Blueshift RESEARCH REPORT

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Camurus and Indivior Set to Significantly Sway the Opioid Abuse Treatment Market

Companies: ALKS, DEPO, LON:INDV, STO:CAMX, STO:ORX, TTNP

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Report Type: ☐ Initial Coverage ☑ Previously Covered ☑ Full Report ☐ Update Rating: 3.5/5

Research Question:

How will the new long-acting buprenorphine options and changing government rules affect the opioid abuse treatment market?

Summary of Findings

- Weekly and monthly injectable buprenorphine treatments that could significantly affect the medication-assisted treatment (MAT) market for opioid abuse disorder include CAM2038 by Braeburn Pharmaceuticals Inc. and Camurus AB (STO:CAMX) as well as Indivior plc's (LON:INDV) RBP-6000. Both products, yet to be approved by the FDA, have performed well in trials and could be available by early 2018.
- Sources were highly interested and even excited about these products, which can prevent diversion, are suitable for a wide patient profile, offer higher dosages, are injections rather than implants, are expected to be competitively priced, and should be more appealing to third-party payers.
- This is a continuation and advancement of the trends found in Blueshift Research's April 8, 2016, report, which found that long-acting implantable and injectable buprenorphine was expected to become an important tool and gain a significant foothold in treating opioid-addicted patients over time.
- Titan Pharmaceuticals Inc.'s (TTNP) and Braeburn's recently approved Probuphine, a six-month implantable buprenorphine, is not expected to be widely adopted. Sources cited the small number of stable recovery patients that would be eligible users, the product's low dosage and high cost ($5,000 to $6,000 per six-month treatment plus physician visits), and the minor procedure required for implantation and removal.
- The U.S. Department of Health and Human Services' rule changes to expand the opioid abuse disorder treatment cap from 100 to 275 patients for physicians as well as the inclusion of nurse practitioners and physician assistants as buprenorphine prescribers are in their very early stages. Sources expect these changes to slowly and minimally expand the number of patients in treatment in the next three to five years.
- The exception will be in urban areas in which physicians are at or near the 100-patient cap, have treatment waiting lists, and can rapidly add patients following certification for the expanded load.
- Sources expressed concern regarding the future of the Affordable Care Act and the related effects on opioid addiction treatment numbers. When Medicaid was expanded under the ACA, treatment populations increased.

Silo Summaries

1) Physicians and Medical Professionals

The addition of new patients seeking MAT is expected to rise very slowly during the next three to five years as physicians gradually expand their patient counts and as NPs and PAs gain certification to prescribe buprenorphine. **The exception will be physicians in urban areas who are at or near the 100-patient cap and have waiting lists.** Probuphine is not expected to have a significant effect on the MAT market; rather, it will serve a small segment of the population that is stable in their recovery program and require a very low dose (8 mg or less) of buprenorphine. **CAM2038 and RBP-6000 are expected to have more success than Probuphine because they are weekly or monthly injections, offer higher doses of buprenorphine, and require that patients return to their physicians for counseling and to be tested for compliance.**

2) Prescription Opioid Sales Channel

Two of these three sources expect the treatment rule changes to allow more access to MAT and, as a result, sales will increase. One of the two said a 10% to 20% increase over time is possible. The remaining source said the expansion of the patient cap was a positive, but expects the rule changes to minimally affect treatment numbers because most family physicians are already at or near capacity with their regular patients. All three expect Probuphine to have minimal uptake because of its limited patient population, its high cost and its required surgical procedure. **Two sources think CAM2038, the weekly or monthly injectable buprenorphine, will be successful; one even said it could gain 30% to 40% share.**

3) Industry Specialists

These five sources think the MAT rule changes will slowly increase the number of opioid abuse patients receiving treatment. One source reported an initial jump in patient number, followed by a slowdown. A second source said the effect will be minimal while a third said the growth will not be a big as expected by the medical community. Two sources said a change may be required in the medical practice business model, with additional and dedicated physicians and support personnel needed to exclusively treat opioid abuse patients. **The use of Probuphine is expected to be limited as the eligible patient population is small, the dosage is low, the cost is prohibitive, and the procedure requires minor surgery.** Long-acting injectable buprenorphine could be promising. Given the high number of opioid overdoses, CAM2038 should be fast-tracked through the FDA.

Buprenorphine

	HHS Rule Changes' Effects on Patient Number	Probuphine Adoption	Interest in Week- and Month-Long Injectables
Physicians and Medical Professionals	Up slightly	Limited	↑
Prescription Opioid Sales Channel	Up over time	Limited	↑
Industry Specialists	Up slightly and over time	Limited	↑

Background

Blueshift Research's April 8, 2016, report found that long-acting implantable and injectable buprenorphine was expected to become an important tool and gain a significant foothold in treating opioid-addicted patients over time. All 15 sources acknowledged the clinical value of treating stable patients with long-acting buprenorphine. Sources' expectations for market penetration varied, but two (a physician and an addiction treatment professional) expected long-acting buprenorphine to claim 20% to 25% share. Weekly and monthly treatments likely would be more widely used than the six-month dosage.

In the United States, opioid addiction has been described as an epidemic, and overdose deaths, including from prescription opioids and heroin, have more than quadrupled since 1999. Overdoses killed more than 28,000 people in 2014; over half of those deaths were from prescription opioids. Ninety-one deaths occur every day as a result of opioid overdose.

The HHS has expanded the maximum number of patients being treated for opioid dependency by a physician from 100 to 275 (commonly called the patient cap), and now allows nurse practitioners and physician assistants to complete the required training and be able to prescribe buprenorphine for up to 30 patients, beginning sometime this year.

New buprenorphine delivery systems are becoming available that are implantable or injectable and last a week, a month or six months, in the case of Titan's and Braeburn's recently approved Probuphine. The drugs are expected to lower the potential for misuse and the effects of physical dependency to opioids and eliminate daily visits to methadone clinics. Two post-Phase 3 drugs that could hit the market later this year or in early 2017 are Indivior's RBP-6000, a monthly injection, and Braeburn's and Camurus's CAM2038, a weekly or monthly injection.

In its third-quarter earnings call, Titan management indicated that since the FDA approval of Probuphine, Braeburn has trained 2,400 healthcare professionals in 50 states and Puerto Rico on how to insert and remove the ProNeura implant, and has obtained third-party coverage from large and regional insurance companies as well as under Medicare, Medicaid and the Department of Veterans Affairs. Adoption of Probuphine reportedly has been slowed by time-consuming paperwork. Braeburn is devoting resources to streamline the process.

Current Research

Blueshift Research assessed how the new long-acting buprenorphine treatment options and changing government rules are affecting the opioid abuse treatment market. We employed our pattern mining approach to establish five independent silos, comprising 21 primary sources (including seven repeat sources) and five secondary sources focused on the opioid abuse treatment market. Interviews were conducted Feb. 12–24:

1) Physicians and medical professionals (10)
2) Prescription opioid sales channel (3)
3) Industry specialists (5)
4) Third-party payers (3)
5) Secondary sources (5)

Next Steps

Blueshift Research will continue to research how changes in patient caps affect the opioid abuse treatment market. We will monitor patient numbers as well as the related effects on the opioid epidemic and the companies that service the treatment communities. We also will assess adoption of Probuphine and the launch of CAM2038 and RBP-6000.

Silos

1) Physicians and Medical Professionals

The addition of new patients seeking MAT is expected to rise very slowly during the next three to five years as physicians gradually expand their patient counts and as NPs and PAs gain certification to prescribe buprenorphine. The exception will be physicians in urban areas who are at or near the 100-patient cap and have waiting lists. Probuphine is not expected to have a significant effect on the MAT market; rather, it will serve a small segment of the population that is stable in their recovery program and require a very low dose (8 mg or less) of buprenorphine. Headwinds for Probuphine's wider use include the procedures required to insert and remove the rods, the product's high cost ($4,000 to $6,000 for six months) compared with daily buprenorphine ($4,000 to $5,000 per year) and methadone ($2,600 to $5,200), and reimbursement challenges. CAM2038 and RBP-6000 are expected to have more success than Probuphine because they are weekly or monthly injections, offer higher doses of buprenorphine, and require that patients return to their physicians for counseling and to be tested for compliance. Unclear reimbursement rules between states have led to many private clinics accepting only cash. Patients then request reimbursement from their health insurance provider. Treatment preauthorization is often required, but some sources said this requirement is easing. The ACA's possible demise is a concern in the battle against opioid addiction.

Key Silo Findings

Opioid Treatment Rule Changes

- All 10 said higher patient caps as well PAs' and NPs' ability to prescribe will increase access to MAT in 3 to 5 years.

Long-Acting Buprenorphine

- Probuphine is another tool in the MAT area, but adoption will be limited.
  - 7 said Probuphine will serve a niche or subset market of stable patients.
  - 1 said 20% of her patients are appropriate for Probuphine.
  - 1 said 80% of his patients could benefit if Probuphine were approved for treatment of chronic pain.
  - 1 simply acknowledged that the clinic's physician was certified to prescribe Probuphine.
- Long-acting injectable buprenorphine is of high interest and expected to serve a wide market if and when approved.
  - 8 said weekly or monthly injectable buprenorphine will be successful if priced competitively.
  - 2 did not comment.

Other Treatment Options

- Alkermes plc's (ALKS) Vivitrol injectable is considered another effective MAT tool.
  - 3 who prescribe Vivitrol said getting preauthorization is a challenge.
  - 2 said the use of Vivitrol is increasing.
  - 1 said Vivitrol is the most viable treatment, and patients are asking for it.
  - 1 does not prescribe it because it does not control patient craving.
  - 1 is considering prescribing Vivitrol.
  - 1 has not experienced any addition sales activity from the company, but its use may increase in the treatment of alcohol abuse.

Pricing and Payment

- MAT pricing:
  - Daily buprenorphine runs $4,000 to $5,000 per year based on dosage and required physician visits.
  - Probuphine is $4,000 to $6,000 for 6 months.
  - Vivitrol is $12,000 to $14,400 per year.

- Reimbursement varies by state, and insurance companies differ on preauthorization requirements. Generally, buprenorphine is a covered drug. Many private clinics accept only cash or Medicare/Medicaid, and patients then must seek reimbursement from their health insurance providers.

Miscellaneous

- The possible repeal and replacement of the ACA are of concern to the medical community, which has seen expanded treatment of opioid use disorder because of the current legislation.

1) Physician at a multicenter addiction research and treatment clinic on the West Coast; repeat source

The patient cap will moderately affect the market because prescribing physicians must meet the cap criteria. Clinics with multiple medical professionals, including PAs and NPs, will have the benefit of greatly increasing their patient load over time. Probuphine is infrequently used because it is difficult to insert and take out. As a result, it will not affect the buprenorphine market. Braeburn will continue to use Probuphine as a training ground to gain access to physicians for its upcoming weekly and monthly injection, CAM2038. This drug, expected on the market within the year, is widely anticipated. Indivior's long-acting buprenorphine, RBP-6000, also is expected to do well. Alkermes' Vivitrol is a deep muscular injection; it may be used more now for alcohol dependency. Overall, opioid prescription dependency is waning.

April 8, 2016, interview: The weekly and monthly injectables still were in the early stages of clinical trials, but they had the potential of being very useful and of changing the market. The weekly dose might be best for the unstable patient needing close follow-up. The implantable six-month rods just received advisory committee approval. The source stressed the importance of companies correctly introducing and targeting their drug, especially Braeburn, which did not have opioid treatment experience. Braeburn had started company training. More opioid treatments have failed than succeeded on the market because physicians have not been comfortable with how they were used.

Opioid Treatment Rule Changes

- "The patient cap increase will affect the market moderately at the most. It will take physicians some time to meet the cap limitations requirements."
- "Most buprenorphine is provided by a select group of physicians, so having more slots will be useful. For some doctors who are at their limit, increasing the cap will be absolutely essential to have more slots, and 275 is a lot of slots. That should be plenty for most physicians."
- "If a clinic has multiple physicians, then they get 275 for each physician and 30 for each physician assistant or nurse practitioner. If they have two physicians, then they get 550 total. That is a good number. You could imagine a 700- or 800-person clinic right now."
- "Some buprenorphine is provided through methadone clinics and clinic-like settings, where it is actually not counted against the physician's cap—or it's not clear [at this time] that it is counted against the cap."
- "It is hard to know how this will affect the methadone clinics. The methadone clinics have a lot of competing pressures right now with giving methadone and benzodiazepine simultaneously. The ACA supported a ton of methadone, like 20%, and no one knows what will happen with the ACA. Methadone clinics are not ideally positioned, and it is a challenging time for these clinics. Even though there may be technically more reimbursement for opioid dependency, they face criticism if they have a patient on benzodiazepines, and they face loss of income with ACA changes. And the clinics rely on a very inexpensive work force; the counselors are getting paid miserably in these programs. There is a lot of pressure on methadone clinics right now."
- "Methadone clinics aren't really the right business model for doing buprenorphine. It's a different clientele. All the patients want buprenorphine because it is take-home. The people on methadone need stabilization. Methadone clinics are outpatient intensive-care units."

Long-Acting Buprenorphine

- "I don't think the rods will affect the market; there will be few patients who will benefit from the rods. I don't know any patients who have gotten a rod yet. … And I'm not sure many people will get one."
- "They are medium-to-difficult to put in; it's up to a 30-minute procedure to put them in because you have to put five of them in. They are pretty hard to take out. It takes a significant effort to remove them, 35 to 45 minutes. The rods become soft and twisty like spaghetti under the skin, and you have to have a special instrument to take them out. And they can break. At the very least, it's a 15- to 20-minute procedure to put them in and a 30-minute procedure to take them out."

- "The best market for the rods is some place where there is very little access to opioid treatments, such as Russia or another country where there is little access to help."
- "To do this procedure, you need to have access to a place to do an operation. I'm an internist, and internist offices aren't set up for this. Psychiatrists can't do this. You need to do this in a hospital or a come-and-go unit. If I were serious about doing this, I'd partner with a plastic surgeon, who could actually put the rods in and take them out."
- "Everyone who puts these rods in must be trained."

Other Treatment Options

- "Braeburn has other reasons for keeping the rod alive: The company has something else up its sleeve that will affect the market and be a complete success, and this is the CAM2038. Right now they are learning how to train people [with the rods], and they are growing and maintaining their buprenorphine relations and the [resultant] interest in a new and improved version."
- "CAM2038 is going to be a killer. This is a once-a-week and a once-a-month formulation, and it works. They've enrolled their trial, and they are going to the FDA. This is exciting. It's a good bet that it will be out within a year."
- "The future looks brightest for the CAM2038 and possibly for the Indivior long-acting buprenorphine product [RBP-6000]. The future is probably most cloudy for the methadone clinics. The office-based clinics are probably more stable right now than methadone clinics."
- "I've used quite a bit of Vivitrol. It is a big injection, and you have to give it deep into a muscle. It is not as easy as a flu shot. You don't get any withdrawal when you stop it, so adherence is still an issue. [If usage is increasing, it may be due to] alcohol use. No one has come around our office to promote it."

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>
> *Physician*
> *Multicenter Addiction Research and Treatment Clinic, West Coast*

Pricing and Payment

- "Buprenorphine reimbursement varies. Some pay for it, but they have different hoops. They all make you jump through some type of hoops. Some of them still demand that you have a paper or detox plan, which is ridiculous."
- "There's a lot of controversy going on about these drugs, such as benzodiazepines."
- "The methadone clinics are covered much easier than everyone, at least for now."

Miscellaneous

- "The prescription opioid epidemic is waning. The back of it has been broken. The next challenge will be drugs like fentanyl or fentanyl-laced heroin. They are being smuggled. They are synthetic, so they don't require fields to grow in; you can make them in a laboratory. Fentanyl will become the primary drug of abuse and greed."

2) Pain management/addiction physician and pharmaceutical consultant in the central United States; repeat source

Upping the patient cap will increase the buprenorphine market for three years, and then it will stabilize. Physicians must simultaneously treat the general population, so the biggest problem is the number of physicians available to take on more patients. Allowing PAs and NPs to do some prescribing will help. However, it remains to be seen how the current administration will view funding for new clinics and treatments. The rods are designed for a small subset of the population and are not expected to affect the market very much. Technical challenges with the rods will hinder adoption. The use of Vivitrol has been increasing because the drug is beneficial for both alcohol and opioid addictions, but the drug's high price will prevent it from overtaking the buprenorphine market.

April 8, 2016, interview: Widespread usage would depend on the FDA marketing the product as a protection mechanism and as a way for physicians to treat patients without overloading their schedules. The DATA 2000's patient load changes could make the buprenorphine market robust in five years. Roadblocks included cost and patient selection. Monthly buprenorphine would become more widely adopted than either weekly or six-month dosages, but daily buprenorphine would continue to dominate the market. Monthly dosages allow the physician to monitor the patient and to be paid for those face-to-face visits. Insurers were more likely to pay for long-lasting buprenorphine because it pushes more users into treatment and involves fewer office visits. Insurers seldom bother collecting on unpaid bills for addiction treatment.

Buprenorphine

Opioid Treatment Rule Changes

- "Upping the patient cap will increase the market. The market will benefit, and we will see a steady increase in buprenorphine usage over time. But in three years it will be about as good as it will get for a while."
- "The bigger problem is the number of providers; this will make the biggest difference. The most important piece of the legislation is allowing physician assistants and nurse practitioners to do the prescribing."
- "The majority of physicians have never hit 100 patients. Most physicians see other patients as well. If you are in primary care, you would maybe see 60 buprenorphine patients because you also take care of other types of patients. So in the progression of things, it will be a while before the numbers bump up."
- "A lot of how this plays out depends on the current administration. I don't believe they will be enthusiastic about the treatment paradigm. Will they be open to new clinics? This may be limited. Our state legislature is considering using $1 million of cannabis-derived tax revenue to fund opioid medical management. There was also new federal money to support new clinics, but all bets may be off."
- "Here, methadone clinics are becoming more involved with buprenorphine. The methadone clinics are not affected by a patient cap because the environment is more controlled. Opioid treatment programs are set up to do daily observed medication administration. This has built-in safety because it limits the amount of methadone and buprenorphine out in the community, where it could be diverted and/or overused."

Long-Acting Buprenorphine

- "The rods will have a greater impact on those patients who are well along into recovery. … It is not for a lot of patients. The rods won't do for early patients; I wouldn't recommend them. Once the rods are removed, you would still have to taper down on buprenorphine delivered in the mouth."
- "Opioid addiction is a chronic disease. Maybe only 15% to 20% of the patients can transition off buprenorphine in nine to 12 months. These patients need to be comfortable in recovery."
- "Overall, only patients on a lower dose of buprenorphine can use the rods. The rods deliver the equivalent of 8 mg per day, but most patients are on 12 to 16 mg per day of buprenorphine given in the mouth by buccal or sublingual route. … The other factor is that physicians want to see their patients on a monthly basis for evaluation, but there will be a significant number of those placed on six-month rods who simply won't come in monthly."
- "The business of these drugs lies within the criminal justice domain, but an amount is put into play in general practice."

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>
> *Pain management/addiction physician*
> *Pharmaceutical consultant*
> *Central U.S.*

Other Treatment Options

- "Usage of Vivitrol is increasing, as it should be. It is my No. 1 go-to now for co-occurring opioid and alcohol addiction, and we will see more data on it in the future."
- "Vivitrol is very effective for alcohol and opioids, and some patients need to be treated for both. What you don't hear is what it can do off-label, and these side issues are important. There is some data on Vivitrol for treating gambling, sex and methamphetamine addictions. This information has not been presented to the FDA, and the drug is not approved for these usages. There is some data on buprenorphine, not head-to-head data, that show a favorable response for cocaine and alcohol addiction, but not tobacco addiction."
- "I consult for Indivior, and they have been very quiet, closed-mouthed about RBP-6000, so I couldn't address that. I expect the company thinks it may be better than CAM2038, which I read about the other day."
- "Other treatment options are stacking up nicely, and market success will be based on performance. Doctors will want monthly delivery because they want to see their patients on a monthly basis most of the time. We will have to see how this all caps out."

Pricing and Payment

- "Vivitrol is extremely expensive, at least $1,000 per month; it used to be $750 per month. It is covered by Medicare. But the high price will prevent Vivitrol from surpassing buprenorphine usage, which easily runs $600 to $800 monthly."
- "Insurers support these drugs although I'm not sure how well. But this is an environment that is very concerned about opioid overdose deaths, so it is expected that treatment options should do well going forward, for a while in any case. The insurers support procedures more than they do office visits."

Miscellaneous

- "We are starting to see more nonbranded information being delivered in continuing medical education events due to the opioid overdose death picture. This is resulting in the delivery of more information about Vivitrol, for example, because the company to date has been more focused on promoting its use in the criminal justice system. Frankly, most office-based practices have heard very little about it. The pharma companies are now giving compensation to speakers—physicians, physician assistants and nurse practitioners—to get the information out."

3) Addiction and university clinical research physician who prescribes Probuphine on the West Coast

Changing the patient cap will take time. A higher patient cap will help those centers with waiting lists and make it easier to accept third-party reimbursement. However, not all centers can accommodate more patients. The implants have a niche role and will rise slowly in use. Insertion and extraction are not necessarily challenging. Some centers have many patients who are appropriate for the rods, but various logistics limit them as candidates. Other roadblocks include the additional training required, higher costs, lack of patient and clinician knowledge, and difficulties with billing, payment and shipping. Vivitrol is on the rise because it is easy to use, and physicians are now embracing MAT.

Opioid Treatment Rule Changes

- "[Upping the patient cap,] especially in markets with waiting lists, should help. This may also make it easier for doctors to accept third-party payer reimbursement for care with buprenorphine, which was limited with the caps. This change should be happening now."
- "[Our resident care center] is small—12 beds, so the patient cap will have no effect on us."
- "Physician assistants and nurse practitioners will be allowed to prescribe opioid therapies, but the pathway isn't available yet. Therapists cannot prescribe medications."

Long-Acting Buprenorphine

- "I see the implant as having a niche role that will grow over time. I have done about four patients in the past year."
- "Probuphine is indicated for stable patients on 8 mg or less of buprenorphine. [The percentage of] patients appropriate for the implant depends on the individual, their preference and their availability. Many of the patients we see are candidates for the rods, but logistic issues limit their choices."
- "It takes me five to 10 minutes to insert the rods and 20 to 30 minutes to remove them."
- "Probuphine [roadblocks] are the additional training required, higher costs, and lack of patient and clinician knowledge."
- "There are also logistic issues with getting the implants. Billing, payment and shipping were a little rough at first, but my office person finally figured it out."

> **I see [Probuphine] as having a niche role that will grow over time. I have done about four patients in the past year.**
>
> *Addiction and university clinical research physician who prescribes Probuphine, West Coast*

Other Treatment Options

- "Vivitrol is on the rise. More and more doctors are starting to embrace MAT, and Vivitrol is easy to use. It just doesn't have a very robust effect."
- "Vivitrol costs $1,000 per month, but no one pays that. Either their insurance pays, or they don't use it."
- "Braeburn's next product sounds great, but it is still in the pipeline."
- "Directly observed therapies have the potential to reduce risk of diversion and ensure compliance. This may well be very appealing to clinicians and third-party payers."

Pricing and Payment

- "Prior authorization is often required, and reimbursement is plan-specific."

4) Research physician at a multicenter addiction treatment clinic in the Midwest; repeat source

The increased patient cap and the use of Probuphine will allow more practices to offer complete treatment services. The number of patients using Probuphine should increase within the year, but this will depend on the possible repeal of the ACA, which currently insures many from the clinic's base of more than 9,600 annual patients. Twenty percent of patients

are appropriate for the implantable rods; 60% are on daily medication; and 100 of this source's patients are on Vivitrol. More patients ask for Vivitrol than buprenorphine or methadone.

April 8, 2016, interview: Long-term treatments would benefit anyone addicted to opioids as long as the medication was coupled with counseling and urine testing. The pace of adoption would vary depending on the required physician training. Weekly or monthly implantable buprenorphine would not be well received because the procedure was too invasive for that length of time. However, six-month implantable rods would be widely adopted. The price of a six-month rod should be comparable to six months of oral medication, and insurers and able patients alike would pay the cost. The source also expected an intermediate range (one- to two-week) treatment to become available.

Opioid Treatment Rule Changes

- "The increase from 100 to 275 patients will push more practices to offer complete treatment services such as counseling in one building. Our treatment center now has all physicians with waivers at 275."

Long-Acting Buprenorphine

- "The long-acting medications will expand the availability of treatment since providers will be less worried about diversion. It is hard to say how long for the implant market to grow; hopefully within the year, numbers will increase. I was on the last phase trial for the FDA, and it took a long time getting finally approval. Probuphine has only been approved by one Medicaid provider in Ohio, which may collapse if the Affordable Care Act is repealed."
- "Twenty percent of our current patients are appropriate for implants; 60% for daily, 10% for weekly, and 10% for monthly."
- "The rods are technically challenging if you haven't sutured in a while. The physician must have done a surgical procedure in the last year—sutures, incision and drainage, etc."
- "I have done training for rod implantation over the last summer to several hundred physicians. Those who have some surgical skill are fine, psychiatrists not at all. I found NPs and PAs to be the most proficient, and they will be great implanters and removers. NPs and PAs can already do implants and removals if they take the training. I personally certified five here in our state. They can't write the script for the rods, however, because they don't have a DATA waiver yet in our state. They will be allowed to get a waiver and prescribe [Indivior's] Suboxone sometime this year."
- "Reimbursement for the procedure is the biggest hurdle, followed by facility-appropriate space and trained implanters."

Other Treatment Options

- "Vivitrol is the most viable treatment I see as a provider. I have over 100 patients on Vivitrol, and they do very well and transition off easily. As long as the ACA pays for the injection, I see more and more patients on it. I have more patients asking for Vivitrol now than methadone or buprenorphine."

> **Twenty percent of our current patients are appropriate for implants; 60% for daily, 10% for weekly, and 10% for monthly.**
>
> *Research physician*
> *Multicenter addiction treatment clinic*
> *Midwest*

Pricing and Payment

- "The only other price point I know is Vivitrol, which is $890 wholesale and $1,200 retail in my locale."
- "I have grave concerns for my patient base, who are people at or below poverty level getting any type of medication-assisted treatment, if the ACA is repealed. Our governor chose not to expand Medicaid and has no plans to do so even if the ACA is repealed. I think a lot of people will lose access and once more be lost. They are homeless or have transitory housing, making them ineligible to vote and, therefore, voiceless in our society."
- "Our opioid treatment program uses methadone, buprenorphine and Vivitrol. Methadone and buprenorphine are dispensed and included in daily rate billed to Medicaid, if the patient has that. We are community-funded, so the rest of the patients are treated using those funds. We must get prior authorization for all Vivitrol injections, and it has been pretty easy. But I see that changing a great deal if the ACA is repealed."

5) Psychiatrist and founder of two psychiatric treatment centers on the East Coast

MAT for opioid addiction was added to this source's psychiatric centers about a year ago. The centers have experienced slow and steady patient growth and now serve approximately 45 patients using daily Suboxone. The expanded opioid treatment cap is a good step in the fight against the epidemic, but it will not mean large numbers of additional patients

can be added overnight. The process takes time and requires certification and preparation to meet the needs of more patients. This source said he will seek certification to expand when his practices reach the 100-patient threshold. He does not use Probuphine, and said implanting and removing the rods may be difficult. He is very interested in the long-acting injectables.

Opioid Treatment Rule Changes

- "The expanded treatment cap is a good thing for fighting the opioid addiction epidemic, but it's not a quick fix."
- "Overall, the rule changes will increase the number of patients that get treatment, but it will be slow process."
- "It takes time to implement and prepare to service these patients. I added Suboxone treatment a year ago at my centers, and we have grown at a slow and steady pace to 45 patients."
- "I do plan to seek the expanded cap when we reach the 100-patient threshold."
- "The rule change to allow PAs and NPs to be directly involved with treatment will be very helpful in combating the epidemic. There is a great need for more treatment options."

Long-Acting Buprenorphine

- "I do think long-acting buprenorphine will lead to better retention of patients and possibly better efficacy. But the rods are really only for patients that already doing well with their recovery effort, and that is not a large number."
- "I do not prescribe Probuphine now. However, I will consider it if it is not too difficult to implant. If it requires making an incision and stitching, I may not want to get involved."
- "I am very interested in the week- and month-long injectable. I think it will be easier than the rods."

Other Treatment Options

- "I don't use Vivitrol, but it has come up in some of our staff discussions and we may start using it. It could be a good alternative for some of our patients."

> **The expanded treatment cap is a good thing for fighting the opioid addiction epidemic, but it's not a quick fix.**
>
> *Psychiatrist*
> *Founder of 2 treatment centers*
> *East Coast*

Pricing and Payment

- "I only accept Medicare, and I have not had any problem with reimbursement for treating patients with Suboxone."
- "Patients that private pay and submit for reimbursement from their insurance providers have not had any problems."
- "Preauthorization is required by some insurers and not by others, and it's not a big deal to get."

Miscellaneous

- "We are in the early phase of mobilizing a medical and societal response to a huge, unmet need of treating opioid-addicted people that want to stop using. It is going to take some time."

6) Physician who is board-certified in addiction medicine

With a 275-patient cap, this physician can maintain patients on Suboxone longer, which helps prevent relapses. He advocates use of affordable, long-acting buprenorphine for chronic pain. He also cited a large market for addiction treatment using buprenorphine, especially if patients are educated about how it will control their pain. Vivitrol works quite well in helping patients stay off opioids, but insurance companies have been requiring preauthorization. Also, it is available only from a few specialty pharmacies, which can create delays in receiving the medication.

Opioid Treatment Rule Changes

- "I'm capped at 275, so I do have that. When I was just capped at 100, I'd take people off the Suboxone faster than I normally would because I'd want new patients. So as soon as I could get somebody off Suboxone, then I could add another patient. So if I have a number of 275, I can keep patients on longer. … After seriously thinking about this for a long time, I realized that some of these people are going to be on it like their insulin for the rest of their lives."
- "I use a lot of buprenorphine for chronic pain. And I want people to be able to have buprenorphine for chronic pain for the rest of their lives because if they have a back injury [as an example] and they stay on buprenorphine, then they never get back on heroin or heavy-duty opioids again."
- "We need to make some big change in the statute. There shouldn't be limits on the number of people we put on buprenorphine. Currently, I'd say 80% of my patients in my pain clinic are on buprenorphine for chronic pain."

- "[In this state] Medicaid will only pay for buprenorphine for three years for a Medicaid patient. They won't pay for any Suboxone or buprenorphine unless it's for addiction. It's really sad because I've had all these patients who have been on buprenorphine once a day for three years. They have a good job and they are doing well, and then the insurance won't pay for it so they have to pay it out of their pocket or risk coming off it and going on another opioid."
- "My nurse practitioner is getting approved [to provide the addiction treatment using buprenorphine]. The [change in the law won't be] implemented until March or April of this year."
- "There are still a lot of people buying things off the street illegally. … There's a big market [for opioid addiction treatment using buprenorphine]. A lot of people will come in to get it, especially if [providers] do good education with it on how it's going to keep them off opioids and it's going to control their pain. It's the legal thing to do to help them."

Long-Acting Buprenorphine

- "Probuphine is out, and I got trained on that. But the trouble is, who is going to pay $5,000 to 6,000 [upfront] every six months to get it put in? You're only supposed to be able to do it for two cycles, which would be one year. I haven't had one insurance approve it. When I got trained a few months ago, it was [expected to last for] about four to six months depending on the patient and how they metabolize it. It only takes me 10 to 15 minutes to put it in, and it still costs about $5,000. If the company was smart, they'd get [long-acting] buprenorphine approved for chronic pain. Can you imagine me putting that into somebody with chronic pain? It'd be worth $5,000 to put in those sticks. Can you imagine six months without pain?"
- "If you didn't have to put patients under the 275 [cap], I'd say most of my patients would go to long-acting. The patch works well for once a week, but if I could have one that goes for four to six months … if it was reasonably priced, 80% [of my patients] would switch over because those things under your tongue don't taste good, and it's hard to remember them every day, and then they get stolen. There are so many variables with it."

There are still a lot of people buying things off the street illegally. … There's a big market [for opioid addiction treatment using buprenorphine]. A lot of people will come in to get it, especially if [providers] do good education with it on how it's going to keep them off opioids and it's going to control their pain.

Physician
Board-certified in addiction medicine

Other Treatment Options

- "I used tons of methadone for chronic pain because I'd dose it three times a day and it doesn't confuse your mind and it gets rid of your pain. But the way methadone clinics are run, they give people a whopping dose at 6 a.m. They have to be there early, and it only lasts in their bodies three to four hours before it starts deteriorating, and then they go into withdrawal until the next morning. The [clinics] never seem to taper the dose for these patients. It's the worst moneymaker in the whole country because you have all these poor addicts who are going there every day and spending their $50 to $100 a week to their get methadone, and it's making them want more and more methadone because they only give them one [big] dose a day in the morning."
- "Methadone is also an NMDA receptor blocker, so it's better for back pain and bone pain than any pill on the market. And it's dirt cheap. I can buy a bottle of 100 methadone for, like, $20 to $30. These methadone clinics are a joke."
- "I love Vivitrol. What I used to do is if the patients wanted to get off heroin, let's say, we'd put them on Suboxone for three weeks and just taper really quickly, and then we'd wait 24 hours to give them a shot of Vivitrol. And I had great success with that. Once patients came off opioids, for the next three to six months they really do well on Vivitrol."
- "Insurers started to throw up these roadblocks. They want preauthorization for it, and it's $1,200 [for a Vivitrol shot a month] if you don't have preauthorization for it. Then you have to get it from only a couple of specialty pharmacies in the country."

Pricing and Payment

- "You just get paid for a regular office visit [for buprenorphine addiction treatment]. The office visit can take 15 to 20 minutes, but some of these Suboxone clinics …. will get a couple of doctors and pay them $100 to $200 an hour and then try to make [the patients] pay $100 to $125 in cash for a [10-minute] visit. And then they have to come in every week or two weeks to get their Suboxone prescription."
- "It's becoming a real moneymaker for some of the business men."
- "My daily [insurance] rates for inpatient and outpatient [addiction treatment] have been cut 75% in the last year. … The government and the agencies say they want to help all these addicts, but nobody on the other end of the payer

scale is paying for it. … Then they make the prices high for the drugs, and you see why these poor kids go back on heroin. It's because there's nobody out there to help them—the insurances or the drug companies."
- "Nobody is using [Depomed Inc.'s/DEPO] Nucynta [for pain]. I haven't seen a script for Nucynta anywhere for a year."

7) Owner of an outpatient medication-assisted treatment program

The 275 cap will increase patient volume but also will make the market more competitive. The clinic plans to use the monthly injection once available. The program does point-of-care urine drug testing at each visit and refers repeatedly noncompliant patients to a more advanced level of care.

Opioid Treatment Rule Changes

- "[The increase in the cap will] obviously make it more competitive for clinics to get patients, and at the same time it's going to allow us to increase our business. We only have one doctor, and that doctor is bumped up against 100 and waiting until he's eligible to increase it to 275. That will allow us to add 175 patients to our clinic, which is a good thing, but at the same time we are having to do more things to attract patients, like more advertising."
- "We are in the process of having a nurse practitioner get certified [to provide buprenorphine treatment]."
- "[The cap for NPs and PAs] is 30 for their first year, and after the first year they can go up to 100. No, it is not 275. I don't think it's ever going to go to 275."
- "As more patients become aware of treatment, hopefully more will seek treatment. I think the fact that the media covers the opioid epidemic is helpful. I can't predict how many patients are going to be seeking treatment. That really depends, and it varies day to day … depending on what is on the street, what the opioid overdose death rate is. … Some weeks we get a lot of calls, and some we get very few calls."
- "We prescribe buprenorphine products. One of them is Suboxone. We also prescribe generic products."
- "There is one long-acting product; it's the implantable device. Our doctor is qualified to do that procedure."
- "We are very interested in the long-acting [injectable buprenorphine] products. It's something we will do once it becomes available. It's not available yet. Just the implantable device is available."
- "There's a Vivitrol monthly injection that's available, but that's not a long-acting buprenorphine product."
- "We are taking new patients, and we don't get flooded with patients. We get a steady stream of new patients, anywhere from three to five a week."

Long-Acting Buprenorphine

- "[Long-acting buprenorphine] will help with diversion. With less of the medication out on the street, I think that would be helpful. It may also push more patients into treatment because they can't get it. They can get less of it."
- "This is a continuum. This is not a sprint. As long as the product is out, it will continue to help the diversion, it will continue to create more treatment for people. There's no set time. It will be ongoing."
- "Patients do find it hard to get off of [buprenorphine], unfortunately. … Most patients come off it because they are relapsing, not because they are weaning off of it."
- "[Once the long-acting injections become available] when our stable patients come in for their monthly appointment with our doctor, we will be doing an injection instead of giving them a monthly prescription. They won't be taking a daily medication. They will just get an injection, and they will forget about it pretty much."
- "I would say maybe 40% [would be candidates for the monthly injection]."
- "For the implantable, I think that's $4,000 or $5,000. We haven't done one, but I have heard insurers are covering it so there's no out-of-pocket cost to the patient."

> **We are very interested in the long-acting [injectable buprenorphine] products. It's something we will do once it becomes available. It's not available yet. Just the implantable device is available.**
>
> *Owner*
> *Outpatient MAT program*

Other Treatment Options

- "Vivitrol is a blocker. We don't use it at the moment because our concern is that it doesn't take care of the patient's craving. … It's a pretty specific medication for a specific patient type. We haven't had any candidates for it yet. [That would be] someone who has a short history of opioid addiction coming out of a rehab, because you need to have no opioids in your system to do it. Most of our patients do have opioids in their system."

Pricing and Payment

- "Suboxone is about $16 a day, I would say, but the patients' insurances almost always cover the medication. We have very few patients who have to pay out of pocket for their medication. [Payers require preauthorization for the medication] about half the time."
- "We do not accept insurance for the office visit. The patient has to pay out of pocket."
- "I don't know what the commercial insurance rate is [for office visits], but it varies widely from company to company."

8) Addiction psychiatrist involved in national policy decision-making, teaching and clinical care

The federal rule changes ideally will triple the number of people receiving treatment with buprenorphine. Success will hinge on whether patients find the system to be simple enough to use. Probuphine will not have a large market because the dosing may be lower than what patients are taking orally. Also, it is costly and involves a six-month commitment.

Opioid Treatment Rule Changes

- "[The change in the treatment cap] will help. I think some people in certain geographical areas are overloaded; they are sort of maxed out at 100, and it will allow them to increase it. I do think there are a number of MDs who are reluctant to use their license, their waiver, so those folks are still going to resist it."
- "With the new 21st Century Cures Act, we are going to see some training of doctors state by state. That might also increase the prescribing capability, and the total number of slots for treatment would expand."
- "In the ideal world, maybe [the MDs, NPs and PAs] will triple the number of folks suffering from addiction who get treated. There are going to be a number of people—maybe half the people—who have addiction who won't want to get treatment, and there may be this invisible barrier that we don't understand because we haven't had enough treatment to give there. … We might be able to get 50% of the people some kind of treatment, but I suspect the people themselves will balk at treatment."
- "If we have 15% to 20% of people who get treatment now and that triples, then we are kind of up to the 50% to 60% range. That would be seriously helpful if that happened. I think [it would take] a couple of years."
- "This is going to depend on government, Medicaid and things like that. The addicts are going to have to see and experience a simple way of getting into treatment. The more preauthorization rules and … when it stops [being simple] … they are just going to roll their eyes [and say], 'All they really want is my money; they don't want to help.' … We are now talking about a complicated medical system that has its own rules, and a political system that has totally different rules, and we have state politics vs. federal politics. If those three systems can coordinate … and you have a centralized community or regional intake system, then you might actually see the improvement pretty quickly."
- "Part of the ambivalence about PAs and NPs [providing the addiction treatment] is they aren't trained as well as doctors. The PAs and the NPs can get their buprenorphine waiver, but they have to do 24 hours of education. The MDs only had to do eight hours of education originally, so maybe the PAs and the NPs will get more appropriate addiction and chronic pain training that would allow them to do a better job."

> **Some people in certain geographical areas are overloaded; they are sort of maxed out at 100, and it will allow them to increase it. I do think there are a number of MDs who are reluctant to use their license, their waiver, so those folks are still going to resist it.**
>
> *Addiction psychiatrist involved in policy decision-making, teaching and clinical care*

Long-Acting Buprenorphine

- "Frankly, I don't think there is going to be a big market [for the long-acting implantable rods] because they can require a six-month commitment [and] because the dose that's given may not be as big as the dose that you get orally. … That's going to depend on the setting. [I]t may be that in the criminal justice system, people might get something started right before they leave jail that will continue to keep them in a nonvulnerable position."
- "If somebody is in a rural setting and the [practice is] the dominant location, they might hold that out [as an option]."
- "I don't see it as taking over the market. It's fairly pricey—somebody has to pay for it. … I think that is going to be a challenge, and I think it will stumble along."
- "Depending on the dosing, [long-acting monthly injections] might work well. … . The injection may not be quite so popular because people don't like getting stuck with needles."

- "It depends on the cost and how it compares to pills. Pills can be $250 to $550 a month. If the injection is in the $300 to $350 range, it might compete very well. If they have it in the $600 to $1,000 range, I don't think it's going to compete well."
- "The rods will affect [the market] a little bit. I think the shot could affect it some. If the injectable can be injected in similar doses to the oral, that could be quite valuable in certain situations. If I were an investor, I don't know that I'd invest a lot of money in it. But from a clinician's point of view, I think the injectable will have some effect."

Other Treatment Options

- "Vivitrol has a role. The context makes a difference. Vivitrol for the street addict walking in your front door doesn't look nearly as exciting as an addictive drug."

Pricing and Payment

- "There are barriers to getting appropriate CPT codes [for addiction treatment]. I do think they do have some CPT codes that are more amenable to that. But when we talk about the co-occurring problems, it may be complicated for the billing department to figure out what to bill for."
- "The drugs are quite expensive. Either you have to have national health insurance that covers it where it's a nonissue, or as I'm seeing locally, in private practices they are finding that Subutex is $350 a month and Suboxone is $500 to $550 a month. If that's a reality when you look at Walgreens and CVS, if those are the numbers … then you have a real financial barrier there."

9) Addiction psychiatrist providing treatment in an academic setting

The expanded patient cap and the use of NPs and PAs to provide buprenorphine treatment hold considerable promise for improving public health. This provider's state Medicaid program does not cover Probuphine. Long-acting injectable buprenorphine could help prevent deadly overdoses.

Opioid Treatment Rule Changes

- "I hope that it will have a huge positive impact. I think the NPs and PAs [having their own cap] is an enormous benefit that can really help have the ability of treatment expansion. I think whether or not the ACA still exists and how much the injectables cost, if they do get approved by the FDA, will be another big factor."
- "[The 275 patient cap] will have a small impact [on the opioid addiction treatment market]. The number that you are going up to is only 175 more patients per doctor, and that's going to be a minority of doctors who apply to do that. I think the individual doctors may be those who want to do this more full time that maybe now are only doing it part time, because you can't have a full-time practice with only 100 patients."
- "There may be slight increases in the number of patients seeking treatment, but I think a large part of that will depend on what happens politically with the ACA. I think a large part of some of the patients getting treatment are people who previously didn't have insurance. And because of the ACA, they were able to get insurance that enabled them to afford treatment or have treatment be paid for when it wasn't previously."

Long-Acting Buprenorphine

- "The Probuphine is the six-month rods that are implanted. Those are for a very specific subpopulation of patients who are really, really quite stable and on low doses of at least no more than 8 mg a day of Suboxone equivalent. … What is really important about it is that it demonstrates that there are patients who get better and stay better and do really, really well and get jobs and all of that. … It really proves it is a chronic medical illness for which people can get into recovery with medication and stay well."
- "The [monthly and weekly] injectables that are in development have the potential to have a much larger impact if the new drug applications that are submitted to the FDA end up getting approved, because those are looking at a wider market of people who have opioid dependence."

> **The [monthly and weekly] injectables that are in development have the potential to have a much larger impact if the new drug applications that are submitted to the FDA end up getting approved, because those are looking at a wider market of people who have opioid dependence.**
>
> *Addiction psychiatrist providing treatment in an academic setting*

- "If you just have to give someone a shot once a month … I think we can actually have the potential to start seeing a decrease in fatal overdoses in the country as well. That's assuming that insurances or payers are going to add that to the formulary, and that it will be priced appropriately to make that possible."
- "One of the things that we have seen with the Probuphine rods is that these very stable patients … love not taking medicine every day anymore. Another step in their recovery is just knowing that they don't have to rely on taking something every day. They really like that."

Other Treatment Options

- "Vivitrol is another helpful medication that I'm grateful for having. It's not a medication that is easy to get people on to who are currently addicted and using because you can't be physically dependent, so that's a challenge. But we are seeing more use of it within the criminal justice system."

Pricing and Payment

- "[Reimbursement] totally depends upon the insurance provider. It's hard to say [what the range of reimbursement is] because I am doing different things with different patients. Medicaid doesn't pay well at all. … In general, the commercial plans pay usually at least twice that of what Medicaid pays."

10) Physician assistant and administrator for a private psychiatric practice providing addiction management services

The larger limits on buprenorphine will greatly augment access to addiction treatment services. This PA's practice has several midlevel practitioners who will provide the medication. Reimbursement shortfalls impede Vivitrol use in the state.

Opioid Treatment Rule Changes

- "In some instances [the 275 cap for doctors] is going to be very beneficial because the model allows for more access to non-addiction psychiatry and non-addiction medicine specialists in more areas for more treatment. And I think as they [increase] their patient limits from 30 to 100 to 275, the providers should get enough experience under their belt to feel comfortable with those numbers—or if they aren't, they shouldn't go to those numbers."
- "In my state, most buprenorphine providers take cash only; some will let the patients file their insurance afterwards. With more competition out there for those cash doctors, I think the prices will go down. But my practice is one of the largest in the state, and we take insurance for treatment. [In the market overall, providers] are going to reach a lot more [people] because there are going to be a lot more doctors requesting [buprenorphine], and it's going to be easier to get through the prior-authorization process and other little stopgaps in the process."
- "The extension from 100 to 275 is going to tremendously reach more patients. I worked with a provider [who had] people [from other states] driving to see him [because] he did nonnarcotic pain management along with the buprenorphine treatment, and he tapped out fast. It's going to allow [preferred] providers like that who have good service and good reputations to expand. … Providers who have a bad reputation and not a good structured program are going to expand their practices too, but I think that's going to be a lot less."
- "With regards to NPs and PAs, finally the system has caught up with modern-day medicine. I can do anything that my supervising physician can do."
- "My physician in my current practice has [several] midlevels, and that extends services tremendously by 30 multiplied by [each midlevel provider]."
- "Our plans are to maximize the buprenorphine program within our practice."
- "[Buprenorphine] will just be a portion of [providers'] practice. I don't believe it's going to be their total practice. Even providers I know who do it on a cash basis often do pain management or some other type of practice on top of the buprenorphine treatment."

The extension from 100 to 275 is going to tremendously reach more patients. I worked with a provider [who had] people [from other states] driving to see him [because] he did nonnarcotic pain management along with the buprenorphine treatment, and he tapped out fast. It's going to allow [preferred] providers like that who have good service and good reputations to expand.

PA and administrator
Private psychiatric practice

Long-Acting Buprenorphine

- "I'm somewhat cynical about [the market effect of long-acting buprenorphine injections] because I currently use Vivitrol injections for long-acting monthly treatment and the cost is quite substantial. And in my state it's really hard to get approval. There's not much access."
- "I don't take Medicaid. I take Medicare and other private insurers, and I have to go through an application process [for Vivitrol]. Even with [one state private plan], some of the patients are getting quoted a $700 copay on a Vivitrol injection. The long-acting rods and some of these other [long-acting] products might be cost-prohibitive."
- "Depending on [cost] and insurance coverage, I'd probably prefer [prescribing long-acting buprenorphine injections] just as much as I prefer the Vivitrol injections over the oral naltrexone."
- "The long-acting, if we could get past the 8-mg dilemma with the rods [and] have a more average range around 16 mg, I think that's going to help with a lot of our diversion concerns. I have quite a few patients whom I'd rather titrate up on an injectable than have them leave with a prescription, knowing that the street value is like two to three times the [cost of the] tablet. It's still being diverted to people who usually can't get the opiate, but still I have to worry about safety for people who are on benzodiazepines and other things for the liability risk. The injectable is going to take a lot of the liability concern off our shoulders."

Pricing and Payment

- "[Most of our patients are on] 16 mg, which is two films. It's about 60 [doses] a month at about $3 each so about $180 a month."
- "[The sublingual tablets] run cheaper, but they are not very preferred because if you try to cut them for less of a dose, they crush and crumble. I don't know that I could tell you offhand [how much cheaper], but I would assume it's somewhere around where the film is."

2) Prescription Opioid Sales Channel

Two of these three sources expect the treatment rule changes to allow more access to MAT and, as a result, sales will increase. One of the two said a 10% to 20% increase over time is possible. The remaining source said the expansion of the patient cap was a positive, but expects the rule changes to minimally affect treatment numbers because most family physicians are already at or near capacity with their regular patients. His other concern is that family physicians have the least experience with opioid abuse disorder. All three expect Probuphine to have minimal uptake because of its limited patient population, its high cost and its required surgical procedure. Two sources think CAM2038, the weekly or monthly injectable buprenorphine, will be successful; one even said it could gain 30% to 40% share. Sources' comments on third-party reimbursement varied. One said Medicaid will cover treatment with preauthorization, but some insurance companies' and Medicare coverage was limited. Another said the expansion of Medicaid in his state has allowed more people to seek treatment; any rollback in Medicaid coverage would be a problem. The third source said some insurance companies require preauthorization and that copays in general are rising. Sources commented on the pricing for medications. Probuphine is $5,000 for six months plus $300 each for required physician visits. Buprenorphine can cost $210 to $1,200 per month depending on dose and brand vs. generic, while methadone is $80 to $100 per week. One source who highly anticipates CAM2038 said a price of $800 to $900 per month is likely. Vivitrol has a treatment role because it is a nonopioid, but it is expensive ($1,500 per month) and has a high dropout rate.

Key Silo Findings

Opioid Treatment Rule Changes

- 2 of 3 expect the new buprenorphine patient cap expansion will increase the treatment market over time.
  - 1 said sales of buprenorphine could increase 10% to 20%.
- 1 said the expansion is positive, but impact will minimal as family physicians have limited room for adding patients.

Long-Acting Buprenorphine

- All 3 said Probuphine use will be limited because of the small eligible patient population, the product's high cost and the surgical procedure required to implant and remove the product.
- 2 said weekly and monthly injectable buprenorphine will be successful.
  - 1 said CAM2018 could capture 30% to 40% of the market, and insurance companies will embrace it.

Other Treatment Options

- Vivitrol is said to have a place in the spectrum of treatment tools, but is expensive and has a high dropout rate.

Pricing and Payment

- Probuphine is $5,000 for 6 months plus $300 each for required physician visits.
- Daily buprenorphine can cost $210 to $1,200 per month.
- Methadone is $80 to $100 per week.
- CAM2038 is expected to be priced appropriately; even at $800 to $900 per month, it is likely to secure coverage.
- Third-party payment varies.
    - Medicaid coverage requires preauthorization, and the amount of coverage varies.
    - The expansion of Medicaid coverage in some states did expand access to treatment, and that may be at risk under the Trump administration.
    - Insurance company coverage often follows Medicaid and varies from company to company.

1) Addiction account manager for a large pharmaceutical firm; repeat source

Increasing the patient cap may increase sales 10% to 20%, but this growth will take time. General practitioners, who prescribe 20% of buprenorphine, cannot increase their patient load very much, and PAs and NPs are just gearing up. Currently, less than one-half of patients who need treatment are receiving help. Probuphine is a niche product and will command no more than 1% of the market because of the extensive physician training and qualifying patient requirements. CAM2038, which should be on the market by late 2017 or early 2018, is the drug to watch and could command up to 40% of the market. Eventually, it will make sense to start treatment with CAM2038, which will cost $500 per month, and then follow with the implantable rods.

April 8, 2016, interview: The long-acting buprenorphine should become widely adopted, depending on how often a patient requires additional oral buprenorphine. This was a big issue in clinical trials. Insurers and physicians would be very excited about weekly or monthly buprenorphine dosages. Physicians likely would first want to see how patients handle the weekly dose before moving onto monthly. Clinics and some physicians might not be happy with having their income slashed given the reduced number of patient visits. Also, some patients might push back because longer-lasting dosages would hinder their diversion efforts. The top drug was Suboxone by Indivior.

Opioid Treatment Rule Changes

- "Upping the number of patients to be treated will affect the market. I think the companies were anticipating more buprenorphine sales, but I'm not sure of the extent it will have, maybe 10% to 20%. It will be something because more patients will have access to buprenorphine. But it will take a while for the practitioners to ramp up."
- "Right now less than one-half of the people who need treatment are seeking treatment. Part of it is that they can't get treatment but want it. Yet some folks aren't ready for the next step."
- "If you look at a big clinic with multiple practitioners and a new cap of 275, you could see three times as many patients as before. A clinic with four doctors could take on 1,000 patients. About 80% of scripts are written in the specialty centers, not a primary care facility. But the general practitioners probably can't increase their patient load by much. If a physician is just getting a license, it will take a while to ramp up to 275 patients."
- "The physician assistants and nurse practitioners have been recently identified, but they aren't there yet. It took a while to decide on the needed training, which has now be specified as 24 hours. This area will start gearing up."
- "When I talk to the doctors, they have never said, 'Where can I get patients? Or where should I advertise?' Instead, since the 275 cap, they are asking if I know of any practitioners who can take on more patients."

Long-Acting Buprenorphine

- "The Probuphine market is a niche market. If the company got 1%, they would be strong. The rods won't affect the market. This is due to a couple of qualifying reasons. In order to use the rods, a) doctors have to be SAMHSA waivered; b) doctors have to go through on-site training to insert and withdraw the rods or risk litigation; this is a surgical procedure, so they need access to an operating room; and c) qualifying patients must be stable and on a low to moderate dose of buprenorphine. Most patients are not stable."
- "The percentage of qualifying patients is very low. The rods are 8 mg, but the standard dose is 16 mg. The patient has to be on 8 mg for a minimum of three months prior to rod insertion, and they must undergo counseling and toxicology studies. It is a very cumbersome prior-authorization process."

- "The target patient is someone who is stable and has strong psychological components. They may be a very busy person who travels a lot or takes care of kids at home, and going in on a weekly or monthly basis would be difficult. Some people are just tired of chasing medication all day. They want to go from existing to living."
- "After six months, when the patient is ready to be weaned off the rods, 50% of the medication is still in the rods because of the half-life. … Some patients could only have the rods for six months, and then go on a lower dose of oral buprenorphine. But you could do six months in the other arm, for a full year of treatment. If the benefit outweighs the risk, you could go higher in the arm and do another six months or year."
- "Five to 10 years ago, the No. 1 treatment was psychiatric care. Psychiatrists still have a major part to play, but they can't do a rod procedure. OB-GYNs are starting to be a part of the rods. They see a ton of pregnant patients with addiction interests. This is of interest to the older docs who don't want to deliver babies anymore."

Other Treatment Options

- "Vivitrol has been out there for a long time. Price-wise, it is very expensive, up to $1,500 per month. You have to be very careful of withdrawal with it. The compliance for these shots varies, and maybe half of the people scheduled show up—on a good day."
- "The criminal justice system uses a ton of Vivitrol. About 80% of all crimes involves drugs and the drug industry."
- "Most patients need the weekly or monthly injections."
- "I hear that the managed care and all the staff come to Braeburn for the opportunity to study and work with CAM2038. In November, Braeburn released three incredible trials. On the primary end, the patient toxicology tests met expectations; secondarily, the product was superior to other products. The company will submit for FDA approval in one to two months, and it will probably be put on fast track. I expect it will be on the market late fourth quarter or the first quarter of 2018. It will be priced appropriately, and insurance companies will embrace it. This will be significant and may divert 30% to 40% of the market."
- "Preliminary discussions of CAM2038 are very enthusiastic and eager. There is a need. The doctors being trained now on rod implantations aren't doing too many rods, but they are making company connections."
- "What makes sense is to have CAM2038, the weekly and monthly injection, on the market before the six-month rods. Then you could start the patient first on weekly, then monthly. And once the patient is stable and on a low dose, have them used the rods. That would be the natural progression. This may be what will eventually happen; people will use CAM2038 first, then move on to the rods."

> **Upping the number of patients to be treated will affect the market. I think the companies were anticipating more buprenorphine sales, but I'm not sure of the extent it will have, maybe 10% to 20%. It will be something because more patients will have access to buprenorphine. But it will take a while for the practitioners to ramp up.**
>
> *Addiction account manager*
> *Large pharmaceutical firm*

Pricing and Payment

- "Some insurance plans don't cover buprenorphine treatment; Medicare, not so much; Medicaid, with preauthorization."
- "Rod insertion and extraction costs around $5,000. The insurance companies will negotiate on what they will pay for the procedure and treatment, but generally the rods are covered if the patients meets the qualifications."
- "For the rods, there is a preprocedure visit and a post visit, both with billing codes. The reimbursement varies by plan, but the ballpark figure is around $300 for each visit."
- "A ballpark figure for CAM2038 would be 16 mg of buprenorphine two times a day or 30 units a month, cost about $500 per month. Even if it were $800 to $900 per month, insurers may back it, even if 40% aversion."
- "It is common for the people to pay cash to see the doctors. Maybe half of the clinics are cash. You have to pay cash to see the doctor and get the treatment. This is common."
- "These drugs are highly diverted, and patients take one, then sell the other back on the streets, often so that they can afford to buy the drugs for themselves. There is a lot of sharing on the streets. Outside of Oxycodone, buprenorphine is the second most diverted medication in the United States."

2) National accounts manager for buprenorphine and methadone; repeat source

Allowing physicians to treat more patients should increase sales, although giving a growth time frame and rate is difficult. The source cited more awareness and funding available now, especially via Medicaid, which should allow more people to receive treatment. However, the future of government coverage is unclear. The implantable rods are too expensive for most patients who use methadone, many of whom are on Medicaid. Vivitrol is becoming more popular because people prefer using a nonopioid treatment, and a monthly injection is more convenient than receiving weekly medications.

April 8, 2016, interview: Long-acting buprenorphine would become widely adopted, especially as the opioid market continued to grow. The DATA 2000 would expand the use of maintenance treatments, allowing people to be treated in physician offices rather than methadone clinics. Less frequent treatment would be more convenient and would reduce diversion. Weekly treatments would be the preferred choice so that patients could continue with regular counseling. Other buprenorphine forms will emerge and change the market landscape. These new brands will come with higher price tags, but pharmaceutical manufacturers probably will make deals with insurers.

Opioid Treatment Rule Changes

- "Allowing physicians to treat more patients will increase the market, produce more sales, although I couldn't say by how much. There is growing awareness about opioid addiction, and in turn, there is more funding and more help. More patients are going to need more help, and now they will have more access to treatment. This problem continues to grow, and it is moving to the upper middle class."
- "The amount of treatment available will all depend on the physician. Some physicians may be of the mindset that patients should be in rehab a certain amount of time, then they should wean off the medication and free up the slots for other patients. You have this thinking vs. the school of thought that opioid addiction is a chronic disease and you need to stay on meds for a long time."

Long-Acting Buprenorphine

- "For the population I work with, the rods are way too expensive. I don't know how they are selling."
- "The weekly and monthly slow-release doses or buprenorphine would be more convenient than the daily dose, although many people with opioid addiction need daily treatment."
- "CAM2038 has better bioavailability than the film, and patients can take a lower dose."

Other Treatment Options

- "Vivitrol is popular because a lot of people prefer using a nonopioid for treatment, rather than using an opioid to treat opioid addiction. Vivitrol stops cravings and does not allow you to feel high. But there are still the socio-psychological issues."
- "The rules for Suboxone are a bit looser than for methadone. The DATA 2000 allows doctors to prescribe buprenorphine in their offices, not just in treatment clinics. This opened up the treatment market to even more people who might have resisted going to a clinic, but are comfortable in a doctor's office."
- "Suboxone stops working at 30 mg. With methadone, the more you give, the more effects it has. It is easier to overdose on methadone than buprenorphine. Methadone is mostly used for people with heroin addictions."

> **Allowing physicians to treat more patients will increase the market, produce more sales, although I couldn't say by how much. There is growing awareness about opioid addiction, and in turn, there is more funding and more help. More patients are going to need more help, and now they will have more access to treatment. This problem continues to grow, and it is moving to the upper middle class.**
>
> *National accounts manager for buprenorphine and methadone*

Pricing and Payment

- "I'm not sure how many insurers would cover the rods."
- "Buprenorphine is not quite 100% office-based. A small amount of buprenorphine is sold to methadone clinics. The majority of the folks on buprenorphine have insurance, and receive buprenorphine in an office situation, where one doctor treats all the patients. It is harder to get buprenorphine reimbursed at the clinics, so it is harder for the clinics to make money on buprenorphine. But this depends on the state."
- "Methadone is dispensed from the clinics on a daily basis because the patients are more unstable; it is not dispensed in an office setting. This depends on the regulations. Depending on the state, some clinics are covered by

Medicaid and state grants; others are not. Most of the people in the methadone clinics are on Medicaid and in the lower middle class. More people self-pay for meth at the clinics. If they don't have insurance, they pay cash."

- "Methadone is very inexpensive and much less expensive than buprenorphine. On an average, 90 mg of methadone costs less than $1 to $2 a dosage or $80 to $100 per week, which includes one to two days of counseling a month. Generic oral buprenorphine costs $105 or so per bottle of 30, and people take two bottles per month; this provides high margins for a company. The buprenorphine film is more expensive than the oral generic buprenorphine."
- "In our state, preauthorization is not needed for methadone. But everything else, film and generic buprenorphine tablets, requires preauthorization. [Orexo AB's/STO:ORX] Zubsolv, a film, is on our preferred drug list."
- "With the expansion of Medicaid, a lot of people have more treatment care. If the government changes things, this could cause problems. Given that this is an epidemic, opioid funding may continue. The new administration sees the benefit of treatment funding. If you have a governor, like we do, or a mayor who has experienced a family member with drug addiction, they feel more compassion and will create more awareness of the problem."

3) Opioid sales representative for an international pharmaceutical firm; repeat source

The cap increase will not change the market because many physicians do not have time to take on more patients. Also, family physicians have the least experience with opioids. The rods are meant for a limited-profile patient and will only affect a small portion of the market. Weekly and monthly buprenorphine will continue to be the most popular treatments, and more treatment options are welcome. Insurance reimbursement is more difficult for those who use opioids for pain, and rising copays make it more difficult for all patients.

April 8, 2016, interview: Long-acting buprenorphine might not be that effective for patients addicted to short-term opioids. Adoption would be slow because of the difficulty in transitioning patients from daily pills to a monthly or weekly regimen. Managed care would appreciate saving money on long-lasting medications. Physicians must be educated on the differences between short- and long-acting drugs, including buprenorphine.

Opioid Treatment Rule Changes

- "It is great that they are increasing patient access to pain medications and addiction treatments, but I don't think the patient increase will change the market. I have never heard of any family practice physicians complaining that they needed more patients. I think many of them may be at their maximum number of patients as it is."
- "I do have some concerns that increasing the patient cap affects the family practitioners, who are the doctors that have the least experience with opioids. I'm sure the doctors would want to add more patients to make more money, but they need to be educated in opioids first."
- "I did not know about the change for physician assistants or nurse practitioners, but again, they need to be educated in this space."

Long-Acting Buprenorphine

- "The rods are designed to give continuous-release low-dose medication, but this is used for a limited-profile patient. The rods would not be used for the many buprenorphine users who need to be seen by their doctor more often, on a weekly or monthly basis."

Other Treatment Options

- "The most frequently used buprenorphine products are those that are given weekly or monthly. This allows the doctors to keep track of their patients and see how they are doing. These people often need to be seen frequently."
- "The rods are another treatment option, and it is always good to have more options available."
- "There are many new buprenorphine products on the market. I believe that there is more research and development with buprenorphine molecules than with any other."

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>
> *Opioid sales representative*
> *International pharmaceutical firm*

Pricing and Payment

- "A 30-day supply of our films, 60 films, sold for $400 to $1,200 cash. Insurance would pick up most of that cost."

- "Our films were sold for pain, not for addiction treatment. We had lots of problems with insurance; it was hard to get them to understand that the film was just for pain. Insurers wanted patients to first try Suboxone, which is a higher-dose medication compared to the film's microgram dose, or hydrocodone, which is a Schedule II drug, rather than our Schedule III, which by the FDA's classification has less potential for abuse. It didn't make sense. The doctors' offices had a lot of hassles with insurance companies."
- "Increasing copays make it more difficult for people to be seen more often."
- "Some insurance companies do require preauthorization, others don't."

3) Industry Specialists

These five sources think the MAT rule changes will slowly increase the number of opioid abuse patients receiving treatment. One source reported an initial jump in patient number, followed by a slowdown. A second source said the effect will be minimal while a third said the growth will not be a big as expected by the medical community. Two sources said a change may be required in the medical practice business model, with additional and dedicated physicians and support personnel needed to exclusively treat opioid abuse patients. Challenging the expansion of treatment is the limited room for additional patients in the primary care setting even though many physicians who are buprenorphine-certified are not near the former patient cap of 100. Other headwinds are the limited number of medical professionals opting for a career in addiction treatment as well as the challenges in treating the opioid abuse patient group. The use of Probuphine is expected to be limited as the eligible patient population is small, the dosage is low, the cost is prohibitive, and the procedure requires minor surgery. Long-acting injectable buprenorphine could be promising. Given the high number of opioid overdoses, CAM2038 should be fast-tracked through the FDA. Three sources commented on reimbursement and coverage, which vary by state for Medicaid. One said preauthorization requirements are declining. Another said MAT is becoming more accepted, but noted barriers to treatment. Two sources think Vivitrol is working well and that Alkermes is successfully marketing to insurance companies.

Key Silo Findings

Opioid Treatment Rule Changes

- All 5 said the rule changes will slowly increase the number of patients seeking treatment.
  - 1 said initially the numbers jumped and now they have slowed.
  - 1 said the expansion will be minimal.
  - 1 said the numbers will grow, but not a large as projected by the medical community.
  - 2 said the medical business model may need more dedicated treatment professionals.

Long-Acting Buprenorphine

- All 5 said the use of Probuphine will be limited due to a small eligible patient population, the low dosage, the high cost, and the implant and removal procedure.
- 2 said long-acting injectable buprenorphine holds promise.

Other Treatment Options

- 2 think Vivitrol work well and that Alkermes has effective marketing.
- 1 said Vivitrol is not working and has a 90% dropout rate.

Pricing and Payment

- 1 said Probuphine costs were $5,000 for a 6-month treatment; Braeburn will front the physician the drug until reimbursed. Probuphine was billed as a medical device and a surgical procedure cost.
- 3 commented on third-party payers.
  - 1 said Aetna and Cigna have done away with preauthorization for buprenorphine, and hope others follow.
  - 1 said Medicaid differs by state on what and how much they will pay. Payments are up in the air due to all the pressure to deal with the opioid crisis.
  - 1 said clinics often only take cash and that reimbursement varies by state.

Miscellaneous

- 1 said MAT is becoming more accepted and that treatment is shifting to physicians' offices.

1) Physician and director of an advocacy group

The cap extension will not have a dramatic effect and will be helpful only for prescribers who have waiting lists. Those who work with a dedicated team could easily treat 1,000 patients, and the cap is a disincentive for creating a model of treating more patients. The rods are an interesting option but are designed for a very small portion of the market. Ultimately, Vivitrol is not working. Alkermes is aggressively marketing the medication to the criminal justice system, but the company has not published a clinical trial that shows a high attrition rate. New injectable buprenorphine in the pipeline could prove very promising. More insurers are removing the prior authorization requirement for buprenorphine, which may interest more PCPs in treating opioid abuse or in upping their patient numbers.

Opioid Treatment Rule Changes

- "The cap extension may not have a dramatic increase across the board. When you look at buprenorphine subscribers across the country, only a small percentage are already at their cap. The cap increase will not have a dramatic impact."
- "The cap increase will be very helpful for subscribers who are at their cap and have waiting lists. In some cases, people are dying of overdoses while on a waiting list. This is not that uncommon, considering how dangerous the heroin supply is right now. I have no doubt that lifting the cap in places where we need it will save lives."
- "Any cap at all is a problem if you are trying to see that more people who have opioid addiction have access to effective treatment."
- "I don't believe there should be any cap for sublingual buprenorphine, and a cap for a monthly injection or the rods makes absolutely no sense. There is an extremely low probability of any type of diversion."
- "The main problem with the cap—and this is less of a problem with the 275 cap or any cap less than 1,000—is it can serve as a disincentive for creating new models of care capable of treating large numbers of people. It makes it difficult for the addiction treatment providers, especially the state-licensed mom-and-pop providers, which have the minimal amount of physician time necessary for their license to develop a business model where they can make it work. If you decide to invest in this program because it is the right thing to do and decide to have a full-time doc, that doctor can only treat 275 patients. There is no way to scale it up. In an ideal treatment system world, there are drug counselors, social workers and therapists who can be working with that subscriber. With a multidisciplinary team, where the patient is being closely monitored, that subscriber could treat at least 1,000 patients."

> The cap extension may not have a dramatic increase across the board. When you look at buprenorphine subscribers across the country, only a small percentage are already at their cap. The cap increase will not have a dramatic impact.
>
> *Physician*
> *Director of an advocacy group*

Long-Acting Buprenorphine

- "If I were investing in sublingual products, I wouldn't be worried about rods eating up market share."
- "It will be interesting to see how implantable rods play out. I'm very happy that we have a new option available."
- "One of the issues is that the rods cater to patients who are already stable on an oral. If you have a patient who is stable on sublingual buprenorphine, there is really not that much reason to switch them over."
- "One of the limits of the rods is that it cannot release as much medication. I believe it's to a maximum of 8 mg per day, and there are patients who do very well on sublingual and get down to 8 mg and 4 mg. The rods would be a reasonable option for those patients. When you are first starting someone on buprenorphine, they tend to need more than 8 mg. Typically, 12 mg and 16 mg is what people get when they are first getting started."
- "There are some reasons to be a little nervous about the rods. It involves a minor surgical procedure to insert. Some people may do not it well, and there may be infections."
- "There are two different injections in the pipeline—competing, long-acting injections—that are pretty close. These will be very promising and something to watch. The monthly injection sounds very exciting. I haven't seen the trial data, but these could be excellent options and could work well for many patients. It would make sense for CAM2038 to be fast-tracked, considering that we have people who are overdosing and the crisis is severe."

Other Treatment Options

- "Buprenorphine is first-line. For patients who may need structure or support, methadone may be your next option. People do have to line up every day to get it, so it is not a great option. There are some people who can recover

without these drugs by using an abstinence-based approach, but they are the minority. Usually patients need a long-term treatment."

- "I don't think Vivitrol is a very good medication for opioid addiction. It is being overprescribed to the wrong patients. It may play a role in patients who have mild opioid use disorder, such as a young person who hasn't been addicted for very long, and you want to avoid putting them on a long-term treatment such as buprenorphine or methadone. Or Vivitrol could also be used for a patient who has been doing well for many years and is in remission. It might make some sense as a bridge to abstinence."
- "Vivitrol is being aggressively marketed for a criminal justice population where you are more likely to see people who are heroin injectors. The people in the criminal justice system are more likely to have moderate to severe opioid use disorder. For that population, Vivitrol is a very dangerous treatment. If a patient misses their injection, Vivitrol actually makes you super-sensitive to opiates; your tolerance doesn't just go down to normal."
- "Vivitrol sounds great, but if I were an investor, I wouldn't be putting money on it. It is being overpromoted. Ultimately, the data will show that it isn't working. If you look at all the drugs available, for some people Vivitrol sounds like the best option, and a lot of people are going for it. But I think they are making a very big mistake. You need to find the right medicine for the right patient. Ultimately, the public and policy makers may start to learn the hard way that this is not the right treatment."
- "There is already some evidence that Vivitrol has increased overdose deaths in patients. Alkermes has data from a registry trial that they did that they never published. They released a little bit of the data, and it was awful; they had a greater than 90% dropout rate. This was not good."

Pricing and Payment

- "I'm hopeful we'll see more payers removing the prior authorization for buprenorphine. It is a first-line treatment for a life-threatening problem, and there shouldn't be any barriers to doctors prescribing it. I don't think they should remove prior authorization on Vivitrol. The reason prior authorization exists is to steer doctors away from prescribing a particular treatment. It makes sense if you don't want to pay for an expensive brand drug when a generic will do the same for much cheaper, so you make the doctor jump through more hopes."
- "Aetna has done away with prior authorization. I believe Cigna has announced that they will. I'd like to see this done across the board. If that happened, more primary care doctors would be interested in treating an opioid addiction or willing to take more patients. That would be very helpful."

2) Researcher in opioid treatment patient cap at a Midwest university

Increasing both the patient cap and the number of counties offering buprenorphine treatment should increase medication usage. Medicaid offers varying state coverage of buprenorphine, even though it is on the formulary, and any future Medicaid changes will raise concerns. Implants will address the diversion issue. Vivitrol is worth the expense because it addresses not only the diversion issue but also adherence problems, and the medication is not an opioid. Also, Alkermes does a great job of marketing the drug to insurers.

Opioid Treatment Rule Changes

- "Certainly, there is a big need for more subscribers who can treat opioid addiction. Should more clinicians increase their patient load, or increase in numbers in counties that currently do not have subscribers, I think you would see an increase in medication usage."
- "Physicians who specialize have patients on long-term regimens and will max out. Before they upped the cap, you'd have physicians who couldn't accept new patients because of their long-term existing patients. I'm not sure of the percentage of capacity, but I think it will be harder to cap with 275. There are only so many patients a physician can carry. The cap issue is not as prevalent with general practitioners. But there is this feeling that there is not enough writing capacity for this medication."
- "On the patient level, if they need help and are ready, they go seek it. I don't think they pay attention to the cap per se. But it is very real if they seek help and can't find someone who can help. Or they may have to travel to a metropolitan area for that help to happen."
- "Around the country, we are still in need of physicians to treat opioid addiction. According to a 2015 study by Bradley Stein, there is a high percentage of counties in the United States that don't have any buprenorphine subscribers at all. … Ohio and Wisconsin have maps that show at least eight or 10 counties without any buprenorphine subscribers

at all. The states are trying to address this issue. I bet if you dug deeper to see how many subscribers could not accept new patients, you get an even bigger number [of counties]. Access will be an ongoing issue."

- "You have a shortage of [practitioners] in the regular healthcare systems and also community-based systems that have trouble affording physicians from other areas. You have these two opposing dynamics."
- "Nurse practitioners and physician assistants tend to be more available, so they may add to the numbers. That is a way to address this problem. It doesn't surprise me [that they may be able to insert implantable rods]."

Long-Acting Buprenorphine

- "The diversion of buprenorphine is one of the criticisms of the drug, and the implants will certainly address that. I have not done any studies on the rods."

Other Treatment Options

- "Avoiding diversion is an argument for Vivitrol. Different medications work for different people. But with Vivitrol, you have … clinicians who have a problem with the diversion issue. And the adherence issue too. Once you get the Vivitrol shot, you are set for 30 days. And Vivitrol doesn't have any opioids in it, so philosophically that works better for people. It is easier to sell to a legislature."
- "Alkermes is effective at marketing on multiple levels, including the state level."
- "I assume that monthly treatment would be better than weekly, to the degree that providers are keeping track of people, and patients are able to demonstrate that they are being responsible. Where is the sweet spot between length of take-home? It's a clinician decision. Most of the organizations I work with, the notion of going straight to 30 days would cause some to raise eyebrows. There are a lot of questions in the initial part of this therapy."

> **There is a lot of momentum now to get MAT, but insurers have their own rules that create barriers.**
>
> *Researcher in opioid treatment patient cap*
> *Midwest university*

Pricing and Payment

- "Part of Alkermes' marketing effort is to bring insurers onboard. More insurers are starting to pay for it; it's actually pretty impressive. It is not a cheap medication."
- "With the insurers, it will be a consistent battle or issue. Their rules will affect access. In Florida, getting Medicaid to pay for buprenorphine is pretty difficult. A Pew study showed that a very low percentage of buprenorphine in Florida is paid for by Medicaid even though the medication is on their formulary. It is probably not easy to get access to the medication as well, or those numbers wouldn't be so low. But Vivitrol is very popular in Florida."
- "Ohio has redesigned their Medicaid program. They've taken Suboxone off the formulary and have replaced it with a generic. That is probably OK, but I know already that there is some alarm."
- "There is a lot of momentum now to get MAT, but insurers have their own rules that create barriers."
- "No one knows what will happen in the future with insurance. How can you even say? With all the public pressure on it right now, you'd think that the environment would be receptive. The benefits were pretty limited for a while. Hopefully, benefits will expand, but I think we will have to wait and see."

Miscellaneous

- "This whole issue of how MAT is part of the constellation of care is an evolving issue. The community is getting more accepting of MAT, and it is getting easier to find support groups. The acceptance issue is pretty big. The other issue is that more and more, this will be done in physician offices. Typically the therapy component will be less. Is that OK? There are differing opinions, but ultimately, we don't know the answer."

3) Licensed clinical psychologist with extensive expertise in addiction management; repeat source

Providers' interest in increasing their treatment caps to 275 patients is quite modest at this point. The source foresees a slow upward trend of people seeking opioid addiction treatment in the next five years or so. Methadone administration for addiction has more clinical oversight than buprenorphine. Still, the source surmises that it would be more difficult for a patient on buprenorphine to take more of that medication to get high, particularly formulations that contain naloxone.

April 8, 2016, interview: Long-acting buprenorphine would help decrease diversion issues, but would take some time to be widely adopted and would not affect treatment outcomes much since buprenorphine adherence was already high. Monthly dosing likely would be the preferred mode to fit into counseling regimens. The CDC guidelines and federal

attention were driving higher buprenorphine use. Buprenorphine was replacing some methadone use although the CDC guidelines actually might increase heroin addiction. Indivior had a good reputation.

Opioid Treatment Rule Changes

- "The impact [of the 275 cap] is slow as far as I can tell. I travel around and talk to prescribers all around the country every week, and I ask about this stuff—are you planning on taking advantage of the new cap and all of that. And I find a very modest interest so far at least with the folks I've been meeting. They say, 'Maybe we will expand a little bit, but we don't really want to add that much more.' Then there was one practice I went to that said, 'We are considering hiring a full-time Suboxone provider there, and that person might take on the larger cap.' So they were still trying to figure out how to work with that."
- "It's probably going to be a slow trend upwards [of people seeking treatment for opioid addiction]. The epidemic is not going away and … as it kind of comes out of the shadow more and more every year, more people are going to be seeking treatment for it. Plus, you have more folks in higher socioeconomic strata dealing with it now than in the past. … I'm kind of looking at this from a five-year point of view."
- "A lot of places I encounter, they are up there in the 100 zone, but the thing is a lot of buprenorphine is prescribed in settings where they aren't dedicated to addiction treatment. A lot of primary care settings will have doctors with the DATA waivers, and they don't have room in their practice to expand it by that much. There is already a lot of pressure for them to have a lot of patients because of lower reimbursement than in the past."
- "So the ones who are truly trying to take advantage of it are shifting some of their strategies. Their business model has to adjust. They have to bring doctors into the practice who will be dedicated Suboxone providers."
- "Most opioid pain management is delivered by primary care doctors across the country, and they don't like dealing with the problems that come with opioids, especially now that there is so much more scrutiny, negative press and all that stuff and pressure from the government and fear. … I'm helping doctors to learn about all the various tools they can use to manage those patients. But these patients require more time than patients without these problems."
- "I have seen practices where they prescribe a lot of buprenorphine [for addiction] and even some practices that do it on a cash basis, and they don't use any tools to manage the risk. I am very concerned about that."

> **The impact [of the 275 cap] is slow as far as I can tell. … I find a very modest interest so far at least with the folks I've been meeting. They say, 'Maybe we will expand a little bit, but we don't really want to add that much more.'**
>
> *Licensed clinical psychologist with expertise in addiction management*

Long-Acting Buprenorphine

- "I've been asking about [Probuphine] here and there. I find there are folks who are curious about it. I'm still unclear about one detail. I read somewhere recently, a review article … that when doctors prescribe Probuphine, it doesn't count towards the cap. They can prescribe as many of those as they want, and they still have the same higher cap. I'm not sure if that's true, but that's what I was just reading."
- "The insurance and money piece is important. If you are talking about the implant, which is the expensive one, most people won't have access to that. There will be a market for it, but it will be a specialty market. There are plenty of wealthy people who have opioid use disorders and want treatment for it."
- "There are important differences [between daily buprenorphine and methadone]. They both work very well. Methadone is a little more dangerous just because chemically, it's just a riskier drug. … Methadone is more stigmatized than buprenorphine. The other thing is because of the regulations around methadone when it's used to treat addiction anyway, there is more scrutiny."
- "Generally, [patients] have to take it at the methadone clinic, and that's an obstacle. A lot of folks don't want to do that. They feel like criminals, and they are hanging out in places where they don't want to be. … But one of the things that makes methadone work well is you aren't just throwing pills at people. … They have to provide other kinds of support and other kinds of treatment. They are clinically providing more scrutiny."
- "As for clinically what's appropriate—[buprenorphine] daily, weekly, monthly dosing—patients have to be motivated. It depends upon what scrutiny is available, how much time the doctor has. Certain patients have just much more complicated lives and a longer addiction history … and there is a black market for this stuff. I'd hope doctors are looking at their patients as individuals and assessing their risks, but I think a lot of them are not."

Other Treatment Options

- "[Vivitrol] is expensive. That can always be the obstacle, and lot of patients won't have access to it. But besides that, clinically it's also hard to get patients to sign onto it because patients are not as motivated to use Vivitrol as they are even buprenorphine. People just sometimes forget that we are talking about an opioid that has some of the same effects on the brain as any opioid. … There's an intrinsic motivation to take [buprenorphine]. It's not just relief."

Pricing and Payment

- N/A

4) Specialist in medication-assisted treatment

Physicians who accept insurance are gaining the most patients under the 275 cap. This source thinks 130 to 140 patients is a more realistic number for an efficient provider to treat. Also, hiring a midlevel provider to provide buprenorphine in a large physician practice would be a smart business move. Cost and patient preference will determine utilization of long-acting injectable buprenorphine. Addicts do not like to abandon the control they feel when taking daily oral medications for their disease. Vivitrol has found a niche in the criminal justice system.

Opioid Treatment Rule Changes

- "The changes [due to the 275 treatment cap] haven't been as robust as people hoped. A lot of the docs whom I deal with did apply to go to 275 and were obviously approved, but most of them are not seeing more than 130 to 150 patients just in terms of being able to handle that volume."
- "The interesting thing that I've noticed is that the docs who went to 275 who got the greatest patient influx were the docs who accept insurance rather than those who only take cash."
- "There seems to be a shortage of doctors who will take insurance vs. those who don't."
- "A lot of patients [on waiting lists] have been taken care of now because of the cap increase, but I don't think it has any real effect on new patients seeking treatment just because there's been an increase in capacity. I don't see patients being privy to that information."
- "When [physicians] were capped at 100, most of the docs, especially in the inner cities, were basically tapped out. … Sometimes they had a waiting list. Across the country … it's maybe almost 50/50 in terms of who is at capacity, whether it's by their own assessment that they only want to see so many patients or they hit the 100 or 275 mark. I know of a small handful [who have hit 275]; again, surprisingly enough they are the ones who only take insurance."
- "If we see a difference in the [opioid addiction treatment] market due to the cap and inclusion of NPs and PAs, it's going to take time. No. 1, the NP and PA groups haven't demonstrated a lot of excitement around doing this. They are not kind of diving into this. … The encouragement of doctors who have larger [addiction treatment] practices to bring in a midlevel provider to help them obviously being cheaper than a doctor would be a good business decision, especially if [the midlevel providers] are supervised."
- "The exact language of the law says if doctors are going to participate in [buprenorphine] treatment of these patients, they only have to have the ability to refer [patients] to counseling."
- "[There are] a lot of folks who do [counseling] in-house. About 20% of the market is psychiatrists. A lot of them will claim they do it themselves while seeing the patient. And then there is a good chunk who refer out as well."
- "To have it all in one clinic with the docs [and counseling] in there—there's a fair amount of that."
- "A lot of [providers] just don't have access to [counseling]. I've been to clinics … where there are no behavioral health professionals or therapists within a 200-mile radius. They basically try to provide some very basic counseling points, motivational interviewing and some other things that have been shown to work."
- "A single provider with a good operational flow in the office can probably adequately treat 130 to 140 patients a month. My opinion is the 275 [cap doesn't help them]."
- "My concern when I first heard about the 275 was more around the lines of pill mills and diversion of Suboxone, and we have seen a lot of that."

> **The changes [due to the 275 treatment cap] haven't been as robust as people hoped. A lot of the docs whom I deal with did apply to go to 275 and were obviously approved, but most of them are not seeing more than 130 to 150 patients just in terms of being able to handle that volume.**
>
> *MAT specialist*

- "The 275 piece is only going to promote more diversion than open access to treatment. I don't think you are going to see a noticeable impact on the opioid epidemic just by raising the cap."
- "I do know we have a significant amount of states that still don't allow [NPs and PAs] to prescribe controlled substances."
- "Definitely [practices are hiring more people]—usually more ancillary staff, medical assistants, billing folks, things like that. From the physician's perspective, no one has really jumped on bringing on NPs and PAs that aggressively."
- "From the counseling standpoint, usually the ones I know who have ramped up and have gone to high numbers in the clinic have needed to hire additional counseling resources as well."
- "Just from a baseline standpoint, it's been shown that at least 60% or more of patients who report to treatment or seek treatment for opioid dependence also have some sort of behavioral health component. … It's very difficult to justify not at least offering or strongly encouraging counseling."

Long-Acting Buprenorphine

- "Probuphine has relatively limited utility due to the fact that it is indicated in patients who are on lower doses of Suboxone than most other patients. … The Probuphine implant is indicated for people who are on 8 mg or less."
- "The other thing is that it requires a small surgical procedure. Although a lot of docs went to the training, it was more out of curiosity and a learning experience than they had any plans to do this. I can think of two doctors whom I have encountered who have utilized it and have had very mixed results with it in terms of control of people's craving."
- "I almost want to tell you [Probuphine] is a dead issue. I don't see that product doing a lot from here on. There's very small utilization across the country. The uptake just hadn't been there, and again I just don't see anything changing that's going to enhance that. It's been out probably close to a year now."
- "Doctors are a little more excited about [the injectables]. I think there are going to be more apt to encourage that or promote that with their patients than they would be the Probuphine implants. Whether the payers cover it or whether the patients decide they want it—those are the two variables right there."

> The 275 piece is only going to promote more diversion than open access to treatment. I don't think you are going to see a noticeable impact on the opioid epidemic just by raising the cap.
>
> *MAT specialist*

- "Any patient who has reached what we call the maintenance treatment of their disease … would be a candidate for a long-acting injectable product. They are showing signs of true recovery."

Other Treatment Options

- "Vivitrol is a small percentage of the market. It's a different drug than buprenorphine in terms of how it acts, but it … produces the same types of outcomes. The challenge is it's a once-monthly injection. It's expensive, and there's a lot of miseducation … in the treatment community about the product. What you don't understand, you tend to fear."
- "The niche that Vivitrol has actually found is in the correctional and criminal justice system. The probation officers and the judges and the drug courts love it because it's not a controlled substance like buprenorphine or Suboxone."

Pricing and Payment

- "Probuphine is $5,000 for a six-month course, and the company actually has a program where they will front the cost of the drug until the doctor gets reimbursed."
- "Probuphine is billed out as basically a medical device and a surgical procedure cost."
- "The clinic might only take cash."
- "[Reimbursement for an office visit] depends obviously on the state and the insurance plan. In some states, the reimbursement is so terrible for these visits that I understand taking cash, because otherwise you couldn't keep the lights on. It's not like that everywhere. For an average visit, if they get $60 or $70, you are getting good reimbursement for a patient encounter. Therapy is usually a little bit less per hour, and then for a urine drug screen, they may give you $20 to do a urine drug screen in a cup. A urine drug test costs [the provider] $3 or $4."

Miscellaneous

- "We are getting there [in terms of the government requiring injectable buprenorphine rather than oral forms for addiction treatment], and there are some states that are bold enough, especially for their Medicaid programs, to do that or require it in the first line. … The problem is, anytime anyone who wants to do anything like that, you get docs fighting it tooth and nail. They are very apathetic about diversion. They actually cite this term called 'harm reduction,' basically saying, 'I think diversion is a good thing because I'd rather have buprenorphine on the street than oxycodone.'"

5) Educator in addictions and addiction treatment

A subgroup of physicians who likely were already full-time treatment providers immediately expanded their caps to 275. The source expects nominal Probuphine utilization for a long while. Suboxone has a strong presence in the market.

Opioid Treatment Rule Changes

- "There's a subgroup that jumped on [the increased 275-patient cap] that really wanted it, and they went ahead and immediately did it. SAMHSA on its website has a record that I think they update almost weekly or at least monthly of how many [physicians] have each waiver level. We kind of looked at that and noticed that when [the 275 cap] was approved, there was a dramatic increase as soon as it was allowed. … Then after that we didn't see much jump in it. It was just creeping up slowly. We just assumed it was people who were already in the business of full-time addiction treatment who were happy to increase [their cap]."
- "As of Monday [Feb. 20, NPs and PAs] can apply. It might have gone through a few days ago, but as of Monday, it's easier to apply. The online form was available."
- "We do a lot of training in opioid prescribing and other treatments. I do think [the opioid addiction treatment market using buprenorphine] will increase over time. It has been steadily increasing slowly based on our rate of training. As long as the opioid epidemic keeps increasing … the treatment will continue to increase."

> **[The opioid addiction treatment market using buprenorphine] will increase over time. It has been steadily increasing slowly based on our rate of training. As long as the opioid epidemic keeps increasing … the treatment will continue to increase.**
>
> *Educator in addictions and addiction treatment*

Long-Acting Buprenorphine

- "The [use of the long-acting Probuphine] is going to be minimal for a long time."
- "New formulas [of buprenorphine] have come out, and they are just really not being used. … Even though there's generic, it's mostly Suboxone. If you talk to the physicians … they don't know buprenorphine. That company has succeeded in marketing [Suboxone]. So I guess the rods people and if the extended-release forms come out, they are going to have to compete with their marketing."

Other Treatment Options

- N/A

Pricing and Payment

- N/A

Miscellaneous

- "[Clinicians] complain about some of the aberrant behaviors that some addicted people have, such as diverting the medication, pretending that they took it when they are actually selling it, broken appointments. It's a group that tends to have a higher rate of not following through. … It's a concern that keeps many providers from starting to try to even treat people with this disorder. It's a real concern, but it's manageable. It may not be as big as they think."

4) Third-Party Payers

These three sources said coverage for MAT varies by insurance company and by state for public health coverage, and is a moving target. The source representing Medicaid said coverage is limited to only one of the three mainstays—buprenorphine, naloxone, and methadone—in 18 states but is available for all three treatments in 32 states. This source also said the number of people eligible for MAT would decline if Medicaid expansion is rolled back.

Key Silo Findings

Long-Acting Buprenorphine

- 1 of 3 said recovering from the last 2 mg of buprenorphine is very difficult.

Other Treatment Options

- 1 has had a successful experience in Europe with naltrexone implants for the treatment of alcohol abuse.

Pricing and Payment

- 1 said coverage by insurance companies generally follows the CMS guidelines, but acknowledged that some insurance companies do not cover treatment at all. Companies that do provide coverage generally cover 50%.
- 1 source representing Medicaid reported coverage in 18 states for 1 drug of the 3 main opioid addiction drugs, while 32 states have coverage for all 3 treatments.
- 1 said insurance coverage varies from state to state but generally has declined overall.

1) Private health insurance broker in the Midwest

Most addiction treatment falls under the rehabilitation category, usually as outpatient care. Insurance coverage varies for rehabilitation, and some insurance policies do not cover opioid recovery. Generally, insurers follow CMS guidelines. Insurers are more likely to pay for opioid treatment than they are for diabetes or hepatitis C. In this source's state, carriers cover 50% of treatment after the deductible has been met. Younger doctors are less likely to prescribe opiates for pain.

Long-Acting Buprenorphine

- N/A

Other Treatment Options

- N/A

Pricing and Payment

- "Honestly, I haven't seen or heard of any problems with insurance coverage for opioids. I've seen problems with insurance for diabetes and hepatitis C, but not opioid treatment."
- "Different insurance companies have different rehabilitation policies, and treatment for addiction falls under rehabilitation in most cases. Some insurance companies won't cover rehabilitation."
- "In our state, most insurers cover treatment recovery as outpatient. The insurers cover 50%, and the patients pay 50% copay. But they first need to reach a deductible. Under the ACA, the lowest deductible is $3,000, and the highest is $10,000."
- "The companies all have a different set of deductibles and copays. They run their own auxiliaries, and spend an enormous amount on them to determine their coverages. It is a whole insular industry; that's the biggest problem. If we eliminate government control, it would work."
- "Reimbursement is all price-driven and negotiated platforms. Insurers negotiate with the drug companies for pricing."
- "Most insurers follow the CMS guidelines, especially if they are offering Medicare supplements. I don't think CMS should dictate what insurance companies do, but the AMA treats everything that CMS does as standards of practice. When you are locked into control boards handling that, there is never an upside to control."
- "People who don't use pain killers, opioids, must still pay for insurance that covers opioid use. I haven't had any clients tell me they wouldn't want this, but they just don't know everything that is covered, and they don't know enough to ask."
- "Physicians, especially the young physicians, are more reluctant to prescribe opioids than the insurers are to pay for it. They've had the problems with opioids heavily thumped into them in seminars and continuing ed. I had a client with a 91-year-old mother, and a young physician didn't want to give her pain killers because the doctor was afraid she would become addicted. It has become ridiculous."

> **Different insurance companies have different rehabilitation policies, and treatment for addiction falls under rehabilitation in most cases. Some insurance companies won't cover rehabilitation.**
>
> *Private health insurance broker*
> *Midwest*

Miscellaneous

- "People need to become educated on the tendencies to become addicted while taking pain medications. I don't know of any insurance classes on this, but there should be."
- "We used to have bronze, silver and gold plans, and it was easy. But now the market is so convoluted."
- "Insurance used to be sold in different buckets, and you'd buy hospital, outpatient, ambulatory coverage, emergency room, only what you needed. Now we can no longer make *a la carte* decisions. One size fits all now, and a 75-year-old-man must buy insurance with a maternity policy."

- "We have an enormous wall chart in the office with all the ACA choices. They should repeal this monstrosity. By 2019, the ACA will be complete, and by 2020, we will have a system similar to Britain or Canada. Our wait times will be unbelievable. We will end up having a dual system; if you have money, you can pay for extra treatments. If not, you wait."
- "If they repeal Obamacare, we will have an immediate jerk to one side and a rush for competition. We will have to wait six to nine months for a set of good plans."

2) Substance abuse and Medicaid public policy analyst at a research center on the East Coast

Medicaid is financed by a number of federal and state funds. Under the current ACA regulations, most opioid abuse treatments are considered optional benefits by the CMS, and as a result, services vary by state. Eighteen states cover at least one of three Medicare-approved medications—buprenorphine, naloxone, and methadone—and 32 states have approved all three. Medicaid expansion, which includes all people at 133% of the federal poverty line, now is also state-optional. Repealing Medicaid would limit the number of people eligible for care, and restructuring Medicaid could limit the money provided for treatment.

Long-Acting Buprenorphine

- N/A

Other Treatment Options

- N/A

Pricing and Payment

- "Medicaid benefits fall into two categories, mandatory and optional, as determined by the federal government, specifically CMS. Mandatory benefits, as the name suggests, must be covered by federal law. These benefits include physician services, in-patient hospital services, seeing a psychiatrist or getting in-patient psychiatric treatment. Each state can also cover additional or optional benefits. There is a broad range that can include prescription drugs and nonclinical services, such as peer support and community residential services. A lot of these coverages are important for people with addictions. Optional benefits really vary from state to state."
- "There are three medications for opioid use disorder recognized by Medicaid: buprenorphine, naloxone and methadone. All of the states cover at least one of the medications, and 32 states cover all three medications."
- "According to the ACA, which was implemented in 2010, Medicaid eligibility was mandatory for some populations of the country but not others. This varies by state, and states can expand their eligibility. One group that was typically left out of Medicaid coverage in a lot of states was childless adults. … A lot of people who didn't have children or didn't have custody of children, such as single adults, were often not eligible for any type of insurance coverage. This has particular implications for people with addictions; it is very common for many of them to be single men."
- "As part of the Affordable Care Act, initially as it was written in 2010, all states were required to extend their Medicaid eligibility so that all adults at or below 133% of the federal poverty line would automatically be eligible for Medicaid regardless of whether they have children or had a disability that made them ineligible. It was just based strictly on income. But then there was a second-part ruling in 2012 that made this optional for states, so they weren't required to extend Medicaid eligibility."
- "Medicaid programs first started being expanded in January 2014. As of today, there are 32 states, as well as the District of Columbia, that have expanded Medicaid eligibility to all adults at or below 133% of the federal poverty level. Many more people are now eligible for Medicaid."
- "Medicaid expansion is often the only way that people with opioid addictions can get any treatment. They can receive medication-assisted treatment along with psychosocial support services."
- "The opioid epidemic is all over [the country], but it is largely concentrated in Appalachia and New England. More than half of the states in those regions have extended Medicaid as part of the ACA, so a lot of those people do have Medicaid coverage right now. I don't know if they will be in the long term."

> **There are three medications for opioid use disorder recognized by Medicaid: buprenorphine, naloxone and methadone. All of the states cover at least one of the medications, and 32 states cover all three medications.**
>
> *Substance abuse and Medicaid public policy analyst*
> *East Coast research center*

- "There are two big policy issues with regard to Medicaid right now: 1) repealing Medicaid, which will limit the number of people eligible for care, and 2) restructuring or refinancing, which will dramatically decrease the amount of money available for Medicaid."
- "All those people who became newly covered by Medicaid may actually become uninsured again. Taking Medicaid away will probably have pretty catastrophic effects."
- "I don't know enough about private insurance to say if they would follow any changes that might take affect with the ACA. Generally, Medicaid is more comprehensive than private insurance."

3) Vice president of an advocacy group on the West Coast

Naltrexone implants have been available in Europe for quite some time, and they appear to be very effective for treating alcohol and drug addictions. Buprenorphine should be used with caution, given the difficulty in weaning off the last few milligrams. Each state has its own insurance model, and benefits vary widely between insurers. Generally, blue states offer better benefits than Southern red states. The industry is fraught with insurer fraud. Should the ACA be repealed, hundreds of thousands of people with opioid abuse could lose their coverage.

Long-Acting Buprenorphine

- "I have seen a lot of my hardcore clients with naltrexone implants from Germany, and I think they are implanted subcutaneous in the leg. Other countries have been using implants—or weekly shots—for a while, but the implants aren't approved by the FDA here. I've seen patients on naltrexone who haven't needed a drink in a year."
- "There is also a new naltrexone implant in Europe that includes something in it to prevent infection. It is not FDA-approved."
- "With buprenorphine, people go through agony to get off the last 2 mg, to finally discontinue buprenorphine."

Other Treatment Options

- "In the old days, I didn't believe in MAT, and to some extent, I still don't. But I've seen patients on naltrexone who haven't needed a drink in a year."
- "I don't think people should be on buprenorphine for life. It is OK for short-term use. People can become addicted to it although that is a different type of addiction."

Pricing and Payment

- "Each state has its own specific insurance model. The insurance companies don't honor our state model, which was developed by the legislature in the late 1970s. It says that people with addictions are best treated in small residential-like settings and not in large institutions. In the small settings, you only have six beds; it is not like a hospital. So if insurance companies try to pay nothing, it is very hard for these centers to survive."
- "In the late 2000s, we had to constantly fight insurance to pay for treatments. It took me 2.5 years to collect all receivables, but I got it. I thought insurance was bad then, but it is nothing like it is now."
- "All of the insurance companies have gone from paying generously to almost paying nothing. In January, we had a meeting with the state's three regulatory agencies. Because of the insurance fraud, we don't have enough in-patient beds to cover the insurance crisis. They are on notice as of right now. This state has a lot of people who need addiction treatment. They created this state model, and they have to stand by it."
- "A year ago, I would have told you Cigna [was better at paying for treatment]; they were always the most reasonable player on the block. But now there is a new Ingenix called Viant [Payment Systems Inc.], a private company. They are supposed to be a for-profit UCR cost-containment vendor. But according to the New York attorney general, basically they are getting paid a percentage of every dollar they save the insurance companies. They are more interested in the bonus at the end of the month than in anything real. And now Cigna is using them too. The head of Cigna Behavioral Health denied that they used them, but that is not true. We filed a complaint with the Department of Labor, and there will be some type of investigation, either through the department or the courts."

The insurance companies don't honor our state model, which was developed by the legislature in the late 1970s. It says that people with addictions are best treated in small residential-like settings and not in large institutions. In the small settings, you only have six beds; it is not like a hospital. So if insurance companies try to pay nothing, it is very hard for these centers to survive.

VP of an advocacy group
West Coast

- "It's impossible to me that in a high-end facility, Cigna allows this group to come in and try to pay only 10¢ on the dollar, basically destroying the value of the insurance policies that all of the Fortune 500 companies use to attract workers in a very competitive work environment."
- "The list of the blue states, state by state, [are better at paying for drug abuse treatment]. It is kind of like blue states vs. red states, in a pre-Trump definition. There are some states that just never want to accept their policies, or they haven't changed since 2009. You can depend on Texas, Louisiana, Alabama, Arkansas, Georgia all to pay really badly. So badly, in fact, that we didn't want to take their insurance. You can depend on New York, New Jersey to pay well. In these states, they have already passed legislation that approves two weeks and one month, respectively, of addiction treatment without prior authorization. California's residency services are full. There is no room. We hope that California also starts a legislative process regarding prior authorization."
- "We are coming to a huge crisis in this state in terms of abuse treatment. More than 10 years ago, all treatment was based on cash. Everyone paid cash. Our patients didn't want their insurance or employer to know about their problem because in those days that was known as a preexisting condition. After the economy crashed, everyone gradually switched to insurance. I believe that you will now see the high end, the rich and the famous, going back to cash because insurance companies are not honoring the benefits of the policies. The healthcare services are trying to set up larger facilities, an efficiency of cost, for the people on Medicaid."
- "When the Affordable Care Act came in, and companies like HealthNet began to offer personal policies with good benefits, we actually had people come into our clinic on those policies who had never had substance abuse treatment before. The amount of mental health coverage was huge compared to other people who came in and had mostly employer-sponsored insurance policies. These latter people were able to get some type of treatment for years and had fewer mental health issues than people who came in through the ACA. It is very frightening to me that the ACA may do away with, in whole or in part, substance abuse and mental healthcare, and there will be not treatment yet again for hundreds of thousands of people, if not more."
- "If the ACA goes away, maybe [our state] will do its own insurance. We certainly can't go back. We are now trifurcated. … A drive is already underway to change the way the state regulates, and possibly be like New York, with everything under the head of the attorney general."

Secondary Sources

These five secondary sources focused on Braeburn Pharmaceuticals being named a "Top 10 Innovative Company in Biotech," the successful results of its multisite CAM2038 trial, the CMS designation of a J-Code for Probuphine, five facts about CAM2038, and data showing dramatically higher health insurance spending on opioid abuse disorder patients.

Feb. 13 PR Newswire article

Fast Company bestowed "Top 10 Most Innovative Company in Biotech" honors on Braeburn Pharmaceuticals.

- "Braeburn Pharmaceuticals was named today by Fast Company as a Top 10 Most Innovative Company in Biotech in conjunction with its annual ranking of the world's 50 Most Innovative Companies for 2017."
- "Braeburn's mission is to develop and deliver individualized, long-acting medicines to patients that suffer from serious, stigmatized neuropsychiatric disorders such as opioid addiction, chronic pain, and schizophrenia. In May 2016, Braeburn's Probuphine® received FDA approval and became the first buprenorphine implant for the long-term maintenance treatment of opioid addiction. This year Braeburn plans to file a new drug application (NDA) for a weekly and monthly injectable buprenorphine for the treatment of opioid dependence, and to progress a six-month risperidone implant for the treatment of schizophrenia."
- "'The team at Braeburn Pharmaceuticals is focused on bringing cutting-edge innovations to underserved patient populations,' said Behshad Sheldon, President and CEO of Braeburn Pharmaceuticals. 'We developed our pipeline strategically to include long-acting injectable and implantable formulations that ensure patients can receive the optimal dose of medication on a continuous, long-term basis. This past year our team accomplished so much, but considering the epidemic scale of opioid addiction in the U.S. alone, our mission remains critical; the potential benefit of our work has never been more apparent.'"

Jan. 23 The Lane Report article

CAM2038 was found to be an effective treatment for opioid abuse disorder patients.

- "A multi-site clinical trial led by researchers at the University of Kentucky Center on Drug and Alcohol Research (CDAR) has demonstrated the effectiveness of CAM2038, a potentially transformative buprenorphine therapy for moderate-to-severe opioid use disorders."
- "The randomized, double-blind clinical trial compared the performance of weekly and monthly CAM2038, a fluid crystal depot buprenorphine therapy developed by Braeburn Pharmaceuticals and Camurus, with the current standard of care, a daily sublingual dose of buprenorphine/naloxone. In this Phase III trial, non-inferiority was demonstrated on the primary responder rate outcome, which was based upon highly sensitive urine testing detecting illicit opioids."
- "Opioid overdose causes more than 30,000 deaths every year, and 2.6 million Americans suffer from an opioid use disorder. More than 12.5 million people misused a prescription opioid pain reliever and 800,000 used heroin in 2015. The National Institutes on Drug Abuse has called for safe, proven solutions to initiate treatment and stabilize patients through an extended opioid maintenance and recovery program. The Surgeon General's Report has called for more access to evidence-based effective treatments, such as buprenorphine, for opioid use disorders."
- "The study's positive results provide a firm foundation of supportive evidence necessary for entering the FDA-approval submission process. Evidence from the trial suggests people with a moderate-to-severe opioid use disorder might benefit from receiving an injectable therapy administered on a weekly or monthly basis. The weekly injection is appropriate for induction and initial stabilization, and the monthly injection is conducive for stabilized patients. Together, both week and monthly medications allow for flexible and individualized dosing that is critical for optimal patient outcomes and recovery from a deadly disease."

Jan. 13 PR Newswire article

Braeburn Pharmaceuticals' Probuphine implant received a J-Code by the CMS.

- "Braeburn Pharmaceuticals, Inc. today announced that the Centers for Medicare & Medicaid Services (CMS) has granted a Healthcare Common Procedure Coding System (HCPCS) code, or permanent J-code, for Probuphine, the first and only six-month buprenorphine implant for the maintenance treatment of opioid addiction. The new J-code (J0570) became effective January 1, 2017 and coincides with the activation of a new field force to drive the next phase of Probuphine adoption."
- "'With patients and providers urgently needing access to evidence-based treatment for opioid addiction, we are pleased that CMS granted a J-code for Probuphine,' said Behshad Sheldon, President and CEO, Braeburn Pharmaceuticals. 'We anticipate that the new code and our expanded commercial team will advance adoption of Probuphine and broaden access for appropriate patients with opioid use disorder.'"
- "HCPCS codes are used by healthcare professionals to identify services and procedures for which they bill public or private health insurance programs. The codes included in the HCPCS set, which is based on the American Medical Association's Current Procedural Terminology, are maintained by CMS and universally accepted by all payers."

Jan. 13 Addiction Professional article

This article presented five facts about CAM2038.

- "1. Could the availability of alternatives to sublingual buprenorphine prove as revolutionary as the introduction of buprenorphine itself? Phase 3 study results for weekly and monthly injections of Braeburn Pharmaceuticals and Camurus's CAM2038 showed not only non-inferiority to the sublingual medication, but CAM2038 outperformed it on negative urine tests for opioids in combination with patient self-reports."
- "2. The Food and Drug Administration (FDA) has granted Fast Track designation for the CAM2038 products, and New Drug Applications are expected to be submitted by the middle of this year. Some patients could be initiated directly to the weekly injection."
- "3. Injectable formulations theoretically can work in conjunction with Probuphine, the six-month buprenorphine implant approved in 2016. Patients stabilized on an injectable could graduate to the longer-lasting implant."
- "4. Michelle Lofwall, MD, of the University of Kentucky Center on Drug and Alcohol Research, the 428-patient Phase 3 study's primary investigator, says injectables could improve treatment adherence and reduce stigma in communities where payers remain concerned about buprenorphine diversion. 'They give patients an opportunity for a better quality of life,' she says. 'They don't have to worry about forgetting their medication.'"

- "5. What factors could stymie progress? 'A lot will depend on what happens with the Affordable Care Act,' Lofwall says. 'If it is dismantled, and parity doesn't exist, many patients won't have access.'"

Sept. 12, 2016, article from NPR Shots Health News

Insurance data has shown a surge in spending on opioid treatment and testing.

- "A report set to be released Tuesday shows a more than thirteen fold increase in spending by health insurers in a four-year period on patients with a diagnosis of opioid dependence or abuse."
- "From 2011 to 2015, insurers' payments to hospitals, laboratories, treatment centers and other medical providers for these patients grew from $32 million to $446 million."
- "The Fair Health study found a sharp difference in how much insurers spend on individual patients with such a diagnosis."
- "On average, insurers spend $3,435 a year on an individual patient, but for those with an opioid dependence or abuse diagnosis, that amount jumps to $19,333. Those numbers reflect what insurers actually paid. The report also includes data on what providers charged, amounts that are lowered by their contracts with insurers."
- "The study, out Monday, builds on a study Fair Health released in early August that found a thirtyfold increase in the volume of insurance claims related to opioid dependence diagnoses between 2007 and 2014."

Additional research by Karen Lusky and Renee Euchner.