An Appraisal of Opioid Treatment Agreements for the Podiatric Physician

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Opioid treatment agreements are written agreements between physicians and patients that represent strategies enumerating the risks associated with opioid medications. These opioid treatment agreements set expectations and obligations, as well as identify responsibilities for both patient and prescriber for opioid therapy. Some critics assert that these agreements are cumbersome and degrade the patient once they enter into these agreements. A systemic literature search and review using the Preferred Reporting Item for Systematic Reviews and Meta-Analyses (PRISMA) tool was used to find citations describing opioid treatment agreements and their use. Then eligible and appropriate citations were dissected and analyzed. Using the available federal and state opioid prescribing policies, best practice guidelines as well as positive aspects of reviewed literature citations and avoiding bias, degrading, or macroaggression language, a non-cumbersome opioid treatment agreement specific to podiatric medicine was created. A balance argument for the use of opioid treatment agreements to avoid opioid use disorder that is grounded in clinical literature and commentaries are presented. A one-page sensible opioid treatment agreement specific to podiatric medicine, which is similar to more complex cumbersome ones that are found in the literature, and that may be used as part of any podiatric procedural or surgical inform consent, was created and is presented for review. The perception of defending opioid treatment agreements as documents of disclosure to assist patients in their autonomy was offered. Building on the systemic review findings and concept of using elements of disclosure, a model for an analgesic treatment as a one-page informational document to enhance podiatric physicians to create a specific individual analgesic treatment agreement mirroring the scope of podiatric practices that can be incorporated into procedural and surgical inform consent documents was offered. (J Am Podiatr Med Assoc 113(3), 2023)

Statistical data collected by Lucas et al[1] in 2019 show that nearly three in five adults (58.9%) experienced pain of any kind for 3 months; 36.5% of adults experienced lower-limb pain. Furthermore, they found that the percentage of adults with lower-limb pain increased with age, from 21.0% for those aged 18 to 29 years and 28.8% for those aged 30 to 44 years to 43.4% for those aged 45 to 64 years and 50.3% for those aged 65 years and older.[1] Their demographic data estimates of lower-limb pain differed among non-Hispanic white (40.1%), non-Hispanic black (36.6%), Hispanic (27.4%), and non-Hispanic Asian (20.6%) adults.[1] Last, a notable finding was that the percentage of adults with lower-limb pain decreased as family income increased, from 42.1% in adults with income less than 100% of the federal poverty level to 35.2% in adults with income 200% or more above the federal poverty level.[1]

Foot and ankle pain is a common ailment in the general population but frequently affects one in five people older than 50 years.[2] Foot pain is a complex phenomenon because it may be caused by local factors defined by structural disorders affecting the load-bearing function of the foot and systemic factors such as dermatologic, vascular, neurologic, and musculoskeletal conditions that may manifest in the foot.[3] People with foot pain often have limited mobility and decreased ability to do everyday activities.[4,5] In addition, people with foot pain are often at higher risk for falling and locomotive disability due to their pain.[2] Belatti and Phisitkul[6] note that chronic foot pain is physically debilitating and calculated that since 2000, foot and ankle surgery for chronic pain has cost the Medicare population approximately $11 billion.

Bowlby and Crawford[7] reported that severe pain has been noted after foot and ankle surgery as well as that there exist current national guidelines for

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chronic opioid prescribing, but guidelines for acute pain have not been established. Sundling et al[8] created a survey and distributed it to podiatric surgeons electronically across the United States. The results of their study showed that podiatric surgeons prescribe hydrocodone/acetaminophen most commonly after surgery, with most prescribing opioids for less than 2 weeks.[8] The investigation by Brooks et al[9] concluded that postoperative opioid prescribing practice variation exists in foot and ankle surgery. Compared with the orthopedic community, podiatric foot and ankle surgeons prescribe approximately 25% fewer opioids at the time of surgery than orthopedic foot and ankle surgeons.[9] Ang et al[10] described acute postoperative pain management protocols in podiatric surgery in Australia, as an agreed-on approach to acute postoperative pain management for podiatric surgeons in Australia was with a stepwise approach, using multimodal therapy, and reserving oral opioids for breakthrough pain.

It has been well established that the opioid epidemic in the United States is multifaceted, but overprescription by providers is part of it. There are clinical literature reports that link legitimate opioid prescriptions with opioid misuse, abuse, and diversion.[11-13] Presently, 38 states require prescribers of opioids to participate in mandated continuing education centered on mitigating strategies to empower these providers to prescribe opioids while avoiding opioid harm. Each state has specific requirements and delineations that may include podiatric physicians who prescribe opioids. It is advised that podiatric physicians review their continuing education requirements to determine whether they must comply with their state's mandated opioid continuing education requirement. Lower-extremity specialists must recognize that any surgical procedure represents a potential gateway to opioid dependence and must recognize and develop methods as they embrace their role as stewards of safe opioid use.[11-13]

Controlled substances agreements, specifically *opioid treatment agreements*, are written agreements between physicians and patients that represent strategies enumerating the risks associated with opioid medications along with the requirements that patients must meet to receive these medications on an ongoing basis. These opioid treatment agreements set expectations and obligations as well as identify responsibilities for both patient and prescriber for opioid therapy. The central theme of this review is to present an opioid treatment agreement for the lower-extremity specialist in the context of podiatric medicine. There is an argument that opioid treatment agreements are justifiable for physicians to use in their provision of care only if they improve patient or public health outcomes, which has yet to be demonstrated. First, a systematic review of the historical and present literature was performed to develop and explore the current concept, intent, and pitfalls of opioid agreements, given both narratively and graphically. Second, the perception of defending opioid treatment agreements as documents of disclosure to assist patients in their autonomy is offered. Last, a model opioid treatment agreement to help podiatric physicians create a specific individual opioid treatment agreement mirroring the scope of podiatric medical practices grounded in currently available literature is offered.

Database Search

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) tool framework was used to search papers and literature for this review. The PRISMA concept allowed for a quality checklist to identify citations most relative to this review. An initial search profile was compiled using key terms, and Boolean logic was used for each electronic search engine, and searches were performed from 1990 to 2022. The databases searched were PubMed, MEDLINE, Cochrane, and TRIP USA (a clinical search engine), and the following key words were used: *opioid*, *treatment*, *agreement*, *control*, and *substance*. The literature selected focused on clinical use of opioid treatment agreements in the context of analgesic care as suggested by clinical best practices, clinical trials, randomized controlled trials, systemic reviews, and reviews. The search was related to published studies across 32 years and identified those that assessed the updated ethics, psychology, intention, and practical use of opioid treatment agreements. Screening of papers involved using a PRISMA checklist: Title, Abstract, Introduction, Methods, Results, and Discussion. Published studies were reviewed and evaluated for quality, relevance, and then inclusion and exclusion criteria. Furthermore, a manual review of the citations' reference lists and bibliographies was undertaken to gather additional information that could lead to further material for this review using a PRISMA checklist. All of the eligible citations were critically reviewed to address the aim of this review (Fig. 1).

Of the 706 citations identified, 125 (17.7%) were duplicates and 274 (38.8%) were removed for titles not being relevant. Of the remaining 307 records

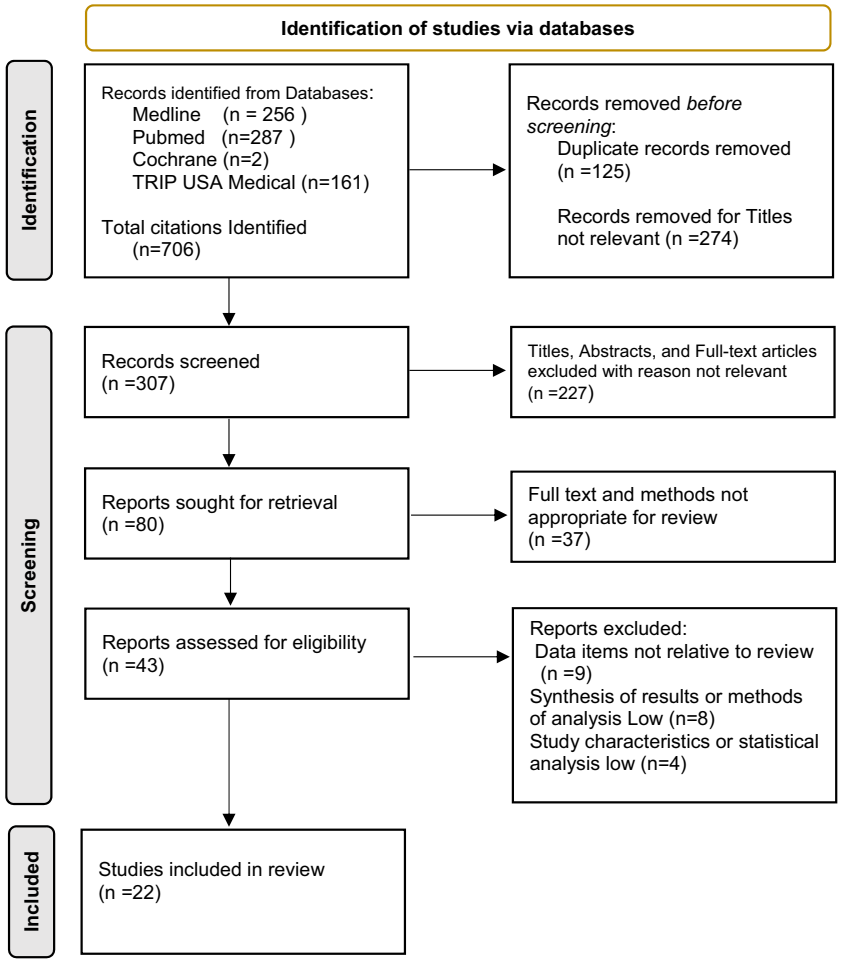

Figure 1. Literature search for opioid treatment agreements.

screened (43.5%), 227 (73.9%) were excluded because the titles, abstracts, and full text were not relevant. Therefore, 80 reports were sought for retrieval; of these, 37 were deemed not appropriate for this review once both the full text and methods were analyzed. Furthermore, the number of reports assessed for eligibility for this review was determined to be 43. After careful study and analysis, 21 reports were excluded for the following reasons: data items not relative to this review (n = 9), synthesis of results or methods of analysis were low (n = 8), and study characteristics or statistical analysis was determined to be low (n = 4). The number of studies included in this review was 22.

Opioid Agreements

Strategies for the podiatric physician to mitigate opioid harm were reported by Smith[14] in 2006 for lower-extremity specialists worried about contributing to this problem of prescription drug abuse. Gibbs and Haddox[15] state three requirements for a controlled substance prescription to be lawful: 1) the prescription is issued for a legitimate medical purpose, 2) the practitioner is acting in the usual course of his or her professional practice, and 3) the medical records indicate the conditions that resulted in issuance of the prescription. Portenoy[16] authored guidelines to not only emphasize but also steer opioid-prescribing providers to achieve optimal safety and efficacy, identifying drug abuse problems and ensuring regulatory compliance when selecting an opioid agent for patients (Table 1). The elements and assertions embodied in these guidelines serve as the keystone for many opioid treatment agreements. Finally, Smith[14] argued, using Mendelson's[17] data, that patients must be advised of the inherent risks of opioid medications, and these risks should be listed on a consent form and the form placed in the patient's medical record.

An affirmation is given that opioid treatment agreements functioning as an outline plan for

Table 1. Guidelines for Podiatric Physicians When Prescribing Opioids

Consider opioid use only after all other reasonable analgesics have failed.
A history of substance abuse and severe character pathology should be considered contraindications.
A single practitioner should take primary responsibility for treatment, and a single pharmacy should fill prescriptions
Patients should give informed consent regarding risk of addiction, potential for cognitive impairment, and likelihood of physical dependence.
Reasonable treatment goals should be established before the start of therapy and should include analgesia and improvement of function with an acceptable level of adverse effects
A reasonable as-needed and dose-escalation scheme should be determined before the start of therapy.
Initially, patients should be seen monthly; when they are stable, less frequent visits may be acceptable.
Episodes of exacerbation may require hospitalization or more careful monitoring.
Evidence of drug hoarding, uncontrolled dose escalation, or other aberrant behaviors may necessitate dose tapering and discontinuation; consultation with an addiction specialist may be warranted
At each visit, a comprehensive reassessment should be completed and documented.

Adapted from Portenoy.[16]

monitoring opioid therapy can be supported and defined, indeed in spirit, as documents of informed consent by relying on Cocanour's[18] definition of informed consent "as an ethical concept that is codified in the law and is in daily practice at every health care institution." Furthermore, Cocanour declares that three fundamental criteria are needed for clinical informed consent: the patient must be competent, adequately informed, and not coerced.[18] Physician-patient interaction is rooted in the ethical concept of beneficence, but during the 19th and 20th centuries, case law and societal changes brought respect for autonomy, and with it informed consent.[18] Federal and state regulatory agencies as well as professional societies have encouraged or mandated written pain treatment agreements for more than two decades to establish informed consent, improve adherence, and mitigate risk. Unfortunately, Tobin et al[19] asserted that the content of these agreements varies, their efficacy is uncertain, and some are stigmatizing or coercive and jeopardize a patient's trust. Moreover, many are written at reading levels beyond most patients' understanding. On the other hand, these investigators believed that a well-written agreement is still an important tool in chronic pain management.[19]

The foremost intent and purpose of an opioid treatment contract is to provide information regarding the benefits and risks associated with opioid use, similar to an informed consent for a medical procedure.[19] These opioid agreements (contracts) are intended to deter abuse, improve the positive outcomes associated with opioid use, and minimize the prescribing physician's risks. As part of an opioid agreement contract, patients must agree to undergo random urine drug screens and pill counts and to receive opioid prescriptions from the physician identified in these agreements only.[19] Naturally, by signing these agreements, patients agree to abide by the opioid dosing and frequency prescribed, participate in certain programs, not request opioids or other pain medicine from other physicians, participate in mental health assessments if necessary, and, to the extent possible, obtain all of their medications from one pharmacy.[19] The contract typically includes a list of actions that would permit the physician to stop prescribing opioids or change the treatment plan. Moreover, these contracts usually include a description of safety risks, potential adverse effects, and tips for medication management.[19] Furthermore, opioid agreements make patients take responsibility for their own behaviors, something that is all-too-often missing from the doctor-patient relationship.[20] The contract clearly spells out expectations and violations of the agreements that can result in the patient no longer being prescribed painkillers from that doctor.[20] Finally, a summary of advantages and disadvantages of opioid treatment agreements[21] that affect the opioid prescriber and the opioid patient is presented in Table 2.

Defending Opioid Treatment Agreements

Medical ethicists have argued that opioid treatment agreements may violate principles of autonomy and use a paternalistic approach to patient care. Rager and Schwartz[22] asserted that patient consent is not needed but desired and that opioid treatment agreements should be universally applied in clinical practices. An astute opioid prescriber should agree on the primary goal of limiting the number of opioid prescriptions to minimize the tragedy of opioid overdose deaths.[23] Second, Rager and Schwartz[22] reframed the justification for the use of opioid

Table 2. Advantages and Disadvantages of Opioid Treatment Agreements

Advantages	Disadvantages
Serves as a tool to educate patients about their treatment plan	Efficacy is not well established and may be limited by patients' misunderstanding
Informs the risks and benefits of treatment	No evidence-based guidelines for developing or revising these agreements exist; increased risk of stigmatization
Clarifies treatment goals	Can suggest distrust between patient and provider
Promotes adherence to treatment	May be applied or interpreted with discriminatory intent
Ideally enhances the therapeutic relationship	Often contain punitive language
Facilitates patients' active role in treatment	Monitoring proscribed by the agreement is not always followed.
States responsibilities of the patient and the physician	

Adapted from Chapman et al.[21]

treatment agreements, defining the roles and responsibilities of doctors and patients to one another in the course of opioid treatment for chronic pain and describing the risks and benefits of therapy for the individual. Last, these reviewers declare that these treatment agreements are now proposed for their use as "surveillance and monitoring" instruments and, therefore, they are specifically meant to disclose the risks of opioid therapy and to describe the other processes and tools used to monitor abuse and diversion of medications.[22,23] Some critical references refer to these agreements as undermining provider and patient relationships, proclaiming that they damage the doctor-patient relationship.[22,24]

One serious concern is that when the agreement is signed, these agreements do not provide the ethical justification for monitoring the drug use and for withholding controlled medications if the patient violates the requirements. Rager and Schwartz[22] state that it is not problematic that signing is not fully voluntary. They declare that the provider could drop the requirement that patients sign the document at all, as long as other methods were used to confirm receipt of the information it discloses.[22] Second, stigmatization has also been widely debated, with studies that have found that these agreements have widely variable wording, in some cases using language that many patients may not understand.[22,24,25] These agreements can add to the stigma that is already associated with chronic pain, making patients feel that they are perceived as criminals.[22-25]

Another concern is the perception that patients are not given a choice about whether to sign these agreements. Again, the words and terms used are not negotiated between doctors and patients or determined through shared decision making but are simply presented to patients to be accepted.[22-25] Some critics express concern that these agreements are coercive because patients have no choice about whether to sign them if they want to receive a prescription for controlled medications. Collen[26] argues that these agreements are "unconscionable," in a legal sense, and thus not enforceable because there is "an absence of meaningful choice on the part of one of the parties together with [opioid contract or opioid treatment agreements] terms which are unreasonably favorable to the other party." A final major concern is that there is inadequate evidence for the efficacy of these agreements because there is inadequate evidence that opioid treatment agreements achieve their goal, which is generally taken to be to "promote patient adherence to opioid therapy."[22-26]

Harris[20] suggests several opportunities to improve the effect of opioid agreements. Regardless of whether a prescriber agrees with the use of opioid agreements or is legally obligated to enter into them under state law, certain measures can be taken to enhance the positive effect of the agreements.[20] These measures include 1) carefully drafting the agreement using plain language that is easily understood by the patient; 2) forcing patients to sign a document loaded with legalese can negate the whole purpose of the agreement; 3) taking time to calmly walk the patient through the terms of the agreement so that he or she understands the expectations and is aware of all actions that could impact treatment; 4) periodically reviewing the terms of the agreement with each patient to confirm that they continue to understand and abide by the expectations and responsibilities agreed to; and 5) for patients violating the terms of the agreement, weaning the patients off the medication, if permitted, instead of completely cutting them off.[20]

McAuliffe Staehler and Palombi[25] investigated and authored a review by collecting studies assessing the value of opioid treatment agreements by using five distinct elements or steps: beginning with a clearly formulated question, using the question to develop

clear inclusion criteria to identify relevant studies, using an approach to appraise the studies or a subset of the studies, summarizing the evidence using an explicit method, and interpreting the findings of the review. They identified 283 articles and found only six studies that were eligible to be evaluated and assessed for quality.[25] This systematic review shows weak evidence to support the effectiveness of patient-prescriber agreements in the reduction and mitigation of opioid misuse and abuse.[25]

Podiatric Medicine Opioid Treatment Agreement Model

The Centers for Disease Control and Prevention (CDC) and American Society of Interventional Pain Physicians guidelines recommend opioid treatment agreements to reduce the misuse and abuse of opioids, but evidence of their effectiveness has not been well established.[25] Building on the research of McAuliffe Staehler and Palombi[25] and serving as a foundation, a one-page "podiatric analgesic treatment agreement mode" (Fig. 2) was created to be used when procedural or surgical interventional therapy is decided by both the lower-extremity specialist and the patient as part of the informed consent process for the intervention. First, the selection of an analgesic product, whether a nonopioid analgesic or an opioid analgesic, can be a dynamic partnership between both parties. Furthermore, if an opioid analgesic is selected, this document contains the purpose of the agreement that offers the patient

Analgesic Prescribing Patient Agreement

Agreement purpose

I the provider, and my office will review this agreement with patients to educate them about and hopefully lower risks of harm from analgesics especially opioids. This agreement will layout the rules for receiving opioids as analgesic therapy. As your analgesic provider, I acknowledge and pledge to you the patient to follow and adhere to both state and federal guidelines, and best practice guidelines for prescribing and monitoring analgesics to include opioid products to avoid medication misadventure. If an opioid analgesic is prescribed Naloxone may also be prescribed.

Analgesic Prescribe:

a. Non-opioid product and frequency_____

b. Opioid product and frequency_____
(Continue below if an opioid product is prescribed)

Risks of Opioids-Discuss with patient:

___Nausea, vomiting, dry mouth, constipation __Increase sensitivity to pain __Opioid Tolerance

___ Opioid Physical Dependence __Sleepiness and dizziness ___ Confusion ___Depression

___ Low levels of testosterone, Low sex drive __Itching and sweating

Risks of opioid side effects and overdose are greater with the following:

___A history of drug misuse, substance use disorder ___Sleep Apnea ____65 years old or older-___ Pregnancy-baby may be dependent on opioids. If patient becomes pregnant, she will inform prescriber.

___Mental Health conditions (depression or anxiety)

___ Use at the same time of alcohol, benzodiazepines, muscle relaxants, sleep medications, and other opioids

Provider's commitment to you the patient

__We will set analgesic treatment goals __We will assess your risk for side effects and overdose

___We will use a multimodal analgesic approach to include referrals when necessary

___We will approach your analgesic goals as a team with other professionals who will assist in monitoring and reviewing treatment goals.

Patient's commitment to analgesic therapy

___I commit to secure my opioid analgesic to avoid accident ingestion, overdose, and theft

___ I commit if my opioid prescription is lost or stolen, I will inform the prescriber ASAP

___I commit to disposal of my opioid analgesics when necessary to avoid opioid overdose

___I commit not to use alcohol and illegal drugs while on analgesic therapy to avoid possible opioid overdose

_____ _____ _____ _____

Patient's Signature DATE Prescriber's Signature DATE

Figure 2. Analgesic prescribing patient agreement.

the commitment by the podiatric physician to enter a partnership with the patient to select the best analgesic, either nonopioid or opioid, class agent. The lower-extremity specialist has grown to accept that any procedural or interventional procedure may require the prescribing of an opioid agent that may be a gateway to opioid harm defined by opioid adverse effects or opioid use disorder.[11-14] Furthermore, this agreement states: "As your analgesic provider, I acknowledge and pledge to you the patient to follow and adhere to both state and federal guidelines, and best practice guidelines for prescribing and monitoring analgesics to include opioid products to avoid medication misadventure." By stating that both state and federal guidelines and best practice guidelines for prescribing medications will be followed thus acknowledges that any state-mandated opioid tablet, or morphine milligram equivalent, or duration limitation need to be explained to the patient as well as the electronic communication intervention known as the prescription drug monitoring program and will be followed when opioid or control substances are prescribed. All 50 states, the District of Columbia, and two US territories have these programs. Prescription drug monitoring programs have evolved to be able to electronically communicate across state boundaries. This introduction purpose paragraph can be used to facilitate an informative dialogue between prescriber and patient. In the spirit of disclosure, the major adverse risks of opioid products are presented. The podiatric physician can use this opportunity to discuss the adverse effects of drowsiness and dizziness and the need to avoid operating motorized equipment after taking opioid medications. Moreover, the concept of increased risks of opioid adverse effects and overdose are presented. The intent of this section is not only to disclose this risk but also to facilitate real identifiable pathophysiology that could increase the potential for opioid drug misadventure, opioid use disorder, and opioid drug overdose as reported in the literature. The intent of the provider's commitment section is to facilitate a dialogue without stigmatization and to set and define expectations for the patient related to the prescriber's responsibilities. One central concept that the podiatric physician can explore is that the prescribing of an opioid analgesic product will not rid the patient's pain completely. In addition, the notification that the patient is not alone in this journey of analgesic empowerment and avoidance of opioid harm can be discussed in the context of an interprofessional health-care team approach. The patient's commitment section allows for the acknowledgment of behavioral interventions as analgesic safety to ensure the security of their opioid prescription, including proper disposal of said prescription. Inherently, this section allows the opportunity for a conversation related to opioid sharing, opioid thief, and illegal opioid use to be undertaken between the podiatric physician and the patient. This may be an opportunity for the prescriber to discuss urine drug testing when the prescriber feels it is warranted. A final point that the lower-extremity physician can emphasize is the coadministration of other agents that may cause central nervous system depression, including alcohol use. This analgesic agreement has a signing section that can be signed by the prescriber and the patient. Given that this model can be incorporated with the procedural and surgical informed consent processes, the patient should not feel marginalized or stigmatized but rather empowered with a sense of greater autonomy that is perceived lacking in current opioid treatment agreements.

Conclusions

Undoubtedly, further studies demonstrating opioid treatment agreement benefits for patient care and establishing the incidence of diversion and iatrogenic opioid use disorders may help substantiate their use. A systematic review of historical and present literature was examined to develop and explore the current concept, intent, and pitfalls of opioid agreements was offered narratively as well as graphically. Second, the perception of defending opioid treatment agreements as documents of disclosure to assist patients in their autonomy was offered. Last, building on the systematic review findings and the concept of using elements of disclosure as a model for an analgesic treatment, a one-page informational document to help podiatric physicians create a specific individual analgesic treatment agreement mirroring the scope of podiatric medical practices that can be incorporated into procedural and surgical informed consent documents was offered.

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