Medical Economics
OCTOBER 10, 2013
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Medical Economics®

OCTOBER 10, 2013

DEBATE ESCALATES over Medicare prices

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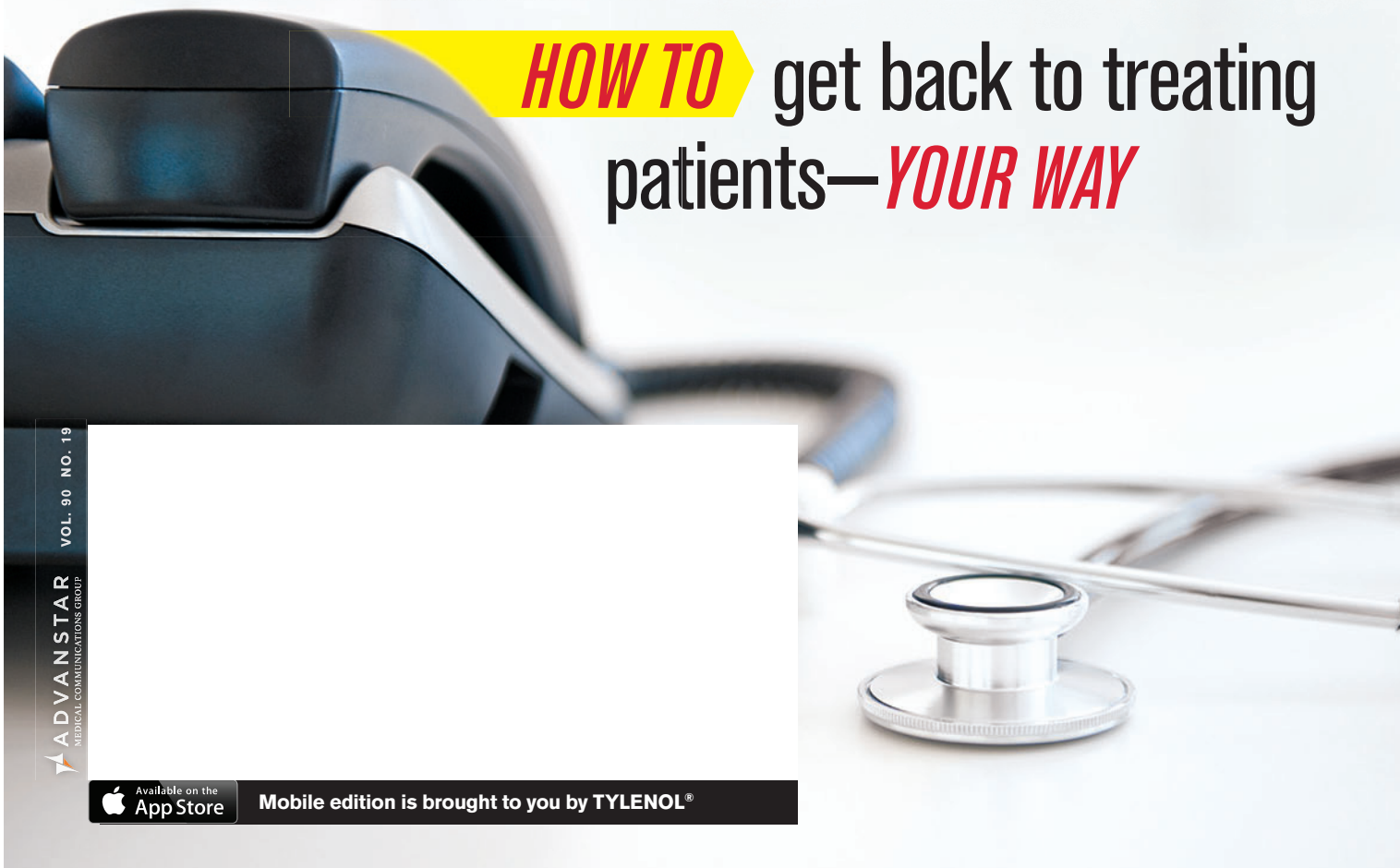
HOW TO get back to treating patients—YOUR WAY



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OCTOBER 10, 2013

Volume 90
Issue 19

IN DEPTH

CURING THE PRIOR AUTHORIZATION HEADACHE

STARTS ON PAGE 24

COVER STORY | OPERATIONS

Requesting coverage for procedures and drugs is time-consuming and frustrating. But you can take steps to make the process easier.

STARTS ON PAGE 24

- Submit requests online
- Reduce inappropriate denials

COLUMNS

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LEGALLY SPEAKING

Lee J. Johnson
How to respond to negative online reviews of your practice

PAGE 54
FINANCIAL STRATEGIES

Frank Cohen
Too many payers can lead to waste and inefficiency.

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

BEHAVIORAL HEALTH MAY BENEFIT YOUR PRACTICE

Few primary care practices have the resources to address the psychosocial issues, such as anxiety and depression, that are behind some 70% of patient visits. An experimental program underway at the Center for Primary Care at Harvard Medical School aims to show that investing in those resources would be beneficial to both providers and patients. Read more details at **MedicalEconomics.com/psychosocial.**

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QUALITY MEASUREMENTS
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VACCINES
FDA approves new 4-strain flu vaccine http://ow.ly/pa9LR #primarycare

SELLLING A MEDICAL PRACTICE
If you're thinking of selling or merging your #medical practice, here's what you need to know. http://bit.ly/183gnPZ

PRIMARY CARE PHYSICIAN SHORTAGE
Study: The U.S. would need 51,880 more #primarycare physicians by 2025 to keep up with the influx of patients http://bit.ly/18WJgu5

TEAM-BASED CARE
How to start building a team-based medical practice http://bit.ly/16b0nFQ

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Save time by making prior authorization requests through the payer's Web site rather than a telephone call.

-Judy Bee, PRACTICE PERFORMANCE GROUP

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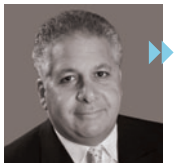

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from the Trenches

> For all the valid criticism of the Affordable Care Act, it is a start. It stakes a claim on big ideas like universal health coverage, the primacy of primary care, holding physicians accountable for more than just writing the prescription, and tying payment to quality and value.
>
> **Jennifer E. Frank, MD, FAAFP,** NEENAH, WISCONSIN

ACA IS A START AT IMPROVING HEALTHCARE

I understand the criticism of the Affordable Care Act (ACA), much of it justified. It is too long for anyone to read, it relies heavily on too many unproven theories (like pay for performance and accountable care organizations,) and it has the potential to make healthcare more expensive rather than less.

But while I am not necessarily a fan of all the ideas in the ACA, I am a fan of the *idea* of the ACA. It is folly to argue that our current healthcare system is effective or sustainable. Something must change. We have a lot of national and international examples of both success and failure and it is important to learn from these experiences. No one does it perfectly, and even good systems can be improved, but our country needs to start somewhere.

For all the valid criticisms of the ACA, it is a start. It stakes a claim on big ideas like universal health coverage, the primacy of primary care, holding clinicians responsible for more than just writing the prescription, and tying payment to quality and value.

I fully expect that portions of the ACA will be complete failures, but if we don't start trialing these ideas, we will remain ignorant of the best way to direct our future healthcare system.

Jennifer E. Frank, MD, FAAFP
NEENAH, WISCONSIN

CANADIAN-STYLE HEALTHCARE WON'T WORK

I completely agree with the views expressed by Craig M. Wax, DO, in his recent editorial. ("ACA: It's not what the doctor [or voters] ordered, August 25, 2013). Anyone who favors a Canadian-style, single-payer healthcare system should read the latest annual report by the Fraser Institute, a Canadian think tank, titled "Waiting Your Turn: Wait Times for Medical Care in Canada."

Their 2012 data shows that the median wait time for Canadian patients to see an orthopedist was 20 weeks, measured from the day of referral by their primary care physicians. Even then, patients had to wait an additional 19.6 weeks for the orthopedist to actually treat them, for a total median wait time of 39.6 weeks, from referral to treatment. That is a long time for a patient in pain.

Medical oncologists had the shortest delays; cancer patients had to wait a median of "only" 4.1 weeks to start chemotherapy, and 4.5 weeks for radiation therapy. For a cancer patient anxious to start treatment, a 1-month delay can seem a lot longer.

Canadian physicians, when surveyed, believed that their patients were forced to wait approximately 3 weeks longer than "clinically reasonable" for ➔ 13

> Over the past several years insurers' intrusions, the burgeoning amount of administrative tasks heaped on physicians' shoulders, and the dissociation of office and hospital practice have combined to radically change primary care physicians' roles.

Edward Volpintesta, MD, BETHEL, CONNECTICUT

elective treatments. The Fraser Institute report estimates that at any one time, approximately 2.5% of Canadians are on a waiting list for treatment.

To prevent defections by delay-weary patients, Canada's provinces have enacted regulations discouraging the private practice of medicine, except for non-covered services. So where do Canadians go when they want prompt care and have the ability to pay for it, despite their high income taxes? In 2012, an estimated 42,173 of them sought medical care in other countries, including the United States, according to another Fraser Institute report, "Leaving Canada for Medical Care 2012," in the May/June 2013 issue of Fraser Forum.

Unfortunately, if the United States follows Canada's lead by adopting a "single-payer" system, Americans will not have the convenience of being able to drive across a nearby friendly border to receive free-market medical care in a technologically advanced English-speaking country.

David L. Keller, MD
REDONDO BEACH, CALIFORNIA

DEARTH OF PRIMARY CARE STUDENTS NOT A SURPRISE

In response to "Many top hospitals lag in graduating PCPs" (August 10, 2013), primary care students are not being taught the skills they need for the future because primary care has been undergoing an identity crisis for more than 20 years and medical educators have done little to acknowledge the fact.

Over the past several years insurers' intrusions, the burgeoning amount of administrative tasks heaped on physicians' shoulders, and the dissociation of office and hospital practice have combined to radically change primary care physicians' roles.

Some physicians say that the time and energy consumed by administrative toil has made them about 30% less effective. For example, dealing with pharmacies, home health agencies, and Medicare, to name just a few of the entities competing for their time, has made them spend almost as much time on paperwork as on actual medical care.

There is a high burnout rate among primary care physicians as they struggle to maintain the "do it all" image of the doctor of earlier times with the overworked modern version.

Many are in denial, but some readily admit that too much paperwork has taken away their enthusiasm and job satisfaction and that they would not recommend a career in primary care to their children.

Also, allowing nurse practitioners (NPs) to practice some aspects of care within the scope of their training and education would spread the workload among more providers and be more manageable for all.

Thus the fact that our best hospitals are not training enough primary care doctors is not surprising. It seems natural for these doctors to be trained outside of the hospital and to have NPs share in providing primary care services.

Edward Volpintesta, MD
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TWEETS FROM AAFP 2013

@MedEconomics:
The future of #healthcare in this country is about teams. We must continue to be the leader of our team. Reid Blackwelder, #MD #aafpsa @aafp

@dwramzimdmph:
Healthcare at 20% GDP is stealing from resources from other sectors of the economy... From the social determinants of health. #aafpsa

@MedEconomics:
The top concern facing family #physicians? #Payment reform, according to @AAFP survey. #aafpsa

@DoctoraChispas:
40% of patients not clear on the care plan when leaving our offices. Health literacy for pt engagement. -Dr. Epperly #AAFPSA

@MedEconomics:
Incentivize #primarycare to keep patients out of #emergency rooms to bend the #healthcare cost curve, says John Bender, #MD #aafpsa @AAFP

@MedEconomics:
Family medicine is aligned to bridge #medical care and public health. That's never really been achieved. Marci Nielsen #aafpsa @aafp @pcpcc

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Medical experts answer questions from family physicians during a panel discussion at the American Academy of Family Physicians (AAFP) 2013 Scientific Assembly. Pictured (left to right): Moderator **Glenn Thayer**, **John Bender**, MD; **Marci Nielsen, Ph.D.,** and **Samuel Nussbaum**, MD.

AAFP EXPERT PANEL: ADVICE FOR FAMILY PHYSICIANS

What's one piece of advice every family physician needs to hear?

Three experts weighed in during AAFP 2013. They are: John Bender, MD, senior partner and CEO at Miramont Family Medicine in Fort Collins, Colorado; Marci Nielsen, PHD, CEO of the Patient Centered Primary Care Collaborative; and Samuel Nussbaum, MD, executive vice president of clinical health policy and chief medical officer for Wellpoint.

Bender:

Resolve to take time to get off the treadmill. Go back to your practices and set aside an hour each week to work with your team.

Nielsen:

Be brave and embrace the power that you already have. You are so powerful and so important to the patients you take care of, but you can be so important to your communities, to public policy makers.

Nussbaum:

You have the most important responsibility and you've accepted that in caring for patients. Put the patient as the focus of all you do.

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Greenway, Vitera join in multi-million dollar merger

TWO OF healthcare's information technology leaders, Greenway Medical Technologies and Vitera Healthcare Solutions, are merging, according to an announcement released by Greenway. The combined companies will serve 13,000 medical organizations and 100,000 providers.

Vitera's owner, Vista Equity Partners, is acquiring all outstanding Greenway stock for $20.35 per share. In total, the transaction is valued at $644 million. Vitera's award-winning electronic health records (EHR) system has been ranked first place by Black Book Market Research and has received industry praise. Based in Tampa, Florida, Vitera's EHR and practice management systems currently serve 415,000 healthcare professionals.

"Combining our business with Greenway Medical Technologies demonstrates our intense focus on growth and our commitment to provide current and prospective customers with proven, integrated and easy-to-use solutions they need to grow profitably, increase practice efficiencies and improve patient outcomes in this ever-changing healthcare environment," said Matthew J. Hawkins, president and chief executive officer of Vitera.

"Healthcare IT mergers increased 21% between 2011 and 2012 from $11.36 billion to $11.96 billion"

Greenway, based in Carrolton, Georgia, also produces EHR and practice management systems. Once the transaction is complete, both Vitera and Greenway's products will be marketed under the Greenway brand.

According to the merger announcement, the company's first priorities will be enhacing its systems to meet Meaningful use 2, payer reform, and the International Classification of Diseases-10th revision (ICD-10) requirements. The companies will continue principal operations in Georgia, Florida and Birmingham, Alabama.

Tee Green, president and chief executive officer of Greenway says the merger will help both companies develop tools to help improve population health by leading the "electronification of healthcare, engaging consumers to manage their own health."

This merger offers a glimpse into what is predicted to be a mass consolidation of the healthcare information technology industry. According to investment bank Berkery Noyes, healthcare information technology mergers increased 21% between 2011 and 2012 from $11.36 billion to $11.96 billion, respectively.

MED APPS FOR PHYSICIANS FACE FDA REGULATION

In recent years, the mobile application market has been flooded with medical apps that do everything from count calories to perform electrocardiography.

The Epocrates 2013 Mobile Trends Report shows that about four out of five physicians, nurse practitioners, and physician assistants are using smart phones every day, and more than 50% of physicians use tablet devices daily.

But now the U.S. Food and Drug Administration (FDA) has announced that it will start regulating medical apps that physicians may be using on those devices. Its guidelines, "Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff," offer information regarding the new regulatory requirements and why they are important for app developers and patients.

"As is the case with traditional medical devices, certain mobile apps can post potential risks to public health," the document states. "Moreover, certain mobile medical apps may pose risks that are unique to the characteristics of the platform on which the mobile medical app is run. For example, the interpretation of radiological images on a mobile device could be adversely affected by the smaller screen size, lower contrast ratio, and uncontrolled ambient light of the mobile platform."

But not all medical apps will be subject to regulation. The FDA will focus on apps meant for physicians and other healthcare providers to use as diagnostic tools and to facilitate patient care.

"We have worked hard to strike the right balance, reviewing only the mobile apps that have the potential to harm consumers if they do not function properly," says Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health, in a statement.

The FDA has already approved about 40 medical apps within the last 2 years and approximately 100 apps in total.

Doctor's Bag

The latest in drugs, devices, technology, and more

INTRADERMAL FLU VACCINE MICRONEEDLE DELIVERY SYSTEM

The Fluzone Intradermal Influenza virus vaccine is the first FDA-approved vaccine of its kind in the United States. Typically, vaccine needles go through the skin, a layer of fat, and then into muscle. Alternatively, Fluzone Intradermal vaccine works by injecting into the skin through a small, ultra-thin microneedle, and is able to use the skin's natural defenses, providing protection similar to a traditional flu shot.

Fluzone Intradermal vaccine's microneedle contains less vaccine than the traditional flu shot (0.1 mL compared to 0.5 mL) and is designed to help protect patients from the flu. Its ultra-thin tip is only 1.5 mm long—the same thickness as a penny. Similar to other flu shots, it is administered in the upper arm.

Common side effects are redness, swelling, and a raised bump at the site of injection. Other side effects include pain and itching. Fluzone Intradermal vaccine is approved only for adults 18-64 years of age; however, other flu vaccines are available for patients 6 months of age and older.

Fluzone Intradermal vaccine is an inactivated influenza virus given for active immunization against influenza disease caused by influenza A and B strains contained in the vaccine.

Sanofi Pasteur | 1-800-VACCINE | www.fluzone.com/fluzone-intradermal-vaccine.cfm

NEW OPTIONS FOR TREATING OPIOID DEPENDENCE

The FDA has approved Zubsolv (buprenorphine and naloxone) sublingual tablets (CIII) for the maintenance treatment of opioid dependence, and they are now commercially available in the U.S.

The higher bioavailability of Zubsolv allows for a lower dose of buprenorphine being administered. In combination with naloxone, this reduces the amount of available drug and the potential for misuse.

Zubsolv is the only opioid dependence treatment available in the highest level of child-resistant packaging (F1), and each Zubsolv tablet is supplied in individual unit-dose blister packages, reducing the chance of pediatric exposure.

The most effective treatment for opioid dependence is a combination of pharmacological therapy and psychological counseling.

Opioid dependence affects nearly 5 million Americans.

Orexo U.S., Inc. | 1-855-ZUBSOLV | www.zubsolv.com

BUTRANS NOW AVAILABLE IN 15 MCG/HOUR DOSAGE

The FDA has approved a new 15 mcg/hour dosage strength of Butrans (buprenorphine) Transdermal System CIII that will be launched commercially in the U.S. in October 2013. Four strengths will now be available: 5, 10, 15, and 20 mcg/hour.

Butrans is indicated for the management of moderate- to severe-chronic pain when a continuous, opioid analgesic is needed. It is the first transdermal system that delivers a continuous release of buprenorphine for 7 days.

The active ingredient in Butrans is buprenorphine, a partial agonist at mu opioid receptor, and a Schedule III controlled substance.

Butrans contains a boxed warning for abuse potential, life-threatening respiratory depression, and accidental exposure. It should not be used as an as-needed (prn) analgesic; for pain that is mild or not expected to persist; for acute pain; or for postoperative pain.

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A history worth repeating

FEW MAGAZINES in the United States can rival the historical impact, depth of coverage, and reader loyalty *Medical Economics* has earned over the last 90 years.

This month the media brand celebrates nine decades as the leading business publication for physicians, and it is coming in a period marked by historic economic change for healthcare.

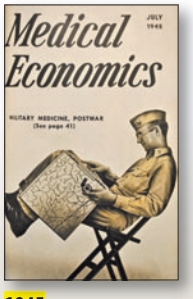
We are entering an entirely new era when it comes to healthcare delivery, access to care, new payment models, and changing roles for physicians in primary care and specialists. Never in history has a profession been held so accountable and so visible in terms of regulation, certification, financial disclosure, outcomes, documentation, liability, and a myriad of other areas.

And while the future course facing physicians is about to change, there is still one important principle and truth that stands the test of time in success or failure: economics. It's key to our survival as a profession. It's almost fitting and ironic that October 2013 marks another date that will forever change the economics of healthcare. That's when Obamacare's insurance exchanges will open for the first time. While opponents of the Affordable Care Act are doing last-minute maneuvering in Congress to financially cripple key provisions of the new law, it is already reforming health insurance, expanding access to healthcare, and creating a slew of new business and administrative challenges for physicians.

"While we should reflect and celebrate the many advances that have helped shape healthcare over the last 90 years, it's even more important to guide the future health of this profession," says Group Content Director Daniel R. Verdon. "That will continue to be the goal of this media brand."

"We live in unprecedented times," adds Georgiann Decenzo, executive vice president of Advanstar Medical Communications Group. "Physicians need answers and solutions to the important business-related challenges they face as professionals today. That is what *Medical Economics* is all about." Decenzo leads a suite of Advanstar healthcare media brands including *Medical Economics,* Modern-Medicine.com, *Contemporary Ob/Gyn, Pediatrics, Dermatology Times, Urology Times, Drug Topics,* and others.

Medicine's influences and advances



1910

1920

1922 Insulin was first discovered (Banting, et al.)

1929 Depression begins

1929 Fleming discovers penicillin; group forms pre-paid hospital service that grows in popularity during economic depression

1930 NIH was created

1932 Bayer's sulfa drug Prontosil investigated and found effective against some bacterial infections

1930

1933 Roosevelt becomes U.S. president and Hitler moves into power as chancellor

1939 World War II breaks out in Europe

1940 Actinomycin is discovered

1940

1944 Active immunization against tetanus, use of sulphonamide drugs and penicillin considered revolutionary advances in care

1945 World War II ends

1948 World Health Organization forms

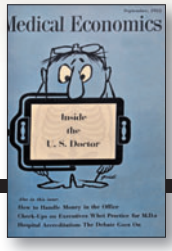
1950

1952 First open heart surgery performed

1953 DNA described

1955 Polio vaccine and tetracycline introduced

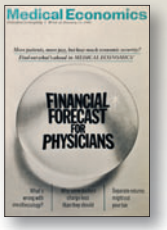
1956 First kidney transplant



1960

1960 Cardiopulmonary resuscitation invented

1962 House calls account for 40% of physician visits



1965 Medicare and Medicaid established

Ninety years ago physicians were dealing with some of the same business problems they face today—getting paid for services.

In fact, a recent survey by the American Academy of Family Physicians says payment reform ranks as the leading concern for family physicians. In October 1923, a passage in *Medical Economics* describes the issue this way: "They say that 'confession is good for the soul,' so let us admit from the start that the average physician is often a poor business man when collecting the money honestly due him. This should not be so."

The 1923 solution? Publish a billing slip with this reminder:

"The Doctor is your best friend in time of trouble and just as in emergencies he strives to help you and yours. You should strive to help him by promptly paying his bills. It may seem a little thing in itself, but when you promptly send your check, you make it easier for the Doctor to mark your account 'paid in full.' And he does not forget. You will do it ultimately. Do it now. Thank you."

While times change, and they bring new sets of economic challenges, it is clear in looking back to 1923 that some of our core economic problems will likely never be solved. But they can be improved. With your help, the editors of *Medical Economics* will offer you solutions to the business problems you face in this new era.

We'll be kicking off a year-long celebration of physicians and their role in society. Look for more details in future issues. ■

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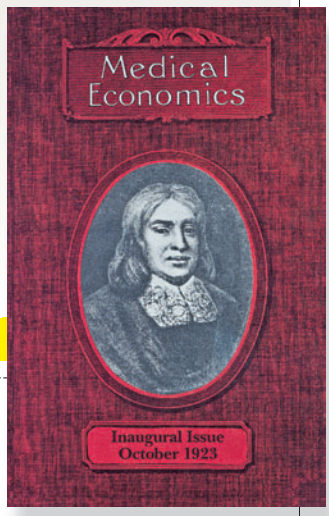

medicaleconomics.com/90

Trends

Is the physician exodus to hospitals being exaggerated?

A new report challenges the theory that the small medical practice is nearly extinct

by **DONNA MARBURY, MS** *Content Specialist*

HIGHLIGHTS

01 Previous surveys about phyisician employment from many organizations left out important metrics that would have determined more specfic reasons behind ownership and hospital trends.

02 The landscape of phyisician employment will continue to be complex due to new payment and team-based healthcare models.

Finding a way to track employment and practice ownership among the physician population is tricky. Recent reports claiming that physicians are moving swiftly away from private practices into hospital employment are based on years of inaccurate data, according to a report released by the American Medical Association (AMA).

IN ITS 2012 Physician Practice Benchmark Survey, the AMA reports that 60% of physicians work in physician-owned practices, and about 53% were self-employed. Conversely, only 23% work for practices partially owned by hospitals and nearly 6% worked solely for a hospital.

Why is AMA's data so different from other reports that document physicians' fleeing to larger groups and hospital systems? The association points to flaws in physician surveying, including its own, and the quickly changing healthcare landscape for years of imprecise data.

Basically, nobody's asking all of the physicians the right questions to understand their work environment.

"Needed innovation in payment and delivery reform must recognize the wide range of practice types and sizes that exist today so all physicians can participate in the move to a more patient-centered system that rewards high-quality care and reduces costs," says AMA Presi-

→22

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BAYER

➔20 dent Ardis Dee Hoven, M.D. in a statement about the survey.

GAPS IN DATA COLLECTION

The statistics from AMA's recent survey seem to contradict other reports of shrinking private practices and solo practitioners being swallowed by large hospital groups.

The AMA debunks the American Hospital Association's (AHA) data showing that physicians employed by community hospitals increased from 160,000 in 2000 to 212,000 in 2012, a 32% increase. The AMA also questions an Accenture report that states thst the number of physicians working at an independent practice would dwindle to 36% this year.

> "MANY DOCTORS LIKE THE LIFESTYLE THAT GOES WITH OWNING A PRIVATE PRACTICE. THIS EXTENDS BEYOND A SPECIALTY."
>
> —CHARLES CUTLER, MD, FACP, CHAIR OF THE BOARD OF REGENTS OF THE AMERICAN COLLEGE OF PHYSICIANS

"While these shifts in practice have been reported in certain locations, whether they are a part of a national trend is unknown because of a lack of recent, nationally representative data on physicians," the authors of the AMA study states.

The AMA also poinys to the Medical Group Management Association (MGMA) Physician Compensation and Production Surveys that state almost half of physicians worked for hospital-owned practices in 2011. The AMA says that the MGMA's membership of predominately large practice groups skews the numbers.

Liz Boten, public relations coordinator for MGMA, explains that the data collected from the physician compensation survey was not gathered to measure ownership trends in the industry. "That particular data is demographic information based on respondents to our survey. The survey is based on a huge pool of respondents, over 60,000 providers, and not just our members. We didn't work with the AMA on this representation of our data," Boten says.

The AMA also explains gaps in its own surveying over the years. Previous AMA surveys failed to ask about specific employment arrangements. After revamping survey methods, the AMA realized that it needed to ask more detailed questions about employment. Now the association says it asks all respondents whether their practice is solo, single-specialty group, multi-specialty group, faculty practice plan, hospital, ambulatory care facility, urgent care facility, HMO, or a medical school.

"This structure allows us to differentiate between physicians directly employed by a hospital and those working (as an owner or employee) in a practice owned by a hospital, something not possible in earlier physician surveys," the AMA states.

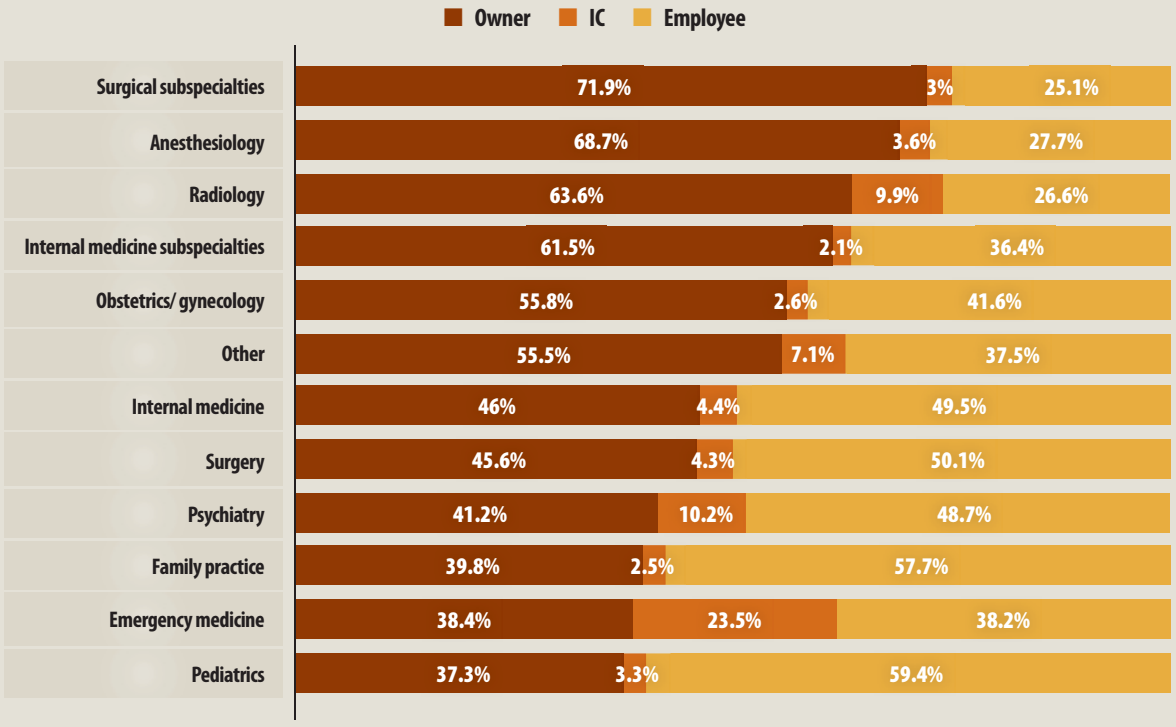
TRYING TO QUANTIFY A TREND

New payment and healthcare models that focus on collaborative and team-based care are the assumed cause of physicians fleeing to hospitals, the AMA says. The AMA survey finds that practice ownership is down by 8 percentage points from 2008, but the decline started before the passage of the Affordable Care Act and other payment model changes. Between 1983 and 1994, practice ownership fell 18% and solo practices fell by 11%.

According to a 2011 study by the *New England Journal of Medical Journal* (NEJM), hospitals began buying primary care physician (PCP) practices in the 1990s in order to ensure flow to specialists within the hospital. "Whereas hospitals prioritized PCP employment in the 1990s, they are now targeting both PCPs and specialists; many organizations are constructing what could effectively become closed, integrated healthcare delivery systems," NEJM stated. "Today, aggressive hiring of PCPs is returning, in part because hospitals fear physicians' becoming competitors by aggregating into larger integrated groups that direct referrals and utilization to their own advantage."

The AMA acknowledges market research suggesting the link between primary care physicians and hospitals in the 1990s. The trend of private practice physicians going to hospitals, the AMA says, may be a result of a regional trend since there is no way to quantify a shift on a national level. Because of "lack of comparable data," from previous years, the AMA says an analysis compared to today's data would "understate the de-

PHYSICIAN OWNERSHIP BY SPECIALTY



*IC (independent contractor)
Source: AMA 2012 Physician Practice Benchmark Survey

gree of integration between physicians and hospitals."

THE SPECIALISTS' ROLE

Another flaw in studies about physician practice ownerships lies in leaving out specialists, according to the AMA. The study finds that surgeons, anesthesiologists, radiologists and gynecologists report ownership of more that 50% of practices in their respective fields. Ownership numbers are lower in pediatrics (37.3%), emergency medicine (38.4%), and family practices (39.8%).

"Researchers looking at single specialty groups in the late 1990s and early 2000s were struck by the almost complete absence of research into the organization of specialty practice," the AMA says.

Internal medicine subspecialists own more than 62% of their practices, while general internal medicine physicians own almost half of their practices. Trying to quantify shifts between employers among internists is difficult, says Charles Cutler, MD, FACP, chair of the Board of Regents of the American College of Physicians. "Some internists practicing primary care may also be certified in a subspecialty and have a blended practice and that's not uncommon. It may be a confusing number," Cutler says.

He agrees that location is one of the biggest factors in whether a physician decides to own a practice or work for a group or hospital. "Many doctors like the lifestyle that goes with owning a private practice. This extends beyond a specialty. In large cities there are university and academic networks and that's a great opportunity. In rural areas there might be no or limited opportunities for the group practice employment model," Cutler says. ▫

@ MORE RESOURCES

Practice owner or hospital employee?

bit.ly/18uJVH2

Curing the prior authorization headache

You probably can't avoid having to get upfront approvals, but you can reduce the hassles and costs they bring

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

HIGHLIGHTS

01 Brand-name medications and high-dollar imaging procedures are the areas of treatment that most commonly require primary care physicians to request prior authorization from payers.

02 Submitting prior authorization requests online, learning payers' formularies for medications, and designating one or two staff members to handle all prior authorizations are ways that practices can streamline the process.

Few words arouse more frustration among primary care physicians (PCPs) than "prior authorization." And it's easy to understand why. The time you and your staff have to spend persuading an insurance company to cover a medication or procedure is an expensive and annoying distraction from the task of caring for patients.

ON THE bright side, while you may not be able to avoid prior authorizations entirely, you can take steps to minimize the hassle and expense they bring.

THE COSTS OF PRIOR AUTHORIZATION

Although prior authorization has been an issue among healthcare providers for at least a quarter of a century, surprisingly little is known about its cost, either to individual practices or to the healthcare system as a whole. In 2006, PCPs spent a mean of 1.1 hours per week on authorizations, primary care nursing staffs spent 13.1 hours, and primary care clerical staff spent 5.6 hours, according to a 2009 study published in *Health Affairs*. The study estimated that the overall cost to the healthcare system of all practice interactions with

➔ 26

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* Practice management (1-10 physicians & 11-75 physicians); and ambulatory EHR (1-10 physicians), as reported in the 2012 Best in KLAS Awards report.

➔24 health plans, including authorizations, was between $23 billion and $31 billion annually.

More recently, a study of 12 primary care practices published earlier this year in the *Journal of the American Board of Family Medicine* put the mean annual projected cost per full-time equivalent physician for prior authorization activities between $2,161 and $3,430. The study's authors concluded that "preauthorization is a measurable burden on physician and staff time."

FOCUS ON MEDICATIONS, DIAGNOSTIC IMAGING

While insurance companies differ somewhat in the areas where they require prior authorizations, the two most common are imaging procedures such as computerized tomography (CT) scans and magnetic resonance imaging (MRI), and brand-name pharmaceuticals.

> "If you have a plan that is ho-hum in its reimbursement and is requiring a lot of time (for prior authorizations) you…should rethink whether you need to participate, because that's coming right out of your wallet."
>
> --JUDY BEE, PRACTICE PERFORMANCE GROUP

"We have to get authorization for most CTs and MRIs, along with some ultrasounds and sleep studies," says Jeffrey Kagan, MD, an internal medicine practitioner in Newington, Connecticut, and *Medical Economics* editorial adviser. Kagan says prior authorizations and insurance referrals together consume about 25% of the time of his practice's two billing clerks and one of the practice's three receptionists.

The practice's prior authorizations for medications usually involve brand-name products for which there is no generic equivalent, or a drug that a patient has taken for years but for which the insurance carrier now requires annual reauthorization.

"This all wastes a lot of our time and it's not reimbursed," Kagan adds. "I feel that if an authorization has to be done the insurance company should allow a higher level of billing for the visit or a surcharge. I'm sure attorneys don't bring motions before a judge for free."

"It's a nuisance, it's time-consuming, and often it's not in the patient's best interest," says George G. Ellis, Jr., MD, a solo internal medicine practitioner in Boardman, Ohio, and *Medical Economics* editorial adviser. He recounts the frustration of dealing with a Medicaid health maintenance organization over the proper medication for treating a patient's gout. The HMO was requiring prior authorization for the drug Ellis wanted to prescribe, but not for a less expensive medication that Ellis felt was contra indicated. "Why should I spend 45 minutes on the phone to prescribe a drug that is indicated versus one that is contra indicated? It's crazy," he says.

Kevin de Regnier, DO, a solo family practitioner in Winterset, Iowa, has seen the demands for prior authorization grow steadily during his 26 years of practice. "When I started out it never came up," he recalls. "Then we started seeing it in a small number of high-dollar medications, then it expanded into more and more branded medications, and then moved into getting procedural prior auths, especially in the radiology field," he says.

The problem now is particularly acute in treatment involving workers compensation claims, he adds. "Now you've got to prior auth every procedure and every referral, even referrals for physical therapy."

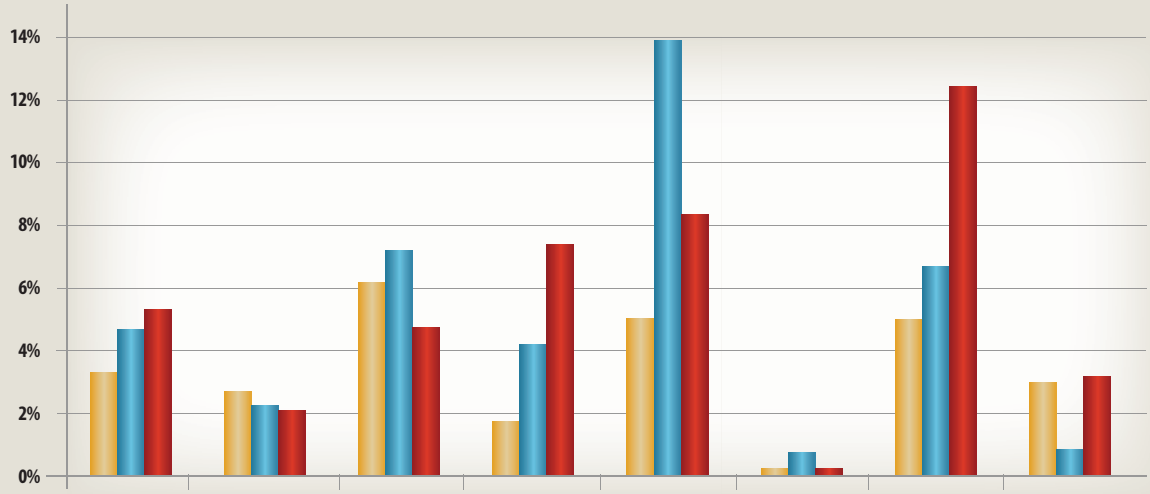
Most of the responsibility for obtaining prior authorizations falls to the practice's three nurses. According to de Regnier, the nurses spend about 10% of their time each day on prior authorization. "It's an unreimbursed cost of providing care, and unfortunately we don't have the financial resources to bring in someone to do prior auth exclusively, even on a part-time basis," he says.

'WE GET NUMB TO IT'

Yul Ejnes, MD, MACP, an internal medicine practitioner in Cranston, Rhode Island, and past president of the American College of Physicians Board of Regents, regards prior authorization as "one of the many hassles we have to deal with, but it's kind of in the background except when things heat up for one reason or another." Such a situation occurred at the start of 2013, Ejnes says, when the state's largest insurer changed its pharmacy benefits manager (PBM). The new PBM had different rules for drugs it would cover, resulting in a flurry of new prior authorizations.

"That reminded us all that it (prior authorization) exists, but on any given day we

PERCENTAGE OF MEDICAL CLAIMS REPORTING A PRIOR AUTHORIZATION, 2011-2013



	Aetna	Anthem	Cigna	HCSC	Humana	Regence	UHC	Medicare
2011	3.50%	3.10%	6.15%	1.68%	5.20%	0.04%	4.92%	3.28%
2012	4.68%	2.29%	7.17%	4.15%	13.95%	0.78%	6.70%	0.79%
2013	5.42%	2.14%	4.74%	7.31%	8.40%	0.04%	12.43%	3.45%

Source: American Medical Association, 2013 National Health Insurer Report Card

get numb to it, like we do to a lot of the other hassles we deal with," Ejnes says.

THE PAYERS' PERSPECTIVE

Despite PCPs' complaints about prior authorization, it's used less frequently now than in the past, says Susan Pisano, vice president for communications for America's Health Insurance Plans, the trade association representing the health insurance industry. "It focuses on really specific things now, such as back surgery and high-tech imaging, where there's clear documentation that something is being overused or misused, and where there's both a patient safety and cost implication.

"There's clear evidence that overuse of high-tech imaging may in some cases be contributing to cancers," she adds. "So you want to make sure the benefit outweighs the risks."

Pisano cites a 2008 study from the U. S. General Accounting Office showing that spending on advanced imaging rose by 17% annually between 2000 and 2006, far faster than less-expensive procedures.

Regarding medications, Pisano says the widespread availability of generics has made prescription drugs more affordable for many patients. "There will always be patients who require the brand name for one reason or another, but when you've got something that works as well and is less costly, you want to make that available to consumers," she says.

EASING THE PRIOR AUTHORIZATION BURDEN

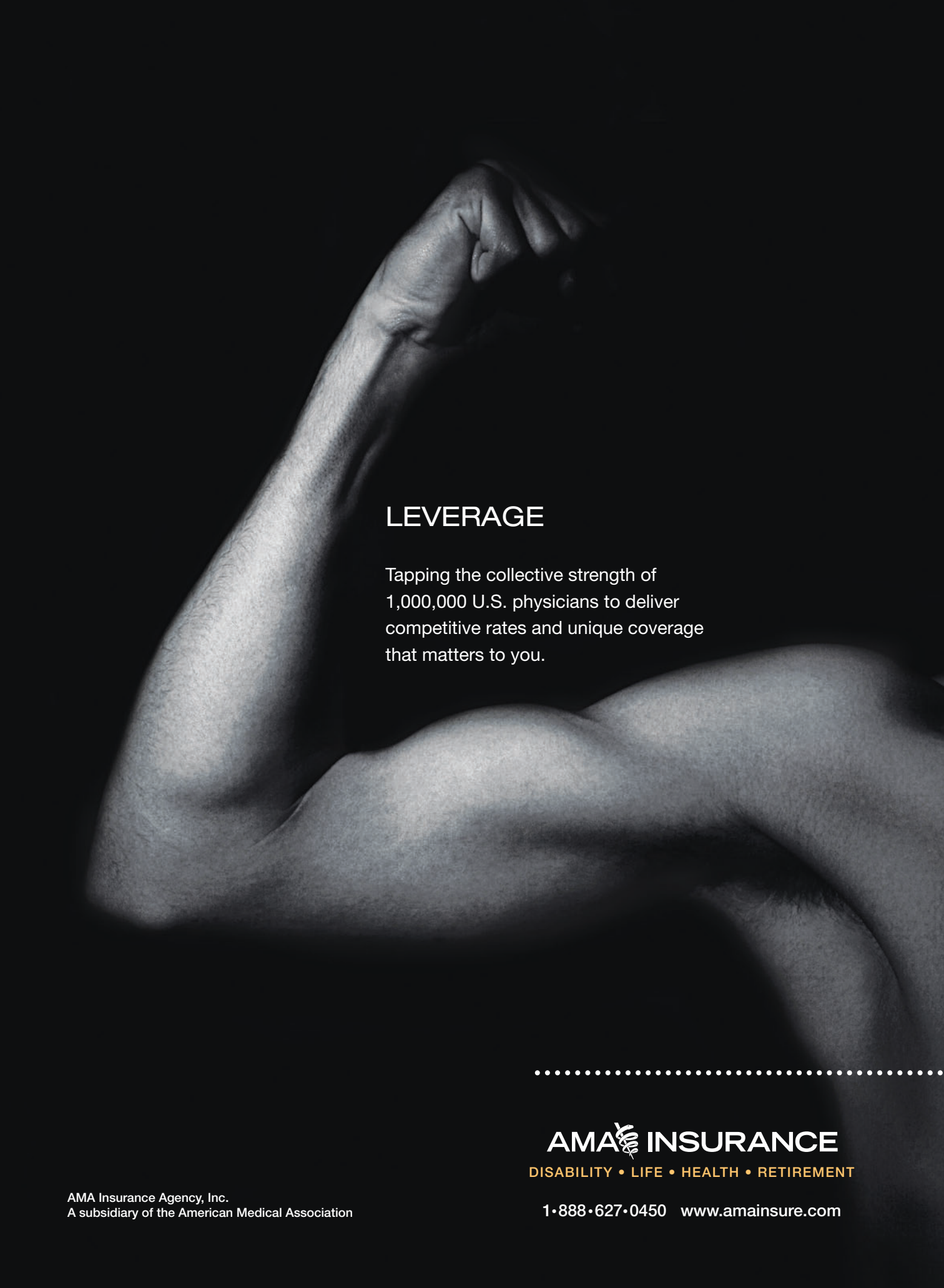
Although prior authorizations may be an unavoidable part of doing business for primary care practices, there are still plenty of steps practices can take to reduce the time and financial burdens associated with them. A good start is to look at how frequently a payer requires prior authorizations and balance that against the payer's level of reimbursement, says Judy Bee, medical practice management consultant in La Jolla, California and *Medical Economics* consultant.

"If you have a plan that is ho-hum in its reimbursement and is requiring a lot of time (for prior authorizations) you probably should rethink whether you need to participate, because that's coming right out of your wallet," she says.

In addition, practices should go through payers' Web sites to obtain prior authorizations whenever possible, says Bee. Going online usually gets a quicker response and avoids wasting time on hold on telephone calls.

Practices with more than one location often can create greater efficiencies by centralizing the prior authorization responsibility, says Owen Dahl, MBA, FACHE, principal of Owen Dahl Consulting in The Woodlands, Texas. Putting just one or two individuals in charge of prior authorizations for the entire practice will enable those employees to become highly skilled in the process and develop relationships with the payers.

Dahl also recommends ➔29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➔27 seeking pre-approval from payers for a plan-of-care if it has proven successful with multiple patients. "Tell the payer that if the patient presents with this disease, this is what we will do, can we get blanket approval for this without having to call every time for authorization if the patient needs a procedure under this treatment plan?" says Dahl. Even if the payer declines, he adds, you've at least opened a dialogue with the payer that could prove useful later on.

The next step is to try and minimize the number of times you're required to get a prior authorization. For medications, Ejnes recommends becoming familiar with insurers' formularies, and developing a list of drugs they all cover for common diseases. For example, he says, if there are multiple choices for medications to treat high blood pressure, but you know all your insurers will cover Losartan as a generic angiotensin receptor blocker, "then just get in the habit of prescribing that drug—always assuming it's appropriate for the patient—and you avoid having to deal with a multitude of prior auths," he says.

Ejnes also instructs his staff to have the forms required for the drugs and procedures that most commonly require a prior authorization easily available, either in hard copy on their computers. "That way when a 'prior authorization necessary' alert comes in, they're not scrambling to download a form," he says.

MINIMIZE HIGH-COST IMAGING TESTS

Robert Eidus, MD, MBA, a family practitioner in Cranford, New Jersey, also tries to avoid prior authorizations, both by minimizing the number of high-cost imaging tests he orders, and by starting patients on generic medications whenever possible. But if ordering an MRI or other high-cost test is called for, he tries to simplify the process with the help of his practice's electronic health record (EHR) system. His practice developed a customized form on its EHR that automatically captures the demographic information the radiology utilization review company usually requires before authorizing payment for a procedure.

The form also includes a reminder at the bottom to see the most recent clinical note for the patient. "When we do a prior auth, a clerical person generates the form and they attach the last note, which streamlines the administrative process," Eidus says.

To reduce the number of what he terms "inappropriate denials," Eidus recommends learning each payer's criteria for authorizing coverage of an imaging procedure and ensuring that the data sent to the approving body clearly meets the criteria.

"When I know I have to do a prior auth, my progress note for that day is designed to clearly justify why I need it," he says. "So it might say the patient has had physical therapy or has severe intractable pain, and make it very clear and ➔31

NCPDP approves standards for ePA

Standards for electronic approvals will whittle down $31 billion in administrative costs

by **JENNIFER WEBB,** *Contributor*

The process of obtaining electronic prior authorizations of prescriptions got easier recently, thanks to the National Council for Prescription Drug Programs' (NCPDP) approval of a standardized process for electronic prior authorization (ePA). The process is designed to give physicians instant approval or denial.

"It's very important for the process to be incorporated into the normal work flow of the prescribers and the people attempting to dispense the medication at the pharmacy," says Stephen C. Mullenix, R.Ph., NCPDP's senior vice president, public policy and industry relations. "This process, as it's been designed, will allow that to occur."

The decision clears the way for health plans to adopt a common ePA form using NCPDP standards that incorporate formulary and benefit information. The availability of "true" ePA means physicians will know, before patients leave the point of care, which drugs are covered for a given condition and what they might cost out of pocket, Mullenix says.

For ePA to be effective, there must be real-time, computer-to-computer communication—not just a Web portal for each individual plan, he says.

No more faxes

NCPDP and other healthcare stakeholders have worked for years to achieve an electronic alternative to the paper requests that physicians fax to health plans seeking approval for drugs. Mullenix says HIPAA first proposed ePA in 2006, but recommended the use of an existing standard. That standard proved inadequate for drugs.

It took 2 years to develop a standard, and 3 more to get pilot studies up and running. When the standard was presented in May, it passed without opposition.

"While it has probably been longer than any of us would like, we do believe strongly we have a solid ePA standard that can be used in the industry," Mullenix says.

Implementation

The next hurdle will be encouraging organizations to implement the standard—a process NCPDP anticipates could take as long as 18 to 24 months.

In the absence of a standard, some health plans have developed their own versions of ePA to increase the efficiency of their network physicians. Administrative delays, repeated phone calls, and wasted time frustrate physicians, pharmacists, and patients, and add up to significant expense.

The Center for Health Transformation, citing a 2009 report in a 2012 white paper on ePA, found that $31 billion is spent each year as physicians work to deal with prior authorization administration. The delays of a paper-based authorization system are especially frustrating given that 52% of office-based prescribers use e-prescribing, yet must resort to the fax or phone to determine if a drug would be covered for a patient.

Dakotacare, a physician-owned plan in South Dakota, has used an ePA program in its network for 7 months. The plan consulted with a third-party technology company and used its platform to develop unique criteria for each diagnosis code. When a physician enters a given code, the screen displays specific questions that indicate whether a drug is covered, says Craig Beers, PharmD, a Dakotacare clinical pharmacist.

For now, the system only covers drugs and extends just to in-network providers. The plan wants to develop it for all physicians and link it to electronic health record (EHR) programs.

The program has produced efficiencies for Dakotacare. Previously, 25% to 40% of authorizations required follow-up with a physician. But now only 10% to 20% do. Reduced manual administration means lower costs.

"Where this really improves the system is between the physician and the plan so it is clear what is needed and what communications are expected," says Daniel Weiss, PharmD, the plan's director of pharmacy benefits.

Plans using ePA also stand to gain in other ways. "These healthcare providers are trying to take care of a specific patient need, and to delay the process is really not helping the provision of healthcare for that patient," Mullenix says.

Source: Managed Healthcare Executive, July, 2013

➔29 distinct so that a reviewer can't miss it."

An additional challenge PCPs sometimes face is patients requesting a brand-name medication before trying a generic. de Regnier says he addresses that situation by asking the patient his or her reasons for requesting the brand-name.

"Usually what you find is they're basing the request on a TV commercial," he says. "If it's appropriate I'm willing to go to bat for them, but usually it's not what they need and won't be approved, so I try to explain that to them."

TARGET THE OUTLIERS

Although many physicians recognize the need to minimize inappropriate use of costly radiology procedures and prescription medications, they say the solution is to find and penalize the relative handful that do so, rather than all physicians.

Such an approach would benefit both payers and providers, says Reid Blackwelder, MD, president of the American Academy of Family Physicians. "Insurance companies don't want to practice medicine," he says. "The costs, in both time and resources, to obtain prior authorization is high for everyone involved.

"Insurance companies should focus on the outliers, those who order tests or utilize services that are not consistent with similar clinical circumstances," Blackwelder adds.

de Regnier estimates that no more than 20% of most insurance companies' physician panels are overprescribing or overutilizing. "And yet the other 80% of us pay the price for that," he says. "So why not work with the physicians' societies to provide a more focused educational program? I think that would be effective and reduce the global cost of caring for patients."

TIPS FOR HANDLING PRIOR AUTHORIZATIONS

Here are steps you and your practice can take to minimize the costs and time required to obtain prior authorization from a payer for a medication or procedure:

- **Whenever possible, use the payer's Web site rather than the telephone.**
- **Look at how many prior authorizations each of your payers required during the past year, and consider dropping them if the payer's reimbursement rates don't justify your time spent obtaining the authorizations.**
- **If you're in a multi-site practice, designate one or two individuals to handle prior authorizations for the entire practice. Make sure those individuals have access to patients' records and providers' notes from throughout the practice.**
- **Make sure you are following recommended treatment guidelines before ordering a high-cost procedure for a patient.**
- **Unless contraindicated, always start patients on the generic form of a medication if one is available in the same therapeutic class.**
- **Make sure you've met all of the payer's criteria before submitting a prior authorization request.**

Legally Speaking

DISGRUNTLED PATIENTS: HOW TO RESPOND TO BAD ONLINE REVIEWS

Q I have a disgruntled patient who came in once and is now bad mouthing me on multiple Web sites that review physicians. She is entitled to her opinion (as long there is no slander). If I called her or you called as my attorney, it might make it worse. Any advice?

ANYONE IIT'S COMMENDABLE you check Web sites and are aware of the impact on your practice. Your basic assessment is probably, and unfortunately, correct.

Defamation is defined by Black's Law Dictionary as "the act of harming the reputation of another by making a false statement to a third person." If the statement is written, the allegation is libel. It's called slander if spoken.

In a defamation case, a plaintiff must prove that a statement is false and that the false statement led to damages. Three elements must be proved: A statement, proof that the statement is false, and damages.

Most comments posted on the Web do not rise to the level of defamation. Most Web sites, including social media and blogs, consist almost exclusively of opinions.

While hurtful and damaging, most posts usually do not contain facts that can be proven true or false. A patient complaning that the doctor "did not listen" or "was sloppy" are opinions. Even accusations that "the doctor was negligent" or "the doctor committed malpractice" are opinions that are a matter of debate.

The typical legal standard is whether a reasonable person would understand a statement to be an opinion or fact. The statement: "In my opinion, Dr. Smith murdered my mother," could be proved true or false by a reasonable person. It could, therefore, give rise to a lawsuit for defamation.

Depending on state law, a statement may be considered "defamation *per se*." That means the it is defamatory on its face and is not capable of an innocent meaning. Examples of defamation *per se* against a doctor could be, "He is practicing without a license" or, "He has been found guilty of Medicare fraud."

The truth is always a defense in any defamation claim. If a doctor really did lose his or her license or was found guilty of Medicare fraud, then the doctor would have no valid lawsuit for defamation. If he or she proves to have a license or a clean Medicare record, then the doctor has a basis to sue.

FInally, consider that libel damages are difficult to prove. The good news is that courts usually hold that damage may be assumed when a statement will harm the person's reputation and business.

Here are some actions you can consider:

- **Reach out to the patient to propose a solution. You can have your staff make a follow-up call and even ask about patient satisfaction.**
- **Don't be confrontational. Offer to see the patient and fix the problem.**
- **Start a positive campaign. Ask loyal patients and respected colleagues to post their opinions online too.**

The Web can be good for a physician's reputation, but it can also be destructive. Be smarter about the Web, and you will be able to protect your good name. ◘

Answers to readers' questions were provided by Lee J. Johnson, ***a health law attorney in Mount Kisco, New York, and a Medical Economics consultant.*** *Send your practice management questions to* ***medec@advanstar.com****.*

ENVISION NEW **POSSIBILITIES**

Invokana™
canagliflozin tablets

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

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

IMPORTANT SAFETY INFORMATION

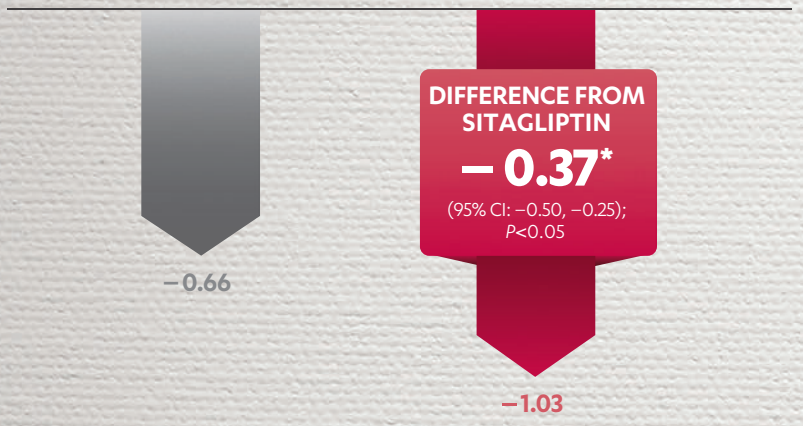
CONTRAINDICATIONS

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

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

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

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



Incidence of Hypoglycemia

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

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

Convenient Once-Daily Oral Dosing[1]

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

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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS and PRECAUTIONS

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

COVERED BY MORE THAN **75%** OF COMMERCIAL HEALTH PLANS[3]

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

Change in Body Weight†

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

- Difference from sitagliptin‡:
  300 mg: **–2.8%**

Change in SBP†

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

- Difference from sitagliptin‡:
  300 mg: **–5.9 mm Hg**

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

†Prespecified secondary endpoint.

‡Adjusted mean.

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

Adverse Reactions

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

References: 1. INVOKANA™ [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; 2013. **2.** Schernthaner G, Gross JL, Rosenstock J, et al. Canagliflozin compared with sitagliptin for patients with type 2 diabetes who do not have adequate glycemic control with metformin plus sulfonylurea: a 52-week randomized trial. *Diabetes Care*. doi:10.2337/dc12-2491. **3.** Data on file. Janssen Pharmaceuticals, Inc., Titusville, NJ. Data as of 8/9/13.

SGLT2 = sodium glucose co-transporter-2.

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

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

- **Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues:** Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA™.
- **Genital Mycotic Infections:** INVOKANA™ increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections. Monitor and treat appropriately.
- **Hypersensitivity Reactions:** Hypersensitivity reactions (eg, generalized urticaria), some serious, were reported with INVOKANA™ treatment; these reactions generally occurred within hours to days after initiating INVOKANA™. If hypersensitivity reactions occur, discontinue use of INVOKANA™; treat per standard of care and monitor until signs and symptoms resolve.
- **Increases in Low-Density Lipoprotein (LDL-C):** Dose-related increases in LDL-C occur with INVOKANA™. Monitor LDL-C and treat per standard of care after initiating INVOKANA™.
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA™ or any other antidiabetic drug.

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

ENVISION NEW
POSSIBILITIES

Invokana™
canagliflozin tablets

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS

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

USE IN SPECIFIC POPULATIONS

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

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

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

Janssen Pharmaceuticals, Inc.

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

OVERDOSAGE

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

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

ADVERSE REACTIONS

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

K02CAN13149

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

Invokana™
canagliflozin tablets

janssen
PHARMACEUTICAL COMPANIES OF Johnson&Johnson

INVOKANA™

(canagliflozin) tablets, for oral use

Brief Summary of Prescribing Information.

INDICATIONS AND USAGE

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

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

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

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

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

ADVERSE REACTIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

INVOKANA™ (canagliflozin) tablets

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

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

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

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

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

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

* Includes placebo and active-comparator groups

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

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

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

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

* Week 26 in mITT LOCF population

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

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

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

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

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

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

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

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

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies

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

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

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

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

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

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

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

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

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

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

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

DRUG INTERACTIONS

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

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

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

USE IN SPECIFIC POPULATIONS

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

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

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

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

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

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

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

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

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

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OVERDOSAGE

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

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

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

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

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

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

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

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

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

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

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

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

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

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

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

Active ingredient made in Belgium

Finished product manufactured by:
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Gurabo, PR 00778

Manufactured for:
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Titusville, NJ 08560

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Practical Matters

HOW TO KEEP YOUR PRACTICE SUPERSTARS

Q How can practices motivate and retain their superstar employees in the face of declining reimbursements?

SUPERSTARS ARE HARD to replace. These employees know your practice, know your patients and have skills and experience that add up to more than one full-time-equivalent on your payroll. You have a superstar if your worker does a great job, has the respect of co-workers and is always reliable. These A-plus workers rarely have bad days and even then they only drop to an A-minus. Doing B-plus work is out of the question for a superstar.

When you lose a star player you don't just lose their work value, you lose a great example for other employees and peace of mind from knowing your work is in good hands. Turnover at this level can demoralize the rest of the staff. They're going to have a heavier workload while you search for a replacement and might dread working an unproven stranger into the office culture.

Superior performers are highly motivated. The smart employer needs to know precisely what it is about the job and workplace that keeps a superstar on the payroll. A good working understanding of Maslow's hierarchy of needs doesn't hurt. [illustration] Superstars are motivated by higher-order needs—esteem conferred by people they respect, a sense of doing important work well, and being part of an effective team.

Your employees can reach superstar status only if their lower-order needs are met: The paycheck is good and working conditions are fair. Good employees may leave because they are lured away (someone else promises something missing in your practice) or because they are driven out (something in your practice is intolerable).

Superstars know they do a great job but they need to know you recognize it and appreciate it. Here are some things you can do to cement stars on the team and help good workers become super.

1. **Recognize good work publicly.** Managers should do it in staff meetings, and it's most effective when celebrated by a physician. Employee of the month is in this category (but we see too many instances where the honor was last awarded in 2006). Heroic handling of a patient situation calls for a "thank you" in public from a doctor or manager at the end of the day. Standing by the back door saying thank you to exiting employees occasionally is a smart use of a doctor's time, even if it has them scratching their heads and wondering what that was all about as they walk to their cars.

2. **Titles confer respect and esteem.** Adding the words "lead" or "senior" to a name badge might even encourage a worker to wear it. "Coordinator" connotes more than "medical assistant" or "receptionist."

3. **Asking workers for help thinking through a practice problem is another way to signal you respect and value employees.** There is no better example of esteem than for a physician to ask an employee for his or her opinions on a tough problem, and it works even if you have already decided what you're going to do. You don't have to accept the advice but it costs nothing to listen to it.

4. **Asking a superstar to mentor newbies on the job is another way to bestow esteem publicly.**

Practical Matters

How do you help an employee with potential become a superstar? If your worker is a B-plus or better employee, make sure you are paying near the top of the competitive market. State and local chapters of the Medical Group Management Association and medical societies often compile compensation surveys. But be careful about "national" surveys since compensation is highly local. Workers in midtown Manhattan or Beverly Hills are paid a premium because of higher living costs.

Once you are paying at the very top of the market, giving a raise could represent wasted money—or worse. Our experience is that overpaid workers often dread the day the boss figures it out and gets even. It can be a source of anxiety that hurts job performance.

Job security, fair treatment, and workplace safety are important to employees. In today's world of declining reimbursements, lower revenue means budget pressure on staff compensation. But that is the employer's problem to deal with. Physicians and managers should never talk about such matters in the presence of the staff because it can cause anxiety about job security, which can lead to distracted job performance and behavior. It can also stoke resentment if the doctor then drives away in a $90,000 car.

Never talk about declining revenue in the presence of the staff—it causes anxiety about job security, which leads to distracted performance and behavior.

Fair treatment is important, especially where superstars are concerned. There's a fine line between recognizing a superstar's accomplishments and creating a 'sacred cow' or favorite in the eyes of other workers. If you allow a superstar to get away with murder (as colleagues may see it), her star may lose its luster.

Creating a safer workplace starts with listening to your staff's concerns. If your employees feel uncomfortable walking to their cars at night, putting lighting in the parking lot would send a message that you care about your workers. Such actions can only create a more loyal workforce.

Remember, workers want a sense of belonging to the team. If you don't have a harmonious team it can be a very difficult problem to correct. Low morale at the office can lead to poor job performance, lack of motivation, and backbiting and gossip.

Show the money

There may be a reward you have not considered. Consider other creative benefits such as:

1. **Leasing a car for the superstar.** A nice car might only cost $400 per month--$2.30 per hour. We know of a front-office staffer who was a single parent with a 16-year-old daughter and only one old car between them. Helping that employee with her transportation needs helped save the practice when the physician was out on disability.

2. **What about tuition assistance for a dependent child at a really great school close to the office?** You could be solving a couple of practical problems for a star player.

3. **How much paid time off does your star receive?** Increasing the paid time off does not raise your overhead at all, but it effectively raises your superstar's rate of pay for the hours worked. Just be sure the time is taken when it least harms daily operations.

The better you know your staff the more responsive you can be when trying to motivate them. Talk to them to find out what they need or wish for. Make their job too good to lose. ◘

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

Money

Uncovering the mysteries of RUC

What is the role of the medical committee that advises Medicare on relative values?

by **SCOTT BALTIC,** *Contributing Author*

HIGHLIGHTS

01 Critics of the Relative Value Scale Update Committee (RUC) claim it undervalues the services provided by primary care physicians, but RUC supporters say primary care compensation is increasing appropriately.

02 Legislation introduced in Congress earlier this year would create an oversight panel to review the work of the RUC.

Physicians who treat Medicare patients instinctively know that there's a process involved in setting payment rates for services and a committee that's responsible for the task. Lately, some industry observers have characterized the group—the American Medical Association (AMA)/Specialty Society Relative Value Scale Update Committee (RUC)—in one of two ways: ▸▸

- As an obscure medical committee that meets three times each year to do tedious evaluations that help the Centers for Medicare and Medicaid Services (CMS) set Medicare rates for physician reimbursements; or
- As a secretive, highly politicized group that wields enormous influence over physician reimbursements—from both Medicare and private insurers—that also has conflicting interests and little oversight.

The answer might be somewhere in the middle, but it depends on who you talk to.

According to the AMA, RUC makes annual recommendations to CMS regarding new and revised physician services and performs broad reviews of the Resource-Based Relative Value Scale (RBRVS) every 5 years. RBRVS is a function that weighs physicians' services relative to their value and time investment to arrive at a benchmark

for compensation on behalf of the Medicare program. It's not actual dollar figures, but relative values.

What is most important to note is the broad influence RUC has on how much physicians get paid both in the Medicare program directly and in the private market. While the committee makes recommendations for relative value, those recommendations carry great weight as industry-wide benchmarks for actual-dollar payment rates.

RUC participants and critics have polarizing views, and there is a need to discover RUC's role in the world of healthcare, both today and for the future. We hope this article produces more light than heat, which might be an improvement over recent mainstream media coverage that over the past few years has explained, and to varying extents, excoriated the RUC.

For example, an article in the Feb. 20, 2007, *Annals of Internal Medicine* discussing the income gap between primary care and specialties blamed the over-representation of specialty physicians on the RUC for the lower incomes of primary care providers (PCPs).

But perhaps the most vilifying headline appeared on a July/August 2013 article in *Washington Monthly*: "Special Deal: The shadowy cartel of doctors that controls Medicare." It and other articles are clear on a number of criticisms.

Critics: There is weak representation of primary care on RUC, therefore RUC is skewed in favor of specialists.

The negative articles criticize RUC based largely on the same issues, with much of the focus falling on the committee's purported effects on reimbursements for PCPs.

The committee is in fact heavier on medical specialists than PCPs by head count, which at least encourages the ongoing tendency for current procedural terminology (CPT) codes to be reimbursed more generously than cognitive codes, such as those for patient Evaluation and Management (E/M). And since PCPs tend to engage in a higher proportion of activities that fall under E/M codes, a related criticism is that the updating process undervalues the work of PCPs.

Even so, issues persist around payments for procedural codes versus those for cognitive codes. "RUC represents that tension, but it doesn't define it," says David Muhlestein, director of research for healthcare consultants Leavitt Partners LLC.

RUC: Primary care compensation is increasing appropriately.

From 1991 to 2011, the portion of Medicare money paid to primary care increased from 37% to 43% while the portion going to surgical specialties dropped from 32% to 21%, according to William L. Rich III, M.D., FACS, an ophthalmologist and former RUC chair. Similarly, reimbursement for routine office visits with established patients (E/M code 99213) has risen from $32 to $66 since 1995, he says.

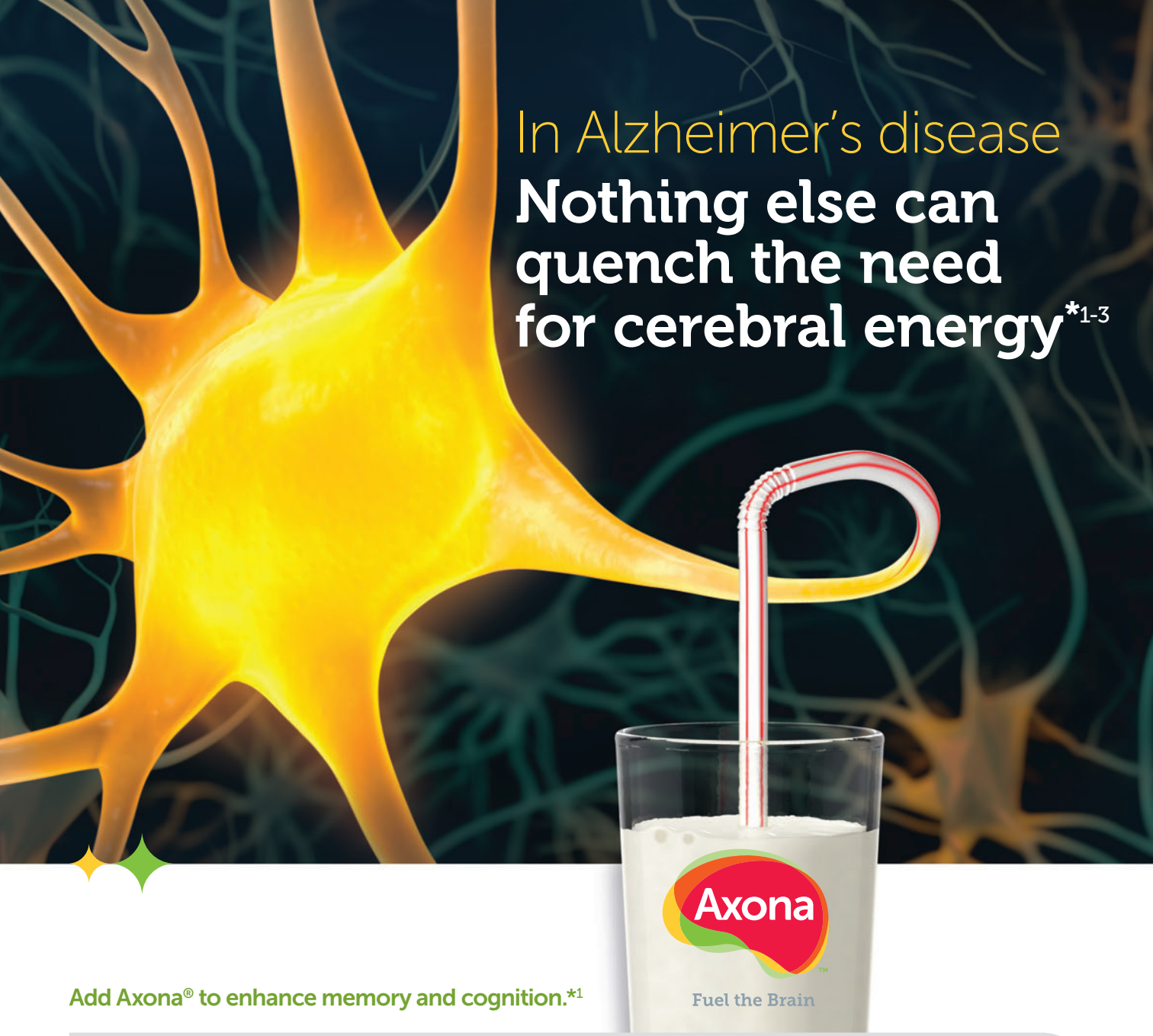
"There has been a redistribution of valuation by the RUC," says Rich. "There has been an absolute shift of dollars to primary care, appropriately. "He adds that in the past 2 years and on its own initiative, RUC has added valuations for care coordination, team education ,and phone calls.

Glen Stream, M.D., past president and former board chair of the American Academy of Family Physicians (AAFP), counters that though the tide is turning back toward primary care, it's only "to a small and inadequate degree." He points out that the common codes (E/M 99213 and 99214, which includes moderate-complexity medical decision-making) are also embedded in many codes for surgical procedures, such as for pre-op and follow-up visits. Therefore, increasing the pay for common codes helps PCPs less than might initially seem the case.

The AAFP has recommended to CMS that the agency create primary-care–specific E/M codes. The academy's position is that evaluation and management work in primary care is more demanding and complex than in specialties, especially with an aging population that often presents with multiple or chronic conditions.

But the whole idea behind RUC and its value determinations is to arrive at relatively fair compensation for time and skill. Each CPT code—created exclusively by the AMA to document healthcare services for the purpose of reimbursement—has a Relative Value Unit (RVU) assigned to it. When the RVU is multiplied by a conversion factor and a geographical adjustment, it produces the compensation for a particular service.

➔38



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Please see full prescribing information at www.about-axona.com.

References: 1. Henderson ST, Vogel JL, Barr LJ, et al. Study of the ketogenic agent AC-1202 in mild to moderate Alzheimer's disease: a randomized, double-blind, placebo-controlled, multicenter trial. *Nutr Metab (Lond).* 2009;6:31. **2.** Cunnane S, Nugent S, Roy M, et al. Brain fuel metabolism, aging, and Alzheimer's disease. *Nutrition.* 2011;27(1):3-20. **3.** National Institute on Aging. Alzheimer's disease [fact sheet]. http://www.nia.nih.gov/sites/default/files/alzheimers_disease_fact_sheet_0.pdf. Reprinted September 2012. Accessed June 4, 2013.

Accera

➔36 RVU numbers are translated into actual reimbursement dollars by the CMS conversion factor, which is flat, or the same for all specialties, says Barbara S. Levy, M.D., the current RUC chair and vice president of health policy for the American College of Obstetricians and Gynecologists. She adds that private insurers' conversion factors are affected by market forces, such as the availability of a given specialty in a certain area, and so aren't necessarily flat.

Although it's not the only formula, private insurers often use Medicare rates as a baseline for their separately negotiated rates with providers. Market forces, quality programs, pay for performance and other factors figure in as well.

Critics: Service time metrics can become out-of-date with medical advances.

Other criticisms of the RUC cover a wide range of issues. For example, the amount of time attributed to many procedures has remained high even as the procedures have advanced to become more routine and to require less of the physician's time than previously documented.

The *Washington Post* article noted that 78 physicians in Florida had—on paper—performed at least 24 hours worth of procedures in a single work day based on RVU figures, which would be clearly impossible in the real world. And reportedly, certain ophthalmologists performed 30 to 40 procedures in a single day, which would have been 30-plus hours worth of work based on RVU figures.

RUC: The numbers must be examined in context.

In a press release shortly after the article appeared, the AMA stated that it had asked to see the magazine's cited data for the Florida physicians, but that the documentation was not provided. Regarding the ophthalmologists, the association noted that the procedures cited appeared to have included LASIK, for which RVU values have never been determined, because the procedure is not covered by Medicare.

As to the system not addressing procedures that have become more efficient, Rich says that over a 10-year period, he went from doing three cataract surgeries in about 7 hours to doing 10, but his reimbursement per surgery declined significantly. The Medicare reimbursement for cataract surgery was $941 in 1995 and is $578 currently (figures not adjusted for inflation), Rich says.

Critics: CMS essentially rubber-stamps the RUC's recommendations.

Historically, CMS has approved more than 90% of RUC recommendations. The raw numbers are hard to argue with, but the reasons for them are hotly debated. Many question whether new payment models will force CMS to push back on some of the RUC determinations.

RUC: The committee is doing its job well.

The fact that CMS accepts the vast majority of the committee's recommendations is an indication of how carefully and fairly the RUC does its job, according to the AMA.

In addition, RUC leaders point to the fact that CMS "listens to every debate," says Rich. So what the committee does and how it does it is completely transparent to CMS. Stream agrees that CMS has been "more discerning" lately about accepting the RUC's valuations.

Critics: RUC is "secretive."

In not publishing the results of RVU votes and in requiring a broad nondisclosure agreement from any non-members allowed to attend a meeting, RUC appears to be less than transparent in its decision-making process. The lack of transparency engenders much of the distrust of the committee, says Stream.

RUC: Some information is better kept within the committee.

RUC meetings are closed for good reasons, principally that new CPT codes requiring an RVU recommendation often involve new medical devices, and RUC doesn't want its deliberations to become fodder for the stock market. "They [CMS] don't want Wall Street responding to the debates in that room," says Rich.

TRANSFORMING RUC FROM THE INSIDE

So is the RUC deservedly as controversial as mainstream media portrays? Or is it more of a lightning rod for a variety of contentious, persistent issues around Medicare reimbursements andfee-for-service payments?

In a September post on the American College of Physicians' ACP Internist Blog, Robert M. Centor, MD, FACP, an academic general internist and associate dean at the University of Alabama School of Medicine, writes: ". . . the RUC did not create the system. They try hard to balance a system that is designed to achieve the wrong outcomes. The RUC has become a very easy and attractive kicking post, but the problem comes from the idea of resource-based relative value units."

And RUC leadership has been moving to address at least a couple of the concerns highlighted by recent media coverage. For example, one allegation has been that RUC members vote in blocs and that the surgeons or other specialties agree to vote in concert. Around 1999 and 2000, Levy says, "there were factions" that would meet separately the night before a meeting to plan their votes, but both she and Rich worked hard to drive that attitude out.

Levy tells members, "When you sit on the RUC, you're representing the house of medicine," not a particular society or specialty. "People are not voting in blocs," currently, she says, adding, "most of our votes are overwhelming. Generally it's not close."

One way she and Rich brought about a cultural shift, Levy says, was procedural. The typical agenda book for a RUC meeting is massive, up to 3,000 pages, so this material is now divided up and assigned to advance reviewers who are from specialties different than the specific codes they're reviewing. These reviewers also become the lead commenters on those codes during the meeting.

In addition, Levy says, RUC votes will be published for the first time after CMS publishes its final rule—likely in November. The votes will be reported only as totals for and against a given RVU assignment, however, not as individual voting records. "We have to have" that level of anonymity, says Levy. She doesn't want to risk RUC members being punished for voting against their specialty society's narrow interests, which she says happens commonly.

The RBRVS update process is based entirely on effort, so it's lacking any elements connected with health outcomes or the value to a patient of a procedure or E/M. RUC's leadership and outside observers agree that the change is unlikely to happen any time soon.

Physician payments should be based to an extent on effort, as they currently are, says Roy Poses, M.D., clinical associate professor of medicine at Brown University, and blogger who has followed the RUC for half a dozen years. But the most important thing to add to the RBRVS, he says, would be "some measure of value for the patient … Ideally, effectiveness ought to be part of it. The problem is, that's really hard to measure."

When the RUC was established, it was supposed to include a valuation proposition, Rich says, but the committee didn't have such tools in 1989. "We're starting to find ways to measure value to the patient," such as patient-related outcomes, he says.

Levy says she'd like to see RBRVS add factors for relative patient benefit, as demonstrated by outcomes research, and add a factor for cost-effectiveness. By law, however, the only factors that can be considered currently in the RBRVS are work, practice expenses, and malpractice insurance expenses, along with "a bit of a geographic modifier," says Levy. As a result, the RUC can't yet consider a procedure's value to the patient or to society.

TRANSFORMING RUC FROM THE OUTSIDE

The Affordable Care Act mandates that CMS establish a process to validate RVUs of physician fee schedule services, and the agency has contracted with the Urban Institute and the RAND Corp. to do so.

The Urban Institute project is intended to give CMS a way to review proposed work RVUs, assess how reasonable they are in terms of external data, and ensure that the overall RBRVS fee schedule is internally consistent within families of services and specialties. The project will examine the work RVUs for 100 services in the physician fee schedule. Clinical panels made up of physicians from a range of specialties will review the new data regarding the time necessary to perform specific services and procedures.

Over a two-year period, the RAND project will build a validation model to predict work RVUs and their time and intensity components.

"The model design will be informed by the statistical methodologies and approach used to develop the initial work RVUs and to identify potentially misvalued procedures under current RUC and CMS processes," ac-

cording to RAND. CMS will provide a sample of CPT codes to test the model.

One of the questions underlying these efforts is who would be better qualified to determine physician work values than the physicians themselves? Could a body substantially different from RUC do the same job, but better?

Levy is skeptical, noting that almost everyone on RUC is a practicing physician. She questions how a non-physician could set RVUs, particularly the aspects of a procedure's intensity and the potential harm that might result.

Health services researchers originally developed the RVU concept, so presumably they would be qualified to do RUC's work, says Muhlestein, though he isn't aware of any significant current research efforts along this line. "It's hard to get non-physicians really interested" in this kind of work, he adds.

On one hand, Muhlestein explains, the reported $7 million that the AMA spends annually to operate RUC is roughly one ten-thousandth of the approximately $60 billion a year that Medicare pays in physicians fees, so more effort in ensuring that RVU allocations are accurate wouldn't be a big hit on the federal budget. On the other hand, he points out, Congress has never given CMS the resources to replace or supplement the RUC.

Calling RUC's procedures "complicated and opaque," Brown University's Poses says RBRVS should be updated by a federal advisory committee whose members are appointed by the federal government; which accepts open, public comments; and which includes "some representation by patients and taxpayers."

OVERSIGHT PANEL PROPOSED

A potential step in the direction that Muhlestein and Poses suggest came in June, when U.S. Rep. Jim McDermott (D-Wash.) introduced a bill that would create a new panel to oversee the RUC.

In a press release, McDermott's office said the RUC "is unevenly weighted by procedural specialists over primary care doctors and relies heavily on anecdotal and self-serving survey evidence, rather than forensic data."

Based on a recommendation from the Medicare Payment Advisory Committee, the Accuracy in Medicare Physician Payment Act of 2013 introduced by McDermott would establish a panel of independent experts within CMS "to identify distortions in the fee schedule and develop evidence to justify more accurate updates."

The panel's members would include patient representatives, and the group would be subject to the Federal Advisory Committee Act, which requires such bodies to hold open meetings and publish their minutes. Under the bill, Medicare could continue to request work from the RUC, but the new panel would both initiate such requests and review the RUC's work.

THE FUTURE OF THE RBRVS

It's clear that RUC is, for better or worse, handcuffed to the RBRVS, which was built on a fee-for-service model. With or without major changes, what might the future hold for the RBRVS?

Even within group practices, accountable care organizations (ACOs) and other care models, rewards need to be apportioned somehow, says Rich, either by RVU or some equivalent, and the current RVU assignments are already very commonly used for such purposes. "These are not going away. They're always going to be needed," he says, even if the fee-for-service model fades somewhat.

Levy adds that in addition to being part of how ACOs apportion salaries, the RBRVS is likely to be part of any bundled-payment valuations.

The RVU is "the default standard" for such purposes, Muhlestein agrees. He notes that Leavitt Partners' Center for Accountable Care Intelligence has been tracking ACOs and their payment arrangements for about 3 years and has concluded that most contracts are still fee-for-service-based. In addition, the ACOs in the Medicare Shared Savings Program are all based on fee-for-service, he says.

In March Catalyst for Payment Reform (CPR), a national, not-for-profit collaborative of large employers, found that 10.9% of commercial healthcare payments today are tied to value rather than volume.

The biggest take-away from the current controversy about RBRVS and its updates, Muhlestein says, is simply that "RUC is still very relevant and will be relevant for a long time."

Start slow with quality-based compensation

Creating a plan to increase pay based performance is a gradual change, not a leap of faith

by **BETH THOMAS HERTZ**

HIGHLIGHTS

01 Quality-based compensation plans will vary based on the size and goals of your practice.

02 Whether or not it is profitable right now, it is a good idea to start thinking about how to implement quality-based compensation plans.

Is it too soon into the era of quality metrics–favoring value over volume–for primary care practices to revise how they pay their employed physicians? Several experts disagree.

Alice G. Gosfield, J.D., an attorney in Philadelphia, Pennsylvania, and a *Medical Economics* editorial consultant, who specializes in health law and healthcare regulation with an emphasis on physician representation, finds that money from value-incentive plans is slowly starting to reach physicians.

She conducted an informal survey of several major clinics in 2007 and found that pay-for-performance dollars were not making their way to physicians. But when she repeated it in 2011, she received twice as many responses and found that more organizations were compensating physicians for quality results.

Some give stipends, while others measure performance, she says. For example, the Billings Clinic, in Billings, Colorado, started with primary care and now each specialty picks its own metrics for compensation bonuses.

Gosfield says groups tend to start with primary care when making this change. "That is likely because it's the place where most patients first access the healthcare system. To get the biggest benefit, they want to make to be sure that their patients coming in the door are treated effectively," she says.

However, some experts are less optimistic that quality metrics will pay enough anytime soon for them to alter private primary care practice compensation.

Reed Tinsley, CPA, a Houston, Texas-based healthcare consultant, says the big question with making such a switch is "What's in it for the practice?"

"Until this market moves to a payment-for-quality system, which I don't think it ever will because no one can define quality, how does a practice benefit in the long run? How is it going it make money doing this? It's not," Tinsley says.

Justin Chamblee, MAcc, CPA, a vice president at Coker Group in Alpharetta, Georgia, says that most private groups, whether they have two or 200 employees, are struggling with this issue.

"One of the things we always recommend to private groups is to make

"PATIENT SATISFACTION SCORES ARE SO IMPORTANT TO A SMALL PRACTICE—I AM AMAZED AT HOW BAD CUSTOMER SERVICE CAN BE."

—REED TINSLEY, CPA, HOUSTON, TEXAS

sure that incentives are aligned. There is a big push to move from volume to value but in many markets, the reimbursement mix may not have changed yet enough to really make this work," he says, adding that practices are still largely paid via fee-for-service.

"We say start thinking about these value-based metrics but don't go crazy changing your compensation model because you can actually do more harm than good by moving to a model that is largely focused on value when your revenue is still being driven by volume," Chamblee says.

Gosfield agrees. "You can't switch your internal compensation system to a methodology that doesn't take into account how the dollars are actually generated into the practice," she says.

MEASURING COMES BEFORE PAYING

However, you will never be able to reward employees based on quality if you do not measure for it. Once employees know you are measuring to determine increased compensation, they will pay attention to it, Gosfield says.

"There are three truisms in quality measurement. First, you cannot improve what you do not measure. The second is, what gets measured is what gets done. If you start to apply quality measures, people will work to get an A," she says. "The third rule is, so be careful what you measure."

Start with one initial quality measurement, she suggests, slowly adding in more, gradually reaching about 8 to 10. The physician' "risk" to their salary should be no more than 5% to 10% of their pay, she says.

BE PROACTIVE

Chamblee says his group recommends that private practices actively seek out value-based options and payments.

"Look at the opportunities related to clinically integrated networks, joining Medicare accountable care organizations, pursuing patient-centered medical home models. There are a lot of potential dollars out there but it's really incumbent upon a private group to go after those," he says.

Finding these opportunities is so important because many private practices now are a zero-sum game: Revenue less expenses dictates what physicians are paid.

"It is a lot easier to start incentivizing based on quality when the funds are coming separately to provide that incentive as opposed to using current dollars that have been earned based upon volume and making physicians earn that money again," Chamblee says.

Tinsley negotiates with numerous managed care plans and says that the one piece of leverage he has is if a practice can show it is more cost-effective than competitors while achieving the same or better clinical outcomes. This differentiation is important because not all physicians drive costs in the network the same way. But he agrees that you have to seek out such opportunities.

"Raises don't come to you. You have to go out and ask for them," and even then many payers will say no because they do not want others providers to demand the same deal, Tinsley says.

"They don't want to get into those politics," he says. "Until the market sits down and says we are going to reward physicians,

I don't care what size of practice it is, I don't see this moving in a non-volume-based reimbursement."

GETTING STARTED

Once quality money is earned, practices can tie the distribution of that money directly to what is driving that revenue, such as achieving specific quality measures. They can supplement that with other metrics that are important to the practice, such as adoption of electronic health records (EHRs) or key measures such as patient satisfaction or keeping referrals and diagnostic testing in-house when appropriate, Chamblee says.

Gosfield and Tinsley agree that patient satisfaction is a good place to start. For example, physicians who earn high satisfaction scores could be eligible for a bonus, similar to productivity bonuses that are currently paid by some groups.

"Patient satisfaction scores are so important to a small practice—I am amazed at how bad customer service can be," Tinsley says.

Existing patients should be the biggest source of referrals in a primary care practice. Are your patients referring friends and family to you? If not, you are not a "referrable practice," he says.

"That can be the physician's fault, it could be the staff's fault, it could be everyone's fault," Tinsley says. "If you have a bad experience in a physician's office, that taintment can go a long way.

Tinsley has seen smaller practices give bonuses in the range of $5,000 to $10,000 for earning high patient satisfaction rates.

Chamblee says one way many practices share money is a scorecard approach. For example, there might be five metrics that the practice values, and each is assigned 20 points. Physicians receive an annual score of up to 100 points for how well they meet those metrics. The score can dictate payment of the dollars.

He also sees other practices, especially small ones, that just divide up any quality bonuses equally since all the physicians likely contributed to achieving those metrics.

"It can really be a simple approach or a more complex one. The more complicated ones are more important in larger practices, where it is more important to drive incentives directly," he says.

For now, Chamblee sees that incentive payments for quality achievement will most likely come in the form of annual or semi-annual bonuses, not permanent salary increases.

"The nature of this type of cash flow makes it hard to pay those on an ongoing basis," he says.

That may change as practices get more per-patient per-month payments from payers, he notes, and the dollars are more predictable.

EVEN IF THE TIME ISN'T RIGHT

Although moving to a more quality-based compensation packages may not help practices earn more money now, practice owners should still start looking for appropriate opportunities to move in that direction, Gosfield says

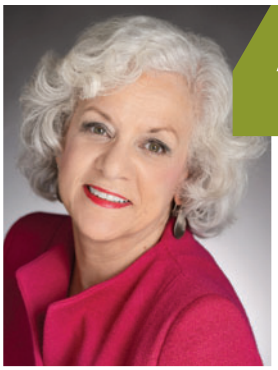
"You can still work on improving around your margins, standardization in the practice, templatized documentation, standardization in use of ancillary personnel, use of standing order sets," she says. "Even before someone pays you differently for your quality results, you ➔50

THE NURSES' ROLE

Justin Chamblee, MAcc, CPA, a vice president at Coker Group in Alpharetta, Georgia, says that nurse practitioners or other advanced practice nurses should be included in practice incentives when appropriate. Primary care is a likely place for that to occur since they more often work in a manner that is similar to a physician there.

"It depends on how they are being used," he says.

If they are seeing patients independently, they should be rewarded as such. If they are more of a support person, as is more typical in a specialist's practice, a less robust structure is probably makes more sense, he adds.



"EVEN BEFORE SOMEONE PAYS YOU DIFFERENTLY FOR YOUR QUALITY RESULTS, YOU CAN BEGIN TO LINK SOME OF YOUR COMPENSATION TO PERFORMANCE ON THOUSE KINDS OF METRICS."

—ALICE G. GOSFIELD, J.D., PHILADELPHIA, PENNSYLVANIA

➔45 can begin to link some of your compensation to performance on those kinds of metrics."

Physicians are bad at focusing on margins and instead focus on revenue, Gosfield says. They really need to ask themselves what they can do in their practice to get better quality results and improve the patient experience of care because that is what they are going to be measured on.

However, Tinsley does not see much value in rewarding physicians to take steps independent of dollars coming in at this point. For example, he sees EHR use as part of the job, not something for which employed physicians should get a financial reward. But he does support incentivizing employees for taking time to participate in activities such as serving on a quality assurance/improvement committee if a practice is part of an independent practice association.

DOWN THE ROAD

Gradually, as quality does become a bigger component in how a practice is paid, compensation packages can change accordingly, the experts say.

"What physicians get measured on is publicly available and increasingly their compensation from payers is going to turn on this stuff," Gosfield says.

Medicare's value-based purchasing modifier will be applied to groups of more than 100 physicians initially but it is inevitable that it will move to smaller groups, she says. In the meantime, smaller groups can take advantage of other opportunities such as Bridges to Excellence.

"That is additional money and practices will have to figure what they will do with it when it lands in the group. What will make your practice better and sustain or improve the results you are getting," Gosfield says.

Chamblee says that how quality incentives for employees look further down the road really depends on where fee-for-service goes.

"Our opinion is that fee for service is going to be around for a long time and volume, to some extent, will always play some role within a practice," he says.

Volume will likely dictate a good part of the compensation arrangement for some time in most markets, he adds, but says that as this model changes, the awarding of incentives should change commensurately.

@ MORE RESOURCES

The PQRS challenge
http://medicaleconomics.modernmedicine.com/medical-economics/news/tags/cms/pqrs-challenge

Learning to make quality pay
http://medicaleconomics.modernmedicine.com/medical-economics/news/learning-make-quality-pay

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Coding Insights

SCRIBES CAN HELP DOCUMENT CARE, BOOST EFFICIENCY

Some of my colleagues are interested in employing a scribe. It seems our productivity has decreased with the implementation of our electronic health record (EHR). What are the duties of a scribe and are they beneficial to a medical practice?

A MEDICAL SCRIBE is an unlicensed, trained medical information manager specializing in charting physician-patient encounters in real-time during medical exams.

A scribe can work onsite at a hospital or clinic, or from a remote, HIPAA-secure facility. A scribe enters information into the electronic health record (EHR) or chart at the direction of a physician or licensed independent practitioner.

The use of a scribe allows the provider to spend more time with the patient while ensuring accurate documentation. The scribe may not act independently but documents the physician's or licensed independent practitioner's dictation and activities.

Scribes also assist the physician or licensed independent practitioner in navigating the EHR and locating information such as test and lab results. They can support workflow and documentation for medical record coding.

Potential scribe duties

- Transcribing details of the physical exam and patient orders. This includes any lab tests, imaging tests, or medications ordered by the physician. A scribe may also be present to record a physician's consultations with family members or other physicians about a specific patient's case.
- Documenting procedures performed by the physician or any other healthcare professional, including nurses and physician assistants.
- Checking the progress of and reviewing lab, X-ray and other patient evaluation data for comparison, and transcribing the results into patient charts so that a patient's workup is complete and the physician can make sound treatment decisions.
- Recording physician-dictated diagnoses, prescriptions, and instructions for patient discharge and follow-up.
- Recording a provider's consultations with other healthcare professionals, patients, and family members.

Medical scribe qualifications

Scribes should have a number of skills to adequately perform the job. Some of those skills include:

- knowledge of medical terminology;
- recognition of the physical exam process and ability to record exam details;
- computer proficiency and ability to quickly learn new applications;
- legible handwriting and ability to accurately record information.;
- organizational skills with focus on tracking patient care and improving patient flow;
- professional demeanor and recognition of privacy considerations for patients and families; and
- the ability to multitask and act calmly in busy or stressful situations.

Scribe signature requirements

There are signature requirements for scribes as noted by organizations that use Joint Commission accreditation.

They include:

- Signing (including name and title), dating of all entries into the medical record. The role and signature of the scribe must be clearly identifiable and distinguishable from that of the physician or licensed independent practitioner or other staff. The scribe cannot enter the date and time for the physician. [RC.01.02.01] Example: "Scribed for Dr. X by name of the scribe and title" with the date and time of the entry.
- The physician or licensed independent practitioner must authenticate the entry by signing, dating, and recording the time (for deemed status purposes). A physician signature stamp is not permitted for use in the authentication of scribed entries. (Note: the physician must actually sign or authenticate through the clinical information system.)
- The authentication must

take place before the physician and scribe leave the patient care area.

- Authentication cannot be delegated to another physician or licensed independent practitioner.
- If the organization determines that the scribe will be allowed to enter orders into the medical record, those orders entered into the medical record cannot be acted on until authenticated by the physician or licensed independent practitioner who provided the orders scribed. Authentication includes the physician signature (electronic or manual) and the date and time (for deemed status purposes).
- The medical practice should implement a performance improvement process to ensure that the scribe is not acting outside of his/her job description, authentication is occurring as required, and that no orders are being acted on before they are authenticated.

(RC.01.04.01)

Evaluating your scribe program

There are several ways to determine the effectiveness of a scribe program using objective metrics. They include relative value units per hour or shift, number of patients seen per hour or shift, clinical versus administrative time, average charge per billable visit, number of incomplete and deficient charts, door-to-discharge time, and patient satisfaction survey results.

*Answers to readers' questions were provided by **Maxine Lewis, CMM, CPP, CPC-I, CCS-P,** president of Medical Coding & Reimbursement in Cincinnati, Ohio. Send your practice management questions to **medec@advanstar.com**.*

Financial Strategies

EXAMINING THE COST OF PAYER RELATIONSHIPS

By **FRANK COHEN, MPA,** *contributing author*

For the past 6 years, the American Medical Association (AMA) has produced the National Health Insurance Report card (NHIRC). This study reports on various metrics that are tied to the cost and efficiency of the claims process by reviewing data for eight of the top payers in the country.

AS THE STATISTICIAN for this project, I have been able to view firsthand how much waste and inefficiency there is within the claims process.

This past year, I participated in the creation of the Administrative Burden Index (ABI), which is a way to monetize the inefficiencies reported in the AMA's report card. The message is that hundreds of millions of dollars are wasted each year due to inefficiency and administrative burdens that are, for the most part, unnecessary. Getting paid from third-party payers for providing a service or performing a procedure for patients has become difficult at best. When you consider the vast number of payers in the mix, it becomes nearly overwhelming.

Keep in mind that most practices have several, if not dozens, of payers. Each payer has dozens of products, and those products have dozens of fee schedules. Each payer also has different contractual issues, rules, edit sets, and a myriad of other medically unnecessary and administratively burdensome procedures that ultimately increase the cost of doing business.

Practices spend between 10% and 14% of their revenue to collect 95% of what they are owed from payers—a statistic that is not repeated in any other industry. According to the AMA payer report card, nearly one in five claims is paid incorrectly. Consider that the more payers, the greater the complexity, resulting in an untenable administrative burden for most practices.

Finding balance

So how many payers are enough? I would frame the question differently: How many of the right payers are enough?

Before answering this question, you should perform some analyses to establish a foundation for comparison. Start by considering your practice's capacity. Do you have excess capacity? In other words, is your practice underutilizing what you have? Or is your practice in an over-capacity situation, where new patient might wait a month or more to see one of your doctors? Maybe the practice is at optimal capacity, where you have enough patients to cover expenses and each additional patient can be measured by variable costs only.

Analyzing costs

The next step is to conduct a resource-based relative value scale-based cost analysis. The goal is to calculate your cost-per-relative value unit (RVU) and use that to estimate what it costs to do business with a particular payer.

For example, say that your average cost per RVU is $30.40. To get the total cost for a payer, multiply the total value of RVUs billed to that provider and then multiply by the cost-per-RVU value.

Let's say that for payer XYZ, I billed out services and procedures that totaled 4,045 RVUs. Multiplied by the average of $30.40, I can estimate my base cost of doing business with that payer at $122,968.

Now, subtract this from the revenue generated from that payer for those RVUs and you have a rough version of a profit/loss statement by payer. In this example, let's say you collected $150,000 from that payer. This would give you a profit of $27,032. Divide this figure by the number of RVUs. This calculation provides a ratio that you can use to compare with the other payers in the practice. In this example, the profit ratio is $6.68 per RVU.

One caveat has to do with adjusting the base cost for waste and inefficiency. I do this by calculating the ratio of submissions to final payment. For example, assume that for payer XYZ I have to resubmit 5% of my claims. This would put the

claims ratio at 1.05, which is multiplied by the base cost amount. This would put the base cost at $129,116 ($122,906 x 1.05). Carry this through the previously discussed calculation, and you end up with a payer profit/loss ratio of $5.16 per RVU.

So if your practice is in an excess capacity situation, you may want to take and keep every contract and every payer that comes along. If your practice is operating at optimal capacity, you can be pickier about which current payers you keep and which new payers you accept.

When you are in an over-capacity situation, you can use this analysis to determine which payers to dump. Contrary to popular belief, dumping payers can (and usually does) improve profitability.

The hostage business relationship

Before we examine this in greater detail, it is important to consider the penetration (or ownership) each payer has with regard to your practice. It is my experience that you would not want any payer to be responsible for more than 10% of your revenue. I know this may sound unrealistic, particularly when considering Medicare, but the fact is that any more than 10% puts you in the "hostage stage" of business relationships.

MANY PRACTICES ARE IN A BAD FINANCIAL POSITION BECAUSE THEY ACCEPTED EVERY PAYER CONTRACT THAT CAME ALONG AND NEVER REVISITED THE CONSEQUENCES OF THOSE RELATIONSHIPS.

Look at the problem this creates with Medicare. Every year, we hear about sustainable growth rate cuts of 20% and 30% to the conversion factor, and every year Congress abates it. But what if this year Congress doesn't bail us out, and the conversion factor dives to $23.45? Many practices would either stop seeing Medicare patients, reduce the number of patients they see or—as many physicians have threatened—stop taking any new Medicare patients.

My point? If you have any payer that accounts for more than 10% of revenue, you will have to give some extra thought to the model I am describing here.

Let's say that I (as a solo doc) see 35 patients per day. At this patient volume, my practice is operating at maximum capacity. It takes a patient 3 weeks to get an appointment with me. I conduct an analysis of the 17 payers with whom I have an agreement and create a worksheet of profit/loss ratios. Dumping payers with a negative ratio is a no-brainer, because I lose money every time I see a patient connected to that payer.

What about payers that have a positive ratio? I cull them based on profitability. Let's say that I decide to dump four payers that account for a total of 9% of my revenue and have the four lowest profit ratios. I will still see 35 patients a day, only each of the patients I see will have a higher profit ratio, meaning that every day will be more profitable without doing any extra work.

The load impact will come on the back end, where the time it takes to see a new patient will drop to, say, 1 week instead of 3. (By the way, an unintended consequence will likely be that I have fewer no-shows as a result of this shortened lead time.)

While this analysis may seem a bit daunting, it is nothing more than the effort required to run a successful business. When I conduct these types of 'shoot-don't shoot' analyses, I consider factors such as accounts receivable days, hassle factor, rework, and denial rates. While it is necessary to be sensitive to the needs of the community and the patient population, profitability has to be a primary goal of any medical practice. Unless you are the federal government, you can only operate at a deficit so long before you have to close your doors.

Choosing to be in a financial relationship with third-party payers increases the complexity of the system and thus requires oversight. Many practices are in bad financial positions because they accepted every payer contract that came along and never revisited the consequences of those relationships. As my friend Henry P. Shaw used to say, "When the pain of where we are becomes greater than the fear of change, we will change."

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

Using EHRs to bring innovation to a rural practice

Can an EHR system bring efficiency to a practice that sees 10 to 15 patients a day?

by **DARIN PAINTER** *Contributing Author*

HIGHLIGHTS

01 Rural practice Pike Family Medince in Zebulon, Georgia, decided to try Aprima's EHR system to improve workflow and patient experiences.

02 Practice owner Dr. Donna Haney says she is concerned about losing her personal connection with patients while inputing EHR information.

With her personal approach, Donna Haney, MD, learns what makes patients tick, not just why they're sick. She shakes unfamiliar hands with sincerity. She talks with people instead of at them. And she's doing her best to learn the nuances of Pike Family Medicine's electronic health record (EHR) system, but she's leery of staring at her laptop too much. She'd rather look people in the eye.

IN THE city of Zebulon, Georgia, about 50 miles south of Atlanta, the 1,200 residents are within walking distance of Haney's office. In this rural region, people are down-home and direct.

"To connect, you have to listen well and try to get to know each patient," says Haney, owner of Pike Family Medicine, a small practice she began in Zebulon in 2000 after serving at a nearby hospital for four years.

"It takes longer than a few minutes to develop trust and a relationship during a patient visit," Haney says. "My style will never be to herd as many people in and out as possible. If I ever feel the pressure to do that, I'll have to find another line of work."

Haney appreciates people more than pixels, and many of Pike County's 320-plus families turn to her for a variety of health and wellness needs. In her mind, the only way to treat the local "salt of the earth" community is to remain grounded.

"I'm basically a solo practice—I don't have a nurse," Haney says. "It's just me and one front-office employee, along with my mother who's in her 70s. She's our part-time biller."

HIGH HOPES AT A CRITICAL TIME

Like her big-city brethren, Haney is in charge of upgrading technology, boosting efficiency, and delivering customized patient care. She believes it's possible to mix Pike Family Medicine's small-town feel—she treats only about 10-15 patients a day—with innovation.

Pike Family Medicine is one of 29 participants in the 2-year *Medical Economics* EHR Best Practices Study, an ongoing project intended to draw out valuable, real-world insight for healthcare leaders. Haney says she figured that using an EHR system could lead to improved workflow and patient experiences. Like other healthcare leaders, Haney realizes her practice's productivity level is contingent upon how quickly and accurately it can acquire, move, and share information.

In May 2012, Haney and her staff began using EHR technology from Aprima Medical Software Inc. The system is designed to help doctors gain more control over their time and their practice.

Aprima sent two on-site trainers to Zebulon to instruct Haney, her mother and the front-office employee—none of whom is "overly comfortable" with computers and software, Haney says.

"I had high hopes that the EHR would make life easier for us after an initial 6- or 8-month period," Haney says. "I wanted to be able to go home at night without two sacks full of charts." She figured the EHR system also might help Pike Family Medicine keep a more accurate record of when patients are due for checkups, labs, and follow-up appointments, she says.

"Ensuring proper patient care while also running a business is a big challenge," Haney says. "Other people who aren't in the medical field may laugh when I say this, but unless you're a super-specialist or a doctor who [dwells on patient volume], it's not simple to make money. To be honest, we barely make ends meet here. The office employee gets paid first, and there are literally times when my paycheck waits. When we started with EHR, I honestly wondered how much longer we could hold on. And I still have that same question today."

BIG CHALLENGES

The staff at Pike Family Medicine had problems learning the EHR system and new ways of handling patient data entry, coding, billing, scheduling, and more.

"We were pretty overwhelmed the first few days, but we're getting more comfortable with it," Haney says. "I must say, though, the trainers were excellent, and I've requested the same ones to come back and provide additional training. They were patient, and took time to show what the system was all about."

Pike Family Medicine's front-office employee welcomes patients and checks them in. She gives them a paper patient history form. Those who have not been to the practice since May 2012 aren't in the EHR system, and so Haney adds their information in Aprima after hours.

The front-office employee brings each patient to an exam room, where Haney takes vital signs, asks about the reason for the visit, forms a diagnosis, completes other patient note information in Aprima, and sends e-prescriptions through the system. She takes her laptop from room to room, so the EHR technology is at her fingertips.

"Actually, the computer is like a barrier between me and my patient. I feel like my back is to the patient too much. I try to turn around and give eye contact, but I'm furiously trying to get information in there so I don't forget by the end of the day. I have to turn around and give them eye contact to make them know I'm listening in addition to typing. The whole thing can get impersonal," she says.

The Aprima trainers assured Haney that it's fine to not complete patient notes while in the exam room, but to at least try to get most of the diagnosis in so she can print out a plan by the time the patient leaves, or mail one in a few days. "In the winter during flu season, I'm not leaving the office until 8 or 9 o'clock, because I don't have Internet access at home," she says.

One EHR feature Haney was excited about, e-prescribing, has been moderately

3 Words That Matter

EHRs affect everything that touches a patient chart, and practices that have recently adopted the technology have experienced different results. There's consensus, however, that these three concepts are critical:

Pause

Don't jump feet-first into an EHR system. Instead, take time to analyze available systems that fit your style and budget, and make certain the system can adapt to your changing needs.

Help

You really can't get enough EHR training, most practitioners and staff members say. Educate the entire team about the potential long-term value of the implementation, and be honest about invariable short-term struggles.

Play

You won't know how to maximize the value of your EHR system unless you're willing to experiment with its functionality. Practices are learning by doing. Consider picking a "point person" in the practice who can lead this charge (and lead meetings about the system), and can help answer specific questions from teammates.

successful, she says. She uses Aprima's handwriting feature on a tablet PC to write new prescriptions or quickly write refills. She can also download a patient's medication history from the pharmacy to learn if any prescriptions may conflict with medications the patient already takes.

"It's convenient, but I've made more mistakes with prescribing since going to e-prescribing. Most mistakes are when I didn't have my cursor in the right spot, or I accidentally clicked on something and didn't realize it," Haney says. Recently, she was on the phone with a pharmacy regarding a patient whocame in July for a wellness check. She sent all the patient's prescriptions through the EHR system, and the system indicated they went through successfully, but the pharmacy didn't get them. "I redo stuff like that every single day," she says.

> "I ALSO STILL HAVE HOPE THAT WE'LL BE ABLE TO KEEP PLUGGING AWAY AND DOING A LITTLE BETTER BECAUSE OF HEALTH MAINTENANCE AND IMPROVEMENTS. TIME WILL TELL."
>
> —DR. DONNA HANEY, PIKE FAMILY MEDICINE, ZEBULON, GEORGIA

Haney quickly cites another EHR issue: LabCorp can automatically place lab results and other information into Aprima, but Pike Family Medicine doesn't send enough labs to qualify for LabCorp's bidirectional interface, she says. This means the practice is getting lab results, but can't send new orders easily. "It takes a few extra steps, including printing the requisition," she says.

Haney says her comfort level with the EHR has improved, but the system still isn't as efficient as she needs. "I still have some hope that we'll get there, and it's a goal to use some features that we don't yet know enough about. That's why I've decided to get some further training. But I have to say, my general attitude toward EHRs is not good," she says.

MAINTENANCE AND FLEXIBILITY

Health maintenance is a key feature of Aprima. The system enables practices to help patients comply with medical advice and best practices via automated alerts. The EHR system can alert Pike Family Medicine to a patient's overdue tests and procedures. Also, Haney can tailor the system's health maintenance feature to fit the needs of different groups of patients. For example, she can customize information by diagnosis or by payer to accommodate carrier guidelines.

Another underused benefit of Aprima, Haney says, is the ability to enter data in her terms. Aprima provides flexible data entry options that can help physicians eliminate busywork by pre-populating fields and providing recommended codes, diagnoses, and links. Doctors can choose the method that's most familiar to them, and adapt to new methods at their own pace.

"The way Aprima enables us to enter data, we can customize the EHR to the way we operate," Haney says. "I've been able to figure out some of that customization myself, and Aprima has Web site videos that can help. But realistically, I'm busy from the time I get here."

That's why she opted to invest in additional on-site training for her and the staff. She also plans to ask the trainers about how to receive customized reports, including a demographic breakdown of her patients. "I know that's something we should be able to pull up right away, but we're so busy every day trying to keep our head above water. The training is going to be a couple thousand dollars, and that hurts."

Next May, when the 2-year study is over and Aprima will start charging Pike Family Medicine an additional monthly service fee for using the EHR system, Haney isn't sure what she'll choose to do. "I could foresee a time where we go to cash-only and say bye-bye to any EHRs, but the government may pass a law saying that's not allowable," she says. "I also still have hope that we'll be able to keep plugging away and doing a little better because of health maintenance and other improvements. Time will tell." ■

@ MORE RESOURCES

For more information about EHR best practices, visit
http://medicaleconomics.modernmedicine.com/EHRBestPractices

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The Last Word

HEALTHCARE REFORM WILL CUT COSTS, IMPROVE CARE

by **PETER B.ANDERSON, MD**

As the various provisions of the Affordable Care Act (ACA) are phased in, there's little doubt that the way physicians look at costs and decision-making will be subject to change. By focusing on quality patient care, there is a very good chance that the payment reforms that are part of the ACA will be something we look back on and wonder why they weren't implemented sooner.

IT'S CLEAR THAT changes are needed and the ACA is conveniently poised to help drive those changes.

Our traditional retrospective, fee-for-service payment system is unsustainable because it does not provide incentives for providing quality care in a more cost-effective way. A blank check is a good analogy for our health-care situation, since only the recipient of a blank check is likely to tout the advantages.

Look at an example of ACA-supported payment reform, the flat fee and assumed risk elements of bundling. Both have precedent in a number of familiar approaches, including global payments for obstetrical care, as well as the lump sums that were implemented at Dr. Denton Cooley's Texas Heart Institute in the mid-1980s.

There are other examples of payment arrangements that span multiple providers in different care settings, so this is not exactly a brave new world. But it is a different one.

Pathway to reform

The shift to quality metrics that bundled payments demand holds promise for higher quality, more coordinated care, a decrease in billing complexity, and overall improved outcomes for patients.

So why are we still hearing about how ACA payment provisions might impact the way physicians think about health costs, particularly with regard to driving behaviors and clinical decisions?

Maybe it's a vestige of the issues left over from years of fee-based abuses. A recent report from the Commonwealth Fund says, "Bundled payments may encourage providers to focus on delivering high-quality, efficient care, but they may inadvertently create incentives for providers to stint on providing appropriate care."

And therein lies the concern—that in response to reforms in general and bundled payments specifically, providers could cut back not only on unnecessary, duplicative, or defensive medicine-based care, but on appropriate care as well.

Formidable safeguards

As a counter, rationing debates and end-of-life discussions have led to ACA restrictions on Medicare service reductions and increased cost sharing by beneficiaries. Beyond that, the medical profession is highly regulated and subject to considerable legal exposure.

In addition, quality measures built into payment mechanisms will help eliminate or reduce unnecessary care.

Then there are the financial incentives. Bundling payments across multiple providers and services creates, by its very nature, a strong collective motivation to assure continuity of care and overall improved coordination. That should, in turn, reduce duplication of services as well as preventable medical errors. Budgetary accountability, with its sharing in financial gains and losses, would also support best practices and more judicious care overall.

Add the Hippocratic oath, the hope that the medical profession remains a calling for most physicians and the demands of conscience–an imperfect but powerful force – and you have some formidable safeguards to ensure appropriate care. ◘

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