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NOVEMBER 10, 2014
VOL. 91 NO. 21

THE 86th ANNUAL

PHYSICIAN REPORT

NATIONAL SURVEY REVEALS

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NOVEMBER 10, 2014

Volume 91
Issue 21

IN DEPTH

SPECIAL REPORT

Money $

Trends *

Operations ( )

Policy

86TH ANNUAL PHYSICIAN REPORT

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- A look at the financial state of physician practices

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How to determine your retirement number

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PRACTICAL MATTERS

Judy Capko
Don't let peak demand sabotage your schedule

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

AMA ISSUES 'BLUEPRINT' FOR FUTURE OF MU

The American Medical Association (AMA) wants doctors to have more flexibility in how they meet the requirements of the meaningful use (MU) program. Its recommendations include lower thresholds for incuring financial penalties and rewards, making the most challenging measures optional, and improving MU's alignment with the Physician Quality Reporting System. Find more details at **http://bit.ly/10e6srZ**

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#Antibioticresistant pneumococcal infections are estimated to lead to more than 19,000 excess #hospitalizations http://ow.ly/D1RBm

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Primary care can extinguish fee-for-service, study says http://ow.ly/CVero #physicians

MEANINGFUL USE
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The case against retail clinics via @TheAtlantic http://ow.ly/CGLAv

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"With planning and sound advice, physicians reach their retirement goals"

—Joel Greenwald, CFP FINANCIAL PLANNER

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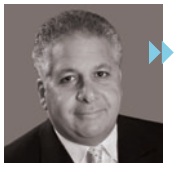

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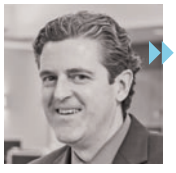

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from the Trenches

> Gevitz has been the preeminent historian of the osteopathic profession for 30 years. His concerns...are troubling, and require extreme caution if the AOA pursues this merger. His apprehensions...spell possible disaster for the osteopathic graduate education system, osteopathic medical school, and the profession's independence. **Craig M. Wax, DO,** MULLICA HILL, NEW JERSEY

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MERGER WITH ACGME COULD DOOM OSTEOPATHIC MEDICAL EDUCATION

Thanks for publishing Shannon Scott, DO's opinions on the Accreditation Council for Graduate Medical Education and Osteopathic Graduate Medical Education merger ("DOs will benefit from unified GME system," September 10, 2014).

Certainly there are many issues and variables to be considered. The concerns I raised about the merger are primarily based in fact on the report of Norman Gevitz, PhD, "The Unintended Consequences of the ACGME Merger." (Available at bit.ly/1sR73KH)

Gevitz has been the preeminent researcher and historian of the osteopathic profession for 30 years. His concerns, as detailed in his report of April 2013, are troubling and require extreme caution if the AOA pursues this merger. His assertions and apprehensions, based on the history and actions of the osteopathic profession at large, spell possible loss and disaster for the osteopathic graduate education system, osteopathic medical schools, and the profession's independence. By 2021, ACGME will be in control of the osteopathic graduate medical education system and will be free to fire all DOs and reject their philosophy in formerly DO training programs.

My concerns are threefold:

1. I am concerned that the AOA (American Osteopathic Association) has been pursuing this for a decade without addressing his work concerns and members' concerns, such as mine. Again, this is an example of the AOA's top-down management style rather than bottom-up parliamentary rule as is expressed in their bylaws and mission.

2. Gevitz's detailed report spells out the domino effect that could result from the ACGME merger of the course. This may result in the loss of osteopathic OGME programs and input in future ACGME programs, and the loss of the profession at large.

3. The AOA steadfastly refuses to publish any editorials or papers that differ from the AOAs official policy in "The D.O." and "The JAOA." Further, the AOA administration has inappropriately tried to withdraw motions and pervert parliamentary procedures at house of delegates business meetings to subvert DO member resolutions and actions.

The osteopathic profession began in 1874 when A.T. Still, MD became frustrated with the current state of medicine and healthcare. His thoughts, actions, persistence and courage to pursue a novel school of medical care are legendary and paramount. We must not allow government and its arbitrary funding goals to determine our profession's course or the care of our patients.

Craig M. Wax, DO
MULLICA HILL, NEW JERSEY

MEDICARE PART B PREMIUMS, DEDUCTIBLES TO STAY FLAT

The costs of premiums and deductibles for Medicare Part B, which covers physician services, will not change in 2015, according to an announcement from the Centers for Medicare and Medicaid Services (CMS).

Premiums for the nearly 49 million recipients will stay at $104.90 and deductibles will remain $147.

This is the second year that the cost of Medicare Part B has not increased for seniors, and CMS says it's proof that the Affordable Care Act is working to improve access to care and slowing healthcare costs.

"The stabilization of Part B premiums is another example of how we are containing health care costs to provide a more sustainable and affordable health delivery system," CMS Administrator Marilyn Tavenner said in a statement. "This means even greater financial and health security for our seniors next year as their premiums will remain unchanged."

CMS says Medicare spending growth has been flat for four years.

AMA STUDY

MOST METRO AREAS LACK PAYER COMPETITION

A new annual study by the American Medical Association (AMA) has found that 72% of U.S. metropolitan areas studied lack significant competition for health insurance, and most were highly concentrated.

The study - Competition in Health Insurance: A Comprehensive Study of U.S. Markets - looked for evidence of highly concentrated areas because they can lead to insurers exercising "market power" including controlling price.

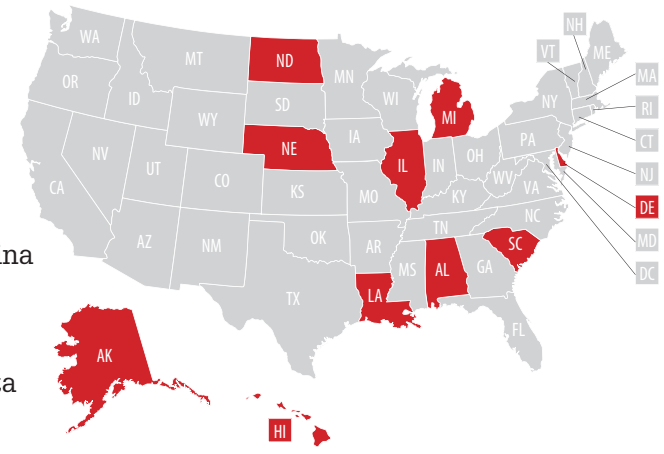
The study found that 17 states have a single health insurer with a commercial market share of 50% or more, and 45 states have two health insurers with a combined commercial market share of 50% or more. In 90% percent of metropolitan areas, just one insurer holds at least a 30% share of the commercial health insurance market.

"The dominant market power of big health insurers increases the risk of anti-competitive behavior that harms patients and physicians," said AMA president Robert M. Wah, MD, in a statement.

TOP 10 STATES

Least commercial payer competition

1. Alabama
2. Hawaii
3. Michigan
4. Delaware
5. Louisiana
6. South Carolina
7. Alaska
8. Illinois
9. Nebraska
10. North Dakota



Source: AMA

MEDICARE FINES RECORD NUMBER OF HOSPITALS OVER READMISSIONS

A record number of hospitals are being fined via Medicare reimbursement cuts for having too many readmissions, according to an analysis by Kaiser Health News.

The $428 million in fines were levied against 2,610 hospitals, with 39 receiving the largest penalty allowed.

Penalties are assessed when the number of Medicaid patients who are readmitted within 30 days of discharge exceeds a national benchmark. The latest penalties are based on readmissions from July 2010 through June 2013, notes the analysis.

This is the third year that the U.S. Centers for Medicare and Medicaid Services (CMS) has levied the penalties. They first went into effect in 2012 following establishment of the Hospital Readmissions Reduction Program (HRRP) as part of the Affordable Care Act. Of hospitals subject to HRRP, 75% are being penalized, says the analysis.

CMS uses a complex formula to determine acceptable readmissionss for each hospital, but their methodology has come under fire, with critics noting that hospitals have to hit a rate lower than the overall industry.

Primary care can kill fee-for-service with diverse payment models

IT'S NO SECRET that primary care is becoming more important to the healthcare landscape. Provisions of the Affordable Care Act (ACA) are expected to add 25 million primary care appointments annually. In order to lower costs and make primary care more accessible as more people seek healthcare, UnitedHealth Center for Health Reform & Modernization and Optum Labs released a report recommending that states the solution lies in phasing out fee-for-service models and incorporating multiple healthcare teams, diverse pay models and technology.

"As much as half of wasteful health care spending results from failures of care delivery and care coordination, as well as overtreatment — all of which could be improved by moving away from the fee-for-service reimbursement model," the report states.

Efficient and easy-to-find primary care services also contribute to the decrease in emergency department visits. Nearly 70% of emergency department visits by insured patients are for non-emergency issues, according to the report.

The report suggests policies and regulations that increase roles for nurse practitioners (NPs) and physician assistants (PAs), thereby making primary care services more attainable and affordable for people living in medically underserved communities. "In the 10% of local markets with the lowest concentration of primary care physicians, the concentration of NPs and PAs was highest, and there were approximately equal numbers of physician and non-physician providers," according to the report.

Reimbursement models would have to be reconfigured to incentivize practices to use NPs and PAs for less-complex patients. "A significant barrier to achieving more dramatic and rapid progress is payment policy. Medicare and Medicaid generally reimburse less for services delivered by NPs and PAs than for the same services when performed by physicians."

Offering different types of services tailored to patients' needs also will help primary care practices transition to value-based payment models and increase patient satisfaction.

The report finds that too many barriers remain in healthcare technology to allow primary care physicians to use it to their advantage. Lack of interoperability between EHR systems, training, maintenance costs and loss of productivity all make utilizing technology difficult. "Investments in the deployment and impactful use of HIT require significant time commitments and upfront costs that will pose difficulty for some primary care practices," the report says.

The study's suggestions for primary care

1	Retail- or urgent care-structured services offered after hours to cut emergency department visits.
2	House calls to patients to evaluate social and environmental factors that can affect health;
3	Group visits with private exams and collective educational classes.
4	Focus on healthcare's "super-users," the 5% of the population who account for 50% of healthcare costs.

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SPECIAL REPORT

The 86th Annual Physician Report

Administrative burdens keep physicians away from patients

by **CHRIS MAZZOLINI, MS** *Content manager*

Most physicians embarked on a career in medicine to help patients. But today, many are finding their days consumed with the administrative burdens required to manage a practice and adapt to the massive changes brought about by healthcare reform efforts, according to results from the 86th annual *Medical Economics* 2014 physician survey.

HIGHLIGHTS

01 When asked what is the biggest issue facing primary care right now, physicians pointed to the paperwork burden, followed closely by reimbursement rates and third-party interference.

THE RESULT: Physicians are working the same long hours, but are seeing fewer patients, despite widespread reform efforts that should be leading to more patient visits, not fewer.

The data paint a picture of a physician who feels overburdened, burned-out, disrespected and disenfranchised, who increasingly believes that the power to make positive changes in the lives of patients has been ripped from his or her grasp and concentrated in the hands of the government and insurance companies, who seek to downplay the importance of medical judgment in favor of "assembly line" medicine.

These burdens are exemplified by time-consuming challenges such as prior authorizations, International Classification of Diseases-10th Revision (ICD-10) preparation, electronic health record (EHR) hassles, maintenance of certification pressures, payer audits and more.

"What's happening to medicine is it's no longer about patient care," says David Cohen, DO, a survey participant who is an independent practitioner in Oakwood, Georgia. "It's about the bottom line. Healthcare has been taken over by MBAs who are not physicians."

Still, most primary care physicians want to help patients and love the practice of medicine when they can cut through the red tape. About 6 in 10 practicing physicians surveyed said they would choose the same specialty if they had a chance to do-over their career.

Yet there is a creeping sense that the lives of physicians are getting worse. Only 43% of practicing physicians said they would rec-

Mean salary comparison

for employed physicians and practice owners

2013 Median income = $213,000

	2012	2013	Difference
Family practice/general practice	$195,000	$195,000	0
Internal medicine	$208,000	$203,000	$5,000
Pediatrics	$195,000	$203,000	$8,000
Cardiology	$381,000	$376,000	$5,000
Hospitalists	$246,000	$250,000	$4,000
Emergency/acute care	$229,000	$226,000	$3,000
Psychiatry	$190,000	$207,000	$17,000
OB/GYN	$263,000	$260,000	$3,000
Dermatology	$368,000	$410,000	$42,000
Ophthalmology	$281,000	$306,000	$25,000
Urology	$388,000	$356,000	$32,000

Source: *Medical Economics* annual physician survey, 2013-2014
*Calculated central value of a set of numbers

Mean* salary gain Mean* salary loss

ommend that their child or a friend's child pursue a career in medicine, frequently citing the enormous debt load required to study medicine.

Asked to name the biggest issue facing primary care, physicians cited the paperwork burden (69%), followed by reimbursement rates (68%) and third-party interference (47%). Other commonly-cited issues include:

- value of primary care vs. specialty care and use of midlevels (44%),
- healthcare reform (41%),
- malpractice/tort reform (38%),
- EHRs (38%),
- doctor shortage (24%), and
- accountable care organizations (20%)

Our coverage of this exclusive research focuses on four areas: physician productivity, ICD-10 readiness, practice finances and compensation and malpractice insurance.

Patient visits

Prior to the launch of the Affordable Care Act, policy experts predicted that the influx of more than eight million newly insured patients would overwhelm the primary care system. So far, however, the new patients have been absorbed with little problem.

Practice finances

Financially, most physician practices are either stuck in neutral or losing ground. Eighty-four percent of the physicians surveyed say their practices are doing the same or worse than a year ago. Nearly 40% say they are doing worse.

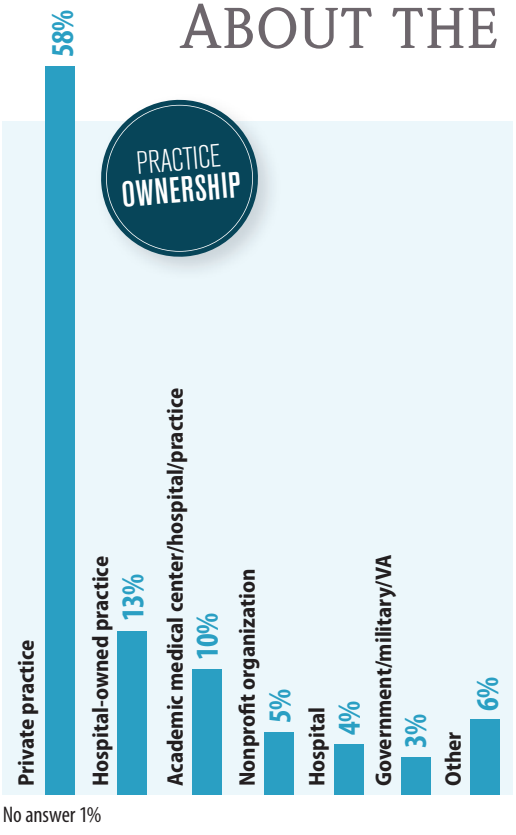
ICD-10 readiness

With 11 months to go until the transition to ICD-10 in October 2015, half of the physicians who responded to the survey said they are not ready for ICD-10.

Malpractice insurance

On the surface, medical malpractice premiums appeared little changed in 2013 for primary care physicians. But a closer look at the results reveals fluctuations in payment amounts depending on a doctor's age, location, workload and practice size.

ABOUT THE SURVEY RESPONDENTS



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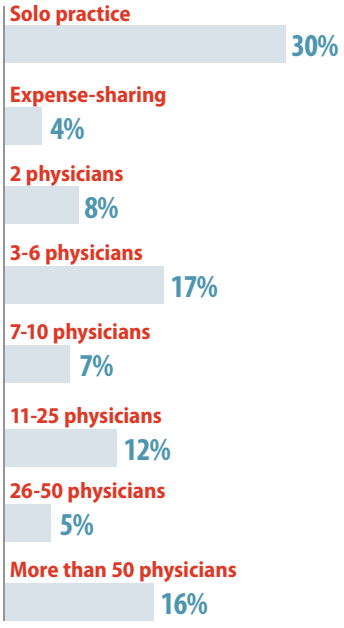
PRACTICE SIZE



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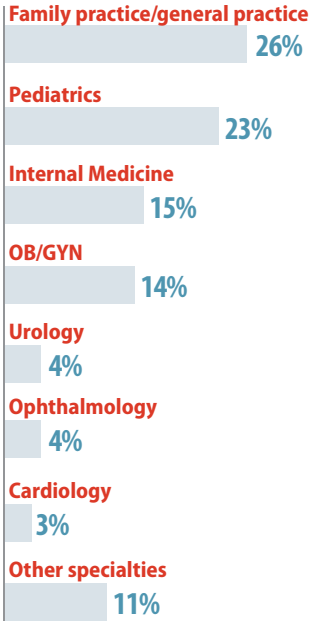
PRIMARY FIELD OF PRACTICE



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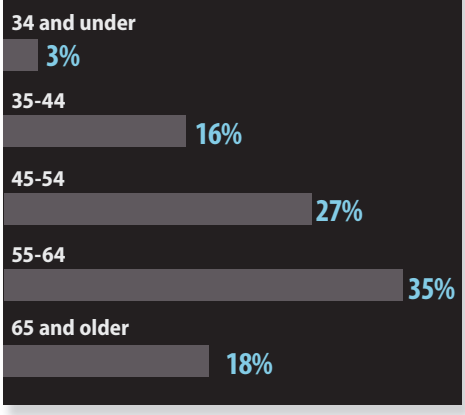
PHYSICIAN'S AGE

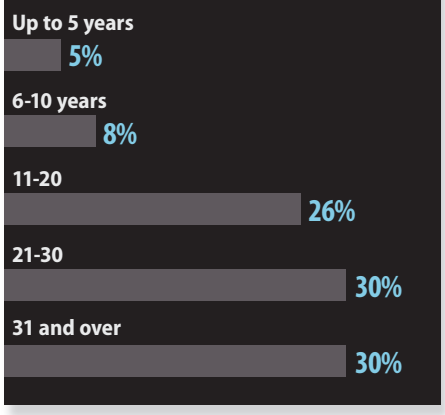
Median = 56 years old



No answer 1%

YEARS IN PRACTICE

Median = 24 years in practice



No answer 1%

PHYSICIAN'S GENDER

No answer 1%

METHODOLOGY

Data for this survey was collected on behalf of *Medical Economics* by Readex Research via online survey from July 23 to August 4, 2014. The survey was closed with 3,635 responses. Qualifying for the final tabulation were the 3,171 respondents who indicated they are actively practicing medicine.

The margin of error for percentages based on 3,171 qualified responses is 1.7 percentage points at the 95% confidence level. Percentages calculated on smaller tabulation bases—for examples, primary field or age—are subject to greater statistical variability.

Primary care physicians seeing fewer patients

Productivity falls, despite flood of newly insured patients covered under the Affordable Care Act

by **ALISON RITCHIE** *Content specialist*

HIGHLIGHTS

01 Practices can help deal with administrative burdens by considering the physician's time as the most important asset.

02 Primary care physicians face an increasing amount of administrative burdens throughout their workday that distract from patient encounters, including prior authorizations and payer requests.

Prior to the launch of the Affordable Care Act (ACA), policy experts predicted that a wave of more than eight million newly insured patients would flood an already strained primary care system. However, those predictions have not yet been borne out.

The 2014 *Medical Economics* Physician Practice Study found that both family physicians and internists saw a significant dropoff in their average number of patient visits per week, despite the number of hours worked remaining steady.

Family physicians and general practitioners reported an average of 89 patient visits per week. That's down from 99 visits per week in 2013. Internists reported a drop from 93 patient visits per week in 2013 to 85 visits in 2014.

This year, the median number of hours worked per week by family physicians was 51, while internists reported 52 hours. That's consistent with the median hours worked per week in 2013, when family physicians and internists reported 50 and 52 hours, respectively.

Experts say the slump in patient volume may be due to several factors, including changes in patient insurance and rising deductibles, the struggles of adapting to electronic health records (EHRs) and increased administrative burdens that are falling on physicians.

ADMINISTRATIVE BURDENS

Primary care physicians face an increasing level of administrative burdens throughout their workday that distract from patient encounters. The most time-consuming of those tasks may be prior authorizations which, according to the American Medical Association, consume an average of 20 hours per week. Walker Ray, MD, vice president of The Physician Foundation and chairman of its research committee, says these tasks wear the most on physician morale.

"Face time with patients is so important to physicians," Ray says. "Patient relationships are the primary reason why doctors go into medicine. This is why doctors give up their 20s and come out with $150,000 worth of debt. This is the premier aspect that gives docs the most professional satisfaction."

A recent survey from The Physician Foundation found that 81% of physicians feel over-extended.

"The physician is the only person in the practice that does not have a job description," says Elizabeth Woodcock, MBA, FACMPE, CPC, a healthcare consultant and author with Woodcock & Associates. "The bottleneck is the doctor, because all of this work is being pushed onto him or her. The physician needs to step back and say, 'I have to figure out how to make the best use of my time.' "

Woodcock says the other benefit of treating the physi-

➔ 16

➔15 cian's time as a practice's most important asset is that it puts the focus back on patient care. "That's a very patient-centric approach, because they want the doctor's time most of all," she says.

Leistikow says when administrative pressures build up, she concentrates on why she went into medicine in the first place. "When I get frustrated, I remember that I am good at taking care of patients, and try to not to focus on that other stuff," she says.

HIGH-DEDUCTIBLE HEALTH PLANS

While millions of patients gained access to coverage through the ACA, high-deductible insurance plans were prevalent throughout the healthcare exchanges. H. Christopher Zaenger, CHBC, president of Z Management Group in Elgin, Illinois, and a *Medical Economics* editorial consultant, says patients with those plans may think twice before actually using their insurance.

"When you're paying for all of your ambulatory care out of pocket, you only really go [to the doctor] when you need to," he says.

For 2014, the maximum out-of-pocket limit for all policies purchased through the ACA is $6,350 for individuals and $12,700 for families, according to the Kaiser Family Foundation. In 2015, that cost will increase to $6,600 for individuals and $13,200 for families. In California, patients who purchased bronze-level plans on the state's insurance exchange had $5,000 deductibles and paid $70 copays for office visits, reports Kaiser Health News.

David Cohen, DO, an independent physician in Oakwood, Geor- ➔18

Median hours worked per week–by speciality

	2008	2009	2010	2011	2012	2013	2014
Family/general	46/46*	46	51	50	50	50	51
Internists	56	46	54	53	54	52	52

* family and general physician hours tabulated seperately these years

Mean patient visits per week–by speciality

	2008	2009	2010	2011	2012	2013	2014
Family/general	112/81*	107	102	96	98	99	89
Internists	94	97	101	92	98	93	85

* family and general physician hours tabulated seperately these years

Patients visits–by speciality

MEAN NUMBER OF PATIENTS SEEN IN LAST FULL WORKWEEK

	Less than 25	25 to 49	50 to 74	75 to 99	100 to 124	125 to 149	150 to 174	175 to 199	200 or more
Family/general	8%	13%	20%	23%	19%	8%	4%	2%	3%
Internists	8%	19%	20%	23%	11%	8%	5%	1%	3%

Median hours worked per week–by specialty

	2009	2010	2011	2012	2013	2014
Family/general	46/46*	46	51	50	50	50
Internists	56	46	54	53	54	52

* family and general physician hours tabulated seperately these years

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Advil®†
(ibuprofen)
200 mg/tablet

***ALEVE*†**
(naproxen sodium)
220 mg/tablet

Hour 0
- Tylenol: 1st dose
- Advil: 1st dose
- *ALEVE*: 1st dose

Hour 6
- Tylenol: 2nd dose
- Advil: 2nd dose

Hour 12
- Tylenol: 3rd dose
- Advil: 3rd dose
- *ALEVE*: 2nd dose

Hour 18
- Tylenol: X END OF THE LINE‡
- Advil: 4th dose

Hour 24

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➔16 gia, says his practice is seeing fewer patients, a drop-off he attributes to patient confusion regarding insurance plans, higher deductibles and copays.

The *Medical Economics* study found that physicians in the Western region of the country saw the largest dropoff in patient visits from an average of 89 patients per week in 2013 to 83 in 2014. By contrast, physicians in the South saw average weekly patients fall from 98 to 94.

Practice management consultant Judy Bee says high-deductibles are designed to limit the amount of healthcare services pa-

Productivity by **gender–overall**

	MEDIAN HOURS PER WEEK						MEAN VISITS PER WEEK					
	2009	2010	2011	2012	2013	2014	2009	2010	2011	2012	2013	2014
Men	46	53	52	51	52	52	102	100	98	100	99	93
Women	46	47	47	47	46	48	78	86	84	82	82	79

Productivity by **age–overall**

	MEDIAN HOURS PER WEEK						MEAN VISITS PER WEEK					
	2009	2010	2011	2012	2013	2014	2009	2010	2011	2012	2013	2014
Younger than 30	46	61	57	52	71	46	56	82	82	84	75	59
30 to 34	46	52	49	49	47	51	87	86	88	83	87	85
35 to 39	46	50	51	48	49	50	88	93	90	93	94	86
40 to 44	46	52	50	50	51	51	97	96	95	95	93	92
45 to 49	56	51	52	52	51	52	97	102	97	98	98	94
50 to 54	56	54	53	53	53	54	97	102	100	103	99	96
55 to 59	46	54	53	52	52	51	103	101	98	101	96	93
60 to 64	46	50	49	50	51	52	97	96	94	95	97	90
65 and older	36	43	43	42	43	41	72	73	76	77	79	71

Productivity by **region–overall**

	MEDIAN HOURS PER WEEK						MEAN VISITS PER WEEK					
	2009	2010	2011	2012	2013	2014	2009	2010	2011	2012	2013	2014
Northeast*	46	52	50	50	49	48	92	96	93	91	90	85
South	46	52	51	50	51	51	97	101	99	99	98	94
Midwest	46	51	52	51	51	51	95	95	91	93	92	87
West	46	50	49	49	49	49	88	88	85	89	89	83

*Called East in 2007 to 2009 survey

Productivity by **community–overall**

	MEDIAN HOURS PER WEEK						MEAN VISITS PER WEEK					
	2009	2010	2011	2012	2013	2014	2009	2010	2011	2012	2013	2014
Inner city	46	52	51	50	53	50	72	95	92	93	85	76
Urban	46	52	51	50	52	51	87	88	88	87	89	87
Suburban	46	51	50	49	51	49	97	98	95	98	96	90
Rural	46	52	53	52	54	53	98	104	99	99	96	91

Source: 2013 Exclusive Physician Earnings Survey

tients use, so it's not surprising that patient volume would decline. She believes the real drain on physician productivity is EHRs.

DOCUMENTATION STRUGGLES

A recent study in *Health Affairs* found that eight in 10 office-based physicians have adopted an EHR system. But with that new technology comes the challenge of documenting patient encounters and attesting to meaningful use.

"What we have are EHRs that are collecting in some cases ridiculous data that is required and that takes a long time to put in, especially when you're new at it," Bee says. "There is so much information on the page that it actually slows down the encounter as the physician tries to wander through it."

To compensate for the added documentation, many physicians have extended their appointment times, in some cases to as long as 30 minutes per patient. Physicians are then left with two options.

"One of the options is to schedule fewer patients. The other is to hire a scribe, and that person is responsible for entering everything during the patient encounter," Bee says. "But in primary care there's not a lot of extra money for hiring scribes, especially when you just paid for an EHR.

Corrine Leistikow, MD, the assistant medical director for family medicine at a clinic in Fairbanks, Alaska, says that family physicians in her clinic are seeing fewer patients per day since her clinic started using an EHR.

"The main complaint from my family docs is spending so much more time on the EHR instead of seeing patients, that if they didn't have the EHR, they could see more patients," she says. "There are really good things about EHRs. They are not all bad. But nobody has figured out a way to make it work for doctors."

RETAIL CLINICS

The decrease in patient visits also corresponds to an increase in the number of retail clinics and urgent care centers.Zaenger says these new competitors are eating into some of the marketplace. "The focus is to keep patients out of the emergency room, so practices are now competing with urgent care centers for primary care services or in some cases Walgreens, Walmart, or CVS MinuteClinics," he says.

With increasing pressure to build their patient volume, Zaenger says some urgent cares are having patients return for follow-up appointments, rather than referring them back to their primary care physician.

To stay competitive, some practices are extending hours and opening on weekends, but that requires investing in staff, including hiring more nurse practitioners and physicians assistants to carry the patient load. Zaenger says he expects the patient volume of midlevel providers to continue increasing, as physicians learn to delegate tasks and take on the more complex cases.

While some physicians fear the extra competition, Bee says retail clinics have been around a long time. For well-established practices, it's unlikely that clinics will contribute to a more significant decline in patient volume.

"They serve a purpose," she says. "If you're nothing special, if you have rotating doctors and nurses, long waits, and not patient-friendly hours, you're not giving [your patients] a whole lot of consumer incentives to come back. Teach your patients when it is appropriate to use them and when it is not."

CHANGING PRODUCTIVITY

Bee is skeptical as to whether productivity levels will begin to trend upward in the coming years. As the healthcare industry shifts to more collaborative care models, including the adoption of patient-centered medical homes, she says physicians may intentionally schedule longer appointments and reduce their patient panel size, in order to provide more comprehensive care.

However, Reed Tinsley, CPA, CHBC, president of the National Society of Healthcare Business Consultants, says he has already seen an increase in patient volume.

As long as the fee-for-service model persists, Tinsley says, primary care physicians in private practice can't rely on established patients to bring in more revenue. They will have to see more patients within the day if they want to remain financially viable.

"It's an issue of reimbursement and having to see more patients just to maintain a bottom line," says Tinsley. "Any physician that's just going to show up and sit on their hands and maintain the status quo is guaranteed to take a pay cut. The winners are the proactive practices, and the losers are the reactive practices."

> "The main complaint from my family docs is spending so much time on the EHR instead of seeing patients… There are really good things about EHRs. But nobody has figured out a way to make it work for doctors."
>
> -Corinne Leistikow, MD, Fairbanks, Alaska

Financial progress stalls
Practices grapple with new pressures

Salaries remain flat as physician practices face lower reimbursements, rising costs and challenging market forces

by **CHRIS MAZZOLINI, MS** *Content manager*

HIGHLIGHTS

01 Healthcare reimbursement is driven primarily at the local level based on provider saturation and payer consolidation, so large disparities often exist between individual markets.

02 Physician practice owners are dealing with stagnant incomes that have not budged in the last few years.

Financially, most physician practices are either stuck in neutral or falling behind, according to results from the 2014 *Medical Economics* Physician Practice Survey. More than 84% of the physicians surveyed said their practices are doing the same or worse than a year ago. Nearly 40% say they are doing worse. Only 15% of those respondents on average say that economic conditions have improved for their practices.

On one side, the costs of running a medical practice are rising, from basic utilities to medical supplies, vaccines and equipment. On the technology front, physicians are forced to implement expensive upgrades to attest to meaningful use and become ready for the International Classification of Diseases—10th Revision (ICD-10).

Preparing for ICD-10 alone can cost even a solo practice upwards of $56,000, says Stanley Nachimson, principal for Nachimson Advisors and author of a study on ICD-10 costs for the American Medical Association.

Meanwhile, reimbursement rates for many common procedures are not keeping up with rising costs, says Elizabeth Woodcock, MBA, FACMPE, CPC, an expert in practice management healthcare consultant with Woodcock & Associates. Private payers still use Medicare as the bellwether for reimbursement rates, so as government payers decrease reimbursements, private payers follow along, she says.

"We're seeing lower reimbursements for just about everything we do, even to the point that some of the reimbursements are less than what the insurance companies will pay," says David Cohen, DO, an independent physician in Oakwood, Georgia.

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Financial state of progress

	2010	2011	2012	2013
Better than a year ago	14%	16%	15%	15%
About the same	43%	44%	47%	45%
Worse than a year ago	39%	37%	37%	39%
No answer	4%	3%	1%	1%

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How much do physicians earn?

Field	Average salary	Median salary
Family practice / general	$195,000	$188,000
Internal medicine	$203,000	$188,000
Pediatrics	$203,000	$188,000
Cardiology	$376,000	$338,000
Gastroenterology	$315,000	$250,000
Hospitalists	$250,000	$238,000
Emergency / acute care	$226,000	$213,000
Psychiatry	$207,000	$188,000
OB/GYN	$260,000	$238,000
Dermatology	$410,000	$313,000
Ophthalmology	$306,000	$288,000
Surgery	$359,000	$313,000
Urology	$356,000	$338,000
Plastic surgery	$297,000	$238,000
Neurology / neurosurgery	$240,000	$188,000
Total	**$235,000**	**$213,000**

Earnings by Gender

MEN

Median: 2013 Earnings: **$212,000** Median age: **58**

	Under $120,000	$120,000 – $149,999	$150,000 – $174,999	$175,000 – $199,999	$200,000 – $249,999	$250,000 – $299,999	$300,000 – $349,999	$350,000 – $399,999	$400,000 or more
2009	15%	10%	11%	11%	17%	10%	8%	5%	13%
2010	17%	10%	9%	10%	16%	10%	9%	5%	14%
2011	15%	8%	11%	9%	16%	12%	8%	5%	15%
2012	15%	9%	8%	10%	17%	11%	9%	6%	14%
2013	14%	9%	9%	10%	18%	10%	8%	5%	13%

WOMEN

Median: 2013 Earnings: **$162,000** Median age: **52**

2009	32%	16%	14%	10%	12%	5%	4%	3%	2%
2010	30%	16%	12%	10%	12%	6%	6%	2%	4%
2011	28%	16%	13%	9%	13%	7%	6%	2%	6%
2012	26%	16%	13%	11%	13%	8%	5%	3%	4%
2013	23%	14%	13%	10%	16%	8%	4%	3%	3%

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One of the problems with primary care, as Cohen sees it, is that physicians "don't get paid for thinking." In other words, all of the work a physician does building relationships with patients, including speaking to them on the phone and after hours, isn't reimbursed in the fee-for-service world. "It's unfortunate, but it's getting harder to make a living in primary care," Cohen says.

Healthcare reimbursement is driven primarily at the local level based on provider saturation and payer consolidation, so large disparities often exist between individual markets, Woodcock says. For example, you can travel an hour outside of Atlanta and see reimbursement rates that are 30% higher.

"It's supply and demand, and it speaks to the dominance of the payers and market dynamics" she says. "When you have that sort of monopoly, especially in so many markets, physicians hands are being tied behind their backs like never before."

Many densely-populated areas are seeing intense competition between providers. At the same time, payers are working to narrow networks. Not only are physicians in these markets seeing reimbursement rates fall, but many physicians are being cut out of networks completely, slicing off a large portion of practice income at once.

Physician practice owners are most impacted by these forces, and as a result are dealing with incomes that have not budged in the last few years, according to survey results. Practice owners saw average incomes remain flat in 2013 at $244,000. Meanwhile, average income for employed physicians has grown, from $211,000 in 2011 to $216,000 in 2012, to $224,000 in 2013, a 6% increase.

"There are difficulties to owning a practice, and [the survey] does speak to a shift in the market from a reimbursement perspective into the hands of health systems," Woodcock says. "Health systems have more dominance in markets than small independent physicians. Physicians who are em-

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What Primary Care Physicians Earn: A 5-year Review

FAMILY/GENERAL PHYSICIANS

2013 Median income = $188,000

	Under $120,000	$120,000 – $149,999	$150,000 – $174,999	$175,000 – $199,999	$200,000 – $249,999	$250,000 – $299,999	$300,000 – $349,999	$350,000 – $399,999	$400,000 or more
2009	24%	18%	16%	12%	13%	7%	3%	2%	2%
2010	24%	17%	15%	13%	15%	5%	5%	2%	4%
2011	20%	12%	16%	12%	15%	9%	4%	2%	5%
2012	21%	13%	13%	14%	18%	7%	6%	2%	4%
2013	19%	13%	13%	14%	17%	8%	5%	2%	4%

INTERNAL MEDICINE PHYSICIANS

2013 Median income = $188,000

2009	21%	12%	20%	14%	13%	6%	12%	8%	13%
2010	21%	13%	12%	15%	16%	7%	6%	4%	3%
2011	17%	13%	13%	12%	17%	11%	6%	3%	6%
2012	18%	10%	10%	12%	17%	11%	6%	4%	6%
2013	20%	12%	11%	11%	23%	8%	5%	2%	6%

PEDIATRICIANS

2013 Median income = $188,000

2009	23%	17%	13%	12%	15%	8%	5%	2%	3%
2010	27%	18%	12%	11%	15%	7%	4%	2%	4%
2011	25%	17%	15%	9%	14%	7%	5%	2%	6%
2012	22%	17%	12%	12%	14%	7%	7%	2%	5%
2013	18%	16%	14%	10%	17%	8%	6%	3%	5%

OB/GYNs

2013 Median income = $238,000

2009	19%	6%	8%	9%	21%	13%	10%	6%	12%
2010	19%	8%	5%	7%	16%	13%	13%	6%	13%
2011	16%	6%	7%	8%	17%	13%	10%	6%	14%
2012	15%	7%	7%	7%	13%	15%	11%	7%	15%
2013	17%	5%	5%	6%	18%	14%	13%	7%	12%

Earnings by Community

INNER CITY

2013 Median income = $188,000

	Under $120,000	$120,000 – $149,999	$150,000 – $174,999	$175,000 – $199,999	$200,000 – $249,999	$250,000 – $299,999	$300,000 – $349,999	$350,000 – $399,999	$400,000 or more
2009	25%	14%	15%	9%	14%	8%	4%	2%	6%
2010	28%	14%	12%	10%	11%	9%	6%	4%	5%
2011	27%	14%	10%	10%	12%	9%	4%	5%	9%
2012	21%	15%	9%	10%	13%	11%	9%	2%	7%
2013	21%	14%	10%	11%	17%	6%	5%	2%	9%

URBAN

2013 Median income = $213,000

2009	21%	12%	11%	11%	14%	8%	7%	4%	11%
2010	22%	11%	9%	9%	14%	9%	8%	5%	12%
2011	19%	12%	12%	9%	15%	10%	7%	4%	11%
2012	19%	11%	11%	11%	15%	8%	8%	5%	9%
2013	16%	10%	10%	9%	17%	9%	9%	6%	12%

SUBURBAN

2013 Median income = $213,000

2009	19%	11%	11%	10%	16%	8%	8%	4%	10%
2010	20%	12%	9%	10%	15%	9%	7%	4%	11%
2011	20%	10%	11%	9%	15%	9%	7%	4%	13%
2012	18%	11%	9%	10%	15%	10%	8%	4%	12%
2013	16%	10%	10%	11%	15%	10%	8%	4%	10%

RURAL

2013 Median income = $188,000

2009	20%	12%	12%	11%	20%	8%	8%	3%	9%
2010	18%	13%	12%	12%	18%	9%	7%	3%	7%
2011	16%	11%	11%	10%	18%	12%	7%	3%	10%
2012	13%	9%	12%	12%	18%	12%	8%	5%	9%
2013	17%	11%	11%	10%	17%	12%	6%	4%	8%

Earnings by Region

NORTHEAST

2013 Median income = **$188,000**

	Under $120,000	$120,000 – $149,999	$150,000 – $174,999	$175,000 – $199,999	$200,000 – $249,999	$250,000 – $299,999	$300,000 – $349,999	$350,000 – $399,999	$400,000 or more
2009	21%	11%	12%	11%	15%	6%	7%	5%	10%
2010	23%	13%	10%	10%	13%	8%	8%	5%	10%
2011	19%	13%	13%	10%	13%	9%	6%	3%	12%
2012	20%	14%	9%	10%	14%	8%	8%	4%	11%
2013	18%	11%	11%	11%	17%	8%	6%	5%	9%

MIDWEST

2013 Median income = **$213,000**

2009	16%	11%	12%	11%	17%	9%	9%	3%	9%
2010	18%	12%	12%	9%	17%	11%	6%	3%	11%
2011	17%	10%	10%	8%	18%	12%	8%	5%	11%
2012	17%	10%	10%	10%	18%	12%	8%	4%	10%
2013	17%	10%	10%	10%	20%	11%	7%	4%	11%

SOUTH

2013 Median income = **$188,000**

2009	19%	12%	12%	9%	15%	10%	7%	4%	9%
2010	20%	12%	9%	11%	16%	7%	8%	3%	10%
2011	18%	11%	12%	9%	14%	10%	7%	4%	12%
2012	17%	11%	10%	11%	14%	11%	8%	5%	11%
2013	19%	11%	11%	11%	17%	9%	8%	3%	11%

WEST

2013 Median income = **$213,000**

2009	23%	13%	10%	12%	15%	7%	7%	3%	8%
2010	23%	12%	9%	10%	16%	9%	7%	5%	10%
2011	20%	10%	11%	11%	14%	11%	5%	4%	12%
2012	18%	11%	11%	11%	16%	9%	8%	3%	11%
2013	16%	9%	9%	10%	18%	10%	7%	5%	13%

➔22

ployed are sheltered from that market force."

Physicians are reacting to these financial pressures in a variety of ways. Many are earning secondary incomes away from their practices. Nearly one-third (32%) of physicians said that they earn income away from their practice or primary employer, mainly through consulting (20%), speaking (12%) non-emergency department hospital work (12%) and non-medical work (12%). The average annual earnings from secondary incomes was $48,800.

The other option is to see additional patients. Physicians who see more patients earn more income, yet another indication that the fee-for-service model is far from dead. Physicians who saw 50 or fewer patients per week earned $169,000 annually on average, while those who saw between 50 and 100 patients earned $220,000 on average. Physicians who saw between 100 and 150 patients earned $274,000.

But seeing more patients is not always so simple, because physicians' time increasingly is taken up with administrative burdens.

OTHER FINDINGS

COMPENSATION Average compensation for internal medicine physicians posted a 2% decline over last year. Pay for family physicians held steady at $195,000. The most significant income gains were noted for pediatricians, psychiatrists, ophthalmologists and dermatologists. Compensation declined for physicians working in emergency and acute care, gynecology and cardiology.

GENDER Male physicians made significantly more on average than female physicians, regardless of whether they were employed in a group practice or maintained an ownership position within a practice. For every dollar earned by a male physician, a female physician earned 74 cents, with males earning $257,000 annually on average, compared to $190,000 for a female doctor. For employed physicians, the annual mean income for females was $180,000, while their male colleagues earned $248,000. Among physicians with a practice ownership position, female physicians earned $200,000 compared to $264,000 for male respondents.

GEOGRAPHY The survey denotes some regional differences in income, but not as large as might be expected based on factors like cost of living, cost of care, reimbursement rates, etc.

HOURS WORKED While seeing more patients can boost income, long hours don't produce the same result. According to the data, median incomes for physicians working 51-60 hours a week hovered around $213,000 ($83.50 per hour, based on 51 hours a week for 50 weeks). For physicians working 61-70 hours a week, the total median rose 11% ($25,000 a year) to $238,000 ($78 per hour, based on 61 hours per week over 50 weeks). Physicians working 71-80 hours a week increased their incomes to $263,000, or $74 per hour (71 hours a week for 50 weeks). Interestingly, however, incomes plateaued for those physicians working more than 80 hours a week and declined for those working 90 or more a week.

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

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS and PRECAUTIONS

- **Hypotension:** INVOKANA® causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA®, particularly in patients with impaired renal function (eGFR <60 mL/min/1.73 m^2), elderly patients, patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system, or patients with low systolic blood pressure. Before initiating in patients with ≥1 of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating

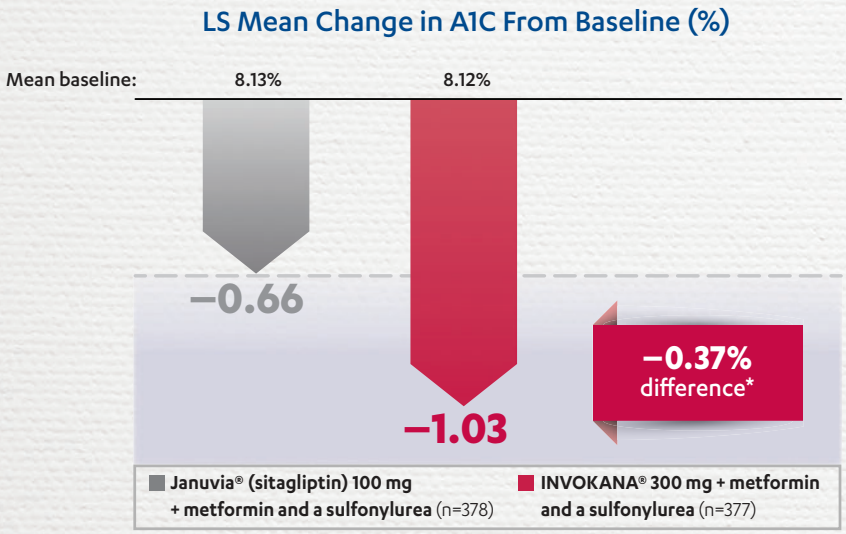
Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.

EXPERIENCE THE DIFFERENCE

INVOKANA® 300 mg vs Januvia® 100 mg

at 52 weeks, each in combination with metformin + a sulfonylurea[2]

Greater reductions in A1C[2]



*95% CI: −0.50, −0.25; *P*<0.05.
LS=least squares.

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

IMPORTANT SAFETY INFORMATION (cont'd)

- **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 initiation. More frequent renal function monitoring is recommended in patients with an eGFR <60 mL/min/1.73 m²
- **Hyperkalemia:** INVOKANA® can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions

INVOKANA® 300 mg demonstrated greater reductions in A1C vs Januvia® 100 mg...
...as well as greater reductions in body weight† and systolic blood pressure[2†]

Greater reductions in body weight[2*†]

Difference from Januvia® 100 mg:
–2.8%; *P*<0.001

Greater reductions in systolic blood pressure[3*†]

Difference from Januvia® 100 mg:
–5.9 mm Hg; *P*<0.001

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

*LS mean.
†Prespecified secondary endpoint.

Incidence of hypoglycemia[2]

INVOKANA® 300 mg: **43.2%**; Januvia® 100 mg: **40.7%**
The incidence of hypoglycemia increases when used in combination with insulin or an insulin secretagogue.

Adverse reactions (ARs)[3]

Incidences of ARs were similar between groups except for:

Male/female genital mycotic infection,
INVOKANA® 300 mg: **9.2%/15.3%**; Januvia® 100 mg: **0.5%/4.3%**

Increased urine frequency/volume,
INVOKANA® 300 mg: **1.6%/0.8%**; Januvia® 100 mg: **1.3%/0%**

Learn more and register for updates at INVOKANAhcp.com

A randomized, double-blind, active-controlled, 52-week study of patients with type 2 diabetes inadequately controlled on maximum doses of metformin (≥2000 mg/day, or ≥1500 mg/day if higher dose not tolerated) and near-maximally or maximally effective doses of a sulfonylurea.[3]

- **Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues:** INVOKANA® can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA®
- **Genital Mycotic Infections:** INVOKANA® increases risk of genital mycotic infections. Patients with history of these infections and uncircumcised males were more likely to develop these infections. Monitor and treat appropriately
- **Hypersensitivity Reactions:** Hypersensitivity reactions (eg, generalized urticaria), some serious, were reported with INVOKANA®; these reactions generally occurred within hours to days after initiation. If reactions occur, discontinue INVOKANA®, treat per standard of care, and monitor until signs and symptoms resolve

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

Invokana®
canagliflozin tablets

IMPORTANT SAFETY INFORMATION (cont'd)

- **Increases in Low-Density Lipoprotein (LDL-C):** Dose-related increases in LDL-C can occur with INVOKANA® (canagliflozin). Monitor LDL-C and treat per standard of care after initiating
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA® or any other antidiabetic drug

DRUG INTERACTIONS

- **UGT Enzyme Inducers:** Rifampin: Coadministration of INVOKANA® with rifampin decreased INVOKANA® area under the curve (AUC) by 51% and therefore may decrease efficacy. If an inducer of UGT enzymes must be coadministered with INVOKANA®, consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA® 100 mg once daily, have an eGFR ≥60 mL/min/1.73 m^2, and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR <60 mL/min/1.73 m^2 who require additional glycemic control
- **Digoxin:** There was an increase in the AUC and mean peak drug concentration of digoxin (20% and 36%, respectively) when coadministered with INVOKANA® 300 mg. Monitor appropriately
- **Positive Urine Glucose Test:** Monitoring glycemic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose test results. Use alternative methods to monitor glycemic control
- **Interference With 1,5-Anhydroglucitol (1,5-AG) Assay:** Monitoring glycemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycemic control

USE IN SPECIFIC POPULATIONS

- **Pregnancy Category C:** There are no adequate and well-controlled studies of INVOKANA® in pregnant women. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters
- **Nursing Mothers:** It is not known if INVOKANA® is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants, discontinue INVOKANA®
- **Pediatric Use:** Safety and effectiveness in patients <18 years of age have not been established
- **Geriatric Use:** 2034 patients ≥65 years and 345 patients ≥75 years were exposed to INVOKANA® in 9 clinical studies. Patients ≥65 years had a higher incidence of adverse reactions related to reduced intravascular volume (eg, hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300-mg dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were ≥75 years. Smaller reductions in HbA1c relative to placebo were seen in patients ≥65 years (−0.61% with INVOKANA® 100 mg and −0.74% with INVOKANA® 300 mg) compared to younger patients (−0.72% with INVOKANA® 100 mg and −0.87% with INVOKANA® 300 mg)
- **Renal Impairment:** Efficacy and safety were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/1.73 m^2). These patients had less overall glycemic efficacy and a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR ≥60 mL/min/1.73 m^2); patients treated with 300 mg were more likely to experience increases in potassium. INVOKANA® is not recommended in patients with severe renal impairment (eGFR <30 mL/min/1.73 m^2), with end-stage renal disease, or receiving dialysis
- **Hepatic Impairment:** INVOKANA® has not been studied in patients with severe hepatic impairment and is not recommended in this population

OVERDOSAGE

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

ADVERSE REACTIONS

- The most common adverse reactions associated with INVOKANA® (5% or greater incidence) were female genital mycotic infections, urinary tract infections, and increased urination

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

References: 1. Data on file. Janssen Pharmaceuticals, Inc., Titusville, NJ. **2.** INVOKANA® [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; 2014. **3.** 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 [published correction appears in *Diabetes Care*. 2013;36(12):4172]. *Diabetes Care*. 2013;36(9):2508-2515.

Invokana®
canagliflozin tablets

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PHARMACEUTICAL COMPANIES OF Johnson & Johnson

September 2014 019891-140813

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 2: Proportion of Patients With at Least One Volume Depletion-Related Adverse Reaction (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 1 of 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.

INVOKANA™ (canagliflozin) tablets

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
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)

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

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]*.

INVOKANA™ (canagliflozin) tablets

Digoxin: There was an increase in the 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.

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

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

USE IN SPECIFIC POPULATIONS

Pregnancy: 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]*.

Medicaid expansion saves hospitals money

HOSPITALS will save $5.7 billion this year in uncompensated care costs due to the implementation of the Affordable Care Act (ACA), according to a new report by the U.S. Department of Health and Human Services (HHS).

Hospitals in states that have expanded Medicaid under the ACA are expected to save up to $4.2 billion from providing less uncompensated care, or 74% of the total savings, while hospitals in states that have not expanded Medicaid are projected to save up to $1.5 billion.

HHS says the savings are the result of large number of Americans who gained health insurance through the ACA. As of July, nearly 8 million Americans had enrolled in Medicaid and the Children's Health Insurance Program as a result of the ACA, according to HHS.

"Hospitals have long been on the front lines of caring for the uninsured, who often cannot pay the full costs of their care," said HHS Secretary M. Sylvia Burwell in a prepared statement.

"Today's news is good for families, businesses, and taxpayers alike. It's yet another example of how the Affordable Care Act is working in terms of affordability, access, and quality," Burwell added.

Many physicians remain unprepared for ICD-10

Why this year's delay and burden on practices is making it difficult for physicians to get ready

by **LISA SMITH** *Content specialist*

HIGHLIGHTS

01 Physicians, health plans and EHR vendors should not assume another delay in the ICD-10 conversion mandate.

02 Due to the increased number of codes, changes in the number of characters per code,and increased code specificity, the transition will require significant planning, training, software and system upgrades, and other investments.

The clinic where Corrine Leistikow, MD, works in Fairbanks, Alaska, was on its way to preparing for the transition to the International Classification of Diseases-10th Revision (ICD-10). But then ICD-10 was delayed until October 2015, and that work ground to a halt in the face of the other burdens of running a medical practice, says Leistikow, the clinic's assistant medical director for family medicine.

Now she plans to hold monthly in-service training sessions with the physicians to study commonly-used codes. "As physicians, we haven't been thinking about it, except to know that it is coming," she says. "We know it is coming and needs to happen but we also know it will be painful."

Leistikow and her colleagues have some company. With 11 months to go until the transition, half of the physicians who answered *Medical Economics*' exclusive 2014 physician survey said they are not ready for ICD-10. The reasons are many, but mostly come down to cost, productivity and technology hurdles, and lack of certainty in the transition.

While many physicians are not ready, the number who are prepared is up significantly from a large-scale survey in 2013 by the Medical Group Management Association in which fewer than 5% of practices reported having had made significant progress towards ICD-10 readiness.

Acknowledging the enormous outlay of resources required to transition to ICD-10, the Centers for Medicare and Medicaid Services (CMS), through congressional action, has twice pushed back the compliance date, first from October 2013 to 2014, and then to 2015.

But physicians, health plans and electronic health record (EHR) vendors should not assume another delay. Stanley Nachimson, principal of Nachimson Advisors and an expert on ICD-10, estimates there is a 75% chance that the ICD-10 transition will actually take place in October 2015. Most EHR vendors have already upgraded their software to reflect the new codes.

"The health plans and vendors are moving forward and getting out ahead of the providers," he says. "It's time for the providers to catch up. Doctors need to be somewhat assertive and start taking steps to move forward on ICD-10. I'm not sure I'd want to take a chance of my revenue getting interrupted."

The move to ICD-10 will improve national healthcare initiatives such as meaningful use, value-based purchasing, payment reform, and quality reporting. "With ICD-9, there were serious gaps in the ability to extract important patient health information needed to support research and public health reporting, and move to a payment system based on quality and outcomes," says Nancy Enos, FACMPE, CPC-I, an

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ICD-10 READINESS

By Specialty

	Yes	No	No answer
Family/General practice	49%	50%	1%
Internal medicine	43%	55%	2%
Pediatrics	55%	42%	3%
OB/GYNs	53%	46%	1%
Cardiology	54%	43%	3%

By Years in Practice

	Yes	No	No answer
2 years or less	50%	48%	2%
3-5 years	48%	50%	2%
6-10 years	56%	42%	2%
11-20 years	50%	49%	1%
21-30 years	52%	47%	1%
More than 30 years	48%	49%	3%

By Age

	Yes	No	No answer
Younger than 30	64%	36%	0%
30-34	51%	46%	3%
35-39	49%	48%	3%
40-44	56%	44%	1%
45-49	48%	49%	2%
50-54	53%	45%	2%
55-59	53%	46%	1%
60-64	47%	51%	2%
65 and older	48%	50%	3%

By Ownership

	Yes	No	No answer
Practice owner	47%	51%	2%
Not a practice owner	54%	44%	2%

By Geographic Region

	Yes	No	No answer
Northeast	49%	48%	2%
South	48%	51%	1%
Midwest	53%	46%	2%
West	54%	44%	2%

By Type of Community

	Yes	No	No answer
Inner city	47%	51%	3%
Urban	51%	47%	2%
Suburban	52%	47%	2%
Rural	48%	52%	1%

By Practice Size

	Yes	No	No answer
Solo	43%	56%	2%
Group of 2	44%	54%	2%
Group of 3-10	49%	50%	1%
Group of 11-25	55%	42%	3%
Group of 26-50	54%	44%	3%
Group more than 50	68%	30%	2%

By Combined Income

	Yes	No	No answer
Less than $60,000	37%	60%	3%
$60,000 - $99,000	39%	60%	1%
$100,000 – $149,000	45%	52%	3%
$150,000 - $199,000	49%	50%	1%
$200,000 - $299,000	55%	44%	2%
$300,000 - $399,000	59%	40%	2%
$400,000 - $499,000	55%	45%	0%
More than $500,000	54%	45%	1%

> "The reality of the [ICD-10] codes is so much of what we document is not for patient care...whether I code asthma in a general code or more specific doesn't impact the care the patient will receive that day."
>
> REID BLACKWELDER, MD, FAAFP, PRESIDENT, AMERICAN ACADEMY OF FAMILY PHYSICIANS

➔25 American Association of Professional Coders-certified ICD-10 instructor.

Enos says the physicians she's been training are finding the new codes much easier to work with. "They're able to find the code they're looking for much more easily than with ICD-9 because they're much more specific," she says.

That specificity also can help an insurer understand a claim more easily, says Enos. "If a patient breaks their right wrist and six weeks later breaks their left wrist, there's no code right now that differentiates between them," she says, adding that ICD-10 codes will also help with complications.

And the fact is that ICD-9 is out of date, with much of the world already using ICD-10. For example, Nachimson says, there is no code for Ebola in ICD-9.

But the burden of the transition is great, and most of it falls on physicians. Due to the increased number of codes, changes in the number of characters per code, and increased code specificity, the transition will require significant planning, training, software and system upgrades and/or replacements, among other investments.

"A lot of the costs and the effort falls on the providers, and they don't necessarily get the direct benefit of the coding change," Nachimson says. "Cost and benefits are not quite aligned."

While CMS has characterized the new codes as a needed benefit, they are an administrative burden for physicians, and mostly benefit insurance companies, says Reid B. Blackwelder, MD, FAAFP, a family physician in Kingsport, Tennessee, and president of the American Academy of Family Physicians.

"I'm not sure there's a clinical benefit to using them," he says. "The reality of the codes is so much of what we document is not for patient care. It's there to support better billing and research documentation. Whether I code asthma in a general code or more specific code doesn't impact the care that the patient will receive that day.

"The codes in and of themselves do not improve (patient) outcomes," he adds.

A sticking point for Blackwelder is that family physicians will only use a small portion of the codes but will still have to spend the money to upgrade their EHR software for ICD-10, and get documentation training for themselves and coding training for staff.

That's an expensive proposition. In a study updated for the American Medical Association in early 2014, Nachimson found that the costs of preparing for ICD-10 could range from $56,000 for a small practice to millions of dollars for large practices and health systems.

Each step in the preparation process involves a significant outlay of cash, says Blackwelder, and without proper testing, there's no guarantee that by the deadline the process will be functional. Nachimson says that some health plans have begun testing, but many have delayed their efforts.

Practice size is a major indication of ICD-10 readiness, according to the survey. Fewer than 44% of solo and two-physician practices said they are ready for the transition. Meanwhile, 49% of groups of three to 10 physicians, and 55% of groups of 11 to 25 doctors said they are ready. Groups with more than 50 physicians are the most prepared, the results show, with 68% ready.

Blackwelder's practice is part of a larger system that's linked to an academic center. Typically, larger institutions have been better prepared, because they have the resources, he notes. His ➔28

Steps to Preparing for ICD-10

Nachimson recommends four main steps that physicians should take to prepare for ICD-10. They are:

Document

Start working now to improve documentation by including the greater detail and specificity required by ICD-10. Better documentation will make the coding transition smoother, and can lead to improved patient care, better care coordination between providers and help alleviate problems during payer audits. Examine your practice's most important diagnostic groups, including the conditions you deal with the most by volume and revenue. Then study the ICD-10 codes for these conditions, begin to understand what the documentation needs to look like and compare it with your current documentation for those conditions.

Check your systems

Work with your vendors to make sure you have the appropriate systems and software versions. If you need to upgrade, determine the costs and whether training is offered.

Prioritize health plans

Contact the health plans you work with to get a sense of their ICD-10 implementation plans and when they will offer testing. Prioritize health plans by the most important to your practice's financial health.

Test, test again

Arrange for testing with the most important health plans.

➔27 practice is already conducting trial runs using ICD-10 codes.

Enos says she's worked with many larger practices that have already turned on ICD-10. "They're actually using the codes and turning them on and having the clearinghouses convert them back to ICD-9. It's good practice," she says.

But Blackwelder says it's the small practices the AAFP represents that really need the testing.

"It's no benefit to our members if (the coding system) works reasonably well for hospitals but not for them," says Blackwelder. "If there are problems with the way they're documenting, then their payments get disputed."

Smaller practices often can't handle a disruption to their revenue stream, says Blackwelder, and it's for that reason that the 115,000-member AAFP pushed for both compliance date delays. The association wants CMS to conduct comprehensive, end-to-end process testing, from documentation to submission to payment, to ensure that the system is operational.

But so far, he hasn't seen any evidence of testing, which he finds troublesome. "The whole purpose of the delay is to make sure the system works by the compliance date," says Blackwelder. "If you don't do any work until the deadline, (the delay) is meaningless."

Enos agrees with a recent Workgroup for Electronic Data Exchange (WEDI) survey that found the April delay has slowed progress. She says the delay is "rewarding the procrastinators."

"I felt very badly for the practices that had already invested time and were ready to go, and I don't know that we're really any further down the road," Enos says.

Nachimson says that while the delay was unfortunate, it probably avoided catastrophe. "I firmly believe the industry would have been in chaos on October 1, 2014, if they had gone ahead," he says.

In the meantime, Enos says, practices should already be in the training phase. Training, she notes, is available from a wide variety of sources, and much of it is free. Yet finding the time for training might be the biggest obstacle, especially for small practices that have fewer staff members with more responsibilities. But Enos says there are many no-cost training webinars offered by CMS, EHR and practice management vendors, and the clearinghouses.

One way for small practices to test documentation is to incorporate ICD-10 codes into charting audits, says Enos. Doing so exposes problems and pitfalls that could lead to claim rejections.

While the preparation requires a significant commitment of time and resources, Enos urges physicians to stay the course. "The efficiencies gained through ICD-10 will be worth the effort," she says. ◘

+ MORE ONLINE

ICD-10: Nine steps to ensure your practice is ready for the transition
http://bit.ly/ZLr8af

Study: Medical practices lag in ICD-10 implementation
http://bit.ly/1xVSHsK

Physicians wait for ACA's malpractice impact

Malpractice insurance premiums remain mostly unchanged from a year ago

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

HIGHLIGHTS

01 Survey results reveal significant fluctuations in premium amounts depending on a doctor's age, location, workload and practice size.

02 Recent consolidations among agents who sell malpractice policies are helping to hold down premium increases.

On the surface, medical malpractice premiums appeared little changed in 2013 for primary care physicians (PCPs). But a closer look at results of *Medical Economics'* 2014 survey reveals significant fluctuations in payment amounts depending on a doctor's age, location, workload and practice size.

The median (midpoint) level of annual premiums paid by family/general practitioners in 2013 was $11,900, unchanged from the prior two years. Internal medicine practitioners reported an overall median of $12,200, a 4.6% decrease from the $12,800 reported for 2012.

Overall, 15% of family/general practitioners and 16% of internists said their malpractice premiums had increased in 2013, while 45% of each group said their premiums remained the same. Eight percent of family/general practitioners and 9% of internists said premiums had come down, and 32% and 30%, respectively, either did not know or declined to answer.

THE IMPACT OF LONG HOURS

Among all categories covered in the survey, the biggest spike in medical malpractice premiums—14.8%—was reported by doctors working more than 90 hours a week, probably reflecting carriers' fear of overwork leading to physician error.

Similarly, PCPs seeing 200 or more patients per week had premium increases of 13%, and those seeing 175 to 199 patients had increases of 9.3%.

PCPs in larger practices also saw substantial increases in their premiums. Those working in practices with 26 to 50 physicians reported a jump of 19.3%, while the median for those in practices with 50 or more physicians went up by 11.9%. The connection between size and premiums is not surprising, especially if the practice has experienced rapid growth, says Jack Meyer, senior vice president for business development and marketing for The Doctors Group, a California-based malpractice insurance carrier.

"Say a five-doctor group grows to a 50-doctor group. We have found in situations like that, where a group grows larger in a short period of time, it can lead to fluctuations in claims," says Meyer. "There's exposure every time you treat a patient."

INSURANCE CONSOLIDATION AND PREMIUM IMPACTS

On the other hand, Meyer adds, recent consolidations among agents who sell malpractice policies are helping to hold down premium increases.

"We're seeing a lot of national brokers buying regional agents," he says. "So now agents, instead of serving three or four markets will have maybe 10 markets, and they're bringing more carriers to more places."

Although it's still too early to gauge the impact of the Affordable Care Act on the malpractice insurance market, Meyer expects the influx of new patients the legislation creates to have "a negative impact" on claims frequency. "It seems logical that if you're treating more patients, chances are it will lead to greater frequency of claims," he says.

OTHER FINDINGS

After seeing their premiums spike a few years ago, younger doctors and those in their first years of practice—usually, but not always, the same group—reported significant decreases in their 2013 premiums. Physicians under age 30 saw premiums drop by 20%, and those in practice for two years or fewer had a reduction of 16.6%. Once they reached the 30 to 34 age group, however, median premium amounts rose by 13.6%.

In terms of geographic region, practices in Western states were alone in seeing premiums rise (up 7.8%). This may reflect a rebound following a significant drop between 2011 and 2012, says Meyers. Another factor, he adds, may be the threat of California voters approving Proposition 46, a ballot measure that would increase the state's cap on non-economic damages that can be assessed in medical negligence lawsuits to over $1 million from the current cap of $250,000. Meanwhile, premiums in the Northeast and Midwest were down by single digits, while those in the South were unchanged from 2012.

A preview of what could happen in California if voters approve Prop 46 may be on display in Missouri. Two years ago that state's Supreme Court overturned a law capping jury awards for pain and suffering at $350,000. Alan Weaver, DO, a solo family practitioner in the rural community of Sturgeon, says his premiums have gone from $1,350 to $1,600 per quarter as a result. Even so, Weaver considers himself fortunate.

Weaver obtains his malpractice coverage through the nonprofit Missouri Doctors Mutual Insurance Company. "If I tried to get insurance through one of the bigger commercial groups the rates would be three to four times that. I know family docs paying $25,000 to $30,000 a year, without doing obstetrics," he says.

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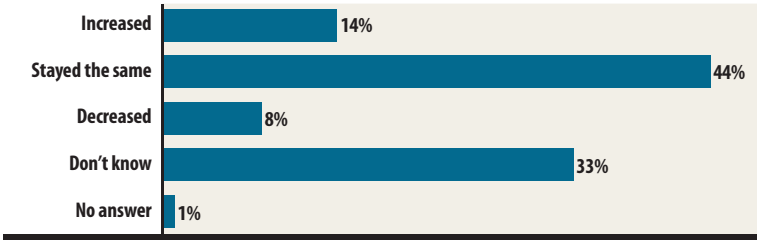
In practice for 27 years,

Change in malpractice premiums for 2013, compared with 2012



Median annual premiums for primary care physicians

	2008	2009	2010	2011	2012	2013
FP/GP	$12,500	$12,600	$12,100	$11,900	$11,900	$11,900
Internal medicine	$12,500	$14,500	$13,100	$12,900	$12,800	$12,200

Median annual premiums by geographic region

	2008	2009	2010	2011	2012	2013
Northeast	$17,500	$19,900	$20,100	$18,500	$18,100	$16,800
South	$12,500	$14,600	$13,600	$12,800	$12,600	$12,600
Midwest	$12,500	$16,400	$14,500	$14,700	$14,200	$13,600
West	$12,500	$14,000	$13,600	$14,300	$12,800	$13,800

Median annual premiums by type of community

	2008	2009	2010	2011	2012	2013
Inner city	$12,500	$15,000	$18,200	$14,700	$16,300	$16,300
Urban	$17,500	$15,300	$14,500	$14,500	$13,800	$13,900
Suburban	$17,500	$16,500	$15,400	$14,500	$13,900	$13,500
Rural	$12,500	$14,800	$13,000	$12,900	$12,000	$13,300

Median annual premiums by hours worked

	2008	2009	2010	2011	2012	2013
30 or fewer	$7,500	$10,000	$8,600	$8,400	$9,200	$9,200
31 to 40	$12,500	$13,400	$12,200	$12,300	$12,100	$11,500
41 to 50	$12,500	$14,100	$13,900	$13,100	$12,400	$13,000
51 to 60	$17,500	$17,300	$17,100	$15,300	$14,900	$14,700
61 to 70	$17,500	$22,800	$17,800	$17,700	$16,300	$17,000
71 to 80	$25,000	$24,000	$26,400	$23,200	$18,800	$18,700
81 to 90	$35,000	$20,000	$21,400	$19,100	$19,300	$18,400
More than 90	$17,500	$27,300	$22,000	$20,000	$29,000	$33,300

Median annual premiums by **age**

	2008	2009	2010	2011	2012	2013
Under 30	$12,500	$10,000	$7,500	$1,500	N/A	N/A
30 to 34	$12,500	$12,800	$11,200	$13,300	$12,500	$10,000
35 to 39	$12,500	$14,400	$14,400	$13,400	$13,200	$15,000
40 to 44	$17,500	$17,400	$15,500	$14,000	$14,500	$14,900
45 to 49	$17,500	$18,200	$16,700	$15,500	$14,400	$14,000
50 to 54	$17,500	$16,500	$15,700	$14,400	$14,400	$14,600
55 to 59	$12,500	$15,700	$15,200	$14,000	$14,000	$14,400
60 to 64	$12,500	$15,500	$14,100	$14,900	$13,900	$13,700
65 and over	$12,500	$13,300	$12,200	$12,900	$12,600	$11,900

Median annual premiums by **years in practice**

	2008	2009	2010	2011	2012	2013
2 or fewer	$10,000	$13,600	$10,000	$14,200	$15,000	$12,500
3 to 5	$12,500	$14,100	$14,300	$13,900	$15,600	$15,000
6 to 10	$12,500	$17,000	$15,900	$13,700	$12,900	$14,100
11 to 20	$17,500	$17,800	$16,500	$14,500	$14,500	$14,500
21 to 30	$17,500	$15,900	$14,900	$14,700	$14,200	$14,300
more than 30	$12,500	$13,600	$12,900	$13,100	$12,900	$12,400

Median annual premiums by **practice size**

	2008	2009	2010	2011	2012	2013
Solo	$12,500	$14,500	$13,600	$13,400	$12,900	$12,600
Expense sharing	$17,500	$15,000	$14,700	$14,900	$13,800	$14,300
2 physicians	$17,500	$17,800	$15,900	$14,600	$13,900	$14,900
3 to 10 physicians	$17,500	$17,400	$17,200	$15,600	$16,000	$15,000
11 to 25 physicians	$17,500	$16,900	$18,000	$13,500	$14,700	$12,900
26 to 50 physicians	$17,500	$15,900	$16,900	$13,000	$15,000	$17,900
More than 50 physicians	$17,500	$14,100	$13,800	$14,100	$14,300	$15,900

Median annual premiums by **patient volumes**

	2008	2009	2010	2011	2012	2013
Fewer than 25	$7,500	$10,400	$9,000	$10,000	$8,200	$9,800
25 to 49	$12,500	$14,100	$12,500	$12,800	$12,900	$13,200
50 to 74	$12,500	$16,700	$14,900	$12,700	$13,600	$13,900
75 to 99	$17,500	$16,200	$15,100	$ 9,200	$14,300	$13,000
100 to 124	$17,500	$16,800	$15,300	$13,000	$13,800	$14,200
125 to 149	$17,500	$14,700	$15,600	$ 9,800	$15,200	$16,500
150 to 174	$12,500	$18,600	$16,700	$10,000	$14,800	$14,300
175 to 199	$15,000	$17,500	$17,500	$16,200	$15,000	$16,400
200 or more	$17,500	$17,400	$16,400	$10,500	$15,400	$17,700

> “If you’re treating more patients, chances are it will lead to a greater frequency of claims.”
>
> —JACK MEYER, SENIOR VICE PRESIDENT, THE DOCTORS GROUP

➔31 Weaver says he stopped providing obstetric and gynecology services other than counseling and assisting in a local hospital’s emergency department (ED) about five years ago in order to hold down his malpractice premiums.

PHYSICIAN STRATEGIES

Concern over rising malpractice premiums also caused William Thrift, MD, to eliminate some services to patients.

A 27-year family practitioner in Prescott, Arizona, Thrift pays about $11,000 for malpractice coverage from Mutual Insurance Company of Arizona. He has stopped working in a hospital ED and treating fractures in his office. The ED work would require a $10,000 annual policy, while treating fractures would hike his premiums by an additional $15,000. “Malpractice is limiting what I can do,” he says.

Thrift also tries to hold down his premiums by maintaining his board certification in family medicine and taking classes in how to document for telehealth. “I try to be diligent about documenting stuff and getting it in the record,” he says. “It’s a big risk when you don’t see the patient and you have to account for what you’re doing and why you’re doing it.”

After providing obstetric services for about 10 years, Thrift stopped after being sued. Although the case was eventually dismissed, he recalls it as “four and a half years of anxiety, even if you’re fairly sure you’re right.

“It’s really hard, not just on the doctor but on the family,” he adds. “A lot of our self-worth is tied up in what we do. So when we hear ‘you’re a bad doctor’ it translates to ‘you’re a bad person.’ And that’s very stressful.” ◘

Financial Strategies

YOUR REAL RETIREMENT NUMBER: HOW MUCH MONEY IS ENOUGH?

by **JOEL GREENWALD, MD, CFP** *Contributing author*

One of the most frequently asked questions by new physician clients is "How much money do I need to retire?" The idea that there is a specific number of financial assets that a physician must accumulate is a powerful and attractive one. This idea of a "retirement number" is reinforced in the media by advertising and by retirement planning books, but it's too simplistic.

WHEN ASKED this question in conversations with physicians, I respond by asking if the person is familiar with the 4% rule—a rough, back-of-the-envelope way to see if someone is close to having enough money to retire.

First popularized in the 1990s, this rule assumes that one can take an initial distribution of 4% of their retirement portfolio, annually increase this withdrawal by an amount based on the prior year's inflation rate, and can continue this process for 30 years of retirement while being unlikely to run out of money. For example, a 60 year old physician with $3 million saved for retirement can withdraw $120,000 from the portfolio in the first year of retirement, index that withdrawal to inflation so they continue to have the same purchasing power, and will be unlikely to run out of money before age 90. Like any rule of thumb, it's convenient, but not sufficiently accurate, especially when one intends to use this rule to make a decision on whether to continue to work or not.

A key point is to consult a financial planner. Why? There are simply too many factors to weigh, and the consequences of making a wrong decision are significant enough that using a financial advisor makes sense. We work with many physician clients who wonder if they have enough saved. The process starts with questions and helping clients make decisions about life in retirement, then uses state-of-the-art software to model different retirement scenarios. What inputs from your life matter?

- **How much do you want to spend annually to live the life you've dreamed of?**
- **How long will you be retired?**
- **What should we assume for a portfolio rate of return and for inflation? For physicians with moderate risk tolerance, we use a return assumption on a diversified portfolio of 5.75% with an inflation assumption of 2.5%. Return assumptions should be modified periodically.**
- **How much of the client's portfolio is pre-tax money in 401(k) plans and IRAs, which will be taxed when withdrawn?**
- **Should we assume the physician will get full Social Security due to them under current projections or will there be changes that result in their payout being reduced or taxed at a higher rate over the next 30 years?**

A plan at age 65 should still be monitored closely every year or two as things change. The physician may decide to buy a second home and withdraw a large amount from the retirement portfolio, or they may choose to start gifting to children and grandchildren. What effect will those decisions have on their retirement plan?

The key is that with some planning and sound advice, you can find out where you stand and how to reach your retirement goals. ◻

Joel Greenwald, MD, CFP, *is a financial adviser and founder of Greenwald Wealth Management in St. Louis Park, Minnesota. Send your financial management questions to* ***medec@advanstar.com****.*

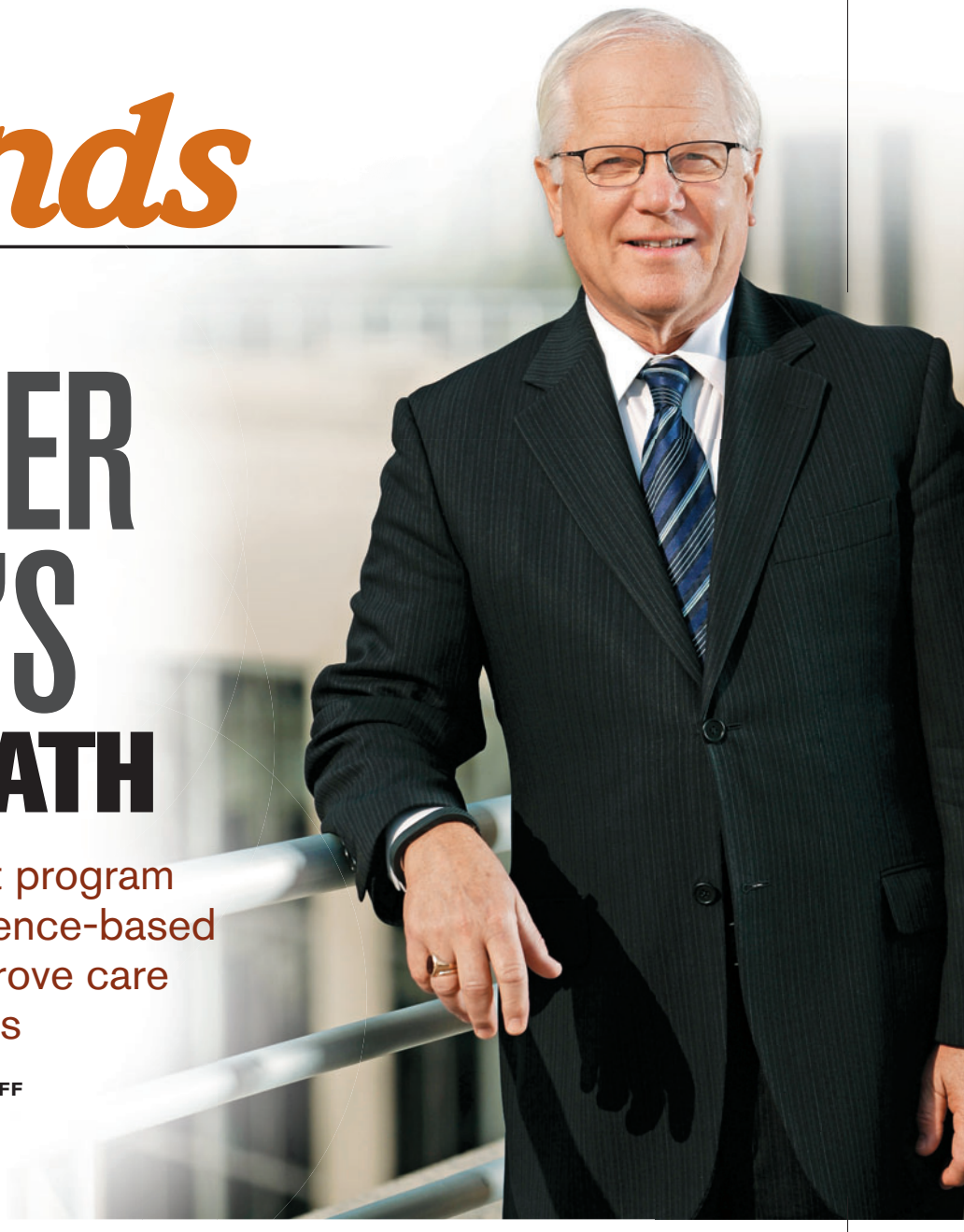
IN DEPTH

Trends

CANCER CARE'S NEW PATH

A new Wellpoint program focuses on evidence-based medicine to improve care and reduce costs

by **MEDICAL ECONOMICS STAFF**



Evidence-based medicine should guide care. It's a simple premise that will have profound effects on the delivery and payment of healthcare in the next few years, says Wellpoint's president and CEO Joseph R. Swedish in an exclusive interview. ➔34

HIGHLIGHTS

01 Wellpoint's strategy is to incentivize evidence-based medicine as a way to improve continuity of care and reduce costs.

02 A participating oncologist would receive a $350 one-time fee at the start of the treatment planning and a $350 per month fee while the patient is active in therapy.

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➔36 In fact, Wellpoint's new Cancer Care Quality Program, developed with AIM Specialty Health, offers physicians a glimpse of how payers may align incentives to reward evidence-based treatment decisions in the future.

The program, launched in six states so far with the intent of expanding to all 50 states by 2016, offers oncologists a $350 one-time fee at the start of treatment planning for patients. The oncology practice will receive $350 a month per patient while the patient is in active therapy and on a WellPoint-endorsed clinical pathway. If a clinical oncologist chooses not to pursue the pathway, he or she simply won't receive the enhanced reimbursement, but would be paid according to the terms of the member's health plan. Initially, the program will be used for chemotherapy and other oncology drugs.

CANCER PREVALENCE RATES FOR 2020

	2010	Assumption for 2020 Projection							
		Base		Trend incidence		Trend survival		Trend incidence & survival	
Site	Base	No.	% change	No.	% change	No.	% change	No.	% change
Bladder	514,000	629,000	22%	576,000	12%	640,000	25%	587,000	14%
Brain	139,000	176,000	27%	174,000	25%	185,000	33%	182,000	31%
Breast (female)	3,461,000	4,538,000	31%	4,275,000	24%	4,597,000	33%	4,329,000	25%
Cervix	281,000	276,000	-2%	245,000	-13%	277,000	-1%	245,000	-13%
Colorectal	1,216,000	1,517,000	25%	1,327,000	9%	1,575,000	30%	1,376,000	13%
Esophagus	35,000	50,000	43%	48,000	37%	62,000	77%	60,000	71%
Head/Neck	283,000	340,000	20%	308,000	9%	346,000	22%	313,000	11%
Kidney	308,000	426,000	38%	487,000	58%	446,000	45%	511,000	66%
Leukemia	263,000	340,000	29%	328,000	25%	356,000	35%	342,000	30%
Lung	374,000	457,000	22%	392,000	5%	481,000	29%	412,000	10%
Lymphoma	639,000	812,000	27%	803,000	26%	841,000	32%	831,000	30%
Melanoma	1,225,000	1,714,000	40%	1,971,000	61%	1,724,000	41%	1,983,000	62%
Ovary	238,000	282,000	18%	232,000	-3%	296,000	24%	241,000	1%
Pancreas	30,000	40,000	33%	40,000	33%	50,000	67%	50,000	67%
Prostate	2,311,000	3,265,000	41%	3,108,000	34%	3,291,000	42%	3,132,000	36%
Stomach	74,000	93,000	26%	80,000	8%	103,000	39%	88,000	19%
Uterus	586,000	672,000	15%	638,000	9%	667,000	14%	634,000	8%
All sites	13,772,000	18,071,000	31%	17,465,000	27%	18,878,000	37%	18,229,000	32%

Source: National Cancer Institute

Base assumes constant incidence and survival
Trend incidence assumes projected incidence trend and constant survival
Trend survival assumes constant incidence and projected survival trend
Trend incidence & survival assumes projected incidence and survival trends

The cancer treatment pathways are based on medical evidence, peer-reviewed published literature, consensus guidelines and the company's clinical policies. A pathway is more specific than a clinical guideline in that it identifies treatments based on clinical benefits, favorable side-effect profiles and cost.

WellPoint's pathways are developed using national clinical guidelines and are reviewed by 10 geographically diverse oncologists who are actively treating patients and working in academic and community oncology groups. Six of those members are on faculty or affiliated with National Cancer Institute-designated cancer centers, seven are affiliated with Blue Centers of Distinction, four are in community practice settings and six have served on national committees for organizations such as National Quality Forum, American Society of Clinical Oncology and Institute of Medicine to improve cancer care.

So far, the program has identified 24 pathways for breast cancer, 16 for colorectal cancer and 22 for lung cancer. The plan is to add myeloma, lymphoma, ovarian and pancreatic cancer pathways this year and in 2015.

The program was created, Swedish says, in response to the rapid development of oncology drugs and diagnostic technologies coming on the market that will accelerate an array of treatment options and costs, some with proven clinical benefits and some without.

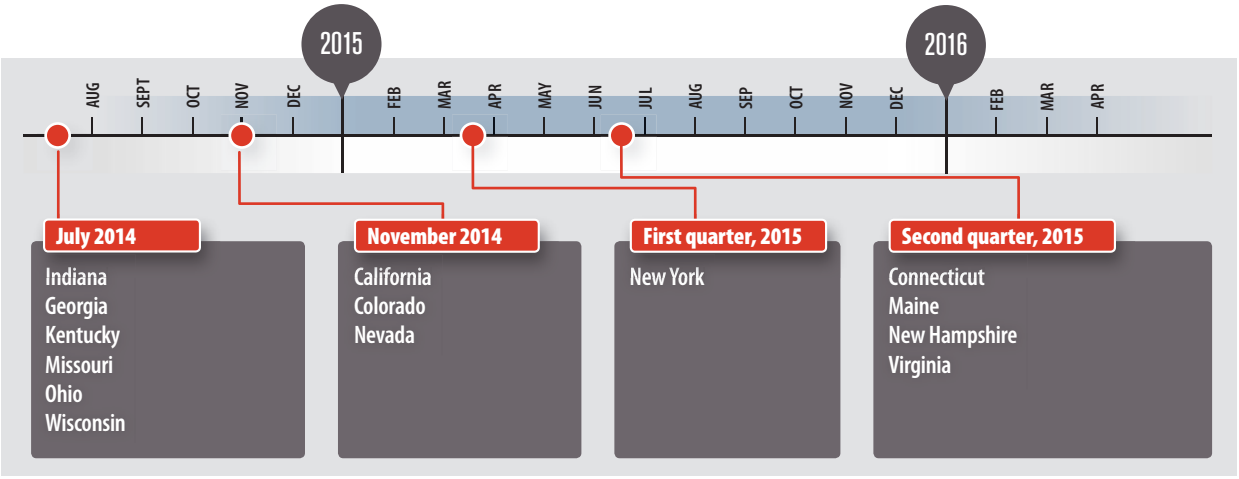
While pharmaceuticals account for just 9% of the total healthcare spend in the United States, specialty drugs have risen to 25% of oncology-related treatment and could grow to 40% over the next few years, Swedish says. Because an estimated 69% of a private practice clinical oncologist's revenue is based on administration of chemotherapeutics, the trend signals a need for better collaboration with this specialty and offering incentives when a physician chooses an evidence-based approach to treatment.

"There are so many technological advancements, not just in the pharma space, but as they relate to diagnostics and other areas," Swedish says. "The consumer is being put in an ever-increasing position of risk, and an ever-increasing opportunity for great success. That is where we believe we have a very significant responsibility to support the decision-making choices that our members must make in this new world."

WellPoint spends about $5.5 billion on cancer care every year. By incentivizing oncologists for choosing evidence-based options to guide their decisions, the company believes it can save $220 million annually, reduce hospital admissions resulting from toxicity problems associated with chemothera-

Timeline for WellPoint's rollout of the Cancer Care Quality Program

(Note: The company plans to expand to all 50 states by 2016.)



Source: WellPoint

5 REASONS to change the oncology model to strengthen patient care and the financial health of oncologists

1 A wave of scientific studies on cancer in the last few years is driving innovation and confusion, and making it difficult for oncologists to stay current, WellPoint contends. Case in point: 180 medical journals are publishing new studies on cancer monthly and quarterly.

2 There are major cost variations for "equally effective treatments." Adjuvant therapy for HER2-negative breast cancer, for example, can range from $13,000 to $32,000 with similar outcomes. Consider non-small cell lung cancer with six platinum-based regimens. The cost ranges from $8,000 to more than $60,000. The most expensive therapy is reported to extend life a few weeks beyond the least expensive therapy, but there is no difference in outcomes between the most expensive regimens and those costing $25,000.

3 Oncology patients require highly complex treatments, therefore, practices have many expenses to support the average staff of seven full-time employees per oncologist.

4 Typically oncologists buy infused chemotherapy drugs and administer them in their offices. Oncologists in independent medical practices earn nearly 69% of their revenue from reimbursements for cancer treatments. The practice is commonly referred to as "buy and bill."

5 While the business model encourages use of more expensive chemotherapies even if less expensive therapies provide similar outcomes, cuts to drug reimbursement and Medicare fees are placing greater financial pressure on community oncologists, which is leading to increased merger and other practice agreements with hospitals.

Source: WellPoint

peutics, improve outcomes for patients and better support oncology practices.

"The pursuit of quality of life is very prevalent and demanding, as it should be," Swedish says. "We need to do our part to make those services available, but at a cost that maps perfectly to the value of the service that is delivered. We have a real opportunity to impact and bend that cost curve as a nation," Swedish says.

KEY COST DRIVERS FOR ONCOLOGY

While costs of caring for cancer patients topped $124 billion in 2010, just a 2% annual increase in costs during the initial diagnosis/care phase and last year of life would increase this country's oncology-related care costs to $174 billion in 2020. A 5% cost increase in those two phases would send the total cancer care spend to $206 billion in the next six years.

And as the U.S. population continues to age, the number of people diagnosed with cancer will climb, steadily. In fact, cancer prevalence rates are expected to increase by 31% to some 18 million people in the United States, according to the National Cancer Institute. Survival rates are also believed to increase by 30% by 2020.

The program's goal, according to WellPoint, is to become the industry standard for "measuring and paying for evidence-based oncology treatment planning and care."

"We want to make certain that our long-term strategic engagement in the market helps us manage to a new future, not just relative to where we are today or where we have been in the past," Swedish adds. "Members are looking for new value and how they access the system, and they want to make certain the value comes to them through technologies that work."

Swedish says this type of program is not only novel, but scalable, and could be adapted to different specialties and subspecialties.

Does this type of oncology program advance quality care, or is it meddling with a patient and physician's treatment decision?

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5 ways to improve patient flow

Good patient flow can increase revenues and boost patient satisfaction

by **MARISA MANLEY** *Contributing author*

Practice managers are focusing more attention on patient flow due to the competition from urgent care centers and larger practices. Today's healthcare environment requires careful planning and management to ensure the efficient flow of patients through and out of the facility.

HIGHLIGHTS

01 When patients are treated in facilities and practices that minimize undue waiting, make destinations apparent and transitions comfortable, they feel respected and cared for. The result is happy, well-treated patients and enhanced practice revenue.

02 The most common bottleneck is at the traditional check-in counter. Operational and architectural changes can solve this.

NO LONGER CAN healthcare practices rely on the single appointment and waiting room process. Managers of healthcare practices of all sizes and types increasingly recognize that effective patient flow is key to increasing revenue and improving efficiency for the practice and providing a positive experience for the patient. As the business manager of a fast-growing orthopedics group explained, "We have to get this right."

In our increasingly busy lives, the experience of going to the doctor or treatment center is no longer simply making an appointment, and waiting to see a provider. Attention needs to be paid to how patients can move seamlessly from check-in to clinical practice areas to check-out, so that providers can operate efficiently and maximize time with patients.

When patients are treated in facilities and practices that minimize undue waiting, make destinations apparent and transitions comfortable, they feel respected and cared for. The result is happy, well-treated pa-

PROVIDE TOUCH-DOWN STATIONS WHERE PROVIDERS CAN WRITE NOTES AFTER A PATIENT VISIT WITHOUT GOING BACK TO AN OFFICE OR NURSES' STATION

tients and enhanced practice revenue.

Here are five guidelines, developed from our experience, for ensuring good patient flow:

1 Clearly define patient destinations

Signage is the key. It may be as simple as lobby or parking lot signs directing patients to the correct floor or door. It may be signs within a practice clearly distinguishing check-in from check-out, or segregating patients by type of service needed.

A suburban specialty practice group with four locations found that its patients prefer visiting their doctor at an older, smaller facility rather than the central office. According to one of the senior physicians it is because "they know just where to go. It is less stressful."

2 Avoid bottlenecks

The most common bottleneck is at the traditional check-in counter. Operational and architectural changes can solve this.

Know your providers' capacities and schedule accordingly. No matter what technology or floor plan you adopt, if your practice overschedules providers, patients will sit in a waiting area and fume.

Consider the strategic use of exam rooms. Know how many exam rooms a provider can typically handle at the same time. For many, it is two or three. Plan accordingly, then consider "swing" exam rooms—extra rooms allocated among several practitioners to absorb patients at times of high demand.

These may be used to enable a patient to see a doctor on schedule, when another patient with a complex visit would otherwise cause a back-up in the schedule.

Be careful not to over-use extra rooms. Parking patients in an exam room and making them wait does not enhance flow.

3 Plan for logical traffic patterns with no crossed paths

Very often a patient checks in, sits in a waiting room, then must cross the path of new patients checking in on the way to an exam room. Plan instead for a traffic flow that moves patients sequentially through a visit without crossing paths or retracing steps.

Some practices now use "just in time" patient service. They have no waiting areas. Patients move directly from check-in to exam room; doctors enter the room from a separate entrance.

Many more solutions are available depending on the size and configuration of the facility. Patients may move from check-in to financial consult to vitals to exam room to check-out without crossing other traffic paths.

In some practices, patients check in and check out at the same counter with the same staff members. Patients who have completed their visits often must wait while a staffer registers another patient. Departing patients do not appreciate this wait.

Moreover, if a patient must handle financial matters at check-out (or check-in), it can create an uncomfortable situation, and depending on the design, may violate Health Insurance Portability and Accountability Act privacy regulations. Use separate check-in and check-out areas, even if the functions are handled by the same staff members.

4 Consider internal traffic flow, including within the reception area

Provide touch-down stations where providers can write notes after a patient visit without going back to an office or nurses' station. One practice prefers stand-up stations for doctors, located close to work stations where medical assistants can provide neces-

BE CAREFUL NOT TO OVER-USE EXTRA ROOMS. PARKING PATIENTS IN AN EXAM ROOM AND MAKING THEM WAIT DOES NOT ENHANCE FLOW

sary back-up. These stand-up work stations keep doctors in the middle of the flow, enable them to complete notes quickly, view records, and then move on.

If you are in a multi-specialty practice, consider the hand-off between specialty areas. In some practices, patients must get dressed again, take an elevator between floors, and return to a public waiting area or otherwise disrupt their visit.

For one facility, the solution is a "warm hand-off." A doctor walks with a patient transitioning from family health to behavioral health. The patient/doctor path is between two separate practice areas, but within the clinical portion of the facility. Thus, the patient perceives the transition as part of a single visit with no disruption.

The same type of transition can apply to patients moving from a clinical visit to physical or occupational therapy.

Let the movement of medical supplies contribute to a smooth flow for patients and doctors. Some practices prefer central storage for medical supplies; some prefer that each room be fully stocked on a rotating basis so that every exam room or clinical area has all the supplies needed.

Some practices prefer carts, fully stocked, that are moveable to exam rooms as needed. There is no single correct solution. Focusing on how the availability of medical supplies affects provider performance and patient experience in the context of how your team functions will help create a solution that enhances workflow.

Consider pods, and reserved or rotating exam rooms. One practice uses exam rooms of various sizes, developed over time to fit into the facility and accommodate growth. One senior practitioner worked in only one exam room; others worked around him. Sometimes this creates a back-up—patients must wait for a room to open up.

Other practices prefer pods. Each practitioner has several assigned exam rooms close together. Generally, each pod is assigned to a single practitioner, but design is standardized, so substitutions are easy. Still other practices line up exam rooms along a corridor like beads on a string. Practitioners use any available exam room.

Many practices feel the pod solution is superior because it enables providers to work efficiently with multiple patients in a compact area and to have assistants working with patients close by. Some practitioners personalize their pods with color or thematic design—this also helps guide patients to their destinations.

5 Parking is part of patient flow

Parking is part of patient flow and can dramatically affect both patient satisfaction and revenue. One primary care practice took the extraordinary step of borrowing money to build a parking garage. In their small town, street parking was limited, and their parking lot could not accommodate all patient traffic.

Because patients could not find parking spaces, many were late for their appointments. Others gave up and became no-shows. Both practice revenue and patient satisfaction suffered.

In many suburban locations, the problem is not as severe, but is still chronic. Patients cannot find spaces or must squeeze into overly small parking spaces.

Another parking issue is an appropriate drop-off area. Can a family member pull into a covered space to drop off an elderly family member or patient on crutches? If so, you have enhanced patient flow and experience.

Whenever you are considering a new facility or improvements to an existing facility, consider parking carefully. You can be certain that your patients do.

Marisa Manley is president of Healthcare Real Estate Advisors (HCREA) in New York, New York. Send your practice management questions to medec@advanstar.com

Practical Matters

DON'T LET PEAK DEMAND SABOTAGE YOUR SCHEDULE

by **JUDY CAPKO** *Contributing author*

Managing a busy appointment schedule always presents challenges, but for practices that have peak seasons where demand is sometimes greater than capacity it can be very costly. Taking action is critical to improving service, and increasing efficiency and productivity.

IT IS POSSIBLE to predict demand and manage the day. Start by examining historical scheduling patterns, which will reveal demand hot spots. Take the trends a step further by analyzing how you met the demand in the past. Explore the number of last minute work-ins that resulted in double-booking, causing everyone to work harder and later. If you are double-booking six patients a day during the winter flu season, it's time to look for solutions.

Some practices think outside the box to ensure they will be staffed based on demand. "We have blackout days for paid time off (PTO)," says Kim Avery, the Administrator for Mid-South Pulmonary Specialists in Memphis. "And if someone calls in sick on a Monday it will cost them double the PTO using up 16 hours of earned time off." They also have PTO specials when things are slow to encourage employees to take time off.

Managing during the transition to electronic health records (EHR) is important to managing workflow and staying on time, too. One practice I work with created a temporary scheduling template where physicians would see one new patient and three post-ops per hour while learning the EHR. They also follow this process for new physicians that are adjusting to the EHR. Avery advised not having all physicians take on the EHR at the same time. "We also give each physician a lighter schedule the first week they transition to our EHR."

The decisions you make and actions you take have great influence on managing the schedule. Look at your options for meeting the demand and get everyone on the same page, and you will find the solution that will work for the team.

Pediatric practices can manage pre-school physicals by not scheduling vacations during this anticipated need. During the winter, offering a 7 a.m. to 9 a.m. Monday walk-in clinic helps lighten the usual Monday demand and control the morning call-ins for appointments. Parents love it.

Primary care practices can create a walk-in clinic from 5 p.m. to 6 p.m. on a Friday to reduce angst for a family facing illness before the weekend. Primary care practices can also prepare for the flu season by offering flu-shot clinics throughout the fall. Pick the day of the week that is historically the slowest and weave in your shot clinic.

A pulmonary practice I work with has developed protocols for ancillary testing on specific new patient types. Staff completes the order and patients are doctor-ready. This helps workflow and maximizes productivity.

There are some things you shouldn't do, as well. One family practice I consulted with had a sign on the check-in counter that read: "Please be patient, we are running behind and are very busy." Remember, your patients are busy too. It's your responsibility to manage the workflow.

Judy Capko *is a healthcare consultant and speaker with Capko & Morgan in Thousand Oaks, California. Send your practice management questions to* ***medec@advanstar.com****.*

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The Last Word

PIONEER ACOs PERFORMANCE MIXED IN FIRST TWO YEARS, CMS DATA SHOWS

by **CHRIS MAZZOLINI, MS** *Content manager*

Is the government's Pioneer accountable care organization (ACO) program in trouble? The program consists of a select group of providers "already experienced in coordinating care for patients across care settings. But the results from the program's first two years, 2012 and 2013, remain mixed as ACOs unable to achieve shared savings continue to drop out.

RESULTS FROM the first two years of the program show that some of the participating ACOs have saved money, while others have actually increased their costs. Meanwhile, participants in the program continue to drop out, including three in September, thinning the ranks from 32 organizations to 19. One of the recent dropouts called the Pioneer ACO program "financially detrimental."

According to the CMS data, half of the 32 original participants had either no savings or recorded losses. The best performing ACO saved about $23 million, or 7% of the ACO's expected expenditures based on benchmarks. The ACO with the largest losses recorded more than $9.3 million in losses, or about 5% of expected costs. Typically, the average spending was about $20 less per month per Medicare beneficiary compared to if the ACO had not participated in the Pioneer program.

The second year saw mixed results as well. Of the 20 ACOs that released results, six lost money while 14 realized savings. Nine were no longer participating and three deferred releasing results until after the third year of the program.

In September, U.S. Health and Human Services (HHS) Director Sylvia Burwell said that providers using the ACO model have saved Medicare more than $372 million.

BY THE NUMBERS

32
Number of ACOs that signed up to participate

19
Number of ACOs that still remain in the program

50%
Pioneer ACOs that had no savings or recorded losses in 2012

$23 MILLION
Amount saved by the best performing ACO in 2012

$9.3 MILLION
Amount lost by the worst-performing ACO in 2012

$20 PER PATIENT
Amount saved, per patient, by the ACOs in 2012.

3
Number of ACOs that declined to release financial results until after 2014, the third year of the program

$372 MILLION
the amount Medicare saved by providers using the ACO model, according to HHS Director Sylvia Burwell

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Reference: 1. Lind T, Rydberg L, Kylebäck A, et al. Esomeprazole provides improved acid control vs. omeprazole in patients with symptoms of gastro-oesophageal reflux disease. *Aliment Pharmacol Ther.* 2000;14:861-867.

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