Eliminate MOC’s cumbersome process and physicians will get on board

Below is a mildly edited version of an email I sent a few months ago to my only child, a partner in our practice of primary care internal medicine.

My Dear Alberto,

I originally got certified by the American Board of Internal Medicine (ABIM) in 1990. I recertified in 2000 and told myself and a few others it would be my last recertification because by 2010, I would be 58 years old, my son would be through with his training and any patient who insisted on a “board certified” doctor could see him.

I was sure that by 2000 I could retire any time I wanted, since the practice of medicine has been so good to us and we’ve been very frugal all these years. Then and now I work principally for the love of medicine and my patients. If the system wants to give me a hard time, I can go concierge or retire completely. The “fat cats” can go to hell. But will they take care of my patients? Of course not. They’re too busy being ivory tower administrators, far away from the trenches in the front lines of medicine, not actually taking care of patients.

In 30 years of private practice, only one telephone caller inquired about my board certification status. I was certified at the time but told the secretary to tell the patient we were not accepting any new patients for several months.

My real objections to the whole certification and recertification process go back a long way. The general practitioner who saved my life in 1975 when I had pneumonia and also inspired me to change career paths was not board certified by the ABIM either.

“In 30 years of private practice, only one telephone caller inquired about my board certification status.”

I only bothered with the whole certification process the first time because in the 1980s the hospitals and insurers were threatening to disaffiliate doctors who were not certified and the literature was saying there was a doctor surplus. Little did they know then and now about the topic of doctor shortage.

The second time I re-certified, I just had to pass the all-day exam, so I reviewed the then-current MKSAP and took the exam. After that, the ABIM changed the whole process to a very cumbersome, expensive, Rube Goldberg-esque experience I had no interest or time to deal with.

Reality then intervened: supply and demand; not enough primary care doctors. The insurers and hospitals backed off their threats in the ensuing years and I breathed a sigh of relief.

Now we have nurse practitioners and physician assistants practicing “primary care.” Nice people I’m sure, but not doctors of medicine. They’re certainly not board certified. So the insurers are going to pay the doctors’ helpers and the not the real doctors? I don’t think so!

I’m 63 years old now. The system knows where I’ll tell them to go if they harass me about board certification. Age, saving and investing in very low-cost indexed mutual funds and municipal bonds has its rewards!

What’s all this got to do with you, my son? You hopefully have another 40 years or more in medicine and it certainly doesn’t hurt to be board certified. If they do change the process to what [the ABIM has suggested in reforms] I’ll probably do it too. Continuous quality improvement is more than a slogan or motto. I try to live by it every day.

Dad

Frank Savoretti, MD, JD, completed his residency in internal medicine at the Bronx-Lebanon Hospital Center, Bronx, New York, after which he opened up his private practice in Johnston, Rhode Island.

Do you agree with the author on MOC? Tell us at medec@advanstar.com

READ MORE INSIDE Inside the revolt against MOC PAGE 24
Inside the physician recertification revolt

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Threading the needle on medical necessity

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5 ways to minimize the damage and improve your practice
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“The practice of defensive medicine will not go away until there are major changes to our medical legal system.”

RICHARD ANDERSON, MD, THE DOCTORS COMPANY

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83.3% Percentage of internists due for recertification that had enrolled in 2015.

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“Anytime there is a handoff to another provider, it adds ... a potential area where errors can occur.”

DANIELLE SNYDERMAN, PHD, THOMAS JEFFERSON UNIVERSITY

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Alternatives to-and skepticism about-MOC

In his opinion piece regarding maintenance of certification, (“Maintenance of certification exams have dubious value,” February 10, 2016), James Merino, MD listed major concerns of a wide number of physicians regarding the whole process of board certification. He stated that “The secure examination needs to be a thing of the past, and I hope that others will continue to protest until our voices have been heard.”

In 2011, the National Board of Clinical Medicine, Inc. (NBCM) was established, in part, to address similar concerns. The NBCM offers an option for physicians with regard to board certification, recertification and maintenance of certification. The format of the NBCM is a one-time, open book, at-home exam whose sources of questions are clearly listed for the physician to review. Questions are based upon published practice parameters and guidelines that relate to the clinical aspects of medicine.

So far, this has been established for allergist/immunologists. We have received overwhelmingly positive and enthusiastic support from physicians nationwide. The NBCM is recognized as a positive move with regard to board certification. Specialties other than Allergy and Immunology are welcome to be part of this process.

The NBCM strongly believes that board certification should be a positive process where learning occurs, and it should be voluntary. Physicians should have options regarding board certification. Board certification should be a voluntary process that offers value to the physician. It should not be used to discriminate against physicians with regard to hiring, insurance network participation or hospital staff privileges.

Medical Economics has been a leader in covering this topic. I am grateful that this magazine continues to offer insight and open discussion with regard to this very important and controversial topic.

Martin S. Dubravec, MD
CADILLAC, MICHIGAN
The writer is the founder and chief executive officer of the National Board of Clinical Medicine, Inc.

I have followed the entire ABIM MOC controversy from its inception and eventually joined the National Board of Physicians and Surgeons, applauding Dr. Teirstein and others for their dedication to a reasonable board certification process. I wonder when member boards will follow suit. Why the silence?

I am involved in the ABOG MOC process, which is very similar. I passed boards in 1994 with flying colors, promised board certification for life, then presto, MOC each year along with its $600-plus price tag this year. Simple math reveals tens of millions of dollars a year to fund an organization that lends little to no contribution to professional development for practicing clinicians.

Roger Brecheen, MD
FORT BRAGG, CALIFORNIA

I can understand Lee Morgentaler, MD’s concerns about “physician extenders” working in a capacity traditionally reserved for doctors. (“Physician extenders are not the same as doctors,” November 25, 2015.) However, primary care has changed over the past few decades, and in most areas of the country primary care doctors’ roles have changed immensely. They are no longer the “do it all” doctors. Many no longer take care of hospital or nursing home patients. Others have limited their practices to only adult medicine but there are other changes as well.

The rapid advances in medicine, the regulations of insurers, and the threat of lawsuits all play a role. In additions many primary care doctors want more free time for family and for personal pursuits. The point is that if physician assistants and nurse practitioners (PAs and NPs) practice within the limits of their training and abilities as recommended by the Institute of Medicine, they could and should join the primary care workforce.

The shortage of primary care doctors is acute and many are overworked and burned out. Nurse practitioners have already gained licensing rights to practice independently. Clearly they have an important role to play in providing primary care.

Edward Volpintesta, MD
BETHEL, CONNECTICUT
The board members and consultants contribute expertise and analysis that help shape the content of Medical Economics.
A recent government report shows the Affordable Care Act (ACA) is still far from achieving one of its many goals, according to a new government report. While the ACA has brought the number of people without health insurance to a historic low, it has yet to reduce visits to emergency departments (EDs), where the uninsured often go to receive care—but are also strained with high volumes of patients and deliver more costly services, reports *U.S. News and World Report*.

Findings from the Centers for Disease Control and Prevention (CDC) suggest that lack of healthcare coverage is not the only major factor keeping people from defaulting to EDs for care, and that ED use “has not changed significantly after the first full year of ACA implementation.”

The CDC report used data from the 2013 and 2014 National Health Interview Survey to assess why and how often people went to the ED. Data from 2014, the year that insurance exchanges in the ACA went into effect, showed the percentage of adults visiting the ED did not change much from the previous year, despite 7.9 million people gaining coverage between the two years.

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**ADULT EMERGENCY ROOM VISITS**

**2013 AND 2014**

- **TOTAL**
  - Two visits or more: 37.7% (2013), 35.2% (2014)
  - One visit: 18.7% (2013), 18.5% (2014)

- **PRIVATE**
  - Two visits or more: 14% (2013), 14.3% (2014)
  - One visit: 10.2% (2013), 10.2% (2014)

- **MEDICAID**
  - Two visits or more: 19% (2013), 16.7% (2014)
  - One visit: 16.7% (2013), 16.7% (2014)

- **UNINSURED**
  - Two visits or more: 18.5% (2013), 16.6% (2014)
  - One visit: 10.5% (2013), 10.7% (2014)

*Source: CDC National Health Interview Survey*
new report from the California Primary Care Association (CPCA) predicts that the state will need to boost its primary care physician (PCP) workforce by 32% over the next 15 years to meet demands of a growing population, reports HealthLeaders Media.

The study suggests that the current primary care workforce is barely enough and that the state will need an additional 8,243 PCPs by 2030.

The report makes several recommendations to help bolster the supply of PCPs, including encouraging the state to do more to create its own supply of physicians. The report notes: “California ranks 43rd in the nation at 17.8 medical students per 100,000” due to a limited medical school capacity, which leads 63% of California medical school students to attend medical school out of state.

“Given that California ranks first in the nation with 62.4% of its in-state medical school graduates subsequently practicing in the state, an expansion in California medical school capacity could result in a much needed increase in the physician supply,” the study explains.

The CPCA study recommends that the state expand loan repayment programs to help new physicians pay back debt, expand new models of care that maximize the use of physician practice staff, and increase the number of residency programs that place residents in underserved facilities such as community health centers.

California needs more primary care physicians

Pfizer makes multi-million dollar Medicaid settlement

In one of the biggest drug pricing settlements in history, Pfizer is paying $784.6 million to settle claims alleging that the practices of its Wyeth subsidiary relating to the calculation of Medicaid rebates for Protonix (pantoprazole sodium) violated the Federal Civil False Claims Act and other laws.

The Department of Justice charged that, between 2001 and 2006, Wyeth did not give state Medicaid programs the same discounts for Protonix, a heartburn drug, that it did for non-government customers.

In a similar settlement, AstraZeneca and Teva Pharmaceutical’s Cephalon unit paid more than $50 million to settle allegations that they underpaid rebates owed to state Medicaid programs. The settlement stemmed from a lawsuit filed by a pharmacist and attorney, who claimed that the two pharmaceutical manufacturers intentionally lowered rebates they owed to Medicaid.

Meanwhile, the Pfizer settlement fully resolves pending legal cases in Federal District Court for the District of Massachusetts.

“The resolution of these cases reflects a desire by the company to put these cases behind us and to focus on the needs of patients,” said Doug Lankle, Pfizer’s executive vice president and general counsel.

New EHR loyalty index shows user satisfaction declines

Customer satisfaction with electronic health records (EHRs) and health IT systems has dropped, according to the latest Black Book Loyalty Index.

Black Book’s index estimates that satisfaction declined by 6% over the past year, from 81% to 75%.

About one quarter of those who reported they were satisfied with their EHRs and health IT products said it was because of high capital investments, rather than actual satisfaction, reports EHR Intelligence.

By examining not only customer behaviors but the motivation behind those behaviors, the index was able to discern several different kinds of loyalty and find the EHR and health information technology products customers say they feel the most genuine loyalty towards.

These loyalty measures are intended to assist vendors make better decisions about the design and development of their products.
As payment models evolve, physicians may have to limit the care they provide or expose themselves to increased legal risk.

**THE EFFORTS** to rid the nation’s healthcare system of waste and inefficiency faces a formidable foe: defensive medicine.

Doctors who prescribe unnecessary tests and procedures out of fear of being sued waste billions of dollars each year. They also expose patients to a host of complications. As such, the practice of defensive medicine has become a matter of national priority for payers and policymakers alike.

The cost is tough to pin down due to variables such as defensive medicine’s use in different specialties and the degree to which overtreatment actually helps or harms patients, but it likely amounts to about $46 billion per year, say researchers at Harvard University and the University of Melbourne. A more-widely cited study from 2007 by the National Center for Policy Analysis, a conservative think tank, put the annual estimated cost of defensive medicine much higher, between $100 billion and $178 billion.

Such waste flies in the face of efforts aimed at payment reform, in which value-based care models, including bundled payments, shared savings and patient-centered medical homes, are fast replacing the fee-for-service model.

Indeed, as payment models evolve, doctors will increasingly be forced to choose between limiting their utilization of healthcare services to augment income and exposing themselves to legal risk. Self-preservation is likely to win, says Richard Anderson, MD, FACP, chief executive officer of The Doctors Company, a provider of malpractice insurance.

“I feel with virtually absolute certainty that the practice of defensive medicine will not go away unless and until there are major changes to our medical legal system,” he says. “Physicians cannot be expected to risk their career or their financial well-being and that of their family’s every time they have a patient encounter and the way our system works today that is at least metaphorically true.”

**MIPS CHANGES THE GAME**

Beginning in 2019, for example, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires the Centers for Medicare and Medicaid Services to replace Meaningful Use, Physician Quality Report-
I feel with virtually absolute certainty that the practice of defensive medicine will not go away unless and until there are major changes to our medical legal system.”

—RICHARD ANDERSON, MD, FACP, CHIEF EXECUTIVE OFFICER, THE DOCTORS COMPANY
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Trends

Defensive medicine

...We are so enraptured with the latest technology that we think these tools give us the answer. What they really do is confirm or refute our diagnostic impression. If you have the wrong impression to begin with ... you can do a million tests and you won’t come up with the right answer.”

—RICHARD ROBERTS, MD, JD, FAMILY PHYSICIAN, FORMER ATTORNEY, AND PROFESSOR AT THE UNIVERSITY OF WISCONSIN SCHOOL OF MEDICINE AND PUBLIC HEALTH

27% of his or her career with an open malpractice claim. Malpractice claims also create collateral damage, says Hill, noting that doctors with claims against them may be less attractive to future employers.

The other major reason defensive medicine is unlikely to disappear with the growth of value-based care is that it seems to work. A 2015 study from the University of Southern California, Harvard Medical School and Stanford University found that higher-spending physicians across all specialties face fewer malpractice claims.

Among internists, researchers found, the probability of experiencing a malpractice charge ranged from 1.5% for those who spent the least, to 0.3% for those with the highest average spending. Researchers also found that the more Cesarean sections an obstetrician performed, the less likely he or she was to face malpractice complaints.

The analysis of physician spending and claims data raises concern that malpractice risk could be an impediment to successful healthcare reform. “More and more, we are relying on physicians to help eliminate wasteful spending in healthcare,” Seth Seabury, PhD, associate professor of research emergency medicine at the University of Southern California’s Keck School of Medicine, who co-authored the study, said in a statement. “However, if physicians perceive that lowering spending will subject them to greater malpractice risk, it will be that much harder to move the needle on healthcare spending.”

If spending continues to shield physicians from liability risk, he adds, “then that incentive will still be there.”

TORT REFORM EFFORTS

Medical malpractice laws, which determine whether a doctor is negligent in treating (or failing to treat) a patient based on the standard of care, vary from state to state. To protect physicians from “jackpot justice” several states, including Texas and California, have passed tort reform legislation, including caps for non-economic damages that limit how much injured patients may receive for pain and suffering.

Physician advocates, however, say that doesn’t go far enough, and that such half-measures have done little to curb the practice of defensive medicine. A 2014 RAND Corp. study found that tort law reforms in Texas, Georgia and South Carolina that raised the threshold for negligence in emergency department settings did not reduce the use of costly and unnecessary defensive procedures, specifically advanced imaging tests (CT and MRI scans.)

The study measured imaging rates, average charges and hospital admissions for fee-for-service Medicare patients. A decade after adoption of tort reform in those states, the report found no reduction in the intensity of care provided.

“I think it unlikely that I will be altering how I practice medicine very much once insurance companies move to value-based care,” says Dale Gray, MD, an internist with AccessDirectCare in Rockford, Illinois. “In the final analysis, if I miss something and get sued, you can be sure that the insurance company won’t be by my side arguing in my defense. It will be just me and the plaintiff; not a good feeling at all. So if I take a financial hit because I order too many tests, which
I don’t think I do anyway, then so be it.”

**POSSIBLE SOLUTIONS**

So what’s the solution? Some policy experts, including some from the Center for American Progress, have proposed “safe harbor” rules to protect physicians who adhere to evidence-based clinical practice guidelines as published by a medical association. The development of those guidelines could present challenges of their own, says Richard Roberts, MD, JD, a family physician, former attorney, and professor at the University of Wisconsin School of Medicine and Public Health. But at least one has already proven effective.

Roberts says that the widely-used Ottawa ankle, knee and foot rules, which are validated clinical decision rules for determining whether an X-ray is appropriate, have been very accurate in identifying patients with fractures and could help lower costs in the primary care setting. “If the physical findings do not fit certain criteria in the guidelines, then the probability that they have a fracture is virtually zero using these rules,” says Roberts. “An X-ray would only waste time and expose the patient to radiation.”

Similarly, the nonprofit organization Patients for Fair Compensation (PFC) proposes a no-blame compensation system as an alternative to traditional medical malpractice litigation. Modeled on the workers’ compensation system, its goal is to ensure that patients receive fair, timely compensation through an administrative process that costs less and yields compensation quicker and more often than today’s litigation-based system.

Fewer than 20% of injured patients today receive compensation, PFC reports. “So long as there’s a litigation threat, doctors are going to do what they believe is necessary to protect themselves, and that’s historically been in the form of defensive medicine,” says Wayne Oliver, executive director of PFC.

The compensation system PFC proposes, he says, also would improve the quality of patient care by encouraging reporting of medical errors and providing data-driven resources so the medical community could learn from avoidable errors in a safe, confidential environment.

“Everyone is afraid to talk about medical errors which leads to discovery and that leads to lawsuits,” says Oliver. “We can’t have an honest discussion, because we’re fearful of litigation.”

So far, however, none of the leading proposals to revamp medical malpractice have made much headway on Capitol Hill. Until such time, primary care doctors may have more success at eliminating non-value-adding practices than any financial incentives the payer community can dream up, says John Meigs, MD, FAAFP, president-elect of the American Academy of Family Physicians.

By practicing patient-centered medicine, he adds, family physicians are better positioned to inject reason into the diagnostic process without subjecting themselves to liability risk. “The patient and the physician are far better off when they know each other and they develop a trust relationship,” says Meigs. “When I know my patients, I can talk to them and explain things a little better. You can tell them, ‘Well, let’s try this and if it doesn’t work you can come back and we’ll try something else.’ You don’t waste as many resources.”

Meigs cites one of his patients with chronic back pain who demands an MRI each time he comes in: “I tell him, ‘No, you don’t. You need to quit picking up heavy things.’ I know him well enough to tell him that.”

Indeed, patients who trust their doctors are more likely to disclose relevant, personal information in the exam room, which reduces the need for diagnostic testing. They also adhere better to treatment plans, which reduces costly hospital admissions and results in better outcomes, because patients who get better rarely sue. Thus, the move to value-based care, which encourages doctors to engage patients as partners, may make a dent in the practice of defensive medicine.

Roberts agrees. “Knowledge of the patient is always way more important than knowledge of the disease,” he says, noting a large percentage of malpractice suits could have been avoided by having a better relationship with the patient. “We have to be partners with our patients. As doctors, we need to know the science as best we can, but we also have to get to know our patients and trust each other.”

Three out of four patients who present with a health issue in the primary care setting, adds Roberts, get better on their own. “It’s mom, chicken soup and time that usually helps them,” he says. “The physician’s job is to not do something to hurt them.”
Roberts notes, too, that defensive medicine often only protects doctors against a perceived risk. Their best protection comes from practicing good medicine. “The mistake we’re making as doctors is that we are so enraptured with the latest technology that we think these tools give us the answer,” he says. “What they really do is confirm or refute our diagnostic impression. If you have the wrong impression to begin with because you haven’t taken a careful medical history, you can do a million tests and you won’t come up with the right answer.”

For patients who demand more healthcare services, says Meigs, physicians should communicate more effectively the risks inherent in overuse of antibiotics, unnecessary diagnostic tests and invasive procedures. All involve an element of risk. Some patients, for example, experience allergic reactions to the dyes used for CT scans. Also, excessive testing opens the door to more invasive surgical procedures. Often, says Meigs, patients who undergo imaging tests rule out a lesser diagnosis, but discover a new complication that requires further testing. “Sometimes someone gets a CT scan of their abdomen and they find they have simple cysts on their kidney, which are almost always benign, but now the patient wants a biopsy,” he says. “Now you’re going down a path of excessive cost and risk and you didn’t need to go there.”

With medical malpractice laws still stacked against them, doctors are unlikely to reduce the costly practice of defensive medicine any time soon, despite payer incentives that increasingly reward for value.

By cultivating patients as partners, however, and communicating the pros and cons of medical intervention more effectively, physicians may be better equipped to develop evidence-based treatment plans that meet the growing demand for quality, cost-effective care, says Roberts.

“You don’t have to be afraid of your patients,” he says. “If you’re trying to practice medicine by looking over your shoulder all the time, you’re going to hit the wall ahead of you.”

5 ways to protect yourself from defensive medicine

1. **Document, document, document.**
   There is no replacement for a well-documented and detailed medical record. This means timely, accurate, detailed, unaltered, and informative records that paint a picture of the thought process that demonstrates a care plan, not just tests ordered medications prescribed.

2. **Patient engagement and communication with a focus on patient satisfaction.**
   A physician who is accessible and honest about care plans and discusses confidence levels with patients and caregivers blunts, if not disproves, claims of negligence in delivering the right care. Patients turn into plaintiffs when they are scared, frustrated, and not properly informed. A defensible physician takes extra steps to ensure that patients understand diagnoses, listen to patient concerns, and treats informed consent as an opportunity to answer questions.

3. **Don’t be arrogant.**
   Too many defensible cases must be settled because arrogant physicians make poor witnesses. A confident physician lets the record speak for itself. An arrogant physician appears defensive under skillful cross examination.

4. **Coordinate, collaborate, and communicate.**
   On average, five different specialists will be involved in the care of a critically ill patient. Poor patient handoff, communication with patients, families, and other consulting physicians can create significant liability because it endangers the patient. A defensible specialist encourages the involvement of patients, families, and especially their primary care physician, who has the best relationship with them and is in the best position to interpret, coordinate, and educate them on clinical decision making.

5. **Seek, embrace, and join the best value-based integrated care systems.**
   Value- and quality-based care models are transforming primary care physicians from fee-for-service providers to integrated clinical managers. The practice of defensible medicine is virtually identical. Information technology and practice transformation enabled population health management employing risk and cost stratification, referral, communication, coordination, and integrated care groups under a common IT platform do much more than improve quality, safety, and clinical outcomes — they do it all at less cost.
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IN DEPTH

Policy

Maintenance of certification: inside the physician revolt

Some physicians are fed up with MOC and ready to flee, but repercussions remain uncertain

by ED FINKEL Contributing author

HIGHLIGHTS

At this point, the number of physicians not recertifying remains relatively modest.

It’s unlikely that many physicians will skip recertification given the increasing trend toward employed relationships within hospital systems that require certification.

THE FRUSTRATION with maintenance of certification (MOC) has led some physicians to consider certifying with a new, alternative board—or opting out of recertification altogether.

New York-based internist Jonathan Weiss, MD, says that until he and others pushed back, the American Board of Internal Medicine (ABIM) was adding more requirements for MOC and reducing the time intervals between them “every time I turned around.” Not only that, but “at no point did I feel the material being asked of me was terribly germane to what I did on a day-to-day basis,” he says. “The process is fatally and fundamentally flawed.”

The outcry over proposed changes to MOC by the ABIM and many of the two dozen other boards that make up the American Board of Medical Specialties (ABMS) led in part to the creation a year ago of the National Board of Physicians and Surgeons. NBPAS bills itself as a lower-cost, lower-hassle version of the ABMS and its boards, with requirements that hew more closely to what doctors actually face in their day-to-day practices.

NBPAS has been growing steadily, but its membership is still modest. Still, its presence and the general frustration with MOC has led to a new set of questions: What happens to physicians who decide not to recertify with the ABMS boards—or decide not to recertify at all? Do they lose hospital privileges? Insurance coverage? And as a result, do they lose revenue?

The experience among physicians not recertifying with ABMS boards has varied to date depending on locations and types of practice. In the meantime, the ABIM and other ABMS boards, which have withdrawn or postponed some of their proposed changes, continue to tinker with their MOC processes, while some wonder whether the NBPAS will grow into a true alternative. Some connected with the group even could see it folding if the ABMS boards make changes that satisfy enough physicians.

“We have sign-ups every day. We still have a lot of challenges, and we’re working through those,” says Paul Teirstein, MD, a cardiologist at Scripps Clinic in La Jolla, California, and president of NBPAS, which had more than 3,300 members and had gained approval at 26 hospitals by early February. It has been adding about 200 new members per month.

Teirstein says his challenges include hos-
hospitals that have contracts requiring ABMS member board certification and the intentions of payers, who are mostly mum to date. “That is a matter of getting through to the right people at payers, getting them to pay attention,” he says. “They’re not against us, it’s just not on their radar.”

Lois Nora, MD, JD, president and chief executive officer of the ABMS, says she has heard scattered reports of physicians deciding not to recertify, although not many. “We are concerned about any single physician who would decide not to continue with board certification. I never want to hear and am concerned if a physician does not want to participate.”

Richard Baron, MD, president and chief executive officer of ABIM, knows of physicians deciding not to pursue MOC but believes the vast majority of physicians see it as a source of pride and recognition. “We think most people out there are saying, ‘We think it’s important to get this right, so we want to work with an organization that has real standards— but evolving those standards in a way that reflects how we practice,’” he says.

By April 1, 2015, 83.3% percent of physicians due for recertification had enrolled to do so, down from 85.7% in 2014, but up from 79.2% in 2013, according to the ABIM. (See chart above.)

The measurable universe of those deciding not to recertify is relatively modest: beyond the signups to date at NBPAS, an organization called Change Board Certification, which was founded in 2010, says it has signatures from 3,275 physicians who want to abolish MOC. And Teirstein predicts a total of 5,000 to 6,000 NBPAS members by the end of 2016.

The Henry J. Kaiser Family Foundation estimated there were 905,000 practicing physicians in the U.S. as of January, while the American Hospital Association (AHA) counted 5,627 registered hospitals, which includes those that are not members of AHA but still meet its registration criteria.

Not surprisingly, Baron hopes the universe of non-certifiers remains small. “But we know that many physicians are frustrated with our current program and we are working hard to listen to doctors and engage with them to make the program more relevant and more meaningful,” he says. “We will continue to improve the program based on what physicians say they want MOC to represent to themselves, their peers and their patients. It will be important to ensure that the MOC credential captures the pride they feel by staying current in their discipline through a process with a binary, consequential assessment anchored in whether a physician is meeting a performance standard.”

**The process is fatally and fundamentally flawed.”**
—JONATHAN WEISS, MD, INTERNIST, NEW YORK

### MOC: Are physicians skipping?

<table>
<thead>
<tr>
<th>Certification expiring year</th>
<th>Number of general internists with IM certificate expiring and subspecialists with a SS certificate expiring</th>
<th>Enrollment* in MOC as of April 1 of certification expiring year</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>11,594</td>
<td>9,109</td>
</tr>
<tr>
<td></td>
<td>78.6</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>12,447</td>
<td>9,855</td>
</tr>
<tr>
<td></td>
<td>79.2</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>12,489</td>
<td>10,704</td>
</tr>
<tr>
<td></td>
<td>85.7</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>13,611</td>
<td>11,333</td>
</tr>
<tr>
<td></td>
<td>83.3</td>
<td></td>
</tr>
</tbody>
</table>

*ABIM says enrollment rate typically reflects an “intent to complete.”

Source: American Board of Internal Medicine

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**TRUTH ABOUT CONSEQUENCES**

But what will happen to the admitting privileges and insurance coverage of the 0.36% of physicians who are members of NBPAS (not to mention others who have not recertified at all) if they’re practicing at one of the 99.5% of hospitals not yet officially taking NBPAS credentials? In many cases, the answer is still unclear.

America’s Health Insurance Plans (AHIP), the trade association representing many commercial payers, has not taken an official position. “Our member plans will evaluate
board certifications among a number of qualifications for inclusion of providers in their networks,” Clare Krusing, press secretary for AHIP, said in an emailed statement. The American Hospital Association (AHA) did not return calls and e-mails seeking comment.

Blue Cross/Blue Shield Senior Manager of Media Relations Robert Elfinger declined to comment, while Aetna, for the moment, is continuing to require certification either through ABMS affiliates or the American Osteopathic Association, although that could change, says Andrew Baskin, MD, national medical director for clinical policy and national appeals.

“We’re following [the discussion] closely, no doubt about that,” he says. “We’d kind of like to see where it settles out. We don’t see a reason to make more.”

By Ed Finkel contributing author

THE BIGGER PICTURE  How the American Board of Medical Specialties and other specialty boards are confronting MOC changes

Leaders of the American Board of Medical Specialties (ABMS) and its member boards say they’ve been searching for the right path since deciding to take the MOC process beyond the once-per-decade requirement and add elements like subspecialty tests and patient ratings to the process.

“We heard physicians didn’t like the stress and cost of examinations. They weren’t finding that the board approval materials were as relevant as they needed to be. They didn’t find the system as user-friendly as they needed it to be,” says Lois Nora, MD, JD, president and chief executive officer of ABMS. “Many of our boards now have better systems in place for recognizing learning activities and giving credit.”

The American Board of Internal Medicine (ABIM), the center of the firestorm during the past couple of years, plans to spend 2016 considering recommendations to make its MOC process less burdensome, says Richard Baron, MD, president and chief executive officer of ABIM. “For example, we know that many people are unhappy with taking the exams in a testing center,” he says. “Testing centers assure that the person you think is taking the test, is actually the person taking the test. It’s an important thing for credibility. So we’re looking at different kinds of remote proctoring options. Are there ways people can establish their identity?”

The ABIM updated its MOC exam last fall by asking practicing doctors to review the blueprint and make sure questions reflected what they were seeing in their practices. “We’re certainly hearing that some people say it covered obscure things, but we’re hearing many more people say it had a good reflection of what they see in their practice,” Baron says. “There was a sense that people may have felt more comfortable with what was on it.”

The American Board of Anesthesiology (ABA) has unveiled what it calls Maintenance of Certification in Anesthesiology Program (MOCA) 2.0. It replaces the once-per-decade exam with a requirement of 30 exam questions per quarter, based on feedback from physicians that they previously did nothing about MOC for 9½ years and then crammed for the exam, says James Rathmell, MD, board secretary for the ABA.

“The biggest discontent was that the exam doesn’t help diplomates to stay current and take care of patients,” he says. “What came up is that, ‘If we were fed information a little bit at a time, every day or every week throughout a 10-year cycle, and then if we got things wrong, the system would tell us why, and give us information to study and learn, and then test us at a regular interval.’ That’s what MOCA 2.0 is.”

The American Board of Emergency Medicine (ABEM) received strong criticism that the patient safety module it developed in conjunction with the American College of Emergency Physicians, was too time-consuming, hard to pass and irrelevant to day-to-day practice, says Barry Heller, MD, ABEM president. So it has suspended that module to revise it and make it more relevant.

The ABEM also altered its practice improvement standards to include a wider variety of diagnoses that are not necessarily seen in the emergency department every day, Heller says. “We’ve made plenty of changes, and we’ve not had quite the pushback that many of the others boards have had,” he says.

Teirstein and his supporters acknowledge the reforms among the ABMS boards but still have questions and complaints. For example, Teirstein charges that ABIM and others boards still have a “conflict of interest” in that they stand to earn money from exams and other MOC requirements; and that while the ABA’s MOCA 2.0 is “innovative,” for example, “they didn’t change the cost at all.

“We’re listening. We’re trying to reinvent this,” he says. “Take the money out of it, and see what you come up with. We don’t make any money. We’re designed not to make money.”

Rose notes that if a doctor wanted to maintain certifications in internal medicine, cardiology and a subspecialty, that could amount to three exams within a decade. “You see how the requirements start to build up,” he says, adding: “I don’t think the final shot has been fired on this whole affair. I think the temperature has certainly cooled. It has been defused. But I don’t think we necessarily know the right and clear path forward.”
“We will continue to improve the program based on what physicians say they want MOC to represent to themselves, their peers and their patients.”

—RICHARD BARON, MD, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ABIM

The ABMS and its affiliates are known entities with which Aetna has had a long history, Baskin says, and he’s not sure whether NBPAS’s requirements are robust enough. “A lot of it centers around completing adequate amounts of CME. Most states already have requirements for CME to get a license,” he says. “I’m not sure yet that there’s enough extra value in that [NBPAS] board certification.”

Baskin says Aetna will know more once the ABMS boards finish their tweaking of MOC requirements. “We’d like to see how the boards respond to their membership,” he says. “I’m convinced that the [ABMS] does not want this to drag on much longer. ... Let’s give them a chance to see if they’re going to make any changes that are going to be acceptable to their constituency.”

Jay Alexander, MD, who practices with NorthShore Cardiology in Bannockburn, Illinois, is Illinois governor for the American College of Cardiology and is board-certified in internal medicine, says he is aware of “plenty” of physicians who have foregone certification.

“It has really created a lot of chaos in this whole recertification process. That chaos is very problematic,” Alexander says. Hospital administrators are concerned about allowing physicians to practice in their institutions, he says, and advises colleagues to continue because “no one knows what happens if you don’t.”

The consequences of not recertifying would vary by location and type of practice, Baron believes. He recalls moving from a rural hospital in Tennessee that had no cardiologists on staff to a hospital in Philadelphia where he needed to consult with a cardiologist on heart-related matters because he was not certified in that specialty.

It’s unlikely that many physicians will skip recertification, given the increasing trend toward employed relationships within hospital systems that require MOC, along with similar mandates among payers to be included in their networks, believes Geoffrey Rose, MD, chief of cardiology at Sanger Heart & Vascular Institute in Charlotte, North Carolina, who recently recertified in cardiology through ABIM.

“You may have some one-offs here and there, in certain situations, where they remain in private practice and it doesn’t seem important,” he says. “But for the majority of practicing physicians, particularly in the way medicine is organizing itself into larger delivery care systems, board certification is becoming as important as one’s licensure. I don’t think opting out is going to be an option for most.”

Those associated with the NBPAS mostly agree that physicians will continue to pursue certification, even if not necessarily with the ABIM and other ABMS boards. “They won’t be able to work in hospitals if they do that [fail to recertify],” Teirstein predicts.

Paul Mathew, MD, a board member of NBPAS and neurologist at Harvard University Medical School and Brigham & Women’s Hospital, Cambridge, Massachusetts, suspects some of those deciding not to recertify are unaware of the alternative the NBPAS presents. “That doesn’t really make sense,” he says of the decision not to recertify. “If people know the story, they’re not going to be not board-certified.”

Physicians will pressure hospitals to change their bylaws to get rid of recertification requirements, predicts Paul Kempen, MD, an anesthesiologist with Trinity Health System in Steubenville, Ohio. “Trouble is going to come up, when patients say, ‘What the hell? I had a doctor,’” he says, if hospitals jettison physicians as a result of a lapse in MOC. “There will be a big, freaking lawsuit, not against ABIM but against the hospital ordering [MOC].”
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No one provides risk management resources like we do. Today, we’ve expanded our insurance support and capabilities even further with client access to VisualDx, the leading diagnostic decision support system; best-in-class online educational programs through ELM Exchange; and timely analysis with our comprehensive Medical Practice Leadership Assessment tool. Find out how our full suite of insurance services and risk management resources can help improve clinical, operational and financial outcomes today by calling (844) 894-0686 or visiting ThinkCoverys.com.
**Coding Insights**

**Code it just right by using clear medical decision-making documentation**

*by Bill Dacey, CPC, MBA, MHA Contributing author*

Q: What is the difference between over-coding and under-documentation?

A: This question must have come up in the context of some type of internal or compliance audit as these are terms most often heard in that area of coding and documentation.

Medicare, as the principal authority and regulatory force in this area, does not usually make this distinction. To Medicare, if you have filed a claim for a service, and the documentation does not support that service, then typically they will call this “over-coded.”

For an internal auditor the term “over-coded” is usually used to indicate that the code selected involves work in the areas of medical history (Hx), physical examination (PE) and medical decision-making (MDM) that does not appear to have happened – specifically in the MDM area.

An encounter is typically rated “under-documented” if the decision-making area leaves significant room for doubt as to the extent of management, or if either the history or exam areas notably lack required detail. Many charts that are rated under-documented fall into the latter category.

An auditor will distinguish between these terms because it is their job to determine what the provider needs help with. Over-coding will require that the provider receive some more in-depth coding instruction. Under-documentation will necessitate some additional education on the details required to bill specific codes.

A chart rated “under-documented” does not adequately meet federal documentation guidelines for the level of documentation of the history, exam, medical decision-making, time or procedure notes. The precise amount and type of documentation pertaining to history of present illness/review of systems (HPI/ROS) and decision-making can be variable.

All federal plan administrators are expressly allowed ‘latitude’ in their ‘interpretation’ of these aspects of the federal guidelines.

Most commercial carriers follow these guidelines in general with some variance in terms of rigidly applying the “guidance.” All audits or reviews are somewhat subjective in that the reviewer is applying the ‘guidelines’ as best he or she can in any given case.

There are three distinct sets of federal documentation definitions and rules that are intended to govern all notes and all provider specialties and types – so you can imagine that they do not fit every note well.

In the spirit of medical necessity, a responsible auditor focuses on having providers concentrate on clarifying the decision-making area of the chart such that it is very clear how many problems, and the nature/status of those problems, were actively evaluated, managed or addressed during any given encounter.

Q: I have noticed that Medicare is not paying for the Chronic Care Management (CCM) code 99487 in January 2106. Why is this?

A: What you are seeing is the patient’s deductible now including the CCM payments that Medicare does cover, but not until the annual deductible has been met. This is not different than the payment criteria for most other Medicare services.

Some services are not affected by deductibles, such as Annual Wellness Visits and certain other preventive services, but most are. You might consider that CCM is preventive—and it is in a way—but it does deal with established chronic problems by definition and so is excluded from the deductible exempt services.
An encounter is typically rated ‘under-documented’ if the decision-making area leaves significant room for doubt.

You may experience some pushback from patients on this. Chances are that when you set them up on the CCM plan, part of the appeal was that Medicare paid 80% of the monthly charge. For many, secondary insurance paid the rest.

This time of year, however, Medicare isn’t going to pay the bulk of the charge, and the secondary payers may not pay the copay because Medicare didn’t cover the principal amount.

Your best bet is to explain to the patients that it doesn’t matter which services they receive, regular office visits or other covered services, Medicare payments don’t kick in until they have met their deductible. Their payments for CCM services will just get them to that deductible threshold sooner.

A: For the specifics of 94660 I would direct you to the October 2014 CPT Assistant published by the AMA. They have answers to frequently-asked questions as well.

Under the Affordable Care Act (ACA), are all payers required to reimburse claims that contain CPT codes (example 99213) with the modifier GE? It has been brought to my attention that a few of our payers will not reimburse claims with this modifier and we want to continue the usage of modifier GE so that we are reporting accurately. Where does it say they have to pay this?

A: Neither the full text version of the ACA nor the Reconciliation Act contain CPT codes 95811 and 95783 are codes for encounters for PAP therapy during diagnostic testing. PAP therapy is then provided to the patient in the context of an EM code or 94660.

Under the Affordable Care Act (ACA), are all payers required to reimburse claims that contain CPT codes (example 99213) with the modifier GE? It has been brought to my attention that a few of our payers will not reimburse claims with this modifier and we want to continue the usage of modifier GE so that we are reporting accurately. Where does it say they have to pay this?

A: Neither the full text version of the ACA nor the Reconciliation Act contain any reference to GC or GE modifiers. The 2011 CMS Transmittal on Teaching Guidelines mentions the ACA in the same general paragraph as a discussion of some GE and GC issues. But these items don’t appear to be related.

When you drill down into that transmittal - Section 100.1.B1 is amended to read: ‘Effective January 1, 1997, services furnished by teaching physicians involving a resident in the care of their patients must be identified as such on the claim. To be payable, claims for services furnished by teaching physicians involving a resident must comply with the requirements in sections 100.1 through 100.16 of this chapter, as applicable. Claims for services meeting these requirements must show either the GC or GE modifier as appropriate and described below.’

These transmittals are designed to apply to CMS programs, Medicare/Medicaid and potentially other governmental programs such as Tricare.

From your question I’m uncertain who the ‘few of our payers’ are. But if they are commercial or non-governmental entities they are not bound in any way to recognize modifier GE or GC.

In fact, it seems their recognition of what these modifiers mean might be the problem. They may not want to pay for a service that was performed solely by a resident.

My question to you is why would you bill a non-governmental payer with a GE on the claim? Of course they could have Medicare primary and a secondary may not pay for this reason.

Q: I have a question regarding billing for a CPAP code. How can we use the code 94660 correctly? My understanding is that it’s for the initiation and management of CPAP. Can we use it every time we show someone how to use their mask, equipment, etc.?

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Q: I have a question about the Primary Care Exception modifier GE for teaching physicians.

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A holistic approach to ICD-10 coding compliance

by LYN TRIFFLETTI, CPC Contributing author

With ICD-10 now a reality, overcoding can result in penalties, while undercoding can mean lost revenue. Here’s how to develop a comprehensive compliance strategy.

Coding Compliance is top of mind for many physician practices now due to the transition to the ICD-10 code set. With the massive expansion of the code set, providers are struggling to know the correct codes to use and the level of specificity required.

If practices don’t have a good grasp of appropriate coding, they could inadvertently undercode or overcode. If an organization undercodes, it may not receive all the reimbursement to which it is entitled and may even receive a denial, depending on the situation. On the other hand, overcoding could result in penalties and other regulatory consequences.

A practice should take the time to understand what’s involved in ICD-10 compliance. Although this may seem daunting, there are resources available online, through vendors and professional organizations that can provide medical practices with the information they need to code correctly. In some cases, these resources also will highlight specific coding areas of which organizations should be aware based on the types of patients they regularly treat.

Next, the practice must audit its current coding processes against the required ICD-10 codes and see if shortfalls exist. This can be done by internal staff or by consultants who are familiar with ICD-10.

After identifying areas of needed improvement, a practice can take steps, such as additional staff training, to make sure those responsible for coding use the appropriate codes going forward.

Training can take many forms, but should include real-world examples and opportunities to practice so that these individuals fully understand what has to change and how they can change it.

To help staff retain information, practices can employ training strategies that encourage knowledge retention. For example, a practice might periodically quiz staff members on certain coding situations or have them engage in sample coding exercises.

Finally, a practice should regularly audit its coding activities. The Office of the Inspector General recommends that a practice audit 10 visit notes per provider per year. This audit should verify proper and complete coding.

Auditing is another area where an outside resource could be helpful. In some instances, practices can send coding samples to an outside vendor for auditing and improvement advice.

Step-by-step

Developing a comprehensive and consistent compliance strategy does not have to be difficult. In fact, practices can treat the concept the way they would any performance improvement opportunity.

First, they must familiarize themselves with the applicable regulatory requirements and determine a method for learning about changes or revisions to these requirements as they arise.

Next, compare current performance against regulations to identify compliance gaps. Devise a plan to respond to shortfalls and close the gaps. Often, mitigation strategies involve training, workflow redesigns or policy and documentation changes.

Continue to monitor compliance to ensure effective. Revisit the topic until performance improves. After compliance is achieved, periodically verify performance, and shift training efforts to promote information retention, helping staff apply what they learn to everyday work processes.

Lyn Triffletti, CCSP, CPCO, CPC, PCS, is the vice president of compliance at Stericycle, Inc. Send your financial questions to: medec@advanstar.com.
In the treatment of type 2 diabetes, along with diet and exercise, INVOKANA® can
AWAKEN A TRANSFORMATION

INVOKANA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. INVOKANA® is not recommended in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- History of a serious hypersensitivity reaction to INVOKANA®
- Severe renal impairment (eGFR <30 mL/min/1.73 m²), 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.

*Data on file. Based on TRx data sourced from IMS NPA Database, weekly data through 12/21/15.
In the treatment of type 2 diabetes, along with diet and exercise, INVOKANA® can

AWAKEN A TRANSFORMATION

INVOKANA® 300 mg is the only SGLT2 inhibitor that demonstrated superior reductions in A1C vs Januvia® 100 mg²⁻⁴

» In a prespecified analysis, superiority was determined once noninferiority was confirmed³

**Adjusted Mean Change in A1C From Baseline at 52 Weeks (%)²**

<table>
<thead>
<tr>
<th></th>
<th>Mean baseline: 8.13%</th>
<th>Adjusted Mean Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Januvia® (sitagliptin) 100 mg + metformin and a sulfonylurea (n=378)</td>
<td>8.12%</td>
<td>−0.66</td>
</tr>
<tr>
<td>INVOKANA® 300 mg + metformin and a sulfonylurea (n=377)</td>
<td>8.13%</td>
<td>−1.03</td>
</tr>
</tbody>
</table>

» INVOKANA® 300 mg difference from Januvia® 100 mg: −0.37% (95% CI: −0.50, −0.25; P<0.05)

Secondary endpoints: Greater reductions in body weight and systolic blood pressure (BP) vs Januvia® 100 mg

**Adjusted mean change in body weight from baseline at 52 weeks²**

» **Difference from Januvia®**: −2.8% (−5.3 lb) (95% CI: −3.3, −2.2); P<0.001

**Adjusted mean change in systolic BP from baseline at 52 weeks³**

» **Difference from Januvia®**: −5.9 mm Hg (95% CI: −7.6, −4.2); P<0.001

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

SGLT2=sodium-glucose co-transporter 2.

**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 m²), elderly patients, patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system, or patients with low systolic blood pressure. Before initiating in patients with ≥1 of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating.
**Similar overall incidence of AEs vs Januvia**

Incidence of any AE, Januvia® 100 mg: 77.5%; INVOKANA® 300 mg: 76.7%

Incidences of specific AEs were similar between groups, except for:

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

*Noninferiority of INVOKANA® + metformin and a sulfonylurea to Januvia® + metformin and a sulfonylurea was assessed based on a prespecified margin of 0.3% for the upper limit of the 2-sided 95% CI for the comparison in the primary last observation carried forward analysis. If noninferiority was demonstrated, then superiority was assessed, as determined by an upper bound of the 95% CI around the between-group difference (INVOKANA® minus Januvia®) of <0.0%. *

**Ketoacidosis:** Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, have been identified in patients with type 1 and 2 diabetes mellitus receiving SGLT2 inhibitors, including INVOKANA®. Before initiating INVOKANA®, consider factors in patient history that may predispose to ketoacidosis, including pancreatic insulin deficiency, caloric restriction disorders, and alcohol abuse. In patients treated with INVOKANA®, consider monitoring for ketoacidosis and temporarily discontinuing in clinical situations known to predispose to ketoacidosis (eg, prolonged fasting due to acute illness or surgery).

**Impairment in Renal Function:** INVOKANA® increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiation. More frequent renal function monitoring is recommended in patients with an eGFR <60 mL/min/1.73 m².

**Hyperkalemia:** INVOKANA® can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.

**Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.**
Urosepsis and Pyelonephritis: There have been reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors, including INVOKANA®. Treatment with SGLT2 inhibitors increases this risk. Evaluate patients for signs and symptoms and treat promptly.

Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues: INVOKANA® can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA®.

Genital Mycotic Infections: INVOKANA® increases risk of genital mycotic infections. Patients with history of these infections and uncircumcised males were more likely to develop these infections. Monitor and treat appropriately.

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

Bone Fracture: Increased risk of bone fracture, occurring as early as 12 weeks after treatment initiation, was observed in patients using INVOKANA®. Consider factors that contribute to fracture risk prior to initiating INVOKANA®.

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

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

UGT Enzyme Inducers: Rifampin: Co-administration of INVOKANA® with rifampin decreased INVOKANA® area under the curve (AUC) by 51% and therefore may decrease efficacy. If an inducer of UGT enzymes must be co-administered with INVOKANA®, consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA® 100 mg once daily, have an eGFR ≥60 mL/min/1.73 m², and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR <60 mL/min/1.73 m² who require additional glycemic control.

Digoxin: There was an increase in the AUC and mean peak drug concentration of digoxin (20% and 36%, respectively) when co-administered with INVOKANA® 300 mg. Monitor appropriately.

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

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

USE IN SPECIFIC POPULATIONS

Pregnancy Category C: There are no adequate and well-controlled studies of INVOKANA® in pregnant women. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters.

Nursing Mothers: It is not known if INVOKANA® is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants, discontinue INVOKANA®.

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

Geriatric Use: 2034 patients ≥65 years and 345 patients ≥75 years were exposed to INVOKANA® in 9 clinical studies. Patients ≥65 years had a higher incidence of adverse reactions related to reduced intravascular volume (eg, hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300-mg dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were ≥75 years. Smaller reductions in HbA1c relative to placebo were seen in patients ≥65 years (~0.61% with INVOKANA® 100 mg and ~0.74% with INVOKANA® 300 mg) compared to younger patients (~0.72% with INVOKANA® 100 mg and ~0.87% with INVOKANA® 300 mg).

Renal Impairment: Efficacy and safety were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/1.73 m²). These patients had less overall glycemic efficacy and a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR ≥60 mL/min/1.73 m²); patients treated with 300 mg were more likely to experience increases in potassium. INVOKANA® is not recommended in patients with severe renal impairment (eGFR <30 mL/min/1.73 m²), with end-stage renal disease, or receiving dialysis.

Hepatic Impairment: INVOKANA® has not been studied in patients with severe hepatic impairment and is not recommended in this population.

OVERDOSAGE

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

ADVERSE REACTIONS

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

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

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 60 mL/min/1.73 m²), end stage renal disease (ESRD), or patients on dialysis [see Warnings and Precautions and Use in Specific Populations].

WARNINGS AND PRECAUTIONS
Hypotension: INVOKANA causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA [see Adverse Reactions] particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²), elderly patients, patients on either diuretics or medications that interfere with the renin-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.

Ketoadosis: Reports of ketoadosis, a serious life-threatening condition requiring urgent hospitalization have been identified in postmarketing surveillance in patients with type 1 and type 2 diabetes mellitus receiving sodium glucose co-transporter-2 (SGLT2) inhibitors, including INVOKANA. INVOKANA is not indicated for the treatment of patients with type 1 diabetes mellitus [see Indications and Usage].

Patients treated with INVOKANA who present with signs and symptoms consistent with severe metabolic acidosis should be assessed for ketoadosis regardless of presenting blood glucose levels, as ketoadosis may be present even if blood glucose levels are less than 250 mg/dL. If ketoadosis is suspected, INVOKANA should be discontinued, patient should be evaluated, and prompt treatment should be instituted. Treatment of ketoadosis may require insulin, fluid and carbohydrate replacement. In many of the postmarketing reports, and particularly in patients with type 1 diabetes, the presence of ketoadosis was not immediately recognized and institution of treatment was delayed because presenting blood glucose levels were below those typically expected for diabetic ketoadosis (often less than 250 mg/dL). Signs and symptoms at presentation were consistent with dehydration and severe metabolic acidosis and included nausea, vomiting, abdominal pain, generalized malaise, and shortness of breath. In some but not all cases, factors predisposing to ketoadosis such as insulin dose reduction, acute febrile illness, reduced caloric intake due to illness or surgery, pancreatic disorders suggesting insulin deficiency (e.g., type 1 diabetes, history of pancreatitis or pancreatic surgery), and alcohol abuse were identified. Before initiating INVOKANA, consider factors in the patient history that may predispose to ketoadosis including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with INVOKANA consider monitoring for ketoadosis and temporarily discontinuing INVOKANA in clinical situations known to predispose to ketoadosis (e.g., prolonged fasting due to acute illness or surgery).

Impairment in Renal Function:
• Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues
• Urosepsis and Pyelonephritis

Hypoglycemia: Hypoglycemia is a potentially serious adverse reaction associated with the use of SGLT2 inhibitors including INVOKANA. Invokana contains canagliflozin, an SGLT2 inhibitor. Due to the mechanism of action, hypoglycemia is more common with INVOKANA than with other oral antidiabetic agents. Invokana should be used with caution in patients who may be at increased risk for hypoglycemia including patients with impaired renal function, and in patients predisposed to hypoglycemia due to medications or other medical conditions.

INVOKANA® (canagliflozin) tablets
Urosepsis and Pyelonephritis: There have been postmarketing reports of serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization in patients receiving SGLT2 inhibitors, including INVOKANA. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated [see Adverse Reactions].

Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues: INSULIN IN ORAL COMBINATION USE. Hypoglycemia is more common with INVOKANA than with other oral antidiabetic agents. 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 and monitor until signs and symptoms resolve [see Contraindications and Adverse Reactions].

Bone Fracture: An increased risk of bone fracture, occurring as early as 12 weeks after treatment initiation, was observed in patients using INVOKANA. Consider factors that contribute to fracture risk prior to initiating INVOKANA [see 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 if appropriate 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:
• Hypoglycemia [see Warnings and Precautions]
• Ketoadosis [see Warnings and Precautions]
• Impairment in Renal Function [see Warnings and Precautions]
• Hypokalemia [see Warnings and Precautions]
• Urosepsis and Pyelonephritis [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]
• Bone Fracture [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 1687 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 female and 72% were Caucasian, 12% were Asian, and 5% were Black or African American. At baseline the population had diabetes for an average of 7.3 years, had a mean HbA1C of 8.0% and 20% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 88 mL/min/1.73 m²).

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

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

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo N=646</th>
<th>INVOKANA 100 mg N=833</th>
<th>INVOKANA 300 mg N=834</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female genital mycotic infections</td>
<td>3.2%</td>
<td>10.4%</td>
<td>11.4%</td>
</tr>
<tr>
<td>Urinary tract infections</td>
<td>4.0%</td>
<td>5.9%</td>
<td>4.3%</td>
</tr>
<tr>
<td>Increased urination</td>
<td>0.8%</td>
<td>5.3%</td>
<td>4.6%</td>
</tr>
<tr>
<td>Male genital mycotic infections</td>
<td>0.6%</td>
<td>4.2%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Vulvovaginal pruritus</td>
<td>0.0%</td>
<td>1.6%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Thirst*</td>
<td>0.2%</td>
<td>2.8%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Constipation</td>
<td>0.9%</td>
<td>1.8%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Nausea</td>
<td>1.5%</td>
<td>2.2%</td>
<td>2.3%</td>
</tr>
</tbody>
</table>

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

1 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).

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

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

4 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).

5 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 for canagliflozin was 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=302), INVOKANA 300 mg (N=3065) or comparator (N=2509) once daily. The mean age of the population was 60 years and 5% were older than 75 years of age. Fifty-eight percent (58%) of the population was male and 73% were Caucasian, 16% were Asian, and 4% were Black or African American. At baseline, the population had diabetes for an average of 11 years, had a mean HbA1C of 8.0% and 33% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 81 mL/min/1.73 m²).

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

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

In the pool of eight clinical trials, 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.

In the pool of eight clinical trials, hypersensitivity-related adverse reactions (including erythema, rash, pruritus, urticaria, and angioedema) 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 dehydrations). An increased incidence was observed in patients on the 300 mg dose. The three factors associated with the largest increase in volume depletion-related adverse reactions were the use of loop diuretics, moderate renal impairment (eGFR ≥ 30 to less than 60 mL/min/1.73 m²), and age 75 years and older (Table 2) [see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Use in Specific Populations].

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

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Comparator Group* %</th>
<th>INVOKANA 100 mg %</th>
<th>INVOKANA 300 mg %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall population</td>
<td>1.5%</td>
<td>2.3%</td>
<td>3.4%</td>
</tr>
<tr>
<td>75 years of age and older†</td>
<td>2.6%</td>
<td>4.9%</td>
<td>8.7%</td>
</tr>
<tr>
<td>eGFR less than 60 mL/min/1.73 m²‡</td>
<td>2.5%</td>
<td>4.7%</td>
<td>8.1%</td>
</tr>
<tr>
<td>Use of loop diuretic³</td>
<td>4.7%</td>
<td>3.2%</td>
<td>8.8%</td>
</tr>
</tbody>
</table>

* Includes placebo and active-comparator groups
† Patients could have more than 1 of the listed risk factors

**Falls:** In a pool of nine clinical trials with mean duration of exposure to INVOKANA of 85 weeks, the proportion of patients who experienced falls was 1.3%, 1.5%, and 2.1% with comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. The higher risk of falls for patients treated with INVOKANA was observed within the first few weeks of treatment.

**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

<table>
<thead>
<tr>
<th>Pool of Four Placebo-Controlled Trials</th>
<th>Placebo N=646</th>
<th>INVOKANA 100 mg N=833</th>
<th>INVOKANA 300 mg N=834</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Creatinine (mg/dL)</td>
<td>1.61</td>
<td>1.62</td>
<td>1.63</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>87.0</td>
<td>88.3</td>
<td>88.8</td>
</tr>
<tr>
<td>Week 6 Change</td>
<td>0.04</td>
<td>0.03</td>
<td>0.05</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>87.0</td>
<td>88.3</td>
<td>88.8</td>
</tr>
<tr>
<td>End of Treatment Change</td>
<td>0.01</td>
<td>0.02</td>
<td>0.03</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>-1.6</td>
<td>-2.3</td>
<td>-3.4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Moderate Renal Impairment Trial</th>
<th>Placebo N=90</th>
<th>INVOKANA 100 mg N=90</th>
<th>INVOKANA 300 mg N=90</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Creatinine (mg/dL)</td>
<td>1.61</td>
<td>1.62</td>
<td>1.63</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>40.1</td>
<td>39.7</td>
<td>38.5</td>
</tr>
<tr>
<td>Week 9 Change</td>
<td>0.03</td>
<td>0.18</td>
<td>0.28</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>-0.7</td>
<td>-4.6</td>
<td>-6.2</td>
</tr>
<tr>
<td>End of Treatment Change</td>
<td>0.07</td>
<td>0.16</td>
<td>0.18</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>-1.5</td>
<td>-3.6</td>
<td>-4.0</td>
</tr>
</tbody>
</table>

* Week 26 in mITT LOCF population

In the pool of four placebo-controlled trials where patients had normal or mildly impaired baseline renal function, the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR below 80 mL/min/1.73 m² and 30% lower than baseline, was 2.1% with placebo, 2.0% with INVOKANA 100 mg, and 4.1% with INVOKANA 300 mg. At the end of treatment, 0.5% with placebo, 0.7% with INVOKANA 100 mg, and 1.4% with INVOKANA 300 mg had a significant renal function decline.

In a trial carried out in patients with moderate renal impairment with a baseline eGFR of 30 to less than 50 mL/min/1.73 m² (mean baseline eGFR 39 mL/min/1.73 m²) [see Clinical Studies (14.3) in full Prescribing Information], the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR 30% lower than baseline,
was 6.9% with placebo, 18% with INVOKANA 100 mg, and 22.5% with INVOKANA 300 mg. At the end of treatment, 4.6% with placebo, 3.4% with INVOKANA 100 mg, and 2.2% with INVOKANA 300 mg had a significant renal function decline. In a pooled analysis of patients with moderate renal impairment (N=1085) with baseline eGFR of 30 to less than 60 mL/min/1.73 m² (mean baseline eGFR 48 mL/min/1.73 m²), the overall incidence of these events was lower than in the dedicated trial but a dose-dependent increase in incident episodes of significant renal function decline compared to placebo was still observed.

Use of INVOKANA has been 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 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. In females, discontinuation due to genital mycotic infections occurred in 0% and 0.7% of patients treated with placebo and INVOKANA, respectively [see Warnings and Precautions].

In the pool of four placebo-controlled clinical trials, male genital mycotic infections (e.g., balanitis, balanoposthitis) occurred in 0.3%, 2.3%, and 2.7% 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 males, discontinuations due to genital mycotic infections occurred in 0% and 0.5% of patients treated with placebo and INVOKANA, respectively. 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).

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 biochemically documented a low glucose value was obtained). Bone Fracture: The occurrence of bone fractures was evaluated in a pool of nine clinical trials with a mean duration of exposure to INVOKANA of 18 weeks. The incidence rates of adjudicated bone fractures were 1.1, 1.4, and 1.5 per 100 patient-years of exposure in the comparator, INVOKANA 100 mg, and INVOKANA 300 mg groups, respectively. Fractures were observed as early as 12 weeks after treatment initiation and were more likely to be low trauma (e.g., fall from no more than standing height), and affect the upper extremities [see Warnings and Precautions].

Laboratory and Imaging Tests: Increases in Serum Potassium: In a pooled population of patients (N=723) with moderate renal impairment (eGFR 45 to less than 60 mL/min/1.73 m²), increases in serum potassium to greater than 5.6 mEq/L, and 15% above baseline occurred in 5.3%, 5.0%, and 8.8% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Severe elevations (greater than or equal to 6.5 mEq/L) occurred in 0.4% of patients treated with placebo, no patients treated with INVOKANA 100 mg, and 1.3% of patients treated with INVOKANA 300 mg. In these patients, increases in potassium were more commonly seen in those with elevated potassium at baseline. Among patients with moderate renal impairment, approximately 84% were taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, angiotensin-converting-enzyme inhibitors, and angiotensin-receptor blockers [see Warnings and Precautions and Use in Specific Populations].

Increases in Serum Magnesium: In the pool of four placebo-controlled clinical trials, male genital mycotic infections (e.g., balanitis, balanoposthitis) occurred in 0.3%, 2.3%, and 2.7% 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 males, discontinuations due to genital mycotic infections occurred in 0% and 0.5% of patients treated with placebo and INVOKANA, respectively. 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].

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies

<table>
<thead>
<tr>
<th>Monotherapy (26 weeks)</th>
<th>Placebo (N=115)</th>
<th>INVOKANA 100 mg (N=115)</th>
<th>INVOKANA 300 mg (N=115)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall [N (%)]</td>
<td>5 (2.6)</td>
<td>7 (3.6)</td>
<td>6 (3.0)</td>
</tr>
<tr>
<td>In Combination with Metformin (26 weeks)</td>
<td>Placebo + Metformin (N=113)</td>
<td>INVOKANA 100 mg + Metformin (N=139)</td>
<td>INVOKANA 300 mg + Metformin (N=136)</td>
</tr>
<tr>
<td>Overall [N (%)]</td>
<td>3 (1.6)</td>
<td>17 (4.6)</td>
<td>17 (4.6)</td>
</tr>
<tr>
<td>Severe [N (%)]</td>
<td>1 (0.6)</td>
<td>3 (0.9)</td>
<td>3 (0.9)</td>
</tr>
<tr>
<td>In Combination with Metformin (52 weeks)</td>
<td>Glimepiride + Metformin (N=402)</td>
<td>INVOKANA 100 mg + Metformin (N=483)</td>
<td>INVOKANA 300 mg + Metformin (N=485)</td>
</tr>
<tr>
<td>Overall [N (%)]</td>
<td>165 (34.2)</td>
<td>27 (5.6)</td>
<td>24 (4.3)</td>
</tr>
<tr>
<td>Severe [N (%)]</td>
<td>15 (3.1)</td>
<td>3 (0.6)</td>
<td>3 (0.6)</td>
</tr>
<tr>
<td>In Combination with Sulfonylurea (18 weeks)</td>
<td>Placebo + Sulfonylurea (N=90)</td>
<td>INVOKANA 100 mg + Sulfonylurea (N=74)</td>
<td>INVOKANA 300 mg + Sulfonylurea (N=72)</td>
</tr>
<tr>
<td>Overall [N (%)]</td>
<td>4 (5.8)</td>
<td>3 (4.1)</td>
<td>9 (12.5)</td>
</tr>
</tbody>
</table>

Increases in Serum Magnesium

Changes from placebo levels were observed with INVOKANA. In the pool of four placebo controlled trials, the mean percent change in serum magnesium levels was 1.6% and 3.6% 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 percent change in serum phosphate levels was 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 3.3% 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 2.1% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively, had hemoglobin above the upper limit of normal.

Decreases in Bone Mineral Density: Bone mineral density (BMD) was measured by dual-energy X-ray absorptiometry in a clinical trial of 714 older adults (mean age 64 years) [see Clinical Studies (14.3) in full Prescribing Information]. At 2 years, patients randomized to INVOKANA 100 mg and INVOKANA 300 mg had placebo-corrected declines in BMD at the total hip of 0.8% and 1.2%, respectively, and at the lumbar spine of 0.3% and 0.7%, respectively. Placebo-adjusted BMD declines were 0.1% at the femoral neck for both INVOKANA doses and 0.4% at the distal forearm for patients randomized to INVOKANA 300 mg. The placebo-adjusted change at the distal forearm for patients randomized to INVOKANA 100 mg was 0%.

Postmarketing Experience: Additional adverse reactions have been identified during postapproval use of INVOKANA. Because these reactions are reported voluntarily from a population of uncertain size, it is not generally possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Ketoacidosis [see Warnings and Precautions]

Urosepsis and Pyelonephritis [see Warnings and Precautions]

DRUG INTERACTIONS

UGT Enzyme Inducers: Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including UGT1A9, UGT2B4, decreased canagliflozin area under the curve (AUC) by 51%. This decrease in exposure to canagliflozin may decrease efficacy. If an inducer of these UGTs (e.g., rifampin, phenytoin, phenobarbital, ritonavir) must be co-administered with INVOKANA (canagliflozin), consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA 100 mg once daily, have an eGFR greater than 60 mL/min/1.73 m², and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m² receiving concurrent therapy with a UGT inducer and requiring glycemic control [see Dosage and Administration (2.3) and Clinical Pharmacology (12.3) in full Prescribing Information].

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

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

Interference with 1,5-anhydroglucitol (1,5-AG) Assay: Monitoring glycemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG interfere with 1,5-anhydroglucitol (1,5-AG) Assay: Monitoring glycemic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests. Use alternative methods to monitor glycemic control.

Urine Test Strips: There is no evidence that INVOKANA affects urine test strips.

Renal Impairment: 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 medication 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.

Ketoacidosis: Inform patients that ketoacidosis has been reported during use of INVOKANA. Instruct patients to check ketones (when possible) if symptoms consistent with ketoacidosis occur even if blood glucose is not elevated. If symptoms of ketoacidosis (including nausea, vomiting, abdominal pain, tiredness, and labored breathing) occur, instruct patients to discontinue INVOKANA and seek medical advice immediately [see Warnings and Precautions].

Serious Urinary Tract Infections: Inform patients of the potential for urinary tract infections, which may be serious. Provide them with information on the symptoms of urinary tract infections. Advise them to seek medical advice if such symptoms occur [see Warnings and Precautions].

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.

Bone Fracture: Inform patients that bone fractures have been reported in patients taking INVOKANA. Provide them with information on factors that may contribute to fracture risk.

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What do physicians owe their kids?

Impart values, consider what-ifs before calling the estate-planning attorney

by JANET KIDD STEWART Contributing author

LLOYD LOCASCIO, MD, and his wife, Cheryl, were determined to make sure their daughters grew up with strong values around money, and to protect them as much as possible, even if something happened to the couple.

“We had a son with severe medical problems who died when he was three and a half,” says Lloyd, a radiologist in Baton Rouge, Louisiana, and a partner in a large group practice. “During his illness we began thinking that if something happened to us we need to make sure [our children were] taken care of, so we started estate planning.”

At the same time, however, the LoCascios wanted to avoid the familiar scenario of wealthy parents doing so much for their kids that, as adults, the children lack ambition and independence.

Regardless of salary differentials, physicians in virtually every specialty feel compelled to help their adult children, but how much is too much? Is there more to estate planning than simply avoiding inheritance taxes? Before putting an estate-planning attorney on the clock, it’s important to think about the financial legacy you want your children to inherit, which has to do as much with financial habits and priorities as it does with taxes and trusts.

“A lot of children are somewhat coddled nowadays, to the point where they expect everything and it comes without a grain of sweat,” LoCascio says. “I wanted my kids to know that the things my wife and I have now, we worked very hard to get them. As the kids get older, we want them to have some skin in the game.”

Couples typically don’t think through these issues as thoroughly as the LoCascios, but their experiences can be a benchmark for others, says Lauren Lindsay, CFP, director of financial planning at Personal Financial Advisors LLC in Covington, Louisiana. She and colleague Robert Reed, CFP, advise the LoCascios, a relationship that includes spending time recently with the LoCascios’ daughter Olivia, a college student, helping her learn to budget her part-time work in-
come, among other financial tasks.

Even before starting college, Olivia says she always knew her parents had been saving, and the family discussed her 529 plan, which is a college savings account that offers tax breaks for contributions and earnings. (See www.savingforcollege.com.) Originally set on attending a private university, she switched at the last minute to a lower cost in-state school when her dad told her whatever she didn’t use, he would pass down to her children for their college some day.

“Money has always been a comfortable topic between me and my parents,” Olivia says. “About the time I started driving, my dad got me my first debit card to make me aware of the purchases I was making. I started out with an allowance and then did some babysitting in high school, both of which taught me the cost of things.”

Her parents also often help with bigger purchases like cell phones and vacations, but she is expected to carry a portion of the costs. As for their estate plans, the couple has stipulations in their documents that require their children to complete college before receiving any inheritance, and stagers that inheritance until nearly middle age instead of making it available immediately, should the couple both pass away while the children are still relatively young. Even at that, expectations for a windfall are low.

**EDUCATION STILL A HIGH PRIORITY**

That attitude is becoming more common as people live longer and therefore have much longer retirements for which to cover expenses, Lindsay says. While many baby-boomer physicians feel the need to use big inheritances to make up for years of not being around much for their kids, younger physicians seem fine with leaving smaller financial legacies, she says. Both groups tend to prioritize education in their estate plans, however.

“There does seem to be more of a concern, not that they owe a big inheritance, but to make sure college is paid for,” she says. “They want their kids not to have student loans like they did,” she says.

Another problem is when children end up with substantially different inheritances. Often, well-intentioned parents try to divide their assets according to their childrens’

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**Leaving it all to charity**

**Options to give back with your financial legacy**

By Janet Kidd Stewart, contributing author

Bill and Melinda Gates famously pledged to donate most of their wealth to charity, as did Warren Buffett. The merely affluent typically leave their money to family members, but for those who don’t want to leave everything to kids—or who don’t have kids—there are a variety of ways to leave a legacy.

“A lot depends on how much money is involved and the client’s appetite for complexity,” notes Susan Repetti, JD, an estate-planning attorney and partner with Nutter McClennen & Fish, a Boston law firm.

Simply naming a charity as a beneficiary of an IRA – or making lifetime rollovers after age 70 ½ to a charity that will count as a required minimum distribution – can get money to the charity without having it tied up in wills and trust documents, Repetti says. Also, unlike heirs, charities don’t have to pay income tax on the gift. And IRA designations tend to generate fewer legal fights than wills, though that may just be due to lack of awareness that assets have been dispersed, she says.

Also, donors are becoming more savvy about ensuring that their estates are going toward very specific causes they support, experts say.

“They are sitting down with representatives of their favorite charities far in advance and coming to agreements on how they want money spent, and the charities are then evaluating whether they are able or willing to commit to that,” Repetti says. Charities are beginning to push back a bit on donors if they find the strings on the money too tight or incongruent with their mission, she says.

Another way to create a legacy during your lifetime that segues into an estate plan is by setting up a donor-advised fund and specifying charities to receive any undisbursed funds at your death. Fidelity, Schwab and Vanguard are three of the biggest.

If you do have family or a trusted friend or adviser, another option is to name successors to oversee the gifts after you’re gone, Repetti says.

An additional way to leave a perpetual giving legacy is via a scholarship fund directly with a non-profit organization that uses interest and earnings off of a principal amount to fund annual scholarships, notes Wendi Temkin, JD, an estate planning attorney in Boulder, Colorado.

“You can really pick and choose how you specifically want to benefit people,” she says. “You can hand money over to an organization for general use or really get into the details and craft a legacy. It’s really your last teachable moment.”
Money Estate planning

“The biggest mistake people make is thinking IRAs go through the will, but they don’t.”
—CAROLYN MCCLANAHAN, MD, CFP, LIFE PLANNING PARTNERS INC., JACKSONVILLE, FLORIDA

needs instead of equally, but the idea frequently backfires, advisers say.

“Part of the problem with estate planning is, it’s a snapshot,” Lindsay says. “A doctor could have a stroke and end up needing crazy amounts of care,” and decimating any inheritance that might have been coming to the siblings of the child who received an inheritance early, for example. Or children’s circumstances could change. A parent might leave more to a social worker daughter and less to a lawyer son, but years down the road the son might face a health issue or layoff, and the daughter’s star may be rising.

Advisers say there are a host of other possible considerations when getting ready to structure an estate for heirs, such as:

01/ Asset location counts
Regularly updating a will or trust can allow flexibility in leaving certain assets to certain children based on their circumstances, experts say.

“If you have one child in a low tax bracket and another in a high one, consider leaving traditional IRAs, which are taxable at withdrawal, to the child in the lower bracket,” Carolyn McClanahan, MD, CFP, an adviser with Life Planning Partners Inc. in Jacksonville, Florida, suggests. Give the higher-bracket child the Roth IRA, which isn’t taxed at withdrawal, she says.

02/ Mind the forms
Particularly for do-it-yourself investors, making sure IRA beneficiary forms are correct is vital, McClanahan says, because there won’t be a planner around to make those reminders.

“The biggest mistake people make is thinking IRAs go through the will, but they don’t,” she says. In other words, even if a will gives assets to heirs equally, for example, if just one child is listed on a beneficiary form, that supersedes the will, she says.

03/ Blended family matters
When working with blended families, setting up an estate plan needs even more careful thought, experts say. Just leaving a lump sum to a spouse with the remainder going to children after the spouse dies can be fraught with conflicts.

If a trust doesn’t specifically state how the money is to be invested and withdrawn, for example, there could either be nothing left for other heirs or not enough income to sustain a spouse during life.

“There is not a lot of portfolio income right now in this environment, which may make a fiduciary take too much risk or too little risk,” says McClanahan.

She helps clients come up with an actual dollar amount that a surviving spouse would need to live on after the first spouse dies. If the trust can’t generate that amount from investment income, then a trustee is allowed to dip into principal to generate the cash flow. It provides flexibility so that the trustee doesn’t have to invest the money in potentially risky ways just to generate the right amount of income, she says.

For example, if a trustee were locked into only taking income, it might cause the portfolio to be heavily skewed toward risky high-yield bonds, she says. Likewise, an investment philosophy tilted too heavily in favor of the children holding the principal might lean aggressively on stocks, creating extreme volatility in a portfolio that is being used for withdrawals to sustain the widow.

04/ When not to take the money
Sometimes, it may make sense to structure assets so that children never actually take possession of all the money, notes Dave Yeske, CFP, PhD,
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“A lot of children are somewhat coddled nowadays ... I wanted my kids to know that the things my wife and I have now, we worked very hard to get them.”

—LLOYD LOCASIO, MD, RADIOLOGIST, BATON ROUGE, LOUISIANA

Estate planning

Managing director of Yeske Buie, a financial planning firm in Vienna, Virginia and San Francisco.

“One way to think about leaving assets is to leave it in trust forever, so that children receive income from the assets but can’t touch the principal,” he says. This strategy carries some creditor protections in addition to ensuring that it will be sustained through multiple generations, he says.

Another way to go is to use matching funds, says Ike Devji, JD, a Phoenix, Arizona attorney specializing in asset protection. Rather than tying distributions to beneficiaries' ages, he says, they can be set up to pay out as a percentage of income earned.

05/ Consider hiring a pro

Particularly when there are several children in a family and sizable assets, it may make sense to hire an institutional trustee at a law firm specializing in probate and estates to oversee a trust rather than giving the task to one sibling, Yeske says.

“There’s a lot to be said for having a professional make sure the tax returns get filed, the bookkeeping is done and investments get managed,” he says. It costs money to hire a professional for these tasks, of course, but it can smooth the process and help sidestep hard feelings if one sibling is chosen over others to run the estate plan, he says.

Devji agrees. Retitling investment accounts and closing out an estate are exceptionally time consuming and people routinely name a sibling without realizing how complicated it can be, he says. Look for someone with a strong professional background and malpractice insurance and give only limited discretion, he recommends.

06/ Define legacy goals

What do we owe our children in terms of an inheritance?

“The one universal theme I hear from clients is they all feel a responsibility to do whatever they can to educate their kids through at least undergraduate school and maybe grad school, so they come out as close to debt-free as possible,” Yeske says. “Then, not as universal, but a majority seems to feel some responsibility to help with a house down payment. After that it really thins out,” he says.

About 20% of Yeske’s clients are physicians. “The biggest thing is to think about how your estate plan is not just a transmission of wealth, but of values,” he says. “The way in which you leave your wealth is the final tangible opportunity to transmit values to your kids. It tells them what you value about them and society as a whole, what responsibilities they have to make their own way and how you’d like all that reflected in your final arrangements.”

07/ Consider other heirs

Naming a favorite charity as a co-beneficiary of the estate not only is becoming more popular, but it is a great way to impart values to kids for years into the future, Yeske says.

He cites a retired physician client who maintains two multi-million dollar IRAs. He keeps one of the accounts, which names a charity as beneficiary, at a static balance, siphoning off earnings annually into the other IRA to continue building his retirement income. The other account fulfills his charitable interests.

08/ Simplicity works

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The one universal theme I hear from clients is they all feel a responsibility to educate their kids through at least undergraduate school and maybe grad school, so they come out as close to debt-free as possible.”

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When wishes change

It’s vital to keep estate documents up to date. In all of her annual client reviews, Lauren Lindsay, CFP, director of financial planning at Personal Financial Advisors LLC in Covington, Louisiana, makes sure IRA and 401k beneficiary forms still carry the correct survivor names, and that any wills and trusts have been updated to reflect altered wishes or changed circumstances. She isn’t an attorney, but advising her clients about when they need to bring in an attorney is a service they appreciate, she says. Do-it-yourself investors, for their part, need to stay on top of this important step, experts say.

Meanwhile, what happens if one or more children demonstrate they aren’t capable of handling their share of an estate? There are ways to navigate that without descending into inequity, some experts say. Carolyn McClanahan, MD, CFP, an adviser with Life Planning Partners Inc. in Jacksonville, Florida, recalls a client who left everything equally to two daughters and didn’t change his will for a decade.

During that time one daughter completed law school and the other got into struggles with addiction. Even if the parent still wanted to leave equal shares to the children—critical in most cases to preserving harmony among them—an updated will and trust could have structured receipt of the funds differently, the adviser says. For example, the child suffering from addiction could receive funds as income off of a principal instead of as a windfall, and it could be administered by a third party.

38 far fewer people need to worry about complex strategies to elude the tax, notes Rebecca Kennedy, CFP, principal with Kennedy Financial Planning, LLC in Denver, Colorado. “It’s more complicated with blended families, but many physicians don’t need the complex planning we once recommended,” she says.

09 Consider insurance

Doctors in blended families who think there may be conflict between children from a previous marriage and a current spouse should explore using insurance as a way to maximize estate assets, Kennedy says.

Assuming the physician is insurable, having policies that pay out an amount equal to (or some share of) the overall estate can create a cleaner break for heirs, she says.

‘IF SOMETHING SHOULD HAPPEN’

Finally, nothing really replaces simple conversations with children over time to communicate wishes and put minds at ease, says Steven Gitt, MD, a Scottsdale plastic surgeon.

“I talked to my [young adult] daughter not long ago and I just said, ‘You know, I’m doing well and healthy, nothing is wrong, but here are the people you need to reach out to if something should happen,’” he says. His own blended family and the employees in his practice count on him to make sure these issues are dealt with, he says. “You need to have these talks.”

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The dangers of writing off patient copays

Doctors have pledged to protect the health of their patients, but they also run a business with legal responsibilities

by ERICA SPREY Contributing author

HIGHLIGHTS

The impulse to help patients by waiving copays is one a physician should resist. Patient cost sharing is viewed as an important component of holding down the rising cost of medical care by commercial and government payers.

It’s natural to want to help your patients; especially the ones struggling to get by on a meager income or retirement pension. At first blush, it may make sense to waive the patient portion of a medical bill after the insurance has paid. But before you put aside a patient’s financial responsibility, consider the legal consequences of doing so. Nowadays, patient discounts, if given incorrectly, can run awry of insurance regulations or even violate federal anti-kickback statutes.

John Meigs, Jr., MD, FAAFP, has practiced as a solo, family physician in rural Alabama for more than 30 years. During that time he says the business of medicine has changed drastically. Prior to the spread of health insurance, physicians would often discount their services for patients who struggled to pay or even give free care for the worst cases.

Now, however, waiving the patient portion of a physician’s fee could potentially land a kind-hearted physician in legal hot water, because failing to collect insurance copays and deductibles could violate contracts with commercial and public payers. It could also negatively impact a practice’s bottom line.

LEGAL CONSIDERATIONS
The American Medical Association’s “Code of Medical Ethics, Opinion 8.03, Conflicts of Interest” states: “Under no circumstances may physicians place their own financial interests above the welfare of their patients. … If a conflict develops between the physician’s financial interest and the physician’s responsibilities to the patient, the conflict must be resolved to the patient’s benefit.”

But as a businessman or woman who has also entered into legal contracts with multiple insurance payers and the federal government, this ethical dictate is not always as simple as physicians might wish.

Attorney Michael Sacopulos, JD, founder and president of Terre Haute, Indiana-based Medical Risk Institute, says that in the vast majority of cases, the physicians he works with are not intent on defrauding payers or the government. “You’ve got a group of people that care about others, or they wouldn’t have gone into healthcare, and they want to provide services,” he says.

But the impulse to help patients by waiving copays is one a physician should resist for several reasons, says Sacopulos. Patient cost-sharing is viewed as an important component of holding down the rising cost of medical care by commercial and government payers.

They reason that if patients have more “skin in the game,” they may make better-informed decisions about when and where to seek medical treatment, and potentially reduce their demands for expensive diag-

Money
Money

WAIVING COPAYS

By Michael Sacopulos

TEST YOUR KNOWLEDGE ON WAIVING COPAYS

1. The prohibition against waiver of copays and/or deductibles applies only to governmental payers.
   A) True  B) False

2. It avoids legal issues to ask a patient to provide an online review of your practice in exchange for waiving a copayment.
   A) True  B) False

3. In addition to monetary penalties, there are possible criminal consequences for improper waiver of deductibles.
   A) True  B) False

4. If a third-party vendor (such as a durable medical goods provider) waives copayments or deductibles in exchange for patient referrals, it is problematic for both the practice and the vendor.
   A) True  B) False

5. A staff member could potentially receive a monetary award for reporting that a practice has improperly waived copays and/or deductibles.
   A) True  B) False

6. Your practice should have a written policy on waiver of copays and deductibles.
   A) True  B) False

7. Documentation of the waiver of any copay or deductible is only necessary for legal compliance reasons.
   A) True  B) False

Key: 1B 2A 3A 4A 5A 6A 7B

Aside from the fact that collecting copays and deductibles is a contractual obligation, if a physician were to routinely waive the patient portion of his or her fee, a payer could take that to mean that the physician’s real usual and customary fee was “x” percent less than originally stated. There have been cases, says Sacopulos, where insurance companies have successfully sued physicians for fraud.

“[Payers and physicians] entered into a contract where they said these are the fees you normally charge … and in fact, what you have done is systematically ignored that. And that is a breach of contract … so you’ve defrauded [the payer],” he says.

Another pitfall for doctors is the possibility of violating the federal Anti-Kickback Statute. There is no lack of news about physicians or medical suppliers who exchange money in return for referrals of new Medicare patients. But even physicians with more altruistic motives could run afoul of federal laws.

The Office of the Inspector General in the U.S. Department of Health and Human Services states in “A Roadmap for New Physicians, Fraud & Abuse Laws” that routinely failing to collect patient copays in any instance other than for individual determination of patient hardship is illegal:

“The kickback prohibition applies to all sources of referrals, even patients. For example, where the Medicare and Medicaid programs require patients to pay copays for services, you are generally required to collect that money from your patients.

FINANCIAL CONSIDERATIONS

Given declining payer reimbursements, failing to collect patient copays and deductibles could also have serious consequences for practice revenue. Barbara Dunn, president of Houston-based MedRecovery Solutions, a medical billing company, says many practices can’t afford not to collect patient balances. “In today’s medical environment, physicians are really hurting themselves [if they don’t collect] because a lot of times the insurance company is paying less than the copay,” she says.

Adding another wrinkle, new high-deductible health plans are making it harder for patients to afford services. Patients may feel unable or unwilling to pay their copays and/or deductibles or skip necessary treatment or testing, says Meigs.

When patients don’t pay their insurance premiums, health insurance companies are asking physicians for refunds for services already rendered, Dunn says, leaving practices to collect from patients who have already demonstrated that they cannot pay.

In cases of true financial hardship, practices can discount treatment fees. The key, Dunn says, is not to make it a regular practice; it must be an isolated incident that is documented in the...
Technology plays a vital role in my field. By treating patients with the latest innovations, I restore more than hearing; I restore hope.
Waiving copays

As long as you bill out the full amount, you can discount anybody’s bill. Just document that the patient has a hardship, and therefore they would discount the patient portion by ‘x’ number of dollars,” she says.

DOING IT RIGHT
To protect your practice’s revenue stream, comply with contractual obligations, and make your front-desk/billing staff’s job easier, it is vital to establish a clear financial policy that spells out provisions for collecting patient copays and deductibles and establishes your policy on patient discounts and charity care.

It doesn’t need to be “pages and pages in a policy manual,” says Sacopulos. “But, I think if [practices] are ever intending to waive off copays and deductibles, it should be done pursuant to a policy with documentation.” Many consultants can provide a template that practices can adopt for their own use.

Here are a few guidelines to follow when creating your practice’s own financial policy:

- **Develop, publish, and train staff on the policy.** Establish the circumstances and qualifying criteria for when your practice will discount patient care, and disseminate that information to staff. By outlining your policies on helping low-income patients, patients without insurance, or patients who may need expensive treatments such as reconstructive surgery, for example, staff will have a consistent policy to follow and will treat all patients alike. This will also protect your practice from embezzlement disguised as waived copays or discounts to staff friends and family members.

- **Develop a system for establishing and documenting financial hardship in the patient chart.** Many physicians are uncomfortable discussing money and often pass that task off to front-desk staff. But it shouldn’t be done willy-nilly. “If you are going to have someone on your staff deal with it, then you need to give them the guidance and the tools to do that in a fair way,” says Sacopulos. He gives his clients a form to use to document patient financial hardship.

- **Make sure that a section is devoted to your policy on professional courtesy.** It used to be common practice to extend discounts to physician colleagues as a professional courtesy, says Meigs. But given contractual obligations to collect patient copays that tradition has fallen by the wayside for many practices. The key, says Dunn, is to make sure that waiving copays is not a routine policy. “More times I see that [practices] will take that patient portion and discount it. And that discounted part is a professional courtesy, but there is still a balance that is billed to the patient,” she says.

- **Institute a system to consistently make a fair effort at collecting outstanding patient accounts.** A typical policy is to send bills to a patient three times, says Dunn. If the patient does not respond, follow up with a phone call and/or a collection letter and document your actions in the patient chart.

If done properly and consistently your practice may safely write off uncollectible copays and/or deductibles, or turn them over to a collections agency. And if the practice is ever audited by Medicare or a private payer, you will have a paper trail that can be easily retrieved from the patient’s chart.

Discounting staff treatment
Providing practice staff with “insurance only” medical care (waiving the patient copay and accepting the insurance reimbursement as payment in full) likely would violate the practice’s insurance contracts. However, practices do sometimes discount staff care as a professional courtesy or an employee benefit. While the custom is well-meaning, it can be problematic, according to Michael Sacopulos, JD, a healthcare attorney. “I think [discounting care] is an employee benefit; I’ve not seen anyone have trouble with that. … The question is do you have to report it as compensation? Technically you are giving them the value of [treatment],” he says.

Experts say that one way for practices to help staff with medical expenses and avoid running afoul of the IRS is to fund a financial vehicle like a Medical Expense Reimbursement Plan (MERP) that reimburses staff members for a portion of their out-of-pocket medical expenses such as copays and deductibles.

Editor’s note: This article was first published in our partner publication, Physicians Practice.
Delivering value-based care means hiring service-oriented staff

by STEPHANIE OVERMAN  Contributing author

If you don’t hire and retain service-oriented staff members who can help you deliver value-based care, be prepared to take a hit to your practice’s bottom line.

“If patients don’t feel like they are getting service—if the person who answers the phone is rude or the doctor didn’t spend enough time with them—they have the choice to leave and go to another doctor,” says Samuel Lee, MD, medical director of ACC North Texas in Fort Worth.

With all the changes in healthcare today, including the Centers for Medicare and Medicaid Services (CMS) setting value benchmarks in the near future, you need to update your hiring strategy, says Rita E. Numerof, PhD, president of the consulting firm Numerof & Associates.

“It’s a different skill set than might have been used five or six years ago. It’s more team-based, more consumer-centered, patient-centered. This is a service business,” she says.

When interviewing job candidates, don’t just look at qualifications such as their education and experience. Look for strong interpersonal skills, Numerof recommends. Look for signs that the individual is a “people person” who will care about the other employees on the team and about the patients and family members who come through the door.

Always look for evidence of good judgment in assessing priorities, protecting patients’ privacy and responding quickly to complaints. “If you’re not coming with good judgment there’s not going to be enough days in the week for me to train you,” she says.

Flexibility is another, especially important skill to look for when you’re hiring a new person for your staff, according to Numerof.

“Most people in physician practices hire too narrowly. They think of the tasks at hand ... and don’t think about what they’re going to need tomorrow.”

If you hire someone new to working in a physician’s office, “you probably don’t have to break any bad habits. You can start fresh and teach them how it’s done now,” Lee says. “If you hire someone who has been doing it for awhile, it’s hard to get them to understand that it’s not just about filling up the schedule.”

“Most people in physician practices hire too narrowly. They think of the tasks at hand ... and don’t think about what they’re going to need tomorrow.”

Send your practice management questions to: medec@advanstar.com.
THE QUESTION OF DISCLOSING MEDICAL MALPRACTICE INSURANCE

by RACHEL V. ROSE, JD, MBA Contributing author

A recent ruling in a New Jersey court serves as a reminder to physicians to check state laws concerning the requirement to disclose medical malpractice coverage.

The issue addressed in Jarrell v. Kaul centered around, “Can plaintiffs maintain a cause of action against a medical doctor for failure to disclose that he did not have malpractice insurance to cover the relevant procedure; and can plaintiffs maintain a cause of action against a medical facility that allowed the medical doctor to perform in the facility procedures for which the doctor does not have malpractice insurance?”

In the State of New Jersey, the answer from the Supreme Court was, “No.”

In this case, the plaintiff/patient, James Jarrell and his wife were awarded $750,000 at the trial court level and then appealed for more money on the premise that the physician did not disclose that he did not have medical malpractice insurance to cover the procedures. The defendant Richard A. Kaul was an anesthesiologist, not a board-certified neurosurgeon or orthopedic surgeon and definitely not fellowship trained in spine surgery.

What the New Jersey Supreme Court did find was, “[a] healthcare facility that grants privileges to physicians to use its facility has a continuing duty to ensure that any physician granted privileges maintains the required insurance,” Judge Mary Catherine Cuff wrote for the court.

Hence, the Jarrells are going back to trial to pursue damages against Market Street, the surgery center, which allowed the physician to operate under these circumstances.

This case raises several issues for physicians. First, it is important to know the medical malpractice insurance laws of the state(s) in which you practice.

Specifically, is there a requirement to carry medical malpractice insurance, and is there a duty to disclose to patients whether or not you carry medical malpractice insurance?

Then there is the practical side:

- Organizations may require it even if it is not required under law;
- Patients may be suspicious if you don’t have it; and
- Your assets may be more vulnerable in the event of an adverse outcome.

Finally, are you operating outside your area of practice and training? Physicians who are operating above board often do a separate residency or fellowship in a certain area to obtain the additional training necessary to perform certain procedures. If you don’t, then you could be opening yourself up to significant liability, as well as unnecessarily harming patients.

In sum, a duty to disclose and what is a prudent business practice do not always coincide.

A duty to disclose and what is a prudent business practice do not always coincide.”
Reducing readmissions
Improving collaboration between physicians and hospitals

by SUSAN KREIMER Contributing author

Barriers exist that make it difficult for primary care physicians to help manage the handoff from the inpatient to outpatient setting.

Primary care physicians who have entered into financial risk-sharing agreements with hospital systems may reap rewards for preventing readmissions.

REDUCING THE RATE of unplanned hospital readmissions has always been important, but it has become even more critical under the Affordable Care Act (ACA) because they are a major driver of healthcare costs and patient harm. Primary care physicians are emerging as a secret weapon in this process.

Hospitalizations represent almost a third of the $3 trillion that the United States spends on healthcare annually. A significant portion of these hospitalizations involve patients returning soon after they are discharged, according to the Institute for Healthcare Improvement, a Cambridge, Massachusetts-based non-profit.

After a patient is discharged, the primary care physician has the challenge of finding out what transpired in the hospital—a feat difficult to accomplish in a 15- or 20-minute office visit, especially without a universal electronic health record, says Danielle Snyderman, MD, who practices family medicine, geriatrics, and primary care and is a professor at Thomas Jefferson University Hospitals in Philadelphia, Pennsylvania.

“Many of us are not the clinicians taking care of patients through the hospital stay,” she says. “Anytime there is a handoff to another provider, it adds to the complexity and is a potential area where errors can occur.”

The ACA levies financial penalties on hospitals for avoidable readmissions of Medicare patients within 30 days of their first discharge. Since the Centers for Medicare & Medicaid Services (CMS) began penalizing hospitals in October 2012, readmission rates have been declining.

The level of fines is tied to the degree of excess readmissions, so those with higher rates than the national average receive lower Medicare payments. Hospitals lose as much as 3% of their total Medicare reimbursement for high rates of patients readmitted within 30 days of discharge.

CMS set the post-discharge time frame at 30 days because readmissions over longer periods could be related to factors beyond hospitals’ control—for example, complicating illnesses, patient behavior or post-discharge care.

Specific medical conditions for which hospitals incur readmission penalties are chronic obstructive pulmonary disease (COPD), heart attack (acute myocardial infarction), congestive heart failure (CHF), and pneumonia. Unplanned readmissions for surgical procedures include hip or knee replacements.
Of the 3,464 facilities included in the CMS Hospital Readmissions Reduction Program, 2,665 of them had excess readmissions on at least one of these measures and are subject to a payment cut for fiscal year 2016—an estimated total of $420 million.

Barriers exist that make it difficult for primary care physicians to help manage the handoff from the inpatient to outpatient setting, acknowledges John Meigs, Jr., MD, a family physician in Centreville, Alabama and president-elect of the American Academy of Family Physicians.

The reasons vary: Sometimes the patient doesn’t identify a primary care provider upon arrival at the emergency department or the hospital fails to give timely discharge information to that physician. In other cases, Meigs adds, the patient hasn’t established a rapport with a primary care physician.

Also, many primary care physicians no longer follow their patients in the hospital, where hospitalists and specialists now oversee much of the care being delivered.

"In many situations, they have very little influence, interaction, or engagement with the inpatient team taking care of that patient. Lack of sharing of information is one of the challenges that needs to be overcome to reduce avoidable readmissions," says Ana McKee, MD, chief medical officer and executive vice president at The Joint Commission, which accredits healthcare organizations.

"We view an avoidable readmission as a failed discharge," she adds. "Once organizations adopt this perspective, they can begin to analyze and understand the causes that lead to readmissions and prevent future recurrences."

**MAKE THE CARE CONNECT**

Under traditional payment models, primary care teams typically struggled without any additional reimbursement for post-hospital discharge coaching to help patients cope in the face of complex chronic and life-threatening illnesses, says David C. Judge, MD, an internist and chief medical officer at Iora Health in Boston, Massachusetts, and a member of the Medical Economics editorial advisory board. Iora provides primary care services to more than 30,000 patients nationally with physicians in capitated and risk-based contracts.

Increasingly, however, payment modalities are emerging as a result of financial support and interventions under the ACA. "Savings for these types of interventions can be used to invest further in primary care," Judge says. "We will see more innovation and progress on this front. It will largely be driven by primary care."

Primary care physicians can help facilitate the exchange of information between hospitals and their practices in several ways. First, they can educate patients about the importance of telling the hospital who their primary care physician is—ideally, at the time of admission. Physicians should also establish good communication with local hospitals, especially discharge planners, so that the hospitals can implement policies and procedures...
Hospital readmissions

“Many of us are not the clinicians taking care of patients through the hospital stay. Anytime there is a handoff to another provider, it adds to the complexity and is a potential area where errors can occur.”

— DANIELLE SNYDERMAN, MD, PROFESSOR, THOMAS JEFFERSON UNIVERSITY HOSPITALS, PHILADELPHIA, PENNSYLVANIA

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to notify physicians of their patients’ discharges, says Meigs. “Hospitals can advise patients to contact their primary care physician, but without timely discharge information from the hospital, the physician cannot be proactive in initiating follow-up visits, medication reconciliation, lab work, and referrals,” he says.

Primary care physicians can bill for these functions under transitional care management CPT codes 99495 and 99496. Transitional care management benefits patients, physicians and hospitals, Meigs says, and will gain traction as the healthcare system gravitates even more toward value-based reimbursement.

Payers will evaluate physicians to a greater extent based on hospitalizations, readmissions and emergency department visits, attributing unnecessary or avoidable uses of resources to the provider who is primarily responsible for a patient’s care. Most often, that’s the patient’s primary care physician.

REWARDS FOR REDUCING READMISSIONS

Primary care physicians who have entered into financial risk-sharing agreements with hospital systems may reap rewards for preventing readmissions. In an accountable care organization (ACO), a physician’s compensation depends in part on the overall cost of care for a defined patient population. “That would definitely put pressure on primary care providers to keep people out of the hospital to begin with and then to keep them from coming back,” says Katherine Hempstead, PhD, director of health insurance coverage initiatives at the nonprofit Robert Wood Johnson Foundation.

The majority of such contracts only specify “upside” terms, in which physicians earn bonuses for meeting performance measures, but don’t incur risks for falling short of expectations. Other contracts delineate both an upside and a downside, with the possibility of greater rewards but heftier losses if disease management goals aren’t met. While the majority of physicians aren’t yet in risk-bearing arrangements, readmissions guidelines spurred new values and norms around improved care coordination, with hospitals reaching out more to primary care providers and vice versa, Hempstead says.

Coastal Medical Inc., a Providence, Rhode Island-based primary care ACO, has implemented multiple strategies to reduce hospital readmissions. For example, it receives daily alerts about hospital admissions, discharges, emergency department visits, and transitions to intensive care units for its patients, says Al Kurose, MD, Coastal Medical’s chief executive officer.

Many of the alerts come from two Providence-area hospital systems. Each system posts alerts via a secure “file transfer protocol,” akin to an electronic mailbox, early every morning. Other alerts to Coastal come from Currentcare, the state health information exchange, for patients who have enrolled in that database, which allows hospitals throughout Rhode Island to transmit updates to those patients’ primary care providers, Kurose says.

Coastal Medical’s nurse care managers track hospital admissions and discharges and call patients to schedule follow-up office visits, inform them of needed tests, and coordinate potential medication changes. In 2015, Coastal implemented a centralized transitions of care team—consisting of a nurse care manager, nurses and medi-
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Hospital readmissions

cal assistants—who now monitor alerts as patients make transitions and contact them to ensure proper follow-up care. The team serves five offices, and Coastal plans to scale up this program in 2016 to encompass all of its locations.

Because Coastal has multiple shared savings contracts based on total cost of care—and a portion of those dollars are reinvested into new programs as well as distributed within the company—Coastal physicians have incentives to reduce preventable readmissions as a way of lowering the overall cost of care. The result, Kurose says, is alignment of incentives between Coastal’s ACO payment models and hospitals’ best interests.

“We’ve had to react to what the hospitals are doing and to work collaboratively with them, but we are really driving the same agenda,” he says. “What you want to do is optimally manage that transition of care from the hospital back home or from the hospital to a skilled nursing facility. This improves the safety of care and experience of care for patients, while also reducing avoidable readmissions.”

MAKING A SMOOTH TRANSITION

Unlike a patient’s primary care physician, other healthcare specialists may not be able to focus as much on other medical problems that can impact care, or the personal values that may influence decision-making, says Snyderman.

“When patients have several chronic and potentially life-limiting medical problems, understanding their personal values may impact choices regarding how aggressive they want their medical care to be,” she explains. “If patients understand that although medical interventions such as dialysis and artificial nutrition may prolong life in select circumstances, pursuing these interventions may not always afford the quality of life many of them seek.”

The recommended length of time between a hospital discharge and the first post-discharge doctor’s appointment has shortened in recent years. It used to be two weeks, but experts now recognize the importance of having patients follow up with

7 Critical Steps for Physicians to Help Reduce Readmissions

Internists and other primary care physicians can have a significant impact on reducing the risk of hospital readmissions, according to David C. Judge, MD, an internist and chief medical officer at Boston, Massachusetts-based Iora Health and a member of the Medical Economics editorial advisory board. He notes that the moment of a patient’s transition from an inpatient facility to home “is a particularly difficult moment” for patients and their families. In order to reduce readmissions, there are several steps physicians can take during this moment, including:

1. Be aware as much as possible regarding the patient’s admission and plan for upcoming discharge.

The primary care team can often share information with the inpatient care team that is critical to the medical management such as medical history or recent evaluations that will influence decision making. Some primary care organizations have the advantage of access to data plans. The primary care team can often share information with the inpatient care team that is critical to the medical management such as medical history or recent evaluations that will influence decision making. Some primary care organizations have the advantage of access to data that informs them on a daily basis regarding which of their patients are currently hospitalized. Many primary care practices and teams nationally do not have timely information and must often rely upon patients, caregivers and families to keep them updated.

2. Reach out to the patient within 48 hours of discharge.

The main goal is to discuss the areas outlined above and gain a deeper understanding of the patient and caregiver questions, concerns and their ability to manage the care plan. This initial contact will often be done by a registered nurse but providers may need to be involved depending upon the complexity of the patient’s situation. There are other care team members who are increasingly playing
their physicians sooner, says Gail A. Nielsen, who trained at the Institute for Healthcare Improvement and works as a consultant in Des Moines, Iowa.

During the office visit, physicians can employ the “teach-back” technique to ascertain how well patients understood post-discharge instructions. Asking patients to repeat directions gives physicians a sense of how well patients will care for themselves outside the hospital, Nielsen says.

CMS encourages primary care providers to collaborate with their state’s Quality Innovation Network and Quality Improvement Organizations, which recruit community stakeholders to form coalitions focused on improving care coordination for Medicare beneficiaries as they transition from one healthcare setting to another.

Leveraging information technology is essential in reducing readmissions. “Access to timely information for all healthcare team members, whether acute or ambulatory, is critical,” according to a CMS official.

By 2019, CMS’s goals are to lower hospital admissions by 20%, reduce readmissions by 20%, and increase community tenure (the number of nights that patients spend in their homes) by 10%. Ongoing follow-up care for high-risk patients is key.

To assist further with transitions, Coastal Medical’s two nurse care managers make daily hospital rounds and another nurse performs these functions in nursing homes.

“...We’ve had to react to what the hospitals are doing and to work collaboratively with them, but we are really driving the same agenda. What you want to do is optimally manage that transition of care from the hospital back home.”

— AL KUROSE, MD, CHIEF EXECUTIVE OFFICER, COASTAL MEDICAL, RHODE ISLAND

an important role in this communication including health coaches and medical assistants for example.

3. Pay particular attention to performing a medication reconciliation process. This is to clarify the medication list and dosing of all medications to be certain that the patient and caregivers understand medication management instructions and potential side effects of medications or signs that the treatment may not be effective.

4. Work to assist the patient and caregiver in managing the scheduling of home services and specialty appointments.

5. Schedule the patient to be seen in the office as quickly as possible, but no later than one week from the date of discharge. This is especially the case for patients who have been quite ill and have complex medical issues. For patients who are very debilitated and cannot easily come to the office, consider a home visit if your organization can enable that to happen.

6. Encourage and empower the patient and caregiver to reach out to the primary care team when additional concerns or questions arise. Scheduled phone check-ins can be incredibly reassuring to patients and caregivers. However, reaching the team with unanticipated and urgent concerns by phone or email will be necessary and the team should do as much as possible to be certain that the patient and family understand how best to do that especially after usual office hours.

7. Consider integrating the discipline of health coaching into your primary care team. Coaches are increasingly playing a critical role in the ways suggested above but also in working with patients to understand how they can increase their self-management skills and gain confidence in managing their health that will enable them to improve their health over time and reduce the risk of hospitalizations.
Operations

Hospital readmissions

TRANSITIONAL CARE MANAGEMENT CODES: THE BASICS

<table>
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<th>Code</th>
<th>MDM level / details</th>
<th>Follow-up communication</th>
<th>Work RVU</th>
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<td>Within 48 hours of discharge</td>
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Source: American College of Physicians

visits. These individuals have a lot of input in the discharge planning process and can help to assure safer care transitions, Kurose says.

On the hospital side, a communications program is operating in full force between emergency physicians at academic medical center hospitals and Coastal physicians. The program stipulates that an emergency department physician call a Coastal Medical patient’s primary care physician soon after the assessment and before any decision on disposition.

At Coastal Medical, the on-call physician reviews the patient’s electronic health record, provides information to the hospital-based team, and participates in a discussion about the plan of care.

For Coastal patients in the Medicare Shared Savings Program, Kurose says, the number of hospital readmissions has decreased by 15% since 2011. Kurose also expects a favorable impact from the disease management programs Coastal is implementing for patients with congestive heart failure and COPD.

One hospital where Coastal patients often receive care has started a joint replacement center. The center’s quality improvement processes and a focus on transitions of care have reduced the number of patients who require stays at skilled nursing facilities after joint replacements, Kurose says. Another hospital has collaborated with Coastal to implement a “warm handoff” from its pharmacists to Coastal’s clinical pharma-
cists for patients with diagnoses specified by CMS in the Hospital Readmissions Reduction Program.

Kurose views the new incentives in a positive light. “More effective management of transitions of care will almost certainly result in better care for patients, reductions in avoidable readmissions, and lower total cost of care,” he says. “These are outcomes that patients, primary care physicians, hospitals, and ACOs should be willing to work together to support.”

There is already a significant awareness nationally of the importance of primary care at moments of transition, and organizations are sharing best practices, internist Judge says. Patients and caregivers who have availed themselves of health coaching resources are experiencing the power of self-management. “This area in particular is an exciting frontier where an incredible amount of progress will be made in the years ahead.”

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Tech Talk

Negative online reviews: 5 ways to lessen the impact

by GABRIEL PERNA Contributing author

Encountering a nasty online review from a patient is a distressing experience for physicians—and can harm the practice’s reputation and bottom line. What can physicians do to protect themselves?

1. **Open the lines of communication**
   If a patient seems frustrated during his visit, ask what is wrong, says Andy Pasternak, MD, a family physician in Reno, Nevada. “Find out if there is anything you can do to remediate the situation,” he says. “Sometimes you can come up with solutions; a lot of times you can’t and you just have to take it as a negative hit.”

   Aaron Braun, MD, medical director at SignatureCare Emergency in Dallas, Texas, also advocates this approach. “Encourage them to call or contact the office or provider immediately with any questions or concerns,” he says.

2. **Get them to say something nice**
   It’s OK to ask patients to leave a good review on one of the physician review sites, says Anthony Oliva, DO, national medical director at Boston-based health tech company, Nuance.

   Tod Baker, chief executive officer of MDValuate, which provides physician performance analytics based on consumer-facing data, agrees. “I’d guess most interactions between physicians and patients are positive,” he says. “If the patient goes away happy and the physician is happy … what doesn’t happen is the physician never asks the patient to help her do something with that [positive feeling]. My recommendation is if you have a happy patient … tell them to go online and talk about their experience.”

3. **Don’t respond to bad reviews immediately**
   Not only do you not want to say something inflammatory in the heat of the moment, you want to be careful about not violating the Health Insurance Portability and Accountability Act and patient confidentiality, says Pasternak. It may make more sense for the physician to call the patient on the phone, he says. Responding online may only make it worse.

4. **Get out in front**
   Some organizations have responded to the trend of patient online reviews by surveying patients on their own. For many, it’s hard to do that without available resources. Still, patient satisfaction scores are already part of government programs, through Medicare’s Physician Quality Reporting System (PQRS) and the Hospital Quality initiative. Baker says that in the near future, most value-based reimbursement efforts will include patient satisfaction scores. In other words, do it now or wait and do it at the last minute.

5. **Get better**
   The best way to avoid getting hammered on physician review sites is to learn from previous mistakes and try to improve based on what you learned from them, say experts. “If something is bad on there … find out if there was anything you could have done differently, so it doesn’t happen again. That’s the biggest thing. Don’t put your head in the sand,” Oliva says.

“The best way to avoid getting hammered on physician review sites is to learn from mistakes you made.”

This article was first published in our partner publication, Physicians Practice. Send your technology questions to: medec@advanstar.com.
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The manufactured interoperability crisis is failing doctors

Oftentimes the most important scientific experiments are the ones that yield the most unexpected results. The key to success is to be open-minded and unbiased enough to change the narrative based on unexpected data.

Today the health IT community faces similar “unexpected results” that conflict with the narrative. A couple of months ago, I attended a health IT meeting on connecting healthcare. Like dozens of similar HIT meetings, the entire event was dedicated to interoperability. The moderator for the first panel asked for a show of hands from the audience on two questions. The first was, “Do you believe there is a crisis in HIT over lack of interoperability?” Out of about 1,000 attendees, about four raised their hands.

Second question: “Do you believe the connectivity crisis can be solved with government policy?” A couple of extra hands were raised, but no more than 10, or about 1% of the audience. The four panelists, all representing major IT or electronic health records (EHR) vendors, were asked the same two questions. None answered yes to either question.

Later in that meeting, a panel of four physicians convened to discuss, “Improving physician engagement through interoperability” for an hour.

The conversation stayed on the subject of interoperability for about five minutes. Then the conversation drifted towards the things doctors really talk about: EHR notes are impossible to read; meaningful use is confusing, impossible to comply with, and adds nothing to patient care, EHRs add dozens of hours per week to a physician’s workload, leaving less time and energy for the patients themselves. And the list went on.

So here is the unexpected result—the “mold in the culture dish.” The interoperability narrative pushed by EHR vendor executives, government and the IT trade groups is accepted neither by those of us who touch patients for a living nor by many who work in health IT. The concept of interoperability has been hijacked by those at the top of the HIT food chain to serve their needs, not the needs of patients and those who give them care.

The Grand Narrative defines interoperability in terms of moving large volumes of medical records between major silos in the healthcare system. While that definition does indeed have some relevance, almost all doctors will tell you that the interoperability we care about the most comes not from a top-down paradigm of healthcare but a bottom-up model that regards every patient as unique. We need interoperability that supports individual patient workflow. Doctors need a system that can, with a single button click, or a couple at the most, do anything from schedule a chest X-ray to order labs to schedule surgery to refer to a specialist.

That capability requires back-end connectivity — interoperability, if you will. It’s hard for docs to think about the “larger view” when our basic IT needs are still unmet. We need interoperability that gets our work done so that we can pay more attention to our patients, not less. We need connectivity to labs, imaging facilities, physical therapists, surgery centers and any place else we send patients to get care. That kind of connectivity does not exist beyond large “closed shop” institutions.

The HIT community is currently obsessed with interoperability, but their definition is misguided. So what will the top of the HIT food chain do with its “moldy culture dish?” Will they follow Sir Fleming’s lead and make the proper adjustments to the narrative? Will they listen to doctors and their own colleagues in the HIT community? Will they redefine interoperability in a more relevant, useful manner?

Let’s talk about it.

Michael Koriwchak, MD, practices in Atlanta, Georgia, and has been working with healthcare IT since 1977. This article was first published in our partner publication, Physicians Practice.
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