THE MOC FIGHT
Physicians battle certification laws

TAKE CONTROL OF YOUR CAREER
6 WAYS TO STAY INDEPENDENT
Aspirin reduces the risk of recurrent ischemic stroke by 22% and recurrent MI* by 31%.

Discontinuation of low-dose aspirin can increase the risk of recurrent ischemic stroke by 40% and nonfatal MI by 63%.

Recommend BAYER Aspirin—First for secondary prevention.

References:

Bayer and the Bayer Cross are registered trademarks of Bayer.

“[If] you raise the [pay] level for women, you raise the level for everyone. So pay equity is critically important.”

JONATHAN LILLY, MD, INTERNIST, DUNBAR, W. VA.

“Anyone who is going to do [value-based care] on their own is taking on a lot.”

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6 in 10

U.S. adults are worried about healthcare cost increases, new poll says
The MOC fight
Physicians battle certification laws

Beware the False Claims Act
Physicians must protect themselves from potential risk

Staying independent
Six ways physicians can team up but retain their autonomy

Pharma discounts
Methods physicians can use to save patients money on drugs

Interoperability
Why physician input remains crucial to technology success

MedicineEconomics.com
OCTOBER 10, 2018 VOLUME 95 ISSUE 19

COVER STORY

THE LAST WORD
Help chronic care patients
Physicians need to be able to spend more time with patients with diabetes, heart disease and other conditions, writes Jeffrey Dlott, MD.

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ACP President Ana Maria Lopez, MD, on gender equality and the importance of teamwork

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The topic of social determinants of health is receiving much attention lately, particularly in academic papers and consumer media. The question for doctors, however, is how do social determinants apply to the everyday practice of medicine?

According to the Centers for Disease Control and Prevention, social determinants of health are the conditions in which people live, learn, work, and play that can affect a wide range of health risks and outcomes. Everything from access to healthy food and housing to safe neighborhoods and education are considered social determinants and, in theory, can serve as predictors of—and factor into—population health.

In practice, however, social determinants take on a more real-world meaning. In a medical setting, they mean asking our patients some nontraditional—and sometimes difficult—questions.

Are you getting enough to eat? Do you feel safe at home? Do you feel lonely or isolated? These are just a few examples of the queries we should be posing to get a complete understanding of our patients’ medical history.

The good news is according to a survey from Leavitt Partners, more than 50 percent of physicians believe assisting patients with social determinants of health matters for wellbeing. The bad news is this research found the majority of physicians do not feel well-positioned to help address social determinants.

In addition, the majority of those surveyed do not believe doctors or insurance plans are responsible for providing that assistance, even though nearly half thought their patients would benefit from this type of assistance.

We physicians have a lot on our plates. But what if there were resources available to help patients without adding more to an already overworked schedule? By incorporating actions to help our patients who need it, we can make strides and enhance patient care and reduce traditional healthcare needs.

Address social determinants of health with patients

MORE ONLINE  To read more, visit bit.ly/address-social-determinants-of-health.
Kenneth Fisher MD is right to criticize the data-collecting frenzy that has been imposed on physicians: “Congress is the largest cause of medical errors” (Second Opinion, July 25, 2018 issue).

The next step in our data-tormented profession will be the network of health information exchange (HIE) which will give physicians instant access to patients’ health records. Ideally, this can be very helpful at times to doctors.

But over the past 43 years as a primary care doctor, I cannot remember a single instance of a patient being misdiagnosed or receiving poor treatment because of the lack of an HIE or EHR. HIE doesn’t necessarily translate into better care because physicians can and should communicate with each other by telephone any really important data that impacts a patient’s health.

Despite their potential for good, EHRs have burdened doctors with pages and pages—sometimes twenty or more—of convoluted hospital discharge summaries, stress tests, sleep apnea tests, and consultation reports overloaded with so much data that finding the actual diagnosis and treatment and information that I need is difficult.

Despite their potential for good, EHRs have burdened doctors with...so much data that finding the actual diagnosis and treatment and information that I need is difficult.

The actual diagnosis and treatment and information that I need is difficult.

The same goes for nursing homes and visiting nurse associations reports. They all contain more information than is needed. It is distracting, time-consuming and enervating.

The electronic ability to gather data has turned into a fetish. With HIE doctors will be tied to their computers. They will have very little downtime. Already the pace of modern medicine has diminished collegiality. Hospital meetings are poorly attended. Morale among physicians is low and burnout is common. Doctors have little time for personal pursuits and family time. Doctors’ hospital lounges are a thing of the past.

The data-collection mania has already taken time away from talking and examining patients. As Dr. Fisher mentioned, it can lead to medical errors. And with instantaneous access to patients’ records, opportunistic personal injury lawyers will have a powerful tool to use against doctors. Soon they will have computer programs that will scour patients’ electronic records and ‘red flag’ any evidence that could be used in malpractice suits. This will increase the number of frivolous lawsuits.

It is important that we communicate our concerns to our medical leaders and our lawmakers.

Edward Volpintesta, MD
Bethel, Conn.
Debate over healthcare costs will dominate midterm elections

A new poll from the Kaiser Family Foundation shows that voters are focusing on the debate over healthcare as they consider candidates in the run-up to the midterm elections in November.

The national poll, which was conducted in late August and released in September, shows that the rising cost of care is overwhelmingly the most pressing issue on voters’ minds.

Here’s a snapshot of the data.

### The most important healthcare issues to voters

“When you say healthcare costs is an important issue for 2018 to talk about, what healthcare issues are you mainly talking about?”

- **Costs:** 27%
- **Increasing access:** 9%
- **Universal coverage:** 8%
- **Medicare/senior concerns:** 7%
- **Prescription costs:** 7%

### Why voters think healthcare costs rising

- **Drug companies make too much money:** 78%
- **Too much fraud and waste in the system:** 71%
- **Hospitals charge too much:** 71%
- **Insurance companies make too much money:** 70%
- **New technology is often very expensive:** 62%
- **Doctors charge too much:** 49%

### 6 in 10 voters are very concerned about the increases in the amount that individuals must pay to obtain healthcare

- **6 in 10 voters** are very concerned about the increases in the amount that individuals must pay to obtain healthcare.

### 4 in 10 insured adults say there have received an unexpected medical bills in the last 12 months

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Source: Kaiser Family Foundation, Kaiser Health Tracking Poll, September 5, 2018
Despite changes this year to make the maintenance of certification (MOC) process easier on internists, the American Board of Internal Medicine (ABIM) still faces strong opposition to the program. In May, South Carolina became the 12th state to pass an “anti-maintenance of certification” law. Legislation has been introduced in more than a dozen other states, according to press reports.

The MOC requirements for internists have become controversial in recent years. Some physicians complained about the cost, the time required to study for and take the exam, testing questions that didn’t apply to their work. On top of that, there is heavy pressure to pass and prevent the loss of certification, which can mean losing insurance panel participation, hospital privileges and sometimes employment. Physicians have also complained about the monopoly that the ABIM and other specialty boards have on doctors’ ability to practice medicine.

In 2015, some physicians formed the National Board of Physicians and Surgeons (NBPS) as an alternative certification for physicians to provide to hospitals and insurance panels. Some hospitals now accept NBPS certification in addition to ABIM and other board certifications, but acceptance isn’t widespread, and insurance panels currently do not accept it.

In response to physician complaints about the MOC process, as of June internists and
nephrologists were allowed to start taking a shorter “knowledge check-in” every two years instead of one longer test every 10 years. The option of the shorter exam will be rolled out to other ABIM specialties in 2019 and 2020. But these changes don’t appear sufficient to appease critics and slow the momentum for additional anti-MOC legislation.

"Physicians are pushing legislation on the state level because they don’t trust the ABMS [American Board of Medical Specialties] and its financial conflicts of interest,” says Paul Mathew, MD, a volunteer board member of the NBPAS in Cambridge, Mass. “Many feel the only way to declaw the tiger is legislative action due to insurance companies and academic institutions having no reason to change their pro-MOC policies.” The ABMS oversees MOC for its 24 boards.

The newer option allows for an online test with 90 questions in one sitting, taken at the physician’s convenience and his or her own computer. It’s expected to take two to three hours. Physicians may consult UpToDate, a clinical decision support tool, as a reference during the exam, unlike the traditional test where no resources are allowed.

Both exams result in recertification if passed. Doctors will still be able to test every 10 years if they prefer.

THE MOC PROCESS VS THE LEGISLATIVE PROCESS

Physicians interviewed say that anti-MOC legislative actions are unrelated to any modifications of the certification process.

While these doctors argue that they’re strongly in favor of continuing education, which is already required in one sitting, taken at the physician’s convenience and his or her own computer. It’s expected to take two to three hours. Physicians may consult UpToDate, a clinical decision support tool, as a reference during the exam, unlike the traditional test where no resources are allowed.

Both exams result in recertification if passed. Doctors will still be able to test every 10 years if they prefer.

Taking the fight to the states:

Legislative action on MOC

A number of state legislatures—prompted by the efforts of physicians, local medical organizations and the National Board of Physicians and Surgeons—have proposed bills to limit the reach of maintenance of certification. Many have succeeded and become law while others have stalled or are still pending.

The bills are a way to bring the issue to a larger audience. “Continued knowledge is always a goal, but you have an exam used for outside purposes. We want to make sure that doesn’t happen,” says Mishael Azam, COO and senior manager of legislative affairs at the Medical Society of New Jersey.

New Jersey’s anti-MOC bill was introduced in the state Senate in June 2017 but died in committee. It forbade board certification as a condition of licensure, reimbursement, employment, or admitting privileges at hospitals in the state. “Even if not signed into law ever, it’s still an important tool to continue our conversation with the [ABMS] board, just them knowing that there’s legislation introduced. They probably don’t want to deal with legislation state by state,” Azam says.

In March Washington state passed what
MOC proponents consider a weak bill, as it only mandates that certification cannot be a condition of state licensure. That was a pre-emptive strike, since MOC isn’t required for state licensure in any state, and there are no current efforts to change that, says Paul S. Teirstein, MD, founder and president of the NBPAS and chief of cardiology for Scripps Clinic in La Jolla, Calif.

The bill was structured that way based partly on “some of the pragmatic concerns of what we could get passed through the legislature,’ and partly on members’ primary concern of not having MOC tied to maintaining licensure, says Denny Maher, MD, JD, general counsel and director of legal affairs at the Washington State Medical Association in Seattle. While bill passage solves one potential problem, says Maher, it does not alleviate member concerns about MOC cost and relevance.

Some states, like Washington, begin with a “starter bill” to introduce the concept to legislators, says Maher. Then, if passed, legislators might introduce a subsequent bill with more teeth. This was the case in Tennessee. That state’s bill prevents healthcare facilities from requiring MOC activities of a licensed physician as a condition of employment or staff privileges.

Four additional states—Texas, Oklahoma, Georgia and South Carolina—have passed comprehensive legislation, generally prohibiting use of MOC as a factor in hospitals privileges, insurance payments, and state licensure.

Washington, Arizona, North Carolina, Kentucky, Missouri, Maine, and Maryland have passed starter legislation. And other states have introduced legislation that is currently pending or has expired. New Hampshire’s House of Representatives passed a proposed law this year, which is currently awaiting action from the New Hampshire Senate. “I think the political activity is pretty impressive, that it’s still going strong despite the changes the boards have made,” says Teirstein.

It’s a difficult process, Teirstein notes, because physicians lobby legislators as volunteers, taking time away from their practices and going up against what he says are highly paid and articulate ABMS and ABIM lobbyists. Sometimes specialty societies, which sell certification review courses and thus have a financial stake, lobby alongside the boards as well. Legislators may not understand the nuances and interests of all involved parties, making it more difficult for physicians to sway them.

ABIM did not respond to interview requests. But Tom Granatir, senior vice president for policy and external relations spokesman for the ABMS, said in an emailed statement: “These physicians may continue to press for legislation that will prevent the need to recertify. We remain committed to an independent program of assessment and will continue to...”
Policy

MOC

oppose legislation that denies hospitals, health systems, insurers, and patients the assurance that their physician’s knowledge and skills are current and up to date, even as the boards work to improve their continuing certification process.

WHAT INTERNISTS THINK OF THE MOC CHANGES

Along with a continued legislative push, “There’s still a tremendous amount of momentum for maintenance of certification reform,” says Teirstein. He sees the testing changes as a step in the right direction. Other critics say the ABIM is not addressing their underlying test concerns.

Their proposal of testing us more frequently is not meaningful,” says Scott Shapiro, MD, a cardiologist in Abington, Penn., and past president of the Pennsylvania Medical Society. The shorter tests are not substantively different than the longer test, and the questions aren’t directly applicable to what the physicians do in practice, says Shapiro. “It’s infuriating to the physicians who wouldn’t mind being tested more frequently, if it’s a process more relevant to our practice, and tailored to how we see patients.”

A concern for rheumatologist Mark Lopatin, MD, FACP, based in Willow Grove, Penn., is that the changes don’t address physicians’ complaints about the exam itself. “They have advertised it as open book, but physicians will have access to only one resource, UpToDate, and it appears that the ABIM has not allowed enough time during the exam for physicians to use that resource the way we do in practice,” says Lopatin.

The test also requires preparation time, which will take physicians out of the office every two years. “The shorter exam does not reduce the amount of time necessary to prepare for it, nor the stress associated with it,” he says.

The ABMS contends that physicians are happy with the new system. “Changes made by the boards in many disciplines have received very positive feedback from diplomates who believe the boards are listening to their concerns and making a sincere effort to make the program more relevant, valuable, convenient, and less costly.”

— TOM GRANATIR, SENIOR VICE PRESIDENT FOR POLICY AND EXTERNAL RELATIONS, ABMS

WHAT OTHER SPECIALTIES THINK ABOUT MOC CHANGES

By Deborah Abrams Kaplan

The ABIM isn’t the only board to change its maintenance of certification (MOC) program under protest from its diplomates, with 22 of 24 boards introducing shorter and more frequent testing options. “The ABMS Boards Community has been making substantial changes to improve continuing certification to lower the costs, increase its relevance to practice, increase flexibility for meeting the standards, and make the whole process more convenient,” says Tom Granatir, ABMS senior vice president, policy and external relations, in an email to Medical Economics.

What do physicians in other specialties think about the changes?

Rheumatology

Mark Lopatin, MD, a Willow Grove, Penn., rheumatologist is grandfathered into a lifetime internal medicine certification, but must pass his rheumatology exam in 2020 to remain certified in that specialty. “I like what I do. I like seeing patients. I like learning things, but I am offended by a high stakes recertification exam that in my mind provides no value,” says Lopatin. “I view it as so onerous that I plan to retire rather than take it again.”

The American College of Rheumatology is looking into changing its affiliation from the ABIM to the American Board of Allergy and Immu-
ceived very positive feedback from diplomats who believe the boards are listening to their concerns and making a sincere effort to make the program more relevant, valuable, convenient, and less costly,” says the ABMS’s Granatir.

**ABMS CONSIDERS ADDITIONAL CHANGES**

In January, the ABMS launched an initiative to further review the MOC process and plans to release a report in early 2019 with recommendations for ABMS boards to use in developing future continuing certification programs.

Labeled the “Vision for the Future,” the initiative “offers an independent and objective analysis of ABMS Member Boards’ approach to continuing certification today, and how it can be optimized for physicians in the future,” say co-chairs Christopher Colenda, MD, MPH, and William J. Scanlon, Ph.D., in an emailed statement to Medical Economics. The Vision Initiative commission is comprised of 27 members, including physicians and representatives of health systems, state medical associations, and specialty medical societies.

The NBPA’s Mathew spoke at a recent Visions Initiative meeting. “I thought it would be like Hillary Clinton getting invited to speak at an RNC [Republican National Committee] meeting,” he says, but “the ABMS officials hosting the meeting were gracious and appreciative of my commentaries on the expensive, time-consuming, onerous, and unproven nature of MOC.” Mathew says he was surprised to see a number of commission members who were opposed to MOC. “I applaud the ABMS for not filling the room with supporters,” he says.

Given the sustained level of physician resistance to the MOC process, Teirstein sees the momentum for both state legislation and exam changes continuing. “I think the ABIM is getting a very clear message that it’s not just going to go away and physicians are disgruntled,” he says.

“Physicians are pushing legislation on the state level because they don’t trust the ABMS [American Board of Medical Specialties] and its financial conflicts of interest. Many feel the only way to declaw the tiger is legislative action.”

—PAUL MATHEW, MD, VOLUNTEER BOARD MEMBER, NBPA

**Family Medicine**

The American Board of Family Medicine (ABFM) launched its Continuous Knowledge Self-Assessment in January 2017. Every three months, diplomates must answer 25 questions, and passing isn’t mandatory. They’re given their results to help them identify knowledge gaps, according to the ABFM. “The changes are much more compatible with my ability to treat patients and do what I need to do to provide quality care,” says Kennedy U. Ganti, MD, FAAFP, a Willingboro, N.J. physician board-certified in both family and preventative medicine, and second vice president of the Medical Society of New Jersey.

He thinks that ABIM is not making enough changes, which frustrates physicians he has spoken with in those specialties. “The changes at the ABIM don’t seem to be congruent with changes made by other specialty boards,” he says, noting feedback received by the medical society. “Personally, I fail to see where high stakes exams are needed, especially if you’re getting routine updates.”

**Technology (ABAI), which has less stringent testing, he says. ABAI is moving forward with replacing its 10-year exam with learning modules that use recently published articles in medical literature as the testing content.**

While Lopatin, who is also a trustee of the Pennsylvania Medical Society, welcomes better educational opportunities, “If ABIM wants to truly provide a service to physicians, there needs to be a paradigm shift where their role changes from enforcers to educators,” he says.
As an adjunct to diet and exercise for appropriate adults with type 2 diabetes

Powerful A1C lowering with STEGLATRO

Statistically Significant Reductions in A1C When Added

Primary end point: A1C change from baseline at week 26

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>STEGLATRO 5 mg</th>
<th>STEGLATRO 15 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=152; BL=8.0%</td>
<td>–0.2</td>
<td>–0.7</td>
<td>–0.8</td>
</tr>
<tr>
<td>DIFFERENCE FROM PLACEBO, %</td>
<td>−0.5 (P&lt;0.001)</td>
<td>−0.6 (P&lt;0.001)</td>
<td></td>
</tr>
</tbody>
</table>

* N includes all randomized and treated patients with a baseline measurement of the outcome variable. At week 26, the primary A1C end point was missing for 10%, 11%, and 7% of patients, and during the trial, rescue medication was initiated by 16%, 1%, and 2% of patients randomized to placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively. Missing week 26 measurements were imputed using multiple imputation with a mean equal to the baseline value of the patient. Results include measurements collected after initiation of rescue medication. For those patients who did not receive rescue medication and had values measured at 26 weeks, the mean changes from baseline for A1C were −0.2%, −0.8%, and −0.9% for placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively.

b Intent-to-treat analysis using ANCOVA adjusted for baseline value, prior antihyperglycemic medication, and baseline estimated glomerular filtration rate (eGFR).

BL=baseline; LS=least squares.
Study design: 463 adults with type 2 diabetes, inadequately controlled (A1C between 7% and 10.5%) on metformin (≥1500 mg/day for ≥8 weeks) and sitagliptin 100 mg once daily participated in a randomized, double-blind, multicenter, 26-week, placebo-controlled study to evaluate the efficacy and safety of STEGLATRO. Study subjects were randomized to STEGLATRO 5 mg, STEGLATRO 15 mg, or placebo administered once daily in addition to continuation of background metformin and sitagliptin therapy. The primary efficacy endpoint was the change from baseline in A1C at week 26.

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

SELECTED SAFETY INFORMATION

Contraindications: STEGLATRO is contraindicated in patients with severe renal impairment, end-stage renal disease, or on dialysis, and/or a history of a serious hypersensitivity reaction to ertugliflozin.

Hypotension: STEGLATRO causes intravascular volume contraction. Symptomatic hypotension may occur after initiating STEGLATRO, particularly in patients with impaired renal function (estimated glomerular filtration rate [eGFR] less than 60 mL/min/1.73 m²), elderly patients (≥65 years), patients with low systolic blood pressure, or patients on diuretics. Before initiating STEGLATRO, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms after initiating therapy.

Ketoacidosis: Ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, has been reported in patients with type 1 and type 2 diabetes receiving sodium glucose co-transporter 2 (SGLT2) inhibitors, including STEGLATRO. Some cases were fatal. Assess patients with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level. If ketoacidosis is suspected, STEGLATRO should be discontinued, patients should be evaluated, and prompt treatment should be instituted. Before initiating STEGLATRO, consider risk factors for ketoacidosis, including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with STEGLATRO, consider monitoring for ketoacidosis and temporarily discontinuing STEGLATRO in clinical situations known to predispose to ketoacidosis (eg, prolonged fasting due to acute illness or surgery).

Additional Selected Safety Information on next page.
SELECTED SAFETY INFORMATION (continued)

Acute Kidney Injury and Impairment in Renal Function: STEGLATRO causes intravascular volume contraction and can cause renal impairment. There have been postmarketing reports of acute kidney injury, some requiring hospitalization and dialysis, in patients receiving SGLT2 inhibitors. Before initiating STEGLATRO, consider factors that may predispose patients to acute kidney injury. Consider temporarily discontinuing STEGLATRO in any setting of reduced oral intake or fluid losses; monitor patients for signs and symptoms of acute kidney injury. If acute kidney injury occurs, discontinue STEGLATRO promptly and institute treatment.

STEGLATRO increases serum creatinine and decreases eGFR. Patients with moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²) may be more susceptible to these changes. Renal function abnormalities can occur after initiating STEGLATRO. Renal function should be evaluated prior to initiating STEGLATRO and periodically thereafter. Use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73 m² and is contraindicated in patients with an eGFR less than 30 mL/min/1.73 m².

Urosepsis and Pyelonephritis: There have been postmarketing reports of serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization in patients receiving SGLT2 inhibitors. Cases of pyelonephritis also have been reported in patients treated with STEGLATRO in clinical trials. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated.

Lower Limb Amputations: An increased risk for lower limb amputation has been observed in clinical studies with another SGLT2 inhibitor. Across seven Phase 3 clinical trials with STEGLATRO, nontraumatic lower limb amputations were reported in 1 (0.1%) patient in the comparator group, 3 (0.2%) patients in the STEGLATRO 5-mg group, and 8 (0.5%) patients in the STEGLATRO 15-mg group. A causal association between STEGLATRO and lower limb amputation has not been definitively established. Before initiating STEGLATRO, consider factors that may predispose patients to the need for amputations. Monitor patients and discontinue STEGLATRO if complications occur. Counsel patients about the importance of routine preventative foot care.

Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues: Insulin and insulin secretagogues (eg, sulfonylurea) are known to cause hypoglycemia. STEGLATRO may increase the risk of hypoglycemia when used in combination with insulin and/or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with STEGLATRO.

Genital Mycotic Infections: STEGLATRO increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncircumcised are more likely to develop genital mycotic infections. Monitor and treat appropriately.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C): Dose-related increases in LDL-C can occur with STEGLATRO. Monitor and treat as appropriate.

Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with STEGLATRO.

The most common adverse reactions associated with STEGLATRO (≥5%) were female genital mycotic infections. Please read the adjacent Brief Summary of the Prescribing Information.
INDICATIONS AND USAGE
STEGLATRO™ is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use
- STEGLATRO is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

DOSE AND ADMINISTRATION
Recommended Dosage. The recommended starting dose of STEGLATRO is 5 mg once daily, taken in the morning, with or without food. In patients tolerating STEGLATRO 5 mg once daily, the dose may be increased to a maximum recommended dose of 15 mg once daily if additional glycemic control is needed. In patients with volume depletion, correct this condition prior to initiation of STEGLATRO [see Warnings and Precautions].

Patients with Renal Impairment. Assess renal function prior to initiation of STEGLATRO and periodically thereafter [see Warnings and Precautions]. Use of STEGLATRO is contraindicated in patients with an eGFR less than 30 mL/minute/1.73 m² [see Contraindications]. Initiation of STEGLATRO is not recommended in patients with an eGFR of 30 mL/minute/1.73 m² to less than 60 mL/minute/1.73 m² [see Warnings and Precautions and Use in Specific Populations]. Continued use of STEGLATRO is not recommended when eGFR is persistently between 30 and less than 60 mL/minute/1.73 m². No dose adjustment is needed in patients with mild renal impairment.

CONTRAINDICATIONS
- Severe renal impairment, end-stage renal disease (ESRD), or dialysis [see Warnings and Precautions and Use in Specific Populations].
- History of a serious hypersensitivity reaction to STEGLATRO.

WARNINGS AND PRECAUTIONS
Hypoglycemia. STEGLATRO causes intravascular volume contraction. Therefore, symptomatic hypoglycemia may occur after initiating STEGLATRO [see Adverse Reactions] particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²) [see Use in Specific Populations], elderly patients (≥65 years), in patients with low systolic blood pressure, and in patients on diuretics. Before initiating STEGLATRO, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms of hypoglycemia after initiating therapy.

Ketoacidosis. Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, have been identified in clinical trials and postmarketing surveillance in patients with type 1 and type 2 diabetes mellitus receiving sodium glucose co-transporter-2 (SGLT2) inhibitors and cases have been reported in STEGLATRO-treated patients in clinical trials. Across the clinical program, ketoacidosis was identified in 3 of 3,409 (0.1%) of STEGLATRO-treated patients and 0% of comparator-treated patients. Fatal cases of ketoacidosis have been reported in patients taking SGLT2 inhibitors. STEGLATRO is not indicated for the treatment of patients with type 1 diabetes mellitus [see Indications and Usage].

Patients treated with STEGLATRO who present with signs and symptoms consistent with severe metabolic acidosis should be assessed for ketoacidosis regardless of presenting blood glucose levels, as ketoacidosis associated with STEGLATRO may be present even if blood glucose levels are less than 250 mg/dL. If ketoacidosis is suspected, STEGLATRO should be discontinued, patient should be evaluated, and prompt treatment should be instituted. Treatment of ketoacidosis may require insulin, fluid and carbohydrate replacement.

In many of the reported cases, and particularly in patients with type 1 diabetes, the presence of ketoacidosis was not immediately recognized and institution of treatment was delayed because presenting blood glucose levels were below those typically expected for diabetic ketoacidosis (often less than 250 mg/dL). Signs and symptoms at presentation were consistent with dehydration and severe metabolic acidosis and included nausea, vomiting, abdominal pain, generalized malaise, and shortness of breath. In some but not all cases, factors predisposing to ketoacidosis such as insulin dose reduction, acute febrile illness, reduced caloric intake due to illness or surgery, pancreatic disorders suggesting insulin deficiency (e.g., type 1 diabetes, history of pancreatitis or pancreatic surgery), and alcohol abuse were identified.

Before initiating STEGLATRO, consider factors in the patient history that may predispose to ketoacidosis, including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with STEGLATRO consider monitoring for ketoacidosis and temporarily discontinuing STEGLATRO in clinical situations known to predispose to ketoacidosis (e.g., prolonged fasting due to acute illness or surgery).
Table 1: Adverse Reactions Reported in ≥2% of Patients with Type 2 Diabetes Mellitus Treated with STEGLATRO® and Greater than Placebo in Pooled Placebo-Controlled Clinical Studies of STEGLATRO Monotherapy or Combination Therapy

<table>
<thead>
<tr>
<th>Number (%) of Patients</th>
<th>Placebo (N = 515)</th>
<th>STEGLATRO 5 mg (N = 519)</th>
<th>STEGLATRO 15 mg (N = 510)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female genital mycotic infections¹</td>
<td>3.0%</td>
<td>9.1%</td>
<td>12.2%</td>
</tr>
<tr>
<td>Male genital mycotic infections²</td>
<td>0.4%</td>
<td>3.7%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Urinary tract infections³</td>
<td>3.9%</td>
<td>4.0%</td>
<td>4.1%</td>
</tr>
<tr>
<td>Headache</td>
<td>2.3%</td>
<td>3.5%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Vaginal pruritus⁴</td>
<td>0.4%</td>
<td>2.8%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Increased urination⁵</td>
<td>1.0%</td>
<td>2.7%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>2.3%</td>
<td>2.5%</td>
<td>2.0%</td>
</tr>
<tr>
<td>Back pain</td>
<td>2.3%</td>
<td>1.7%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>1.0%</td>
<td>1.2%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Thrust⁶</td>
<td>0.6%</td>
<td>2.7%</td>
<td>1.4%</td>
</tr>
</tbody>
</table>

¹ Includes: candidiasis, genital infection fungal, vaginitis, vulvoanogenital, vulvovaginal mycotic infection, and vulvovaginitis. Percentages calculated with the number of female patients in each group as denominator: placebo (N=280), STEGLATRO 5 mg (N=267), STEGLATRO 15 mg (N=245).

² Includes: leukovans, balanoposthitis, genital infection, and genital infection fungal. Percentages calculated with the number of male patients in each group as denominator: placebo (N=280), STEGLATRO 5 mg (N=252), STEGLATRO 15 mg (N=245).

³ Includes: cystitis, dysuria, streptococcal urinary tract infection, urethritis, urinary tract infection.

⁴ Includes: balanitis candida, balanoposthitis, genital infection, and genital infection fungal. Percentages calculated with the number of male patients in each group as denominator: placebo (N=280), STEGLATRO 5 mg (N=267), STEGLATRO 15 mg (N=245).

⁵ Includes: pollakiuria, micturition urgency, polyuria, urine output increased, and nocturia.

⁶ Includes: thirst, dry mouth, polydipsia, and dry throat.

Volume Depletion. STEGLATRO causes an osmotic diuresis, which may lead to intravascular volume contraction and adverse reactions related to volume depletion, particularly in patients with impaired renal function. STEGLATRO less than 60 mL/min/1.73 m² is associated with increases in serum creatinine and decreases in eGFR (see Table 2). Patients with moderate renal impairment at baseline may also increase the risk of hypotension in other patients at risk for volume contraction and adverse reactions related to volume depletion, particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²). In patients with moderate renal impairment, the incidence of renal-related adverse reactions was 0.6%, 2.5%, and 1.3% in patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively. STEGLATRO may also increase the risk of hypotension in other patients at risk for volume contraction (see Use in Specific Populations).

Table 2: Changes from Baseline in Serum Creatinine and eGFR in the Pool of Three 26-Week Placebo-Controlled Studies and a 26-Week Moderate Renal Impairment Study in Patients with Type 2 Diabetes Mellitus

<table>
<thead>
<tr>
<th>Pool of 26-Week Placebo-Controlled Studies</th>
<th>Placebo (N=515)</th>
<th>STEGLATRO 5 mg (N=519)</th>
<th>STEGLATRO 15 mg (N=510)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Mean Creatinine (mg/dL)</td>
<td>0.83</td>
<td>0.82</td>
<td>0.82</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>89.5</td>
<td>88.2</td>
<td>89.0</td>
</tr>
<tr>
<td>Week 6 Change</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td>0.00</td>
<td>0.03</td>
<td>0.03</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>-0.3</td>
<td>-2.7</td>
<td>-3.1</td>
</tr>
<tr>
<td>Week 26 Change</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td>0.01</td>
<td>0.00</td>
<td>0.01</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>0.7</td>
<td>0.5</td>
<td>-0.6</td>
</tr>
</tbody>
</table>

Moderate Renal Impairment Study

<table>
<thead>
<tr>
<th>Placebo (N=154)</th>
<th>STEGLATRO 5 mg (N=158)</th>
<th>STEGLATRO 15 mg (N=155)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline Mean Creatinine (mg/dL)</td>
<td>1.34</td>
<td>1.38</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>46.0</td>
<td>46.8</td>
</tr>
<tr>
<td>Week 6 Change</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td>0.02</td>
<td>0.11</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>-0.6</td>
<td>-3.2</td>
</tr>
<tr>
<td>Week 26 Change</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td>0.02</td>
<td>0.08</td>
</tr>
<tr>
<td>eGFR (mL/min/1.73 m²)</td>
<td>0.0</td>
<td>-2.7</td>
</tr>
</tbody>
</table>

Renal-related adverse reactions (e.g., acute kidney injury, renal impairment, acute prerenal failure) may occur in patients treated with STEGLATRO, particularly in patients with moderate renal impairment where the incidence of renal-related adverse reactions was 0.6%, 2.5%, and 1.3% in patients treated with placebo, STEGLATRO 5 mg, and STEGLATRO 15 mg, respectively.

Table 3: Incidence of Overall* and Severe† Hypoglycemia in Placebo-Controlled Clinical Studies in Patients with Type 2 Diabetes Mellitus

<table>
<thead>
<tr>
<th>Monotherapy (26 weeks)</th>
<th>Placebo (N = 153)</th>
<th>STEGLATRO 5 mg (N = 156)</th>
<th>STEGLATRO 15 mg (N = 152)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (N %)</td>
<td>1 (0.7)</td>
<td>4 (2.6)</td>
<td>4 (2.6)</td>
</tr>
<tr>
<td>Severe (N %)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>2 (1.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Add-on Combination Therapy with Metformin (26 weeks)</th>
<th>Placebo (N = 209)</th>
<th>STEGLATRO 5 mg (N = 207)</th>
<th>STEGLATRO 15 mg (N = 205)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (N %)</td>
<td>9 (4.3)</td>
<td>15 (7.2)</td>
<td>16 (7.8)</td>
</tr>
<tr>
<td>Severe (N %)</td>
<td>1 (0.5)</td>
<td>1 (0.5)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Add-on Combination Therapy with Metformin and Sitagliptin (26 weeks)</th>
<th>Placebo (N = 153)</th>
<th>STEGLATRO 5 mg (N = 156)</th>
<th>STEGLATRO 15 mg (N = 153)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (N %)</td>
<td>5 (3.3)</td>
<td>7 (4.5)</td>
<td>3 (2.0)</td>
</tr>
<tr>
<td>Severe (N %)</td>
<td>1 (0.7)</td>
<td>1 (0.6)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In Combination with Insulin and/or an Insulin Secretagogue in Patients with Moderate Renal Impairment</th>
<th>Placebo (N = 133)</th>
<th>STEGLATRO 5 mg (N = 148)</th>
<th>STEGLATRO 15 mg (N = 143)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (N %)</td>
<td>48 (36.1)</td>
<td>53 (35.8)</td>
<td>39 (27.3)</td>
</tr>
<tr>
<td>Severe (N %)</td>
<td>3 (2.3)</td>
<td>5 (3.4)</td>
<td>3 (2.1)</td>
</tr>
</tbody>
</table>

* Overall hypoglycemic events: plasma or capillary glucose of less than or equal to 70 mg/dL.
† Severe hypoglycemic events: required assistance, lost consciousness, or experienced a seizure regardless of blood glucose.
Geriatric Use. Safety and effectiveness of STEGLATRO in pediatric patients under 18 years of age have not been established.

Renal Impairment. The safety and efficacy of STEGLATRO have not been established in patients with type 2 diabetes mellitus and moderate renal impairment. Compared to placebo-treated patients, patients with moderate renal impairment treated with STEGLATRO did not have improvement in glycemic control, and had increased risks for renal impairment, renal-related adverse reactions and volume depletion adverse reactions (see Dosage and Administration, Warnings and Precautions and Adverse Reactions). Therefore, STEGLATRO is not recommended in this population.

Overdosage. In the event of an overdose with STEGLATRO, contact the Poison Control Center. Employ the usual supportive measures as dictated by the patient’s clinical status. Removal of ertugliflozin by hemodialysis has not been studied.

For more detailed information, please read the prescribing information. usp欣8835;+1712000

DIAB-1251861-0003 06/18
Three billing codes physicians should start using more

What are some overlooked codes that are available to use for services physicians are already providing regularly that may be overlooked?

Physicians and practice administrators are always looking for how to maximize profits. As a coding/billing consultant, chart auditor, and educator, I’m often asked about ways to improve coding. Here are three codes that I find are often misunderstood, underused, or unknown.

Practices that know about these codes—and how to use them—may be able to earn additional reimbursement.

1. Telephone services (99441-99443)

Doctors’ offices are busy places, and it isn’t unusual for patients to call in asking to speak with the doctor. CPT offers codes to report telephone services provided by a physician or other qualified health care professional who may report evaluation and management (E/M) services. These codes can only be reported for an established patient and are not billable if the call results in the patient coming in for a face-to-face service within the next 24 hours (or next available urgent visit). These calls are also not billable if they refer to an E/M service performed within the last seven days. The codes are selected from code range 99441 to 99443 and are based on the time spent: 5-10 minutes, 11-20 minutes, or 21-30 minutes, respectively.

2. 99058: Services provided on an emergency basis

What can you do when your providers already have a packed schedule and a patient walks in demanding to be seen?

What if a scheduled nurse visit is more serious than anticipated, and the provider is called to step in and spend a great deal of time with that patient? When a patient is seen on an emergency basis in the office—and it disrupts other scheduled office services—you may be able to report add-on code 99058 for additional reimbursement.

3. 96160: Health risk assessment

Providers can bill code 96160 when they perform a health risk assessment with a patient or caregiver guardian in order to assess the risk of conditions such as mental disorders. They can also report 96160 when administering a patient-focused health risk assessment. Providers should report 96161 for a caregiver-focused health risk assessment, such as depression inventory, for the benefit of the patient.

Mike Enos, CPC, CPMA, CPC-I, CEMC, is a partner at Enos Medical Coding, based in Warwick, Rhode Island. He has more than 10 years of experience in medical coding, billing compliance, and revenue cycle management. Send your coding and billing questions to medec@ubm.com.
Lines of credit for medical practices

by STEPHANIE BOUCHARD Contributing author

It is a common business strategy for medical practices to use lines of credit from a bank or other financial institution. With this business tool, medical practices reap many benefits, including the ability to bridge unexpected shortfalls in cash flow.

Which is exactly how Jeffrey Kagan, MD, an internist practicing in Newington, Conn., and a member of the Medical Economics editorial advisory board, has used his practice’s line of credit. “Every once in a while, things get a little behind, so we draw on a line of credit and then we pay it off,” he says.

A good example of this is when an insurance company that paid in 30 to 45 days suddenly—and without notice—began paying in 60 to 90 days, Kagan says. Slow or delayed reimbursement is the most common likely scenario practices need a line of credit for, but there are many other uses, he notes. Some of those are hiring a temporary replacement for an employee out on medical leave; needing to replace a broken piece of equipment; or a natural disaster that closes the practice temporarily.

“It’s nice to have a line of credit to fall back on once in a while,” he says. “It takes a lot of stress off if you have a pile of bills to pay.”

A business line of credit allows borrowers to draw money from a predetermined credit limit as the money is needed, says Matt Jones, director of business lending at the National Institutes of Health Federal Credit Union (NIHFCU) in Rockville, Md.

Borrowers pay interest only on the amount of money they actually need at a given time and are only required to pay the monthly interest payment, says Jones. With a line of credit, the financial institution doesn’t apply the monthly payments to both the principal and the interest; borrowers must put in the money to pay both. So unless borrowers make an effort to pay off the principal, it is still owed, even if they pay the interest for years, Jones says.

Many owners of medical practices have and use a business credit card to meet some of the practice’s short-term financial needs. A business credit card typically has an interest rate of between 10 percent and 27 percent, whereas a business line of credit usually is in the 5 percent range. Additionally, lines of credit can be in the six digits or higher—far more than is available with a business credit card, he says.

GETTING A SAFETY NET

Obtaining a line of credit generally is a pretty straightforward procedure, says James Edwards, a managing director in the medical specialty group of SunTrust Private Wealth Management in Atlanta, Ga.

The application process usually takes about two weeks. Potential borrowers meet with a representative of a financial institution and discuss...
Living on a sailboat while still practicing medicine didn’t seem like a realistic goal, but then Dr. Robin Mangione was introduced to locum tenens. It not only made practicing medicine while sailing a possibility, but it suited it perfectly.

“I was always afraid that medicine was going to keep us from doing this,” she says, “but quite the opposite: it has actually been the thing that has made it possible. It’s allowed us to travel and do and see things and meet people that I wouldn’t have the opportunity to do prior.”

The origins of a lifelong dream

Dr. Mangione and her husband began sailing in 1999, and what started as “cool way to spend time together and travel” evolved into a full-blown romance with the sailing life.

“My husband read Maiden Voyage by Tania Aebi who, between the ages of 19 – 21, completed a solo circumnavigation of the globe, and after reading it he fell in love with the idea of sailing. So we bought a sailboat and taught ourselves to sail,” she shares.

“Locum tenens has allowed this dream to be a reality,” she says.

“It’s allowed us to do this while we’re young and healthy, since sailing is physically demanding.”

Sailing has provided them seemingly endless opportunities for exploration

Because of their mobility, they’ve been able to see parts of the world that just wouldn’t have been possible if they lived permanently in their home in Arkansas. The amount of locum tenens assignments has made seeing the different parts of the country a lot easier, and Dr. Mangione is able to pick and choose where and how long her assignment will be; she also uses this autonomy to decide how long between assignments she’d like to take off.

Assignments of three to four months is the perfect amount of time for exploration, but Dr. Mangione says she also likes to choose assignments of a week or weekend, since right now she’s decided not to work full time.

“We’ve stayed in the Keys for three months, we’ve stayed in Titusville, Florida, for a winter,” she says. “I took an assignment near Baltimore, in the Annapolis area for about four or five months, and we were in Maryland so that we could be near DC. So, we travel in between those places, but we’ll usually stay in a marina, pick an area we’re going to hang out for a while, and really explore that area.”

Dr. Mangione says that without the flexibility of locum tenens, she and her husband wouldn’t be able to fully appreciate the local area and culture of each assignment’s location – or follow their dream of nautical living.

Learn more about Dr. Mangione and locum tenens at locumstory.com
Money

Lines of credit

“The practice's needs. Applicants need to provide their financials—typically about three years' worth. The bank will review those and an-
alyze the practice's accounts receivables to determine possible cashflow gaps.

For establishing a new practice, the bank will want to review the physician's business plan as well as revenue and expense projections for the next two to three years, Edwards says. The personal financial statement of the physician (or physicians, if a group practice) is also required.

The amount of the credit line is based on a ratio that factors in the needs and size of the practice and the accounts receivables if the practice is already established. The typical term of a line of credit is about a year, but that can vary and can be renewed annually, he says. The interest rate is tied to the U.S. prime interest rate or London Interbank Offered Rate.

Medical practices shouldn't hesitate to apply for a line of credit because having one should be standard operating procedure, Edwards says. “It's quick access to funds and eliminates business disruptions that could be caused by not having access.”

IT'S ALL ABOUT BEING PREPARED

Typically, a line of credit costs medical practices nothing until they're used, although some financial institutions require a small annual fee, says NIHFCU’s Jones. Therefore, because there are no or minimal costs to having a line of credit, he says it makes good business sense for medical practices to have one.

“It’s healthy for a business to have an approved line of credit of some sort that they can access quickly to navigate short-term liquidity issues,” he says. “I would relate it again to personal life where most people have that credit card that they have stashed off to the side just in case they need it.”

Common scenarios for a line-of-credit use

A line of credit lets medical practices manage cashflow by providing liquidity when it is needed. Lines of credit are commonly used when:

- There is slow or delayed reimbursement from payers.
- Patients have trouble with paying their deductible resulting in delayed or partial payment, or they can't pay any of it.
- A new practice is starting up or an existing practice is expanding
- Staff is being added or replaced or a temporary employee is needed to cover a staff absence, such as maternity leave.
- Practices want to take advantage of economies of scale; for instance, by being able to buy five boxes of gloves at a discounted rate of 20 percent rather than buying one or two boxes at full price.
- Small equipment purchases that don’t rise to the level of an equipment loan are needed.
- Unexpected property maintenance arises, such as an air conditioner needs replacing.
- Technology upgrades, such as when a new version of needed software is released and the old version is no longer supported.
- A failure to meet MIPS and MACRA regulations results in a decrease in reimbursement from Medicare.
- Computer glitches result in bills not being sent.
- A weather-related disaster affect the practice.
- Short-term disability results in loss of income not covered by insurance.

“It’s nice to have a line of credit to fall back on once in a while. It takes a lot of stress off if you have a pile of bills to pay.”

— JEFFREY KAGAN, MD, INTERNIST, NEWINGTON, CONN
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For Ana Maria Lopez, MD, MPH, FACP, the new president of the American College of Physicians, looking toward the future of medicine means first looking to her own past.

As the child of two pathologists, Lopez remembers sitting around the dinner table while discussions of the day’s tissue slide discovery was the main topic. She also remembers matter-of-factly announcing a “syncopal episode” as a six-year-old to her teachers on the playground one day when a classmate passed out.

“I remember thinking, back to age three or four, that I wanted to go into medicine but somehow knowing that I was going to be a different type of doctor [than my parents], because I was going to talk to patients,” Lopez says. “I really remember wanting to be there for people.”

She attended Bryn Mawr College in Pennsylvania, worked in a women’s health clinic, which she continued doing after graduation, and in 1988, earned her medical degree at the Sydney Kimmel College of Medicine of Thomas Jefferson University.

She moved to Arizona for her residency, later serving as medical director of the University of Arizona’s telemedicine program. In 2004, she was named one of the “Best Doctors in Tucson” by a local publication—a list she’d continue to appear on for years to come.

Lopez recently returned to Thomas Jefferson University as vice chair of medical oncology. This happened to coincide with another Philadelphia-based honor, serving as the 2018-2019 president of the American College of Physicians for a one-year term.

As only the seventh female physician to hold the distinction in the organization’s 103-year history (most presidents serve only one-year terms), Lopez is well aware of the significance of her new role. And if she needed any reminding, her office at the ACP’s headquarters features an eight-foot cardboard cutout of Elizabeth Blackwell, MD, the first woman to gain her medical degree in the United States, that sits right next to her desk.

Medical Economics recently visited Lopez for a wide-ranging question-and-answer session. An excerpt of that interview follows.

**Q.** How do you view the state of women in medicine today?

**Ana María Lopez:** It’s true that we’ve come a long way, and that’s incredibly positive. When I reflect back on the women who pre-
ceded us, I think of my mother who was one of three women medical students in a class of about 200. Those were pioneers, and they paved the way. So I have incredible gratitude to the women that came ahead of me.

But there still are a lot of issues. There’s pay equity, [which is a] big issue. There are family leave policies. Here we are in 2018, and that’s still an issue. It’s pretty significant. And then there’s leadership development, career development, mentorship, all of those areas … where making an impact in any of those areas is not a benefit only for women, it’s a benefit for everybody.

Sometimes we have this [thought process] that if women get paid more, somebody is going to have to be paid less. It’s not that sort of thing. You raise the level for women; you raise the level for everyone. So pay equity is critically important, and we are in a society where that’s how value is measured.

We have family leave [as an issue], and we’re not talking just for women, and we’re not talking just about being pregnant, but adoption, and caring for elders. We really want to be a community where it’s acknowledged that people have personal lives, and they have needs and demands in those lives, and they can take time to take care of those needs.

Then there’s leadership development, faculty development, and career development; [these are] so important for everyone. This is what allows young people to really be the best that they can be. And it also gives a responsibility to all of us who have benefitted from those opportuni-

ties to help people who are earlier in the process.

I always remember people that have been meaningful in my life. There was a radiology professor and I was always in awe of him because he would look at films and what he could see was incredible. And I would always say, ‘it’s just amazing how much he knows.’ And then one time he said, ‘we’re all on a learning curve, we’re just at different points.’ And so that spoke to me. …It’s incumbent on me to share what I know.

There’s a long way to go and there’s a long way to go that will not be alienating to our male peers because it will improve life for everyone.

Q: **MEC:** What is the ACP doing or what do you feel like you can do in this position to promote some of the issues that you mentioned?

---

**Ana Maria Lopez, MD, FACP**

- Born in Bolivia; moved to U.S. at 16
- Earned MD at Jefferson Medical College in Philadelphia
- Residency in internal medicine at University of Arizona Health Sciences Center in Tucson
- Former instructor of social behavioral sciences and preparation for clinical medicine at University of Arizona
- Former research assistant professor of medicine at Arizona Cancer Center at University of Arizona
- Former medical director of telemedicine program and women’s health initiatives at University of Arizona
- Former associate vice president for health equity and inclusion at University of Utah Health Sciences Center; director of cancer health equity at Huntsman Cancer Institute for University of Utah
- Current vice chair of medical oncology at the Sidney Kimmel Cancer Center at Thomas Jefferson University in Philadelphia

---

“Everybody wants to do a good job. There’s not a sense that I don’t want to do the right thing, but how we measure is so important. Are we measuring the right thing, and are we measuring what really impacts patient care?”
Lopez: We need data. For my first job, I met with my division chief; my division chief said ‘welcome, you’re a new research assistant professor and here’s your salary’ and I just said ‘thank you.’ I didn’t know the market or what any of that is. Having data available and having it published can make such a difference.

For academic medicine, for example, the Association of American Medical Colleges has a book and you go in there by specialty, by rank, by part of the country, it will say, here’s kind of what you should expect. Just to have that available is a great first step.

At my former institution, there was a clear effort to have data, for example, by rank. Here’s where people tend to be as assistant professor, here’s where people tend to be as associate, and so on. And, if someone was being paid way high or way low there would be a flag.

So, there are folks that are looking. Maybe you just hired an assistant professor who is a man for this amount and now you’re hiring an assistant professor who is a woman at a much lower or much higher amount, how come? And ask for a rationale, to understand why that is. Having data allow for those sorts of questions to be raised, and then it’s not just, ‘it’s just how it is.’

Q: MEC: What does it mean to you to be in this position of leadership at ACP, both as a physician and as a woman?

Lopez: What I love about the ACP is the coming together of different perspectives to talk deeply about a topic, to respect differences, and to learn from each other, so you actually end up in a new place than where you started from, a place from where we can move forward.

That is incredibly powerful and that, to me, is really what medicine is about, the capacity to always learn and move actionable knowledge forward. There’s also the responsibility of being a role model. I remember a student saying to me once that she’d heard me give a talk, and that made her think, maybe I could do that. In being a role model, we have to remember, you don’t always know when you’re serving that role.

Q: MEC: What do you think are the biggest challenges facing internal medicine physicians today?

Lopez: Probably the area that holds the greatest risk is the high level of burnout. When you think that for physicians, it is basically the equivalent of a whole medical school class that commits suicide each year, that’s pretty striking. Thinking about the factors that may contribute, perhaps sense of loss of control, being pulled in too many directions, and too much burden, we can think about the opportunity for action.

The American College of Physicians has resources that can help around wellness, can help around administrative burden, can foster resilience, and help create medical organizational structures that actually help clinicians be well.

Q: MEC: How do you personally make the time and make sure you maintain balance? How do you avoid burn-out and getting professionally frustrated?

Lopez: Time is the most valuable thing that we have. It’s the most valuable gift. Even with my children, one of the things we talk about is, I don’t need another [thing]; I need time together. I really take that to heart, any time that I’m with someone to really try to be as present as possible and to be as focused as possible.

I find that not feeling the pressure of what else I could be doing, not trying to think, ‘oh, I could be doing such and such’ is helpful. I’m a very visual person, so I used to have this vision that I’d be doing whatever I was doing, but I had this parallel...
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"Sometimes we have this [thought process] that if women get paid more, somebody is going to have to be paid less. It’s not that sort of thing. You raise the level for women; you raise the level for everyone. So pay equity is critically important."

Q: MEC: What are your thoughts regarding the changes in terms of healthcare delivery since the election?

Lopez: There is a sense that folks [in Washington, D.C.] are listening. How that will translate into policy, we’ll see. And there can be ramifications that may be unintended. There’s a lot to look at. There’s been a lot of conversation around performance measures.

I’m convinced, as I travel and meet internists across the U.S. and internationally, everybody wants to do a good job. There’s not a sense that I don’t want to do the right thing, but how we measure is so important. Are we measuring the right thing, and are we measuring what really impacts patient care?

Thinking about performance measures and working with our colleagues that are working in that space is very, very important. The House Ways and Means Committee has had a couple of roundtables all around red tape, and ACP has been very fortunate to have been able to participate in those.

There are some rules that are out for comment now, and we ask for members’ input. And ACP will be providing feedback.

Again, something that I very much value about the American College of Physicians is that there’s communication in both directions, including hearing closely from members. The ACP has a center that focuses on patients, hearing from patients, hearing from caregivers, hearing from families, and keeping the patient at the center.

As the ACP provides comments on policy topics, that’s the perspective we bring to the table.

Q: MEC: Do you feel like the nation’s internists still rely on and trust the ACP to represent them?

Lopez: In going to chapter meetings and going to different forums and meeting people, there’s so much kinship to the college. And there’s so much that people really find of value which is very, very heartening.

And at the same time, there’s this tremendous opportunity to listen and to understand because there really are regional differences. There are lots of different types of practices and even within the type of practice there may be regional differences.

There needs to be a lot of communication. One of the things that I may hear is, ‘oh I wish the College were doing something here.’ And we may be. We just haven’t communicated it well enough to let people know about it. It’s great to hear the tremendous kinship that people have for the American College of Physicians, and to listen, learn, and find ways to share better.

Q: MEC: What about those who aren’t ACP members?

Lopez: There can be a variable sense of frustration just around where medicine is right now. My response to that is: We have to be a part of the solution. The ACP is part of the solution. Join us.

The practice of medicine is different than it was 10, 20, certainly 50 years ago. Going back is not a viable solution. We have to come together for the benefit of our patients, People need care today.
Legally Speaking

Don’t risk a violation of the False Claims Act

Why physicians need to ensure their HIPAA and Anti-Kickback Statue compliance is in place before engaging with pharmaceutical and medical device representatives.

Anti-kickback
Originally passed in 1972, the Anti-Kickback Statute (AKS) is one of the pre-eminent federal fraud and abuse statutes because of its impact on healthcare providers, pharmaceutical, and medical device relationships.

Fundamentally, the AKS is a criminal statute that prohibits transactions intended to induce or reward referrals for items or services reimbursed by the government payers. Like most laws, there are “safe harbors:” categories of conduct that, if met, do not necessarily render the activity illegal. On July 29, 1991, the Office of the Inspector General issued the first in a series of regulations implementing the safe harbors.

In 1996, the AKS was further amended through HIPAA, which made three changes to the AKS:

- extending the statute to apply to services covered by the “federal health care programs,”
- adding a new safe harbor concerning certain risk-sharing arrangement, and
- enhancing communication between the OIG public.

In 2010, the Affordable Care Act (ACA) became law and made a number of changes to the AKS, including “expanding” its intent standard and specifying that violations of the AKS may trigger liability under the False Claims Act.

HIPAA
When most people think of HIPAA, they think of the privacy and security of protected health information, establishing the requirement for a National Provider Identifier, and the portability of health insurance.

However, recent False Claims Act cases further highlight the nexus between the AKS and HIPAA. The AKS makes it unlawful for a person to offer any remuneration (directly or indirectly) in return for a referral, or purchasing or recommending or arranging for the purchase of covered items or services that are paid for by any federal healthcare program.

Analogous to the AKS, it is prohibitive to directly or indirectly receive “remuneration from or on behalf of the recipient of the protected health information in exchange for the protected health information.” Both statutes provide for both civil and criminal penalties.

Physicians beware
Pharmaceutical and medical device companies are disregarding patient privacy protections and paying (directly or indirectly) to gain access to medical records in order to increase sales, a clear violation of both HIPAA and the AKS.

Physicians should be conscience of accepting meals, speaking engagements and services, and granting access to pharmaceutical representatives.

“Physicians should be conscience of accepting meals, speaking engagements and services, and granting access to pharmaceutical representatives.”

Rachel V. Rose, JD, MBA, advises clients on compliance and transactions in healthcare, cybersecurity, corporate and securities law, while representing plaintiffs in False Claims Act and Dodd-Frank whistleblower cases. Send your legal questions to medec@ubm.com.
How physicians can join forces to remain independent

Six model physicians can explore to create economies of scale while preserving some career autonomy

by JAMES F. SWEENEY Contributing author

HIGHLIGHTS

► An IPA is a network of physicians formed to share services, improve care, reduce overhead and negotiate with other entities, including payers.

► Hire an expert in healthcare law to help evaluate contracts and other team-up options.

Internal medicine and other primary care practices that want to stay independent are joining together in a variety of practice models and corporate structures they hope will give them a better chance of survival.

The shift to value-based care, consolidation among healthcare providers and an emphasis on finding efficiencies are making it difficult for smaller practices to succeed alone. So they’re turning to organizations that help practices transition to value-based care by providing the administrative support, tools and negotiating leverage that comes with size.

“I think (independent) practices are looking for a way to survive. There are a lot of practices that would like to try to make it on their own and they want to find the model that lets them do that,” says Kenneth Hertz, FACMPE, principal consultant with Medical Group Management Association (MGMA).

Though the organizations have common goals, there are differences among them and practices should do their homework to find the best fit, says Hertz. For example, many practices join Accountable Care Organizations (ACOs), which are groups of healthcare providers, potentially including doctors, hospitals, public and private health plans, and others, who come together to provide coordinated care to Medicare patients. But there are multiple types of ACOs, each with its own features, to choose from.

And there are other options as well, such as independent practice associations (IPAs), clinically integrated networks (CINs) and divisional mergers. “The key to it is knowing what you want and what you want for your patients,” Hertz says. You’ve got to think it through very well and you’ve got to ask a lot of questions. You can’t ask too many questions.”

Six options are highlighted below:

1. ACOS LED BY PRIVATE FIRMS

Jonathan Lilly, MD, an internist in Dunbar, W. Va., knew his practice would need help negotiating value-based care if it wanted to remain independent.

That’s why Dunbar Medical Associates, which has seven physicians and five non-physician practitioners in two offices, has contracted since 2016 with Aledade, a Maryland-based company that forms ACOs with independent practices. Dunbar is in an Aledade-led ACO with 16 other practices.

Aledade uses the practices’ data to track patient care and identify where practices can provide better service. Among other things, it identifies high-risk patients, flags emergency department visits, tracks im-
munizations and wellness visits, manages specialist referrals, and alerts the practice to cases in which chronic care management is needed, says Lilly.

“They help us to identify (patients) who are more fragile and who need additional attention,” he says.

Aledade, which works with 275 practices in 18 states, uses its proprietary population health and workflow tools to analyze practice and ACO data and recommend the correct action for them to take, says Vice President of Provider Networks Dan Bowles, MBA, MPP. “Having the data is good, but you need to know what to do with the data. You’ve got to mine the data in an efficient way,” he says.

Aledade takes a share of practice reimbursements earned through the Medicare Shared Savings Program (MSSP).

Dunbar earned shared savings reimbursement for 2016, the first year it worked with Aledade, and expects to earn it for 2017 as well, says Lilly. (The reimbursements for 2017 have not been announced yet).

Lilly says his practice plans to stay in the ACO because it’s not sure it could remain independent without that assistance. “Anyone who is going to do [value-based care] on their own is taking on a lot,” Lilly says.

2 HOSPITAL-LED ACOs

Some independent practices that want to avoid being bought by large healthcare systems are instead joining ACOs led by those same systems.

Many healthcare networks, such as Deaconess Health System in Evansville, Ind., are forming ACOs that offer primary care practices tools and resources to help them realize the benefits of value-based care. The Deaconess system includes five regional healthcare facilities and more than 160 primary care providers in Indiana, Illinois, and Kentucky.

“The practices understand the pressures they’re up against and they know they have to seek some outside help,” says Fredrick Wallisch, MD, who owned his own practice before joining Deaconess where he recruited members for the healthcare system ACOs.

Now working for Evolent Health, a consulting firm that works with Deaconess and other organizations on the transition to value-based care, Wallisch says hospital-led ACOs offer easy integration with and access to a healthcare system, in addition to the usual service sharing, back office, population management, and data services support. In addition, many practices were already affiliated with Deaconess before joining the ACO, which gives them a level of familiarity, he says.

The Deaconess ACO is attractive to many practices, Wallisch says, because, as a CMS Next Generation ACO, its members are exempt from reporting requirements under the Merit-based Incentive Payment System and are eligible for greater financial incentives.

3 CLINICALLY INTEGRATED NETWORKS

CINs can give internal primary care practices the advantages of practicing integrated medicine within a large network of providers, but without becoming employees of a healthcare system.

A CIN is a collection of healthcare providers, such as physicians and hospitals, that work together to improve care and reduce costs. They generally share record sys-
tems, track data and rely on evidence-based care. CINs were created by the Federal Trade Commission (FTC) to serve the commercial or self-insured market while ACOs treat Medicare patients.

The FTC requires a CIN to include: clinical practice guidelines to improve performance, financial incentives for achieving goals, physician leadership and commitment, and development of infrastructure and technology. CINs can jointly negotiate contractual fees if the primary purpose of the negotiation is to improve care. CINs can support ACOs or patient-centered medical homes as part of the network by acting as a mechanism for sharing infrastructure and development costs.

Independent practices can reap substantial benefits from CIN membership, says Gene Good, JD, CPA, chief executive officer of DoctorsManagement, a Knoxville, Tenn.-based practice consulting firm. He cites the potential for higher negotiated rates with private payers, help with care quality reporting, and a harmonious relationship with local hospitals that belong to the CIN.

“Because you are willing to follow their clinical protocols, the hospital will be less likely to compete by buying another private practice,” Good says.

Practices that join CINs should retain an escape clause if physicians are unhappy with the results, including the right to opt out of the negotiated rates and to do quality care reporting on their own, if necessary, he says, adding that practices must guard against any infringement on their judgement.

“Make sure there are no onerous restrictions on your clinical protocols, including restrictions on patient treatment or physician referral options for your patients,” Good says.

There is no limit to the number of practices that can belong to an IPA, though they usually are located in the same area. The larger the association, the greater its negotiating clout.

A collection of independent practices in Vermont formed IPA HealthFirst, after two previous tries as ACOs failed to produce the hoped-for savings, says Chief Medical Officer Paul Reiss, MD.

Banding together is necessary in Vermont because the state is particularly challenging for independent practices, says Reiss. It’s small (pop. 623,000), consistently ranks among the healthiest states and is dominated by a single healthcare system, the University of Vermont Health Network, which gives it the upper hand when negotiating with small practices.

The IPA, which includes about 150 physicians and non-physician practitioners in 74 practices, offers members group purchasing, negotiated premiums on malpractice insurance, network-wide contracting with payers, a medical school loan repayment program, and more, says Reiss.

Practice managers and physicians regularly share ways to economize and become more efficient, he says.

“It’s a difficult situation, no doubt, but the IPA definitely helps us hang onto our independence,” he says.

**DIVISIONAL MERGERS**

In a divisional merger, two or more practices form a single corporate entity that, due to its larger size, can have greater clout in negotiating with private payers, healthcare systems, vendors, and others, Glaser says. It differs from an IPA in that it requires the practices to become a single legal entity with centralized decision-making, consolidated billing with accounting and financials and other services.

Divisional mergers are an increasingly popular option for internal medicine and other primary care practices that want to become larger without surrendering their individual autonomy, says David Glaser, JD, a healthcare attorney with Fredrikson & Byron in Minneapolis.

A divisional merger can make ancillary services more efficient—and profitable—because of the larger combined patient base. Also, practices in a divisional merger can

**“Because you are willing to follow [the clinical integrated network’s] protocols, the hospital will be less likely to compete by buying another private practice.”**

—GENE GOOD, JD, CPA, CHIEF EXECUTIVE OFFICER, DOCTORSMANAGEMENT, KNOXVILLE, TENN.
“Anyone who is going to do [value-based care] on their own is taking on a lot.”

—JOHN LILLY, MD, INTERNIST, DUNBAR, W. VA.

Trends

Staying independent

can add complementary ancillary services, as well as share such things as EHRs, IT, and other back office support, Glaser says.

Though the combined entity is governed by a supervisory board with directors from each member, each practice retains a great deal of financial and operational independence, Glaser says. For example, member practices do not need to be in the same building or even the same city and revenue flows are kept largely separate. Of course, being farther apart can make it more difficult to coordinate and share services.

The divisional merger must be structured carefully to avoid Stark law violations, Glaser says. Also, a divisional merger between two small practices might not deliver the desired leverage in negotiations. And, like in many marriages, frictions can arise between partners. Nonetheless, it can work, Glaser says: “Doctors are an independent lot and, structured correctly, the divisional merger lets them stay that way.”

INSURER-LED ACOs

Given the many points of friction between independent physicians and private payers, it might be surprising that practices are joining ACOs led by insurance companies. But several health plans, including some of the largest in the country, such as Aetna and UnitedHealthcare, have formed ACOs. They emphasize that they have the patient data and resources to evaluate patient outcomes.

Brown & Toland Physicians, a San Francisco-based IPA, says it’s achieved shared savings working with a variety of insurer-led ACOs. The network of 2,100 Bay Area physicians, most of them in small practices, cares for more than 335,000 HMO and PPO patients, says John Long, MD, vice president of external relations.

The ACOs have been successful in helping member practices stay independent largely by cutting costs and earning shared savings by demonstrating improvement in the various value-based care programs, Long says. The private insurers’ expertise in identifying lower-cost treatment options has been helpful in that regard, he says.

Brown & Toland President Joel Klopus, MD, says physicians should not be wary of insurer-led ACOs because the IPA has largely been able to resolve conflicts in favor of the doctors while providing them with additional revenue needed to stay independent.

TAKING ACTION

Hertz recommends hiring legal counsel expert in healthcare law to help evaluate the options, as well the contracts, incorporation papers, and other legal documents. Above all, he says, a practice should know the details of any new affiliation and how it will affect the practice: “Know what you have to gain and what you have to lose.”

There is no simple formula that will determine for a practice which structure is best, Hertz says. Each practice must decide its own best course, based on its circumstances, available options, possible partner organizations, and the desires of its physicians.

And while the array of choices and the pressure to choose the right one can be intimidating, experts agree that the worst thing a struggling independent practice can do is nothing at all.

“Be willing to try something,” says Good. “If you think you can hide your head in the sand, you won’t survive.”

IPA vs ACO: What’s the difference?

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<thead>
<tr>
<th>An Independent Physicians Associations is a business model for the purpose of negotiating reimbursement, forming contracts with larger scale and thus more favorable terms and other such matters.</th>
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<tr>
<td>An Accountable Care Organizations (ACO) is a network of providers—it can be owned by physicians, a hospital, a health system or a payer—focused on coordinating care between providers with the goal of improving patient outcomes and keeping costs low. Physicians in an ACOs typically have some manner of risk-sharing built into their compensation, in which they can receive bonuses—and sometimes payment reductions—depending on patient outcomes and cost utilizations.</td>
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<td>IPAs can belong to ACOs</td>
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It’s become a well-accepted mantra among physicians to “ prescribe generics whenever possible” as a means to keep out-of-pocket costs down for patients. But when a brand-name medication is the only or best option to treat a condition, manufacturer coupons and discount cards can sometimes help patients save money at the pharmacy.

Physicians generally do not receive much information about how such direct-to-consumer (DTC) advertised savings programs work, and should be mindful of their numerous caveats and limitations.

The first challenge is keeping up with the rapid growth of such programs. “Newer, more expensive drugs will almost always have some sort of patient assistance program,” says Ana María López, MD, MPH, FACP, president-elect of the American College of Physicians. “I think a lot of people are probably aware that these are out there. But there are so many plans and it’s very variable; it’s hard for a physician or office to keep track of it all.”

Several years ago, coupons and discount cards began replacing the drug samples pharma reps used to offer physician offices—and quickly. The Physician Payments Sunshine Act of 2010 increased scrutiny of financial relationships between clinicians and pharmaceutical manufacturers. According to health data firm IMS Health, coupons were available for just 86 indications in 2009, and shot up to 395 indications by 2012.

Today, discount repository internetdrug coupons.com (see sidebar) claims to offer discounts on more than 50,000 medications nationwide.

RULES AND RESTRICTIONS
Federal anti-kickback statute prohibits these discounts, which are funded by manufacturer subsidies, from being used with drug coverage provided through Medicaid or Medicare Part D.

However, patients with government insurance may use the coupons for drugs that are not covered by their formularies, notes Edward Kaplan, a senior vice president for Segal Consulting, which provides benefits, compensation, and human resources advice to employers. “It’s rare—and applies mostly to specialty drugs,” he says.

Most often, patients acquire drug coupons by downloading them after hearing about them through DTC advertising, says Lopez. For example, a TV commercial for Nexium (esomeprazole), used to treat heartburn, concludes with a message that if consumers have trouble paying for the medication, AstraZeneca “may be able to help.”
CLARIFY BENEFITS, UNDERSTAND HURDLES

There are also circumstances in which a patient will request a prescription to match a coupon they’ve obtained, says George G. Ellis, Jr. MD, FACP, chief medical adviser for Medical Economics.

“We run into this difficulty constantly because pharma is advertising directly to consumers,” he says. Ellis declines to write a prescription under these circumstances.

Similarly, time limitations on discounts generally are not mentioned in TV advertising. “You have to be careful because these copay assistance programs are not guaranteed forever,” says Kaplan. “The manufacturer can discontinue them at any time.”

Patients can then find themselves having to pay the full copay out of pocket. And even if a cheaper alternative exists, patients may be reluctant to stop taking a brand to which they’ve become loyal, Kaplan explains.

Therefore, physician offices should warn patients that there’s no guarantee a pharmacy will accept a given coupon or that the savings will continue long-term. “We used to have some coupons [in the office] for specific drugs, but even those applied to a very narrow group of people,” Lopez says. “You have to be careful you know who is receiving them so that they won’t end up disappointed.”

If a patient requests a medication that is appropriate and recommended for his or her condition, Ellis may be willing to give it a try, he says, but insurer red tape may still complicate matters.

“Take a drug like Farxiga (dapagliflozin) [used to treat Type 2 diabetes]. They want to see you first tried metformin and possibly something else before you step it up to Farxiga,” he says. “We’re being forced through step therapy, and between pharma and the insurance industry, we are squeezed really badly.”

WORKING WITH REPS AND VENDORS

Key resources for understanding the ins and outs of manufacturer discounts are the pharmaceutical representatives themselves, although physician interaction with reps has diminished in recent years. Drug manufacturer websites often spell out additional guidance for prescribers.

“I don’t do lunches anymore or go to dinner meetings,” says Ellis. “If a rep comes in and asks to talk to me for a few minutes, I’ll give them two minutes. I won’t see more than four or five reps per day, and all I care about hearing is what’s new and what they can offer to help my patients.”

During these brief encounters, reps often explain and provide coupons to distribute to patients. Ellis will then ask the rep to give the coupons to staff at the front desk, who will hold them and document that inventory. “We have a logbook so the staff know that if a branded drug is being prescribed, they know what coupons are up front that patients could use.”

For practices that have the capability, one or two employees could become the experts to talk with patients about prescription-savings opportunities, says Lopez. “Or it might be as simple as suggesting to a patient to go online and see whether the manufacturer offers a savings plan.”

“All I care about hearing [when I talk to drug reps] is what’s new and what they can offer to help my patients.”

—GEORGE G. ELLIS, JR. MD, FACP, CHIEF MEDICAL ADVISER, MEDICAL ECONOMICS.
The electronic health record (EHR) system was envisioned to be a patient-centric modality to increase access to patient health information across concrete boundaries in a secure manner. It increased the conscientious patient’s access to personal health information through secure patient portals. It enabled providers to have remote access to patient data.

Despite the technological revolution, it has left providers and patients equally dissatisfied. Patients now share their face time with providers with a documentation screen. Providers are caught in a cloud-based web between EHR documentation, electronic pre-certifications, prescription faxes and endless static across telephone lines with automated callers.

The Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009, was signed into law Feb. 17, 2009. The technology revolution in patient health information has also brought the formidable challenges of data security, transfer and ownership.

Healthcare is at a very interesting juncture that we are calling “mining is the new medicine.” A medical mining consult for a patient is in the foreseeable future. This is given the conglomeration of all patient data points and its interpretation, which requires the recognition of infinite patterns. The pattern recognitions then require further interpretation in the context of current guidelines and risk-to-benefit ratios. The operational success with medical mining rests in the ability to sift through all relevant patient data, which might be at the current time securely resting across multiple healthcare systems and non-affiliated Institutions as individual data silos.

A BRIEF HISTORY
The 2015 Edition Health IT Certification for EHR technology must be met under the MACRA proposed rule. JASON, founded in 1960 provides independent consulting services to the U.S. government on defense science and technology. It is a scientific advisory group that made recommendations to embark on Stage 3 of Meaningful Use, focused on a functional interoperable EHR system.

The JASON report and subsequent briefings, reviewed the shortcomings with two of the world’s largest EHR systems, the Veterans Administration Vista and the DOD system using the Armed Forces Health Longitudinal Technology Application (AHLTA). Several private commercial EHR systems...
have also thrived in the past decade. The JASON study process involved an expert panel from the academic, industry, and government sectors.

In addition to interoperability, the report identified setbacks in the health infrastructure. JASON has emphasized the importance of standardization and data security between the shared data systems and data ownership.

JASON briefings have several recommendations, including unbiased third-party certifications through organized “code-a-thons.”

The buzzword in health IT is “interoperability.” We have progressed from an era of EHR implementation and adoption to open data exchange between providers in healthcare and patients. Despite the initial dissatisfaction between the patients and the providers with shared screen time, there is an impetus to unify record across systems and make the patient in charge of sharing relevant health data with providers.

EMERGING STANDARDS
An Application Programming Interface (API) is a protocol allowing data sharing between software applications. This interface bridges two applications, allowing data flow regardless of the original inception or design. The API task force has systematically investigated security concerns and the potential risks. Data breach associated with HIPAA approved APIs versus the non-HIPAA regulated fitness trackers. An API that has gained notice by the Centers for Medicare & Medicaid Services (CMS) is Fast Healthcare Interoperability Resources (FHIR).

Graham Grieve is the architect-developer of FHIR (pronounced “fire.”) It remains a draft standard and application programming interface and is currently in FHIR Release 3 (STU) - FHIR v3.0.1. Health Level Seven International (HL7) is a nonprofit, ANSI-accredited standard-developing organization that has an oversight on FHIR. The FHIR platform is currently being tested by different organizations.

The next crucial and sensitive operation to be tackled is data security. Currently the applications OAuth 2.0 and OpenID are being used for security and authorization. CMS and ONC have requested public feedback as part of the proposed rule for MACRA implementation and Health IT certification respectively for the FHIR v3.0.1.

INTEROPERABILITY TRENDS
The Argonaut Project, launched by HL7 in 2014, is a privately funded initiative to further interoperability standards. The Argonaut sponsors consist of vendors and healthcare provider sites: Accenture, athenahealth, Cerner, Epic, McKesson, Meditech, Surescripts, The Advisory Board Company, Beth Israel Deaconess, Intermountain, Mayo Clinic, Partners HealthCare and Boston Children’s Hospital.

A previous version of FHIR was used by Regenstrief Institute to test data transferability between the Epic EHR and the open, epic API. The Indiana Network for Patient Care (INPC) was able to authenticate proof of work and data integration. The MIT Media Lab has used the Ethereum blockchain Application platform to generate a “MedRec” prototype equipped with smart contracts. MedRec team has been industriously exploring options to integrate the interoperability with systems like Epic and Cerner.

THE FUTURE
Future developments should allow interpretation of healthcare data from a vast distribution ledger, to decipher patient relevant clinical insights.

Such a development can be expected from blockchain technologies. This will enable cost effective evidence based medicine practices across nonaffiliated healthcare systems. As patient-related data is entered into this unified EHR and as transactions occur from multiple sources of origin, the question would be, what is the clinical relevance? Each transaction, with its unique numeric code, creates a distinctive node in the audit trail.

Some important questions remain, including, “can a patient also enter a transaction?” Physicians are important stakeholders in the clinical data by their deductive reasoning with clinical decision making. Another question: Who will own the data when the data resides in multiple interoperable EHRs: the physician, the patient, or the hospitals?

Physician input will go a long way in making interoperability a success. As responsible physicians, can we accept and excel with the new wave of “the medical mine”? □

Nita K. Thingalaya, MD, is an internal medicine hospitalist with over 15 years’ experience as a practicing physician. She is currently medical director in healthcare utilization with experience in clinical research and informatics. The article is independent of her affiliations past or present.

Arunkumar N. Badi, MD, PhD, is a practicing ENT and sleep medicine specialist (dual board certification) and also an adjunct professor at University of Texas Dallas Department Of Electrical and Computer Engineering.
Physicians need more time with chronic care patients

Ten to 20 minutes. That’s the length of time the average primary care physician spends during a consult with older patients with multiple chronic conditions, according to a 2017 study in medical journal BMJ Open. Often it’s even less, given time constraints and competing priorities.

For most physicians, the most rewarding part of the job is the relationships we cultivate with our patients. And these relationships are especially true for the three in four Americans 65 years and older who have two or more chronic health conditions. By developing strong relationships with our patients, we’re not only able to treat their immediate conditions, but also address any accompanying social and emotional issues that could influence health outcomes.

But 10 minutes isn’t enough time to do all that we want to do and have all the conversations that we want to have with our patients. How do we address this gap in care so our sickest patients get the care they need?

Quest Diagnostics recently commissioned a survey to find out how primary care physicians and Medicare-age patients view managing their multiple chronic health conditions. About 66 percent of primary care physicians say they don’t have the time and/or bandwidth to worry about patients’ social issues, and 44 percent of patients don’t tell their doctor about those issues.

And only 3 percent said a consult one to two times a year was sufficient to deliver care for these patients.

The responses underscore gaps in care related to behavioral health issues, and the solitary journey many patients feel they are on when it comes to their health. The survey found that patients tell their doctor about their different medical conditions, they do not tell them about other issues they are facing such as loneliness, financial issues, and/or transportation issues. One-third of patients say sometimes they feel like no one understands what they are going through.

One can argue that there’s a disconnect between patients and their PCPs, but there doesn’t have to be.

CMS began to reimburse for chronic care management (CCM) services in January 2015 as a means of supporting patients in between physician visits. CCM services are non-face-to-face services provided to Medicare beneficiaries who have multiple chronic conditions. CCM services may provide 24-hour access to qualified providers for patients who could benefit from assistance on meeting care plans, scheduling doctor visits, medication management, and escalating emergency issues. Services reimbursed under these new rules include electronic and phone consultations with trained professionals.

The Quest survey found that most PCPs (84 percent) said a CCM service could help them deliver care to chronic care patients. Yet about half did not know CMS reimburses for such services. CMS estimates 70 percent of Medicare beneficiaries—roughly 35 million people—have two or more chronic conditions and would be eligible for the care services.

As the population ages, services that help support patients between the traditional physician consult will be essential to effective care.

Jeffrey Dlott, MD, is the medical director of Quest Chronic Care Management.
Best thing said / advice given by a patient

Maria Young Chandler, MD, MBA
Business of Medicine / Pediatrics
Irvine, Calif.
“I feel like you’re my sister, not my doctor.”

George G. Ellis, Jr., MD
Internal Medicine
Boardman, Ohio
“Listen to your patients to truly understand them.”

Antonio Gamboa, MD, MBA
Internal Medicine / Hospice and Palliative Care
Austin, Texas
“Take a good vacation every year (not that I do).”

Jeffrey M. Kagan, MD
Internal Medicine / Hospice
Newington, Conn.
“Take time to go boating.”

Melissa E. Lucarelli MD, FAAFP
Family Medicine
Randolph, Wis.
“You’re already helping me by just being here.”

Joseph E. Scherger, MD
Family Medicine
La Quinta, Calif.
“Attitude makes all the difference.”

Salvatore Volpe, MD
Pediatrics/Internal Medicine / Pediatrics
Staten Island, N.Y.
“Spend more time with your family.”

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Advertising in Medical Economics has accelerated the growth of our program and business by putting me in contact with Health Care Professionals around the country who are the creators and innovators in their field. It has allowed me to help both my colleagues and their patients.
“That’s not the policy towards drugs. That’s the insurance company’s philosophy on claims.”

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