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# Prescriber Perspectives on Opioid Prescribing in New Jersey and Impact of 2017 State Legislation (Extended Report)


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# Prescriber Perspectives on Opioid Prescribing in New Jersey and Impact of 2017 State Legislation (Extended Report)

**Jennifer Farnham, M.S. and Stephen Crystal, Ph.D.**

## Executive Summary

This summary describes high-level findings from our 22 interviews with New Jersey opioid prescribers. The main report contains extensive quotations from the interviews as well as references to relevant literature.

### *Background*

- New Jersey, along with other states, has seen an increase in drug-related deaths and overdoses, with opioids constituting the bulk of the increase.
- Many states have undertaken policy efforts to restrict the supply of prescription opioids that could easily be misused.
- In 2017, the New Jersey legislature passed, and the governor signed, legislation that restricted initial opioid prescriptions for acute pain to a 5 day supply, required pain management contracts and monitoring for longer-term usage (some patients are exempt), and eliminated prior authorization requirements to access substance use treatment. The measure passed in February 2017 and went into effect in May 2017.
- Our qualitative inquiry involved reaching out to a variety of prescribers for in-depth telephone interviews to assess how this new legislation had affected prescribers' practices and patients.

### *Methods*

- Twenty-two opioid prescribers practicing in New Jersey were interviewed (21 by phone, one by email) between September and December 2018 regarding their thoughts on the impact of New Jersey legislation that took effect in May of 2017, as well as other influences on opioid prescribing (Centers for Disease Control (CDC) or insurer guidelines, public knowledge of increased deaths from opioid overdoses, etc.).
- Prescribers were identified via Medicare Part D public data for 2016. Our initial goal was to obtain several higher than average prescribers, in higher than average opioid-prescribing specialties, in each of 3 regions of the state to ensure that we were speaking

with prescribers who were affected by the new legislation. However, because so few specialists accept Medicaid (of 14,637 prescribers who served dual eligible participants in the 2016 Medicare data, only 3,703 (25%) had actually billed Medicaid, according to the Center for State Health Policy's Medicaid claims database), we adjusted our strategy to recruit more primary care doctors. And, while all interviewees prescribed opioid medications to some degree, not all were higher than average. At least 266 prescribers or organizations were contacted, and all who expressed interest were interviewed.

- There were 13 men and 9 women interviewed. Twenty were physicians, while two were advanced practice nurses (APN's). Interviewees were about equally split among physician-owned practices, academic medical settings, federally qualified health centers (FQHCs), and hospital systems or settings. With regard to specialty, interviewees were not always exclusive to one specialty. Specialty areas included internal medicine (11 practitioners), pain management (three anesthesiologists and one physical medicine and rehabilitation), addiction medicine (three), two each from palliative care/hospice and HIV, and one each from emergency medicine, geriatrics, neurology, oncology, oral surgery, psychiatry, and rheumatology. Years of experience ranged from one to more than 30, with 17 having more than 10 years of practice. Interviewees were about evenly distributed among the North, Central, and Southern regions, with 41% from the South. Though we achieved some diversity among our interviewees, they may not be representative of New Jersey prescribers overall in part because they were willing to talk for an hour or more about prescribing and patient care with only a $125 gift card incentive.
- Interview questions were developed in advance, and follow-up questions were created as interviews proceeded to assess interviewee reactions to emerging themes.

## *Interview Findings: Assessment of 2017 Legislation*

- <u>5 Day Limitation on New Prescriptions for Acute Pain.</u> For most of our interviewees, some limitation on prescribing seemed reasonable and the potential burdens of the rule were diminished by the perceived public health benefit. Many interviewees were already limiting their prescribing enough that the law did not particularly affect their practice. A few would prefer a longer period to allow for patients to check in after the initial prescription, because it was hard to circle back with them within five days. One noted some negative health effects from patients taking too many NSAIDs when they were not able to get back to the prescriber within five days. However, many noted a standard past practice of a 30 day prescription, which most seemed to think was excessive. Many reported a positive effect of the law on their interactions with patients because it gave them support in limiting prescribing. One prescriber described the effect in the following way: *"I think like all the things with the opiate law, it's meant to complicate things enough that you think twice about prescribing something. ... one of the ... organizing principles of*

*this law seems to be just make it a little bit more annoying … And I don't know if that's a bad thing. … It's probably decreased my prescriptions for incidental opiates. Has it changed things dramatically? I don't think so. It's not burdensome enough to make it not worth doing.” (9)*

- Prescription Monitoring Program (PMP). Interviewees spoke very highly of the New Jersey PMP as a tool for responsible prescribing. Most had begun using it well before the new law. A few felt that it took up significant time to use (about 5 minutes of a 15 minute visit) or otherwise had mixed feelings. Two wished it were possible to default to all states rather than having to select additional states (including more states increases the time for searches to complete). One mentioned that an autocomplete that would fill in the names of patients searched previously would be helpful. One collaborates with social workers and would like them to be able to check, one desired to have other drugs that affect the central nervous system listed (such as serotonin-norepinephrine reuptake inhibitors (SNRIs), selective serotonin reuptake inhibitors (SSRIs) and tricyclics), and one noted that mail order pharmacies do not appear to report.
- Monitoring Longer-Term Usage.
    - *Pain Contracts*. Most interviewees who prescribed opioids long term were already using pain contracts before the law passed. Those who were using them prior to the law’s passage generally found them to be a good practice that helped them monitor patients’ progress and inform patients about the risks of opioids or other controlled substances. Those who started because of the law seemed more likely to find them burdensome—more about protecting prescribers from liability than building a good patient relationship. One prescriber noted some disagreement in his practice with regard to whether cancer patients should be required to have agreements. Palliative care patients are exempt from the NJ law, but some prescribers still find it best practice to do agreements with them.
    - *Urine Screening.* Urine or other types of screening presented some logistical issues for practices that had not incorporated it prior to the law. A few interviewees expressed some hesitance about the interpretation of the results of screening analyses, and one who had expertise in the area talked about how complicated it could be due to substances being changed as they are metabolized, and the necessity of knowing how long certain substances stay in the body.
    - *Dealing with Nonadherence.* Possible screening results that would trigger some kind of action included finding additional substances (raising questions of a concern for the patient’s health due to substance abuse) or not finding evidence of the substance (raising questions of diversion). Interviewees differed in their responses to these findings. Comprehensive practices offering substance abuse treatment could continue relationships with patients under these circumstances

by increasing monitoring, but other practices would often begin a tapering plan (if additional substances were found) or dismissal (if prescribed substances were not found).

- Availability of Treatment for Substance Use. Interviewees generally reported no change in the availability of treatment for substance use due to changes in the law, though one who treated patients with SUD who had private insurance appreciated the removal of prior authorizations for their clients. Several saw some movement toward greater availability of MAT (medication assisted treatment), though they did not attribute this to the law. Several raised the issue of affordability in SUD treatment and one mentioned barriers in terms of the structure of existing treatment with respect to requiring intensive treatment that people weren't willing to attend, showing up instead in the emergency room. Many had the sense that people who wanted treatment could get it, but they generally did not follow up with people who they referred to treatment to check on the results from the referral.

  Because the law did not change the prior authorization requirement in Medicaid (this was removed later, in April 2019), access to substance use treatment for this population was still difficult at the time of our interviews, as was access to other services for Medicaid patients, such as specialty care and physical therapy. Providers also reported trouble gaining approval for extended release buprenorphine injections for patients who had trouble taking medication in a timely way or for whom there were diversion concerns.

  In addition to the prior authorization barriers, providers wanting to offer substance use treatment together with primary care encountered problems with licensing and reimbursement—two providers mentioned a long wait for a license, delaying treatment; one provider was going ahead without the license; and one reported having to let in-house psychiatric staff go because of the lack of licensure and felt it created a gap in their services. Other than several FQHCs or prescribers who were already providing addiction treatment, prescribers we interviewed were not interested in taking on medication assisted treatment in their practices (discussed in more detail in the next section).

- Unintended Consequences. Many, though not all, of our interviewees thought that there was an increase in untreated pain due to increasing restrictions on opioid prescribing, including the New Jersey law as well as changing norms about opioid usage influenced by other factors including the release of the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain, communications from insurers or other health care organizations, and attention by the media and community institutions about the opioid crisis. In addition to prescriber reluctance, several interviewees mentioned patient reluctance to take opioids (or pressure from family members to avoid), even when the prescriber was concerned about patients' pain.

Interviewees noted health problems that could arise with long-term use of non-opioid pain relievers, such as organ damage from non-steroidal anti-inflammatory medications or acetaminophen. They also discussed insurance approval barriers to opioid alternatives such as Lyrica® and diclofenac patches or gel, lidocaine patches, and treatments such as physical therapy, acupuncture, and massage.

There was concern among some interviewees that the New Jersey law as well as other attention to the opioid crisis was leading to prescriber or patient avoidance of opioid medications even when they were clearly indicated, as in cases of cancer pain, recent surgery, or sickle cell crisis. Authors of the CDC guidelines have noted that some practices have gone beyond their recommendations, and the US Department of Health and Human Services published a new "Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics," which reminds clinicians that dependence occurs after more than a few days of use and notes potential harm in reducing dosages abruptly.

- Thoughts on Whether the Law Would Reduce Risk of Overdose Deaths. Most interviewees didn't offer a direct opinion on this. Two were hopeful that prescribing restrictions could prevent addictions that might otherwise have occurred. However, several noted that most overdose deaths are from illicit rather than prescribed opiates, so that the effects would be indirect. Several interviewees felt that access to adequate substance use treatment and mental health treatment would be key in reducing overdose deaths.

## *Interview Findings: Other Themes*

- (New) Awareness of Opioid Harms. Several interviewees with more years of experience discussed past pressures to treat pain as the 5th vital sign, coupled with beliefs that opioids were not harmful, as driving high levels of opioid prescribing. Others noted longstanding stigma toward longer-term opioid use as well as addiction treatment that had co-existed with the focus on aggressively treating acute pain (i.e., negative attributions of drug seeking among chronic pain patients). More newly trained prescribers had been warned of the dangers of opioids early on, including opioid-induced hyperalgesia, risk of addiction, risk of diversion to people other than the patient for whom the medication was prescribed, and risk of death or injury from overdose. Many interviewees mentioned the risk of opioid-induced hyperalgesia (i.e., increased sensitivity to pain), particularly at larger doses, something they attempted to discuss with patients, often unsuccessfully. All were familiar with opioid dependence, and many had observed addictive behaviors as well in their patients, or treated patients with past addiction to opioids. All were aware of the risks of death or injury from overdose. Some had suspicion of illicit use or diversion among their patients. Most had not experienced an overdose

among their own patient population, and none mentioned experiencing a patient overdosing on medications that the interviewee had prescribed.

- Striving to Balance Harms and Benefits of Opioid Prescribing. Interviewees' prescribing decisions depended on what they believed about the potential benefits of opioids versus the potential harms to patients by not prescribing. Differences in their views and experiences led to different philosophies of opioid prescribing. Many explicitly mentioned an inherent duty to avoid suffering in patients—from pain, including the pain or potential adverse outcomes of withdrawal symptoms--and felt that prescribing opioids was part of that responsibility. Those who perceived less benefit from opioids were less likely to prescribe them, and were less concerned about avoiding withdrawal symptoms in patients. Several prescribers were very concerned about diversion, feeling that they would have responsibility (not in a legal, but rather a moral sense), if a medication they prescribed was sold or misused by someone other than the patient for whom they prescribed it. Several mentioned that they were either considering, or actually offering or prescribing naloxone for patients getting opioid prescriptions, particularly those at higher dosages.
- Reduction/Avoidance of Opioid Prescribing. Data from the New Jersey prescription monitoring program show opioid dispensations declining in 2016, 2017 and 2018 after a high in 2015. Interviewees mentioned a decreasing willingness to prescribe opioids among their colleagues, including some who have decided not to prescribe opioids at all.

  Reduction/avoidance seemed to stem from at least three causes, according to our discussions with interviewees:

  1) Increased awareness of the potential for harm with opioid prescriptions—from hyperalgesia even if taken as indicated, illicit use either by the person to whom they prescribed it or someone else, and overdose.
  2) The logistical burdens in complying with New Jersey's 2017 law and other changes in organizational procedures or professional norms that called for more investigation and documentation in opioid prescribing.
  3) Stigmatization of patients asking for pain relief. One of our interviewees mentioned having noted such stigmatization 10-15 years ago when he was in a position to be meeting doctors throughout the state, and one long-term practitioner likened current events to a resurgence of opiophobia from 20 or more years ago. So while the stigmatization may not be new, the opioid crisis may reinforce a preexisting tendency to stigmatize.

  One of our prescribers, while noting that they had been affected by the increasing unwillingness of primary care providers in particular to prescribe opioids, thought it was not necessarily all bad, because some providers did not have a good knowledge base for opioid prescribing. In addition to prescriber reluctance, some interviewees mentioned

reluctance among patients or their families to using opioids. In some instances the interviewee seemed to feel neutral or positive about this. However, in other cases the interviewee believed that the reluctance impeded patient care.

- Doubts about Opioid Efficacy for Chronic Pain. Many of our interviewees doubted that opioids were very useful in the treatment of chronic pain due to tolerance or the development of hyperalgesia, in which a patient's pain could become worse. However, most interviewees, and particularly those who focused more on pain treatment, seemed to feel that in some cases, opioids were the best choice available. There was general agreement with the CDC guidelines that opioids should not be the first-line treatment for chronic pain. Their doubts, as well as their decisions to continue to use opioids in some cases, are borne out by the literature regarding pain medications.
- Gaps in Pain Treatment. Pain is a common condition. Many of our interviewees noted gaps in pain treatment for patients, in several respects:
    1) *Tendency of Primary Care Practitioners to Refer Patients to Pain Management Practices for Treatment of Pain*. This was not necessarily a problem in and of itself, except that there were perceived gaps in the populations served by pain management practices. Several primary care providers told us they had few options for pain management referrals for their Medicaid patients, and one pain management doctor noted that reimbursement was poor, so that some of his colleagues did not accept Medicaid. One primary care interviewee who was willing to prescribe for pain with consultation from a pain management practitioner described frustration in his attempts to develop good working relationships with any such practitioners (due to limited numbers of such practitioners in his area that accepted Medicaid patients, his primary constituency, and the focus of practitioners on procedures rather than development of a treatment plan that could include a primary care practitioner).
    2) *Limits on Insurance Coverage, Particularly for Medicaid Patients*. Many interviewees reported (and we found in our recruiting efforts) that many pain management practices did not accept Medicaid, leaving Medicaid patients with few choices. This was also true for non-opioid pain treatments like physical therapy, acupuncture, chiropractic care, massage, and non-opioid medications such as Lyrica®, lidocaine, and diclofenac.
    3) *The Concentration of Pain Management Practices on Procedures, Often with the Exclusion of Medication or Behavioral Interventions*. If the procedures offered did not work for patients, or they did not wish to undergo procedures, there were few choices for patients to help manage pain. Several interviewees, including those offering such procedures, noted that procedures held potential risk as well as potential rewards. Prescribers looking to refer patients for pain management,

including narcotics if necessary, described frustration at their perception of the procedure concentration of pain management practices. Two prescribers tempered their frustration with the realization that pain management practitioners were making practice decisions for what the interviewees felt were legitimate reasons. Two pain management prescribers acknowledged some concentration of the field on procedures but noted reasons other than reimbursement for this, including better results and avoiding opioids.

4) *A Lack of Effective Treatments for Chronic Pain*. None of our interviewees seemed to believe that opioids should be a front-line treatment for chronic, non-cancer pain, but they did note that in some cases it was the best option to improve patient functioning.

- Medical Marijuana. Though most of our interviewees were not involved in prescribing it, medical marijuana was raised by several interviewees as a topic of interest among prescribers and patients. One had reviewed existing literature and thought it held a lot of promise, and one had positive reports from patients who used it, but another felt that their patients who used it were overcharged and did not benefit. Several thought it was cost-prohibitive for Medicaid patients. Two were skeptical given the lack of clinical research.
- Barriers to Addiction Treatment. Other than several FQHCs or prescribers who were already providing addiction treatment, prescribers we interviewed were generally not interested in taking on medication assisted treatment in their practices. There were various reasons for this, including a lack of staff to implement the more intensive counseling needed, a perceived lack of expertise in treating addiction, and fears of the type of patient population that such an offering would attract.

  Phone surveys with substance use treatment facilities in New Jersey in 2018 showed that only about half of them offered medication assisted treatment. Our interviewees who provided substance use treatment were serving mostly Medicaid patients and were significantly burdened by prior authorization requirements (which, as noted above, were removed in April 2019, after our interviews) as well as trouble gaining approval for extended release buprenorphine injections for patients who had trouble taking medication in a timely way or for whom there were diversion concerns. On the positive side, Medicare and Medicaid data for New Jersey show an uptick in MAT medications, and the New Jersey Department of Human Services (which oversees Medicaid) is actively encouraging addiction treatment with buprenorphine with enhanced rates and technical assistance, with positive early results.

  Interviewees in FQHCs faced long waiting periods to become fully licensed to offer substance use treatment. There seemed to be differences of opinion as to what the

specific requirements were. Some FQHCs offered treatment without getting the certification.

Limits on coverage for opioid alternatives raised challenges for how to treat pain for patients receiving addiction treatment.

The regulation of methadone clinics was perceived by the few who had experience with it as overly rigid and segregated from other sources of care, which prevented it from being optimally effective because methadone providers can't discuss pain or other issues the patient may be having and adjust the dosage accordingly.

- Insufficient Access to Behavioral Health Treatment, Particularly in Medicaid. Several interviewees noted that behavioral health co-morbidities appeared to them to exacerbate chronic pain conditions in their patients, but they had a difficult time finding psychiatric treatment for patients. This shortfall was felt most acutely by those trying to find psychiatric care for their Medicaid patients.
- Barriers for Medicaid Patients. In addition to barriers mentioned earlier with respect to a general shortage of specialists serving Medicaid patients and lack of access to treatments requiring out-of-pocket payments due to the limited financial resources of Medicaid patients, interviewees mentioned pain management and orthopedic specialists as difficult to find. Some also raised the HMO structure of Medicaid as restrictive (requires referrals and an assigned primary care provider). Interviewees also mentioned other barriers, including transportation, housing, food, access to employment and a reliable schedule.

# Prescriber Perspectives on Opioid Prescribing in New Jersey and Impact of 2017 State Legislation (Extended Report)

**Jennifer Farnham, M.S. and Stephen Crystal, Ph.D.**

## Background

New Jersey, along with other states, has seen an increase in drug-related deaths and overdoses, with opioids constituting the bulk of the increase.[1] While fentanyl and heroin have overtaken prescription opioids in reports of overdose deaths, research indicates that beginning in the 1990s, users began using prescription options and later transitioned to heroin (Cicero, Ellis & Harney 2015; Cicero et al. 2014; Mars et al. 2014; Unick et al. 2013). So, it makes sense to undertake policy efforts to restrict the supply of prescription opioids that could easily be misused, and many states have done so (NCSL 2019). National studies show opioid prescriptions declining both before and after the CDC issued its 2016 guidelines (Dowell et al. 2016), but accelerating thereafter (Bohnert et al. 2018; Zhu et al. 2019). Changes in prescribing practices in New Jersey may be driven by pressures from many sources.

In 2017, the New Jersey legislature passed, and the governor signed, legislation that restricted initial opioid prescriptions for acute pain to a 5 day supply, required pain management contracts and monitoring for longer-term usage (some patients are exempt), and eliminated prior authorization requirements to .access to substance use treatment for state-regulated plans (this excludes Medicaid and self-insured plans). The measure passed in February 2017 and went into effect in May 2017.[2] Implementing regulations specified requirements not spelled out in the statute, such as random urine screens at least every 12 months.[3] Exempted are patients who are in "active treatment for cancer, receiving hospice care from a licensed hospice or palliative care,

[1] NJ's drug related deaths increased from 1,223 in 2012 to an estimated 3,118 in 2018. In 2012, heroin was detected in 514 deaths, compared to 1,613 in 2017. Fentanyl was identified in 42 deaths in 2012 and 1,429 in 2017. Oxycodone and methadone stayed close to 300 and 120, respectively, in this time period. (Source: Overdose deaths listed at https://www.njcares.gov/). Rates of increase nationally for fentanyl exceeded 100% annually from 2011 to 2016 (Spencer et al. 2019). In the US, deaths involving fentanyl and heroin first exceeded deaths involving prescription opioids without other synthetics (i.e., fentanyl) in 2016 (National Institute on Drug Abuse 2019).

[2] P.L. 2017, c. 28. See https://www.njconsumeraffairs.gov/prescribing-for-pain/Pages/default.aspx for a copy of the law, regulations, FAQs, and other reference materials for prescribers and patients.

[3] See, e.g., NJAC 13:35-7.6 for physicians and NJAC 13:37-7.9A for nurses (available at https://www.njconsumeraffairs.gov/prescribing-for-pain/Pages/default.aspx).

or is a resident of a long term care facility, or to any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence."

Our qualitative inquiry involved reaching out to a variety of prescribers for in-depth telephone interviews to inquire as to how this new legislation had affected prescribers' practices and patients. We recruited 22 prescribers using Medicare Part D public data, a prescriber list provided by Horizon NJ Health, a list of federally qualified health centers (FQHCs), and a variety of referrals from physician colleagues.

# Methods

## *Recruitment*

Recruitment took place from September to December of 2018. Our initial plan was to recruit prescribers who prescribed more than average for their specialty group in each of 3 regions of the state in the 8 highest opioid-prescribing specialties, as determined by the Medicare Part D public data for 2016.[4] We wanted prescribers who accepted Medicaid as well as Medicare patients and those with other types of insurance, and thought that restricting our sample to Medicare prescribers who served dual-eligible individuals would be a good proxy for this. This idea proved to be incorrect. After finding in our initial outreach efforts that many in our first recruitment pool did not, in fact, accept Medicaid, we ran their National Provider Identifier (NPI) against CSHP's Medicaid claims database to better identify those that served Medicaid patients. Out of 14,637 NPIs who served duals in the 2016 Medicare data, 85% were listed as a service provider on one or more Medicaid claims in 2017, but only 25% (3,703) had actually billed Medicaid, and this latter characteristic seemed to be the best predictor of whether a provider actually accepted Medicaid. Restricting the prescriber population in this way meant that many specialties had few providers to recruit from. Primary care doctors, on the other hand, generally accepted Medicaid. So, we adjusted our criteria downward from 3 in each specialty group (one in each region) to one in each specialty group. We concentrated more on primary care doctors and also contacted all FQHCs in the state, looked at academic medical centers for our specialties of interest, and obtained a list of prescribers from Horizon NJ Health (the state's largest Medicaid Managed Care plan).

[4] We used the SAS zip code to county file (sashelp.zipcode) together with the zip code in the Medicare Part D file, to assign prescribers to counties, and grouped counties into the following regions: 1) North: Bergen, Essex, Hudson, Morris, Passaic, Sussex, Union, Warren; 2) Central: Hunterdon, Mercer, Middlesex, Monmouth, Somerset; and 3) South: Atlantic, Burlington, Camden, Cape May, Cumberland, Gloucester, Ocean, Salem. This resulted in a general sample (i.e., all listed NPIs) of 14,654 prescribers in the North (47%), 8,581 prescribers in Central (28%), and 7,870 prescribers in the South (25%).

Prescribers were contacted via fax, email and/or telephone with a letter, an information sheet about the study, and the interview questions. Prescribers were offered a $125 Visa gift card as an incentive to complete the interview. Follow-up emails and phone calls were made after the initial outreach. At least 266 prescribers or organizations were contacted. All who expressed interest were interviewed. Table 1 shows the characteristics of the interviewed prescribers.

**Table 1: Interviewee Characteristics**

| | Number | Percent |
|---|---|---|
| Total Interviewed | 22 | |
| Phone | 21 | 95.5% |
| E-mail | 1 | 4.5% |
| | | |
| Men | 13 | 59.1% |
| Women | 9 | 40.9% |
| | | |
| Physicians | 20 | 90.9% |
| Advanced Practice Nurses | 2 | 9.1% |
| | | |
| **Practice setting/context** (not mutually exclusive) | | |
| Physician-owned practice | 7 | 31.8% |
| Academic appointment/setting | 7 | 31.8% |
| Federally qualified health center (FQHC) | 6 | 27.3% |
| Hospital system/setting | 7 | 31.8% |
| | | |
| **Specialties** (not mutually exclusive) | | |
| Internal medicine | 11 | 50.0% |
| Pain management (3 Anesthesiologists, 1 Physical Medicine & Rehabilitation) | 4 | 18.2% |
| Addiction medicine | 3 | 13.6% |
| Palliative care and/or hospice | 2 | 9.1% |
| HIV | 2 | 9.1% |
| Emergency medicine | 1 | 4.5% |
| Geriatrics | 1 | 4.5% |
| Neurology | 1 | 4.5% |
| Oncology | 1 | 4.5% |
| Oral surgery | 1 | 4.5% |
| Psychiatry | 1 | 4.5% |
| Rheumatology | 1 | 4.5% |

***Continued on next page***

**Table 1: Interviewee Characteristics (continued)**

| | Number | Percent |
|---|---|---|
| **Years of Experience** | | |
| 1-4 | 2 | 9.1% |
| 5-9 | 3 | 13.6% |
| 10-14 | 4 | 18.2% |
| 15-19 | 5 | 22.7% |
| 20-29 | 4 | 18.2% |
| 30+ | 4 | 18.2% |
| | | |
| **Region** | | |
| North | 7 | 31.8% |
| Central | 6 | 27.3% |
| South | 9 | 40.9% |

Note: "not mutually exclusive" means that interviewees could belong to more than one of the categories noted (for instance, those with an academic appointment may, in addition, practice in another setting; also, practitioners sometimes had more than one specialty area).

### *Interviews*

Interviews were conducted by phone, except for one prescriber who opted to respond via email. The length of interviews was generally about an hour, although they ranged from 20-120 minutes. Fifteen interviews were conducted jointly by Ms. Farnham and Dr. Crystal and seven were conducted by Ms. Farnham. Twenty of the telephone interviews were audiorecorded and transcribed; comprehensive notes were taken for the other.

### *Analysis*

As we conducted the interviews, we noted emerging themes and explored them with respondents. After the completion of all interviews, we reviewed all the transcripts comprehensively, noting interviewee comments about the 2017 legislation as well as other themes that emerged.

## Interview Findings

### *Caveat about Participants*

Our participants represented a self-selected group of prescribers who work with Medicaid patients, prescribe opioids, and are willing to talk about it for an hour with a researcher. Our participants were incredibly thoughtful and very concerned about patient care. While we achieved a good variety of prescribers in terms of region of the state, specialty area, and other

characteristics, it is likely that our group of participants is not representative of New Jersey prescribers as a whole.

## *Assessment of 2017 Legislation*

**5 Day Limitation on New Prescriptions for Acute Pain**

For most of our interviewees, some limitation on prescribing made sense and the potential burdens of the rule were diminished by the perceived public health benefit.

Many interviewees were already limiting their prescribing enough that the law did not particularly affect their practice. For example:

- *"It's just sort of a practice we were already doing. If we were giving out medications for acute pain, we were already limiting it." (3)*
- *"it is so crazy that a surgeon or a dentist would give somebody 100 Percocet for anything. I've had a tooth pulled, I've had dental work, I never take the stuff. But even if you have a low pain tolerance, you don't give somebody 100 pills. You give them five days, even that might be too much. So I agree with that completely." (14)*
- *"There's been once or twice since [the 5 day limit was passed] where I had someone with acute pain where I was writing for five days, and then there was another five days that we did it because things weren't getting better. But it really didn't, I don't think, impact what I was already doing." (7)*
- *"Not a huge deal for us. Occasionally we see somebody who let's say was in the ER and broke their leg and was given opiates in the hospital, and then it becomes a little bit confusing for what to do with them, because let's say they can't get into the office to be seen by us and ortho won't see him stuff like that, but it hasn't been a huge thing. I think, again, it's been a good thing to keep prescriptions down. … I think that's one of the things that the law is intended to do is not have bottles of Percocet sitting in people's medicine cabinet, and I agree that that is a good thing and a good public health intervention, and, honestly, if the side effect of it is that I have to write a prescription that is maybe a little bit ... doesn't quite reflect how the patient's [using] it, fine." (9)*

Some, however, would prefer a longer period to allow for patients to check in after the initial prescription.[5] One interviewee noted, *"I think the five day rule is stupid because it's not a one size fits all kind of situation … the state might've been advised to have a range, like 5 to 14 days, as long as it doesn't go immediately to a month, you have to have some flexibility. Some patients*

[5] A640 and A2347 in the 2018-2019 New Jersey legislative session seek to increase the limit of new opioid prescriptions to 7 days rather than 5. We sought comment from the offices of the primary sponsors. One did not respond. The other indicated that it was the sponsors personal experience as a practitioner that led them to think it was a better idea rather than hearing from constituents.

*have transportation problems. And then as I said, some conditions obviously are gonna require a somewhat longer initial course of treatment" (1).* Another noted a disruption in the continuity of care for patients due to the 5 day rule: *"With my five-day patients, and I don't have many of them, that is a problem, because I'm not even there within that five-day block. Then, I have to have another prescriber see them, so that has been a problem ... It doesn't become a problem for me as much as it does for either their primary, or for the specialty, the orthopedic specialty, or the surgical specialty" (19).* They noted that this had resulted in negative health effects for a few patients: "*sometimes, these patients are then without medication. When that happens, they'll typically say to me, "Well, I took four ibuprofen, over the counter ibuprofen, about every three hours." That's not helping them either. Now, they have GI distress, that kind of thing. So it has [been a problem], but it hasn't been a major problem. There's a select sample that that's really been a problem for" (19).* A pain doctor in an orthopedic practice told us that the 5 day limit was a problem for surgeons, "*I've talked with a number of guys in the practice, and the five days really for them, it's really onerous, because if the guys operate on a Tuesday, those people are running out on Saturday and Sunday, and they call for a refill and you can't really do a refill for Percocet*" *(17).* A primary care doctor felt that practices could support limitations, though they didn't feel strongly about exactly what the limitation would be: "*we have patients who have surgeries and we work with the surgeons and other physicians on their general pain meds that they need after having a surgery. I think this means that you have to be more mindful because it's a five-day prescription. It mainly means that you write five days and then you automatically have to schedule a call, a nurse visit, some check-in to say are you okay or do you need more? And all that the law requires is that then that person has a check-in at that point, and it does mean at the end you have to set practices around that. I think a lot of people have demonstrated that they don't need more than three days of narcotic, let alone even five. Some people need five and, of course, some people need more, seven to ten. We're all different. We all metabolize opioids differently. They all act differently in our bodies. So it makes sense that we're going to have a range. I don't feel strongly about the exact number that it was limited to, but I do feel strongly about limiting*" (18).

Many interviewees reported a standard past practice among a variety of practitioners (that is, not just their own practice, but their understanding of general practice) of a 30 day initial supply prescribed after a variety of procedures or diagnoses (see Reider 2019 and Appleby & Lucas 2019 for a more general discussion). A 2017 poll conducted in New Jersey found that 31% of adults said that they or a family member living with them have been prescribed an opioid in the past year, and 36% of the recipients said they kept, or planned to keep, unused portions of the prescription for potential future use (Cantor, Brownlee & Chou 2017). Medicare Part D data show New Jersey as having one of the lowest rates for beneficiaries receiving an opioid prescription (21% in 2019, where the range was 18% in Hawaii to 42% in Alabama) (OIG 2019). The Office of the Inspector General in the US Department of Health and Human Services has followed opioid

prescribing in Medicare Part D and found that problematic prescriptions indicating excessive amounts of opioids or doctor shopping have dropped from 2016 to 2018, but that there are still substantial numbers of patients receiving excessive amounts (OIG 2019).

Many of our interviewees thought a 30 day supply was excessive, but one noted that it gave them desired flexibility. Some example quotes on past practice:

- *“I think before was just some amount of carelessness or what went into rote prescriptions … and people were just getting used to writing 30-day supplies or large numbers of prescriptions when a lot of those ended up having leftover prescriptions, leftover pills in people's cabinets and ending up causing problems.” (18)*
- *“prior to that, I think a lot of people were doing 30 day scripts.” (12)*
- *“example of how it would have been better if I had been able to, in the old days I could have given him a month, without a problem, without fear of that and that would of held him off. Now, I can't really do that … I have to extend it because I believe he's in severe, legitimate pain. So, I will, I'll have to document it. You know, why I did that and if someone from the DEA came knocking, then they'll definitely want to see documentation, and I don't disagree with them. But it just adds to the burden, you know, when you're taking care of patients.” (10)*
- *“When patients initially came to be seen for interventional pain management, I would give them a 30-day supply of opioids. That was my practice. That was my habit.” (15)*
- *“they're not just going to get opiate medications prescribed blindly, which may have been a practice that was more common, especially in these past 20 to 30 years I would say where it was kind of routine to do that kind of a thing.” (12)*
- *“I did a general surgical internship … in like [mid 2000s] ... It was routine. … People were getting bombarded with the meds in the PACU, they were getting bombarded on the floors, and then we sent them home with like 40 or 50 Percocet, and that's where I think a lot of this came from. That there was the overprescribing, there was no one was allowed to have pain in the PACU, it was unacceptable, can't have it, and there was the expectation that people were going to be pain-free ... You know, yes, you're like, "Well, I'm in pain." Well, you just had a major abdominal surgery, yeah, you're going to be in pain.” (17)*
- *“In speaking to colleagues like the orthopod colleagues who used to write a lot of prescriptions for Percocet, they would discharge somebody and give them 120 pills. And so inadvertently, those pills, the 90 that left end up in the medicine cabinet and then somebody takes them and they're either taking them and using them for recreational purposes or selling them. That's kind of how this whole fiasco, I think, developed on a larger scale.” (20)*
- *“I think prescribing has just been out of control, so we have to have some top down regulation.” (21)*

On the positive side, the 5 day limit gave prescribers support in limiting their prescribing, which many seemed to appreciate as such limitations can lead to unpleasant interactions with patients:[6]

- *"Well, I'm thankful for the change because actually now I can say it's the law to them, "And no, I cannot hand you gobbles of meds. This is all I can give you for now, and you need to come back and see me." Some of them come back when they're supposed to, and some of them don't. No, I think it's taken pressure off the providers giving us the law behind it, and the patients know that. [asked if there are ever times they want to give more than 5 days]… No, not really, no. No, I'm actually really very happy with the law, and the restrictions, and the oversight and kind of keeping us in the right direction." (13)*
- *"It's helpful, in one sense, in that if I really don't want someone to get started on that product, I … say "Hey, they'll give you five days for that, but after that, probably not going to be able to do this."" (10)*
- *"You don't have to argue with somebody about why you're giving them five days instead of 10 days worth. You can just say I'm limited by the law, this is all I can give you. So that actually can be helpful." (3)*
- *"I do think providers feel a bit relieved. … And laws like these have made it much easier to explain to patients why you will not write the prescription. … I would speculate that the law is also helpful in the sense that it makes uniform across the board. … it is increasingly easier to deal with those patients, simply because now the law, for lack of a better phrase, feels like it's in our corner, or on our side. Cause a lot of times, these patients understandably will get agitated and occasionally combative, and it is helpful to say that, "Hey, it's not me who can't prescribe this. I can't by law provide this but let's talk about some of the other things I can do to help. Because I very much would like to." And I think being able to cite legislation, or law, restricting our ability to give a prescription that we were admittedly unlikely to do so anyway, is helpful. And I think the uniform application of that, and again, I can't state with confidence whether or not it's being exercised uniformly, but in theory at least if it is, I would think it again would cut down on drug-seeking behavior. Only because I've had my fair share of folks who walked out irate that we're unable to write a prescription that we felt was not indicated. And quite literally asked, "Well how far is [other hospital] from here? How far is the nearest emergency room? I'm just gonna go there". And it still happens but I feel like it's happening to a lesser extent. And I would imagine if they were greeted with the same reply at the next hospital and the next, that it would make that type of behavior less." (6)*
- *"For me it's made my practice easier, because patients are ... everybody in New Jersey's aware of the legislation and patients don't get as upset now because of what they*

[6] While none of our interviewees described feeling threatened, such anecdotal accounts do exist (Molke 2017).

*understand about the risk of opioid therapy. When I'm not going to prescribe they're like, "Okay, yeah, that's fine." I mean, for my practice it's made it easier for me. I don't think that the patients, my patients anyway, are suffering any more than they were before because of the legislation." (15)*

- *"For me, it's been nice that I can say, "Well listen. I can only write you a five day supply, now with the new New Jersey laws, and if you want to continue after that we have to go through this step, that step." And I think for a lot of people, putting those set of barriers in place for patients, it's just one more thing that they kind of have to go through, so it's a little bit of deterrence for them as well." (17)*

One primary care doctor summarized the effect of the 5 day restriction as follows, noting that the restrictions led to reduced prescribing of opiates but did not eliminate it: *"I think like all the things with the opiate law, it's meant to complicate things enough that you think twice about prescribing something. ... one of the ... organizing principles of this law seems to be just make it a little bit more annoying so that they think a little bit about it. And I don't know if that's a bad thing. If I'm talking to a patient and I'm like, "Well, I could give you 15 tramadol or I could just give you a different NSAID." I'm probably just going to give them a different NSAID because it's going to take me three minutes to do an opioid contract, so I think in that sense, it's good. It's probably decreased my prescriptions for incidental opiates. Has it changed things dramatically? I don't think so. It's not burdensome enough to make it not worth doing. Again, I don't prescribe that much." (9)*

**Prescription Monitoring Program**

Interviewees spoke very highly of the New Jersey PMP as a tool for responsible prescribing:

- *"very helpful in that you can really track people's use and avoid misuse." (1)*
- *"super easy to access. And very, very helpful. … the PMP is wonderful." (3)*
- *"I think it's the best thing ever. I love it." (11)*
- *"the fact that I can press a button and see that this patient is getting narcotics from three other doctors in two different states makes the whole computer revolution ... that alone made all this aggravation worthwhile. That changed so much. It's so important to be able to do that. I'm so shocked when this first came out and I noticed patients who I thought I knew well, were doctor shopping. That also changed my perception of what I was doing." (14)*
- *"it's wonderful and transformative. It's probably the best website that I use in my life. It is amazing and it's super fast. It reflects everything. It really transformed care when it came in ... Especially in a place like a community health center where, again, transient population, patients will come in and before you had to try to figure out if someone's for real or not, and it has really revolutionized care. That was probably the thing that helped*

*me the most to just clean up the practice in terms of weeding out people who were abusing substances, so I have nothing but good things to say about it. It is wonderfully well run the website, it works all the time, it works how it should, you can add states to it, I like the fact that they're collecting gabapentin data. I think that's been very helpful. We actually had a patient here, my patient here, who fiddling around with gabapentin, he ended up going into some sort of detox from gabapentin, and we were able to fish it out by being able to physically see all the treatments that he was getting from the ER and other places. He was going in and getting like 300 milligrams gabapentin, then 400 milligrams of gabapentin, and then 600 milligrams. He was able to keep the insurance company allowing the prescription because he kept changing the dose. We were able to see that on the PMP and just shut it down. Nothing but positive things to say about that." (9)*

- *"we can just go and look and see exactly what they're getting, when they received it last, so for me it's been great. I love having this tool in my arsenal." (17)*
- *"I mean like with any extra click, docs are always gonna complain. You've gotta click, put in your user name, password, all that stuff. It's like an extra step. But is it something that I find to be useful, 100 percent yeah. I think that definitely helps with making sure patients aren't prescription hopping and going from practice to practice asking for scripts. And it's really easy to regulate these patients. Now that it's right there, docs can't be like, "Oh, I didn't know." It's like it's right there, check it." (12)*
- *"We check it for every patient every time. I find it invaluable. I can't imagine working without one." (18)*

Most had begun using it well before the new law. A few felt that it took up significant time to use (about 5 minutes of a 15 minute visit) or otherwise had more mixed feelings than those presented above:

- *"It's cumbersome. It's helpful. It's important. I need to do it, but it's cumbersome. Your password changes fairly quickly. I think it gets updated every three months. When you're not on it a lot, it can be challenging. Sometimes it's hard to get into from where you are; if you're working in the electronic health record, then get out of that to get into the database. To do all this, it can be challenging. I think it's accurate. It's certainly reassuring and necessary, but it probably adds over five minutes to a visit to engage in it. The patient information doesn't get pulled over to the site, so you're having to kind of toggle back and forth to identify the patient. You have to make sure you have the right patient. Patients will often have, because if they use more than one pharmacy, the pharmacies may have them slightly different in terms of addresses, spellings and things like that. … It's more the forensic part of it at times that can be a little overwhelming." (7)*
- *"I think the PMP is a very helpful ... it's again, it's another difficult requirement for physicians to waste their time with to accomplish their goal of getting the information.*

*And that doesn't take long, but everything is added ... an additional action that we have to take every time we see a patient. So you add each one of these things up, it takes us so much longer to take care of our patients nowadays. But I think it's helpful. To be able to see exactly when the medication was prescribed, and taken, and picked up by the patient. … When I first started with the PMP we were seeing that, that they were being prescribed by other people. But we put a clamp on that once we're able to get this information. So we don't see it any longer. The PMP is helpful in that regard." (4)*

- *"We're now mandating that the database needs to be checked. I don't know how much they police about it, but I know it got my attention. You know, it's a little bit of burden, right? After the visits over, I've got to get on this database and supposedly if I delegate that, you get a 10 thousand dollar fine for delegating it. … I think the database, was a step in the right direction, even though it is a bit of a pain. I think they could do a better job, be clearer with the regulations, It's kind of almost like a rumor." (10)*

Two wished it were possible to default to all states rather than having to select additional states (including more states increases the time for searches to complete). One mentioned that an autocomplete that would fill in the names of patients searched previously would be helpful.

One collaborates with social workers and would like them to be able to check: *"It's great that we can designate nurses to do it. Boy, would it be awesome if social workers could do it. If you're trying to do integrated behavioral health and your social worker can look at the PMP, and so, sometimes they see, I guess the sort of patients without it, and we don't need to see them that regularly, if they can't run the report, they can miss that the patient got a script from somewhere." (8)*

One desired to have other drugs that affect the central nervous system listed: *"Psych meds are not on there, and the reason why I would like them on the PMP is because particularly with opiates, they both affect the central nervous system, and I'd like to know, if I'm prescribing Tramadol, 70% of Tramadol affect the norepinephrine. Well, so do the SNRIs, and the SSRIs, they affect, and the tricyclics, they all affect the serotonin, and the dopaminergic system, which can cause a crisis syndrome with these dopaminergic systems. If I know that they're on them, then I can make an educated decision, on whether I'm going to give this patient this medication versus the other, but they're not on there, so I don't know. I'd love to have the psych medication, the tricyclics, the SSRIs, the SNRIs, I would love to have them on the report." (19)*

Finally, one noted that they had seen gaps in that some pharmacies (particularly mail order) do not report: *"not all drugstores put in the medication. I have a new patient who came to me, brought his pill bottles and brought his readout from his pharmacy, about what he takes. Yet,*

*there's nothing in the PMP about the medication …. There was nothing, I went back two years, and this readout showed at least a year's worth of opiate, and it's not in his profile. These are on mail order, if they get it mail order, that's not in there either." (19)*

**Monitoring Longer-Term Usage**

Pain Contracts. Most, though not all, of our interviewees who prescribed opioids long term were already using pain contracts before the law passed:

- *"this was already established in our practice." (12)*
- *"I think we always had a pain meds agreement, so for patients that I thought maybe were going to be more difficult I always did the agreement with, but now since I did the [name] project we really do it with everybody. It's not just for pain meds. It's for any controlled substance." (13)*
- *"Long before. I've been doing them for 20 years." (14)*
- *"The health center has had controlled and dangerous substance policies for well before the prescribing law, and I think everyone was in agreement it was best practice before the law was enacted. In the EHR, there's a standardized form that we're supposed to be completing for each opiate prescription or certainly chronic opiate prescriptions that is a checklist of all the things. There's a CDS contract. We've agreed we're going to be doing urine testing or drug testing around a certain number of times; that I've looked at the database and that I've discussed other treatment modalities with the patients and so on and so forth. That gets embedded into the EHR, and I'm supposed to fill it out each time I prescribe." (7)*
- *"Yes, definitely [predated the legislation]. We've been doing that ever since we started doing MAT. That whole [program] really helped us sort of get those tools in place for both MAT, but also to standardize our pain management." (8)*
- *"I think the changes that we made was immediately doing an opiate agreement at the first prescription. What we were doing before is there was some sort of vague determination like, "We prescribed you enough, you seem to be getting the prescription once and a while, so probably makes sense now to do an agreement." And obviously the people that I have who come monthly, yes, they've always been on agreements, but I think now the change has been we just immediately do it." (9)*
- "*I've had pain management agreements for a long time." (20)*

Those who were using them prior to the law's passage generally found them to be a good practice that helped them monitor patients' progress and inform patients about the risks of opioids or other controlled substances:

- *"Every single patient that comes in that's going to be on a controlled substance in our clinic, we have a … new patient packet that we go over with them, and our treatment*

*agreement is one of the things in the packet. And we basically talk to patients about having a controlled prescription and monitoring of that and we talk about safety. We talk about making sure that it's kept in a secure place. We talk about not mixing it with other controlled substances in that agreement. We tell them that anytime you're given a controlled substance we ask that nobody ever share or sell that medicine, that it's only for them - kind of the basic standards things in there for health and safety of themselves and the general public. And then we talk about the frequency that we see them in the office and that they have to come in to have a controlled prescription and that we do regular urine screening, and we can do regular med counts. We just try to put all those things out in the very beginning … in a consultative way so that we can talk to them about the regular clinic practices so that they never feel like they're being targeted and that all of the things that we might ask them to do at any time in their treatment are laid out right in the beginning. So if somebody calls on a holiday or a weekend or they lost their prescription, it's very clearly written in there that we cannot replace lost or stolen prescriptions because they're controlled substances, things like that. … But we don't fire patients from our practice except under very extreme circumstances that have safety issues. If it's ever happened, it's happened one time. So in general, our patient agreements don't include dismissing somebody from our practice. It may include helping them find a different treatment that is more effective for them." (18)*

- *"if I'm going to write them chronic narcotics … I'm getting the opioid contract signed early … My major driving point with them, and I think this makes a big impact on them ... is tolerance. So I say, "Listen ..." You come in and you say, [doctor], look, my pain's pretty well controlled on three Percocet a day." I say, "Well that's fine. That's great. That might last you another two days, two weeks, two months, and that three's going to turn into three-and-a-half or four. And then ... Because the body treats narcotics the same way it treats alcohol. The first time you had a drink, you felt a little bit tipsy, then you noticed the more you drank that one beer every day, you didn't get that same tipsy feeling anymore, and the next think you know it takes one or two beers. Well the same thing happens with narcotics so ..." That's how I really kind of steer the conversation. Because I don't know ... When I talk to them about respiratory depression, they're like, "That's fine. I'm not going to overdose. I'm not going to be taking enough where I fall asleep." So I really hammer home the tolerance and then more of the dependence ... I always tell them, yeah, I mean it's in our opioid contract, that risk of respiratory depression and death, so on and so forth, but ... Yeah, I mean, I do worry about it, but I'm just trying to do the right thing for the right patient with the minimal amount of medication that keeps them comfortable and just go from there." (17)*
- *"They sign a contract with me about various things that we can both negotiate and/or comply with. One of the things I've asked is that, if I'm starting them on an opiate, they*

*see a substance use counselor. If they have mental issues, a mental health counselor, and/or many of them will also see my psychiatric APN … this is a pain management agreement that I have developed, and it includes things such as compliance. It includes things like urine screening, about their ability to try different types of therapies. Sometimes, people come in and because of prior experience, they know that an opiate will take care of their pain, so they'll say, "I don't need anything else, I just need blank, like Percocet." I don't just prescribe opiates. I want to look at other types of medications, particularly gabinoids, muscle relaxants, if it's low back pain, different types of things that have proven in the literature to really substantially affect the pain that you're describing. That doesn't mean I will not prescribe an opiate. We have a prescription monitoring report in New Jersey, so if I look on that, and in the first past year they have been on opiates, I take a look at that, and the patient and I discuss that. My first appointment with my patients is always an hour to an hour and a half, because I have a lot of things we need to discuss. … it includes everything that the State wanted in it. I do include a few more things … It's very comprehensive. There was a tool kit, a pain tool kit that came out a few years ago. … I've constructed my contract with a lot of the things that were in this pain tool kit, which talked about different kinds of contracts. … you have to have some kind of an agreement for a couple of reasons. Not just so those patients knows exactly what to expect, and you know what you are ... you tell them exactly what constitute a continued relationship. For instance, if I'm giving somebody a pain medication, and it's not improving their function, and it's not improving their quality of life, and I've gone up as far as I really feel that the patient needs to control this pain, then, there's no reason to give this opiate. Sometimes, I will decrease the opiate because it's not giving them a good quality of life, or function, it's not giving them any benefit. There's really no reason in prescribing this medication, so we need to look at other things that may help them, like acupuncture, or a joint replacement. If I had avascular necrosis of the hip, and it's continually getting worse, all I'm going to be doing is going up, and up, and up, and up. In my contract, I think it says something about, that it's not that you are going to be pain free, but we are going to improve your function and improve your quality of life, that's why we're doing this. I've always had a contract. It's also a way for the patients to know that if they're not complying to the agreement, that I ... we will discharge them from the practice. I explain that in great detail, not in the contract, but verbally, that I would never, if they were taking the medications, but they were not complying with any other types of treatment, that I would not cut them off and stop treating them, but I will wean them off the medication and then discharge them." (19)*

- *"I think that we've reviewed a CDS agreement is really important in terms of setting the expectation for the patient. Because without that, you have very little to fall back on in terms of what was discussed and your ability to document that you've reviewed all those*

*substantive issues with the patients before you've agreed to prescribe. [interviewer: Do you feel like those documents actually help you to educate patients and help in facilitating a discussion with them?] Sometimes. I think it's imperfect. I think sometimes people are in such distress that I don't think the totality of what they're agreeing to is sinking in. They may just be saying, "Okay, I'm signing this because this is what I need in order to get treated for my pain," and what is being expected is not totally reflected on at the time they're executing the agreement. But I've found it very helpful to go back and say, "Look, this is what we agreed to, and you're stepping outside of that, so here's what we need to do."" (7)*

- *"I don't hand a contract to everybody because sometimes I feel it's inappropriate. But I have a tendency to do it. I would say at least half if not maybe close to two thirds I do. And I also do pretty routine urine drug screens. And then again, that's up to my ... discretion … I'm not going to do it to somebody who's dying with cancer pain; I'm just going to treat them and do the right thing. I wasn't taught to do any of that. I've learned that along the way. And it's an extremely valuable tool. Very, very valuable tool. [interviewer: And were you doing the pain management agreements before the law required that at the third prescription?] In talking to colleagues over the years we were moving more and more in that direction, but I've had pain management agreements for a long time actually. And one of the reasons is just so that patients realize they should only be getting them from me. They realize that they should be using one pharmacy, all of the little tricks that over the years you became aware of. It's kind of like an education tool. I actually have been using it for quite a long time. And when I first came to [location] I did acquire quite a few sort of non cancer patients. I learned pretty quickly to weed some of those people out because some of them indeed were inappropriate. So there's definitely a significant amount of scrutiny in regards to deciding who you think is going to benefit from the use of opiates and who is not. But I don't want the government to tell me that." (20)*

Those who started because of the law seemed more likely to find them burdensome--a box-checking exercise that was useful to neither prescriber (except with respect to protecting oneself from accusations) nor patient:

- *"this is probably a minority opinion, but I've never seen the benefit of pain management agreements. The main benefit of them is to the physicians, that if they find somebody breaking some rule, they can say, "You agreed to abide by this rule, and now I'm done with you." But I don't know that they really do anything to educate the patients or do a better job of getting satisfactory patient compliance as opposed to just building a proper therapeutic relationship or therapeutic alliance with the patient. They mostly serve legal purposes. … all these things are formalities in the sense that no one actually ... I think I would be surprised if people really went through this in detail with every individual patient*

*unless they have a mid-level practitioner to do it for them, because it would be a very lengthy process. I've spoken to one person that I work with who used to work in pain management, and she sort of confirmed my suspicions that there's not a lot of conversation on these points. We just have the people check the forms off. So unfortunately, it's like so many other things that are mandated, what you get is the thing checked off, but not necessarily done. [asked how often uses them] Now, I use them all the time since the law was passed. I never used them before."* … [estimates highest number would be 25 patients on agreements] *(1)*

- *"If it wasn't for the regulations, I don't know that I would, you know that's yet another thing that has to be done in the office, right? … In some cases, the patient's misbehaving, you can point to it as they've violated this court ordered contract. But I would say most of the time, it's more of a burden, than you know it is helpful. So it's not that it's never been helpful, it's usually not. … You could tell they [designers in the organization] did that in a rush, and it wasn't very practical and it turned out to be three and a half pages when it really could have been condensed … and that's the one you're supposed to use. … it wasn't done well. … the people who put it together, they're not physicians, they're not in an office. They don't know how to make a form. (10)*
- *"we instituted that last year. You know, when the laws came out. [interviewer: Have you found that to be helpful?] No. … I mean, if the contract is really between ... every time you see a patient you're really making a contract with the patient physician relationship. And these things on paper don't really mean anything. You can come back to it, if you have a problem with a patient, and say, "You signed this and that." But it comes down to the personal contact." (4)*

On the idea of burden, one interviewee noted: *"I think that burden was there before and people were just ignoring it. You know, because it's best practice quite honestly."* (7). Another interviewee treating cancer patients noted some disagreement in his practice regarding which patients should require agreements: *"There has been an ongoing debate in the [name] system about whether patients with cancer related pain should be required to have an opiate agreement. Pain management favors it, and oncologists tend to be resistant. … Our [organization's] pain service performs an opioid safety review … [interviewer: Approximately how often do you now use pain management contracts with your patients who receive opioids?] Fairly often. [interviewer: What criteria do you use to decide on requiring a pain management contract?] Concern that patients will consider the use of opioids stigmatizing if they have to sign a contract. When I explain that it is part of the times, understanding. If I think it will be for "some time", will try to have one done." (22)*

A study in a Pennsylvania clinic showed that patients had generally poor recall of contract items (Bahniwal, Sell & Waheed 2018). Tobin et al. (2016) review the history of contracts and suggest methods of improving their effectiveness.

Screening. Urine or other types of screening presented logistical issues for practices that had not incorporated it prior to the law: *"I haven't done a lot of the urine testing it wasn't clear to me how to go about getting it. Somebody had to clarify how to obtain that, which took a little time." (1)*. One interviewee noted *"when I see patients I'm all by myself" (15)* – this prevented them from implementing urine screening. A few interviewees expressed some hesitance in the interpretation of the results of screening analyses, and one who had expertise in the area talked about how complicated it could be:

- *"I must acknowledge that the tests are imperfect and I worry that at times I've been concerned that I don't always know the limitations of those tests" (7)*
- *"we talk about urine being only one tool in our toolbox, and they're not 100%. So we use that just as one tool." (3)*
- *"What are you looking for in a drug urine screen... What do these numbers mean? What does these substances mean? Like for Oxycodone, I'll find Oxycodone, but there's Oxymorphone, too, which is a metabolite, and how long does that stay in the urine, and what does that tell you? Versus just the Oxycodone. You could scrape a little bit of Oxycodone into your urine when you give me a sample, and you can have a high Oxycodone dose. If you don't have any Oxymorphone dose, that's telling me you're not taking it regularly. You haven't taken it probably for a week, or two, but all prescribers, some prescribers who really don't know the intricacies of it will just say, "Oh, they have a lot of Oxycodone, they're taking it." I think education is key." (19)*

Dealing with Nonadherence. Possible screening results that would trigger some kind of action included finding additional substances (raising questions of a concern for the patient's health due to substance abuse) or not finding evidence of the substance (raising questions of diversion). Interviewees differed in their responses to these findings. Comprehensive practices offering substance abuse treatment could continue relationships with patients under these circumstances by increasing monitoring, but other practices would often begin a tapering plan (if additional substances were found) or dismissal (if prescribed substances were not found):

- *"it would be patient dependent and it would involve probably referring them to behavioral health and pulling them closer rather than pushing them away. I don't know if that makes sense. Something shows up that shouldn't be there. That doesn't mean that I just cut you off and you can't come in my building anymore. It means you need to come in more frequently here, we need to figure out what's going on." (3)*

- *“If it's not going well, meaning if somebody's not taking their medicine as prescribed … we ask them to come in even more frequently. We'll see them twice a week, three times a week, and then up to five days a week. So they'll come in Monday through Friday and check-in with our front desk, our outreach health worker, our nurse. Then we can even go up to the point of having people doing observed medication in the office where they bring in their medication and take it in the office up to five days a week. And we do that for patients who really want to stay on buprenorphine because they feel like it's helping and yet they're still struggling with using or struggling with not taking it every day or having lost their prescription, things like that. And we've found that that helps patients when they have a severe use disorder or chaotic social lives, that we can offer them that support. So basically, we say if you're not doing well, we want to see you more, not less. We don't kick you out if you're not doing well; we bring you in closer. And then if we've tried all those things … we'll say, hey, we've got other medicines. We have other things we can do. We can help you get into inpatient. We can help you get into methadone. We can get you into a detox and then transition you to Vivitrol®. So that's how we work.” (18)*
- *“when we do the urine drug testing and we're seeing foreign substances that we didn't expect, that the patients didn't report, we don't tolerate that. So either they get that in line, or we don't see them. They don't come back.” (4)*
- *“Then I have to put the hammer down. By that mean, I put them on an involuntary wait, so if they're on narcotics, they wait. They're kicking and screaming sometimes, about that almost. It depends what happens, you try not to pull out the hammer. You try to make it but sometimes you have to and over the years, I've had to.” (10)*
- *“if they violate it basically I take them off, and they know that. I mean I wean them off. But they're told upfront. And if it's somebody who did it kind of like not on purpose, I don't know, maybe they're in the hospital, and the hospital sent them home with something, then I'll just kind of reschool them that they have to only get it from me. But the people that are running out early and begging for more, and that kind of stuff, I don't allow that. I mean we don't kick them out … I just won't order opioids for them. I think that I'll tell them they have to go to pain management, and get whatever other modality they can get, or they can try and see an orthopedic, that kind of thing. I mean we've had people that I've kicked off and put back on again because they just couldn't find any other place to go, and I think I do have a patient who continually overtakes at times, but he knows now that if he overtakes he can't ask me for more. They seem to be able to buy it off the street around our area, so if they run out they buy... which is not something we encourage.” (13)*
- *“Okay, so, urine drug screen comes back, and it shows an illicit like cocaine. There's black and white and there's gray areas. I try to... take as much gray the black and white as possible. But cocaine is one of the things like, okay, you have cocaine in your system, our*

*work here is finished. And I have a conversation where like, "Look, you can't be on this medication. You can't be doing cocaine and taking morphine at the same time. I can't write you for the morphine, I can't write you for narcotics anymore, so ..." But what I do ... Because you can't just cut them off. Right? … you can't let them go into withdrawal and let them flap out in the breeze. So what I normally will do is, depending on how much medication they're doing, I'll write them for, say, either some kind of a tapering dose or … I'll say, "Listen, there's like a one month supply of your medication. This is the last opioid prescription you'll be getting from this office. You talk to your primary care physician. Speak to your insurance company. You need to find …[a] pain management physician that can help you out, but we can't write you for narcotics after this unless it's an emergent situation." … at my discretion, if it's something really bad, then I'll discharge them. But there's always a little bit of wiggle room. Like we say you're not going to get it and fill it early. If they come in a couple days early, like two, three days early, well that's fine. That's really theoretically a violation of the opioid contract, but be able to say, "Okay, listen, you can't do this." But if they do it habitually then we'll get to the point where like, "Okay, here's a one month supply, go find somebody else." [interviewer: Do you make efforts in those cases to refer people to drug abuse treatment?] Yes... And it's interesting to see how many people, the negative reaction they have, and it's like somehow it's my fault that I'm discharging them. You're doing cocaine and you clearly have a problem. You know? So yeah, I mean, I talk to them about it … I'm like, "Listen, you clearly have a problem. This is something you have to do. I can't write you for narcotics anymore. I can do like this tapering dose for you so you don't go into withdrawal, but ..." I offer them some other treatments that are non-opioid related, but you talk to them about going to detox or something along those lines, yeah, I've had that conversation before, absolutely." (17)*

- *"if they're not complying to the agreement ... we will discharge them from the practice" (19)*
- *"someone who is not taking the medicine versus abusing, we do totally different things. So if they're not using and soliciting, we dismiss them from the practice. We don't even bother trying to send them to another pain doc in the area because of fear of solicitation. We put it in their chart and make sure it's very evident that they were soliciting the medicine. It's very rare that we ever have that happen, but we've had some circumstances where they were soliciting and taking the medicine. If a patient is abusing the medicines and taking it too often ... get them at least sent to addiction medicine and then speak to them about a plan to wean them to something much more suitable for them, like a Suboxone® or a methadone treatment plan … we don't continue to allow patients to abuse narcotics if they are found to have them. We address it, we find a solution, whether it's weaning them off, trying different interventions, using non-opiate analgesics, offering them addiction services, and even seeing behavioral and psychiatry." (12)*

- *“we don't fire patients from the practice for violations of our contract. I think the only people I have not prescribed for, and I acknowledge it's not totally perfect, but when their urine drug test comes back without the drug in their urine. That to me raises all kinds of concerns about diversion and it's being sold, and we just have to be cognizant that the patient population we take care of that may be a possibility.” (7)*
- *“Basically I can recall in the last year maybe one or two instances. And it was dealt with in two different ways. One lady, I made it clear to her that I wasn't gonna allow her to take more than a certain amount of narcotics. I added to her regimen tramadol as well as the narcotics, 'cause I was unwilling to increase the narcotics. … There was another lady who was overusing her meds, and she said to me, "You know, you really should increase them." So I said, "Listen, I'm gonna increase them just one time, and if it becomes an ongoing issue, then I'm not gonna do it anymore." There was another lady, this was actually before the law came into play who was clearly overusing her meds, and I just told her, "I'm not gonna give you these meds anymore." She had a problem both with narcotics and with benzodiazepines. I didn't get rid of her as a patient, but I told her I wouldn't give her these meds. And I haven't since … a man who clearly was getting meds from multiple pharmacies. There was another guy who was from me and from somebody else … I said, "No, I can't write them for you then." And he stopped seeing me.” (1)*

**Availability of Treatment for Substance Use**

Interviewees generally reported no change in the availability of treatment for substance use due to changes in the law, though one who treated patients with SUD who had private insurance appreciated the removal of prior authorizations for their clients.

Several saw some movement toward greater availability of MAT, though they did not attribute this to the law:

- [on whether treatment providers offer MAT] “*I think there's been some movement … so many people have gotten converted that those people are a little bit shunned … five years ago [not offering MAT] was the viewpoint to have. So I think it's slowly changing. But the people that are hanging on the hardest are the people who work in very intensive services and intensive programs, and especially the ones that are 12 step based, like fellowship programs. So a lot of the inpatient rehab, a lot of the detox places, a lot of AA and NA meetings, that's still very much in the 12 step culture. And so that whole idea that you're substituting one addiction for another. There's been so much education the last couple years, so I feel like the needle is moving on that. But we do have a lot of inpatient facilities that we work with, and it's very hard to refer our patients there, 'cause they wanna detox them off everything and send them out on nothing. And it's a huge problem still. And I think the state and the federal government needs to step in and stop accrediting people if*

*they don't provide MAT and whatnot. I think we need to have some licensing requirements that are changed*." *(21)*

- *"I think the medically-assisted treatment is becoming more widely available here … with [organization] now having a Suboxone®, you know, an MAT practice. The goal for the health center is to be able to develop a cadre, so I think the plan now is that we're all going to be trained for the Suboxone® waiver and to be able to prescribe. Because I think what holds practices back is it becomes one person's job, and that person quickly burns out, so you have to distribute it across the whole practice if MAT is going to be available. … It was harder for a while for people; it was harder even not that long ago for people to get into MAT here … and I think there's more options for that now." (7)*
- *" there are now other options where I can send them somewhere and they can be put on [medication]. You know, as an example. I'm thinking of a woman that I was taking care of, within the last year we were in that situation. Ultimately, that's what happened with her. That turned out to be a good option, she was very resistant to that, and threw up every excuse you could imagine. I just had to dig my heels in on that one. I put her on an involuntary wean, and it was either she was going to be on nothing or at least consider that option. In the end, she considered that option. I believe she wound up on that, at least she was started on it, I don't know what happened after that because I no longer see her. I didn't discharge her as a patient per se, but she discharged herself." (10)*

However, several raised the issue of affordability in SUD treatment:

- *"the problem is that they don't accept all insurance plans.... so it can be very expensive. Most people are not going to be able to afford to pay out of pocket." (14)*
- *"We're not putting enough money, for example, in rehabilitation and behavioral modification. You can't send patients to that unless they have a lot of money. … true behavior modifications, rehabilitation programs, those things are extremely expensive. Most people can't afford them." (20)*
- *"MAT, it hardly exists for Medicaid patients. … I imagine that the majority of patients who are in need of intensive services for substance abuse are on Medicaid or would qualify for Medicaid." (9)*

In addition to financial barriers, one interviewee mentioned barriers in terms of the structure of existing treatment "*we require them to go to an IOP [intensive outpatient] or some very intensive program with groups multiple times per week. And somebody might be trying to start working or taking care of their kids or doing other stuff, and we're kind of like no, you have to meet this level of care or we won't give you the treatment, rather than like meeting the person where they are. So I think we have to have much more flexible and on demand outpatient services because people instead just get worse and worse and worse and come into the emergency room when things have*

*gotten really bad, because they're not able to engage with outpatient services at a level that matches their needs. So I think we're a little bit too strict in that way too*." *(21)*

Many had the sense that people who wanted treatment could get it, but they generally did not follow up with people who they referred to treatment to check on the results from the referral: *"No one came to me and said, "I couldn't find the clinic." No one. I would hear of it. If somebody comes and says, "Oh, I am cold-turkey, I couldn't find the clinic," so I would do something. But they all have Google, and they found this clinic easily. I never had a problem. And we have a clinic from our hospital, so it's not a problem. The problem is they don't want to go over there." (2)*

Because the law did not change the prior authorization requirement in Medicaid (this was removed later, in April 2019 (Stainton 2019)), access to substance use treatment for this population was still difficult at the time of our interviews, as was access to other services for Medicaid patients, such as specialty care and physical therapy. The effect of prior authorizations on patient care is a national topic of discussion--the American Medical Association commissioned a survey of physicians about the effects of prior authorization requirements generally on their patients. Twenty eight percent reported a serious adverse effect on patient health as a result of authorization delay or denial (American Medical Association 2019), leading the AMA to petition Congress for access to timely treatment.[7]

Some descriptions of the effects of prior authorization for MAT:

- *"We actually hired someone, whose sole job at this health center is to obtain prior authorizations. That's how heavy a burden it is. So yeah and our patients would be waiting 24, 48 hours and that's a really vulnerable window right there. … eliminating prior authorizations … would be huge in encouraging other providers to provide the service. 'Cause they all know, like I don't have the capacity to be able to do all those prior auths. I can't be on the phone all the time, so I can't do this work. You can take away that administrative burden, you might find more people." (3)*
- *"would be great not to have to get a prior authorization for every single patient of ours who is on buprenorphine. That would be like a full-time nurse that we got for free. It takes a lot of time." (8)*
- *"So prior authorization is what kills us because we spend a lot of time on the phones prior auth... It might take them only 48 hours to turn around and give us that prior auth, but it still takes a long time." (11)*
- *"I have two nurses, and that's almost all that they do all day is prior auths [for MAT and other treatments], and referrals, so this huge layer of extra stuff because insurance issues*

[7] Petition text available at https://fixpriorauth.org/sign-petition (accessed October 15, 2019).

*is taking them away from really doing nursing is what I'd have to say. We do it. We're very aggressive with our patients because I only have a handful of patients and I have decent staff, so we can do it. I know a large clinic would find that completely overwhelming." (13)*

- *"It's unbelievable. The amount of time that I spent dealing with prior authorization issues just today was ... It's incredible. It's an incredible amount of effort on my part, my nurse, my front desk staff, our program assistant, our health coach. Literally every one of our team members ends up working on this because patients go to a pharmacy, they reject their prescription. Now we need a different prior auth or a new prior auth if their dose is changed. .. all Medicaid." (18)*
- *"I was talking to another physician here this morning, and they said the prior auths are the number one reason they don't bring more people into their private practice on buprenorphine. It's just a staggering amount of personnel time, and sometimes you have to get a prior auth before the very first dose. And then it could be anywhere from three to six months later. Sometimes they only give you a month and they want more information. It's all kind of faxes back and forth. Not uncommonly, the claims get denied, because they can't read the [inaudible] or they didn't think they were in psycho social treatment. So you have to go back and forth and battle with them. So it's literally hours every week dealing with prior authorization requirements, which is such a huge headache." (21)*

Providers also reported trouble gaining approval for extended release buprenorphine injections for patients who had trouble taking medication in a timely way or for whom there were diversion concerns:

- *"the Sublocade [injectable buprenorphine] has been an interesting challenge. … through some of the other payers, we've been able to get patients the Sublocade. [MCO's] model is a buy-in bill where you have to order the Sublocade and then submit the claim and you get reimbursed. Because the Sublocade is $1,300 out of pocket, we wanted clear confirmation from [MCO], not only that they're going to pay it, but how much are they going to reimburse. And despite going through several different avenues, we haven't gotten an answer back from [MCO] about that. Again, last week … talk to another location that had ordered Sublocade for her [MCO] patients and had not been reimbursed for it. … Sublocade is obviously much harder to divert than buprenorphine. Even though it's much more expensive, in the long-term, if the patient is stable on it, it's going to be very helpful." (8)*
- *"We have not yet successfully gotten Sublocade covered by a Medicaid provider, though I feel like we're close with [MCO]. … We have a large subset of our patients who … I think would do much better on the monthly buprenorphine." (18)*

In addition to the prior authorization barriers, providers wanting to offer substance use treatment encountered problems with licensing and reimbursement. A 2016 report noted that both licensing and reimbursement barriers hindered the integration of behavioral and physical health care in New Jersey (Jacobi, Ragone & Greenwood 2016). FQHCs faced long waits to become fully licensed to offer substance use treatment—there seemed to be differences of opinion as to what the requirements were, and some offered treatment without getting the certification. One provider (not at an FQHC but with interest in expanding access to MAT) said *“there's a lot of confusion over this. So if you're an individual prescriber doing buprenorphine, that's definitely not a problem in any setting. The difference is when you add in counseling. But you can have a set up where you hire a separate counselor and you're prescribing and still not get state licensing. And different people in the state will tell me different things. And I had a person tell me that they've seen the licensing person say two different things to two different organizations from the same regs, so I think it's really a very confusing gray area. Right now, it's taking New Jersey about a year to license programs under DMHAS, the Division of Mental Health and Addiction Services. Which is a tremendously long wait time. So given the current crisis, there's certainly no time for all these places to get licensed, nor is it necessary.”* (21) Another provider who had gotten the license said *“It took us one full year.”*

A provider who was offering MAT without the mental health license, noted: *“We don't have a mental health relations license. … controversial topic for FQHCs. But we do not have one and we are sure they're not going to supply one at this point. Our services, when we have our behavioral health counselor seeing patients side by side with our medical providers, they're providing behavioral health within the scope of primary care, using an entirely different set of codes than a mental health license facilities will do for mental health evaluations and mental health professionals. It means there's a different set of clinical staff than can be billed for. So we can bill for licensed clinical social workers, we cannot bill for case managers, psychiatric prescribers, peer recovery support specialists. There is some gaps there. … One of the biggest challenges to sustainability is that many of the Medicaid payers will not pay for behavioral health visit and a medical visit on the same day. That, of course, is integral to the integrated behavioral health concept. … they won't pay us when we actually do it. That's one thing that could really change in terms of sustainability.” (8)*

Another provider who was offering MAT had to let in-house psychiatric staff go because of the lack of licensure and felt it created a gap in their services: *“We have in-house LCSW who evaluates people, and we used to have in-house psychiatric nurse practitioners for chronic depression related to pain and things like that. We no longer do because we found out as we're a federally qualified health center, but apparently New Jersey because we're not licensed as a mental health facility we actually can't have in-house psychiatric care, and so since we lost our in-house*

*psychiatric care, it's been a big problem, huge problem. It's one of our biggest issues to not have mental health treatment because the other clinics are just overwhelmed and there's a really long wait to get anybody to see a psychiatrist on Medicaid. If they do go to see the psychiatrist, and they miss even one appointment they'll like not see them anymore, so it's very unforgiving, which makes no sense to me because some of these people are mentally ill. They're all mentally ill, and so they can't get themselves up out of bed, or they can't remember their appointment, that's because of their illness. They shouldn't be penalized." (13)*

One provider at an FQHC awaiting certification described the situation: *"I have a waiver to prescribe Buprenorphine … We do some Vivitrol®, that's about it … The issue has been that the state government, the state has required FQHCs to have a substance abuse treatment license in order to provide MAT, and there have been some rule changes that I think are in draft right now that it should allow us to do it as long as we have MOUs set up with some treatment programs, but for a while, even though there's this massive need ... there's nobody who does Suboxone® for Medicaid patients. … government regulations here have made it very challenging for FQHCs to go forward"* (9). For now, this provider's patients have to switch their assigned PCP to their Suboxone® provider, but that person does not treat their other health issues: *"I have [several] patients that I can think of right now who are stable on Suboxone®, just stable. These are probably the patients that I will merge back into my practice because one of them pays cash to somebody, $150 a month to get, she's got Medicaid, $150 just to get a Suboxone® prescription, and she's able to make it work, and then [number] of them go to [city 20 miles away], and they have to be PCPs there, but they're not really doing primary care. These are people who have massively complicated other medical issues going on, but the only way for them to access Suboxone® is to have their PCP, that doctor, because that's the only person who does Suboxone® for Medicaid, and that person is sort of ... I think, doing Suboxone® every month, and having them come, but really not addressing broader health issues with these patients, and it's a big challenge." (9)*

Another FQHC provider in a different region mentioned a similar phenomenon: *"There's a lot of providers that provide MAT cash paying service. So you want your medication for a week, then you are able to walk into certain facilities where there's pain management or certain other doctors that are specialty offices that are not necessarily primary care, pay your $150.00 that they charge, get it for a week. And who knows, you might take, you might not take it. I don't know what happens with that. But the state needs to really help us get better reimbursement. Help primary care get reimbursed for what they do, especially if they're MAT providers if that means working on our student loans, if that means getting a better reimbursement model, having more training involved, giving us grant funding to have care managers, hiring care managers or project managers that will help us do the legwork of prior authorizations. Keeping all of our Excel sheets up to date with all the patients, the DEAs that we need, that way if the DEA knocks on our door*

*we can be like here are our patients. There's so much work involved that you can do it in an eight-hour workday and not take your work home. And sometimes I feel like it's not even worth it because you're not getting reimbursed. … FQHCs cannot bill for urine specimens. We can't bill for these urine cups that are really costly and expensive. Or make them affordable for us to buy so that we can do these urine screens-…we're not allowed to, from a Medicaid perspective. They actually block FQHCs to bill for this special cup that we use, or even any kind of testing that we do in our office. We get a flat reimbursement rate from the state, so we can't double dip and bill for every little thing. We just get one flat fee, so they feel like that one flat reimbursement rate should cover everything that we do in the office." (11)*

Other than several FQHCs or prescribers who were already providing addiction treatment, prescribers we interviewed were not interested in taking on medication assisted treatment in their practices. We will discuss this in more detail in the next section on general themes we observed.

**Unintended Consequences**

Many, though not all, of our interviewees thought that there was an increase in untreated pain due to increasing restrictions on opioid prescribing, including the New Jersey law as well as changing norms about opioid usage influenced by factors including the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain[8] (Dowell et al. 2016), communications from insurers or other health care organizations, and attention by the media and community institutions about the opioid crisis. In addition to prescriber reluctance, several interviewees mentioned patient reluctance to take opioids (or pressure from family members to avoid), even when the prescriber was concerned about patients' pain. A national survey of primary care physicians conducted in 2014 found that 89% of them thought that people with opioid use disorder were self-medicating untreated pain (Kennedy-Hendricks et al. 2016). Peck, Parker and Sigmon (2019) found that nearly half of young adults reporting nonmedical use of prescription opioids in the 2016 National Survey on Drug Use and Health gave pain relief as a reason (this was more than twice the percentage reporting feeling good/getting high), suggesting that efforts to reduce misuse among young adults should focus on pain management. A study of primary care practices in Michigan in 2018 found that 41% of them were not willing to provide care for new patients taking opioids (42% were willing to schedule an initial appointment; the remaining 17% wanted more information), leading the authors to question whether access to primary care was reduced for patients taking opioids (Lagisetty et al. 2019). A 2018 survey by the North Carolina Medical Board found that 21% of practitioners discharged or transferred care of established chronic pain patients and 13% stopped accepting new patients with chronic pain, raising questions about

[8] See https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

access to care for chronic pain patients (North Carolina Medical Board 2018). The American Society of Clinical Oncology (ASCO) (2019) found that 92% of oncology practices were concerned that restrictions on opioid prescribing would result in undertreatment of pain and that 40% of oncology practices say patients had trouble filling prescriptions. Page and Blanchard (2019) discuss ASCOs policy statements. The President of the American Academy of Pain Medicine describes the suicide of a patient when the physician tried to reduce his dose, partly due to external pressure on his prescribing (Webster 2014).

Our interviewees had a variety of views. One provider did not feel there were negative effects in terms of increased pain among the patients they served: *"I don't feel that it's negatively impacting … They might be a little disgruntled about the fact that I tell them that, "I can write you a five day supply and you can call me in five days or you can come in in five days and we can talk about it," but I don't think that anyone is out there flapping in the breeze, writhing in pain because of the five day. I think it's that seven days would just be easier for the surgeons. But I don't think it's caused any kind of undue stress on the patients. I don't think anybody's flapping in the breeze with untreated pain, no." (17)*

Several other providers felt the picture was mixed:

- *"I really think that depends upon if they were pre-established before they came to primary care with pain management, then I would say they're over medicated. But if they are not established with pain management, and recently, due to the changes in prescription opioids, then I would say they're under managed. [Interviewer: So some people end up with untreated pain?] That's correct. (11)*
- *"I think that's a hard question to answer, because you're always gonna have to some extent some patients who feel like they're not getting their pain treated because they only wanted opiates. And they're fixated on the idea that opiates are the only thing that helped. And those are the most challenging patients of them all … I always set the expectation, we're going to make the pain manageable. That's why it's called pain management. And we can't make it 100 percent go away. If we do, that's great. If we don't that's what was expected. And we have to find a way to help your pain ultimately without using just opiate medications, because there's a risk of addiction" (12)*
- *"Yeah, maybe there are some who are not getting their pain treated because of the legislation. But there are a lot of patients who are no longer being prescribed opioids who did not need opioids. I think it's more the latter than the former. The patients who really do need opioids, I'm still giving them to them. The patients who I've been giving opioids for years, they still get opioids from me 30 days at a time. … I don't even think it's undertreatment, because it's never been proven to be effective long-term." (15)*

One provider noted that the five day rule caused problems for some of their patients: *"With my five-day patients, and I don't have many of them, that is a problem, because I'm not even there within that five-day block. Then, I have to have another prescriber see them, so that has been a problem. Or sometimes, these patients are then without medication. When that happens, they'll typically say to me, "Well, I took four ibuprofen, over the counter ibuprofen, about every three hours." That's not helping them either. Now, they have GI distress, that kind of thing. So it has [been a problem], but it hasn't been a major problem. There's a select sample that that's really been a problem for." (19)*

This same prescriber, together with others, described reluctance to prescribe, leading to untreated pain or other negative effects, such as gastrointestinal problems from NSAIDs (see Foglia 2019) or turning to illegal sources:

- [interviewer asked if prescriber believed there was untreated pain] *"Very much so. … I see it personally in my own prescribing approaches to the patient, and they're having that same difficulty when they see consultants and other physicians where people are not prescribing the opiates anymore. And sometimes they're in pain, we're resistant, we're reluctant to prescribe. I'm not sure if it's the wrong thing or the right thing, but, you know, I think there is ... especially for a short lasting type of pain, there are people ... let's say somebody comes in with renal colic, we're less likely to give oxycodone. We still do it, but probably less often. And then ... so patients are suffering. … [interviewer: Do you think this is harmful to patients?] Of course. Of course, I mean, potentially. And I don't know if it's harmful in terms of their ability to resolve their illness or their accident, but certainly harmful in terms of causing them suffering." (4)*
- Interviewee who didn't want to be recorded noted that some people with legitimate pain would not be treated because of reluctance of prescribers, and that some patients are suffering. (5)
- *"I've seen more instances than I can count of providers withholding opioid from patients who, based on my clinical judgment, very much need it. So I think the example that comes to mind most often, is of someone a sickle cell pain crisis. And I think that population is one that frequently experiences pain crises. Opioid-based analgesic pain killers are absolutely indicated to help break those pain crises, or tide them through, during the episode. I time and time again will see providers, give either no, or minimal doses, or less than the indicated amount of opioid medication to those patients. And then come back and make the comment that ... not only express a sort of pride in not giving the patient the opioid, but implying that the patient is ultimately drug-seeking. And so, I see that time and time again, and I think sickle cell pain crises are sort of a particularly complex and important because I think, it isn't lost on me that most of these patients are also individuals of color, predominantly those who are African American. … And that I think has*

*unintended consequences. Folks with sickle cell pain crises, those with cancer pain, and others are sort of caught are the unintentional victims of that mindset. So I think it just needs to be a more thoughtful approach to not use it when they're not indicated, but to also keep in mind a subset of circumstances in which they are indicated." (6)*

- *"I often worry about legislative solutions to prescribing because I think they tend at times to me almost feel a little bit too emotional, and I worry that people are at risk for being under-treated for pain at times because of the challenges that we've been talking about in terms of treating. I think access to the multi-modality stuff that we were talking about in terms of other solutions to manage pain and for people to have the time to really engage substantively in those conversations." (7)*
- "[Interviewer: Do you think there's more people who are not getting their pain treated appropriately?] *That is a fair statement. Yes." (10)*
- *"We have a subset of patients who have been cut off of chronic opioids, and we offer buprenorphine as a treatment for them. I talk to them a lot about the fact that this can be a parachute. It may not feel exactly the way you felt before when you were on your stable dose, but you can use this medicine. I think it's really important that as we're cutting down or even tapering or trying to limit opioid prescriptions that we have a way out for patients, that we have a treatment plan, that we're not just cutting people off because we've had many, many patients flood our emergency rooms and other local emergency rooms being cut off of opioid medications. I think training more doctors in this option and buprenorphine as a treatment option would help that. We work really closely with our palliative care doctors as well as other pain doctors so that if they are tapering the patient and it's not going well, they will actually send them to us so that we can help with other options. So I do think it's an important component to have. … We've seen patients cut off of opioids and just showing up in the ER in acute withdrawal, and we've seen patients who were slowly cut off, tapered off, any number of things and then ended up switching to heroin. … A large population of ours started as prescribed pain medication and then ended up going to buying it when they ran out of their prescription, and then went from buying it to heroin … Our emergency department sees about [10-20] overdoses a day. The max has been [25-35] in one day. So we treat quite a lot of acutely ill patients … The prescribing laws certainly make it more complicated to prescribe, and there's going to be another subset of people who are getting cut off there. I think that the key is that we have to be really mindful about training physicians how to do this well and how to take care of people if their chronic opioid prescription isn't the right thing anymore. So, yes, we want you to prescribe less and, yes, we want you to take better care of people when you're prescribing less, which means getting them into an appropriate clinic, getting your buprenorphine waiver, figuring out how to safely take care of people, doing really good urine screening,*

*continuing to have that philosophy that we have, which is you don't take somebody out if they're not doing well, you help them find a safer and better treatment alternative." (18)*

- *I'm only there [a few] times a month … I see at least one or two patients a month that have come to me from another prescriber. The reason being is the prescriber is either no longer going to prescribe it, and that's typically your primary care doc. They will say to the patient, "You have to get a new prescriber, because I cannot do this. My practice is not going to prescribe opiates at all." That's one. The other is they have gone to someone who has been giving them high amounts, and high doses, and they now cannot prescribe opiates. Either the DEA, I don't know the background, but either the DEA has come in, and restricted their DEA, or stopped their DEA. Some of the prior prescribers have left the country. They were from other countries, and they just closed up their practice. When you look at, going to the PMP report, you'll see that these are patients that were getting 30 milligram oxycodone, and they were getting 180 to 240 pills a month, and now, they're no longer prescribing for this patient. … they got it two months ago, so if they're really taking this much, they could absolutely not have any. When you call to get an appointment with me as a new patient, it takes two to three months to get an appointment with me. My next question is, so what are you doing? Because it they really required that high of a dose, A, I talk about, "Well, how are you feeling?" I talk about all the signs, and symptoms of withdrawals without calling them withdrawal. Many of them have not had that, and I'll say to them, "Then, what are you doing for this pain?" Nine out of 10 times it's, "My mother is giving me some, and my friend is giving me some, or I bought it on the street." That's nine out of 10 times. In addition to that, in between the medication, they've reduced their amount of opiates per day, because they could only buy so much, because it's expensive. They're also taking three or four Motrin every three to four hours, and now having a lot of GI complaints. ... more than not having the medication, they've just found other sources. And/or they go to the ER. Even though they may only get five pills, okay, they go to the ER, that's the other thing that I'm seeing. … my patients, when they run out, because I won't give them more, or I can't give them more, will go on the street and buy. Those are the patients that we try and find a happy medium of what they're comfortable with and what I will prescribe for them to prevent them from going to the street. If they do, then they know that I'm going to start decreasing the amount and discharging them from the practice." (19)*
- *"That just fundamentally is the problem. There are not enough physicians out there to take care of these people, so what do they do? … patients with chronic pain, even cancer pain, that don't have access. What do they do? They go to the streets. They go to the streets. And they just perpetuate the cycle. …I've had patients come in who are ... I've had patients who I've had to let go. That couldn't get off the street stuff. I had a sickle cell patient that I'd screened that had cocaine in his urine that was telling me he was using*

*cocaine for dental pain. I mean, I don't even understand the true scope … there's a whole other side that I think people are not paying enough attention to. Or they say they are, but nobody's doing anything major about it." (20)*

- *"On the one hand, I think prescribing has just been out of control, so we have to have some top down regulation. On the other hand, it's upsetting that the pendulum swings too far in the other direction. My [relative] just recently had surgery in her abdomen, and she was given no opioids, and she was in a lot of pain. And she went back to the doctor, who was a very young doctor. And he told her that one pill of an opioid can get you addicted, and so that's why he wouldn't prescribe it for her, kind of no matter what. So that's the pendulum swinging too far in the other direction. Like we do want people to have those several day prescriptions for opioids that the need post surgery and they're having really acute pain. So in that sense, I think this law has scared off providers from dealing with it at all. They have this idea that the regulations are so burdensome they don't want to get involved in it. But on the other hand, there is good data … if you get an ED prescription for five days worth versus 10 days, you see a huge difference in how many people are still on opioids one year later. So even though it seems kind of unbelievable, these short prescriptions that people are getting in the moment can really affect what happens long term. And so based on that data, I think the law does make sense. So I'm like kind of right in the middle on it where I feel two ways about it. I do know that a lot of people have gotten much more worried about chronic pain prescribing, and I have heard a few stories of people being very abruptly cut off their meds because of the law, even though those were chronic pain patients who were already grandfathered in, the prescriber got really nervous and cut them off, then they came to me for buprenorphine treatment. So that happened with a couple people." (21)*
- *"I had an elderly man with severe pain from [condition] who was seen by multiple providers before seeing me (for [cancer] followup) and I was the one to prescribe an opioid." (22)*

In the short term, untreated pain increases people's suffering. In the longer term, interviewees were concerned about a decreased quality of life for some patients, including the ability to be employed or participate in social life. Research has shown a link between chronic pain and suicide (Petrosky et al. 2018; Racine 2018). Interviewees noted health problems that could arise with long-term use of non-opioid pain relievers, such as organ damage from non-steroidal anti-inflammatory medications or acetaminophen. They also discussed insurance approval barriers to opioid alternatives such as Lyrica® and diclofenac patches or gel, lidocaine patches, and treatments such as physical therapy, acupuncture, and massage.

As noted in the quotes above, there was concern among some interviewees that the New Jersey law, as well as other attention to the opioid crisis, was leading to prescriber or patient avoidance of opioid medications even when they were clearly indicated, as in cases of cancer pain, recent surgery, or sickle cell crisis. In October 2019, the US Department of Health and Human Services published a new “Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics,” which reminds clinicians that dependence occurs after more than a few days of use and notes potential harm in reducing dosages abruptly. Earlier in 2019, the authors of the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain noted that “some policies and practices purportedly derived from the guideline have in fact been inconsistent with, and often go beyond, its recommendations” and that there are gaps in pain treatment (Dowell et al. 2019). The FDA issued a statement (Throckmorton 2019) and a Drug Safety Communication (FDA 2019) in April 2019 regarding the need to carefully taper opioids. The CDC authors and FDA were responding, in part, to a Consensus Panel Report which agreed with the guidelines but noted implementation challenges (Kroenke et al. 2019) and a “Call for an Urgent Action on Forced Opioid Tapering” by pain experts and leaders (Darnall et al. 2019). The Veterans Administration is investigating harms and benefits of dose reduction or discontinuation among chronic pain patients, with some evidence of harm in certain groups (Mackey et al. 2019). Peer reviewed qualitative investigations in two states (California and Indiana) show some harmful effects on patients from increased regulation of opioid prescribing (Gruß et al. 2019; Al Achkar et al. 2017). Reports of harmful withdrawal of opioid treatment can be found among reports from nonprofit organizations (Human Rights Watch 2018) and in media reports (Achenbach & Bernstein 2019; Farmer 2019; Freyer 2017; Hoffman & Goodnough 2019; Ray & Hoffman 2018; Llorente 2018; Stone 2018). Regulations vary among states—in addition to limiting days of prescriptions, some states limit amounts to a certain morphine milligram equivalent (MME) per day (NCSL 2019). In some cases, prescribers may taper patients even if they are supposed to be exempt, as described in Stone (2018).

**Thoughts on Whether the Law Would Reduce Risk of Overdose Deaths**

Most interviewees didn’t offer a direct opinion on this. Two were hopeful that prescribing restrictions could prevent addictions that might otherwise have occurred.

- *“prevent addiction maybe. Reduce overdoses of prescription meds maybe, but I think that obviously if they can't get what they need they are going to use illegally … in the last two months I had two people die of overdoses, and my patients who are using heroin come in, and they know numbers of people that have died of overdoses that they are begging for the Buprenorphine. They know there's bad heroin out there.” (13)*
- *“these short prescriptions that people are getting in the moment can really affect what happens long term. And so based on that data, I think the law does make sense.*” (21—

see extended version of quote on page 31 where prescriber notes concerns in practice about harm from too much reduction in prescribing)

However, several noted that most overdose deaths are from illicit rather than prescribed opiates, so that the effects would be indirect.

- *"the other thing is that I'm convinced that a lot of overdoses are ... strong fentanyl getting into the drug stream ... from China." (14)*
- *I don't hear of a lot of patients being prescribed opioids, or in combination with benzos or muscle relaxers for pain management. Those are not the people who are overdosing. It is … you know, your plumber comes to your house and goes through your cabinets and takes your opioids, and then it's Friday night and he has pills from other houses that he went to, and then ... those are the people that are overdosing, because they don't know how to ... they're not used to taking those medications." (15)*
- *"most people who overdose, they don't overdose with opiates … Unless somebody's suicidal. … most of them are heroin overdose." (2)*
- *I've been to some big ... conferences, to try to figure out this data that we've been getting about who are the people that are dying and where are they getting the medications from? Nobody really knows except to say, for example, my strong suspicion is that the great majority of people who end up overdosing are not getting the drug from their doctor. They're getting it from somewhere else, or they're using street drugs. And a lot of that is mixed up in that data." (20)*
- *"all of our patients who overdose, I am pretty sure they all overdosed on what we think is probably heroin and fentanyl. But some of them came to us as straight heroin users and some of them came to us as chronic pain patients." (8)*

While opioid prescriptions, particularly at higher doses, raise the risk of overdose ( Bohnert et al. 2011), investigations in other states utilizing PMP data have shown that those dying by opioid overdose do not necessarily have a history of opioid prescriptions (Abbasi et al. 2018; Hall et al. 2008, Mercado et al. 2018, Paulozzi et al. 2012). Several interviewees felt that access to adequate substance use treatment and mental health treatment would be key in reducing overdose deaths:

- *"if you really wanna do something about drug addiction, you have to have more programs to treat addicts. This whole thing that the state is doing isn't really gonna do what ... it's really more to show that they've responded to public outcry as opposed to actually addressing the problem."(1)*
- *"Besides obviously, ultimately deciding to remove heroin off the streets, getting people more in touch with Narcan, making it easier for primary care providers to prescribe Suboxone®." (11)*

- *“We want to reduce any barriers to people getting life-saving medications. That includes buprenorphine, methadone, Vivitrol® or depot naltrexone. That also includes emergency naloxone. We should not have prior authorization for emergency naloxone. And that's one big category. We need to increase access to any modalities that can reduce harm and infection rates. Syringe access programs that are evidenced based, infectious disease testing, low-barrier access to people being able to go in and get care. There are a lot of regulations around that, and that's another big component that helps our patients. Just start getting access to things that they need and then it's a door into kind, empathetic treatment. Then I think that some of the other biggest things for our patients are then long-term care for them, which includes wraparound care - so that's housing and job opportunities as people are in recovery.” (18)*
- *“it's difficult to get them the care that they need on the addiction side. I just was working on this with a patient very recently, and spoke to a psychiatrist yesterday about being so grateful that she was willing to work with them on that level while I worked with them on the pain level. But you know, true behavior modifications, rehabilitation programs, those things are extremely expensive. Most people can't afford them. … I think a lot of money needs to be thrown into that. Because that's at the heart of the problem, as far as I'm concerned.” (20)*
- *“we have to have much more flexible and on demand outpatient services because people instead just get worse and worse and worse and come into the emergency room when things have gotten really bad, because they're not able to engage with outpatient services at a level that matches their needs.” (21)*

Mathematical modeling of supply side restrictions suggests that limiting access to prescription opioids alone are not likely to reduce deaths and that other interventions (access to treatment, harm reduction, and reduction of the illicit opioid supply) will be necessary (Chen et al. 2019; Pitt et al. 2018). While most restrictions on prescribing are too new to be evaluated (Parker, Strunk & Fiellin 2018), investigations of prescribing restrictions in West Virginia found that deaths from prescription opioids decreased after restrictions were enacted, but deaths from illicit opioids increased (Gurka et al. 2017). Investigations of pill mill laws in Ohio and Tennessee found no effect on opioid-related deaths (Brighthaupt et al. 2019). British Columbia, in Canada, saw fentanyl as a factor in overdose deaths in 2012, with large increases in 2015 and 2016. An investigation of techniques used to combat illicit fentanyl (take home naloxone kits, supervised consumption sites and MAT) found that all prevented deaths, although the numbers of opioid deaths have not changed (Irvine et al. 2019).

## *Other Themes*

**Past Pressure to Treat Pain as a Vital Sign**

Several interviewees with more years of experience discussed past pressures to treat pain as the 5th vital sign, coupled with beliefs that opioids were not harmful, as driving high levels of opioid prescribing (see Rummans, Burton, & Dawson 2018, mentioned to us by one interviewee).

- *I was around when pain was ... the [fifth] vital sign … you would be reprimanded in residency rounds if you didn't ask the patient how bad his pain was and what you could do to get his pain better. Isn't it amazing how it's 180 degrees. It's the complete opposite nowadays." (14)*
- *"I think a lot of this … started in the PACU. … I don't think that the patients were getting properly prepped for their post-operative pain. … if people were sitting in the PACU and they were having like two or three out of ten pain, they were getting hit with fentanyl, morphine, or whatever, because … If we don't control pain, people are going to complain, people aren't going to come our hospital, our Press Ganey scores are going to be terrible because we didn't treat the patient's pain well. So there was that whole thing about pain is the fifth vital sign, we can't have people in pain, no one can be in pain. And it's unreasonable to expect … there was this expectation people were going to be pain-free, and if people weren't pain-free in the PACU, and they went up to their room and they still had pain, then they didn't think their pain was being well-controlled, people's Press Ganey scores got slammed. … then the orthopedic surgeons, general surgeons, didn't want their scores to go down because they sent people home in pain, so then they would send people home with ... 40 or 50 Percocet. Didn't matter what ... People were getting bombarded with the meds in the PACU, they were getting bombarded on the floors, and then we sent them home with like 40 or 50 Percocet, and that's where I think a lot of this came from. That there was the overprescribing, there was no one was allowed to have pain in the PACU, it was unacceptable, can't have it, and there was the expectation that people were going to be pain-free ... You know, yes, you're like, "Well, I'm in pain." Well, you just had a major abdominal surgery, yeah, you're going to be in pain." (17)*
- *"part of the change is not just related to the regulations, part of it is just change in terms of our understanding in medicine what took place over the last 25, 30 years, where we were much more ... where pain was this vital sign for some time. And we were much more likely to prescribe narcotics and advance the dose of the narcotics and opiates more freely. And we've learned not to do that because patients got addicted." (4)*
- *"I think we got here because in many ways it was a bit of a perfect storm, certainly over-marketing and over-academic detailing about pain management, and that coupled with everyone in primary care reporting pain as a fifth vital sign or however we were phrasing it. And it's unusual for someone to come in and say, "I don't have any pain."" (7)*
- *"I think that we are … culturally still very much struggling to dig ourselves out of the 90s,*

*where as a profession, we and the drug companies hand in hand, and the Drug Commission, became convinced that we would eradicate pain as a human experience and shut our eyes to the long-term physiologic effects of opioid use." (8)*

**Stigma of Long-Term Opioid Use, Addiction Treatment**

Others noted longstanding stigma toward longer-term opioid use as well as addiction treatment that had co-existed with the focus on aggressively treating acute pain (i.e., negative attributions of drug seeking among chronic pain patients).

- *"I can think of at least three or four instances in recent weeks, in which we've been informed that buprenorphine is now stocked … we're allowed to initiate it, that the healthcare system … is in favor of us doing so. But whenever I have raised the question of starting someone on it … I've been informed that [supervising] physicians have asked me to not do so. … And so I think that there's like this larger stigma and reticence to treat opioid addition with medications. … I remember at least two [supervising] physicians saying that, "It's not like opioid withdrawals have killed anyone. I wouldn't bother."" (6)*
- *"when I used to speak throughout the state [about a painful condition, 10-15 years earlier]… The impression I had is that every family doctor that I spoke to feels that if his patient is asking for a narcotic, he must be an addict. I first didn't believe it, but the more I spoke, the more I realized that these family doctors actually believe that everybody they're seeing is looking for drugs and is a drug addict. In my experience, it's been just the opposite. In my experience, most people don't want to be on narcotics, but pain can destroy their lives. Sometimes, putting them on a narcotic can turn their life around for the good. … when I look at someone, I don't automatically think that they're an addict. People can be in pain and pain can destroy your life, so I like to say a few good words for the people living in pain out there. I really think the family doctors are missing the essence of pain when they think all these patients who are looking for pain meds are addicts." (14)*
- *"goes back to like 1914, to the Harrison Narcotics Tax Act, which is this act that functionally served as prohibition, but was really just meant to tax heroin and cocaine that were moving across state borders. And it was really like when the DEA first got started and this crackdown got started, etc. and they ended up arresting 20,000 doctors over several decades for providing morphine to people who were addicted to morphine. So it was kind of this really ugly time in the history of American medicine, where doctors felt persecuted for treating patients with addiction. And unfortunately I think the psychological ramifications of that are still here today, where we have an entirely different treatment system for addiction, and all these weird regulations and licensing requirements and we're barely allowed to prescribe buprenorphine, that's only since 2002. But since the 1960s, we've only been able to do the methadone as a pharmacological treatment for people with opioid use disorder. And I think a lot of that goes back to stigma*

*and fear and drugs are bad and all kinds of failed public policy basically."*[9] *(21)*

One prescriber who prescribed opioids for pain and also provided MAT drew a distinction between the way they saw prescribing and the way they had been taught: *"everything we were trained was there's the appropriate pain medicine patient and then there's the one who is abusing or misusing, diverting, etc. … starting to recognize that they're all in some degree one and the same, and that it's really a disservice to a patient to almost kind of pretend that here's this way where we're going to make the pain go away. It's going to be great and there's never going to be problems. It's much better to, from the very beginning, just say this is an extraordinarily powerful, yet dangerous tool, and we want to be really straightforward about the ins and outs. We want to always have an exit strategy. Then the same is true when we see patients for MAT, we always say to them, so you're going to get to the point where you haven't used opiates in three years, you're doing great. You may want to try tapering off your medication. You may not. You may want to say in maintenance, but you're going to live another 50 years. It's not if, but when, somewhere along the way you're going to have physical or mental pain, and you're going to be at extraordinarily high risk for relapse and you're going to want to have a plan in place for how else are you going to deal with that physical or emotional pain, because it happens." (8)*

**(New) Awareness of Opioid Harms**

More newly trained prescribers had been warned of the dangers of opioids early on, including opioid-induced hyperalgesia, risk of addiction, risk of drug diversion to people other than the patient for whom the medication was prescribed, and risk of death or injury from overdose.

Many interviewees mentioned the risk of opioid-induced hyperalgesia, particularly at larger doses, something they attempted to discuss with patients, often unsuccessfully.

- *[interviewer: "In your own clinical experience, if you get someone on a stable dose of opioids for a long time, do you see the development of hyperalgesia?] Sometimes … this is a guess, maybe about a fifth or a quarter of cases." (1)*
- *"There's evidence that it actually makes chronic pain worse the longer that you're on them. … [interviewer: Have you seen that, the hyperalgesia, in people who take them long term?] Absolutely." (3)*
- *"it's our responsibility as medical providers to be very straightforward about the risk and benefits. I think the hardest piece of that conversation is we know that chronic use of opioids creates significantly hyperalgesia. We actually don't know how that happens at the receptor level. But we know that that's the case. We know that in as much as there is evidence that suggests that you're more likely to die and more likely to suffer if you take*

[9] See Drug Enforcement Administration: The Early Years: https://www.dea.gov/sites/default/files/2018-05/Early%20Years%20p%2012-29.pdf.

*opiates in the long-term. But each individual patient has the experience of, I had pain, I took this medication, I have now taken it for a long time. When I don't take it, I have terrible pain. When I do take it, that terrible pain goes away. Therefore, the way our brains are wired, I conclude that I need this medication to treat my terrible pain. Giving to the point of, if and when we can get your receptors back to normal, your pain probably wouldn't be any worse than anyone else with your condition. And you would have decreased the risk of morbidity and mortality. That's a really hard place to get to in a conversation. Takes a whole lot of continuity of care and continuing to have that same conversation over and over again. You have to wait for the patient to sort of be ready and notice the harm the medication is causing them." (8)*

- *"I think like 30, 40 years ago the studies showed that okay …opiates have no ceiling effect. And then we realized, okay, well there kind of is a relative glass ceiling … to the effect of how effective the opiates are. … Some people say 90 oral morphine equivalents. Some people say 100. Some people- [interviewer: Hyperalgesia also, it wasn't really out there as much.] Yeah. It wasn't no. And so you took these patients with extreme pain, and then they're still on high dose opiates, and then they come off the opiates, and they actually feel better." (12)*
- *"The one thing that also scares me and anyone who deals with pain should know this is that sometimes being on narcotics for a while can actually give you pain. Then, you're chasing this pain that is given by narcotics. That's something that I'm sure people, including myself, can miss. That's what I'm saying, you really need a real specialty just dealing with pain, because these little nuances can change things." (14)*
- *"Well the first thing I do is I tell them … "You're on more medication than people who are dying of cancer. … You are on enough medication that if I took the amount of medication that you're taking, I'd stop breathing about half an hour." Right? Kind of try to put it in perspective for them. And then I tell them, first off, it's not sustainable. … I have my conversation with them about defining terms, about tolerance, dependence, addiction and so on and forth, and I define all the terms for them, and then I through, I'm like, "Listen, the problem is, and there's a good body of evidence that talks opioid induced hypersensitivity, and we're actually ... By giving you this much medication or even increasing your amount of medication, we might actually be increasing your pain." … generally speaking, those conversations don't go well. And it's very hard to get through to those people ... we talk about the etiology of their pain and then I have to start trying like, "There has to be a better option for you, whether it's non-opioids ..." Where we talk about spinal cord stimulators, or potentially even an intrathecal pump, but I always try to tell people, like, "Listen, I would suspect that we could probably cut your medication in half and your pain probably wouldn't be significantly worse." … I just had a patient two weeks ago who I had that same conversation with … He comes in last week and he says to me,*

*he's like, "Oh, by the way, I stopped taking my medication a week or two ago. "I'm like, "How'd that go?" And he's like, "Well … pretty shitty for about a week or two." I'm like, "All right. So what prompted you to do that?" He's like, "Well, I just kind of just got sick of it … after a couple days I thought I had the flu, so I went to the primary care ..." He listed like every single withdrawal symptom you could imagine. I'm like, "How you doing now?" And so this about like a week after. And it's like, "Well how you doing now?" He's like, "I'm fine." [doctor asked] "How's your pain?" He's like, "Well, no worse than it was." … That's only happened maybe a couple times over the course of my career, but it was really gratifying, and he walked out, and he's halfway down the hall and he just kind of stopped and turned around and said, "I really just wanted to thank you because I've been doing this for eight years and no one ever sat down to really talk to me about all this stuff." … I had another girl who was doing the same thing. … she comes back like a month or two later. … she's like, "Well I haven't had my meds in a month." … I'm like, "Okay? And how's your pain?" She's like, "Actually, it's fine. It's no better than it was when I was doing MS Contin 30 twice a day and 15 a couple times for breakthrough pain." I'm like, "Exactly. Now go home armed with that information and please don't take it ever again."" (17)*

- *"there is a downside that's inherent in opiates that can cause the patient a lot of grief. Opiates at higher doses can cause the opposite effect. They don't take away the pain, they make the pain worse, for example. … Or you can develop seizure disorders or develop certain movement disorders from the toxicities of opiates over the long term. Nobody really knows if there is a dose where their potentially long term toxicities are permanent with the use of opiates.... They're kind of a necessary evil because they don't cause end organ damage, and what I mean by that is they don't affect the kidneys or the liver. They're not toxic to some of those important organs. They can be toxic if you want to look at it this way; to the brain in that they can cause confusion or loopiness or some of these cognitive side effects that we hear about that can occur with somebody, maybe even a loved one that you've had experience with who is on opiates. And then of course the other big downside is the potential for addiction and even death if they're taken irresponsibly." (20)*

All were familiar with opioid dependence, and many had observed addictive behaviors as well in their patients, or treated patients with past addiction to opioids. All were aware of the risks of death or injury from overdose. Some had suspicion of illicit use or diversion among their patients. Most had not experienced an overdose among their own patient population, and none mentioned experiencing a patient overdosing on medications that the interviewee had prescribed.

**Striving to Balance Harms and Benefits of Opioid Prescribing**

Interviewees' prescribing decisions depended on what they believed about the potential benefits of opioids versus the potential harms to patients by not prescribing. Differences in their views and experiences led to different philosophies of opioid prescribing. Many explicitly mentioned an inherent duty to avoid suffering in patients—from pain, including the pain or potential adverse outcomes of withdrawal symptoms--and felt that prescribing opioids was part of that duty:

- *"one day, we took a Hippocratic Oath and that's right in the Hippocratic Oath, that you have to relieve your patient's pain. So either you weren't truthful when you took that oath ... and unfortunately medicine is a risky business. We have to do whatever we can for our patients, even if it means going out on the limb. Even on the narcotic limb, if you have to … Whenever I give somebody a narcotic, not only do I know the patient well, but I know the family. I make sure that I know the grandkids. Do the grandkids have friends? Do the grandkids have issues? Do the friends have issues? It's usually not the person that's gonna be addicted to the stuff, it's gonna be someone else who gets a hold of them. So for me to start somebody on a narcotic is a big ordeal. I spend a lot of time ... I sweat on every patient. I hate to put people on narcotics … So I'm super sensitive to writing any narcotic, but I do it." (14)*
- *"I have some friends of mine who are providers, that under no circumstances now are they prescribing any opioids at all, period. Yes, I see that, and I can't think of anyone who's said they've ramped it up, you know, everyone's kind of taking it down. Though, I haven't shut it off completely. I can't do that, and I don't think that's right. You know, some patients really do, they'll come in severe pain exacerbation. And, for that circumstance, the opioids do work. No doubt it will help them get out of pain." (10)*
- *"We've always been strong as an organization that we do not give any pain medication within our organization…. Let's say they are newly diagnosed cancer, those are the exceptions that I do have for giving out pain medications, but again, we have always followed the five-day rule. And then we always resort back to the specialist. So let's say they're newly diagnosed cancer and they're having pain. They would have to get it from the oncologist, or the person that's following them for that actual symptom." (11)*
- *"We're not a big practice overall where we give out opioids, but with like some patients I don't really have any other choice. …* [asked if they see patients coming from other prescribers who are no longer prescribing opioids] *For a while I would get a patient who would say they wanted to transfer into the project from somewhere else, and then we would find out that it was because they couldn't get opioids any longer in that practice. We would just tell them upfront that we wouldn't do that. I only do it for somebody I know, and I know well, and I've worked up. I won't just have people walk in the door and say they need this. … if they don't let me work them up the way I need to to get the answers then I don't give them anything." (13)*

- *I don't typically start patients on chronic long-term opioid therapy. So the ones that I inherited, they are physically dependent on opioids now and that's the only reason that they're still on them and trying to get them off. It's hard when they've been on them for years. I do want to get everybody off of opioids, but they're physically and mentally dependent on them. As long as I can keep their dose reasonable and not escalate it and make sure they're taking them as prescribed, those few patients that I have, I still prescribe on a monthly basis." (15)*
- *"I always start with non-opioids. But when patient comes to you after pain management failure, or the steroid injection and everything, they already passed this level. … I always ask them to bring me a couple of last notes from their pain management doctor, and in their notes it's always written, steroid injections, or whatever they did. So I already have documentation that was done. Not necessarily by myself, but if they failed that level I don't have to go back, I think. … And I do all these tests. We do this saliva test, we send it to the laboratory and they show what it is in their body." (2)*

Those who perceived less benefit from opioids felt less strongly about prescribing them, or about avoiding withdrawal symptoms in patients. Several prescribers were very concerned about diversion, feeling that they would have responsibility (not in a legal sense, but in a moral sense), if a medication they prescribed was sold or misused by someone other than the patient for whom they prescribed it.

- "*My caution has been much greater ... over the diversion, because now* [working in outpatient vs. hospital], *I don't have control over how much they receive, what it is they get and/or don't get with other medications that may influence the opiate. I think that has really changed my practice, working in an outpatient arena, particularly with the majority of my patients who have had a substance and/or an opiate use disorder prior in their life, sometime in their life." (19)*
- *"So if I write a prescription for an opiate, I have to know that some of what I'm writing is going to end up on the street. Whether that's the case or not, if I'm gonna write that prescription, I'm gonna have to be okay with that going out into the street." (3)*
- *"the only people I have not prescribed for, and I acknowledge it's not totally perfect, but when their urine drug test comes back without the drug in their urine. That to me raises all kinds of concerns about diversion and it's being sold, and we just have to be cognizant that the patient population we take care of that may be a possibility." (7)*
- *"it is great to be able to provide buprenorphine in primary care, because the worst that's going to happen is someone's not going to take it and do what they were going to do anyway. If it gets diverted, someone is probably going to take it when they're feeling sick. It doesn't have that same lethality when it's diverted that methadone has." (8)*

Several mentioned that they were either considering or actually offering or prescribing naloxone for patients getting opioid prescriptions, particularly those at higher dosages. Two interviewees discussed giving naloxone to everyone:

- *"we do give out Narcan to everybody. I think the Narcan is a good thing. I think it sort of gets the word out. But it's only treating individuals who are overdosing. So it'd be nice to catch them before they actually do that. So it's certainly valuable, and it gives people a tool to save lives and you can't argue with that. But it'd be nice if we paid more attention to prevention and treatment. … We give it out to anybody who wants it. So I carry some. Staff members carry it. Whoever wants it we have it. We got a large donation of it, so we're able to just give it out to anybody who wants it. People walk out with it, MAT patients, patients on opioids, again anybody who wants it can have it." (3)*
- *"I prescribe naloxone for every single patient that I prescribe a controlled substance … [interviewer: Do you think that should be a universal best practice?] I think it should be … I say, "You should have the antidote to this medicine. What if somebody else took it? What if a kid accidentally took it? You have a dangerous medicine in your house." I think we have to have a conversation about how that medicine is dangerous and why it's dangerous …And we're getting to the place where opioid overdose is so common that I've used my own naloxone kit that I have in my house several times - once for somebody in the street, once on somebody in my waiting room. I don't have any controlled prescriptions, and I've used two naloxone kits in the past six months. So I think in general, a lot of people should just have it available these days." (18)*

Two interviewees mentioned selective naloxone prescriptions:

- *"we are recently giving Narcan to anybody on higher doses of opioids so that they have it in their house. [interviewer: That's in case they accidentally … take another dose or something like that?] Correct. Their family is being instructed what to use it for, and what to do." (13)*
- *"Naloxone is now prescribed regularly" (22)*

Two interviewees were talking and/or thinking about naloxone for their patients:

- *"I don't send people, and I probably should, I don't send people home with the prescription for Naloxone. And maybe I should. If you want to talk about maybe if you get to a certain morphine milligram equivalence that you're going to require people get sent with a prescription for Naloxone, and I'm not sure how you necessarily I guess prove that they fill it or have it available … people walk around with EpiPens all the time … And it's probably not unreasonable that if you … pass this certain number that we've come to agreement that you're the much higher risk for respiratory depression and overdosing... I think that's probably a reasonable expectation down the line … The problem with doing the Naloxone*

*thing ... The problem you don't want to run into is you don't want to give people a ticket to ... You don't want to give them the out. You don't want to say, "Oh, here, you can use this, here's this." You don't want them to ... Eventually they're going to be playing the game, and then they'll eventually overdose and they won't get the Naloxone in them. So I did want to kind of loop back to that." (17)*

- *"[interviewer: Are you prescribing Naloxone, or talking about Naloxone with your patients?] I talk about it, but I'm not prescribing it as of yet. Anybody that has a psych diagnosis always sees our psych APN, if they have a co-occurring diagnosis, they always, they have to see that person." (19)*

This balance, which bioethicist and former pain patient Reider (2018) notes is necessary to reconcile the moral dilemma of the potential benefits and potential drawback of opioids, is very difficult.

**Reduction/Avoidance of Opioid Prescribing**

Data from the New Jersey prescription monitoring program show opioid dispensations declining in 2016, 2017 and 2018 after a high in 2015.[10] Interviewees mentioned a decreasing willingness to prescribe opioids among their colleagues, including some who have decided not to prescribe opioids at all. We saw some mention of this in the section on untreated pain, and the following are additional examples:

- *"people stopped prescribing narcotics to their patients, that they have been prescribing narcotics for simply because of the new law. I've considered doing that, but I spoke to some colleagues who I figured had patients that they treated in the same way, and they told me they were just taking care of their existing patients. So I decided to do the same thing. … I have a gentleman who has a painful [condition] ... he was already getting his narcotics from his primary care doctor. When the law came in, the primary care doctor says, "I can't do this any longer," which I felt was a bit of a misstatement. It's, "I don't wanna do it any longer," and sent the gentleman to a pain management physician. And the pain management physician wanted to take him off all narcotics and just try him on some sort of spinal cord stimulator or something of the sort. And it was sort of a two edged sword. On the one hand, one could see in retrospect that he tolerated a good part of the reduction, but they weren't really treating the patient, they were treating the law. And so, I decided to take over his narcotic prescription at a reduced dosage to what he had been on before. But that was somebody that I knew and I had a relationship with… Of the [colleagues] that I work with, probably none of them prescribe narcotics, 'cause it's just not worth it to them. … I'm probably one of the more willing to do it in the group.*

[10] See https://www.njcares.gov/.

*[interviewer: And you're doing that out of your sense of professional responsibility to your patients?] Yeah, basically. I don't like to do it. It's a pain in the neck. I mean, it was before, and now it's more so." (1)*

- *"I have some friends of mine who are providers, that under no circumstances now are they prescribing any opioids at all, period. Yes, I see that, and I can't think of anyone who's said they've ramped it up, you know, everyone's kind of taking it down. Though, I haven't shut it off completely. [interviewer: Do you get patients that have been let go from other practices, either because they haven't complied with some pain agreement, or just because their provider is not providing opioids anymore?] Yeah. Both. More so the latter, circumstance. Less so that they were fired. Then, sometimes you don't know." (10)*
- *"[increased] referrals since the CDC guidelines and everything has come out. That was just an initial wave of kind of ... I think prescribers were getting a little uncomfortable with pain patients in general. So we saw a big influx of them." (12)*
- *"a lot of doctors we refer to now are not even prescribing opioids anymore. It's tough, and I feel bad for the patients, but I don't want to do it either. Everybody's being scrutinized. I get letters all the time that some of these patients I have on opioids, they're also getting benzodiazepine from another physician, or a muscle relaxant from their primary care physician. I mean, everything's being monitored. I don't want to have patients on opioids either. There's other non-opioid alternative that are still effective. Patients are getting addicted and overdosing. That's the world we live in now." (15)*
- *"I certainly prescribe less potent narcotics and for shorter duration now." (16)*
- *I get more opioid takeovers from ... Most of them are from primary care physicians in the area because of the new regulations, and even some who just aren't comfortable, and even before the regulations were put into place they would get people sent to me because the patients, the amount of milligrams or number of pills or something, primary care doctor was getting a little bit squirrely with and uncomfortable burning through that much medication. … But I do feel like there's a little bit of ... I don't know if dumping is really quite the right word, but ... Some of the primary care physicians really are kind of using it as a shield, that they'll tell patients, and this happens all the time, and it's really quite irritating, and this has been going on for years, that the primary care physicians will just tell patients that they... can't write narcotics. Which just flat-out isn't true. They have the DEA number, they can write them, and don't tell the patients that they choose not to. I've had people come in with some stories like, "Well my primary care physician said that her lawyer told her that she can't write narcotics." I'm like, "Well, that's just not the way life is. She had the DEA, she can write them, she chooses not to, but I'll help you out, but just so you know that you're kind of getting a little bit of the royal runaround." So I do find that annoying on some levels. But I can certainly if understand primary is not wanting to get involved in writing chronic narcotics scripts, but there's a fine line … as far as our practice*

*is concerned, we have not been flooded by people coming in from primary care physicians saying ... Look, and I can't ... I'm writing them for two or three Percocet a day for whatever, and they can't write them for me anymore. You know, some of the primary care physicians are still comfortable writing for two or three Percocet a day, which is reasonable. But if the patients come in and that two or three turns into three or four, and they're not getting their pain covered because of tolerance, dependence, whatever is going on with that patient, then I'm fine with taking them over. Every once in a while I'll see a patient come in whose primary's been writing them for like two tramadol a day for a year but can't write that anymore. I'm like, "Wow, I mean, it's not that big of a deal, but I'll help you out just because that particular primary care has been good to me with its referral base, so I'll take that too." But at this point I don't think there's an undue stress on the system for people to handle this influx of opioid prescription writing duties somehow." (15)*

- *[Interviewer: do you see people whose doctors just don't wanna continue their prescriptions anymore because it's too much of a hassle?] That's right. Not from the doctor whom they saw before. Most of these doctors, right, they give shots, and patients refusing shots. And so he just needs pure medications like this." (2)*
- *"I'm concerned about the greater repercussions. If I were a primary care person, I probably would choose just not even to get involved. It's just easier. A lot of energy goes into working with patients who are using these kinds of drugs. And it can be challenging, hence I've really limited it to cancer patient population. But even in the cancer patient population, it can be very challenging. It's like a cover your ass approach. And if you think about it, that is a huge barrier to good patient care. I mean, people are scared. ... maybe they are crooks, maybe they're criminals, that they lost their licenses. There's certainly a few bad apples. But the great majority of physicians are trying to do good. And they're trying to help their patients." (20)*
- *"I think this law has scared off providers from dealing with it at all. They have this idea that the regulations are so burdensome they don't want to get involved in it. (21)*
- *"because of the restrictions and the more difficult process of prescribing narcotics, we're probably limiting them more." (4)*

We also saw an example of this in our recruiting—one prescriber returned our faxed invitation with a note that they did not prescribe opioids. Medicare data showed this prescriber declining from having around 100 Medicare opioid beneficiaries in 2014 to about half that in 2016. In 2016, they were still above the 75th percentile with respect to the number of Medicare opioid beneficiaries among prescribers in their specialty group.[11] So, this was a notable change in practice for this prescriber. We did not note a dramatically lower number of opioid prescribers

[11] For this kind of information, see Medicare Part D Opioid Prescriber Summary File, various years, accessed January 29, 2019 from https://data.cms.gov/browse?tags=opioidmap.

overall in the data from 2015 to 2016, though there were fewer (we did not examine the number of opioid beneficiaries per practitioner). A national physician survey asking for the first time in 2018 found that 69% of doctors (77% percent of primary care doctors and 65% of specialists) had reduced their prescribing (The Physicians Foundation 2018).

Reduction/avoidance seemed to stem from at least three causes, according to our discussions with interviewees:

1) Increased awareness of the potential for harm with opioid prescriptions—from hyperalgesia even if taken as indicated, illicit use either by the person to whom they prescribed it or someone else, and overdose.
2) The logistical burdens in complying with New Jersey's 2017 law and other changes in organizational procedures or professional norms that called for more investigation and documentation in opioid prescribing.
3) Stigmatization of patients asking for pain relief. One of our interviewees mentioned having noted such stigmatization 10-15 years ago when he was in a position to be meeting doctors throughout the state,[12] and one long-term practitioner likened current events to a resurgence of opiophobia from 20 or more years ago. So, such stigmatization is not new, but the opioid crisis may reinforce a preexisting tendency to stigmatize.

One of our prescribers, while noting having been affected by the increasing unwillingness of primary care providers in particular to prescribe opioids, thought it was not necessarily all bad, because some providers did not have a good knowledge base for opioid prescribing: *"I'm only there four times a month … I see at least one or two patients a month that have come to me from another prescriber. The reason being is the prescriber is either no longer going to prescribe it, and that's typically your primary care doc. They will say to the patient, "You have to get a new prescriber, because I cannot do this. My practice is not going to prescribe opiates at all." … I think if a primary care provider is not comfortable with prescribing opiates, and doesn't really know the drugs itself, they don't know the interactions... I have had people who have had post-op pain and they're prescribed a long acting, Oxycontin, versus Oxycodone, for instance. They don't need a long acting. Why are you giving somebody a long acting when it's time released over a 12 hours versus something for the acute pain now that may alleviate the pain, and then, allow them to do okay with a Motrin? Because they don't know how to prescribe these medications. I've had a primary care provider who gave somebody a 10-milligram Percocet, and when he said that wasn't enough, they gave a him 75 mic Fentanyl patch, and the person was groggy and didn't understand why. Somebody who really doesn't know the intimate details of how to prescribe these drugs and how to combine them with the adjuvants that are really the most beneficial, I don't blame them*

[12] See quote on page 36.

*for not wanting to prescribe that medication. Even if all they did was do a pain management consultation, so that they're seen, and then the professional can come back to them and say, "This is how I would manage this patient." Then, the primary wants to prescribe it, I think that's much safer than just the primary prescribing it, honestly. I appreciate primaries who do that as a consult, and then say, they'll take on the patient. My biggest clog is when they don't want to prescribe at all, so now, I'm the only one that can do it and I have a limited number of slots that I can see patients at. Again, with the legislation, I would say, twice for new opiate prescriptions, even if it's Tylenol Number Three, or a tramadol, should be for seven days, twice. Then, if they needed after that, the prescriber can start making the decision on how to wean them off. I think primary care providers should have education on opiates, and what are the most appropriate to prescribe for an initial acute exacerbation of something. They have a fracture in the tibia or something, because of a fall, a recent trauma. That would be a great benefit, why you use long acting versus short acting, and how to prescribe that combination, and wean somebody off. It's not just the medication itself. Everybody can look up the medication, it's how do you finesse that long versus short, or together and then, how do you wean them off? What do you look for in a functional assessment and what kind of a checklist do you want to look at for a functional assessment and quality of life to see if there's a benefit to the drug you're prescribing. That education absolutely needs to be out there peer to peer, for, not only physicians, but for nurse practitioners, and for physician's assistants. Anybody who prescribes these drugs should have to have that education. … with all the scrutiny, you find more and more who won't prescribe because they don't have the knowledge base, and they're fearful of their license, which is actually not such a bad thing. I think the scrutiny is great, but I think if they had the education, how to write up a contract? What should be in a contract? That kind of thing. What are you looking for in a drug urine screen, and what does ... What do these numbers mean? What does these substances mean? … I think education is key." (19)*

In addition to prescriber reluctance, some interviewees mentioned reluctance among patients or their families to using opioids. In some instances the interviewee seemed to feel neutral or positive about this:

- *"Patients are aware of opioid epidemic and willing to try lower doses." (22)*
- *"A lot of patients don't even want opioids anymore. So I think it's been good." (15)*

However, in other cases the interviewee believed that the reluctance impeded patient care. One interviewee was quite troubled in our first interview (before we began recording) about a long-time patient whose spouse was concerned about addiction because, though his dose was stable, he wanted the medication before the next dose was due, so the doctor had referred them to a pain/addiction clinic, later saying *"Maybe I didn't need to give him Percocet all these years for his … pain."* The spouse's reluctance had made the prescriber question his treatment. The prescriber

called back a couple of weeks after our initial interview, very shaken to find that the patient, stepped down from Percocet to tramadol, had died, and that staff in the rehabilitation center felt that his pain had been a major factor in his death. Another prescriber noted: "[interviewer: it sounded like you were maybe concerned about patients not seeking treatment for pain, like being too worried about opioids or something like that.] *Absolutely … I'm seeing it in most of my cancer patients. But with some gentle discussion and some time in getting to know them and learning about what they've tried to do, I usually am successful in getting patients to go with some kind of a conservative measure that they're comfortable with. And that pays off a lot of times. But I'm absolutely on a greater level concerned about that. … All of this stuff to me is a big distracter. It increases the stigma that they have to go through in dealing with it. I have to reassure people about what they're doing all the time because of that. I mean, even from their own family members. From the pharmacists. It's unfortunate. … I can't overemphasize to you how important it is to understand that the use of opiates is a legitimate medical practice. And I have that discussion all the time with patients. I try to get them comfortable with it, because there's this whole other side which is the downside. Which we've already discussed and know a lot about. But I want people to feel that this is legitimate medical practice. This is standard of care. This is how we do it. And these are the up points and these are the good sides, these are the down sides. These are the risks, these are the benefits. We have all of that informed consent discussion. But it is legitimate medical care. And I'm afraid that even that is threatened. I have a partner who feels that they're evil. It just kind of gets me on my soapbox." (20)*

**Doubts about Opioid Efficacy for Chronic Pain**

Many of our interviewees doubted that opioids were very useful in the treatment of chronic pain due to tolerance or the development of hyperalgesia, in which a patient's pain could become worse. Two interviewees cited research:

- *"Some of the research studies have not really shown, in my opinion, that patients are necessarily better off being on opioids as a treatment." (10)*
- *"It's never been proven that long-term opioids ever worked for chronic pain. They've only caused harm. … we still do it. And I don't understand it, because it has never been proven to work for chronic pain over long-term, and doctors are still prescribing them." (15)*

Several others cited experience in addition to research, often with mixed results:

- *"I think there's a significant amount of times where opiates don't change the outcome, like if you're looking at functionality or returning back to work, whatever the end goal may be. But opiates generally don't help that much, especially in the younger population or mid-range age patients. I find that it's helpful for older patients who are more sedentary because of severe arthritis and it helps them just feel better. But otherwise, yeah, I don't think in general it makes a significant change in terms of outcomes." (12)*

- *“if you just use opiates, you are going to be destined to tolerance, and dealing with increasing amounts of medication that your patient is going to start to request. I think whereas it's really good for that visceral type of pain, I don't think that it's the only thing that you should be using. For instance, if you have bone meds with cancer, the nonsteroidal, the cortisone types of ... like … dexamethasone, are exceptionally good medication to use to mediate the pain. They will mediate it better than just increasing the opiates, because the opiates are going to cause the sleepiness, the tiredness, the constipation. Then, eventually, the tolerance, where they're going to be requesting more. I think the use of adjuvant medications is essential in treating pain, because they have different ... they look at different systems to help mitigate the pain. Do I think that it helps with the pain? I do, but I think only when we combine it with other medications to look at different avenues of this pain, look at not only the central aspects of pain, but the peripheral aspects of pain.” (19)*
- *“the pain world is not really my world. But I would agree that the evidence is really lacking for long term management with opioids. But there is that whole cohort of people that have stayed on their opioids and it's been years. And they're doing well and they're functional with it. So I don't think a rapid taper for those people is helpful.” (21)*
- *“[Interviewer: have you also evolved towards the assessment that long-term opioid therapy is not particularly effective in pain management?] Correct. I mean, of course. We've seen patients who have escalating doses, and then once you escalate the dose, then they get adjusted to the new dose and this tolerance, and then we have to try and escalate further. So there's a limit, so yes, that we have, because of that experience that we've have had personally, but it's also because of the experience of medical society now—I mean, all physicians, we've experienced it here as well.” (4)*
- *“I think there's been a fairly substantial change in the way opiates are prescribed, and I think those changes were in large amount due to just the overwhelming data that they were more and more associated with poor outcomes. In addition, the use of things like urine testing for substances abuse and doing controlled dangerous substance contracts has led just to probably a more thoughtful use of the medication and just that over the years I think many of the prescribers, myself included, have become concerned that it's a minority of people who you're using chronic opiates for who are really improving and functioning better while on them. … I used to have a fair number of patients on chronic opiate therapy, and over the years I have titrated them off because it was clear we just weren't getting where we needed to go. Occasionally, that's come with violations of the CDS contract that we have repeated positive urine tests for substances, urine tests that are negative for the drug I'm actually prescribing, so they're either not using it or using it in an inappropriate way. So the number of patients that I have on chronic opiate therapy is very tiny right now. I think if I were to take new pain patients, I would certainly work*

*with them if they came in on opiates, but I would be looking to move it off, again because my experience is as a long-term strategy it is the unusual patient that is stable on these medicines. I certainly would be very circumspect about starting anyone on a chronic opiate therapy without totally exhausting many other avenues of pain management." (7)*

- *"There's really good evidence and this is why they're not recommended for chronic pain. People who are on opiates for chronic pain, their daily pain scores are as bad or worse than people with comparable conditions who are not on chronic opiates. That's clearly demonstrated by the evidence. That's not an anecdotal question. I think the individual patient experience is a very different thing and that's where the conversations get so challenging. … Wherever there has been attempts to look at this, there is no evidence that people have decreased morbidity and mortality or lower pain scores. There is good evidence that they have increased morbidity and mortality. That's why there is a strong recommendation that just like chronic benzodiazepine is not recommended as a long-term treatment for anxiety or panic, chronic opiates are not recommended for the treatment of pain. Now that doesn't mean that we have a great solution for all the people who are already on them, but that's sort of ... I think of that as … generally accepted consensus, in as much as there is any evidence in this field." (8)*

Most interviewees, and particularly those who focused more on pain treatment, seemed to feel that in some cases, opioids were the best choice available.

- *"I think that there are patients who can benefit from opiates, no matter what. There are always gonna be a subset of patients who do benefit. Our patients who had multiple back surgeries or who have palliative cancer pain and who have debilitating contractures or whatever it may be, there's always that subset of patients who there's really nothing else that we can really do." (12)*
- *"In my experience, most people don't want to be on narcotics, but pain can destroy their lives. Sometimes, putting them on a narcotic can turn their life around for the good. … I have one patient, for example, who [found professional success after] … living with terrible pain. He had no creativity, that was all lost, he just was in pain all day. Now, he's back to [work]. That's one of few examples that when I look at someone, I don't automatically think that they're an addict. People can be in pain and pain can destroy your life, so I like to say a few good words for the people living in pain out there. I really think the family doctors are missing the essence of pain when they think all these patients who are looking for pain meds are addicts." (14)*
- *"we see lots of patients, and … almost everybody needs a narcotic after surgery." (16)*
- *"There's always going to be a certain subset of the chronic pain players who, no matter what you do for them, they're going to have to be on narcotics." (17)*

There was general agreement with the CDC guidelines that opioids should not be the first-line treatment for chronic pain. Their doubts, as well as their decisions to continue to use opioids in some cases, are borne out by the literature regarding pain medications—while opioids have not proven very effective in relieving chronic noncancer pain, neither have other medications such as NSAIDs, antidepressants, or anticonvulsants (Busse et al. 2018; Shapiro & Wilhelm 2018).

**Gaps in Pain Treatment**

Pain is a common condition. As of 2016, an estimated 20% of adults (50 million) in the US had chronic pain (at least most days for the past 6 months), and an estimated 8% (nearly 20 million) had high-impact chronic pain which limited life or work activities on at least most days for the past 6 months (Dahlhamer et al. 2018). The National Academy of Sciences, Engineering and Medicine (2017) notes that there are serious gaps in physician training regarding pain as well as substance use, and that insurance coverage for pain treatment is limited. Tobin et al. (2016) note that population access to board-certified pain specialists is limited and that many exclude Medicaid patients. Opinion research shows that patients prefer nonpharmacological pain treatments (Gallup 2017), but a study covering multiple insurers in 16 states showed that coverage of such treatments was limited and that patients faced higher relative co-payments for nonpharmacological treatments compared with medication (Heyward et al. 2018). Another analysis of the same data showed that insurers lacked strategies to improve chronic pain treatment or to integrate pharmacologic and nonpharmacologic treatments (Lin et al. 2018). Patients who want to reduce or eliminate opioids may find it difficult to get good medical support, as shown in an account from a highly educated pain patient attempting to wean off opioids based on a doctor-provided schedule (Reider 2017).

Many of our interviewees noted gaps in pain treatment for patients, in several respects:

1) <u>Tendency of Primary Care Practitioners to Refer Patients to Pain Management Practices for Treatment of Pain.</u> This was not necessarily a problem in and of itself, except that there were many perceived gaps in the availability of pain management care and limitations in the populations served by pain management practices. Several primary care providers told us they had few options for pain management referrals for their Medicaid patients, and one pain management doctor noted that reimbursement was poor, so that some of his colleagues did not accept Medicaid. One primary care interviewee who was willing to prescribe for pain with consultation from a pain management practitioner described frustration in his attempts to develop good working relationships with any such practitioners (due to limited numbers of such practitioners in his area that accepted Medicaid patients, his primary constituency, and the focus of practitioners on procedures rather than development of a treatment plan that could include a primary care practitioner): *"Pain management virtually doesn't exist..... when*

*you can get somebody into pain management, a lot of times the pain management doctors refuse to do any sort of oral medications. All they want to do is just do injections, and they'll tell patients that, which, honestly, is just absurd because if pain management as a specialty doesn't manage pain management in a comprehensive way, then who is supposed to do that? It's like the cardiologists deciding that they just don't want to treat atrial fibrillation anymore, right? "We're just not going to do that because we think it's too high risk." It's like, if they don't do it, who does this? It tends to fall down to another primary care. Unfortunately, Medicaid patients get stuck, and we get stuck as well. … we need pain management consultation, we need somebody to come in, spend an hour with the patient, and say, "Alright, what's driving your pain? What are some modalities that you've tried?" And sort of figure out what's a comprehensive plan here.... we send patients to cardiologists, I'm not saying, "Hey, cardiologist, see my patient every month and manage their blood pressure." What I'm asking is, "Give us some guidance here for what we should do with this patient's cardiac condition, and then we'll help to put the plan into action, you don't need to see them that much, but once and a while we'll need you to check in and tinker with things, give us some feedback, see how things are going." Part of that plan for pain management might be opiates, but having a thoughtful, thorough pain management evaluation that gives a whole list of modalities is really the standard of care, and no one's doing that. There's all sorts of resources for diagrams of patients to describe where their pain is coming from, but I don't have an hour in primary care to do this, and perhaps they don't have an hour in pain management to do it for Medicaid patients, but ... I mean everything's about reimbursement, so people will be happy to do things if they're reimbursed well for it, but I think what's really lacking for patients is ... we're talking about opiates, but we're really not talking about comprehensive care for pain management. I know that we're trying to walk back this opioid crisis, which obviously makes sense, but we also need to be walking forward this more sensible plan to actually provide good care for patients." (9)*

2) <u>Limits on Insurance Coverage, Particularly for Medicaid Patients.</u> Many interviewees reported (and we found in our recruiting efforts) that many pain management practices did not accept Medicaid, leaving Medicaid patients with few choices. This was also true for non-opioid pain treatments like physical therapy, acupuncture, chiropractic care, massage, and non-opioid medications such as Lyrica®, lidocaine, and diclofenac.
    - *"I think the challenge that when you're working with an underserved population in general is access to other modalities can be cumbersome." (7)*
    - *"We do have an anesthesia pain clinic and a PM&R pain clinic here … and if we stabilize them from an opioid perspective, we are able to get them into one of those other clinics, but they have extremely long wait lists for Medicaid patients. So it's just always a challenge. There's not enough integrative medicine and alternative pain treatments*

*for our patients. So we do have access to it here in the health system, just not enough. [interviewer: we have heard some complaints about some of the alternate treatments being more difficult to access like Lyrica®, like Flector® patches or Lidoderm® patches and some of those medications. Do you find that too?] Yes, we do. A lot of prior authorizations required. It goes against my mantra of make the bad hard and the good easy, which I think we always need to focus on. We want to make the treatments that are helpful for our patients and have less side effects, complications, use disorder potential and we want to make the treatments that are really safe easier to access. And then there are other things like acupuncture, massage, yoga, stuff like that. Insurance just doesn't cover that. … grant, that allowed us to spend money on specific things including wellness, housing, transportation. We include wellness through zen yoga and meditation and other things." (18)*

- *"In large quantities it's so tough to get those things pre-certified, so the practical, harsh reality of working in an office is as it is, you're trying to get so many things pre-certed that it actually turns more to over the counter. Believe it or not, go to old Bengay®, which is a topical silicate. Menthol is a counter irritant. Aspercream®- … now you have to fill out paperwork … as opposed to I just script you. … So you know Flector® was tough, Lidoderm® would be another example of a local anesthetic patch. … not all physical therapy is created equal, so I am really really adamant that they go to a legitimate physical therapy place … good therapy can work wonders. Bad therapy is a waste of time, money, and then it prejudices that patient against exercises … [interviewer asked about insurance coverage for PT] it's a little harder, but not as tough as it is for some of the imaging, and some of the medications. [asked about Medicaid] The preferred places won't accept Medicaid, because it pays so poorly. So, then my options are more restricted. Sometimes I have to send them to a hospital situation, and sometimes the hospital therapy is not geared very well for outpatient. It's better for inpatient. They're used to people who are in bed, and they are just trying to mobilize them in a bed. They just do range of motion, so you have to send them to a hospital, and that's not as good in my experience. So Medicaid's a problem trying to describe them PT, it can definitely be a problem." (10)*
- *"I find the biggest issue to be about approval of these non-opiate medications, which are really difficult to get approved. 'Cause a lot of times we've actually gone by what they have asked, they being the insurance company, which medicines they want us to try, which medications they want them to go at, which milligram. We've gone into that specific detail. And yet, we still, after following all of their step one, two, three process, we still end up at the same point where they just don't approve of it. So it's very hard to treat a patient effectively … We find it difficult to get Flector®, diclofenac patches. 5 percent lidocaine, we've had more success with, 4 and 5 percent, but it used to be*

*difficult. Lyrica® is next to impossible to get approved." (12)*

- *"[interviewer asked about access to PT for Medicaid patients] We can get people there. They're generally not so impressed with the care they get, and it could be because they're Medicaid. I'm not sure, but they get minimal attention when they go I think. … I wish desperately we had access to massage therapy because that would be extremely helpful to so many patients. It's hard to believe insurance won't cover something like that. … Flector® patch, they definitely don't pay for unless they have private insurance. But the Voltaren cream or gel I can usually get. Lidoderm® I can no longer get. We used to get it. We can't get it anymore. So right, a lot of that. … I haven't had trouble with Lyrica® yet, I don't think, but I barely have anybody on that. We only use Lyrica® really for fibromyalgia, so as long as you use it for something that it's indicated for I can get coverage. But yeah, I mean it's very hard. … I think of modalities, the … project that taught me was really run out of a pain management group … they were able to get their patients all kinds of complimentary modalities, and those are things that we can't get for our patients. … if you can't do anything else, then really all we can do is give them a pain pill, and to me that's not the way to do it of course, but if they aren't really leaving you with very few other options." (13)*
- *"Lidoderm®, no one pays for them. You have to have great insurance [interviewer: Is that because there's some available over the counter now?] Yes. But the ones that are prescription work better. Yeah, that's true. Lidoderm® patches really help people. Flector® patches you can never get anymore. Yeah, so for people who had a stomach ulcer, they can't take or Diclofenac, they used to have these patches and a lot of people found it helpful." (14)*
- *"For nonnarcotic medications being covered, I feel like it's been pretty much the same since the legislation changed for opioids. But since before the legislation, definitely it has gotten harder to get nonopioid medications covered, which really doesn't make sense to me because the two sides are fighting against each other. They don't want us to prescribe opioids, yet they won't cover other medications that are effective and nonaddicting and non-abusable. It's like, what do you do? You have these patients on opioids, you want to get them off, but there's no alternatives because their insurance is not covering it. … the reimbursement rate for interventional pain management procedures is extremely low for Medicaid patients, so that's why our surgery centers don't participate with Medicaid as a primary." (15)*
- *One of the other medications that I really like and get shot down a lot ... a long-acting version of gabapentin. It's ... Gralise®, and [Horizant] They're antiepileptics but they're long-acting. So the problem I have when I write for gabapentin is that ... The main complaint we get is sedation. So people, "I couldn't tolerate it. I take my evening dose it's fine. I take my morning dose and I feel like a zombie." So Gralise is nice because*

*you can ... You give them the medication, they take it at like 6:00 at night, and the sedation, if it's going to hit them, hits them around midnight, 1:00. They don't get that hungover feeling the next day. But even though it's long-acting gabapentin, and it's an antiepileptic, you can't ... It's really hard to get it approved unless you're treating the patient for postherpetic neuralgia. So it doesn't have the indication necessarily for radicularpathic or neuropathic pain, which ... So things like that are monumentally frustrating. … I have a lot of people who tell me that the Lidoderm® patches are helpful, and I just tell them, "Well then just go buy the 4% patches over the counter, because I can't get the 5% approved for you." … I have a tough time getting Flector® approved as well. Because if it's not for, you know, whatever, they're not approved for lower back pain. [asked about NSAIDS] I use them as much as I can. But you have to worry about the people who are renal impaired or the people who have peptic ulcer disease, history of GERD and what have you, and now there's a number of medications like Vimovo®, which is basically Naprosyn coated with omeprazole. But then again, hard to get approved. … You can't just write it for whomever. It always becomes a stumbling block. But I use nonsteroidals as much as I can, within reason. Not the long-term, because you can't ... I try not to keep people on long terms, like, "Listen, we're going to burn a hole in your stomach." But, you know, I really like the inflammatories. The antiepileptics, like gabapentin and stuff like that, I use those a lot too. And then just, you know, as long as they can tolerate the side effects or what have you, I'll try my hand at whatever kind of is in the arsenal, if you will. But the patches I said are hard to get approved. Things like the Vimovo® and the Duexis are kind of sometimes hard to get approved. So sometimes your hands are tied." (17)*

- *She could not take gabapentin. … The Duloxetine didn't do anything. They were telling me, when I was calls for peer to peer, because I prescribe Lyrica®, and she had had Lyrica® by another prescriber, probably last year, but then, didn't need it, so it was stopped. They refused to give me the Lyrica®. I did peer to peer a few times, and they said, "This sounds like it's something that we can do. You'll know in 24 hours." In 24 hours, it was denied. I finally did find someone at [insurer], it was in the pharmacy, that actually gave approval for it. Now, I have another person, same problem with Lyrica®. They wanted me to prescribe, Amitriptyline, which is a tricyclic. I didn't feel comfortable doing a tricyclic with this particular patient … The other thing that I'm having a problem with is I do prescribe, either a Lidocaine gel, or a Voltaren gel, depending on their pain. I'm having more and more insurers deny the cream, telling me that they can buy something over the counter. I'm having more and more prescribers say no to that. I'm trying to think what else. I don't use the patches, the Flector® patches as much as I use the Voltaren gel, because the gel seems to ... the patches fall off and the gel doesn't. I usually give them the gel. … Outpatient wise, I*

*use more adjuvants. I use more muscle relaxants, creams. I have a compounding pharmacy that will put together some creams that have a little gabapentin in it, that have some Lidocaine in it, that type of thing. That has been very beneficial for my patients. … my biggest problems is that my patients don't have the money … to buy this medication. … my Medicaid population, unless I could find a funder that's going to pay for it, they typically will not get it filled. … I had a patient on Oxycontin... I'm trying to slowly wean her off the medication.... I've weaned the short acting now down to twice a day, and I'm trying to start weaning the long acting. … I had to do a peer to peer, and they don't do three times a day, two eight hours, for long-acting. … They approve only two 12. That's really impinging on my ability to decrease this long-acting for this patient. … It's the Medicaid insurer." (19)*

3) <u>The Concentration of Pain Management Practices on Procedures, Often with the Exclusion of Medication or Behavioral Interventions.</u> If the procedures offered did not work for patients, or they did not wish to undergo procedures, there were few choices for patients to help manage pain. Several interviewees, including those offering such procedures, noted that procedures held potential risk as well as potential rewards. Risks may be discovered among commonly performed procedures (see e.g., Kompel et al. 2019 and Kijowski 2019).

Prescribers looking to refer patients for pain management, including narcotics if necessary, described frustration at their perception of the procedural concentration of pain management practices:

- *"Well, this is a bias of mine, and I'll admit to it. I don't think pain doctors really wanna prescribe narcotics. My experience is that pain doctors, and again this is a bias, like to do procedures. … They don't really wanna treat pain. They may be obliged to in a certain proportion of cases, which perhaps I underestimate, but they don't really wanna do this. So I see people going to pain doctors for their pain, and the first order of business is a number of injections. Only if the injections don't work for some reason do they eventually wind up on pain meds." (1)*
- *"Most of these doctors, right, they give shots, and patients refusing shots. And so he just needs pure medications like this." (2)*
- *"I can't find anybody who wants to take on pain management prescribing, and narcotic prescribing. That's not something you can find anymore. … Right, they just wanna do the procedures and get paid, you know." (4)*
- *Certainly, the pain management practice at [location], it is involved and will see our patients. I think the challenge I have is they tend to be heavily procedure dominated and so that the support of counseling, the mental health comorbidities may need to be addressed. I don't think at some pain management practices that those are being*

*adequately addressed. So I think there's a tendency to, from what I've seen for the pain management practices … it's, "Okay, we can do these injections, these injections," but beyond that, the old what I used to know as pain management where there was a psychologist and a pharmacist and maybe even a toxicologist who's integrated into the practice to help manage the patients is hard to find. … Right now it's a proceduralist-dominated specialty. I think the data is missing there just like it was missing for opiates. But it is, unfortunately, I think what's being reimbursed for." (7)*

- *"pain management will only do interventional kind of procedures, they won't actually give medications." (13)*
- *"Down over the years, I have ... it's really bothered me. The fact that what you … think is a Pain Clinic, is a Procedure Clinic. Unfortunately, there's so much money ... to be made in giving injections and then the injections don't work, which they don't in many cases. Then, the pain doctors, they don't want to follow the patient. So they're not giving the pain meds. Some of them do, but most of them around here don't. … I'm super sensitive to writing any narcotic, but I do it. I do it more than most doctors because I probably get the worst pain patients. … we had a rule that we would not take Pain Doctors patients. Because for years, every Pain Doctor once they made their fortune and the patient was no better, they would send them to me. … That got them somewhat upset. There are a few that … I have much more respect for." (14)*
- *"The surgeons, they do their surgery, and then we're PCPs and pain management, we're left with ... because they don't want to prescribe opioids. They just want to do surgery. Then we're left with trying to figure out." (15)*

Two prescribers described how some patients, having undergone unsuccessful interventions, were wary of them:

- *"[on procedures] if they're given appropriately to the right patient it works fabulous, but again I have a lot of patients that just refuse it. They don't anybody sticking needles in their spine no matter what we tell them as far as how well it can help them. [interviewer: it sounds like you think [procedures] can be helpful, it's just that your particular patient population is sort of wary of those procedures] You know, some of them have been. I mean others have utilized it, and maybe 50/50 if it helps, but the ones it helps it was great. Some people that I have on pain meds now have very, very chronic orthopedic conditions for the most part. I don't think I'm treating anybody for anything, short-term pain. It's like they've already had back surgery, they've already had neck surgery. They have just a lot of severe orthopedic issues, and the orthopedist is willing to do pain management, but that means they have to go to them monthly, and often they don't want to go there monthly." (13)*
- *"For somebody who has failed back surgery syndrome, spinal cord stimulation is an option ... I exhaust everything before telling the patients they're going to be on opioids for the*

*rest of their life, because they're not going to work, you're going to get tolerant, they're going to stop working and you're still going to have pain. It's just a cycle. [interviewer: Do you see a number of patients with failed back surgery?] I do, yeah … In the 90s and early 2000s, everybody was having surgery and fusions. I would say those surgeries were 50/50 back then, and a lot of those patients now are worse off than they were before the surgery. I have [number] patients like that who are on chronic opioids that I inherited." (15)*

Two prescribers tempered their frustration with the realization that pain management practitioners were making practice decisions for what the interviewees felt were legitimate reasons:

- [interviewer: Have you seen any changes in your ability to refer for pain after this law?] *We already have a lot of problems … The pain clinic here is primarily a non-opioid pain clinic, which I think it's good in one way. They're trying to do the right thing. But in the other way, they're really only offering patients like nerve blocks or NSAIDs, so a lot of patients end up not going to them. And also, I've heard that you have to submit your imaging ahead of time and go through a screening process to even get into the clinic, so I haven't been successful in referring anyone here. Most of my patients who are in pain clinic kind of found it on their own at an outside place. And I actually know the pain management people, and I know they're good doctors and they're trying really hard, I just, they're worried about becoming a pill mill clinic, so they have a very strict no opioid use, which can be difficult when you're dealing with people with true pain conditions. (21)*
- *"First of all, if you're going to a pain management physician practice ... many times, they're anesthesiologists who do pain management. ... They want to do injections. They want to do interventional pain management. … Again, they want to do it for legitimate reasons. They don't want to addict the patient. It's not lucrative, financially, I will tell you, to prescribe pain management medication, because you're just doing an office visit symptom management. It's much more lucrative to do a procedure, and/or a combination of both." (19)*

Two pain management prescribers acknowledged some concentration of the field on procedures but noted reasons other than reimbursement for this, including better results and avoiding opioids. One also noted some risks involved.

- *[interviewer: pain management … becoming more procedural, the incentives are for people to use nerve blocks and interventions.] "Yeah, I mean a couple reasons. One, it definitely pays better. Two, it's gratifying, you get an immediate, response. Sometimes, so that is part of it. And, three, as we said it's becoming more regulatory with the narcotics and if you can't do that, what are you gonna offer them? … there are some things that can be really really helpful, and other things that are going to be subject to abuse. People will*

*do them inappropriately, because it generates money for a practice. You kind of see every variation, but I would say in a properly selected patient, under confident hands, with someone who's well trained, takes the time to get retrained, and keep up with things they can be really helpful. And, potentially dangerous. … There's things that happen. … especially nerve blocks. So, if they are people who try them under ultrasound and are not trained well under ultrasound, get too confident, they wind up stabbing the nerve or god forbid, injecting into the nerve, because they kind of see the nerve a bit, but they don't see the needle. You know, there's some technical things related to that." (10)*

- *"our volume is pretty large. We're definitely seeing a high demand for it. I think with more education and the way that a lot of the … primary care docs in the area are learning more and more about what interventional pain doctors can do, they're sending more referrals over to get epidurals, nerve blocks, physical therapy, whatever may be necessary. They're starting to do interventions much earlier. And I think that's helping a lot of these patients stay away from starting opiates right off the bat like they used to be. … I think overall everyone's... moving in the right direction. I think that there were practices that probably were a little procedure heavy, and less on the PT side of things. But I think overall, most practices I've seen have moved in the right direction and done that more, where we're seeing a combination of physical therapy, non-opiate analgesics, chiropractic work, acupuncture and interventions whenever necessary." (12)*

One pain management practitioner who did interventional procedures as well as limited opiate prescribing described some frustrations of their own with reimbursement for newer procedures: *"There's a lot of things we can do now that we weren't able to do before … if I can take a patient who's doing like 40 milligrams of oxycodone a day and getting them down to doing like five or 10, and if I have to repeat that eight months, a year or so later, I'm fine with that. You would think that the insurance companies would be fine with that too, but I've had any number of conversations with a couple of the medical directors at the insurance companies. I'm like, "You do realize that we're getting good results with this?" And you just tell the guys, like, "Listen, I've had people that have like 75% reduction in their pain and they've gone from four Percs a day to one or none, and you're not willing to pay for this? You'd rather have them come in and get four Percocet a day for the rest of their life. You're not seeing the long term here." But since it's not approved, Medicare ... It's weird the way some people pay for stuff and some people don't, but suffice it to say that there are definitely options out there for people that are non-narcotic and the insurance companies just need to get more onboard. But it's also the onus is on us to do more research on it, do some class one studies and get some good double-blinded studies and just kind of see how people do with these procedures and ... So there's a lot of people in pain management, they're doing a lot of good work out there … will help reduce the narcotic load for that patient population as well. So we just got to get the insurance companies onboard to start*

*paying for some of these things that don't have a really very long track record, but these are very prominent things, modalities for these people." (17)*

4) <u>A Lack of Effective Treatments for Chronic Pain.</u> None of our interviewees seemed to believe that opioids should be a front-line treatment for chronic, non-cancer pain, but they did note that in some cases it was the best option to improve patient functioning.[13]

More from the primary care doctor on this issue, covering many of the issues mentioned above: *"I think there's been a dereliction of duty by the pain management community, by the pain management specialized physicians in terms of taking over pain management in a broad sense. They're anesthesiologists mostly, and they seem to be interested in billing and not interested in actually taking care of pain management … maybe that's a reimbursement issue, maybe we need to build pain management into primary care in a better way and reimburse that differently, reimburse comprehensive pain management evaluation in a different way, because it takes a while. Maybe we need to be talking about how we reimburse mental health professionals for helping with pain management. We're currently happy to use our substance abuse money and our behavioral health funds to treat addiction, but we're not using it at the beginning which is somebody has chronic low back pain, what do we do? How do we help that person deal with it? Maybe it's medical marijuana, maybe it's chiropractor care, or maybe it's some low dose NSAID, maybe it's an antidepressant, maybe it's something else. Maybe it's some topical treatment. Topical NSAIDs are not covered, we can't get Voltaren patch through Medicaid. Why not? Why can't we get a Lidoderm® patch, why isn't that on the formulary, I can get oxycodone, but I can't get something that's completely benign for a patient, so getting very simple pharmacologic changes that other modalities would be helpful, because the issue really is pain management at the outset. That's the root cause here. It's not opiate addiction. Opiate addiction doesn't just magically appear. If you talk to people who are addicted to opiates, the vast majority of them got hooked because of some orthopedic injury, had a car accident, had a football injury, and all sorts of stuff.... over half the patients have the exact same story. It's like, "Oh, yeah, I was in a car accident, broke my leg, and then I got on some Percocet and just got on more and more and more, and then I couldn't afford it, and then I got on heroin, and now heroin's got fentanyl in it, so people are dying." But if we can learn how to treat pain better in the beginning, I think we can not even get on that opiate path." (9)*

**Medical Marijuana**

Though most of our interviewees were not involved in prescribing it, medical marijuana was raised by several as a topic of interest among prescribers and patients. One had reviewed existing

[13] See quotes on page 50 about opioids being the best choice.

literature and thought it held a lot of promise: *"cannabis combined with opioids can increase the potency of the opioid for pain relief quite a lot. I think there's some animal studies where codeine, it was like nine times stronger. Morphine was three and a half time stronger when you combine ingestion with cannabis. And that does not increase the risk of respiratory depression. And there's also epidemiologic data showing in medical cannabis or in legalized cannabis states, you see reduced rates of opioid prescriptions and reduced rates of opioid overdose deaths. So I think we have to have a much broader kind of web for what we're using for pain management strategies, and potentially combining things like cannabis and opioids to get peoples' doses down. … I kind of had my vague impression that marijuana was okay, but I wasn't sure, and … I did kind of a deep dive into the literature and kind of became caught up to date on exactly what's going on in the cannabis world. And I was just blown away by the amount of good and beneficial medicinal effects you can see coming out of it. And the really lack of harm, that it's the least harmful drug of abuse that we have, right next to LSD, which both of them are in schedule one. And there's just tremendous amounts of people that are using it for seizures and pain and insomnia and anxiety and mood improvement. Just like a huge, it can even help tumors, we're not sure about which cancers and whatnot, but they've shown distinctively in animal models it can help tumor growth and reduce it and whatnot. So there's so many medicinal effects of it. So it's kind of ridiculous that it's not available. And the government even has a patent on cannabinoids for medical purposes. So it's just kind of ridiculous we have it in the schedule one status that can't be studied. And especially now given this crisis, we really need to open up the research to it." (21)*

One had positive reports from patients: *"Some of my patients will smoke marijuana, and that's giving them some good pain relief"* (19). One felt that their patients who used it were overcharged and did not benefit: *"everybody thinks marijuana is the panacea and it's not. ... These doctors charge a fortune. Most of them, that I send, don't even examine the patient and they won't give you marijuana unless I give them a letter that says they need marijuana. But you would think for that type of money, they would do a full exam and say, "Yeah, I think this guy needs this drug." But no, I have to write the prescription. Isn't that peculiar? … Most of my patients who end up on marijuana find out that it really is not helping them. Surely, not as much as they thought it would." (14)*

One noted "*Widespread interest in whether marijuana could be useful as an opioid sparing drug"* (22), but two were skeptical given the lack of clinical research:

- *"even though Medicaid doesn't pay for it, some of my chronic pain patients as I've suggested that this isn't the best way for them to manage their pain, they've engaged in medical marijuana treatment and gone to physicians that do that. We don't do it. We haven't taken that on as being a prescriber of that at the [organization]. I think there's a lot in play here, and it's a little hard to parse out where everyone's landing. … I think we*

*tend to look for simple solutions, just like we thought or it was being put out that chronic opiates were a solution for chronic pain, and I have a little bit of the same concerns about the commissioner's push on marijuana. I'm not sure I totally understand all the data that's there for its efficacy, how it's going to be used, but I think to push it as a fundamental solution to some of this or a cornerstone solution to some of this I think may be shortsighted." (7)*

- *"And it's coming into play because supposedly it might be opiate sparing, but what a mess medical marijuana is. Another field where there's absolutely minimal scientific evidence. And yet the states are choosing to allow Americans to ingest it without any FDA scrutiny, and given that the government still considers it to be an illicit substance…. Because supposedly it can't kill you. That doesn't mean it doesn't have negative and bad side effects, or very negative complications. Or even deadly complications. We don't know that for sure…. Go try this, go try that. I don't discourage people from experimenting with it. I tell them they're experimenting with it. I tell them if you are going to do it, go through dispensaries, don't get it on the street because you never know what's in it. But I'm not involved with the state program myself because I just philosophically, I'm not ready to be involved with it. And I think a lot of my colleagues feel that way. It's kind of more of a popular vote issue, if you get what I mean. … It hasn't been led by the scientific community and that's what made me kind of sway and get into that topic. I think in regards to opiates we definitely need more information, we need more research." (20)*

Several thought it was cost-prohibitive for Medicaid patients. In addition to the quote above, noting that patients are charged a fortune, were the following thoughts:

- *"they don't go for medicinal marijuana, even though I can write a prescription for it, that they should be seen, because they meet the criteria, they don't go because it's so expensive for the first visit. The first visit, they have to see the pain medical professional at the clinic. Then, they have to purchase an amount. One or two of my patients have come back and said, "It was $300, $400 to start, because of all the cause of the additional consultation and purchase. I can't afford that. I could go on the street, and buy some for 20 bucks, and it will be adequate. It's an adequate amount for me. I don't need to go to these medical marijuana places." (19)*
- *"the state has been trying to get people to prescribe medical marijuana. [organization] clinicians are actually prohibited … from prescribing medical marijuana, which is probably a good thing for us. … our patients can't really access it anyway. Undocumented patients are not going to expose themselves to this. … our Medicaid patients … you have to have one PCP... A lot of the docs who do medical marijuana prescriptions are PCPs, so even though they're just doing this sort of consultative work with medical marijuana … [patients] have to change their PCP to whoever that person is providing Suboxone® or*

*medical marijuana in order to get a discounted thing. Otherwise, it's pay cash for it, and that's $200 every three months or something seems to be the going rate. And Medicaid's not paying for medical marijuana, so it's $400 for an ounce of marijuana or something like that from the dispensary, so someone who gets Medicaid makes by definition less than $1200 a month, and then we're charging them $200 every three months plus $400 a month. That's not a feasible answer as an adjunct to pain management. So as much as medical marijuana has been put out there as something that exists, it's just not realistic for our patients. I have one patient who we've been trying to get to do this for like two years, and he can't get the money together to get his appointment with the other doctor, much less get down to [town] and spend 400 bucks and drive." (9)*

**Barriers to Addiction Treatment**

Phone surveys with substance use treatment facilities in New Jersey in 2018 showed that only about half of them offered medication assisted treatment (Clemans-Cope, Epstein & Winiski 2019). Some treatment providers are skeptical of MAT (Feldman 2018), often because they feel that MAT is still a form of substance use. As mentioned earlier, those we spoke with who provided substance use treatment were serving mostly Medicaid patients and were significantly burdened by prior authorization requirements (these were removed in April 2019, after our interviews) as well as trouble gaining approval for extended release buprenorphine injections for patients who had trouble taking medication in a timely way or for whom there were diversion concerns. On the positive side, Medicare Part D data for the nation show that prescriptions for buprenorphine and naltrexone have increased by close to 50% from 2016 to 2018 (methadone is not covered under Part D), and naloxone prescriptions have increased by more than 5 times in that period (OIG 2019). Upward trends can also be seen in New Jersey Medicaid (Agrawal et al. 2019). The New Jersey Department of Human Services is encouraging addiction treatment with buprenorphine by creating centers of excellence that provide training and technical assistance in addition to treatment, premier providers (including FQHCs and methadone providers) who are paid a bundled rate, and office based addiction treatment by primary care providers who employ navigators to address patient psychosocial needs (NJ DHS 2019b). As of October, 2019, these efforts have served over 1,000 unique individuals (NJ DHS 2019a).

In New Jersey, FQHCs faced long waiting periods to become fully licensed to offer substance use treatment. There seemed to be differences of opinion as to what the specific requirements were. Some FQHCs offered treatment without getting the certification.

Limits on coverage for opioid alternatives raised challenges for how to treat pain for patients receiving addiction treatment.

The regulation of methadone clinics was perceived by the few who had experience with it as overly rigid and segregated from other sources of care, which prevented it from being optimally effective because methadone providers can't discuss pain or other issues the patient may be having and adjust the dosage accordingly (those who commented on this perceived methadone itself as effective): *"the field of addiction medicine where we had methadone clinics is still clinging to sort of these, what I think of as now outdated models of addiction medicine, where rather than harm reduction, they're really looking at almost a crime and punishment model. That's effective for some people who are ready for that. But the challenge is the average provider in methadone, whether it's the prescriber or the counselor or the nurse, is not going to be able to have those more sort of evidence-based conversations about well, what are we going to do about your pain? What are we going to do about the fact that you are not adequately dosed at a hundred milligrams, but my guidelines say I can't go above a hundred milligrams because you're still using cocaine, etc., etc. They're very bound by a very tight set of regulations, which are understandable again, given the harm of methadone, the potential harm. But that potential harm isn't fixed by those regulations, just like the potential harm of prescribing opiates isn't fixed by what we've done with legislation at the state level. Any time you tighten things up, then you need to have an alternate structure for treating those people who you're going to lose with that tightening up. … Unfortunately, if you take a methadone clinic, most of the regs they have are not going to allow them to do" [things like harm reduction, peer or peri-support, and motivational interviewing]. (8)*

Other than several FQHCs or prescribers who were already providing addiction treatment, prescribers we interviewed were generally not interested in taking on medication assisted treatment in their practices. There were various reasons for this, including a lack of staff to implement the more intensive counseling needed, a perceived lack of expertise in treating addiction, and fears of the type of patient population that such an offering would attract. Media accounts can reinforce fears of patients in terms of behavior or volume (Rinker 2018):

- *"a number of comments that my colleagues will make, that make it very clear that their belief is that opioid use disorder is very much still in their minds, a lifestyle choice … So I think that stigma is certainly an element of it but I do think that there's other policy barriers from the reimbursement not being great for it, to it being so many hoops to jump through … the waiver needed to prescribe buprenorphine, the additional restrictions that are put on methadone. I think that those are all things that require revisiting and I think could be done ... partly would require federal legislation, the other parts could be done through rule-making changes." (6)*
- *"I'm not really qualified to deal with those kinds of things. So those kinds of patients wouldn't come to me. … I don't have any desire to get into this kind of thing … the last thing I wanna be is a magnet for people who want pain meds. … I don't want that kind of population. I have more than enough work as it is. If I have patients of mine that have a*

*problem, I'll try to help them out. But... I already have more than enough business." (1)*

- *"Right. I've been offered to be trained for buprenorphine therapy, but I feel like I would have like a line out the door if I did that, so I kind of don't want to be focused on substance abuse, I want to be focused on [type of] care, which is what I'm supposed to be doing. … I don't think I would have the time, that's the issue. I mean I can only see because of the grant [types of] cases. But if other [types of] patients in the area found out that I was doing this, they would maybe flock over, and that would be overwhelming for what I'm doing." (13)*
- *"[interviewer: It sounds like you have some training in … addiction or some exposure to that that you haven't decided to bring that into your practice. Is that something you think about?] Yeah. I would have if we had a practice that was set up to handle that. But … when I see patients I'm all by myself. … you need a nurse practitioner or a PA, somebody to see the patient on a weekly basis, do the urine drug screen, see them when they're in withdrawal, do the induction. I'm not equipped for that." (15)*
- *"I don't have a license to write for Suboxone®. It's not something I'm really planning on doing. The problem I have with that is... You kind of draw the crazies out sometimes. People find out you're writing for Suboxone® or you're writing for medical marijuana ... And I'm not ready to go down that road with people." (17)*
- *"I don't feel comfortable in that, because all this buprenorphine itself is the source of opioids. Like the day before they said, "Oh, methadone will help with this addiction." Forget it. They asked methadone for nothing. So I just don't do that." (2)*

In our recruiting, we observed a small number of practices that offered MAT along with other types of care (generally primary care), but we did not succeed in recruiting these practices to the study. The receptionist at one practice we contacted that advertised MAT on its web site did not know what it was, when we asked if they provided it. This pattern of low MAT knowledge/availability has been found in at least one other state: a phone survey of Michigan primary care practices conducted in 2018 found that very few practices provided medications for opioid use disorder, and for 41% of them, staff weren't initially sure how to answer the question about whether addiction treatment was offered (Lagisetty et al. 2019).

**Lack of Sufficient Behavioral Health Treatment, Particularly in Medicaid**

Several interviewees noted that behavioral health co-morbidities appeared to them to exacerbate chronic pain conditions in their patients (noted in literature by de Heer et al 2014; Bair et al. 2003) but they had a difficult time finding psychiatric treatment for patients. This shortfall was felt most acutely by those trying to find psychiatric care for their Medicaid patients:

- *"Well, you know the key I think to reducing overuse of narcotic analgesics is actually more effective treatment of depression … depressed people, and again I haven't seen the*

*research, this is simply a clinical impression, they have distorted pain sensation. And depressed ... there's a lot of somatization and depressed people often have pain. So if you can treat depression, that probably would do a lot to reduce the narcotic problem. … I can barely get psychiatric help for patients. It's extremely difficult, especially if people have poor insurance, finding a psychiatrist is like pulling teeth." (1)*

- *"but apparently New Jersey because we're not licensed as a mental health facility we actually can't have in-house psychiatric care, and so since we lost our in-house psychiatric care, it's been a big problem, huge problem. It's one of our biggest issues to not have mental health treatment because the other clinics are just overwhelmed and there's a really long wait to get anybody to see a psychiatrist on Medicaid. If they do go to see the psychiatrist, and they miss even one appointment they'll like not see them anymore, so it's very unforgiving, which makes no sense to me because some of these people are mentally ill. They're all mentally ill, and so they can't get themselves up out of bed, or they can't remember their appointment, that's because of their illness. They shouldn't be penalized." (13)*
- *"Insurance companies do not pay Psychiatrists adequately. If I had to choose one specialty, including [*own specialty-not Psychiatry*], that I think insurance companies should pay more, I would say it's Psychiatry. Not only do they not pay them, so the Psychiatrist can't spend enough time, they just give drugs. They don't really give them the time that they used to when I first went into practice." (14)*
- *"It's really hard to find people whose insurance will pay for stuff like that, for like the psych evals and see if they're decent candidates... [interviewer mentioned mental health parity] Right, but how much of it's going to be reimbursed? That's a whole 'nother can of worms you're opening up there, with how much does your insurance company reimburse for mental health services [interviewer: But I'm sure that's quite prominent in your (pain) population, right? Depression, other kinds of mental health problems.] Oh, yeah, I mean, we know that both fuel each other." (17)*

**Barriers for Medicaid Patients**

Interviewees brought up numerous barriers to care for Medicaid patients. Many have been mentioned earlier. Below are some additional examples.

- *"[interviewer: Do you refer for nerve blocks?] We do, but it's very difficult to find physicians willing to see the patients.... I would say we have a reasonable percentage of Medicaid population. And to tell you the truth, we can't find anybody to refer them to." (4)*
- *"[interviewer: Do you refer patients to pain management doctors?] Yeah. We do. I do. Again, I think for uninsured patients and patients with Medicaid that can be challenging, and I think part of that is that pain management has the same challenges that we do in primary care in terms of patients having appropriate access to alternative modalities." (7)*

- *"limited access still in … County for orthopedic doctors for Medicaid patients, so we have only one place we can go for somebody that has a back injury, and that's … Ortho Clinic for Medicaid patients." (13)*
- *"I for instance have an employee PPO insurance plan, and I can choose just to go directly to a specialist and make an appointment, whereas people on Medicaid have to go to their primary care doctor and get a referral for that other doctor, and then go to the specialist. And so these are already people with tons of barriers, in terms of having access to a phone, transportation, having a reliable daily schedule. And so to make them jump through extra hoops to get to a specialist is really challenging for them. … If you have money, you can find privately whatever you need to find. It's only Medicaid patients that really suffer in this way." (21)*

In addition to limited provider participation in Medicaid and more restrictive coverage generally, Medicaid enrollees also struggle with access to transportation, housing, food, access to employment, and general financial resources. These additional barriers caused patients much stress and anxiety, and interfered with their ability to access health services.

# Summary and Discussion

New Jersey's 2017 legislation restricting initial prescriptions for acute pain to 5 days, requiring monitoring of longer-term prescriptions, and reducing restrictions on coverage of substance abuse treatment is one of many actions taken by state and national leaders to address the opioid epidemic. In late 2018, we spoke with a diverse group of 22 prescribers in New Jersey regarding their thoughts on the 2017 law and opioid prescribing (including medication-assisted treatment). Though diverse, the group is not likely to be representative of all New Jersey prescribers—our interviewees were probably more likely than the average prescriber to prescribe opioids, and particularly interested in doing so in a thoughtful way (we offered a $125 gift card for interviewees, which is not a large amount to most clinicians relative to their salary or service/procedure reimbursement).

Many interviewees agreed that some restriction on prescribing was warranted, though opinions differed as to the ideal restrictions. Many were happy to have the regulations as backup for their discussions with patients, as many wanted to restrict their prescribing due to their concerns for addiction, diversion, or lack of efficacy of opioids. Most clinicians prescribing long-term for chronic pain had already implemented the measures required by the legislation (though a few found them burdensome). Comments were very positive regarding the New Jersey Prescription Monitoring Program, which allows prescribers to see what prescriptions for controlled substances have been filled by the patient.

Unless they were already providing it, most prescribers we spoke with were not interested in providing medication assisted treatment (MAT) for opioid use disorder, seeing this as beyond their scope of expertise, impossible given the structure of their practice (e.g., solo and small-group practitioners without needed support staff), or undesirable given the patient population seeking this treatment. These responses are important in the light of current initiatives to increase engagement of primary care providers in offering MAT, highlighting the complexities of recruiting additional providers, particularly in solo and small-group practice. Prior authorization restrictions were a significant barrier to those providing MAT to Medicaid beneficiaries; the removal of these restrictions in April 2019 (after the conclusion of our interviews) may have improved access to treatment. In July 2019, the governor signed into law legislation requiring that MAT be provided without prior authorization.[14]

Some interviewees were hopeful that prescribing restrictions could reduce opioid exposure and addiction, but several noted, as found by Cicero and Ellis (2017), that the availability of illicit opioids and the lack of available treatment for mental health issues facilitate addiction.

There was some concern among interviewees that prescribing had gotten too strict in some cases, and that people with a legitimate need for opioid medications were not getting them. This could be due to any or all of several potential reasons: overzealous interpretations of the cautions raised in the New Jersey law or other guidelines; avoidance of opioid prescribing due to increased regulatory oversight and the burdens of documentation; and stigmatization of patients seeking treatment of pain. In 2019, the FDA and US Department of Health & Human Services released statements discouraging prescribers from abruptly tapering patients from opioid therapy (FDA 2019; Throckmorton 2019; U.S. Department of Health and Human Services 2019), and the authors of the CDC guidelines noted that practitioners were going beyond what the guidelines recommended in ways that could harm patients (Dowell et al. 2019).

Interviewees seemed to agree that opioids were not the first choice for chronic non-cancer pain treatment, and in many cases were not effective or even harmful (with risk of dependence and hyperalgesia) but many noted that in some cases opioids were the best choice available, and that some patients achieved a better quality of life with opioid treatment.

Several gaps in existing pain treatment were identified. Interviewees noted a procedural focus by many pain management practices that neglected patients for whom procedures were ineffective or undesired, particularly given what appeared to be an increasing tendency of primary care doctors to refer patients with pain to pain management rather than treating them

[14] P.L. 2019, c.163, approved July 15, 2019 (from A4744/S3314).

directly. Additionally, significant insurance coverage barriers were noted with respect to many medications or treatments serving as opioid alternatives, such as Lyrica®, diclofenac patches or gel, lidocaine patches, and massage therapy. Finally, some interviewees noted a lack of good treatments for many types of chronic pain, which affects a significant portion of the population. Though most of our interviewees were not involved in prescribing it, medical marijuana was raised by several as a topic of interest among prescribers and patients. One had reviewed existing literature and thought it held a lot of promise, one had positive reports from patients, one felt that their patients who used it were overcharged and did not benefit, and several were skeptical given the lack of clinical research. Several thought it was cost-prohibitive for Medicaid patients.

Significant barriers to all types of treatment were noted for Medicaid patients. This includes access to clinicians (including those treating pain such as pain management specialists, physical therapists, chiropractors and acupuncturists), many of whom do not accept Medicaid.

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# Appendix: Recruitment Letter, Informed Consent & Interview Questions

Continued on next page.

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November 15, 2018

Dear Prescriber:

We are writing to invite your participation in a research study examining the impact of the 2017 legislation limiting the dispensing of opioid prescriptions.[1] Support for this project is provided by the Horizon Foundation for New Jersey. As part of this study, we would like to speak with a sample of physicians from different specialties across the state who prescribe opioids to learn if/how this legislation has affected their practices and their patients. We estimate that these telephone interviews will take 30-60 minutes, and we would like to have all interviews completed by late November.

Please contact Jennifer Farnham, Senior Research Analyst at the Rutgers Center for State Health Policy, if you are willing to participate (jfarnham@rutgers.edu or 848-932-4675). Enclosed is our interview guide, along with an information sheet regarding our project. Of course, you may decline to answer any of the questions. With your permission, we would like to audio record the interview to assist in documenting your responses. Interviews will be transcribed and analyzed by the team to create a report to the Horizon Foundation, which will be posted on the Center for State Health Policy's website. Interviewees will not be named in the report. If quotations are used, they will be edited to remove information that could identify any individual. Lastly, we would be happy to offer you a $125 Visa Gift Card to compensate you for your time in completing the interview.

Thank you for considering this invitation. Should you have any questions, please feel free to contact Jennifer Farnham, at jfarnham@rutgers.edu or 848-932-4675.

Best regards,

Joel C. Cantor, Distinguished Professor and Director, Center for State Health Policy

Stephen Crystal, Board of Governors Professor of Health Services Research and Distinguished Research Professor

[1] P.L. 2017, Chapter 28, available at https://www.njconsumeraffairs.gov/prescribing-forpain/Documents/Opioid-Law.pdf

**(IRB Attachment 4): INFORMATION SHEET**

You are invited to participate in a research study that is being conducted by Dr. Joel C. Cantor, who is a Distinguished Professor of Public Policy and the Director of the Center for State Health Policy at Rutgers University. The purpose of this research is to determine the effect of recent changes to the rules of opioid prescriptions on prescribers and their patients.

Approximately 24 prescribers will be recruited for key informant interviews. Each individual's participation will last approximately 30-60 minutes, depending on how much they have to say.

This research is confidential. Confidential means that the research records will include some information about you and this information will be stored in such a manner that some linkage between your identity and the response in the research exists. Some of the information collected about you includes your name and contact information. We will take notes on your responses and will audiorecord if you agree to that later. Please note that we will keep this information confidential by limiting access to the research data and keeping it in a secure location on password protected computer files or in locked file cabinets.

The research team and the Institutional Review Board at Rutgers University are the only parties that will be allowed to see the data, except as may be required by law. If a report of this study is published, or the results are presented at a professional conference, only group results will be stated. If you agree to recording, quotes may be used, but only if they do not contain identifying information. All study data will be kept for at least three years.

There are no foreseeable risks to participation in this study. To thank interview participants for their time, we offer a Visa gift card of $125 to be sent after the interview.

Participation in this study is voluntary. You may choose not to participate, and you may withdraw at any time during the study procedures without any penalty to you. In addition, you may choose not to answer any questions with which you are not comfortable.

If you have any questions about the study or study procedures, you may contact Dr. Joel Cantor at jcantor@ifh.rutgers.edu, 848-932-4653, or 120 Paterson St., 5th Floor, New Brunswick, NJ 08901.

If you have any questions about your rights as a research subject, please contact an IRB Administrator at the Rutgers University, Arts and Sciences IRB at humansubjects@ored.rutgers.edu, 732-235-2866, or Liberty Plaza / Suite 3200, 335 George Street, 3rd Floor, New Brunswick, NJ 08901.

**Audio Addendum**

We are asking for your permission to allow us to audiorecord our interview as part of the research study. You do not have to agree to be recorded in order to participate.

The recording(s) will be used for analysis by the research team and possibly for quoting in reports, if the quotes do not identify individuals or organizations.

If you say anything that you believe at a later point may be hurtful and/or damage your reputation, then you can ask the interviewer to delete the recording.

The recording(s) will be stored on password protected computers or in locked file cabinets. The recordings will be kept for at least 3 years.

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***For IRB Use Only. This Section Must be Included on the Consent Form and Cannot Be Altered Except For Updates to the Version Date.***

Document Version: v1.0 — Rutgers eIRB Approved 9/5/2018; Expires 2/3/2019
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**Attachment 7: Interview Guide, Prescribers (Horizon Foundation Opioid Analysis)**

1. Can you briefly describe your practice with respect to the kind of patients you treat?
    a. Do you specialize in certain patients or conditions?
    b. How long have you been practicing this type of medicine?
2. Have you changed the way you prescribe opioids during the past five years or so? If so, how, and what led you to change? (Probe for thoughts on ideal clinical use of opioids)
3. Have you increased your use of non-opioid and/or non-pharmacological pain management interventions in the past couple of years? If so, which modalities?
4. In 2017, New Jersey passed a law and regulations related to the treatment of pain or addiction. Patients in active treatment for cancer, receiving hospice or palliative care, residents of a long-term care facilities, or receiving medications for substance use disorder are exempt from some restrictions. For each of the following elements of the law, please tell me if these changes have affected the way you practice or refer patients for pain or addiction.
    a. More insurance plans are now required to cover treatment for substance use disorder <u>without initial prior authorization.</u>
    b. Initial prescriptions for opioids for acute pain are now limited to a 5 day supply and prescribers are required to check the prescription monitoring program and educate patients about risks and alternative treatments, prior to issuing a prescription.
    c. A pain management agreement is now required at the third prescription for many types of patients.
    d. Providers must now review at least every 3 months many types of patients who are continuously prescribed opioids, including conducting a random urine screen at least once per year.
5. Approximately how often do you now use pain management contracts with your patients who receive opioids? What criteria do you use to decide on requiring a pain management contract? How often do you find nonadherence, and how is that handled? Have you been contacted by regulators or other parties about your use of pain management contracts?
6. Have you been contacted by third parties, such as insurers, state agencies, or law enforcement in the last year about other aspects of your management of opioid treatment?

7. Have there been positive effects and/or negative effects of the new laws for your patients? (Probe for consequences for different types of patients—acute, chronic, palliative, addiction, demographic or socioeconomic differences)

    a. Have the new laws been effective, in your experience, in: reducing transition from short term to long term opioid use, reducing risk of opioid use disorder, reducing risk of overdose, or improving access to medication assisted treatment for opioid use disorder?

    b. Have your patients experienced unintended negative effects of the new laws such as untreated pain, turning to illicit drugs, or other negative effects?

8. How easy is it for patients with opioid use disorder to access appropriate treatments, including medication assisted treatment? How could access be improved?

    a. Do you have a waiver to prescribe buprenorphine? If not, would you consider applying for a waiver to use this modality? Why or why not?

9. Do you have any feedback about the prescription monitoring system? (Probe for typical use, experience filing suspicious activity reports)

10. What additional state actions would be helpful in reducing the risk of opioid use disorder and overdose?

11. Is there anything else you would like to add about state policy toward opioid prescribing or access to substance use disorder treatment that I haven't already asked about?

[Confirm mailing information for gift card]

Thank you ….

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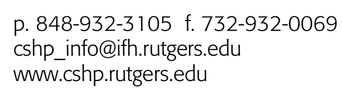

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