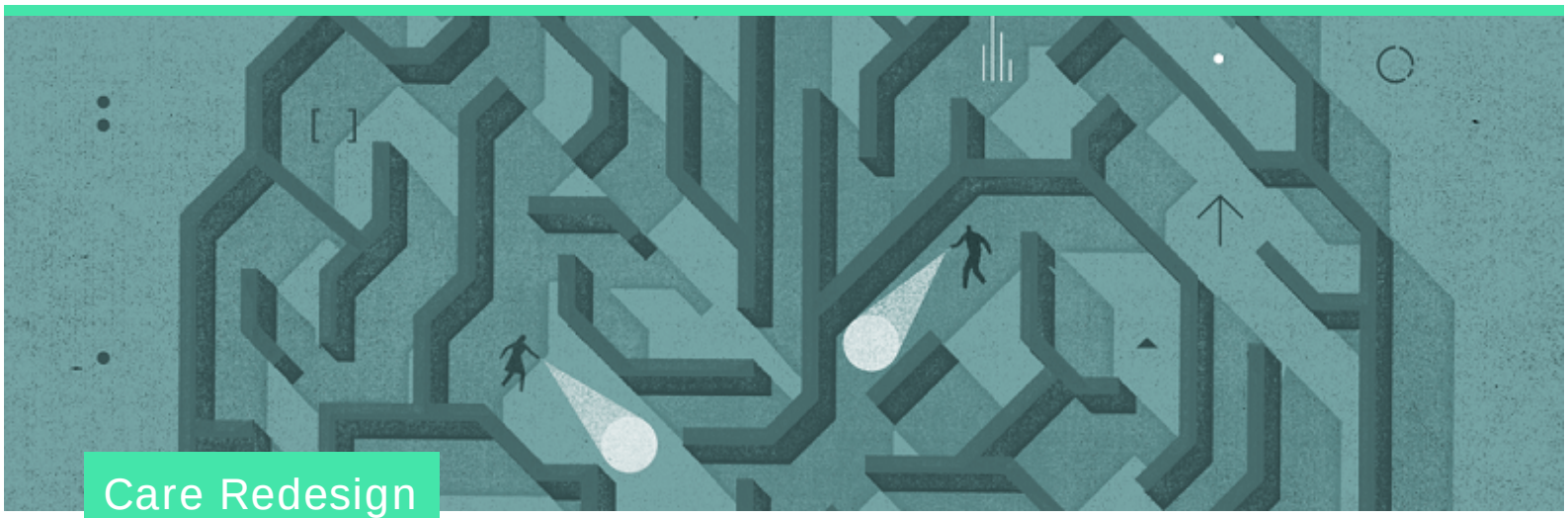

Care Redesign

The Physicians' Quandary with Opioids: Pain versus Addiction

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Marilyn Serafini

Health Care Journalist

Sue Glod, MD, is frustrated with the nation's opioid crisis, but not for the obvious reasons. As a palliative medicine specialist at Penn State College of Medicine in Hershey, Pennsylvania, she sees patients who are struggling with life-threatening illnesses such as advanced cancer. While her mission is pain relief, a flood of new prescribing rules severely limits her options and burdens her staff with extensive administrative hurdles, she says.

"Drugs are being denied by insurance companies" and pharmacies aren't stocking sufficient quantities of opioids, she says, "leaving our staff to go through a lot of paperwork, so there are wait times."

Glod describes a breast cancer patient who recently had trouble with a prior authorization policy for a prescription of opioids. After several days of pain and withdrawal symptoms, the patient landed in the emergency room.

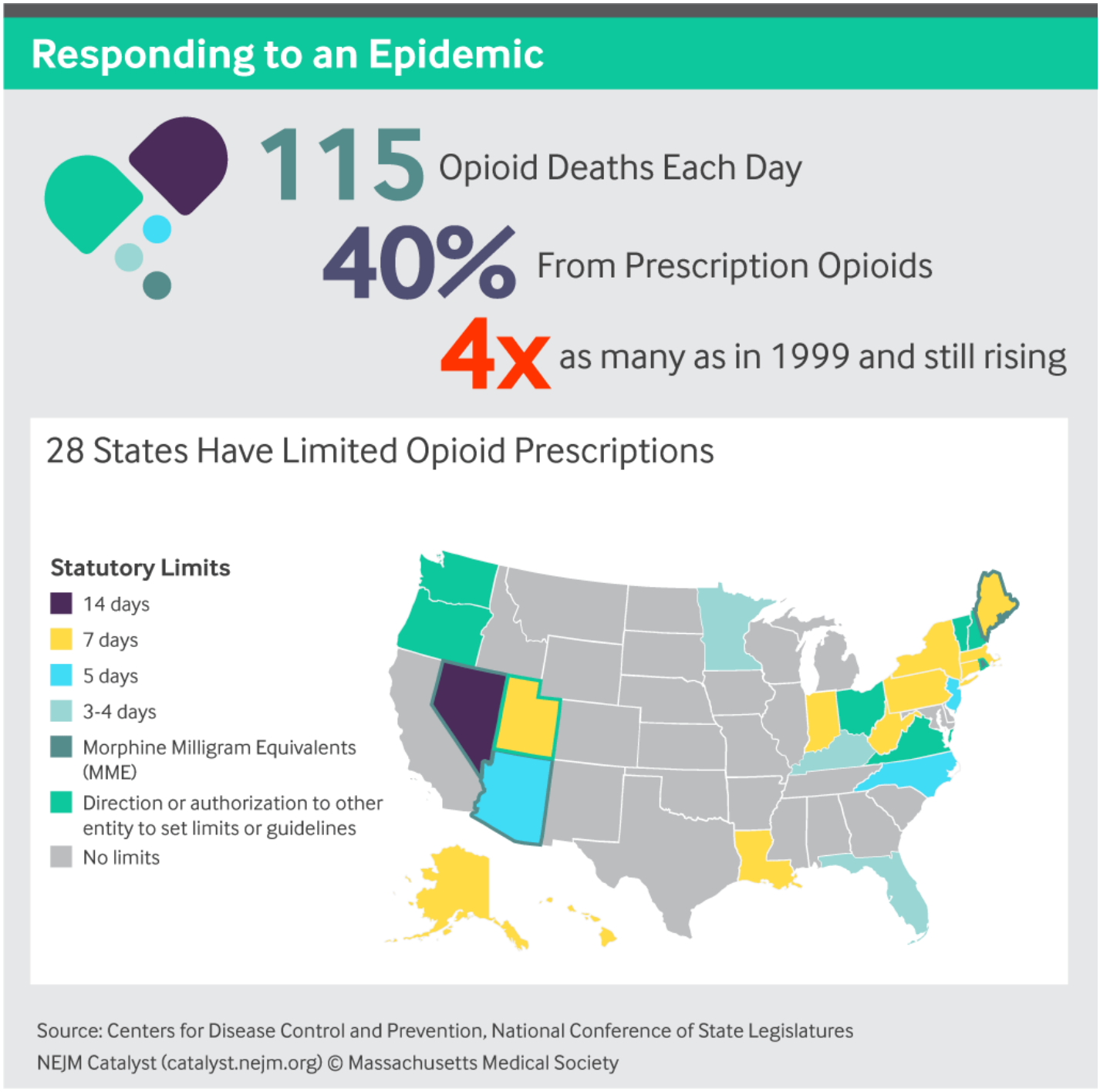
Many frontline physicians and clinical leaders feel caught in the middle — acknowledging the national crisis of opioid addiction and wanting to adhere to the new guidelines, but also wanting to decrease patients' pain."

Concern over the national opioid epidemic has resulted in a crackdown on physician prescribing abilities. Many frontline physicians and clinical leaders feel caught in the middle — acknowledging the national crisis of opioid addiction and wanting to adhere to the new guidelines, but also wanting to decrease patients' pain.

The quandary is illustrated in two federal policies issued in March 2016. The same week that the Centers for Disease Control and Prevention (CDC) launched a national opioid response, a federal advisory committee announced a National Pain Strategy declaring pain a "significant public health problem" and calling for a broad set of solutions. The opioid guidelines have received far more attention, however. Although the CDC's limits on prescription duration and dosage were recommendations, many states turned them into laws that limit physicians' ability to provide opioids for more than a few days. Some of the state laws allow flexibility in treating chronic pain patients, but not all. Meanwhile, health plans, pharmacy benefit managers (PBMs), and pharmacies have jumped in with their own restrictions.

The Opioid Retreat

With opioid deaths at an all-time high — 115 Americans dying every day from overdoses in 2016, and still rising — it's no wonder there's been a stampede toward new policy for prescriptions. The CDC's online resources on opioids notes, "We now know that overdoses from prescription opioids are a driving factor in the 16-year increase in opioid overdose deaths. The amount of prescription opioids sold to pharmacies, hospitals, and doctors' offices nearly quadrupled from 1999 to 2010, yet there had not been an overall change in the amount of pain that Americans reported. Deaths from prescription opioids — drugs like oxycodone, hydrocodone, and methadone — have more than quadrupled since 1999."



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With the slogan of "Empowering Providers," the CDC rolled out clinical practice guidelines for primary care physicians, rather than specialists. Literature accompanying the guidelines notes that "primary care providers account for nearly half of all dispensed opioid prescriptions and their prescribing rates have increased at high rates compared to other specialties." The guidelines suggest limiting initial opioid prescriptions to 3 days, stating that more than 7 days "will rarely be needed," and include exceptions for active cancer, palliative, or end-of-life care.

The CDC also cautions against prescribing more than 90 morphine milligram equivalents (MME) per day, claiming there's no evidence that higher dosages reduce pain over the long term, and that there's a greater risk of overdose. (The potency of opioids is measured by comparing them to equivalent dosages of morphine.)

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Just under half of states have followed with laws that closely track the CDC guidelines, according to the National Conference of State Legislatures (NCSL). Most limit initial opioid prescriptions to 7 days, although the limit in Kentucky is 3 days, in Minnesota 4 days, and in New Jersey and North Carolina 5 days. Some states, but not all, include exceptions for chronic pain.

Massachusetts Medical Society (MMS) issued "Opioid Therapy and Physician Communication Guidelines" that are similar to CDC recommendations. Massachusetts was the first state to pass a law limiting opioid prescriptions. MMS President Henry L. Dorkin, MD, FAAP, says, "Battling the opioid epidemic calls for an attack on many fronts, not the least of which is reducing new cases of opioid use disorder among our patients. The MMS recognized that by improving our opioid prescribing practices, we could help ensure that in Massachusetts, physicians would be part of the solution to this crisis. . . . The most recent data from MassPAT, the state prescription drug monitoring system, showed a roughly 30% drop in the number of prescriptions written from the fourth quarter of 2017, as well as a similar decrease in the number of individuals receiving opioid prescriptions for the same period." (MMS owns NEJM Group, which publishes NEJM Catalyst and the *New England Journal of Medicine*.)

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A common strategy among states is to require prescribers to participate in monitoring programs through which clinicians consult a database for a patient's prescription history before writing a script. As of June 2016, nearly all states had operational systems or had passed legislation and were in the process of creating such systems, according to the U.S. Drug Enforcement Agency (DEA). However, some of the systems don't communicate with each other, making it hard to detect addicts who border-hop to get multiple prescriptions, says Michael Munger, MD, FAAFP, President of the American Academy of Family Physicians. He's a family physician in Kansas, but worries he can't access neighboring Missouri's system.

At the federal level, Medicare issued a proposed rule February 1 to create a "trigger" at pharmacies for beneficiaries with Part D prescription drug plans. If a beneficiary presented a prescription for more than 7 days of opioids exceeding a dosage of 90 MME, then it could go through only after the plan sponsor consulted with the prescriber.

Meanwhile, many insurers and pharmacies are instituting their own rules. In an October blog post, Richard Bankowitz, MD, MBA, FACP, Executive Vice President for Clinical Affairs at America's Health Insurance Plans, wrote that Cigna would no longer cover most OxyContin prescriptions in 2018, instead directing patients to a "covered abuse-deterrent equivalent." Anthem has reduced opioid prescriptions by 30%, 2 years ahead of schedule, and Independence Blue Cross has restricted initial prescriptions of low-dose opioids to 5 days or less.

And, as of February 1, CVS Caremark, which is the in-house PBM for CVS Health, is limiting most new opioid prescriptions to 7 days.

Pain Remains

Cindy Steinberg was scared of opioids and never imagined she'd use them. But she also never thought she'd be crushed underneath a large file cabinet and some cubical walls, leaving her with permanent, debilitating back pain. Before she gave up on her career as a business executive, she would lie on the floor to lead meetings, and years later can only be upright for an hour at a time.

After 5 years of unsuccessful nerve blocks and other treatments, Steinberg agreed to try an opioid. She took it for 10 years and was able to begin a new career as an advocate for people with chronic pain.

Cindy Steinberg was scared of opioids and never imagined she'd use them. But she also never thought she'd be crushed underneath a large file cabinet and some cubical walls, leaving her with permanent, debilitating back pain."

Steinberg is well aware of the toll from opioid abuse, and is all for efforts to stem addiction and overdose deaths. At the same time, she says, the swift national response lauded for decreasing prescriptions by 30% is unintentionally harming some chronic pain patients who have a legitimate need for opioids. Steinberg, Policy Council Chair for the Massachusetts Pain Initiative and National Director of Policy and Advocacy for the U.S. Pain Foundation, runs a monthly group for people with chronic pain and says she's been inundated with urgent requests for help.

To be sure, 11% of Americans face daily pain, and in 2011

the Institute of Medicine (IOM) called for a national response. "Given the burden of pain in human lives, dollars, and social consequences, relieving pain should be a national priority," according to an IOM report, "Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research."

The IOM report served as the basis for a comprehensive National Pain Strategy issued in 2016 by the Interagency Pain Research Coordinating Committee. A press release from the U.S. Department of Health and Human Services commented, "The goals of the National Pain Strategy can be achieved through a broad effort in which better pain care is provided, along with safer prescribing practices, such as those recommended in the recently released CDC Guideline for Prescribing Opioids for Chronic Pain."

The Big Chill

Nonetheless, in response to the addiction crisis, state laws have led some prescribers to reduce dosages for chronic pain patients or even to abruptly cut off prescriptions. "There's a plethora of guidelines that make it very confusing, and some physicians are opting not to prescribe [opioids] based on a one-size-fits-all regulatory approach," says Patrice Harris, MD, MA, a psychiatrist who is the immediate past Chairperson for the American Medical Association (AMA).

"The AMA has heard from both physicians and patients that in some cases there have been issues regarding access to treatment for pain," Harris says.

Robin Hamill-Ruth, MD, past President of the American Board of Pain Medicine, takes particular issue with the CDC's dosage recommendations. The effective dosage often depends on how individuals metabolize drugs, and some need more to achieve the same effect, says Hamill-Ruth, who is also Associate Professor Emerita of Anesthesiology and Critical Care Medicine at the University of Virginia Health System. "CDC didn't factor that in at all" and "people are taking the CDC guidelines as sacrosanct."

Although physicians generally are getting more training in opioid prescribing, some clinics have cut opioids from their practice completely, says Glod, including some primary care clinics at Penn State.

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For pain patients, the impact of the new guidelines is serious, says Jan Chambers, President of the National Fibromyalgia and Chronic Pain Association. In surveys her group has conducted, nearly 38% of chronic pain patients report considering suicide, many stating the reason as increased difficulty accessing opioid therapy.

Kansas, meanwhile, is considering legislation that would require the state pharmacology board to set alarms if prescription numbers or dosages exceed a certain level, says Mike Hockley, JD, an attorney in Kansas City who suffers from chronic pain. "It's like a bowling alley," he says. "If you're outside the lane, it's presumed to be an abuse."

A 78-year-old woman on the West Coast says she is so terrified of retribution against the physician prescribing her opioids that she won't share her name. She has chronic pain from childhood polio and has had multiple back surgeries. As in other states, the health department where she lives is tracking prescribing, and that has made her physicians nervous, she says. First her primary care clinic ceased all opioid prescribing, then her pain specialist cut her off. Despite the help of patient advocates, multiple pain clinics declined to take her as a patient, while family and friends scraped together excess pills from their medicine cabinets to keep her stable until she found a specialist to prescribe for her. Now, she says, that clinician is fearful of crossing prescribing lines and has told her the clinic may not be around much longer.

Alternatives To Opioids

Despite disagreement about the appropriate use of opioids for chronic pain, there is broad support for non-narcotic medications and non-pharmacologic treatments. That includes medications such as ibuprofen, exercise such as yoga, and treatments such as physical therapy, nerve blocks and other injections, massage, acupuncture, and cognitive behavioral therapy (CBT).

Still, there are often obstacles to access, even when "that is the best course of treatment decided by the patient and physician," says AMA's Harris, who notes the possibility of increased copays and prior authorizations, for example. Others cite coverage and unavailability of services —

particularly in rural areas — as the main obstacles.

Hockley is a success story, but only because of his strong finances, he says. He broke multiple bones 14 years ago in a bicycle accident, and while he can get through the workday, he's typically in too much pain to do much else. He's had surgeries and spinal blocks, and he used to take opioids, but now he follows a strict regimen that includes physical therapy, which his insurance covers. But he also visits his chiropractor frequently, gets massage, does Pilates, takes ibuprofen, and works out with a trainer. "Fortunately, I have the financial means to pay for that."

One reason that primary care physicians currently handle most pain treatment is that their numbers are much larger than the 2,300 board-certified pain specialists."

According to Kim Holland, Vice President, State Affairs, for the BlueCross BlueShield Association, there's "not a lot of real solid evidence for many things outside of chiropractic care, physical therapy, or occupational therapy, so those have been the primary types of covered treatment for pain," although some plans also cover acupuncture.

Chambers is particularly critical of Medicaid, saying that most states cover few alternatives, which is "keeping a whole class of people down by not giving them access to things that will keep them in the workforce."

Safina Koreishi, MD, Medical Director of the Columbia Pacific Coordinated Care Organization (CCO), says Medicaid coverage can be complicated, however. CCOs like Columbia Pacific coordinate care for Medicaid patients in Oregon. It developed a pain-based clinic in 2015 and spread it to three counties in 2016. Columbia Pacific has expanded coverage to acupuncture, CBT, and other alternatives, but people aren't showing up, Koreishi says. "Primary care clinicians will say, 'go to the behavioral health clinic for CBT,' and the clinicians there will say 'it's physical health, so go to your primary care physician.' We're trying to figure out how to train primary care physicians to do CBT so patients can get the services."

One reason that primary care physicians currently handle most pain treatment is that their numbers are much larger than the 2,300 board-certified pain specialists, according to the American Board of Pain Medicine.

One pain specialist in New York City argues, however, that primary care physicians have neither

the time nor the expertise to handle pain treatment without regularly turning to opioids. "If there are people who need opioids, they've got to let it come to me to take a crack at it with injections and procedures. . . . Let me decide that," says Corey Hunter, MD, Executive Director of the Ainsworth Institute of Pain Management.

Hamill-Ruth, who recently retired, agrees that specialists are in a better position to treat pain correctly. "The stuff I want to do takes more time," she says. "Opioids are an important tool in what we do. Having said that, 1 in 10 people on them does well with them. . . . The vast majority of people getting them in bigger doses over the long term aren't changing their behavior."

Preventing Deaths

Even if new prescribing rules are successful at preventing addiction on the front end, overdose deaths from both prescription and illicit opioids remain on the rise and are demanding attention.

By no means do we argue that SIFs are the only solution to the opioid crisis, but every physician knows that you can't help a patient who isn't alive."

The use of illicit fentanyl is particularly problematic; people using heroin may be unaware that it is cut with fentanyl, which can cause an overdose so quickly that many die with the needle still in their arm. To combat overdoses, some cities and health systems are creating safe rooms where opioid users can receive monitoring, and also medication to quickly reverse an overdose, without fear of arrest.

MMS has adopted a policy in support of a state-led pilot program to study whether supervised injection facilities (SIFs), staffed by trained clinicians who can intervene in case of an emergency, may help save lives in Massachusetts. "We looked at the published data from SIFs in other countries, and the evidence was clear: these facilities save lives and help open the door for those with substance use disorder to get help," Dorkin says. "By no means do we argue that SIFs are the only solution to the opioid crisis, but every physician knows that you can't help a patient who isn't alive."

Part of the problem, says Regina LaBelle, who was Chief of Staff in the Obama White House Office of National Drug Control Policy, is that many doctors don't understand addiction well. Right now, only about 10% of substance use disorders get treatment, she says. Physicians "don't

want those patients or know how to treat them" because patients with addiction are difficult to treat, take time, and reimbursement is low.

For starters, more addiction specialists are needed and they must be strongly connected to primary care practices, says a primary care physician in New York who asked not to be named. "In most health systems, the patient gets a referral to an addiction specialist, and half the time the patient doesn't show up, so instead we need better integration so there can be a warm handoff from the doctor to the specialist."

The AMA's Harris sees Virginia as a model. Through a federal Medicaid waiver, the state has expanded benefits for comprehensive substance use disorder treatment, including community-based addiction and recovery treatment services, as well as inpatient detoxification and residential treatment.

The American Academy of Addiction Psychiatry acknowledges a shortage of specialists. "The patient population is underserved, and an increase in mandates for addiction treatment from federal and local governments and third-party payers has led to a demand for credentialed addiction specialists," according to its website.

If they're not comfortable, it's a good thing [for them to refrain], but the right thing to do is to find a way to become comfortable."

A big reason why the focus of opioid treatment is on the prevention side is that there is no agreed-upon standard of care on the substance use disorder side, according to the Blues association's Holland. And there are barriers to those treatments that are supported by evidence.

One important tool in addiction treatment is medication-assisted therapy, which involves the use of less-addictive opioids. Right now, physicians generally have three treatment drugs to work with: buprenorphine, methadone, and naltrexone. Methadone must be administered in an office, but patients can take buprenorphine at home. Prescribers must complete 8 hours of training and apply for a waiver, according to the Substance Abuse and Mental Health Services Administration. The DEA also requires special record-keeping.

"We know that more physicians are getting the waiver" for buprenorphine, says Harris, "but some say the training and increased documentation requirements are a barrier. The president's opioid

commission has recommended that the DEA look at that."

As clinical leaders seek solutions, the tension between wanting to prevent addiction and wanting to treat chronic pain is likely to persist. "Some people won't prescribe anything because they're so worried" about causing addiction, according to Glod, who says she's particularly concerned about physicians who are pulling back on prescribing opioids out of worry for the possible consequences. "If they're not comfortable, it's a good thing [for them to refrain], but the right thing to do is to find a way to become comfortable."

Marilyn Serafini
Health Care Journalist

DISCUSS HIDE 2 RESPONSES + ADD A RESPONSE

Naishadh Patel

Pain is subjective, so we can't judge. Before prescribing narcotics, spend time with patient and ask in detail. (at least 20 min.) Ask about when, which condition, weather, etc. That is more effective than narcotics. Alternative medicine gives an excellent results.

May 02, 2018 at 11:28 am REPLY

Don

As an EMT I find that 99.9% of the current opioid crisis is being caused by heroin laced with Chinese made fentanyl. Most of the current victims I treat with naloxone never were prescribed opioids. Their friends turned them on to the dirt cheap heroin that is flooding the streets.

May 02, 2018 at 9:31 am

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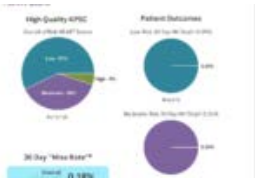

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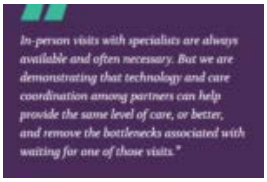

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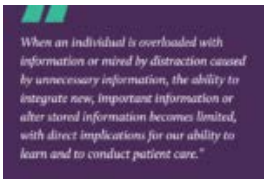

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