainly strain medical practices, says Manard. "These patients are likely to have longstanding significant health needs. Doctors should carefully consider which exchange or Medicaid plans they want to participate with to prevent oversaturation of the practice, especially with lower paying carriers."

@ MORE RESOURCES

Study: PCPs must delegate some preventive, chronic care
http://bit.ly/18kslDf

Full schedule needn't close practice to new patients
http://bit.ly/1gCxtY0

Practical Matters

MANAGING STAFF PERFORMANCE WITH REVIEWS AND RAISES

by **KEITH BORGLUM, CHBC** *Contributing author*

"Having employees is like having diabetes. There is no cure, only management." It's one of my favorite human resources sayings because of its stark and simple truth. No matter if you are a good manager of your staff or not, at some point you will (or should) have to review their performance and consider raises.

HERE ARE SOME things to keep in mind when reviewing your employees' performances and determining when raises are appropriate.

Set goals for managers, staff

Setting clearly defined goals is critically important to achieving success. In fat, most managers want to create teams that outperform expectations. But to achieve it, as a leader of the practice, you have to offer the vision. A basic truism about goals is that they should be "challenging yet attainable, clear and unambiguous, written and measurable."

The first step, therefore, is to write down your own goals—as they pertain to staff—in compliance with the above guidelines.

Once your own goals about staffing are established, draft a set of goals for your staff. These can include tangible targets such as, "Be at your workstation, ready to work, at the beginning of your work period" or intangible goals like, "No staff is to ever say an unkind word to patients—or each other—in the workplace."

Once you have your draft of goals assembled, have a staff meeting to review and approve your personal management goals, and the goals for staff performance. This allows staff to have the opportunity to question and clarify the issues.

This group process invariably results in a higher quality set of goals, pleases staff to have the opportunity to contribute, and strengthens peer pressure on performance within the team.

Managing goal compliance

Once goals are established, staff achievement and compliance needs to be managed.

New staff members or new goals should be individually reviewed until they are achieved. Have a written schedule for yourself to do so that it remains prioritized; otherwise it's easy to rationalize doing tasks other than reprimanding staff. A sample schedule might be weekly for a month, monthly for a quarter, then quarterly thereafter.

Having a written structure for the review is helpful. Organize a checklist of the goals with some form of grading. Staff should be familiar with the checklist on which they will be reviewed, in order to aid them in compliance and preparation.

Rewarding performance

Rewards for performance don't have to be monetary. Simple praise may be enough much of the time.

When you praise staff, do it "publicly" in front of other staff and patients. When you need to correct or reprimand them, do it privately.

Raises should still occur when appropriate. Once an employee is compensated at market rate, experts favor raises for good performance rather than for time-in-grade. Don't give a raise to an employee whose performance is worsening. Save it for employees that improve skills, certifications, or licensure. ■

@ MORE ONLINE

See a sample performance review at

MedicalEconomics.com/staffreviews

Answers to readers' questions were provided by ***Keith Borglum,*** *Professional Management and Marketing, Santa Rosa, California. Send your practice management questions to* ***medec@advanstar.com****.*

Legally Speaking

PRESCRIBING BLACK BOX DRUGS: HOW TO WATCH FOR LIABILITY TRAPS

by **BARBARA D. KNOTHE, JD** *Contributing author*

The Food and Drug Administration's black box warning is the strongest advisory that prescription drugs can contain without being pulled from the market in the United States. If improperly prescribed, drugs with a black box warning can lead to serious adverse events. How can prescribers reduce the legal risks of prescribing drugs with black box warnings?

PRESCRIBERS RISK malpractice claims based on negligence or lack of informed consent for not providing the patient or patient's representative with information to make an informed decision about whether to use the drug.

Since the number of drugs with black box warnings has increased, prescribers must keep up to date. Prescribers should consider using electronic prescribing software that warns the clinician if a potential problem is identified, or subscribing to email notices or other applications that alert the prescriber to new warnings as they are issued.

The warnings can be vague and difficult to interpret. In those cases, we recommend seeking clarification from a specialist or the manufacturer.

Consider alternatives first

The clinician should consider whether equally effective and safer alternatives exist, whether the potential benefits of the drug outweigh the safety concerns, and whether the patient is an appropriate candidate for the drug.

This analysis should be clearly documented in the patient's medical record. Any patient selection criteria or recommended monitoring should be closely followed.

Get patient consent

The risk-benefit analysis must involve the patient or the patient's legal representative. The patient must be informed about the black box warning, and the risks and benefits of and alternatives to treatment, including no treatment, and their informed consent obtained for the treatment. Ideally, informed consent should be in writing, with an acknowledgment of the warning and the discussion the patient has had with the clinician prior to consenting to the treatment as well as their understating of any necessary monitoring.

If written informed consent is not feasible, the medical record must reflect that the patient was informed of the warning, that the risks, benefits and alternatives were explained to the patient or the patient's representative, and that they consented to the treatment following the discussion. Clear documentation of appropriate patient selection and informed consent is critical to the defense of any malpractice action arising out of the prescribing of a drug with a black box warning.

Use with caution

Clinicians should not permit patient pressure to influence selection of a drug that is not appropriate for the patient.

Despite the publicized warnings about these drugs, studies have shown that patients still receive prescriptions for these drugs in violation of black box warnings with some regularity, and that adverse events occur. Some states are considering subjecting the prescribing of drugs with black box warnings to regulation. Drugs with black box warnings can be viable treatment options so long as the proper steps are followed and the matter is thoroughly documented. ◻

Barbara D. Knothe *is a partner in Garfunkel Wild, P.C.'s Health Care Practice Group, in Great Neck, New York. Send your practice management questions to* ***medec@advanstar.com****.*

Coding Insights

TALK WITH YOUR VENDOR NOW ABOUT ICD-10 UPDATES

We are worried that our vendor won't be ready for the ICD-10 updates by October 1, 2014. What are some of the questions we can ask and how do we ensure that our vendor is ready?

THIS IS A GREAT question because most vendors will need to update their systems to be able to support the International Classification of Diseases, 10th edition, Clinical Modification (ICD-10-CM).

You'll first need to assess how the ICD-10-CM conversion will impact your practice. This means that you should list all your computer systems that currently include diagnosis coding, starting with your practice management system and electronic health record (EHR). Other systems that could be impacted include a disease management registry, e-prescribing module, and code selection software.

Once you've assessed your practice's software systems that need to be updated for ICD-10-CM, you can then contact your vendor(s) for each of these systems. The American Medical Association (AMA) suggests asking your vendor the following questions:

Will you be doing updates to my system?
Some systems may be too old and the vendor may no longer support them.

When will you be installing the updates to my system?
Vendors have many customers, and it may take time before the vendor can complete the work on your system.

Will there be a charge for the updates to my system?
Check your contract, but also confirm costs with the vendor. Some regulatory updates are done at no charge, but the vendor may also have to make improvements to your system in order to be able to install the updates.

How long will my system be down during the installation of the updates?
You will need to be prepared for how you will complete ongoing tasks while the system is down.

Will my practice management system support entering the ICD-10 codes and then transmitting the code to my billing vendor, clearinghouse, and/or payer?
You will want to confirm that your system will support entry of the ICD-10 codes and transmission of the codes.

If your system will not support this, you will need to work with the organization(s) you are transmitting the data to and determine how you will send the ICD-10 codes to them. Your billing vendor or clearinghouse will be unable to convert an ICD-9 code to an ICD-10 code for you. You will have to be able to send the ICD-10 code for the claim and other transactions.

Will you complete any testing of my system after you complete the updates?
Practices will want to complete "internal" testing of their systems to make sure they can enter and generate ICD-10 codes when appropriate. Your vendor may do this when they install the updates, but you will need to confirm this with them.

What services or products are you providing to support ICD-10?
Ask your vendor what additional services or products they have available to support ICD-10 coding.

While the services or products may add additional costs to your system, they may support easier and more efficient coding.

Coding Insights

Meaningful Use impacts

For physicians participating in the Meaningful Use of Electronic Health Record (EHR) Program for Medicare or Medicaid, be aware that any claims submissions problems that occur after October 1, 2014 as a result of moving to ICD-10 could disrupt your reporting requirements for the EHR program.

Work with your vendor to ensure the EHR updates are completed, along with the ICD-10 updates, prior to October 1, 2014 and consider completing your EHR reporting prior to the switch to ICD-10.

More questions to ask your vendor

The Centers for Medicare and Medicaid Services (CMS) advise physicians to ask the following questions:

- Will a mapping or crosswalk strategy be used between ICD-9 and ICD-10 code sets?
- What is your timeline for system modifications and what do those modifications include?
- Will you continue to support applications or are you discontinuing some products in the wake of the ICD-10 transition?
- Are there any new hardware requirements associated with ICD-10-related software changes?

BE AWARE THAT ANY CLAIMS SUBMISSIONS PROBLEMS THAT OCCUR AFTER OCTOBER 1, 2014 AS A RESULT OF MOVING TO ICD-10 COULD DISRUPT YOUR REPORTING REQUIREMENTS FOR THE EHR PROGRAM.

- Will training be provided for any new ICD-10-related functionality, and is there a charge?
- Is there a phased approach for implementing ICD-10?

Questions to ask a new vendor

For new vendors, the following questions are suggested:

- How does your product simplify my organization's transition to ICD-10?
- How does the functionality offered by your system compare with my current system?
- Does your implementation require a complete system conversion?
- Based on what I already have in place, how much will it cost to convert to your system?
- What are the costs of maintenance for your product?
- Who in this area is using your current system? Talking to vendors' existing clientele in your area about their experience with that vendor may help you identify if the vendor's services are a good fit for your organization.
- What kind of product quality guarantees do you offer, and are these guarantees included in the contract?
- What is your timeframe for implementation?

It can't be stressed enough: Practice owners need to work with their vendors now to make sure that your system updates are done in plenty of time for you to be prepared for the October 1, 2014 deadline.

@ MORE RESOURCES

Related coverage by **Renee Stantz** at *MedicalEconomics.com*:

Demystifying Medicare's 'incident to' billing by nurse practitioners, physician assistants
http://bit.ly/18ZFKoI

Are you Documenting Shared/Split Visits Correctly?
http://bit.ly/1bGCFbu

Tips for testing ICD-10 in 2013
http://bit.ly/16gnbX6

RACs reviewing POS coding for physician services in an outpatient setting
http://bit.ly/17MtCpG

You will pay the price if you do not meet e-prescribing requirements
http://bit.ly/HGrrKE

Behavioral counseling key to reimbursements for obesity
http://bit.ly/1gtPYfW

Clarifying new place of service rules
http://bit.ly/1azBWXc

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

INVOKANA™ is the #1 branded therapy prescribed by endocrinologists when adding or switching non-insulin type 2 diabetes medications*

ENVISION NEW **POSSIBILITIES**

Invokana™
canagliflozin tablets

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

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

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

IMPORTANT SAFETY INFORMATION

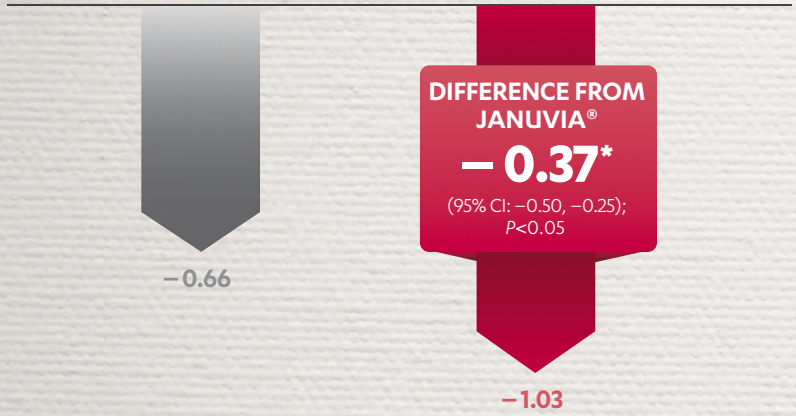
CONTRAINDICATIONS

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

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

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

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



Incidence of Hypoglycemia

With metformin + a sulfonylurea over 52 weeks: INVOKANA™ (canagliflozin) 300 mg: **43.2%**; Januvia® 100 mg: **40.7%**[1]

- Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue[1]

Convenient Once-Daily Oral Dosing[1]

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

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS and PRECAUTIONS

- **Hypotension:** INVOKANA™ causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA™, particularly in patients with impaired renal function (eGFR <60 mL/min/1.73 m^2), elderly patients, and patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (eg, angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA™ in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.
- **Impairment in Renal Function:** INVOKANA™ increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA™. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m^2.
- **Hyperkalemia:** INVOKANA™ can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically after initiating INVOKANA™ in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.

COVERED FOR >**75%** OF COMMERCIALLY INSURED PATIENTS WITHOUT PRIOR AUTHORIZATION[3]

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

Change in Body Weight†

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

»Difference from Januvia®‡:
300 mg: **–2.8%**

Change in SBP†

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

»Difference from Januvia®‡:
300 mg: **–5.9 mm Hg**

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

†Prespecified secondary endpoint.

‡Adjusted mean.

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

Adverse Reactions

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

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

SGLT2 = sodium glucose co-transporter-2.

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

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

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

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

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

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

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

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

ENVISION NEW
POSSIBILITIES

Invokana™
canagliflozin tablets

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS

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

USE IN SPECIFIC POPULATIONS

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

  These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- **Nursing Mothers:** It is not known if INVOKANA™ is excreted in human milk. INVOKANA™ is secreted in the milk of lactating rats, reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA™ showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs in utero and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from INVOKANA™, a decision should be made whether to discontinue nursing or to discontinue INVOKANA™, taking into account the importance of the drug to the mother.
- **Pediatric Use:** Safety and effectiveness of INVOKANA™ in pediatric patients under 18 years of age have not been established.
- **Geriatric Use:** Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA™ in nine clinical studies of INVOKANA™. Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA™ (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300-mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were ≥75 years of age. Smaller reductions in HbA1C with INVOKANA™ relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA™ 100 mg and -0.74% with INVOKANA™ 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA™ 100 mg and -0.87% with INVOKANA™ 300 mg relative to placebo).
- **Renal Impairment:** The efficacy and safety of INVOKANA™ were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/1.73 m^2). These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR ≥60 mL/min/1.73 m^2); patients treated with INVOKANA™ 300 mg were more likely to experience increases in potassium.

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

Janssen Pharmaceuticals, Inc.

Canagliflozin is licensed from Mitsubishi Tanabe Pharma Corporation.

November 2013 004991-131021

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

OVERDOSAGE

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

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

ADVERSE REACTIONS

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

K02CAN13149

Please see brief summary of full Prescribing Information on the following pages.

Invokana™
canagliflozin tablets

janssen
PHARMACEUTICAL COMPANIES OF Johnson&Johnson

INVOKANA™

(canagliflozin) tablets, for oral use

Brief Summary of Prescribing Information.

INDICATIONS AND USAGE

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

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

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

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

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

ADVERSE REACTIONS

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

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

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

Pool of Placebo-Controlled Trials: The data in Table 1 is derived from four 26-week placebo-controlled trials. In one trial INVOKANA was used as monotherapy and in three trials INVOKANA was used as add-on therapy *[see Clinical Studies (14) in full Prescribing Information]*. These data reflect exposure of 1667 patients to INVOKANA and a mean duration of exposure to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

INVOKANA™ (canagliflozin) tablets

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

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

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

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

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

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

* Includes placebo and active-comparator groups

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

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

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

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

* Week 26 in mITT LOCF population

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

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

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

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

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

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

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

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

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies

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

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

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

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

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

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

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

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

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

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

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

DRUG INTERACTIONS

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

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

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

USE IN SPECIFIC POPULATIONS

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

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

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

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

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

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

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

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

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

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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:
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Financial Strategies

THINKING OUTSIDE THE BOX ABOUT PRACTICE PROFITABILITY

by **FRANK COHEN, MPA** *Contributing author*

What is the primary responsibility of a medical practice? Typically, the most common answer I hear is "providing quality care to our patients." While I would never argue about the importance of quality patient care, I want you to really think about its placement in the scale of priorities. In the world according to Frank, profitability is the most important responsibility of a medical practice. Here's why.

A MEDICAL PRACTICE is a business. What separates us from a convenience store, a dry cleaner or a car dealership are the products and services we sell. I know this is not often a popular analogy with physicians, because it does not factor in your work as a healer.

But there are economic realities of a business that need to be considered. Unless you are the federal government, you can only operate at a deficit for so long before your practice closes and creates a huge hole in the community.

Defining profitability

So how do we define profitability? The basic answer is revenue over expense.

Profit is simply the difference between revenue and expense. To improve profits (or profitability), then, one only has to increase revenues, decrease expenses or contribute to some combination of the two. Sounds simple, but it's not easy.

Cutting expenses

Let's talk first about expenses. We could, for example, cut staff pay and benefits. But what happens when your cuts make the services you offer below market value? You lose staff and when that happens, you have a reduction in continuity of care, which translates to a reduction in quality.

So how about eliminating full-time equivalents (FTEs)? That works as long as you don't cross below the value of diminishing returns.

For example, in one practice I worked with a few years ago, they reduced their coding staff from eight FTEs to six FTEs in an effort to reduce costs. Each coder was responsible to produce a certain volume of properly coded claims per day. By reducing the number of FTEs, the number of claims per day per coder increased and as it did, we noticed that the number of coding errors (unclean claims) also increased. This resulted in a 15% increase in rework, which, in turn, ended up costing 22% more than it would have had they maintained the original staffing level. In this case, the practice administrator failed to test this idea first and as such, missed the potential consequences down the road.

The bottom line is that quality is expensive, and we can only cut costs so much before we begin to negatively impact the quality of care, which, if you recall, is normally what folks assign to the primary responsibility of their medical practice.

Constraints to increasing revenue

How about just increasing revenues? That is, after all, the numerator and this is a simple equation.

The biggest constraint is that we operate within a complex environment. And while there is simply not enough space in this article to get into all the details, the principal component of a complex system is that there are many interdependencies. One of those is the third-party payer market. With the exception of deductible and copay amounts (which can be a nightmare to calculate), the bulk of your payments comes from a third party—arguably, from companies or groups that do not have your best interest at heart.

Think about this; the primary role of your practice is to get paid a reasonable amount for providing

Financial Strategies

your patients with quality healthcare services. The primary role of the payer (with the exception of Medicare), is not to pay you reasonably for the quality healthcare services delivered to their subscribers.

Based on my research with the AMA's National Health Insurance Report Card, in one out of five claims, the insurer pays nothing and in the remaining claims, nearly one out of five are paid in error. The fact is, as long as you choose be in partnership with third-party payers, your ability to affect your revenue is slim to none.

You could just charge more, but what is amazing to me is that what you charge has virtually no effect on what you get paid. As you remain dependent upon third parties for payment, you surrender much of the control over your revenue.

Ways to increase revenue

There are some things you can do. For example, diligence with regard to estimating copay and deductible make it easier to know what to collect at time of visit. Again, you are dependent upon the payer to be able to give you accurate and timely information on their subscribers.

Having a consistent policy that everyone agrees to regarding payment at time of visit can substantially increase cash flow and reduce accounts receivable. In fact, in every practice that I have consulted where there is a standardized policy and training for staff on how to collect at time of visit, daily revenue as a percent of charges is significantly higher than in those practices that do not employ this type of policy and training. For some practices, dropping payers completely can often result in a more profitable practice. I know that this is hard for some to believe, but according to a study conducted by Jonathan Gruber in 2007, practices are 1.7% more profitable with uninsured patients than with insured patients.

Thinking outside the box

- Build policies and get diligent in estimating copays and deductibles to collect at the time of the visit.
- Build a communications strategy to educate and Inform patients about payments at the time of the visit to reduce accounts receivable.
- Review payer contracts. Dropping poor payers can result in a more profitable practice.
- Improve efficiency by engaging in Lean and Lean Six Sigma techniques.

Find inefficiencies and stop them

Finally, and perhaps the best solution, is to become more efficient in what you do. This often requires the practice to engage in Lean and Lean Six Sigma (LSS) projects, management techniques that are designed to improve quality, outcomes and increase profitability all at the same time. I have been involved in dozens of LSS projects for dozens of medical practices and in nearly every one, the results are nothing short of stellar. In one case, I discovered a duplicative step in the patient visit process that wasted around three minutes per patient visit.

The physicians, however, were not as impressed as I was, stating that three minutes "was not their problem." Yet, they saw over 100 patients a day, which calculated to 300 minutes (or five hours) per day of wasted time.

Recovering only a fifth of that (one hour per day) allowed them to see four more patients per day, resulting in over a quarter of a million dollars per year added to the bottom line.

Think outside the box

The idea is to step outside of our canonical understanding of profitability and consider doing things differently. My friend Henry Shaw had a favorite saying: "If what you are doing is working, keep doing it, but if it is not, then do something different." This is a decision that needs to be made individually by each practice, but look at what you are doing closely because it may just be that, in this dynamically changing marketplace, what you have been doing doesn't work any more. ◻

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*The author is senior analyst with The **Frank Cohen** Group, LLC in Clearwater, Florida, and a Medical Economics editorial consultant. Send your practice management questions to **medec@advanstar.com**.*

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Technology

Cardiologist says EHR needs more custom features

A Georgia specialist finds it hard to jot life details about patients on stagnant EHR fields

by **DARIN PAINTER** *Contributing author*

HIGHLIGHTS

01 Use templates within the EHR system to customize screens that help your workflow more efficient.

02 Take advantage of any free training that your EHR has to offer online or through webinars to beging customizing your EHR experience.

When visiting Doris E. Tummillo, MD, many patients bring their great-grandchildren. She seems to recall their names on first glance, and often asks questions that make everyone in the room feel comfortable: "How is Margaret feeling these days? Are you still walking a few miles a week?"

FOR TUMMILLO, a cardiologist in Augusta, Georgia, those questions were easier to ask when she could quickly flip through a patient's paper chart and read her handwritten notes. "In addition to reading my little scribbles and looking at patient photos on charts, I would clue myself in to a lot of information from recorded notes—about the severity of a patient's condition, about recent family tragedies and so on," she says.

She can still add that kind of information using an open comments field in her practice's electronic health records (EHR) system, she says, but "the biggest issue I'm having with these electronic records is the notion that each one looks and feels the same for all patients—it's really no fault of the software, but there's a sameness to EHR that I don't like."

Patients have appreciated Tummillo's desire to connect with them since she began

her cardiology practice more than 20 years ago. She sees between 20 to 25 patients a day, a number that hasn't changed since the spring of 2012, when her practice adopted ABELMed EHR from ABEL Medical Software Inc. Tummillo is one of 29 participants in the 2-year *Medical Economics* EHR Best Practices Study, an ongoing project intended to draw out valuable, real-world insight for healthcare leaders.

"Overall, it has actually been pretty good, although none of us wanted to make the transition at first," she says. "It's nice to pull up medical histories and other details quickly, without having to flip though a chart. We were able to start using the software within a few hours of training, and the ABEL support people have been extremely helpful when questions arise."

THE VALUE OF CUSTOMIZATION

The big question for Tummillo when her practice began using ABELMed EHR was: "Will this make us more efficient?"

"So far it hasn't," she says, "but I'm hoping it will eventually."

The "old" technology of paper records might seem antiquated, but it's flexible, she says, and therefore allows variations in workflow, procedures, training, and other conveniences that software can't manage. (See "More Productive? 4 Factors to Consider")

"I have to see patients in the room and then work in the system later—I can't do both at the same time, and I don't want to hire a scribe," Tummillo says. "That said, it's easier to access records and see data, and it's faster to get all information like lab results and medication details in one place."

Tummillo believes one key to improved efficiency might be further use of the system's specialty templates. "We all have our own special ways of doing things on a chart. I want to replicate them as much as possible so the electronic form isn't as generic," she says.

Essentially, Tummillo aims to remove and organize a multitude of fields and prompts to help her navigate interaction with patients and data input during an exam. She wants to be able to pick diagnostic codes faster, or orders associated with those codes.

ABELMed EHR enables users to create and customize a range of clinical docu-

More Productive? 4 Factors to Consider

We are seeing the same number of patients as before, but productivity isn't only about patient volume," says Tummillo. Physicians say the effect of an EHR on productivity can be measured in other ways, too:

1. **Volume** How many visits per day occurred before EHR implementation? How about in the 30 days after implementation? How about the average number of monthly patients after 3, 6 and 12 months? (A dip in productivity is common and typically lasts several months.)
2. **Intensity of service** Divide total receipts deposited monthly by the total number of visits for that month. The result is the average dollars received per visit. Compare this number before and after EHR implementation.
3. **Overhead expenses** Are you saving money because of EHR, after taking into account the number of employees needed (and their salaries), outside services needed and other costs (equipment, servers, etc.)? If so, do the savings offset the cost of implementing and maintaining the technology?
4. **Free time** This is harder to quantify, but has your quality of life improved after implementing EHR? How much time do you spend "catching up on charts" as opposed to spending time with family or on hobbies? Consider tracking the time you're spending on work while away from the office.

mentation templates, including ones for office encounter notes, progress notes, procedures, and immunizations. The clinical findings Tummillo uses to create one template can be saved as building blocks for other templates to reduce duplication of efforts and save time, according to ABEL Medical Software Inc. The company ships the software to new clients with a database of more than 20 templates to start, and new ones can be added regularly or by request.

Today, when a new patient enters the practice, he or she registers at the front desk. Contact and insurance information are entered into ABELMed EHR, and once in an exam room, a nurse adds other details such as medications, allergies, and chief-complaint notes. "When I see that patient, the flow is still the same as it was before EHR, but the way information is recorded is so different," Tummillo says.

After the visit, she might view the patient's cumulative profile (essentially a snapshot of overall health), then click on "Encounters" to update information about his or her coronary disease. A staff member may later click on "Referrals and Consultations" to generate referral letters quickly from existing notes, "Patient Education" to prepare instructions and other materials for the patient to take when leaving the office, and "Billing" to automatically create bills using CPT-4 and ICD-9 codes.

"There are a lot of features and capabilities we can use," Tummillo says. "We need to get more comfortable with them, and that will take more time."

THE IMPORTANCE OF TRAINING

It's typical for practice workflows to slow by as much as 50% during an EHR implementation, experts say. Entering all the necessary information can be extremely time-consuming.

When undergoing EHR implementation, Tummillo says, it's critical to take advantage of the vendor's training opportunities and educational resources. "For us, this has been an excellent experience. It's not easy to be adequately trained, and ABEL goes out of the way to get us information we need, when we need it."

One area that consistently leads to successful EHR implementations is the creation and use of EHR "super users" to help train other staff and physicians—something Tummillo says she regrets not doing before her practice began using ABELMed EHR. "Having someone on staff who could train other people here anytime—that would be so much better."

She says ABEL provides free, easy-to-follow online sessions that are based on client feedback and questions. The vendor also offers nearly 100 on-demand webinars covering topics such as security (for example, assigning a role to a member), front desk reception tasks (color-coding appointments), clinical staff tips (adjusting the view of the dashboard), e-prescribing features (sending prescriptions electronically) and more. Tummillo and her staff recently needed help managing error messages received from pharmacies, and received helpful information from ABEL quickly, she says.

> "The biggest issue I'm having with these electronic records is the notion that each one looks and feels the same for all patients—it's really no fault of the software, but there's a sameness to EHR that I don't like."

As she and her staff continue to learn more about the EHR system, Tummillo says, the practice will be better positioned to attest for Meaningful Use. ABELMed EHR makes it easier for the practice to achieve those incentives because it provides easier clinical documentation, faster report generation and more accurate monitoring of core meaningful use measures such as clinical quality, Tummillo says. ■

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PERSPECTIVE

WHEN EXPERIENCE TRUMPS EVIDENCE

by **JOHN WAYNE COOPER, MD**

In the real world of treating patients, diagnoses are complicated and apparent risk factors sometimes amount to nothing. But after a patient dies of a complicated medical issue, the physician's soul searching begins: *Did you see the signs? Did you interpret the symptoms correctly?* One physician's story about the death of a long-time patient has lessons for all providers about the value of experience, and what doctors learn along the road of their career.

It was around 3 p.m. when my office nurse pulled me out of my exam room.

"Doc, I've got Vern's wife on the line and she sounds pretty worried. Can you talk to her now?"

"Martha, what's going on with Vern?" I asked Vern's wife.

"I don't know, but he says his pain is getting worse and he doesn't want to get out of bed," Martha said, her voice attempting to conceal her anxiety.

I told Martha that I would come by their house and check on Vern in a couple of hours after I was done with office appointments.

A PATIENT WITH CHEST PAIN

Earlier in the week Vern was in the office complaining of what he thought was a spider bite on

➔66

HIGHLIGHTS

01 Experience-based medicine is a personal and dynamic learning process based on the everyday experiences in the life of every clinician.

02 Remember that completely unrelated, coexisting disease processes can share similar signs and symptoms.

03 The presence or absence of measurable risk factors does not infallibly predict future health.

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"Had oversimplification of Vern's condition prejudiced my clinical decision-making? Probably so. A fine line exists between arriving at a timely treatment decision based upon reasonable evidence versus delaying important management while on a fishing trip for red herrings. How can I apply my experience with Vern to help me be a better doctor?"

64 his lower left chest. A few days earlier he had noted a red spot on his skin and he felt some tenderness in the area of his left chest wall but attributed it to a pulled muscle. Otherwise he said he was feeling okay.

When I looked at Vern's chest I saw a bunch of tiny blisters on a streak of reddened skin overlying his left six rib. The diagnosis in my mind was straightforward: Herpes zoster.

The year was 1982 and medical science had little to offer the shingles sufferer other than pain relief while waiting for the condition to run its course. I explained this to Vern as he left the office with a prescription for pain medicine and advised him to follow up if needed.

The phone call from Martha was a little disquieting since neither she nor Vern were alarmists.

As I started off on my house call my thoughts turned to wondering what possibly could be the cause of Vern's decline. Aside from occasional exacerbations of his emphysema Vern's health was reasonably good for a man in his mid-70s. His only cardiac risk factor was his history of heavy cigarette use, but he'd thrown out his cigarettes at least 10 years earlier. Blood sugar and lipids were normal as was Vern's blood pressure.

Probably all that was needed was some reassurance and a readjustment of his pain medication with a possible addition of steroids.

Martha met me on the walkway up to the house, her face seized with fear.

"After I covered him with a blanket he seemed to quiet down and I thought he went to sleep," she said.

"That was about an hour ago. Just before you came I looked over at him and he didn't seem to be breathing. I thought it was just my imagination because I've been so worried about him. Come in here. He's in the bedroom."

QUESTIONS THAT COME AFTER

I followed Martha into the dimly lit room, hesitating for a moment hoping to see Vern breathing. I could detect no respirations. I rushed to his bedside to undertake a more detailed examination finding Vern's eyelids half open and motionless. Pinkness had left his face and there was no pulse.

"Vern is gone," were words I wish I never had to say and I'm certain were words that Martha dreaded to hear.

Martha, sobbing, threw herself into my arms saying, "It can't be true, but I know it is."

In a soft voice I said to Martha, "Let's just lift the blanket over Vern and you can sit next to his bed while I call the corner. They will help take care of everything."

Within about half an hour the people from the coroner's office arrived and gently removed Vern's body.

I asked Martha if I could help her with anything. She said no, but she accepted my offer to stay with her until she called her children. I also added that I had no explanation for Vern's death, but the coroner's office should be helpful with an answer.

The answer came a week later. The coroner's office told me that Vern's death was due to a massive heart attack because of extensive coronary arteriosclerosis.

EXPERIENCE- VS. EVIDENCE-BASED MEDICINE

Never to be answered adequately were the

> "I perceive experience-based medicine as a personal and dynamic learning process based on the everyday experiences in the life of every clinician. It involves the personal discovery and application of principles necessary for improving patient care as well as encouraging physician humility and integrity."

questions: Was some of Vern's chest pain due to pre-infarction angina? Did I overlook doing something that could have prolonged Vern's life? The soul searching has never ended.

If Vern had presented without an apparently obvious cause for his chest pain, would I have undertaken some kind of cardiopulmonary evaluation? Yes. I would have at least listened to his heart and lungs. Had oversimplification of Vern's condition prejudiced my clinical decision-making? Probably so.

A fine line exists between arriving at a timely treatment decision based upon reasonable evidence versus delaying important management while on a fishing trip for red herrings. How can I apply my experience with Vern to help me be a better doctor?

A part of my 10th grade curriculum was world history—a class with the reputation for monotony but a necessity for that high school diploma. A part of each homework assignment was the memorization of dates, events, places, and so on. In addition our teacher, Mr. Wayne Jones, required each student to be prepared to discuss a principle underlying a particular historical event—nurturing the habit of critical and analytic thinking. Mr. Jones taught that a principle is a general belief that you have about the way you should behave. I've learned to apply these lessons to the practice of medicine and treating patients.

What I call experience-based medicine differs from evidence-based medicine in that it expands decision-making beyond mathematical estimates of the risk of benefit and harm, derived from research projects of many people on multiple population samples.

I perceive experience-based medicine as a personal and dynamic learning process based on the everyday experiences in the life of every clinician. It involves the personal discovery and application of principles necessary for improving patient care as well as encouraging physician humility and integrity.

With the help of Mr. Jones and Vern I'd like to share with you a couple of principles I have adopted based on experience-based medicine.

First, always remember that completely unrelated, coexisting disease processes can share similar signs and symptoms.

THE LIMITS OF RISK FACTORS

Second, the presence or absence of measurable risk factors does not infallibly predict future health.

The story of Adele illustrates the second point. A few years before she died, Adele was noted to have a cholesterol of 360.

"I don't like pills and I'm not going to take any. I feel pretty good so put your prescription pad away," she replied when I advised her to begin a statin for what I considered to be a worrisome cholesterol level.

"OK, but be very careful with the fats in your diet," I told her, thinking to myself: Hey, it's a free country.

Adele did go on to die—from pneumonia the day after her 101st birthday.

Well doc, what do you think of that?

John Wayne Cooper, MD, is a family physician practicing in Novato, California. This piece was originally submitted as part of the 2013 **Medical Economics** *Doctors' Writing Contest.*

"One must always remember that completely unrelated, coexisting disease processes can share similar signs and symptoms. The presence or absence of measurable risk factors does not infallibly predict future health."

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The Last Word

2014 MEDICARE PHYSICIAN FEE SCHEDULE: FOCUS ON CHRONIC CARE

by **ALISON RITCHIE** *Content associate*

High-quality care and efficiency—those are the two points that the Centers for Medicare and Medicaid Services (CMS) emphasized with the release of its 2014 Medicare Physician Fee Schedule. Included in one of the provisions, primary care physicians will begin to see reimbursements for chronic care management services outside of face-to-face visits, beginning in 2015.

"HEALTHCARE IS changing, and part of delivery system reform is recognizing this and making sure payment systems account for these changes," said CMS Principal Deputy Administrator Jonathan Blum in a written statement. "We believe that successful efforts to improve chronic care management for these patients could improve the quality of care while simultaneously decreasing costs, through reductions in hospitalizations, use of post-acute care services, and emergency department visits."

The rules also allow payments for telehealth services in rural areas that qualify as health professional shortage areas. A change to the Physician Quality Reporting System (PQRS) gives eligible physicians the option to report quality measures through qualified clinical data registries.

> "We believe that successful efforts to improve chronic care management for these patients could improve the quality of care while simultaneously decreasing costs..."
>
> – JONATHAN BLUM, CMS PRINCIPAL DEPUTY ADMINISTRATOR

CMS estimates that approximately $87 billion will be paid to physicians under the 2014 fee schedule.

But it also maintains the sustainable growth rate (SGR) pay cuts, which has prompted forceful pushback from physician groups, including the American Medical Association (AMA) and the American Academy of Family Physicians (AAFP).

"The AAFP is disappointed that current law continues to require CMS to issue a physician fee schedule that slashes payment by 20.1 percent next year," said Reid Blackwelder, MD, AAFP president in a written statement. "The schedule reflects the flawed sustainable growth rate formula that dictates Medicare payment for physician services. That formula must be repealed, and the AAFP urges Congress to act quickly to do so."

Congressional leaders have a plan that would repeal the SGR and implement a 10-year pay freeze and performance-based incentive program. But it's unclear whether the proposal will garner enough support to pass before the looming Jan. 1 deadline.

"The clock is ticking. At stake are innovations that would make Medicare more cost effective for current and future generations of seniors," said AMA spokesman Robert J. Mills in a written statement. "These innovations are not possible if physicians are worried about drastic cuts to Medicare rates that have remained almost flat since 2001, while the cost of caring for patients has gone up by 25 percent."

@ Share your thoughts about the 2014 Medicare Physician Fee Schedule. Write us at medec@advanstar.com. Your comments could be included in the next issue of *Medical Economics*.