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The United States Preventive Services Task Force (USPSTF) was established in 1984 as an independent panel of experts whose goal was to establish guidelines for preventive services for use by the medical profession and patients. The panel is comprised of 16 individuals, many of whom are practicing clinicians and all of whom have expertise in certain preventive disciplines.

In so doing it provides the medical profession and the public with specific guidelines for offering such services. But in my opinion, some of its recommendations cause confusion among patients and physicians and lull them into a complacent attitude toward preventive care.

The USPSTF lists 96 different conditions for which it has published recommendations. But nowhere is there any recommendation on how often to have a general checkup, or even whether to have one. The task force doesn’t touch that subject, because despite its denial that recommendations are made without concern for cost-effectiveness, the “annual physical” is usually not covered by insurance or considered cost-effective. But every patient who, as a result of a checkup, has been found to have some abnormality for which they were asymptomatic feels it was money well spent.

In the early 1970s, clinical staff and faculty professors in my family medicine residency were vigorously promoting the annual checkup as an effective, logical means for patients to become part of the “medical system” and have their health needs addressed. We residents found that to be a great idea and a meaningful change from the episodic care delivered for decades. It was an uphill battle, but one that physicians were winning. In my practice of 40 years, I did two to four adult complete physicals, and numerous Pap smears, pelvics and breast exams, four days each week, to provide my patients with the best preventive care I could offer. It seemed to be very effective, and patients were appreciative and compliant in scheduling each year.

Then along came the USPSTF, and the preventive care paradigm shifted. Suddenly, mammograms were more harmful than helpful because they led to unnecessary additional mammogram views and biopsies. Prostate-specific antigens (PSAs) were taboo, too, because they led to “unnecessary” prostate biopsies. Pap smears were no longer helpful for finding cervical cancer and were done too frequently to be cost-effective.

In short, just when the medical profession was influencing the preventive medicine attitudes of Americans, the USPSTF recommended against services that had become commonplace and widely accepted.

The USPSTF has earned the respect of healthcare providers in all clinical disciplines, and provides helpful guidelines for performing preventive services. Certainly, the vast majority of the USPSTF’s recommendations are sensible and noncontroversial, because they are well-proven and time-tested.

As guidelines change, the time between essential procedures lengthens, increasing the risk of missing changes in a patient’s health. I think these time lapses are a disservice to patients, because they begin to adopt a “if I don’t feel bad, I must be OK” approach to health screenings. It is the duty of every healthcare professional to know the health history and lifestyle of all patients and advocate on their behalf for appropriate screenings based on that knowledge, in spite of USPSTF guidelines, because they are just that, guidelines. The public is better served with this attitude.

William M. Gilkison, MD, is a family physician in Greenwood, Indiana. Do you agree with his opinion on USPSTF guidelines? Tell us at medec@advanstar.com
Population health challenge

Closing care gaps for better outcomes

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MORE ON LEAVING INDEPENDENCE FOR EMPLOYMENT ON PAGE 42

“To do population health well, it will take a larger scale than smaller ... practices have. But it’s possible to share resources.”

LAWRENCE CASALINO, MD, PROFESSOR, WEIL-CORNELL COLLEGE

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Number of states with laws permitting physician-assisted suicide

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Recertification is crazy and unfair

I attempted the (MOC) exam last fall and failed after hours of practice trying to prepare studying things I have not done in 20 years, i.e. vent settings and renal calculations.

The knowledge that we are tested on is for people coming straight out of residency, not a PCP who has been in a successful office practice for 20 years. I was going to attempt it again in the fall of 2016, but only because my hospital, which I never admit to, requires it for me to remain affiliated with them even though I am using the hospitalist service 100%.

The whole thing is crazy. My specialty now is suboxone maintenance and there was not one question on the test concerning this.

Lisa M. Noyes-Duguay, MD
WESTERLY, RHODE ISLAND

MOC is scary, ‘extortion’ at best

I am a board certified neurologist since 1997, re-certified by MOC in 2007 and I absolutely will not be participating in MOC again. The Newsweek articles were such an eye opener that I actually feel violated.

It represents extortion at its best and what is even scarier is that I suspect the boards will lobby the insurance companies, Medicare, and all of their political allies to require doctor be board certified in order to participate. They will be losing millions of dollars if they don’t and I don’t think they are going to cave that easily.

Denise Bongiovanni D.O.
DENVILLE, NJ

Physicians should drop MOC now

The solution to abolishing (MOC) prior to 2020 is to simply not take the exam. Once a critical number of physicians are not boarded by the ABMS the problem is gone.

I understand there are some situations where there may be immediate adverse consequences to not recertifying but there are also a lot of individuals that could drop it to help move the ball forward.

My wife and I just dropped ABFP/ MOC certification.

We will continue to be board certified – through the National Board of Physicians and Surgeons – join even if you don’t drop ABMS right now.

John Nolte, MD Family Practice
Miriam Nolte, MD Family Practice
ANCHORAGE, ALASKA

Trump may not be far off with Medicaid reform

In response to “Donald Trump unveils seven-point healthcare reform plan (MedicalEconomics.com, March 3, 2016),” (this is) not a bad start. States should control Medicaid. State governments can be inept but at least they can address individual regional attitudes in a country with large regional differences, and state governments are more accessible to their constituents. Moreover, the multiple laboratory concepts (are) valid.

I love the idea of medical providers posting prices. Anything that moves the system away from the third party paysers is good.

Anthony M. Perry, MD
SCRANTON, PA

Just say no to recertification

The solution to MOC is for all 905,000 physicians to just say no. Then, the MOC people will go away as will the requirements for MOC per hospital and insurance contracts.

The second best solution in our democratic society is to put it to a vote, board by board. Physicians already have to pass medical school, muster out of residency programs, pass a certification exam, report CME hours, perform well by hospital quality assurance, and withstand reviews of their treatment programs by insurers and online sites. And then there’s torts.

So just what does MOC do for us? After 38 years private and academic practice, my answer is that MOC is a guppy tax. Don’t stand for it.

As Jefferson said: “Disobedience to tyranny is obedience to God.”

Anthony E. Foley MD
DAYTON, OHIO
Navigating HIPAA

Practices that send email appointment reminders, upgrade their technology, or contract with third party vendors should beware. Absent proper protocols, such actions can expose providers to risk. Indeed, compliance with HIPAA is now far more complex than it was before regulators cracked down, delivering bigger fines and aggressive enforcement.

bit.ly/hipaamistakes

HIPAA resource center

The latest on how to keep your practice compliant with federal privacy and security rules

MedicalEconomics.com/tag/hipaa-resource-center

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REMEMBER WHEN THAT WAS ALL YOU HAD TO DEAL WITH?

LET DOCTORS BE DOCTORS
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The American Board of Internal Medicine (ABIM) announced findings from a recent survey about potential changes to the current maintenance of certification (MOC) assessment. All ABIM Board Certified physicians were invited to participate in the survey, and more than 9,200 responded.

Results from the survey, "Improving the MOC Assessment Experience," were presented to more than 70 leaders of medical societies attending an ABIM meeting on Friday, April 8.

The ABIM board of directors and council are considering physician-guided recommendations about options for updating the MOC assessment process as well as a timetable to seek feedback from physicians, launch a pilot, evaluate the pilot and ultimately implement changes. ABIM will share the timetable later this spring.

Maintenance of certification

**ABIM survey finds physicians want MOC changes**

86% responded positively to the idea of taking an assessment at home or in their office rather than in a testing center and were comfortable with potential tasks necessary to facilitate secure, remote assessment.

79% responded positively to the idea of taking shorter knowledge assessments that would allow them to skip the full-length MOC exam.

76% responded positively to the idea of using online resources during an assessment.

56% responded positively to the idea of shorter, more frequent knowledge assessments; responses to options regarding the preferred length and frequency of assessments varied widely.

76% want maintaining their board certification to signify that they are staying current in the knowledge they need to practice.
The Centers for Medicare & Medicaid Services (CMS) took another step in moving primary care away from the traditional fee-for-service payment model.

The agency announced in April the Comprehensive Primary Care Plus (CPC+), a program CMS says will make it easier for primary care doctors to deliver the best outcomes for patients covered by Medicare and pay them for achieving results and improving care. The program ratchets up the financial consequences for physicians who fail to meet quality and utilization metrics.

"The Comprehensive Primary Care Plus model represents the future of health care that we’re striving towards," Patrick Conway, MD, CMS deputy administrator and chief medical officer said in a press release. "By supporting primary care doctors and clinicians ... we can continue to build a healthcare system that results in healthier people and smarter spending of our health care dollars."

The initiative can accommodate up to 5,000 practices, or more than 20,000 providers and 25 million patients across the country.

The CPC+ program represents the next step in CMS’s intention to emphasize quality and outcomes over volume when reimbursing primary care physicians. Early in 2015 CMS laid out a goal of tying 30% of Medicare payments to quality and value via alternative payment models by the end of 2016 and 50% by the end of 2018.

Practices will participate in the initiative on one of two tracks. In Track 1, practices will receive a monthly care management fee from CMS in addition to fee-for-service payments under the Medicare physician fee schedule. Practices choosing Track 2 will also receive a monthly care management fee, but instead of full fee-for-service payments they will receive what CMS describes as "a hybrid of reduced Medicare fee-for-service payments and up-front comprehensive primary care payments for those services." The goal is to allow practices more flexibility in delivering care outside of the traditional face-to-face encounter.

Practices on both tracks will receive data on their costs and utilization patterns, as well as up-front incentive payments. Payments for practices on Track 1 will be $2.50 per beneficiary per month, while those on Track 2 will be $4 per beneficiary per month. Practices will either keep or repay the incentive payments based on their ability to meet quality goals.

CPC+ also calls for Medicare to partner with commercial and state payers to help practices deliver advanced primary care, a concept that focuses on elements such as accessibility to services, care that is proactive and comprehensive and patient engagement.

Physician organizations cautiously support the initiative. In a written statement, the American College of Physicians (ACP) says it’s encouraged by the availability of two tracks for participating in CPC+, "with different delivery requirements and payment methodologies that reflect the diversity in primary care practices."

The American Academy of Family Physicians (AAFP) expressed support, saying the program is "another important step toward transforming the way patients get care, the quality and efficiency of that care, and the overall improvement of health in the community."

Ransomware attacks present data security problem for hospitals

Nearly 75% of U.S. hospitals responding to a recent poll could have been hit with ransomware in the last year and many might not even know it, according to a Healthcare IT News and HIMSS Analytics Quick HIT survey.

“Over half the people we polled indicated that they had some sort of ransomware attack,” says Brendan FitzGerald, HIMSS analytics research director for advisory solutions.

Furthermore, 25% are either unsure or have no way of knowing whether ransomware attacks were perpetrated against them.

That means about 75% of respondents either were or could have been targeted with a ransomware attack, Healthcare IT News reports.

Very few ransomware attacks have been successful to date, the website writes—which explains why only a handful catch the public’s attention.

About 50% of respondents said they are unsure or have no way of knowing if they managed to find such attacks.

How ready are hospitals for a successful ransomware attack? “Seventy three percent of the health systems we surveyed have a business continuity plan in place, so if something happens they are prepared to address it,” FitzGerald said.

Of the remaining 26%, only 3% answered that they are unsure, while 23% said they do not have a business continuity plan in place should a ransomware attack occur.
Preventing malpractice lawsuits due to EHR errors

The rise of electronic health records that don't always work well can lead to liability risks if managed incorrectly

by AINE CRYTS Contributing author

HIGHLIGHTS

- Slow down while documenting a patient visit in the EHR — while continuing to maintain eye contact with the patient.
- With EHR alerts, physicians should think about whether the alert highlighted something they should have known already.

AN ELDERLY female patient with nose/ear complaints mistakenly received a prescription for Flomax—a treatment for enlarged prostate, which isn’t approved for use by women and has a side effect of hypotension. The mix-up happened because the prescribing physician’s electronic health record (EHR) had no drug alert for gender, according to The Doctor’s Company, a Napa, California-based insurer of physician and surgeon medical liability.

According to the company, user factors, which means how physicians and others use the EHR, contribute to 64% of its EHR-related claims, while system factors—such as a system design failure or lack of alert—contribute to 42%.

Diagnosing and treating patients is enough to keep any physician on their toes. Add to that the responsibility of documenting care in the EHR and it creates “a perfect storm of too much complexity,” says Howard Marcus, MD, an internal medicine physician in Austin, Texas, and a consultant for The Doctor's Company. “I am really disappo
Certainly not easy to talk to a patient while documenting the encounter, you have to make sure you have the right details in the EHR that are accurate for the patient you’re seeing.

Peter Basch, MD, who practices internal medicine in Washington, D.C., also counsels physicians to slow down while documenting a patient visit in the EHR—while continuing to maintain eye contact with the patient. “You don’t want to miss anything as a physician, and you want to make sure that the patient understands you correctly,” he says. His recommendation to physicians is to abbreviate their findings in an initial note, instead of writing full sentences about what’s unique to the patient. Then they can go back into the record later and update with their full findings.

He says patients sue physicians when they feel disrespected and that physicians aren’t paying attention to them. “That’s what makes patients angry and feel harmed. Yet another reason that reviewing a chart with the patient during their appointment is so valuable. Navigating through the chart with the patient is also a great way to correct the record in real time,” he says.

Basch, who also chairs the American College of Physicians’ Medical Informatics Committee, says patients’ lawyers would have to prove that harm was done, not just that the physician read something wrong or spelled a name wrong. “People don’t sue you because of a comma, if no harm was done.” A good alternative is to work with a scribe in the exam room, says Sharona Hoffman, JD, professor of law and bioethics and co-director of the Law-Medicine Center at Case Western Reserve University Law School in Cleveland. Prescription errors can also put patients at risk, so she recommends having another medical professional check the label to confirm the proper dosage. For example, a nurse could have another nurse double check or include it in the quality control process to ensure another pharmacist confirms the dosage.

EHRs and metadata
When a malpractice case comes to trial, metadata—the data that serves to analyze or interpret clinical information within the EHR—is important. The case’s outcome can depend on metadata that reveals the alerts the physician saw while documenting care in the EHR, when the patient’s record was accessed, and how the information was presented, says M. Re Knack, JD, a healthcare and litigation attorney with Ogden Murphy Wallace in Seattle.

Prior versions of patient records exist. That can happen when a physician dictates a report, then corrects the record because it was transcribed improperly. This is where the plaintiff’s attorney will “find the jewels,” she says.

Basch isn’t as worried that metadata will lead to being sued by his patients. Whether someone can prove that you looked at a particular note in the EHR, you can still be sued, he says. In his opinion, physicians should be less concerned about timestamps and more worried about whether they paid attention when they saw an alert or they should have taken a few minutes to review a patient’s labs.

With EHR alerts, physicians should think about whether the alert highlighted something they should have known already, he says. Maybe that was an alert recommending an eye exam for a diabetic patient or another alert for a colonoscopy for a 50-year-old man, says Basch. Physicians need to pay attention to any alerts that come up, especially if they point to something a physician should know anyway. “Suits aren’t brought because of an alert. Suits are brought be-
EHR-related claims broken out into system factors and user errors

The Doctors Company, which has closed on 97 EHR-related claims between 2007 and 2014, categorizes these types of claims into eight system factors and seven user factors.

**EHR system factors**
Technology, design, and security issues

- Failure of system design: 10%
- Electronic systems/technology failure: 9%
- Lack of EHR alert/alarm/decision support: 7%
- System failure—electronic data routing: 6%
- Insufficient scope/area for documentation: 4%
- Fragmented EHR: 3%

**EHR user factors**
EHR-related issues attributable to users

- Incorrect information in the EHR: 16%
- Hybrid health records/EHR conversion: 15%
- Prepopulating/copy and paste: 13%
- EHR training/education: 7%
- EHR user error (other than data entry): 7%
- EHR alert issues/fatigue: 3%

Source: The Doctors Company

cause a reasonable provider should have known better,” he says.

Hoffman says that doctors often protest that the majority of alerts are unhelpful, that they’re distracting during the patient visit and take time away from the patient. But physicians shouldn’t miss critical alerts. If they’re annoyed by the barrage of alerts, physicians should work with their EHR vendor or their IT department to adjust the alerts, rather than turning off alerts on their own, advises Hoffman.

“What’s important to consider is that alerts are filtered properly and tailored to the patient population you’re serving,” says Hoffman.

Physicians should always make sure to pay attention to defaults within the EHR, in particular when it comes to the date care was provided.
Suits aren’t brought because of an alert. Suits are brought because a reasonable provider should have known better.”

—SHARONA HOFFMAN, JD, CO-DIRECTOR, THE LAW-MEDICINE CENTER AT CASE WESTERN RESERVE UNIVERSITY LAW SCHOOL, CLEVELAND, OHIO
The population health CHALLENGE
Closing care gaps for better outcomes

by KEN TERRY Contributing editor

HIGHLIGHTS

A big challenge for primary care physicians is that PHM requires the cooperation of specialists and hospitals in their medical neighborhood.

FEE-FOR-SERVICE MEDICINE is on the way out. That may be hard to believe if most of your income still comes from such payments, which reward physicians for the volume of services they provide. But it’s clear that payers are increasingly emphasizing reimbursement methods that reward value, rather than volume—and that that transition is accelerating.

On March 3, the U.S. Department of Health and Human Services (HHS) announced that it had reached its goal of tying 30% of Medicare payments to alternative payment models (APMs) nearly a year ahead of schedule. By the end of 2018, HHS predicts, about 50% of Medicare payments will be going to APMs such as accountable care organizations (ACOs), patient-centered medical homes (PCMHs) and bundled payment arrangements. Medicare’s new physician payment methodology, which takes effect in 2019, will be another step away from fee for service. Private payers are moving in the same direction at a similar pace.

As reimbursement shifts from pay for volume to pay for value, population health management (PHM) is gaining traction among physicians and other healthcare providers. In this care delivery model, a key ingredient of both ACOs and PCMHs, providers focus on optimizing the health of their entire patient panel, rather than just diagnosing and treating individual patients when they present for care.

First in a series In our series on Population Health Management (PHM), Medical Economics will discuss the challenges facing physicians as they set off on this epochal journey and how some practices are dealing with them. In part two, we’ll focus on the technological tools available to support PHM, how to select the right solutions, and what to do with them. The third part will explore the operational requirements for PHM, especially in the areas of health monitoring, care coordination, and patient engagement.
Whether practices are contracting with payers for shared savings or are taking on financial risk for the care they provide, they must learn how to manage population health to succeed under value-based reimbursement. The measures used in determining value-based payments are quality, costs and patient experience; no healthcare organization can do well on those indices unless it can manage population health to prevent people from getting sick or sicker.

In a practice or organization that embraces PHM, physicians and their care teams stress preventive care and proactively manage chronic diseases. Care managers provide extra assistance to high-risk individuals, and physicians work with other providers to improve transitions of care, especially after hospitalizations.

PHM requires an organized, planned approach to care both during and between office visits. It also requires improved coordination of care across care settings. Physicians lead care teams that include lower-level clinicians and other professionals, often including behavioral specialists, pharmacists, and social workers.

Additionally, PHM emphasizes patient engagement to improve health behavior and the ability of patients to care for themselves. Practices reach out to patients who have care gaps, whether or not those people seek care. Access to providers is increased; patients are educated about their conditions and the importance of following their care plans; and care managers check in regularly with chronically ill patients to see how they’re doing.

**CULTURAL CHALLENGE**

There are significant cultural, financial, and technological barriers to PHM, with culture by far the biggest obstacle, says David Nash, MD, founding dean of the Jefferson College of Population Health in Philadelphia.

While payers are pushing doctors into value-based care and alternative payment models, he notes, it is “presumptuous” to maintain that physicians will suddenly start to practice differently than they have for their whole careers. “It’s not realistic. It’s like turning a battleship around inside the Panama Canal.”

Nash ticks off some of the reasons why physicians find it difficult to embrace PHM. First, he says, they’re used to thinking that more care is better, not that less is more. Second, they’re not accustomed to following the latest evidence-based practice guidelines, he says. Doctors must also get used to “hitherto unthinkable levels of public scrutiny and accountability,” such as the comparative reports on medical groups’ cost and quality that are now published in California. Groups cannot score high on these report cards unless they manage population health well.

Physicians must also get used to the idea of being part of care teams, which are fundamental to PHM. Care teams are also central to PCMHs, which play an important role in PHM and are building blocks of ACOs. Doctors have no experience in working in a team setting, Nash notes. Staff members, too, are used to doing things a certain way and don’t welcome change.

Christopher Berard, DO, who practices internal medicine with two colleagues in Babylon, New York, recalls that in 2011, just after his practice acquired an electronic health record (EHR) system, he wanted to seek PCMH recognition from the National Committee on Quality Assurance (NCQA). But the practice wasn’t ready for it.

“It was too much change too fast,” he recalls. “You still need to maintain your volume to stay afloat. And just adopting the EHR cut my productivity to 80% of normal.”

Berard and his colleagues later delegated some duties to their staff to do PHM. For example, when a patient calls for a refill, staffers now glance through the chart to see whether the patient is overdue for a visit or has had a prescribed blood test. With the help of Beacon Health Partners, the physician-led ACO to which the practice belongs, the group has obtained its PCMH certification.

**MEDICAL NEIGHBORHOOD**

Another big challenge for primary care physicians is that PHM requires the cooperation of specialists and hospitals in their medical neighborhood. Historically, information exchange between PCPs and these other players has been limited and often not timely. But to manage population health, doctors and their care teams must coordinate patient care with other providers. So they need to know what is happening with their patients at all times.

Whether the PCPs refer patients to spe-
Some say you should focus mainly on the 5% of patients who drive about 50% of health costs. Others say you should raise all boats, you’ve got to tackle everybody and look at the social determinants of health."

—DAVID NASH, MD, FOUNDING DEAN, JEFFERSON COLLEGE OF POPULATION HEALTH, PHILADELPHIA, PENNSYLVANIA

Specialists or patients self-refer, it is incumbent on the specialists to keep the PCPs informed and send them consult reports on a timely basis. Similarly, patients’ personal doctors—who, in some cases, may be specialists—should be informed when the patient is admitted to the emergency department or is admitted to or discharged from the hospital. Not only is this information essential to continuity of care, but it is vital to any organization that takes on financial risk.

Specialists are more likely to cooperate if they have the promise of a stream of referrals, say observers. Primary care physicians will only get the attention of specialists, Nash says, if it’s a pocketbook issue.

Robert Fortini, PNP, chief clinical officer of the Bon Secours Virginia Medical Group (BSVMG) in Richmond, Virginia, notes, “The specialists at BSVMG are very receptive. They’ve figured out that the medical home team—especially the nurse navigator—is their feeder mechanism.”

Berard and Keith Hoerning, DO, an internist who belong to the same ACO, say that the ACO specialists have been cooperative, in some cases more so than other consultants. But they both practice on the south shore of Long Island, and most of the ACO specialists are on the north shore, making it difficult to send patients to them. Also, Berard says, he still refers to a lot of his old specialists because “you try to use the guys you trust.”

Ken Cohen, MD, medical director of Denver’s New West Physicians, says his primary care group has taken a very aggressive approach to collaborating with specialists. The practice has trimmed the number of consultants its doctors use from about 700 to 250, keeping only those who are high quality and cost-effective.

“We have narrowed them down to a very small, engaged panel who are willing to work with us on the efficient use of technologies, generic prescribing, and tight communication with the PCPs,” he says. As a result, these specialists receive nearly all the referrals from the group, which has about 200,000 patients.

Persuading hospitals to cooperate with primary care doctors on PHM is problematic unless the physicians are employed by or affiliated with a healthcare system. When independent doctors join together in an independent physician association (IPA) or an ACO to compete effectively in the market, Nash says, “That’s a threat to the core business of the hospital.”

This might explain the difficulties that the Beacon ACO has had in working with hospitals. For example, admission-discharge-transfer alerts from hospitals are “huge” in PHM, says Simon Prince, MD, co-founder and former president of Beacon Health Partners. But Northwell Health (formerly NorthShore-LIJ), the dominant health system in the area, never supplied the ACO with those alerts. Later, when the ACO formed a partnership with Catholic Health Services (CHS), another health system, CHS began providing those alerts to the ACO.

Some independent groups have decided not to work with hospitals at all. Early on, Cohen says, New West decided that “hospital priorities will never be commensurate with population health management priorities. There’s too much focus on bed occupancy and the latest technology. It’s just not going to work. So our focus has been to control all aspects [of hospital care] internally and to look at every-
thing we do as a cost center." As part of this strategy, New West employs its own hospitalists, he adds.

**FINANCIAL BARRIERS**

Although elements of PHM are included in the NCQA criteria for medical homes, a small practice can’t manage population health on its own. Aside from the need to coordinate care across care settings, the organizational, technical and financial demands are too great for a small practice. So many physicians have formed IPAs and/or ACOs to tackle the elements of PHM that they can’t cope with themselves and to pool the necessary resources.

"To do population health well, it will take a larger scale than smaller or even medium-sized practices can have," notes Lawrence Casalino, MD, professor of public health and chief of the division of health policy and economics at Weill-Cornell College in New York. "You really can’t have a nurse care manager for an eight-physician practice. There’s not enough volume to support him or her."

But with an IPA or ACO, he says, "it’s possible to share such resources across practices without necessarily having to be in the same ownership structure." The IPA or ACO also can provide IT support and help member practices become patient-centered medical homes, as the Beacon ACO has done.

Even with this help, PCMHs specifically have to overcome serious financial challenges. For example, this model requires about twice as many support staffers per full-time physician as a conventional primary care practice, according to recent studies. Some health plans support PCMHs with care management fees and/or shared savings. Practices that invest in population health management must either quickly land such value-based contracts—perhaps as part of an ACO—or must find other ways to increase their fee-for-service revenues, or both.

Securing value-based contracts doesn’t necessarily mean that a practice will be successful with them. A couple of the groups interviewed for this story, for example, have built or joined ACOs, but those organizations have not cut costs enough to receive bonuses under the Medicare Shared Savings Program (MSSP).

To reduce the pain of this transition, some groups are adding PHM components in ways that can generate extra revenue. For example, they may identify patients’ preventive and chronic care gaps and bring them into the office so they can receive the recommended services. This is not as simple as it sounds, because it involves the use of EHR reports or standalone registries to identify the patients with care gaps. Practices must also deploy staff to reach out to those patients or buy one of the software products that automatically call or email the patients. Nevertheless, this can be an effective transitional strategy.

"There’s a great ROI for physicians, because it’s feeding the fee-for-service model," notes John Moore, founder and CEO of Chilmark Research, a company that publishes reports on health IT. "More patients are coming in the door and you’re closing the care gaps, which is a win-win for physicians."

**CHRONIC CARE MANAGEMENT**

Another winner for some practices is Medi-
To do population health well, it will take a larger scale than smaller or even medium-sized practices can have.”

—LAWRENCE CASALINO, MD, PROFESSOR OF PUBLIC HEALTH, CHIEF OF THE DIVISION OF HEALTH POLICY AND ECONOMICS, WEILL-CORNELL COLLEGE, NEW YORK

care’s Chronic Care Management (CCM) program, which includes a new code (99490) for appropriate non-visit care of Medicare patients with two or more chronic conditions.

Since that code pays an average of $40 per beneficiary per month and involves only 20 minutes of care management, it has gotten the attention of many physicians. The key drawback of the program is that it requires hiring nurse care coordinators, who are expensive. But Emerald Physicians in Hyannis, Massachusetts, reports that they have that problem licked.

“When CCM was first announced, it was like manna from heaven,” says Cormac Coyle, MD, founder and medical director of the Cape Cod group, which includes 24 physicians and 26 midlevel providers. “We had been waiting for something like this for 20 years. Now there was a true ability to focus on prevention and to get paid to do it.”

Emerald Physicians has created a CCM unit that includes 15 nurses and will soon expand to 25. “CCM is producing a direct return on investment,” Coyle says. “By the second or third month, the average nurse is breaking even on that, and by month four or five, they’re making a small profit.”

There are other ways to support care coordinators. For example, the nurses could provide services in Medicare’s Transitional Care Management Services program, which allows physicians and certain non-physician practitioners to bill for improving post-discharge care. They could also do the bulk of annual Medicare physicals. But ultimately, the key to making the PHM infrastructure pay is to take financial risk, says Fortini. Full-risk capitation, he says, “is where we have to go. We might as well gear up for it.”

Bon Secours Virginia Medical Group has been doing just that for the past several years, reversing, for example, its ratio of primary care doctors to specialists so that the former are now the majority. But the 624-provider group still hasn’t garnered shared savings in the MSSP. It has had some success with commercial contracts, netting $800,000 in shared savings from Cigna last year. But Fortini says the group isn’t ready to accept downside risk yet, although it has discussed that with some payers.

It takes a long time to build the infrastructure and the know-how needed to assume risk. For example, New West Physicians, which holds Medicare risk contracts and commercial shared savings pacts, has a very strong financial base. But it has been developing its PHM capabilities for more than 20 years. It had to trim its specialist panel, start a hospitalist program that provides 24/7 coverage for its hospitalized patients, and create a case management program for post-acute care and high-risk patients, among other changes. In the past few years, the group has also learned how to use its EHR to improve chronic disease care.

One of the keys to New West’s success is how it compensates physicians. “A lot of it is alignment of incentives,” Cohen says. “If you do population health management well, it aligns very well with the Institute of Medicine Triple Aim, which is optimal patient service, optimal quality of care and optimal efficiency. By doing that, the bonus revenues are such that you can design compensation incentives that reward physicians for actively managing their panels. When that happens, everything works. The incentives are there and the funding is there to account for the extra work involved.”

The New West compensation package encourages physicians to work hard, but also
There’s a great ROI for physicians, because it’s feeding the fee-for-service model. More patients are coming in the door and you’re closing the care gaps, which is a win-win for physicians.”

— JOHN MOORE, CHIEF EXECUTIVE OFFICER, CHILMARK RESEARCH

Rewards them for other things. The ratio of incentives is 60% for production, 30% for controlling utilization of resources, and 10% for quality of care, Cohen says. The group does so well financially that its primary care physicians earn significantly more than the average generalist. Not surprisingly, the group’s physicians are pretty happy, according to a study done by independent researchers.

**SETTING PRIORITIES**

With so many moving parts, PHM is a complex mechanism to grasp in its entirety. Different groups have set different priorities as they tackle what Nash calls “an amazing transformation” of healthcare. One basic issue is whether to focus on managing high-risk patients who generate the majority of health costs, or to manage the entire patient population to prevent people from getting sick or sicker.

Experts are divided on this question, Nash notes. “Some say you should focus mainly on the 5% of patients who drive about 50% of health costs. Others say you should raise all boats, you’ve got to tackle everybody and look at the social determinants of health,” Nash falls somewhere between these two camps. It’s very important to manage high-risk patients, such as those who have hepatitis C or who have bone-marrow transplants, because they drive a big chunk of the cost, he notes. But he also understands the argument for taking better care of the whole population.

BSMVG is in the “raising all boats” party. Fortini summarizes the argument in favor of whole population health this way: “It’s a no-brainer under value-based payment. The colonoscopy avoids the bowel resection. That’s where the money is.”

New West Physicians also addresses the needs of its entire population, Cohen says. But it has put a lot of effort into improving outcomes for hospitalized patients to lower the readmission rate. All its patients are contacted within 24 hours after discharge, and the hospitalists communicate directly with the PCPs to pick up any hospital-related issues, he notes.

As a result, he says, the group’s 30-day readmission rate for Medicare patients is 6.7%, compared to Medicare’s average rate of 18%. “It’s a matter of organizationally designing a system so you’re touching all of your patients all the time.”

It’s hard to do that without using health information technology. Nevertheless, while Cohen’s group relies on its EHR to support its PHM effort, he feels that the value of health IT has been overrated. A more critical factor, he says, is leveraging the doctor-patient relationship to improve outcomes.

Other physicians express similar sentiments. “Technology is important,” says Gretchen Hoyle, MD, of Twin City Pediatrics in Winston-Salem, N.C. “But the technology is a tool for the humans who do the real interaction.”

Nash doesn’t dispute this, but he emphasizes that data is indispensable for some purposes, including providing doctors with performance data so they can improve. “All of population health comes down to appropriate use of the data,” he says. “If you don’t have the data, you can’t compete. The only way we’re going to close the feedback loop down to the individual doctor or group of doctors is with good data. Once you have the data, you can leverage the data to change the culture.”
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Population health’s impact on private practice

Managing populations presents challenges to small practices that require innovation and careful planning

by NICOLE LEWIS  Contributing author

As the push to implement population health initiatives gets underway, Lonnie Joe, MD, is still mulling over whether his private practice can survive the changes he’ll have to make to participate in this emerging model of care.

Like many private practice physicians, Joe, an internist who has been practicing for almost three decades, is trying to tailor his four-year-old group practice in Detroit, Michigan, to meet the defined goals of population health: identifying groups of patients with specific medical conditions such as diabetes, hypertension, or cancer, and implementing a variety of health management approaches to improve these patients’ outcomes.

With a population that is aging rapidly (the number of people aged 65 and older is projected to be 83.7 million by 2050, compared with 43.1 million in 2012), the urgency to build a smarter healthcare system that targets older patients, patients with specific medical conditions such as diabetes, hypertension, or cancer, and implementing a variety of health management approaches to improve these patients’ outcomes.

Population health is one of many health reform initiatives that stakeholders claim will slow the rise in healthcare costs and improve patient outcomes. However, for small-to-medium size physician practices, implementing this model often will require redesigning their practices as they adopt new incentive payment models that involve taking additional steps to closely monitor patients so as to improve their health.

Such an endeavor requires additional staff, better patient engagement and more technology to support population health initiatives.

“Implementing a long-term population health strategy at private practice physicians’ offices requires a team-based model of care with skilled personnel and infrastructure, all of which requires adequate financial support,” says Nitin Damle, MD, FACP, president-elect of the American College of Physicians.

For Joe, the costs are too high and the goals are difficult to achieve.

“It’s expensive,” Joe says. “For a start, I would have to hire a full-time employee to call my patients to remind them of appointments, follow up with medication adherence and perform other mundane tasks.”

Those “mundane tasks” are the meat and potatoes of what will make population health a success, says David Nash, MD, MBA,

Nash says private practices will need to contend with four key tactical realities:

- managing their test ordering behavior,
- coordinating care with other practitioners,
- referring patients to specialists and
- admitting their patients for both acute and chronic care.

“In a world that is focused on improving population health, profligate testing and wasteful prescribing would have to end,” Nash says. “For example, prescribing a statin for an 87-year-old woman or ordering a prostate-specific antigen test on a 92-year-old man makes no clinical sense.”

IDENTIFYING BARRIERS
While the fundamental requirements for supporting population health targets call for a new approach to delivering care, the limits that come with practicing medicine among low-income, chronically ill patients has restrained Joe’s 14-member private practice from fully participating in an initiative that would help the 100 patients (65% are senior citizens and 60% suffer from diabetes) that Joe sees every week.

A basic requirement for a successful population health initiative, Joe says, is an office that’s accessible to the population it serves, but this is often a challenge, particularly in poor communities. Many of Joe’s patients are covered by Medicaid, don’t have a car and depend on relatives to take them to doctor appointments. If these relatives are working on the day of the appointment the patient won’t come to see him.

“I have patients that have to make a choice between paying for transportation or paying for their copay—they can’t pay both,” Joe says.

Another challenge is access to the Internet. To coordinate care and engage patients, healthcare providers are increasingly using emails, but many of Joe’s patients can’t be reached that way.

“Fifty percent of the patients that my physician practice serves do not have access to the Internet, and many of my older patients don’t know how to send or receive emails.”

—LONNIE JOE, MD

Even with these challenges, Joe recognizes that population health is the care model of the future.

With this in mind, Joe met earlier this year with a health plan offering incentive payments if his practice targeted groups of patients and implemented policies that met medical benchmarks as a way to demonstrate improvements in patient outcomes.

“The health plan’s incentive program is attractive because it’s dollars we don’t have, but there’s a downside,” Joe says.

He noted that in order to meet the incentive plan requirements his office would have to hire an employee to contact patients on a full-time basis.

“That would cost our office approximately $40,000 per year, which means we would spend more than we would receive in incentive payments,” says Joe, who is also a speaker for the National Medical Association’s House of Delegates. “I have not seen very many approaches under the banner of population health that address the day-to-day issues our private practice has to tackle in order to advance a population health strategy.”

As healthcare reform presents endless challenges and changes, Joe is thinking about his next moves. He might join an accountable care organization, a hospital or a larger health system.

Whatever he does, Joe says the current trend doesn’t bode
Operations  
Population health and small practices

→27 well for physicians seeking to lure younger physicians to join their group practice.

“What we are seeing is that initiatives like population health are turning many younger physicians away from private practice. They prefer to join a hospital or healthcare system that has deep pockets, all the technology they need and a good salary,” Joe says.

**MIPS DECISIONS LOOMING**

Even as small private practices face significant hurdles to adopting population health, the drive to implement measures that improve outcomes while developing payment models tied to quality metrics is advancing at a rapid pace.

In line with this shift, the U.S. Department of Health and Human Services has set a goal of tying 85% of all traditional Medicare payments to quality or value by the end of 2016 and 90% by 2018 through programs such as the Hospital Value Based Purchasing and the Hospital Readmissions Reduction Programs.

Last year’s passage of the Medicare Access & CHIP Reauthorization Act of 2015 (MACRA) has heightened the sense of urgency among healthcare stakeholders to develop new initiatives that will transform the payment system from a fee-for-service model to one that rewards paying for value and better care.

As new payment and care models emerge, population health is forcing private practice physicians to reconsider how they’ll manage every step of their engagement with patients.

With costs a growing concern Damle, who is part of an eight-physician internal medicine in Wakefield, Rhode Island, says adequate funding could be achieved if health plans reimburse providers through innovative payment models, which include a per-member per-month fee, enhanced fee-for-service payments, a population-based global payment and pay-for-performance initiatives to cover the costs of implementing and practicing population health.

Damle says that health plans provide his practice with a baseline fee-for-service payment for seeing patients at the office, and an oversight member-per-month payment. The practice also receives reimbursements for reporting quality measures to programs that the private health plans operate.

“We also receive payments for meeting quality measures such as smoking cessation counseling, blood pressure control in hypertensive patients, diabetes control, colon and breast cancer screening and other quality metrics,” Damle says.

However, the payments don’t always cover the costs associated with the expense of new technology and personnel needed to support these programs.

“When we add up what we spend to support population health targets and subtract what we receive in reimbursements from the insurance companies, we break even. It’s not profitable. It’s really a matter of quality more than anything else,” Damle explains.

What shouldn’t be forgotten in this equation is the benefits population health initiatives provide to health insurance companies.

“Health plans receive a good return on investment. The patients they insure are healthier, have fewer complications and end up in the emergency room or are admitted to the hospital less frequently,” Damle says.

**EMBRACE THE EARLY STAGES**

Unlike Joe, Damle’s population health initiatives benefit from serving a middle-to-high-income population of patients who have jobs, cars to drive to their appointments and ready Internet access.

Still, to curb costs and improve quality measures, Damle’s practice is considering joining an accountable care organization to leverage technology and tap the expertise of personnel such as pharmacists, behavioral health specialists and clinical nurse managers to support patients with complex needs.

As private practice physicians find their footing in the population health model, other healthcare stakeholders are embracing it. The Healthcare Information and Management Systems Society’s research division, HIMSS Analytics, recently released an addendum to its December, 2015 Population Health Essentials Brief.

The additional research, which focuses on chronic disease management and preventive health and wellness, shows that of the nearly 200 healthcare executives interviewed, more than half of those without a population health initiative at their organization said they plan to implement population health programs in the future.

HIMSS research also shows that the lead-
“When we add up what we spend to support population health targets and subtract what we receive in reimbursements from the insurance companies, we break even. It’s not profitable. It’s really a matter of quality more than anything else.”

— NITIN DAMLE, MD, FACP, INTERNIST, WAKEFIELD, RHODE ISLAND

ing areas of focus for organizations with chronic disease management initiatives in place are diabetes (75.9%), congestive heart failure (58.6%) and chronic obstructive pulmonary disease (41.4%).

Respondents indicated a strong effort to tackle chronic diseases, specifically diabetes and congestive heart failure, says Brendan FitzGerald, director of research for HIMSS Analytics.

Physicians such as Yong Ki Shin, MD, and his wife, Clara Shin, MD, also are seeing this trend, but doubts abound as to whether population health strategies can effectively work to combat patients with chronic diseases in lower-income communities. The couple operates a two-person internal medicine practice in Montesano, Washington, which has a population of 4,000. Yong Ki Shin, who has been practicing for two decades, says that approximately 25% of his patients have diabetes, and 70% are over age 65.

Among his concerns is that population health programs don’t take into account the differences between rural and urban patient populations or income disparities.

“Patients in cities where the population has jobs and high incomes are going to have better access to care than patients living in rural areas where incomes are below the national average. The way I see population health is that one size doesn’t fit all,“ Yong Ki Shin says.

He adds that practices should not be denied incentive payments because their patients don’t visit the doctor or practice medication adherence. He notes, for example, that healthy individuals that are not mentally ill have more energy and resources to take care of their diabetes.

“If you are uneducated, have limited income to pay for insulin or if you are addicted to pain medicine and you have bipolar disorder taking care of diabetes is going to be much more difficult,” Yong Ki Shin says.

Still, even if he declines to take dollars from health plans that offer population health incentives, his practice will survive largely because of his income from other jobs. He is assistant dean and clinical associate professor of Medicine at the University of Washington School of Medicine, and treats patients at the Grays Harbor County Jail.

As physicians prepare to meet the demands of this new initiative, HIMSS’ FitzGerald says it’s worth remembering that population health and the cost models to support it are still in the early stages of development.

“The use of at-risk cost structures are limited and they are essential in practicing true population health,“ FitzGerald says. “For physician practices who are looking to initiate population health programs I would recommend they get executive/physician buy-in and move forward as a team, start where they see the most need within their current population and be consistent in their approach.” ☞

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Capturing chronic care revenue requires IT infrastructure

by DAVID RATHS Contributing author

When Curtis Story, MD, a solo primary care physician in Port Charlotte, Florida, first heard that Medicare would begin paying physicians for offering patients chronic care management (CCM), he was optimistic that the additional revenue would bolster his practice for work it was already doing. But more than a year later, he has yet to bill for CCM.

STORY IS NOT alone. A 2015 survey of 309 provider organizations by PYA and Enli Health Intelligence found that early adopters are struggling with physician engagement, patient education, efficient processes and regulatory compliance. To bill for CCM services, practices must offer 24/7 access to care management services, a platform for direct patient-practitioner communication and the ability to manage transitions between providers and settings.

Story couldn’t figure out how to make the program’s requirements fit with his practice’s workflow. For instance, he found that the requirement for tracking the time he, his medical assistant and care coordinator spend on tasks for these patients, and the time spent billing for the new code, would be inconvenient and time-consuming. His electronic health record (EHR) system doesn’t have features to help him with these tasks. “I am not sure it would be worth the effort,” he says.

“Having the IT capability in place to support CCM is absolutely a huge issue,” says Naomi Levinthal, MS, a senior consultant with The Advisory Board, a technology, research and consulting firm. She adds that very few of the firm’s clients are billing for CCM. The Centers for Medicare & Medicaid Services requires practices to use EHRs that meet its certification standards when billing for CCM.

To comply, physicians are finding they have to work with their EHR vendor or develop workarounds of their own, she says. “I imagine many providers will be going to their EHR vendor and saying this is something they want to do and asking for help,” she says. “It would behoove the industry to make this as easy as possible.”

Traditionally, physicians were told never to code based on time, but CCM is among a handful of relatively new codes that require tracking the amount of time spent on the activity, says Atlanta-based practice consultant Elizabeth Woodcock, MBA, FACMPE. She adds that practices had gotten used to not being paid for non-face-to-face work. “Now they can,” she says.

**Make a list**

For practices considering whether it is worthwhile to try enrolling their patients, Woodcock has some “old-school” advice: create a list of 20 potential high-need patients and tape it by the phone.

“Don’t bill yet; just mark how many minutes you spent with each patient. At the end of the month, add it up and see how many patients you spent 20 minutes on,” she says. Then try to determine if that time is financially worth tracking and billing for, and working on technology integration.

**Outside help**

Another option is to outsource the CCM responsibility to one of the independent firms springing up to provide the required services. Michael Paul Gimness, MD, a solo family practitioner in Plant City, Florida, pays a company to help manage CCM, yet still sees significant revenue from his 147 enrolled patients.

Story and his staff members haven’t given up on CCM. “We still talk about it every week,” he says.

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IN DEPTH

Policy

Physician-assisted suicide up for debate in states

What role should physicians have in states where assisted suicide is allowed?

by JOHN N. FRANK Contributing author

HIGHLIGHTS

Most proposals are modeled after Oregon’s law. One provision of the legislation is that a request from a terminally ill patient must be made in the presence of a doctor.

THE BATTLE OVER passing what proponents call end-of-life bills and what opponents call physician-assisted suicide legislation already has surfaced in New York, Colorado and Maryland this year. Expect roughly 20 other states to consider similar legislation before the year is out.

The differences in language used by the two sides demonstrate how sharp the ideological divisions are and how fierce the lobbying is likely to be for and against these measures.

Enactment of these laws protects physicians from liability if they prescribe end-of-life medications for terminally ill patients who request them and after the patients have complied with the requirements of the legislation. But laws currently in effect do not compel doctors to write such prescriptions if their moral or religious beliefs preclude them from doing so, say proponents. Opponents have concerns, however.

“We think it’s going to fundamentally change the doctor-patient relationship,” says David Stevens, MD, president of the Christian Medical & Dental Association, which opposes physician-assisted aid in dying. “Can you easily trust a doctor who can cure you or kill you?”

The American Medical Association’s (AMA’s) official position on the matter is to oppose what it terms physician-assisted suicide. “Allowing physicians to participate in assisted suicide would cause more harm than good. Physician-assisted suicide is fundamentally incompatible with the physician’s role as healer, would be difficult or impossible to control, and would pose serious societal risks,” states AMA ethical opinion 2.211.

The American Academy of Family Physicians “doesn’t have a policy specifically on physician-assisted suicide,” according to a spokesperson, but follows the AMA Code of Ethics. Through its own ethics guidelines, the American College of Physicians “does not support legalization of physician-assisted suicide or euthanasia,” according to its manual.

On the state level, however, the story is
different. “Almost in every state where it has been legalized, the state medical association has taken a neutral stance. Whenever that happens, it passes,” says Stevens.

That was the case in California, for example, which enacted a bill last year. Backers say California’s move means momentum is on their side in 2016.

CALIFORNIA A HARBINGER?

“With the win in California last year, it only makes sense to go after the big and impactful states. That will lead to other states after them,” says Peg Sandeen, PhD, MSW, executive director of Death with Dignity, one of the groups supporting right-to-die legislation.

“Our work in California really changed the narrative,” agrees Jessica Grennan, national director of political affairs and advocacy for Compassion & Choices, which led efforts to pass the California legislation. Legislators in other states have been in touch to discuss lessons from California they can apply in their states.

The widely-reported saga of Brittany Maynard, the 29-year-old California woman who moved to Oregon so she could end her life rather than continue suffering with terminal brain cancer, helped garner the support needed to pass the California legislation. Maynard’s husband has spoken in other states in support of the end-of-life option legislation, Grennan says.

In addition to pushing measures in state legislatures, backers have used court challenges. States that have enacted so-called death with dignity statutes include Oregon, California, Washington and Vermont, while the Montana Supreme Court decided the end-of-life option is legal in that state.

STATES TO WATCH

States to watch this year in addition to those listed above include Minnesota, Massachusetts and Iowa, Grennan says.

The issue is likely to surface in 20 to 25 other states over the course of the year, predicts Diane Coleman, president and chief executive officer of Not Dead Yet, a group opposing right-to-die legislation. Congress has shown no appetite to address such a controversial issue and is even less likely to do so during an election year, both sides agree.

Some medical groups have backed end-

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**Key Death with Dignity Laws in brief**

**OREGON**

Oregon’s Death with Dignity Act passed in 1994 but didn’t go into effect until after withstanding a 1997 ballot initiative attempt to overturn it. Proposals in other states now often mimic key provisions of its law.

Specifically, the Oregon law “allows terminally-ill Oregonians to end their lives through the voluntary self-administration of lethal medications, expressly prescribed by a physician for that purpose,” according to the state’s health department. The law requires that a terminally ill patient request medication in writing that will end his or her life. The request must be witnessed by two people who can attest that the patient is capable of making such a decision and is not being coerced.

Among the law’s requirements for an attending physician are that he or she make the diagnosis of terminal illness, ensure that the patient is making an informed decision, discuss alternative care options with the patient, review risks associated with the medication to be prescribed and refer the patient to a consulting physician who will confirm the diagnosis. Since the law was enacted, 1,327 people have requested the prescriptions and 859 have died after taking the medications, according to state data.

**CALIFORNIA**

Governor Jerry Brown signed California’s End of Life Option Act on Oct. 5, 2015, making California the largest state in the country to permit physician-assisted suicide. The statute took effect in January.

The California law is modeled on the Oregon statute but also allows patients who do not speak English to have an interpreter. A patient must submit two oral and one written request to a physician for the needed medication. Physicians are not permitted to be one of the witnesses who see a patient request end-of-life medication under the California statute. The law has a sunset date of January 1, 2026 unless it is renewed by the state legislature.

“Medical decisions belong to patients and their care providers and [physician-assisted suicide] falls into that category.”

—DEBORAH VOZZELLA HALL, MD, PRESIDENT, AMERICAN MEDICAL STUDENTS ASSOCIATION

Students Association, for example, signed on to a letter of support for the California legislation, says Deborah Vozzella Hall, MD, national president of the association.

“Medical decisions belong to patients and their care providers and this falls into that category,” says Hall. “We have really...
Policy

Physician-assisted suicide

long supported the idea of autonomy for patients, understanding that there have to be appropriate measures in places to make sure that a terminally ill patient isn’t suffering from depression or external pressures.

In Colorado, both the Denver and Boulder medical societies are supporting a proposal, says Grennan. “We’re starting to see more support across the board from physicians,” she says.

THE OREGON MODEL

Most proposals are modeled on the Oregon law, which was passed in 1994 but did not go into effect until after voters had defeated a 1997 ballot initiative to repeal it. It has since withstood a variety of legislative and legal challenges.

It requires a patient diagnosed as terminally ill to “make a written request for medication for the purpose of ending his or her life in a humane and dignified manner,” according to text of the legislation. The request has to be witnessed by two people, one of whom is not related to the patient nor entitled to any portion of the patient’s estate. The request has to be made in the presence of a doctor.

The law also outlines requirements for the attending physician, including his or her diagnosis and prognosis and discussion of feasible alternatives such as hospice care. It also stipulates that a physician does not have to provide end-of-life medication, saying only that if a doctor does not want to participate he or she should transfer a patient’s records to a new provider selected by the patient.

Maryland’s proposed law also requires doctors who do not wish to participate only to transfer records, notes Shane Pedergrass, a member of the Maryland House of Delegates and a sponsor of the legislation. “We’re trying very hard to not make people who have a particular belief system not do what they want,” she says of doctors who may have moral or religious objections to aiding in end-of-life care.

Pedergrass’s bill is titled the End of Life Option Act, an attempt to defuse some of the language-related rancor associated with the issue, Pedergrass notes.

Pedergrass’s bill never made it out of committee, however, as the Maryland General Assembly ends its year. A state senate version of the bill was withdrawn as well.

Opponents do not believe the law’s safeguards for doctors or patients are sufficient to prevent abuses. They worry that patients may be coerced into requesting to end their lives by family members or doctors.

“The risks of mistakes, coercion and abuse are too great,” says Not Dead Yet’s Coleman. Such laws are “extremely dangerous public policy for old and disabled people,” she says.

Stevens echoes Coleman’s concerns. “They’re making a tragic mistake,” he says of those who back such legislation. “Once you say that suffering merits this if people want it, there’s no logical place for people to draw the line.”

Opponents also worry that insurance companies will push for end-of-life options rather than pay for prolonged care for terminally ill patients.

Proponents such as Pedergrass counter that the insurance argument is being used to divert attention from an honest discussion of whether people have the right to end their lives as they wish. “Once you see someone suffer and be completely unable to relief that suffering, you’re one bad death away from supporting this,” Pedergrass argues.

MORE AHEAD

Moving from private practice to an employment situation
Page 42

Tail malpractice coverage: Do you need it?
Page 49
We stand with doctors. When shady litigants challenge the good name of one of our members, we are fierce and uncompromising. Our powerful attorneys have well-earned reputations for unyielding defense and aggressive counter-action. Our relentless defense of the practice of good medicine is just one of the reasons we are the nation’s largest physician-owned medical malpractice insurer, with 78,000 members.

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Understanding medical necessity and how it controls your payment

by BILL DACEY, CPC, MBA, MHA Contributing author

A lot of the questions and answers I see in Coding Insights involve “medical necessity.” Who defines this? How does this directly impact payments?

A: Good questions. Most contracts between a provider and a payer state somewhere that payment will be made to the providers for “covered and medically necessary service,” and define the term “medical necessity.” These are also often related to other limitations on payment.

Most physicians have a kinder version of necessity: Is a particular intervention capable of providing a medical benefit to a given patient at a given point in time?

The example contractual language below is what governs your payments:

“The PLAN reserves the right to determine whether in its judgment a service or supply is medically necessary. Medically Necessary Services are: a) consistent with the symptom or diagnosis and treatment of the condition, disease, ailment, or injury; and b) not primarily for the convenience of the subscriber, his or her physician, or other provider; and c) not primarily custodial care. The PLAN shall not be obligated to pay for and the physician shall not charge subscriber for services denied by the PLAN as not being Medically Necessary.”

The fact that a physician has performed or prescribed a procedure or treatment or the fact that it may be the only treatment for a particular problem or injury does not mean that it is a medically necessary covered health service as defined in the covered person’s benefit contract.

Q: I hear a lot about note cloning. Is there an actual law or rule about this that can be enforced?

A: Yes there is. Medicare was the first payer many years ago to publish some very specific guidance on this—it is a Medical Necessity violation.

Documentation is considered cloned when each entry in the medical record for a beneficiary is worded exactly like or similar to the previous entries. Cloning also occurs when medical documentation is exactly the same from beneficiary to beneficiary. It would not be expected that every patient had the exact same problem or symptoms and required the exact same treatment.

Cloned documentation does not meet medical necessity requirements for coverage of services rendered due to the lack of specific, individual information. All documentation in the medical record must be specific to the patient and her/his situation at the time of the encounter. Cloning of documentation is considered a misrepresentation of the medical necessity requirement for coverage of services. Use of this type of documentation will lead to denial of services for lack of medical necessity and recoupment of all overpayments made.

Not all copying, cut/paste is inappropriate. It has become commonplace to carry forward some HPI info from the admit, or earlier days in a hospitalization, to provide context for later days. And this is fine as long as we can see what work is done that day. After the “common” portion of a note, say “today …..” or date it and label a section as “Interval History.”

Payers do not mind how you do your work, they just need to be able to see what work is done that day. After the “common” portion of a note, say “today …..” or date it and label a section as “Interval History.”

Payers do not mind how you do your work, they just need to be able to see what work is done that day. After the “common” portion of a note, say “today …..” or date it and label a section as “Interval History.”
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Surviving the transition from independent to employed

Employees give up some control but gain freedom from paperwork along with new career opportunities

by JANET COLWELL Contributing author

HIGHLIGHTS

- Taking some time to find the right fit can help minimize the culture shock that some physicians experience.
- A larger company might offer more income and career advancement potential, whereas a smaller employer might pay less but offer physicians more control over their day-to-day practice.

ROBERT BAILEY, MD, had been in private practice for almost 15 years when he was recruited to lead a urology division in the employed physicians group owned by Phoenix Children’s Hospital in Arizona in 2011. Although he might not have entertained the idea a decade earlier, Bailey decided that joining a larger system made sense from both a clinical and financial perspective.

Like Bailey, many physicians see employment with a medical group or hospital as a way to escape the administrative burdens of running a private practice. Surveys show a steady migration away from independent practice as physicians grapple with new delivery models and more complicated billing and coding requirements—on top of the everyday concerns of running a small business (see sidebar, “An Exodus From Private Practice.”)

While moving to a hospital or health system eliminates those burdens, physicians should count on making a few trade-offs, according to their peers and hiring executives. In exchange for more financial security and freedom from paperwork, physicians must accept less control over the way they practice medicine. The key is going in with open eyes, having made a conscious decision to give up some things in exchange for others that are more important to overall job satisfaction.

“Physicians who were partners in a practice and used to making their own decisions face the biggest challenges when they become employees,” says Tommy Bohannon, vice president of sales operations at Merritt Hawkins, a Dallas, Texas-based national healthcare search and consulting firm. “They may no longer have a say in who to hire, what hours the clinic is open, or what hours they work—that’s the biggest adjustment for many.”

Even when physicians are cognizant of those trade-offs, they might underestimate the difficulty of switching from an entrepreneurial to a corporate culture, says Gail Gazelle, MD, a physician career coach and an assistant professor of medicine at Harvard Medical School in...
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Boston, Massachusetts. “One of my clients thought he had his dream job but he hadn’t thought it through,” says Gazelle. “When he found out how stifling the corporate culture was at his new job, with very little room for creativity or input on how many patients he would see, he was in a state of shock.”

FINDING THE RIGHT FIT
Taking some time to find the right fit can help minimize the culture shock that some physicians experience. Experts advise performing due diligence in the months leading up to accepting and starting a new job in order to vet prospective employers and weigh the pros and cons of different options.

The key to happiness as an employee is going into the job with realistic expectations, says Allan Cacanindin, senior vice president at physician recruitment firm Cejka Search, based in St. Louis, Missouri. He recommends connecting with physicians who already work at the organization.

Ask them about the work environment, whether they feel restricted in the way they deliver care, and how productivity-based bonus structures have affected their income, he says. Get a sense of what it’s like to work as part of a care team and how that might affect your interactions with patients. “For many physicians, the concept of sharing the care of their patients and developing relationships as a team is new,” notes Cacanindin.

The prospect of losing control or “being asked to practice in a way that doesn’t meet their own moral compass,” is the biggest fear for many physicians when they contemplate leaving private practice, says Gazelle.

For example, while there’s pressure to stay on schedule in private practice, physicians generally make their own decisions about how much time to spend with individual patients, she says. As employees, however, their every decision may be recorded on a computerized dashboard where the entire team can see how far behind they are, how many charts are still open, or how many patient messages are in their inbox.

For many physicians that kind of accountability seems like a reasonable trade-off for having a more stable income and better work-life balance, notes Bob Collins, managing partner in charge of physician recruitment for The Medicus Firm, based in Dallas, Texas.

A larger company might offer more income and career advancement potential, whereas a smaller employer might pay less but offer physicians more control over their day-to-day practice, such as scheduling, staffing, and time spent with patients.

“Physicians have to be comfortable with the framework they’re entering into knowing that there will be give and take in any situation,” says Collins. “Your ability to influence change in a large organization is likely to be minimal because the larger the company, the more likely they are to need standard processes and procedures to operate efficiently.”

As an employer, John Hamilton, senior vice president and chief operating officer of Phoenix Children’s Medical Group, believes....
in confronting physicians’ concerns head-on during hiring negotiations. He urges prospective employees to think carefully about the pros and cons of becoming employed before making a move.

“I’m very upfront with people that this will change their lives and there’s no surefire way to know how it will go,” says Hamilton. “But you can work through a lot of the tough issues and start to form a relationship and build trust in the due diligence process.”

Signing on with an organization that you already know and trust makes the adjustment a bit easier, notes Bailey. Prior to joining Phoenix Children’s, Bailey and his partners had served on committees at the hospital and formed personal relationships with administrators and physician peers.

“We knew what we were joining and that it wasn’t just some big faceless corporation that we had no track record with,” he says. “We knew this was a group that we truly wanted to partner with.”

EMPLOYERS CAN EASE TRANSITION

The same factors that are driving many physicians out of private practice are increasing demand for physicians’ services. As hospitals and health systems form accountable care organizations and implement population health management strategies, they are rapidly adding employed physicians, especially family practitioners and general internists (See sidebar, “An exodus from private practice, on page 46).

Retaining those physicians is just as important, if not more so, as getting them in the door, recruitment experts say. Consequently, many employers are becoming more sensitive to physicians’ concerns and offering programs and benefits aimed at helping them make the transition from private practice.

To prevent physicians from feeling alienated and keep them on board, the larger systems are making significant efforts to give physicians a say in the running of their practice, says Bohannon.

Phoenix Children’s is one example. It has tried to achieve a balance between integrating new physicians into its system and allowing them to retain some measure of independence, such as developing their own scheduling templates, says Hamilton.

“Our strategy is to maintain as much of an independent practice’s individual brand as we can, particularly in primary care,” he says. “We want them to focus on good quality care while we eliminate some of the headaches.”

It’s also important for employers to keep physicians engaged well past the honeymoon period. After some time on the job, physicians often start to get a little disconnected and employers have to be mindful of engaging them down to the individual provider level, says Hamilton. Physicians have a tendency to want to lead and drive change, or at least participate in discussions, so they can get frustrated if they’re not part of the decision-making.

At Cleveland Clinic’s main campus in Ohio, new hires participate in a week-long orientation process designed to educate them about the history and culture of the system as well as its employee benefits and programs. It also offers a coaching and men-

Tips for navigating the corporate culture

Moving from independent practitioner to employee can be a culture shock. Physician executives and recruitment experts offered these tips to help you find the right fit and thrive in your new position:

Look for employer support. Many employers offer onboarding and orientation programs for new employees. “Physicians shouldn’t be expected to just show up and start seeing patients,” says Tommy Bohannon, vice president of sales operations at Dallas, Texas-based search firm Merritt Hawkins. “Some companies have teams of relationship professionals to oversee the orientation in addition to ongoing retention efforts.”

Be opportunity-focused. “If you’re too focused on location, you may end up taking a position that doesn’t meet most of your professional needs,” says Bob Collins, managing partner in charge of physician recruiting at The Medicus Firm, based in Dallas, Texas.

Perform due diligence. Talk to current staff physicians about the work climate and productivity expectations. “You should vet every organization very carefully and find out exactly what your responsibilities and accountabilities will be,” says Allan Cacanindin, senior vice president at physician recruitment firm Cejka Search, based in St. Louis, Missouri.

Accept trade-offs. “While there are things you’ll give up, there are things you will gain,” says Collins. “You’ll have more support and you won’t have to invest time in running a business.”

Be a team player. “The two most important qualities our employer clients look for are the ability to be a team player and to provide good customer service,” notes Bohannon.
An exodus from private practice

Despite their reservations about losing autonomy, physicians have been leaving private practice in droves over the past decade, according to industry surveys. As demand for physicians increases, independent practitioners are looking for employment opportunities that allow them to maintain their income while relinquishing the administrative hassles of running a business.

Last year, approximately 95% of physician searches involved employed settings, up from 50% in 2004, according to search firm Merritt Hawkins’ 2015 Review of Physician and Advanced Practitioner Recruiting Incentives. Demand is highest for family physicians and general internists, while specialists who manage women’s health and long-term chronic conditions, such as obstetrician/gynecologists, pulmonologists, and cardiologists, are also in heavy demand.

With so many opportunities opening up, physicians are becoming more optimistic about their future earnings potential and career opportunities, according to The 2015 Physician Practice Preference & Relocation Survey by The Medicus Firm, based in Dallas, Texas. Other trends highlighted in the survey include:

The percentage of physicians that expect their compensation to “INCREASE SIGNIFICANTLY” rose

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<tr>
<th>Year</th>
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The most favored practice setting is SINGLE-SPECIALTY, unchanged from a year ago.

Physicians are slightly MORE OPTIMISTIC about healthcare reform, with almost 17% giving it an ‘F’ grade, compared with 22% in 2014.

toring program in which new employees are assigned individual peer mentors to help them navigate the workplace.

Moving to an employed situation is a trade-off for many physicians says Bradford Borden, MD, Cleveland Clinic’s associate chief of staff and chair of the Emergency Medicine Institute, who leads the clinic’s recruiting efforts. After years of being their own boss, it’s not always easy to adjust to a team environment.

While acknowledging that physicians will have to relinquish some control as employees, Borden points out that working for a larger organization also opens up opportunities for leadership, education and research that might not be available to physicians in private practice.

Those opportunities present an attractive trade-off for many physicians who see working for a large employer as a way to advance their career, says Cacanindin.

“Physicians who are business-savvy are drawn by the potential to stand out and perhaps take on a medical directorship that will provide extra income,” he says. “We’re now starting to see physicians who want a seat at the table and organizations are responding to that desire because their voices carry weight with other providers in the organization.”

When hiring, employers look for qualities in physicians that indicate a good fit with the corporate culture, says Bohannon. They want expert clinicians who are also willing to be good corporate citizens, operate effectively in a team environment and pay attention to customer service.

“No organization wants to hire a physician who will have trouble working with others and collaborating,” says Bohannon. “It may seem like a cliché but being a team player can go a long way toward determining whether someone succeeds or fails when they make the transition to employee.”

Ultimately, transitions from private practitioner to employee work out when there’s flexibility on both sides, he says.

“The more sophisticated employers treat physicians as partners and value their feedback,” says Bohannon. “If you’re coming from an environment with a lot of autonomy, you need to pay attention to that and find out the philosophy of your potential employer in order to set yourself up for success.”
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What government auditors are focusing on this year

by SARAH WISKERCHEN, MBA, CPC Contributing author

The Office of the Inspector General (OIG) publishes an annual Work Plan that describes its priorities for investigating and preventing fraud, waste and abuse in federal healthcare programs. Here are four takeaways from this year’s report.

1 Evaluation of Medicare’s EHR incentive payments

This year, the OIG is evaluating all payments made to providers to confirm that the reporting criteria were truly met. If you met the criteria, and completed all appropriate requirements, there is little to worry about. OIG wants to make sure all incentive payments made to providers were justified.

2 Prolonged service codes

Prolonged services CPT codes (99354-99357) are intended to describe additional care provided to a patient after an evaluation and management (EM) service has been performed. They are to be billed as add-ons to a primary EM code.

The need for prolonged services is considered to be “rare and unusual.” OIG wants to ensure that the prolonged services Medicare and Medicaid paid for were really necessary. If not, they might ask for the payment back.

You would be wise to review the documentation for all prolonged services billed to Medicare or Medicaid. If the note meets payer requirements, you can rest easy. If not, it may be time for documentation refresher training.

3 Payments to providers who order and refer Medicare services and supplies

The Centers for Medicare & Medicaid Services requires that physicians and nonphysician practitioners who order certain services, supplies and/or durable medical equipment (DME) be Medicare-enrolled physicians or nonphysician practitioners. The OIG plans to review select Medicare services, supplies and DME to determine whether the payments made to the providers were in accordance with Medicare requirements.

Were the providers who billed these charges legally permitted to do so? If providers in your practice order such supplies and equipment, but are not enrolled in the Medicare program, that’s a problem.

If your practice has ineligible providers who have ordered and have been paid for these services and supplies, it may be at risk for an audit or payback.

Be aware of the risk—and enroll any currently non-enrolled provider if he or she is ordering supplies and equipment.

4 Oversight of provider-based status and comparison of provider-based and freestanding clinics

Although this inquiry area falls under the “hospital” directives, it may impact physician practices that are hospital owned. Provider-based status can result in higher total Medicare payments for services furnished at provider-based facilities, and may increase coinsurance liabilities for beneficiaries.

In addition, the OIG will be monitoring freestanding and provider-based physician offices to determine and compare the costs for similar procedures. Oversight of provider-based billing is handled by hospital administration, but physicians need to know that this is being scrutinized.

Sarah Wiskerchen, MBA, CPC, is a senior consultant and coding instructor with Chicago-based KarenZupko & Associates, Inc. This article first appeared in our partner publication, Physicians Practice. Send your questions to: medec@advanstar.com.
Do you need malpractice tail coverage?

by ERIK LEANDER Contributing author

In today’s evolving healthcare system, physicians are changing practice settings more often than ever. Whether it’s leaving private practice for hospital employment, merging practices, opting to join a group practice or moving to a new state—any career change can mean a change in medical malpractice insurance. Physicians considering terminating a claims-made insurance policy due to a career change or any other reason need to be aware of the importance of tail malpractice coverage.

TAIL MALPRACTICE coverage provides insurance coverage for claims brought after a claims-made insurance policy is terminated. Claims-made policies (the most common type of medical malpractice insurance policy) provide coverage for claims brought against a physician resulting from services the physician provided during the time the claims-made policy was continuously in effect.

This means there is no coverage for a claim brought after a claims-made policy is cancelled or not renewed. Tail malpractice coverage solves this problem.

Practice change scenarios

Whenever a physician terminates a medical malpractice claims-made insurance policy, for any reason, the issue of tail malpractice coverage needs to be addressed. Here are some typical scenarios physicians might face when terminating a claims-made policy:

Leaving a solo or group practice to become a hospital employee.

Hospitals typically provide medical malpractice insurance for the physicians they employ. However, if a physician was insured under a claims-made policy prior to hospital employment, hospitals will often require the physician to purchase tail malpractice coverage to cover any claims that might arise from the physician’s prior practice.

In negotiating hospital employment, a physician may be able to have the hospital pay for the cost of tail malpractice coverage or the hospital might allow the physician to continue their current coverage, so that tail malpractice coverage isn’t necessary. Additionally, the hospital may be willing to provide prior acts coverage under the hospital’s own insurance program. It is important to discuss these options early in negotiations with the hospital.

Merging an independent solo or group practice with another independent practice.

In this scenario, prior acts coverage would usually be available through the insurance company that ends up insuring the merged entity. This would eliminate the need to purchase tail malpractice coverage. Once again, it is important to discuss this early in any negotiations.

Leaving an independent group practice or hospital employment group to start a solo practice or join another independent or hospital group practice.

When a physician moves from a group practice to a solo practice or a different group practice, the prior practice may require the physician to purchase tail malpractice coverage. This requirement is often part of the employment agreement with the group practice.

Prior to signing an employment agreement, it may
be possible to negotiate that the new practice be responsible for purchasing the departing physician’s tail malpractice coverage. Or the policy insuring the departing physician’s new practice setting could include prior acts coverage for the previous policy, which may satisfy the requirement to purchase tail malpractice insurance.

Moving to a different state, where the current insurance provider does not offer coverage.
Not every insurer offers coverage in every state and locale. A relocating physician may be able to keep his or her current medical malpractice insurance company, but there is no guarantee.

Depending on the location, insurance rates may also increase or decrease based on the local medical malpractice insurance market. Physicians should contact their insurance company ahead of time to find out whether or not they can keep their current policy and to ask about any policy or rate changes due to the move.

If it’s possible to keep the current policy, it probably won’t be necessary to purchase tail malpractice coverage. If the current insurer cannot provide coverage in the new state, it may be possible to find an insurer that provides coverage in both the physician’s new and old state. In this case, the new insurer should be able to provide prior acts coverage for the physician’s former state, avoiding the need to purchase tail malpractice coverage.

Retirement from medicine.
The good news is that many medical malpractice insurance companies provide free tail malpractice coverage to retiring physicians. However, the insurer may include restrictions based on the physician’s age and the number of years continuously insured with the current insurance company.

Physicians planning for retirement should talk to their insurance company about their plans to make sure they are properly covered. No one wants to spend their retirement years worrying about potential malpractice claims!

Permanently leaving the practice of medicine for another reason.
Physicians who are permanently leaving the practice of medicine for a reason other than retirement, such as disability or a career change, will need to make sure they have tail coverage. Physicians suffering from a disability that prevents them from practicing medicine may find that their insurance company provides tail malpractice coverage at no cost. This depends on factors such as the nature of the disability, so physicians will need to contact their insurance company.

Physicians leaving the practice of medicine for a different career opportunity will need to purchase tail malpractice coverage to cover any claims brought against them after they have quit practicing medicine.

4 ways to get tail malpractice coverage

1. Purchase it from the insurance company that provided the claims-made policy that is being cancelled or not renewed. Depending on the number of years the claims-made policy was in effect, the cost of tail malpractice coverage could be 200% or more of the last policy premium.

2. Purchase standalone tail malpractice coverage from a new insurance company, which may be less expensive than purchasing it from the previous insurer. This new insurance company would only provide tail malpractice coverage for claims brought in the future, from services provided while the physician was continuously insured under the claims made policy being cancelled.

3. Obtain prior acts coverage from the new insurer taking the place of the cancelled insurer, which eliminates the need to purchase tail malpractice coverage. This is typically the most cost-effective option when continuing in practice, but it may not be available in all situations.

4. Receive free tail malpractice coverage in the event of death, disability or retirement. Many medical malpractice insurers offer this benefit, but may differ on the definition of disability or the age at which retirement tail malpractice coverage is provided at no cost. Insurers may also require physicians to be continuously insured with them for a certain number of years before qualifying for tail malpractice coverage at no cost upon retirement.

Erik Leander is the chief technology officer and chief information officer of Cunningham Group, a medical malpractice insurance agency.

Send your legal questions to: medec@advanstar.com
EVERY EMPLOYEE in your practice is critical to its success, but in an era marked by new performance mandates and integrated care, the physician-administrator team plays an increasingly vital role.

The most productive management teams leverage each other’s strengths. They collaborate in pursuit of common goals and inspire their staffs to deliver the highest quality of care.

But simply pairing a physician and a nonphysician manager doesn’t guarantee success. They must also work well together, communicate their vision clearly, and foster an environment of mutual respect.

“This may be the most critical part of a practice,” says Ken Hertz, FACMPE, a medical practice consultant with the Medical Group Management Association Health Care Consulting Group, noting the lines that once separated the business and clinical sides of a practice have long since blurred. “The back office and clinical side are now totally integrated so it’s almost become seamless.”

To meet performance measures established by public and private payers, he says, physicians and office managers must merge their collective expertise to survive. “From the clinical side, there is such a large amount of data and information that needs to be captured and analyzed and reported that it’s critical for the physician and administrator dyad to be highly functioning,” says Hertz.

Indeed, the push for quality improvement is here to stay. Beginning in 2019, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) will replace Meaningful Use, Physician Quality Reporting System (PQRS), and the Value-Based Payment Modifier system with a single program: the Merit-Based Incentive Payment System or MIPS.

MIPS will reimburse physicians based on their composite score for quality, efficiency, meaningful use of electronic health records, and clinical practice improvement.

“As physicians need to be more involved in business processes, it is essential that one
physician or more be delegated as a liaison who works directly with the administrator," says Susan Childs, a medical practice consultant with Evolution Healthcare Consulting in Rougemont, North Carolina. "When physicians and staff work together, they can continually update processes as well as identify problems sooner, instead of catching them on the back end."

MAKING A MATCH
The success of a physician-manager team hinges largely on how well they work together. Two leaders who butt heads are likely to send mixed messages to their staff, creating unnecessary friction.

To optimize productivity, practice leaders must pair physicians and administrators who complement each other. This requires thoughtful recruiting.

Situational questions are most effective in determining candidates who might be a good fit, says Hertz. Ask how they reacted in the past when faced with an irate patient, how they might handle a disruptive physician, or what they would do if an employee consistently came in late.

In smaller practices, in which the physician owner chooses his or her own administrator to team with, the physician should be more introspective.

"Self-awareness is critical," says Hertz. "Ask yourself, 'Who am I? What kind of people do I work best with? What are my expectations of an administrator? Do I have a sense of humor? What do I tolerate and what do I not?''"

Healthcare staffing firms, including American Consultants in Overland Park, Kansas, often use personality tests to screen job candidates. The results don’t necessarily rule applicants out, says Jeremy Toon, the firm’s vice president of executive search, but instead may help identify ways in which the candidate may complement the team or existing culture.

“The reality is that people have to be able to work together," says Toon. "A good administrator has to have leadership abilities and be able to lead through strong personalities and not take it personally."

The Advisory Board Company, a Washington, D.C.-based consulting firm, offers additional guidance on its website for establishing an effective leadership dyad. A physician leader, it notes, should have sterling clinical credentials, top-notch relationship and influence skills with physician peers, and be a systems thinker.

The administrative leader must bring to the position core management skills (finance, staff and operations), credentials, and a persistent, organized and detail-oriented personality. He or she should also relate well to leaders across the organization.

As for shared attributes, the firm suggests that both parties must be able to communicate effectively, enjoy working as part of a high-performance team, have problem-solving skills and be respected by their peers.

COMMunicate your vision
Such skills are necessary if the team is to convey its vision, values and purpose, says Lynn Lillie, MD, a family physician in Woodbury, Minnesota, and a board member of the American Academy of Family Physicians. "Even smaller groups need to define where they want to be," she says.

The physician-administrator team must decide what they want to achieve, so they can jointly manage toward that goal. Are they trying to get more patients through the door, lessen wait times on the phone, or improve billing capture? "Management teams need to be absolutely resolved to having clearly defined goals," says Lillie. "If you can agree on a common goal, the rest becomes tactical."

Giving staff members a purpose is equally important, she says. "One of the most amazing leaders I ever worked for did not allow the concept of 'that’s not my job,'" says Lillie. "If you were a medical director and there was a piece of trash on the floor, you picked it up. You didn’t call housekeeping. That empowered everyone on the team to

" The best model is when you truly do have two equal partners managing the clinical and clerical side of the practice. Blame regulatory changes if you want, but it’s just too much to throw on the physician’s shoulders these days.”

—TRAVIS SINGLETON, SENIOR VICE PRESIDENT, MERRITT HAWKINS, DALLAS, TEXAS
Physician-manager teams stay focused on the single goal of improving the care of the patient.

The housekeeping staff didn’t just “clean rooms.” Instead, their job was to keep patients safe. A dirty exam room, after all, means the possibility of infection. “Every member of the team must feel they have a purpose,” says Lillie.

**MUTUAL RESPECT**

The physician-manager relationship must also be rooted in mutual respect. They must trust each other’s ability, value each other’s contribution, and view themselves as equal partners.

“It’s critical that the physician and the administrator have a good relationship and you develop that by respecting the other,” says Hertz.

A doctor who barges into the manager’s office while he or she is meeting with a staff member or working on payroll shows disregard for the administrator’s role and responsibilities.

Likewise, an administrator who walks into the clinic area while the physician is seeing patients and asks him to sign 12 checks right away shows a lack of respect. Respect also means resolving differences professionally, using open and honest communication. “When issues arise, the manager should talk directly to his partner,” says Hertz. “The administrator shouldn’t talk to physician B about physician A. He should talk to physician A.”

Joint managers at the helm of the practice should also solicit input from staff on a regular basis, and work through any challenges that might arise, says Lillie. “One of the big lessons I learned in working for a large academic medical center was that once a quarter, if not more frequently, we would close for lunch and everyone would sit down and talk about what’s working and what’s not,” she says. “It’s important to listen to the perspective of everyone in the group, because unless you’ve walked in the shoes of the person answering the phones or doing billing, you don’t know what their experience is.”

This type of dialogue encourages staff members to problem-solve together, reinforces the common goal and gives all team members a voice. “It gives everyone an opportunity to be heard and sends the message that everyone in the office is important,” says Lillie.

That doesn’t mean decision-making is a democracy, however. “Everyone’s input is important, but it should still be clear who has the final say,” she says.

An effective physician-manager team is greater than the sum of its parts. By pooling their expertise and motivating their staff, they can position the practice to not only survive, but thrive in the era of regulatory and payment reform.

“The best model is when you truly do have two equal partners managing the clinical and clerical side of the practice,” says Travis Singleton, senior vice president at Dallas-based physician staffing firm Merritt Hawkins. “Blame regulatory changes if you want, but it’s just too much to throw on the physician’s shoulders these days. Physicians need an administrative counterpart, someone who they trust and is well-trained.”

**Take Time To Play Together**

In the high-pressure healthcare setting, stress is inevitable. Physician-manager teams can help let off steam and create bonding opportunities for themselves and their staff, by creating and participating in social outings that let their humanity shine, says Ken Hertz, FACMPE, a medical practice consultant with the MGMA Health Care Consulting Group.

Leadership can organize staff retreats, close the office for a catered lunch, or sponsor a family day at the ballpark, for example.

“This is really first and foremost a workplace of people who are helping people,” says Hertz. “If we don’t treat our staff and leadership like people, they’re not going to treat patients like people.”

Hertz says his practice held an annual crawfish boil, distributed an e-newsletter to congratulate staff on work anniversaries and personal achievements, and celebrated birthdays.

“There are so many opportunities to bring people together and the result is, I think, a much happier workplace which results in better staff retention and a higher level of service to the patients.”

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Editor’s note: This article first appeared in our partner publication, Physicians Practice.
Financial Strategies

Choosing the best physician disability insurance policy

by RICHARD REICH Contributing author

Physicians are some of the hardest working individuals in the country. Years of rigorous training culminate in long hours at the practice. Even physicians can overlook the importance of protecting their ability to earn a living. When something as trivial as a sprained wrist can prevent a doctor from completing their daily tasks, disability insurance becomes a real consideration.

MEDICAL SCHOOL tuition has never been higher. According to CBS News, the average physician graduates from medical school with an average of $166,750 in student debt. With another five to six years earning $50,000 a year as a resident in training, compounded interest will send that student debt through the roof. It takes some physicians 30 years to pay off their student debt. Depending on the interest rate of the loan, the debt total could creep to over $400,000. That’s a herculean financial burden for someone that’s just starting a career.

Fortunately, doctors are still some of the top earners in the country. Online salary information provider Payscale estimates that most physicians can earn anywhere between $166,080 and $288,414 a year. However, with retirement savings, mortgage payments and the years it takes to wash away the pains of student debt, many doctors cannot afford to go without a paycheck for a week, let alone several months.

The likelihood of becoming disabled
A doctor’s life isn’t necessarily a dangerous one, but that doesn’t mean that they aren’t immune from injury or illness. The Council for Disability Awareness reports that a typical female in her mid-30s has a 24% chance of becoming disabled for at least three months during her professional career, while the typical male in his mid-30s has a 21% chance of becoming disabled for at least three months during his professional career.

It’s easy to see how three months without work could be damaging to a physician’s finances. If a minor hand injury puts a new doctor out of work for three months, making those monthly student debt payments would be a difficult challenge. That doesn’t even include a physician’s cost of living, saving for retirement or any overhead expenses for those in private practice.

The best disability insurance for physicians
While the need for disability insurance is clear, it’s important for physicians to understand that not all disability insurance policies are the same. Physicians need what is known as own-occupation disability insurance. The term “own-occupation” means that the policyholder will receive benefits when they are unable to perform the duties essential to their specific occupation. Physician disability insurance also needs to account for the individual’s specialty such as radiologist or orthopedic surgeon.

If a doctor becomes partially disabled and can still perform a portion of his daily responsibilities, he will need what’s called a residual disability provision in their insurance policy. This helps recoup a portion of a doctor’s lost income if they can return to work in a limited setting.

Selecting a policy
As some of the nation’s highest earners, physicians need to make sure that their insurance provider is financially competent.
Medical Strategies

Financial Strategies

The male physicians in our practice pay less for their disability insurance than the women, even though we all have similar incomes, are about the same ages and practice primary care. Why is that?

Q:

A:

They may be paying less due to a variety of factors. For example, your age when the policy was issued plays a part in determining the premium amount. The younger the insured is when the policy is issued, the lower the premiums are for the same benefits.

Another factor could be the amount of disability benefit issued. The more disability benefit the insured will receive, the more premium he or she will be required to pay.

The length of the benefit period also will play a role in the premiums. The longer the insured will receive benefits should he or she become disabled, the higher the premiums. The longer the elimination period—the period after a disability begins but before the insured begins receiving benefits—the lower the premiums paid.

Another reason may be that contracts can have different definitions of disability. One is an own occupation definition of disability. With own occupation coverage, if the insured becomes disabled, benefits are still payable even if he or she is able to gain employment in another profession. Group or individual plans that are not own occupation-specific may only cover total disability and not pay benefits if the policyholder is partially disabled or can do other work.

Finally, if your colleagues bought coverage as a part of a group plan, they may have received a multi-life discount, which can account for a 15% to 30% discount on the premiums. If they leave the group they could take the coverage with them, pay the premiums on their own, and keep the coverage.

Terms to know when shopping for coverage

Elimination period:
The amount of time during which the policyholder will not receive benefits, beginning at the start of the disability and lasting until the first benefits check is received. Policies with longer elimination periods tend to have a lower monthly premium. Most elimination periods start at 30 days and can last as long as one year.

Residual Disability:
Also known as partial disability, residual disability takes effect when the policyholder goes back to work part-time. The policyholder receives a portion of their disability benefits based on how much of their income may still be missing. Without residual disability, the policyholder would lose all of their benefits if and when they return to work in any capacity.

Waiver of Premium:
Allows the policyholder to stop paying their monthly premiums once they become disabled and after the end of the elimination period. Certain policies may extend the waiver of premium until the policyholder fully recovers from their injuries.

Rehabilitation Benefit:
Provides some financial reimbursement to the policyholder as they enroll in an approved physical rehabilitation program. The rehabilitation benefit stipulates that the policyholder will not lose their original benefits during their time in the program and provides some additional funding to help pay for the cost of the program.

How to purchase coverage

When a physician is ready to purchase disability insurance, he should consider using an insurance broker who specializes in this coverage. Comparing quotes across multiple insurance companies is key to making sure that a physician receives the policy that is best tailored to them, at the best possible price. For physicians, few decisions are as important as choosing the right disability insurance policy.

Richard Reich is president of Intramark Insurance Services and has more than 25 years of experience as a nationally licensed insurance broker. Send your financial questions to: medec@advanstar.com.
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n the average medical practice, the burden on physicians to meet differing quality measurement standards set by payers is substantial. Commercial health plans, the Centers for Medicare & Medicaid Services (CMS) and state Medicaid managed care plans all have different metrics for evaluating quality care. “On average, family physicians have to report their performance on quality measures to seven different payers,” says Kate Goodrich, MD, MHS, director of the Center for Clinical Standards and Quality at CMS. Now CMS is seeking to ease that burden by identifying quality measures for seven specific areas or clinical conditions, and it intends to incorporate those measures into regulations it will propose under the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. MACRA calls for CMS to establish new systems for rewarding physicians for delivering quality care. “If you’re a doctor reporting on 35 to 40 different measures, you can’t focus your quality improvement because those efforts are too diffuse,” says Goodrich, who still works one weekend per month as a hospitalist.

In February, CMS and America’s Health Insurance Plans (AHIP), the trade association for commercial health insurers, identified quality measures for physicians in primary care (including those in accountable care organizations and patient-centered medical homes), cardiology, gastroenterology, doctors serving patients with HIV and hepatitis C, medical oncology, obstetrics and gynecology and orthopedics. Designed to improve and simplify quality reporting among clinicians and public and private payers, the measures will make it easier for health insurers and clinicians to promote population health and coordinate care more efficiently, says Clare Krusing, AHIP’s director of communications.

Health plans will begin implementing the measures as contracts renew or are modified. CMS is already using these measures and will implement new core measures and eliminate redundant measures as needed. Shari Erickson, MPH, vice president of governmental affairs and medical practice for the American College of Physicians (ACP), is optimistic about the new quality measures but also is concerned that they don’t go far enough. On March 1, ACP sent a 42-page letter to CMS containing more than 30 recommendations.

Among ACP’s suggestions is using MACRA to build a learning healthcare system, as the Institute of Medicine (now the National Academy of Medicine) recommended in 2011. New payment systems being designed under MACRA should incorporate lessons from past quality measurement efforts and allow for innovation. “We hope these additional recommendations will make the quality measures from AHIP and CMS even better over the long term,” Erickson says. The new measures are the result of efforts over the past two years by AHIP, CMS, the National Quality Forum and organizations representing physicians, patients, and others to identify useful measures to reduce the burden, costs, and variability inherent in requiring physicians to meet multiple measurement standards, CMS says.

AHIP expects to continue working with CMS to develop new measures, improve the ones issued this year, and incorporate lessons learned from science and evidence-based medicine, Krusing says.

Joseph Burns is an independent journalist in Falmouth, Massachusetts. Do you agree with pay based on adherence to quality measures? Tell us at medec@advanstar.com
INDICATIONS AND USAGE

Reduction of Risk of Stroke and Systemic Embolism in Nonvalvular Atrial Fibrillation: XARELTO® is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. There are limited data on the relative effectiveness of XARELTO and warfarin.

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Patients with Prosthetic Heart Valves: The safety and efficacy of XARELTO have not been studied in patients with prosthetic heart valves. Therefore, use of XARELTO is not recommended in these patients.

Acute PE in Hemodynamically Unstable Patients or Patients Who Require Thrombolysis or Pulmonary Embolectomy: Initiation of XARELTO is not recommended acutely as an alternative to unfractionated heparin in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

ADVERSE REACTIONS

The following adverse reactions are also discussed in other sections of the labeling:

- Increased risk of stroke after discontinuation in nonvalvular atrial fibrillation [see Boxed Warning and Warnings and Precautions]
- Bleeding risk [see Warnings and Precautions]
- Spinal/epidural hematoma [see Boxed Warning and Warnings and Precautions]

Clinical Trials 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 rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

During clinical development for the approved indications, 16528 patients were exposed to XARELTO. These included 7111 patients who received XARELTO 15 mg or 20 mg orally once daily for a mean of 19 months (5585 for 12 months and 2512 for 24 months) to reduce the risk of stroke and systemic embolism in nonvalvular atrial fibrillation (ROCKET AF; 4726 patients who received either XARELTO 15 mg orally twice daily for three weeks followed by 20 mg orally once daily (EINSTEIN DVT, EINSTEIN PE) or 20 mg orally once daily (EINSTEIN Extension) to treat DVT, PE, and to reduce the risk of recurrence of DVT and of PE; and 4487 patients who received XARELTO 10 mg orally once daily for prophylaxis of DVT following hip or knee replacement surgery (RECORD 1-3).

Hemorrhage: The most common adverse reactions with XARELTO were bleeding complications [see Warnings and Precautions].

Nonvalvular Atrial Fibrillation: In the ROCKET AF trial, the most frequent adverse reactions associated with permanent drug discontinuation were bleeding events, with incidence rates of 4.3% for XARELTO vs. 3.1% for warfarin. The incidence of discontinuations for non-bleeding adverse events was similar in both treatment groups.

Table 1 shows the number of patients experiencing various types of bleeding events in the ROCKET AF trial.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>XARELTO N = 7111 n (%/year)</th>
<th>Warfarin N = 7125 n (%/year)</th>
<th>XARELTO vs. Warfarin HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Bleeding</td>
<td>385 (3.6)</td>
<td>386 (3.5)</td>
<td>1.04 (0.90, 1.20)</td>
</tr>
<tr>
<td>Intracranial Hemorrhage (ICH)</td>
<td>55 (0.5)</td>
<td>84 (0.7)</td>
<td>0.67 (0.47, 0.93)</td>
</tr>
<tr>
<td>Hemorrhagic Stroke</td>
<td>36 (0.3)</td>
<td>58 (0.5)</td>
<td>0.63 (0.42, 0.96)</td>
</tr>
<tr>
<td>Other ICH</td>
<td>19 (0.2)</td>
<td>26 (0.2)</td>
<td>0.74 (0.41, 1.34)</td>
</tr>
<tr>
<td>Gastrointestinal (GI)</td>
<td>221 (2.9)</td>
<td>140 (1.2)</td>
<td>1.61 (1.30, 1.99)</td>
</tr>
<tr>
<td>Fatal Bleeding</td>
<td>27 (0.2)</td>
<td>55 (0.5)</td>
<td>0.50 (0.31, 0.79)</td>
</tr>
<tr>
<td>ICH</td>
<td>24 (0.2)</td>
<td>42 (0.4)</td>
<td>0.56 (0.35, 0.96)</td>
</tr>
<tr>
<td>Non-intracranial</td>
<td>3 (0.0)</td>
<td>13 (0.1)</td>
<td>0.23 (0.07, 0.82)</td>
</tr>
</tbody>
</table>

Abbreviations: HR = Hazard Ratio, CI = Confidence interval, CRNM = Clinically Relevant Non-Major.

Note: The figure above presents effects in various subgroups all of which are baseline characteristics and all of which were pre-specified (diabetic status was not pre-specified in the subgroup, but was a criterion for the CHA2DS2 score). The 95% confidence limits that are shown do not take into account how many comparisons were made, nor do they reflect the effect of a particular factor after adjustment for all other factors. Apparent homogeneity or heterogeneity among groups should not be over-interpreted.

Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and to Reduce the Risk of Recurrence of DVT and of PE: EINSTEIN DVT and EINSTEIN PE Studies: In the pooled analysis of the EINSTEIN DVT and EINSTEIN PE clinical studies, the most frequent adverse reactions leading to permanent drug discontinuation were bleeding events, with XARELTO vs. enoxaparin/Vitamin K antagonist (VKA) incidence rates of 1.7% vs. 1.5%, respectively. The mean duration of treatment was 208 days for XARELTO-treated patients and 204 days for enoxaparin/VKA-treated patients.

Table 2 shows the number of patients experiencing major bleeding events in the pooled analysis of the EINSTEIN DVT and EINSTEIN PE studies.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>XARELTO† N = 4130 n (%)</th>
<th>Enoxaparin/VKA† N = 4116 n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major bleeding event</td>
<td>40 (1.0)</td>
<td>72 (1.7)</td>
</tr>
<tr>
<td>Fatal bleeding</td>
<td>3 (0.1)</td>
<td>8 (0.2)</td>
</tr>
<tr>
<td>Intracranial</td>
<td>2 (0.1)</td>
<td>4 (0.1)</td>
</tr>
<tr>
<td>Non-fatal critical organ bleeding</td>
<td>10 (0.2)</td>
<td>29 (0.7)</td>
</tr>
<tr>
<td>Intracranial†</td>
<td>3 (0.1)</td>
<td>10 (0.2)</td>
</tr>
<tr>
<td>Retropertioneal†</td>
<td>1 (0.1)</td>
<td>8 (0.2)</td>
</tr>
<tr>
<td>Intracutaneous†</td>
<td>3 (0.1)</td>
<td>2 (0.1)</td>
</tr>
<tr>
<td>Intra-articular†</td>
<td>0</td>
<td>4 (0.1)</td>
</tr>
<tr>
<td>Non-fatal non-critical organ bleeding†</td>
<td>27 (0.7)</td>
<td>37 (0.9)</td>
</tr>
<tr>
<td>Decrease in Hb ≥2g/dL</td>
<td>28 (0.7)</td>
<td>42 (1.0)</td>
</tr>
<tr>
<td>Transfusion of ≥2 units of whole blood or packed red blood cells</td>
<td>18 (0.4)</td>
<td>25 (0.6)</td>
</tr>
<tr>
<td>Clinically relevant non-major bleeding</td>
<td>357 (8.6)</td>
<td>357 (8.7)</td>
</tr>
<tr>
<td>Any bleeding</td>
<td>1169 (28.3)</td>
<td>1153 (28.0)</td>
</tr>
</tbody>
</table>

* Bleeding event occurred after randomization and up to 2 days after the last dose of study drug. Although a patient may have had 2 or more events, the patient is counted only once in a category.
XARELTO® (rivaroxaban) tablets

1 Treatment schedule in EINSTEIN DVT and EINSTEIN PE studies: XARELTO 15 mg twice daily for 3 weeks followed by 20 mg once daily; enoxaparin/VKA (enoxaparin: 1 mg/kg twice daily, VKA: individually titrated doses to achieve a target INR of 2.5 (range: 2.0-3.0))
2 Treatment-emergent major bleeding events with at least 2 subjects in any pooled treatment group.
3 Major bleeding which is not fatal or in a critical organ, but resulting in a decrease in Hb ≥ 2 g/dL and/or transfusion of ≥ 2 units of whole blood or packed red blood cells

EINSTEIN Extension Study: In the EINSTEIN Extension clinical study, the most frequent adverse reactions associated with permanent drug discontinuation were bleeding events, with incidence rates of 1.8% for XARELTO vs. 0.2% for placebo treatment groups. The mean duration of treatment was 190 days for both XARELTO and placebo treatment groups.

Table 3 shows the number of patients experiencing bleeding events in the EINSTEIN Extension study.

Table 3: Bleeding Events* in EINSTEIN Extension Study

<table>
<thead>
<tr>
<th>Parameter</th>
<th>XARELTO† 20 mg (N = 598)</th>
<th>Placebo† 20 mg (N = 590)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major bleeding event§</td>
<td>4 (0.7)</td>
<td>0</td>
</tr>
<tr>
<td>Decrease in Hb ≥ 2 g/dL</td>
<td>4 (0.7)</td>
<td>0</td>
</tr>
<tr>
<td>Transfusion of ≥ 2 units of whole blood or packed red blood cells</td>
<td>2 (0.3)</td>
<td>0</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>3 (0.5)</td>
<td>0</td>
</tr>
<tr>
<td>Menorrhagia</td>
<td>1 (0.2)</td>
<td>0</td>
</tr>
<tr>
<td>Clinically relevant non-major bleeding</td>
<td>32 (5.4)</td>
<td>7 (1.2)</td>
</tr>
<tr>
<td>Any bleeding§</td>
<td>104 (17.4)</td>
<td>63 (10.7)</td>
</tr>
</tbody>
</table>

* Bleeding event occurred after the first dose and up to 2 days after the last dose of study drug. Although a patient may have had 2 or more events, the patient is counted only once in a category.
† Treatment schedule: XARELTO 20 mg once daily; matched placebo once daily
‡ There were no fatal or critical organ bleeding events.

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: In the RECORD clinical trials, the overall incidence rate of adverse reactions leading to permanent treatment discontinuation was 3.7% with XARELTO. The rates of major bleeding events and any bleeding events observed in patients in the RECORD clinical trials are shown in Table 4.

Table 4: Bleeding Events* in Patients Undergoing Hip or Knee Replacement Surgeries (RECORD 1-3)

<table>
<thead>
<tr>
<th>System/Organ Class</th>
<th>XARELTO 10 mg (N = 4847)</th>
<th>Enoxaparin† (N = 4524)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injury, poisoning and procedural complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound secretion</td>
<td>125 (2.8)</td>
<td>89 (2.0)</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>74 (1.7)</td>
<td>55 (1.2)</td>
</tr>
<tr>
<td>Muscle spasm</td>
<td>52 (1.2)</td>
<td>32 (0.7)</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syncope</td>
<td>55 (1.2)</td>
<td>32 (0.7)</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td>96 (2.1)</td>
<td>79 (1.7)</td>
</tr>
<tr>
<td>Blister</td>
<td>63 (1.4)</td>
<td>40 (0.9)</td>
</tr>
</tbody>
</table>

* Adverse reaction occurring any time following the first dose of double-blind study medication which may have been prior to administration of active drug, until two days after the last dose of double-blind study medication.
† Includes the placebo-controlled period of RECORD 2, enoxaparin dosing was 40 mg once daily (RECORD 1-3)

Other clinical trial experience: In an investigational study of acute medically ill patients being treated with XARELTO 10 mg tablets, cases of pulmonary hemorrhage and pulmonary hemorrhage with bronchiectasis were observed.

Postmarketing Experience: The following adverse reactions have been identified during post-approval use of rivaroxaban. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Blood and lymphatic system disorders: agranulocytosis, thrombocytopenia
Gastrointestinal disorders: retroperitoneal hemorrhage
Hepatobiliary disorders: jaundice, cholestasis, hepatitis (including hepatocellular injury)
Immune system disorders: hypersensitivity, anaphylactic reaction, anaphylactic shock, angioedema

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* Bleeding events occurring any time following the first dose of double-blind study medication (which may have been prior to administration of active drug) until two days after the last dose of double-blind study medication. Patients may have more than one event.
† Includes the placebo-controlled period for RECORD 2, enoxaparin dosing was 40 mg once daily (RECORD 1-3)
‡ Includes major bleeding events following XARELTO treatment, the majority of major bleeding complications (>60%) occurred during the first week after surgery.

Other Adverse Reactions: Non-hemorrhagic adverse reactions reported in ≥1% of XARELTO-treated patients in the EINSTEIN Extension study are shown in Table 5.

Table 5: Other Adverse Reactions* Reported by ≥1% of XARELTO-Treated Patients in EINSTEIN Extension Study

<table>
<thead>
<tr>
<th>System/Organ Class</th>
<th>XARELTO N = 598</th>
<th>Placebo N = 590</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal pain upper</td>
<td>10 (1.7)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>8 (1.3)</td>
<td>4 (0.7)</td>
</tr>
<tr>
<td>Toothache</td>
<td>6 (1.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>6 (1.0)</td>
<td>3 (0.5)</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sinusitis</td>
<td>7 (1.2)</td>
<td>3 (0.5)</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>7 (1.2)</td>
<td>3 (0.5)</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back pain</td>
<td>22 (3.7)</td>
<td>7 (1.2)</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>10 (1.7)</td>
<td>5 (0.8)</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oropharyngeal pain</td>
<td>6 (1.0)</td>
<td>2 (0.3)</td>
</tr>
</tbody>
</table>

* Adverse reaction (with Relative Risk >1.5 for XARELTO versus placebo) occurred after the first dose and up to 2 days after the last dose of study drug. Incidences are based on the number of patients, not the number of events. Although a patient may have had 2 or more clinical adverse reactions, the patient is counted only once in a category. The same patient may appear in different categories.

Non-hemorrhagic adverse reactions reported in ≥1% of XARELTO-treated patients in RECORD 1-3 studies are shown in Table 6.

Table 6: Other Adverse Drug Reactions* Reported by ≥1% of XARELTO-Treated Patients in RECORD 1-3 Studies

<table>
<thead>
<tr>
<th>System/Organ Class</th>
<th>XARELTO 10 mg (N = 4847)</th>
<th>Enoxaparin† (N = 4524)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injury, poisoning and procedural complications</td>
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</tr>
<tr>
<td>Wound secretion</td>
<td>125 (2.8)</td>
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</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>74 (1.7)</td>
<td>55 (1.2)</td>
</tr>
<tr>
<td>Muscle spasm</td>
<td>52 (1.2)</td>
<td>32 (0.7)</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Syncope</td>
<td>55 (1.2)</td>
<td>32 (0.7)</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td>96 (2.1)</td>
<td>79 (1.7)</td>
</tr>
<tr>
<td>Blister</td>
<td>63 (1.4)</td>
<td>40 (0.9)</td>
</tr>
</tbody>
</table>

* Adverse reaction occurring any time following the first dose of double-blind study medication, which may have been prior to administration of active drug, until two days after the last dose of double-blind study medication.
† Includes the placebo-controlled period of RECORD 2, enoxaparin dosing was 40 mg once daily (RECORD 1-3)
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Nervous system disorders: cerebral hemorrhage, subdural hematoma, epidural hematoma, subarachnoid hemorrhage. Clinical trials have not been conducted in these conditions.

Skin and subcutaneous tissue disorders: Stevens-Johnson syndrome

DRUG INTERACTIONS

Rivaroxaban is a substrate of CYP3A4, CYP2J2, and the P- and gp- and ATP-binding cassette G2 (ABCG2) transporters. Inhibitors and inducers of these CYP450 enzymes or transporters (e.g., P-gp) may result in changes in rivaroxaban exposure.

Drugs that Inhibit Cytochrome P450 3A4 Enzymes and Drug Transport Systems:

In drug interaction studies, conducted in subjects with normal renal function, evaluation of the use with drugs that are combined P-gp and CYP3A4 inhibitors (e.g., ketoconazole, ritonavir, clarithromycin, and erythromycin) or a moderate CYP3A4 inhibitor (fluconazole), increases in rivaroxaban exposure and concentration were observed. The increases in exposure ranged from 30% to 160%. Significant increases in rivaroxaban exposure may increase bleeding risk [see Clinical Pharmacology (12.3) in full Prescribing Information].

When data suggest a change in exposure is unlikely to affect bleeding risk (e.g., clarithromycin, erythromycin), no precautions are necessary during coadministration with drugs that are combined P-gp and CYP3A4 inhibitors.

Avoid concomitant administration of XARELTO with combined P-gp and strong CYP3A4 inhibitors (see Warnings and Precautions).

Drugs that Induce Cytochrome P450 3A4 Enzymes and Drug Transport Systems:

Results from drug interaction studies and population PK analyses from clinical studies indicate coadministration of XARELTO with a combined P-gp and strong CYP3A4 inhibitor (e.g., rifampin, rifabutin) decreased rivaroxaban exposure by up to 50%. Similar decreases in pharmacodynamic effects were also observed. These decreases in exposure to rivaroxaban may decrease efficacy [see Clinical Pharmacology (12.3) in full Prescribing Information].

Avoid concomitant use of XARELTO with drugs that are combined P-gp and strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin, St. John's wort) [see Warnings and Precautions].

Anticoagulants and NSAIDs/Aspirin:

Single doses of enoxaparin and XARELTO given concomitantly added in an additive effect on anti-factor Xa activity. Single doses of warfarin and XARELTO resulted in an additive effect on factor X (FⅩa) inhibition and PT. Concomitant aspirin use has been identified as an independent risk factor for major bleeding in efficacy trials. NSAIDs are known to increase bleeding, and bleeding risk may be increased when NSAIDs are used concomitantly with XARELTO. Coadministration of the platelet aggregation inhibitor clopidogrel and XARELTO resulted in an increase in bleeding time for some patients [see Warnings and Precautions].

Avoid concurrent use of XARELTO with other anticoagulants due to increased bleeding risk unless benefit outweighs risk. Promptly evaluate any signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs (see Warnings and Precautions).

Drug-Disease Interactions with Drugs that Inhibit Cytochrome P450 3A4 Enzymes and Drug Transport Systems:

Results from a pharmacokinetic trial of rivaroxaban with erythromycin indicated that patients with renal impairment coadministered XARELTO with drugs classified as combined P-gp and moderate CYP3A4 inhibitors (e.g., diltiazem, verapamil, dronedarone, and erythromycin) have increased exposure compared with patients with normal renal function and no inhibition use. Significant increases in rivaroxaban exposure may increase bleeding risk.

While increases in rivaroxaban exposure can be expected under such conditions, results from an analysis in the ROCKET AF trial, which allowed combined administration of rivaroxaban and weak or moderate P-gp or CYP3A4 inhibitors (e.g., amiodarone, diltiazem, verapamil, chloramphenicol, cimetidine, and erythromycin), did not show an increase in bleeding in patients with CrCl 30 to <50 mL/min [Hazard Ratio (95% CI): 1.05 (0.77, 1.42)] [see Use in Specific Populations].

XARELTO should not be used in patients with CrCl 15 to <30 mL/min who are receiving concomitantly combined P-gp and moderate CYP3A4 inhibitors (e.g., diltiazem, verapamil, dronedarone, and erythromycin) unless the potential benefit justifies the potential risk [see Clinical Pharmacology (12.3) in full Prescribing Information].

USE IN SPECIFIC POPULATIONS

Pregnancy:

Pregnancy Category C: There are no adequate or well-controlled studies of XARELTO in pregnant women, and dosing for pregnant women has not been established. Use XARELTO with caution in pregnant patients because of the potential for pregnancy related hemorrhage and/or emergent delivery with thrombosis. The anticoagulant effect of XARELTO cannot be reliably monitored with standard laboratory testing. Animal reproduction studies showed no increased risk of structural malformations, but increased post-implantation pregnancy loss occurred in rabbits. Avoid the use of XARELTO during pregnancy only if the potential benefit justifies the potential risk to mother and fetus [see Warnings and Precautions].

Rivaroxaban crosses the placenta in animals. Animal reproduction studies have not been conducted in humans to determine whether rivaroxaban causes fetal harm when administered to a pregnant woman or can affect reproductive capacity. As with any potential exposure to a thrombosis and platelet aggregation inhibitors, the potential increased incidence of post-implantation pregnancy loss in rabbits. Rivaroxaban increased fetal toxicity (increased resorptions, decreased number of live fetuses, and decreased fetal body weight) when pregnant rabbits were given oral rivaroxaban during the period of organogenesis. This dose corresponds to about 4 times the human exposure of unbound drug, based on AUC comparisons at the highest recommended human dose of 20 mg/day and about 30% weight decreases when pregnant rats were given oral doses of 120 mg/kg. This dose corresponds to about 14 times the human exposure of unbound drug.

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Labor and Delivery: Safety and effectiveness of XARELTO during labor and delivery have not been studied. Avoid the use of XARELTO during labor and delivery with thrombosis and platelet aggregation inhibitors, unless the potential benefit justifies the potential risk to mother and fetus [see Warnings and Precautions].

Nursing Mothers: It is not known if rivaroxaban is excreted in human milk. Rivaroxaban and/or its metabolites were excreted into the milk of rats. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in infants from rivaroxaban, a decision should be made whether to discontinue nursing or discontinue XARELTO, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established. Rivaroxaban is not recommended for administration to children or adolescents [see Warnings and Precautions].

Geriatric Use:

Of the total number of patients in the RECORD 1-3 clinical studies evaluating XARELTO, about 54% were 65 years and over, while about 15% were >75 years. In ROCKET AF, approximately 77% were 65 years and over and about 15% were >75 years. In the EINSTEIN DVT, PE and Extension clinical studies approximately 37% were 65 years and over and about 16% were >75 years. In clinical trials the efficacy of XARELTO in the elderly (85 years or older) was similar to that seen in patients younger than 65 years. Both thrombotic and bleeding event rates were higher in these older patients, but the risk-benefit profile was favorable in all age groups [see Clinical Pharmacology (12.3) and Clinical Studies (14) in full Prescribing Information].

Females of Reproductive Potential:

Females of reproductive potential requiring contraception should discuss pregnancy planning with their physician.

Renal Impairment: In a pharmacokinetic study, compared to healthy subjects with normal creatinine clearance, rivaroxaban exposure increased by about 44% to 64% in subjects with moderate renal impairment. No pharmacodynamic effects were also observed [see Clinical Pharmacology (12.3) in full Prescribing Information].

Nonvalvular Atrial Fibrillation: In the ROCKET AF trial, patients with CrCl 30 to 50 mL/min who were administered XARELTO 15 mg once daily resulting in serum concentrations of rivaroxaban similar to those in patients with normal renal function administered XARELTO 20 mg once daily. Patients with CrCl 15 to 30 mL/min were not studied, but administration of XARELTO 15 mg once daily resulted in serum concentrations of rivaroxaban similar to those in patients with normal renal function [see Dosage and Administration (2.3) in full Prescribing Information].

Treatment of DVT and/or PE, and Reduction in the Risk of Recurrence of DVT and/or PE:

In the EINSTEIN DVT, PE and Extension clinical studies, rivaroxaban was effective in reducing the risk of recurrence of DVT and PE [see Clinical Pharmacology (12.3) in full Prescribing Information].

Hepatic Impairment: In a pharmacokinetic study, compared to healthy subjects with normal liver function, AUC increases of 127% were observed in subjects with moderate hepatic impairment (Child-Pugh B). In the EINSTEIN DVT, PE and Extension clinical studies, rivaroxaban was effective in reducing the risk of recurrence of DVT and PE in subjects with severe hepatic impairment (Child-Pugh C) has not been evaluated [see Clinical Pharmacology (12.3) in full Prescribing Information].

Avoid the use of XARELTO in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy.

OVERDOSAGE:

Overdose of XARELTO may lead to hemorrhage. Discontinue XARELTO and initiate appropriate therapy if bleeding complications associated with overdosage occur. A specific antidote for rivaroxaban is not available. Rivaroxaban systemic exposure is not further increased at single doses >50 mg due to limited absorption. The use of activated charcoal to reduce absorption is not recommended. Supportive therapy should be given as warranted.

Active Ingredient Made in Germany

Finished Product Manufactured by: Janssen Ortho, LLC

Gurabo, PR 00787

or

Bayer Pharma AG

51368 Leverkusen, Germany

Manufactured for: Janssen Pharmaceuticals, Inc.

Titusville, NJ 08560

Licensed from: Bayer Healthcare AG

51368 Leverkusen, Germany

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03876-150812
IMPORTANT SAFETY INFORMATION

WARNING: (A) PREMATURE DISCONTINUATION OF XARELTO® INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA

A. PREMATURE DISCONTINUATION OF XARELTO® INCREASES THE RISK OF THROMBOTIC EVENTS

Premature discontinuation of any oral anticoagulant, including XARELTO®, increases the risk of thrombotic events. If anticoagulation with XARELTO® is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

B. SPINAL/EPIDURAL HEMATOMA

Epidural or spinal hematomas have occurred in patients treated with XARELTO® who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- Use of indwelling epidural catheters
- Concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants, or fibrinolytic therapy.

REFERENCES:
IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS AND PRECAUTIONS (cont’d)

Spinal/Epidural Anesthesia or Puncture (cont’d): An epidural catheter should not be removed earlier than 18 hours after the last administration of XARELTO®. The next XARELTO® dose is not to be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, the administration of XARELTO® is to be delayed for 24 hours. Should the physician decide to administer anticoagulation in the context of epidural or spinal anesthesia/analgesia or lumbar puncture, monitor frequently to detect any signs or symptoms of neurological impairment, such as midline back pain, sensory and motor deficits (numbness, tingling, or weakness in lower limbs), or bowel and/or bladder dysfunction. Instruct patients to immediately report if they experience any of the above signs or symptoms. If signs or symptoms of spinal hematoma are suspected, initiate urgent diagnosis and treatment including consideration for spinal cord decompression even though such treatment may not prevent or reverse neurological sequelae.

Use in Patients With Renal Impairment:

• Nonvalvular Atrial Fibrillation: Avoid the use of XARELTO® in patients with creatinine clearance (CrCl) <15 mL/min since drug exposure is increased. Discontinue XARELTO® in patients who develop acute renal failure while on XARELTO®.

• Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE: Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population.

• Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Patients who develop acute renal failure while on XARELTO® should discontinue the treatment.

Use in Patients With Hepatic Impairment: No clinical data are available for patients with severe hepatic impairment. Avoid use of XARELTO® in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy, since drug exposure and bleeding risk may be increased.

Use With P-gp and Strong CYP3A4 Inhibitors or Inducers: Avoid concomitant use of XARELTO® with combined P-gp and strong CYP3A4 inhibitors (eg, ketoconazole, ritonavir, lopinavir/ritonavir, ritonavir, indinavir, and conivaptan). Avoid concomitant use of XARELTO® with drugs that are P-gp and strong CYP3A4 inducers (eg, carbamazepine, phenytoin, rifampin, St. John’s wort).

Risk of Pregnancy-Related Hemorrhage: In pregnant women, XARELTO® should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO® dosing in pregnancy has not been studied. The anticoagulant effect of XARELTO® cannot be monitored with standard laboratory testing and is not readily reversed. Promptly evaluate any signs or symptoms suggesting blood loss (eg, a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).

Patients With Prosthetic Heart Valves: The safety and efficacy of XARELTO® have not been studied in patients with prosthetic heart valves. Therefore, use of XARELTO® is not recommended in these patients.

Acute PE in Hemodynamically Unstable Patients/ Patients Who Require Thrombolysis or Pulmonary Embolectomy: Initiation of XARELTO® is not recommended acutely as an alternative to unfractionated heparin in patients with pulmonary embolism who present with hemodynamic instability or who may receive thrombolysis or pulmonary embolectomy.

DRUG INTERACTIONS

Avoid concomitant use of XARELTO® with other anticoagulants due to increased bleeding risk, unless benefit outweighs risk. Promptly evaluate any signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs.

XARELTO® should not be used in patients with CrCl 15 to <80 mL/min who are receiving concomitant combined P-gp and moderate CYP3A4 inhibitors (eg, diltiazem, verapamil, dronedarone, and erythromycin) unless the potential benefit justifies the potential risk.

USE IN SPECIFIC POPULATIONS

Pregnancy Category C: XARELTO® should be used during pregnancy only if the potential benefit justifies the potential risk to mother and fetus. There are no adequate or well-controlled studies of XARELTO® in pregnant women, and dosing for pregnant women has not been established. Use XARELTO® with caution in pregnant patients because of the potential for pregnancy-related hemorrhage and/or emergent delivery with an anticoagulant that is not readily reversible. The anticoagulant effect of XARELTO® cannot be reliably monitored with standard laboratory testing.
#1 PRESCRIBED NOAC IN THE US*1

SIX INDICATIONS STRONG

- To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (AF). There are limited data on the relative effectiveness of XARELTO® and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well controlled
- For the treatment of deep vein thrombosis (DVT)
- For the treatment of pulmonary embolism (PE)
- For the reduction in the risk of recurrence of DVT and of PE following initial 6 months treatment for DVT and/or PE
- For the prophylaxis of DVT, which may lead to PE in patients undergoing knee replacement surgery
- For the prophylaxis of DVT, which may lead to PE in patients undergoing hip replacement surgery

NOAC = non-vitamin K antagonist oral anticoagulant
*Among Factor Xa inhibitors and direct thrombin inhibitors.
†Based on the following registries, claims databases, and studies: Optum Labs=16,253; IMS Health LifeLink=1,648; Truven Health=5,562; Danish registry=1,303; XAMOS®=8,778; Symphony=3,654; ORTHO-TEP=1,943; Japanese registry=1,035; Dresden NOAC=1,776; XALIA=2,505; DDD database=27,467; XANTUS=6,784.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information, including Boxed WARNINGS, or visit www.XareltoHCP.com/PI.
Real-world safety outcomes from one ongoing US study of 27,467 nonvalvular AF patients

Results based on 15 months of data from an ongoing, 5-year postmarketing safety surveillance study to evaluate major bleeding in patients receiving XARELTO® in a real-world clinical setting. Cases of major bleeding were identified through electronic health records from the US Department of Defense database, from January 1, 2013, to March 31, 2014.

**RATES OF BLEEDING**

<table>
<thead>
<tr>
<th>Event</th>
<th>Rate (per 100 patient-years)</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major bleed</td>
<td>2.86</td>
<td>478</td>
</tr>
<tr>
<td>Fatal bleed</td>
<td>0.08</td>
<td>14</td>
</tr>
<tr>
<td>Intracranial</td>
<td>0.1% (n=36)</td>
<td></td>
</tr>
<tr>
<td>GI bleed</td>
<td>1.5% (n=423)</td>
<td></td>
</tr>
</tbody>
</table>

**COMORBID PATIENTS STUDIED**

- 87% with comorbidities including:
  - diabetes
  - heart failure
  - renal disease

Mean age: 76

**RESULTS ARE NOT INTENDED FOR DIRECT COMPARISON WITH CLINICAL TRIALS**

A validated computer database algorithm developed by Cunningham et al, which identifies bleeding-related hospitalizations from a primary discharge diagnosis, was used to identify major bleeding events in this study. The definition of major bleeding is not an exact match with the ROCKET AF trial.

**LIMITATIONS:** This is a retrospective study and there is no comparator arm in the trial. Differences in study design, patient populations, definition of safety outcomes, and data collection methods make it difficult to make comparisons with clinical trials.

**RATES OF BLEEDING IN ROCKET AF (N=7,111)**

- The event rate per 100 patient-years was 3.6 (n=395) for major bleed and 0.20 (n=27) for fatal bleed
- 0.8% of patients experienced an ICH (n=55) and 3.1% of patients experienced a GI bleed (n=221)

**IMPORTANT SAFETY INFORMATION (cont’d)**

**USE IN SPECIFIC POPULATIONS (cont’d)**

- **Labor and Delivery:** Safety and effectiveness of XARELTO® during labor and delivery have not been studied in clinical trials.
- **Nursing Mothers:** It is not known if rivaroxaban is excreted in human milk.

**Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.

**Females of Reproductive Potential:** Females of reproductive potential requiring anticoagulation should discuss pregnancy planning with their physician.
IMPORTANT SAFETY INFORMATION (cont’d)

OVERDOSAGE

- Discontinue XARELTO® and initiate appropriate therapy if bleeding complications associated with overdose occur. A specific antidote for rivaroxaban is not available. The use of activated charcoal to reduce absorption in case of XARELTO® overdose may be considered. Due to the high plasma protein binding, rivaroxaban is not expected to be dialyzable.

ADVERSE REACTIONS IN CLINICAL STUDIES

- The most common adverse reactions with XARELTO® were bleeding complications.

Published safety outcomes in real-world patients, from observational studies

NOAC = non-vitamin K antagonist oral anticoagulant
† Among Factor Xa inhibitors and direct thrombin inhibitors.
‡ Based on the following registries, claims databases, and studies: Optum Labs=16,253; IMS Health Lifelink=1,649; Truven Health=5,583; Danish registry=1,203; XAMOS=4,778; Symphony=9,654; OPTIMO-TEP=1,048; Japanese registry=1,035; Dresden NOAC=1,776; XALIA=2,005; TOP database=27,487; XANTUS=6,744.

Please see Important Safety Information on preceding pages.

Please see accompanying Brief Summary of full Prescribing Information, including Boxed WARNINGS, on preceding pages, or visit www.XareltoHCP.com/PI.

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