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Original Scholarship

The Legal Landscape for Opioid Treatment Agreements

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Policy Points:

- Opioid treatment agreements (OTAs) are controversial because of the lack of evidence that their use reduces opioid-related harms and the potential risks they pose of stigmatizing patients and undermining the clinician–patient relationship.
- Even so, their use is now required in most jurisdictions, and their use is influencing the outcomes of civil and criminal lawsuits.
- More research is needed to evaluate how OTAs are implemented given existing requirements. If additional research does not resolve the current level of uncertainty regarding OTA benefits, then policymakers in jurisdictions where they are required should consider eliminating OTA mandates or providing flexibility in the legal requirements to make room for clinicians and health care institutions to implement best practices.

Context: Opioid treatment agreements (OTAs) are documents that clinicians present to patients when prescribing opioids that describe the risks of opioids and specify requirements that patients must meet to receive their medication. Notwithstanding a lack of evidence that OTAs effectively mitigate opioids' risks, professional organizations recommend that they be

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implemented, and jurisdictions increasingly require them. We sought to identify the jurisdictions that require OTAs, how OTAs might affect the outcomes of lawsuits that arise when things go wrong, and instances in which the law permits flexibility for clinicians and health care institutions to adopt best practices.

Methods: We surveyed the laws and regulations of all 50 states and the District of Columbia to identify which jurisdictions require the use of OTAs, the circumstances in which OTA use is mandatory, and the terms OTAs must include (if any). We also surveyed criminal and civil judicial decisions in which OTAs were discussed as evidence on which a court relied to make its decision to determine how OTA use influences litigation outcomes.

Findings: Results show that a slight majority (27) of jurisdictions now require OTAs. With one exception, the jurisdictions' requirements for OTA use are triggered at least in part by long-term prescribing. There is otherwise substantial variation and flexibility within OTA requirements. Results also show that even in jurisdictions where OTA use is not required by statute or regulation, OTA use can inform courts' reasoning in lawsuits involving patients or clinicians. Sometimes, but not always, OTA use legally protects clinicians from liability.

Conclusions: Our results show that OTA use is entwined with legal obligations in various ways. Clinicians and health care institutions should identify ways for OTAs to enhance clinician–patient relationships and patient care within the bounds of relevant legal requirements and risks.

Keywords: opioids, chronic pain, pain management, opioid treatment agreements, drug laws, narcotic laws.

For over two decades, the drug overdose crisis has been one of the most pressing public health challenges facing the United States.[1] Opioids have been, and remain, a key driver of the overdose crisis, with a majority of overdose deaths involving an opioid.[2] Unsurprisingly, throughout the decades-long crisis, clinicians, professional organizations, and policymakers have tried and implemented various mechanisms that are described as efforts to reduce the risks of opioids both for individuals and the public health.[3,4]

One such mechanism is an opioid treatment agreement (OTA)—sometimes also referred to as an opioid contract, pain management agreement, narcotic agreement, or pain contract. OTAs are documents that clinicians present to patients when prescribing opioids that not only enumerate the risks of opioid therapy as informed consent documents would but also specify requirements that patients must meet to receive their medication. For example, an OTA might state that a patient must arrive on time for appointments, be respectful of office staff, and undergo routine urine drug testing and pill counts as well as require the patient to acknowledge that the health care professional may discontinue care if such conditions are not met.

The benefits of OTA use started to be discussed in the medical literature as early as 1981,[5] and OTAs have been widely used in clinical practice since at least the 1990s.[6,7] Nearly as long, OTAs have been controversial.[8] On the one hand, OTAs might help clinicians and patients work together and might help ensure that patients are aware of both the risks of opioids and the kinds of monitoring and surveillance that come with using controlled substances.[9–11] On the other hand, OTAs might stigmatize patients, strain clinician–patient relationships, contribute to health disparities by reifying clinician bias, and task patients with disproportionate or unusual responsibilities for their medical care or for public health benefit.[12–17] Moreover, there is a lack of evidence that OTAs are effective at reducing opioid misuse or diversion.[18,19]

Nevertheless, today, OTA use is generally recommended. In the Centers for Disease Control and Prevention (CDC)'s most recent clinical practice guidelines for prescribing opioids, the agency recommends the use of OTAs while also acknowledging "clinical evidence reviews did not find studies evaluating [their] effectiveness."[19] Professional organizations, such as the Federation of State Medical Boards and the American Society of Interventional Pain Physicians, likewise recommend OTA use.[20,21] The Food and Drug Administration (FDA) and certain professional organizations, such as the American Pain Society, have published model OTAs for use.[22–24]

Increasingly, jurisdictions have begun to codify these recommendations, legally requiring that clinicians use OTAs in various circumstances. Legal scholars have noted the emergence of such legal requirements in specific jurisdictions,[13, 25, 26] but no research to date provides a comprehensive assessment of the laws governing clinicians' use of OTAs across the United States. Similarly, although clinicians perceive that using OTAs provides them with legal protection[27, 28]—and legal scholars have suggested that OTA use may now be the standard of care for purposes of medical malpractice[25]—no research provides a thorough assessment of the ways in which OTA use (or the failure to use an OTA) has influenced criminal and civil litigation involving patients and clinicians.

Understanding precisely what the law requires in different jurisdictions, how OTAs might affect the outcomes of lawsuits that arise when things go wrong, and, importantly, when the law permits flexibility, can help health care institutions and clinicians find opportunities to identify and adopt ways of using OTAs that mitigate the risk of opioids while reaping any potential benefits for individual patients and the public health. These data can also be used by policymakers to reevaluate the effectiveness of their legal requirements related to OTAs and compare their requirements with other jurisdictions. Accordingly, we surveyed the laws and regulations of all 50 states and the District of Columbia to investigate the legal landscape for OTAs. We sought to identify not only which jurisdictions require the use of OTAs but in those jurisdictions that do require OTA use, the circumstances in which OTA use is mandatory and the terms OTAs must include (if any). We also sought to investigate

how OTAs influence outcomes of lawsuits and, to do so, surveyed criminal and civil judicial decisions in which OTAs were discussed as evidence on which a court relied to make its decision.

Methods

State Statutes and Regulations

To identify which jurisdictions OTA use is required and to better understand what parameters those jurisdictions that do require OTAs impose, we used a public health law research method known as policy surveillance that involves "the systematic, scientific collection, and analysis of laws of public health significance."[29,30] We collected and analyzed both statutes (laws passed by state legislatures and signed by state governors) and regulations (rules established by state agencies, such as state medical boards) because both statutes and regulations are ways in which jurisdictions can impose legally binding requirements to use OTAs.

To identify relevant laws and regulations, in 2022, our law student research assistants, with guidance from a faculty member of our university's law library, completed several related searches in two leading legal databases (Westlaw and Lexis). In both databases, statutes and regulations for all 50 states and the District of Columbia were searched for the following terms: "medication agreement," "treatment agreement," "pain management agreement," "opioid agreement," "narcotic agreement," "pain contract," "narcotic contract," "pain medication contract," and "pain management contract." Searches in the two legal databases were also supplemented with searches on jurisdictions' own websites that provide statutes and regulations to help ensure a complete set of relevant provisions were identified.

Our research assistants initially reviewed the statutes and regulations, and the investigator with legal expertise then completed a secondary review. We used MonQcle, a legal research software, to code the statutes and regulations.[31] We coded statutes and regulations first for whether an OTA was required in any circumstances. We considered an OTA to be required if the statute or regulation expressly stated that a prescriber must use or document the existence of one generally or if the statute or regulation expressly stated that a treatment agreement must be documented for reimbursement. If an OTA was required, we then coded for (1) whether the requirement was in a statute or regulation, (2) whether the OTA requirement applied to receiving nonopioid drugs, (3) whether OTA use is required only for certain prescribing (e.g., duration or doses), (4) whether OTA use is required for patients with cancer who otherwise meet any criteria for the OTA requirement, (5) whether OTA use is required for patients with noncancer terminal conditions who otherwise meet any criteria for the OTA requirement, and (6) whether the statute or regulation specifies any

terms that must be included in the OTA. These coding questions for the research will be made available online on The Policy Surveillance Program's website (lawatlas.org), contemporaneous with publication.

Judicial Decisions

To better understand the kinds of lawsuits involving health care professionals and patients in which OTA use influences outcomes and how OTA use influences lawsuit outcomes, we conducted a review of written judicial opinions that discuss OTAs up to 2023. Our law student research assistants, with guidance from a faculty member of the university's law library, completed several related searches in two leading legal databases (Westlaw and Lexis). Both databases were searched for all written opinions in all federal and state courts, including both criminal and civil cases, without a time restriction, that used any of the following terms: "medication agreement," "treatment agreement," "pain management agreement," "opioid agreement," "narcotic agreement," "pain contract," "narcotic contract," "pain medication contract," or "pain management contract." These are the same terms that were used to search for relevant statutes and regulations. Although civil and criminal court cases are quite different, we chose to review decisions in both contexts to better assess the accuracy of clinician perceptions that OTAs can be used for legal protection—either against criminal charges or against civil financial liability.

Because our focus is on the ways in which OTAs might mitigate the risks of opioid use and impact the clinician–patient relationship, we excluded written opinions that exclusively concerned patients' claims for government or private benefits, such as claims for social security or long-term disability benefits, or cases for which the court mentioned an OTA in passing, but evidence about how the OTA was used was not part of the court's reasoning. If there was an appeal in a relevant case and both a trial court and an appellate court discussed OTAs in written opinions, we included the trial and appellate opinions separately.

Our research assistants initially reviewed all included written opinions, and the investigator with legal expertise completed a secondary review. We recorded case names and citations and developed brief summaries of the legal issues in the case. We coded the cases for the following characteristics: (1) the year the case was decided, (2) the state wherein the conduct at issue in the case occurred, (3) the year(s) in which the conduct at issue occurred, (4) whether the case was civil or criminal, and (5) whether the OTA was used as evidence that supported the clinician's position (e.g., a position that discontinuing prescribing was appropriate), including developing brief descriptions of how OTA use factored into the court's reasoning.

Results

State Statutes and Regulations

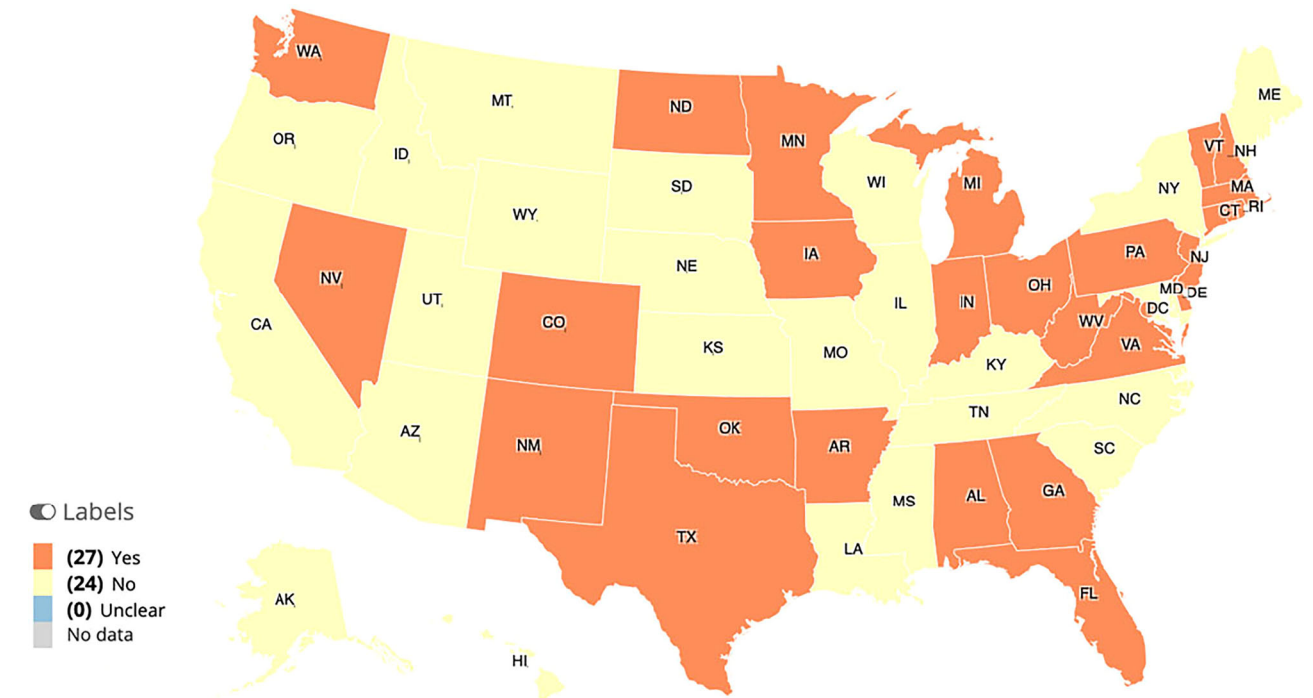
The statutes and regulations in 27 jurisdictions (26 states and the District of Columbia) require the use of an OTA in at least some circumstances, leaving 24 jurisdictions where OTA use is not legally required (Figure 1; Table 1). Of the 27 jurisdictions that require OTA use, eight impose the OTA requirement in a statute, 14 impose the OTA requirement in a regulation, and the remaining five jurisdictions impose the OTA requirement in both a statute and an implementing regulation. The earliest legal requirement was introduced in 2012 in the District of Columbia through regulation, and the latest of the legal requirements to date was introduced in 2022 in Oklahoma through statute (Table 1). The full data set for the research also will be made available online on The Policy Surveillance Program's website (lawatlas.org), contemporaneous with publication.

Of the jurisdictions that impose an OTA requirement, 17 imposed the requirement only for the prescribing of opioids and not any other drugs (Table 2). West Virginia, as one example, requires OTA use for "medication[s] listed as a schedule II opioid drug." Ten jurisdictions imposed their OTA requirement for the prescribing not just of opioids but also for other classes of drugs. For example, Nevada's statute requires a "practitioner" to "enter into a prescription medication agreement with the patient" if the practitioner "intends to prescribe a controlled substance listed in schedule II, III, or IV for more than 30 days for the treatment of pain," a category that is broad enough to cover both opioid and nonopioid controlled substances.

All 27 jurisdictions that require OTA use do so only for certain kinds of prescribing of the covered drugs (Table 2). In most of these jurisdictions (21), the OTA requirement is triggered based on duration of prescribing, such as when clinicians prescribe for "chronic pain" (e.g., in Alabama and Indiana); when clinicians prescribe for a defined period of days (e.g., more than 90 days, as Georgia specifies), weeks (e.g., more than 12 weeks, as Connecticut specifies), or months (e.g., more than 3 months, as New Jersey specifies); or when clinicians prescribe a certain number of times (e.g., West Virginia's requirement is triggered by the third prescription).

For five of the six remaining jurisdictions, both duration and dosage or patient characteristics trigger the OTA requirement. Delaware and Iowa require OTA use when prescribing for chronic pain and the patient is at high risk of a drug "abuse" or substance use disorder. Ohio's requirement applies to prescribing for "subacute or chronic pain" when the clinician increases the opioid dosage to a "daily average of 80 morphine equivalent dose (MED) or greater." Oklahoma generally requires an OTA at the time a clinician issues a third prescription for an opioid or when an opioid is prescribed for more than 3 months but also requires an OTA at the time of the first opioid prescription for a minor or a pregnant patient when a patient is prescribed a

Figure 1. Jurisdictions That Require the Use of an OTA



OTA, opioid treatment agreement.

Table 1. Jurisdictions That Require the Use of an OTA[a]

Jurisdiction	Is OTA Use Required?	Year Effective	In Statute or Regulation?	Citation
Alabama	Yes	2013	Regulation	Ala Admin Code r 540-X-4-.08[32]
Alaska	No	–	–	–
Arizona	No	–	–	–
Arkansas	Yes	2015	Statute	Ark Code Ann §20-7-707[33]
California	No	–	–	–
Colorado	Yes	2017	Regulation	7 Colo Code Regs §1101-1103:17 Exhibit 9[34]
Connecticut	Yes	2019	Statute	Conn Gen Stat Ann §20-14s[35]
Delaware	Yes	2013	Regulation	Code Del Regs 1700-1718.0[36]
District of Columbia	Yes	2012	Regulation	DC Mun Regs Tit 17, §4616[37]
Florida	Yes	2021	Statute	Fla Stat Ann §456.44[38]
Georgia	Yes	2020	Regulation	Ga Comp R & Regs 360-3-.06[39]
Hawaii	No	–	–	–
Idaho	No	–	–	–
Illinois	No	–	–	–
Indiana	Yes	2021	Both	Ind Code Ann §25-22.5-2-7[40]; 844 Ind Admin Code 5-6-5[41]
Iowa	Yes	2019	Regulation	Iowa Admin Code r 653-13.2(124,148,272C)[42]
Kansas	No	–	–	–
Kentucky	No	–	–	–
Louisiana	No	–	–	–
Maine	No	–	–	–
Maryland	No	–	–	–

Continued

Table 1. (Continued)

Jurisdiction	Is OTA Use Required?	Year Effective	In Statute or Regulation?	Citation
Massachusetts	Yes	2016	Statute	Mass Gen Laws Ann Ch 94C, §18A[43]
Michigan	Yes	2014	Regulation	Mich Admin Code R 418.101008a[44]
Minnesota	Yes	2022	Regulation	Minn R 5221.6110[45]
Mississippi	No	–	–	–
Missouri	No	–	–	–
Montana	No	–	–	–
Nebraska	No	–	–	–
Nevada	Yes	2018	Statute	Nev Rev Stat Ann §639.23914[46]
New Hampshire	Yes	2020	Both	NH Rev Stat §318-B:41[47]; NH Code Admin R Med 502.05[48]
New Jersey	Yes	2021	Both	NJ Stat Ann §24:21-15.2[49]; NJ Admin Code §13:35-7.6[50]
New Mexico	Yes	2016	Regulation	NM Admin Code 16.10.14.9[51]
New York	No	–	–	–
North Carolina	No	–	–	–
North Dakota	Yes	2015	Statute	ND Cent Code Ann §65-05-39[52]
Ohio	Yes	2020	Regulation	Ohio Admin Code 4731-11-14[53]
Oklahoma	Yes	2022	Statute	Okla Stat Ann Tit 63, §2-309I[54]
Oregon	No	–	–	–
Pennsylvania	Yes	2019	Both	35 Pa Stat and Cons Stat Ann §52B02[55]; 28 Pa Code §26.4[56]
Rhode Island	Yes	2017	Regulation	216 RI Code R 20-20-4.4[57]
South Carolina	No	–	–	–
South Dakota	No	–	–	–
Tennessee	No	–	–	–

Continued

Table 1. (Continued)

Jurisdiction	Is OTA Use Required?	Year Effective	In Statute or Regulation?	Citation
Texas	Yes	2020	Regulation	22 Tex Admin Code §170.3[58]
Utah	No	–	–	–
Vermont	Yes	2019	Regulation	VT Code of Rules 13-140-076[59]
Virginia	Yes	2018	Both	Va Code Ann §54.1-2928.2[60]; 18 Va Admin Code 85-21-90[61]
Washington	Yes	2019	Regulation	Wash Admin Code 246-919-910[62]; Wash Admin Code 246-919-915[63]
West Virginia	Yes	2019	Statute	W Va Code, §16-54-4[64]
Wisconsin	No	–	–	–
Wyoming	No	–	–	–

OTA, opioid treatment agreement.
[a]The most recent legislation or statute that requires OTAs is presented.

Table 2. Characteristics of OTA Requirements

Jurisdiction	Requirement Also Applies to Nonopioid Drugs	Requirement Is Only for Certain Prescribing	Requirement Applies to Patients With Cancer	Requirement Applies to Patients With Noncancer Terminal Conditions	Requirement Includes at Least One Term That Must Be Included in the OTA
Alabama	Yes	Yes	Yes	Yes	Yes
Arkansas	Yes	Yes	No	No	No
Colorado	No	Yes	Yes	Yes	Yes
Connecticut	No	Yes	Yes	Yes	Yes
Delaware	Yes	Yes	Yes	Yes	Yes
District of Columbia	Yes	Yes	Yes	Yes	Yes
Florida	Yes	Yes	No	Yes	Yes
Georgia	Yes	Yes	No	No	No
Indiana	No	Yes	Yes	Yes	Yes
Iowa	No	Yes	No	No	Yes
Massachusetts	No	Yes	Unclear	Unclear	Unclear
Michigan	No	Yes	Yes	Yes	Yes
Minnesota	No	Yes	Yes	Yes	Yes
Nevada	Yes	Yes	No	No	Yes
New Hampshire	No	Yes	No	No	Yes
New Jersey	Yes	Yes	No	No	Yes
New Mexico	Yes	Yes	Yes	Yes	Yes
North Dakota	No	Yes	No	No	Yes
Ohio	No	Yes	No	No	Yes
Oklahoma	No	Yes	No	No	Yes
Pennsylvania	No	Yes	Yes	Yes	Yes
Rhode Island	No	Yes	Yes	Yes	No

Continued

Table 2. (Continued)

Jurisdiction	Requirement Also Applies to Nonopioid Drugs	Requirement Is Only for Certain Prescribing	Requirement Applies to Patients With Cancer	Requirement Applies to Patients With Noncancer Terminal Conditions	Requirement Includes at Least One Term That Must Be Included in the OTA
Texas	Yes	Yes	Yes	Yes	Yes
Vermont	No	Yes	No	No	Yes
Virginia	No	Yes	No	No	Yes
Washington	No	Yes	No	No	Yes
West Virginia	No	Yes	Yes	Yes	Yes

OTA, opioid treatment agreement.

benzodiazepine and an opioid together or when a patient is prescribed opioids at a dose exceeding 100 MED. New Mexico requires OTA use for "patients with chronic pain" or "patients with substance use disorders" (but does not specify that a patient must have both chronic pain and a substance use disorder to trigger the OTA requirement).

Only the District of Columbia appears to have an OTA mandate fully unlinked from the duration of prescribing, requiring clinicians to use an OTA when prescribing to a patient "determined to be at high risk for medication abuse or have a history of substance abuse."

Thirteen of the jurisdictions that require OTAs do so for patients with terminal conditions and cancer (Table 2). One jurisdiction (Florida) applies its OTA requirement to patients with noncancer terminal conditions but not to patients with cancer. Of the remaining 13 jurisdictions, nine expressly exclude both patients with cancer and patients with noncancer terminal conditions. Two jurisdictions exclude patients with terminal conditions (Georgia) or who are receiving hospice care (Iowa), which are categories that are sufficiently broad to also exclude certain patients with cancer even though the relevant regulations do not explicitly mention patients with cancer. One jurisdiction (Ohio) expressly excludes from its OTA requirement patients in hospice care and patients with "terminal cancer or another terminal condition," meaning that some patients with cancer—those not in hospice or not classified as having "terminal cancer"—are subject to the OTA requirement. We were unable to determine whether the remaining jurisdiction (Massachusetts) applies its OTA requirement to patients with cancer or noncancer terminal conditions because the statute references guidelines that are not publicly available.

Finally, 23 of the 27 jurisdictions that mandate OTAs specify at least one term that must be included in the required OTA (Table 2). The number of terms specified, and the content of those terms, vary from jurisdiction to jurisdiction. For example, North Dakota requires that an OTA "restrict treatment access and limit prescriptions to one identified single prescriber," and Virginia requires that an OTA specify that clinicians will check the prescription drug monitoring program and patients will give permission for urine drug screening and consultations with other prescribers and dispensers. Washington, meanwhile, requires eight provisions that must be included in an OTA:

1. The patient's agreement to provide samples for biological specimen testing when requested by the physician;
2. The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost prescriptions and early refills;
3. Reasons for which opioid therapy may be discontinued;
4. The requirement that all opioid prescriptions for chronic pain are provided by a single prescriber or a single clinic, except as provided in Washington Administration Code 246-919-965 for episodic care;

5. The requirement that all opioid prescriptions for chronic pain are to be dispensed by a single pharmacy or pharmacy system whenever possible;
6. The patient's agreement to not abuse alcohol or use~~receive~~ other medically unauthorized substances;
7. A violation of the agreement may result in a tapering or discontinuation of the prescription; and
8. The patient's responsibility to safeguard all medications and keep them in a secure location.

Three jurisdictions (Arkansas, Georgia, and Rhode Island) do not specify any terms that must be included in the required OTAs. Arkansas and Rhode Island, however, list provisions that "may" be included in the OTA (but are not required to be included), such as requirements for urine drug screening, pill counts, and an agreement not to use alcohol or other medically unauthorized substances while being prescribed opioids. We were unable to determine whether the remaining jurisdiction (Massachusetts) specifies provisions that must be included in an OTA because the statute references guidelines that are not publicly available.

Judicial Decisions

After excluding cases outside the scope of our research, our data set of judicial decisions that discuss OTAs included 33 written judicial opinions (Table 3). The earliest decision in our data set was written in 2004 (*Armstrong v Louisiana State Board of Medicine*[67]), and the most recent decisions were written last year in 2023 (*Masood v Division of Professional Regulation of Department of Financial and Professional Regulation*,[79] *United States v Heaton*,[95] and *Wecker v Salem Clinic*[97]). The earliest conduct discussed in any case dates to 1992 (*State v Christensen*[88]), whereas the most recent occurred in 2022 (*Wecker v Salem Clinic*[97]; Table 4).

The 33 written opinions arose from conduct in 20 different jurisdictions (Table 4). Six jurisdictions were represented in multiple cases (nine cases from California; three cases from Ohio; and two cases from Delaware, New York, Oregon, and Wisconsin). Of the 20 jurisdictions represented in the written opinions, only nine are jurisdictions that require OTA use (Delaware, Florida, Georgia, Iowa, Nevada, Ohio, Oklahoma, Texas, and Virginia). A total of 12 written opinions (six civil and six criminal) came from these nine jurisdictions (three from Ohio, two from Delaware, and one each from the remaining seven jurisdictions; Tables 1 and 4).

Civil Cases

Of the 33 written opinions, 25 were civil cases (Table 5). Of those 25 civil cases, 22 fell into one of three categories: "Eighth Amendment" cases (10 cases), in which an

Table 3. Written Judicial Opinions That Discuss OTAs

Case Name	Citation
Anderson v Tate[65]	No 2:12-CV-0261 MCE KJN, 2012 WL 1120677 (ED Cal April 3, 2012)
Andrew v Hamilton County Public Hospital[66]	No C 17-3053-MWB, 2018 WL 4169094 (ND Iowa August 30, 2018)
Armstrong v Louisiana State Board of Medical Examiners[67]	868 So 2d 830 (La App 4 Cir 2004)
Cambronero v Meli[68]	No 20-CV-1635-BHL, 2022 WL 1504928 (ED Wis May 12, 2022)
Davis v High Desert State Prison[69]	No 2:11-CV-2296-GEB-CMK, 2014 WL 530265 (ED Cal February 7, 2014)
Delaware Board Of Medical Licensure and Discipline v Grossinger[70]	224 A3d 939 (Del 2020)
Estate Of Watson v King[71]	223 NC App 361, 734 SE2d 138 (2012)
Franson v United States[72]	No 3:19-CV-01983-AC, 2021 WL 2232054 (D Or May 10, 2021)
Gala v Bullock[73]	250 A3d 52 (Del 2021)
Green v Nangalama[74]	No 213CV2390KJMCMKP, 2017 WL 4038344 (ED Cal September 13, 2017)
Halloran v Kiri (Appellate)[75]	173 AD3d 509, 102 NYS3d 579 (2019)
Halloran v Kiri (Trial)[76]	59 Misc 3d 1217(A), 106 NYS3d 728 (NY Sup Ct 2018)
Harris v Debellis[77]	No 2:14-CV-14342, 2015 WL 12927885 (SD Fla September 23, 2015)
Kerns v Hoppe[78]	128 Nev 910, 381 P3d 630 (2012)
Masood v Division of Professional Regulation of Department of Financial and Professional Regulation[79]	2023 IL App (1st) 220657
McDow v Nevarez[80]	No 2:20CV583 (RCY), 2021 WL 2416857 (ED Va June 11, 2021)
McGowan v McArdle[81]	No 19-CV-978-JDP, 2021 WL 2117165 (WD Wis May 25, 2021)
Nava v Velardi[82]	No 15CV1156-AJB(BLM), 2018 WL 3773848 (SD Cal August 9, 2018)
Osborne v Arizona Medical Board[83]	No 1 CA-CV 16-0250, 2017 WL 2544508 (Ariz Ct App June 13, 2017)
Owens v Clark[84]	No 215CV0982TLNKJNP, 2018 WL 4090600 (ED Cal August 27, 2018)
Ramirez v Swingle[85]	No 2:11-CV-0045 LKK KJN, 2012 WL 5828549 (ED Cal November 15, 2012)

Continued

Table 3. (Continued)

Case Name	Citation
Shank v State Medical Board of Ohio[86]	2012 Ohio Misc LEXIS 6127 (June 18, 2012)
Smith v Fu[87]	No 19-02119 BLF (PR), 2020 WL 5217198 (ND Cal September 1, 2020)
State v Christensen[88]	2020 MT 237, 401 Mont 247, 472 P3d 622
State v Newland[89]	2009 WL 765152, 2009 WL 765152
State v Wiedeman[90]	286 Neb 193, 835 NW2d 698 (2013)
State v Petromilli[91]	2017 WL 1494498, 2017-Ohio-1511
Tilford v Chau[92]	No 12CV2507-GPC MDD, 2014 WL 2965320 (SD Cal July 1, 2014)
United States v Blair[93]	No ACM S32328, 2016 WL 6575018 (AF Ct Crim App October 25, 2016)
United States v Evans[94]	892 F3d 692 (5th Cir 2018)
United States v Heaton[95]	59 F4th 1226 (11th Cir 2023)
United States v Lague[96]	971 F3d 1032 (9th Cir 2020)
Wecker v Salem Clinic[97]	325 Or App 736, 529 P3d 991 (2023)

OTA, opioid treatment agreement.

Table 4. Dates and Locations of Conduct in Written Judicial Opinions

Case Name	Year of Judicial Decision	Location(s) of Conduct	Year(s) of Conduct
Armstrong v Louisiana State Board of Medicine[67]	2004	Louisiana	1993-2002
State v Newland[89]	2009	Ohio	2006
Anderson v Tate[65]	2012	California	2008
Ramirez v Swingle[85]	2012	California	2009
Shank v State Medical Board of Ohio[86]	2012	Ohio	2003-2008
Estate of Watson v King[71]	2012	North Carolina	2006-2007
Kerns v Hoppe[78]	2012	Nevada	Unclear
State v Wiedeman[90]	2013	Nebraska	2010
Tilford v Chau[92]	2014	California	2012
Davis v High Desert State Prison[69]	2014	California	2010-2011
Harris v Debellis[77]	2015	Florida	2012
United States v Blair[93]	2016	Oklahoma	Unclear
State v Petromilli[91]	2017	Ohio	2014
Green v Nangalama[74]	2017	California	2010-2011
Osborne v Arizona Medical Board[83]	2017	Arizona	Unclear
Nava v Velardi[82]	2018	California	2014
Owens v Clark[84]	2018	California	2014
United States v Evans[94]	2018	Texas	2010-2011
Halloran v Kiri (Trial)[76]	2018	New York	2012-2013
Andrew v Hamilton County Public Hospital[66]	2018	Iowa	2012-2016
Halloran v Kiri (Appellate)[75]	2019	New York	2012-2013
Delaware Board of Medical Licensure and Discipline v Grossinger[70]	2020	Delaware	2014

Continued

Table 4. (Continued)

Case Name	Year of Judicial Decision	Location(s) of Conduct	Year(s) of Conduct
Smith v Fu[87]	2020	California	2018
State v Christensen[88]	2020	Idaho and Montana	1992-2012
United States v Lague[96]	2020	California	2007-2016
Franson v United States[72]	2021	Oregon	2015
Gala v Bullock[73]	2021	Delaware	2016
McGowan v McArdle[81]	2021	Wisconsin	2019
McDow v Nevarez[80]	2021	Virginia	2020
Cambronero v Meli[68]	2022	Wisconsin	2019
Wecker v Salem Clinic[97]	2023	Oregon	2022
United States v Heaton[95]	2023	Georgia	2010-2015
Masood v Division of Professional Regulation of Department of Financial and Professional Regulation[79]	2023	Illinois	2017-2018

Table 5. Characteristics of Civil Cases

Case Name	Case Summary	Protective of Clinician?	Description
Green v Nangalama[74]	Eighth Amendment: incarcerated patient alleged Eighth Amendment violation because he was not referred to a specialist.	Yes	OTA imposed requirements on the patient but did not guarantee a referral to a specialist.
Cambronero v Meli[68]	Eighth Amendment: incarcerated patient alleged Eighth Amendment violation because their pain medication was discontinued.	Yes	Patient failure to follow OTA provided evidence prison physician was justified in discontinuing prescribing.
McGowan v McArdle[81]	Eighth Amendment: incarcerated patient alleged Eighth Amendment violation for undertreatment of their pain.	Yes	Patient refusal to sign OTA provided evidence that the clinician did not undertreat pain by declining to prescribe narcotic medication.
Anderson v Tate[65]	Eighth Amendment: incarcerated patient alleged Eighth Amendment violation partly because they were asked to sign an OTA.	Neither	Patient did not sign OTA; court dismissed claim.
Nava v Velardi[82]	Eighth Amendment: incarcerated patient alleged Eighth Amendment violation partly because they were asked to sign an OTA.	Yes	Requiring a patient to sign an OTA specifying that prescribing could be discontinued at any time was not evidence of deliberate indifference to patient.
Ramirez v Swingle[85]	Eighth Amendment: incarcerated patient alleged Eighth Amendment violation partly because their pain medication dose was reduced.	Yes	Patient signing an OTA containing the new dose provided evidence the reduced dose advanced a legitimate treatment goal.

Continued

Table 5. (Continued)

Case Name	Case Summary	Protective of Clinician?	Description
Davis v High Desert State Prison[69]	Eighth Amendment: incarcerated patient alleged Eighth Amendment violation partly because their pain medication was discontinued.	No	Patient signing and following an OTA provided evidence that pain medications were discontinued arbitrarily.
Owens v Clark[84]	Eighth Amendment: incarcerated patient alleged Eighth Amendment violation partly because their pain medication was discontinued.	Yes	Patient failure to follow the OTA provided evidence the prison physician was justified in discontinuing prescribing.
Smith v Fu[87]	Eighth Amendment: incarcerated patient alleged Eighth Amendment violation partly because their pain medication was discontinued.	Yes	Patient failure to follow the OTA provided evidence the prison physician was justified in discontinuing prescribing.
Tilford v Chau[92]	Eighth Amendment: incarcerated patient alleged Eighth Amendment violation partly because their pain medication was discontinued.	Yes	OTA provided evidence that the patient was not entitled to narcotic medication.
Armstrong v Louisiana State Board of Medicine[67]	Medical board: physician challenged state medical board disciplinary action.	No	Physician prescription of OTA for part of relevant time was not sufficient to correct for other failures to comply with the state "pain rules" for prescribing.
Delaware Board of Medical Licensure and Discipline v Grossinger[70]	Medical board: physician challenged state medical board disciplinary action.	No	Physician failure to follow the OTA provided evidence that relevant regulations were violated.

Continued

Table 5. (Continued)

Case Name	Case Summary	Protective of Clinician?	Description
Gala v Bullock[73]	Medical board: physician challenged state medical board disciplinary action.	No	Physician failure to use an OTA provided evidence that relevant regulations were violated.
Masood v Division of Professional Regulation of Department of Financial and Professional Regulation[79]	Medical board: physician challenged state medical board disciplinary action.	No	Physician failure to use an OTA provided evidence that relevant regulations were violated.
Osborne v Arizona Medical Board[83]	Medical board: physician challenged state medical board disciplinary action.	No	Physician failure to follow the OTA provided evidence that relevant regulations were violated.
Shank v State Medical Board of Ohio[86]	Medical board: physician challenged state medical board disciplinary action.	No	Physician failure to follow the OTA provided evidence that the physician fell below the minimal standards of care.
Franson v United States[72]	Negligence: patient alleged medical malpractice, breach of contract, and libel after physician discontinued prescribing opioids.	Yes	Patient failure to follow the OTA provided evidence that the physician was justified in discontinuing prescribing.
Wecker v Salem Clinic[97]	Negligence: patient alleged medical malpractice, breach of contract, and intentional infliction of emotional distress after the physician–patient relationship was terminated.	Yes	Patient failure to follow the OTA provided evidence the physician was justified in ending the relationship and that the patient knew that certain conduct could result in termination.

Continued

Table 5. (Continued)

Case Name	Case Summary	Protective of Clinician?	Description
Halloran v Kiri (Appellate)[75]	Negligence: patient's family alleged medical malpractice and lack of informed consent causing the patient's death.	No	Physician failure to follow the OTA provided evidence that the patient did not give informed consent to opioid treatment.
Halloran v Kiri (Trial)[76]	Negligence: patient's family alleged medical malpractice and lack of informed consent causing the patient's death.	No	Physician failure to follow the OTA provided evidence that the patient did not give informed consent to opioid treatment.
Kerns v Hoppe[78]	Negligence: patient's family alleged medical malpractice and negligence causing the patient's death.	No	Patient signing an OTA was not sufficient to show the patient assumed the risks of receiving opioids.
Estate of Watson v King[71]	Negligence: patient's family alleged wrongful death caused by negligent care.	Yes	Patient failure to follow the OTA provided evidence that the patient negligently contributed to his own overdose.
McDow v Nevarez[80]	Other: patient alleged constitutional violations and breach of contract after being terminated from a practice.	Neither	Patient failed to follow the OTA described by the court; court dismissed claims for other reasons.
Harris v Debellis[77]	Other: patient who was arrested alleged a law enforcement officer violated their constitutional rights and state law.	Neither	Patient failure to follow the OTA provided evidence of probable cause to arrest for withholding information from a health care practitioner under Florida law.
Andrew v Hamilton County Public Hospital[66]	Other: physician sued former employer after being terminated.	No	Physician failure to use OTA provided evidence that the defendant fired the plaintiff because of dangerous prescribing practices.

OTA, opioid treatment agreement.

incarcerated person alleged a violation of their right under the Eighth Amendment of the US Constitution to be free from cruel and unusual punishment that was based on how their pain was treated while incarcerated; "medical board" cases (six cases), in which a physician challenged a state medical board's decision to take disciplinary action against the physician; and "negligence" cases (six cases), in which a patient, or a patient's family member, alleged that the care provided to the patient was negligent in some way or informed consent was not obtained. The three remaining cases did not share common characteristics ("other" cases). One case involved a patient alleging breach of contract and constitutional violations after a pain management clinic discontinued its relationship with the patient. One case involved a patient alleging that a law enforcement officer violated state law and their constitutional rights in arresting the patient for drug-related offenses. One case involved a physician suing a former employer after being terminated.

In 11 of these 25 civil cases, the court discussed the OTA as a piece of evidence that supported the clinician's position; in 11 cases, the court discussed the OTA as a piece of evidence that did not support the clinician's position; and in three cases, the OTA was neither supportive of nor not supportive of the clinician's position (e.g., because the case did not involve a clinician as a party or the court dismissed the case for other reasons while nevertheless discussing the OTA).

Of the 11 cases in which the OTA was used as a piece of evidence that supported the clinician's position, eight of the cases were Eighth Amendment cases (e.g., the incarcerated patient's failure to follow an OTA was cited as evidence that the clinician was justified in discontinuing prescribing of pain medication) and three of the cases were negligence cases in which the patient's failure to follow an OTA provided evidence that the clinician was justified in discontinuing either prescribing or the clinical relationship. None of these cases occurred in jurisdictions that require OTA use.

Of the 11 cases in which the OTA was used as a piece of evidence that did not support the clinician's position, six consisted of all the state medical board cases (e.g., the physician's decision to continue to prescribe to patients who were not following their OTA was cited as evidence that the physician violated relevant regulations), three were negligence cases (e.g., a patient signing an OTA was determined insufficient evidence to show that the patient assumed the risk of using opioids or the physician failing to follow the OTA was cited as evidence that a patient did not give fully informed consent to opioid treatment), one was an Eighth Amendment case in which a patient signing and following an OTA was cited as evidence that the prescribing of pain medications was discontinued arbitrarily, and one was the "other" case in which a physician sued a former employer, for which the physician's failure to use OTAs was cited as evidence the physician was justifiably fired for dangerous prescribing practices. Five of these cases occurred in jurisdictions that require OTA use.

Criminal Cases

Eight of the written opinions in our data set were criminal cases (Table 6). In four of the cases, a clinician was the criminal defendant, and in all four of those cases, the OTA was cited as a piece of evidence that the clinician acted wrongfully, supporting the criminal conviction (e.g., a clinician's failure to follow an OTA provided evidence that the clinician knew they were distributing controlled substances outside the course of professional practice). Two of the four clinician-defendant cases occurred in jurisdictions that require OTA use.

In the other four criminal cases, a patient was the criminal defendant. In all four of these cases, a clinician was not a party to the case, nor was a clinician's conduct relevant to assessing the defendant's conduct; accordingly, in all four cases, the OTA neither supported nor failed to support a clinician's position. In all four cases, however, the OTA was cited as evidence that the patient acted wrongfully, supporting criminal conviction (e.g., the patient signing an OTA requiring them to seek medications from only one prescriber was cited as evidence the patient knew they would have to mispresent their medical history to acquire more drugs from additional prescribers). All four patient-defendant cases occurred in jurisdictions that require OTA use.

Limitations

There are several limitations to our research. For our reviews of both statutes and regulations and judicial decisions, our data sets may be incomplete. First, both data sets represent a snapshot in time. Jurisdictions' laws and regulations may have changed and new judicial opinions may have been written since our data sets were collected. Additionally, our search terms, although intended to be comprehensive, may have failed to identify relevant statutes, regulations, or cases (or relevant statutes, regulations, or cases may be missing from the databases that we searched). Additionally, for the statutes and regulations specifically, we did not Shepardize each law and regulation we identified (in legal databases, "Shepardizing" refers to tracing the document's use in legal opinions) and doing so may have uncovered additional cases.

Specific to our review of state statutes and regulations, our coding was based on the plain language of the statutes and regulations alone. For example, we did not search for and review any jurisdiction's guidance documents that may suggest a different interpretation than that derived from the plain language of the statutes and regulations themselves. Accordingly, in some instances, our coding may not reflect how stakeholders interpret and apply the statutory or regulatory language in practice. Further qualitative research should be done to determine how these legal requirements are understood and operationalized. We also did not examine any requirements to use OTAs beyond the realm of statutes and regulations (e.g., from particular health systems or physician practices).

Table 6. Characteristics of Criminal Cases

Case Name	Case Summary	Protective of Clinician?	Explanation
United States v Heaton[95]	Clinician defendant: physician appealed a criminal conviction for aiding and abetting the acquisition of controlled substances by deception and unlawfully dispensing.	No	Physician failure to follow the OTA provided evidence that they knew they were distributing outside the course of professional practice, supporting criminal convictions.
United States v Evans[94]	Clinician defendant: physician appealed a criminal conviction for distributing controlled substances, money laundering, mail fraud, and conspiracy.	No	Physician use of OTAs was not sufficient to overturn convictions; jury could reasonably conclude that these were mere formalities. The risk-assessment tools meant little, as they were never followed up on.
State v Christensen[88]	Clinician defendant: physician appealed a criminal conviction for negligent homicide, criminal endangerment, and criminal distribution of dangerous drugs.	No	Physician failure to use an OTA provided evidence supporting criminal conviction.
United States v Lague[96]	Clinician defendant: physician assistant appealed a conviction for distributing controlled substances outside the usual course of professional practice and without a legitimate medical purpose.		

Continued

Table 6. (Continued)

Case Name	Case Summary	Protective of Clinician?	Explanation
	No	Physician assistant falsely documenting patient compliance with an OTA provided evidence of wrongdoing.	
State v Wiedeman[90]	Patient defendant: patient appealed a criminal conviction for acquiring a controlled substance by fraud.	Neither	The OTA provided evidence that the patient knew they would have to misrepresent their medical history to acquire drugs.
State v Petromilli[91]	Patient defendant: patient appealed a criminal conviction for deception to obtain a dangerous drug.	Neither	The OTA provided evidence that the patient knew they would have to misrepresent their medical history to acquire drugs.
United States v Blair[93]	Patient defendant: patient appealed a military conviction for wrongful possession and use.	Neither	Patient failure to follow the OTA provided evidence supporting criminal conviction.
State v Newland[89]	Patient defendant: patient appealed a criminal conviction for deception to obtain a dangerous drug.	Neither	The OTA provided evidence that the patient knew they would have to misrepresent their medical history to acquire drugs.

Specific to our review of written judicial opinions, our data set cannot capture cases that have been decided without written opinions or lawsuits that have settled or been dismissed before coming before a court. Lawsuits that result in written opinions may be distinct from these other kinds of lawsuits in various ways that our research cannot assess. Additionally, it is possible that some civil or criminal actions are never filed because those who would file them are deterred from doing so by a clinician's compliance with an OTA. Our data set does not include lawsuits considered but never filed, and for this reason, OTAs may serve as legal shields for clinicians in ways that our data cannot detect. Our review also does not include state medical board decisions or Drug Enforcement Agency administrative law judge decisions related to clinician failure to abide by legal requirements.

Discussion

Our results confirm that OTA use is entwined in various ways with the law. Based on our analysis of state statutes and regulations, we observed that OTA use is now required in most of the United States. But even in jurisdictions where OTA use is not required by statute or regulation, our analysis of written judicial opinions demonstrates that how OTAs are used (or the fact that an OTA was not used) can inform courts' reasoning in lawsuits involving patients or clinicians. Our focus in this study is to identify these requirements and cases, and we suggest that future research should engage in more normative and qualitative analysis regarding the relevant rules and legal arguments to better assess how these different legal requirements are interpreted and implemented.

Requirements Based on Duration of Prescribing and Stigma

The most consistent characteristic of the statutory and regulatory OTA requirements is to use the duration of prescribing to trigger the requirement to use an OTA. Twenty-six of the 27 jurisdictions that require OTA use do so at least partly based on the duration of prescribing, uniformly imposing the requirement for long-term opioid therapy (though "long-term" is operationalized differently in different jurisdictions). This consistency may reflect the evidence that long-term use of opioids may be associated with increased risks of patient harm and substance use disorder while being supported by only limited evidence of effectiveness.[19,98] If so, this characteristic of OTA laws and regulations may suggest that the legal requirements sensibly are intended to target the riskiest forms of prescribing and to protect the patients least likely to benefit and at greatest risk of adverse outcomes.

However, there also is a paucity of evidence that OTAs, at least as currently used, in fact reduce opioid-related harms or diversion.[18,19] Moreover, 48% of

jurisdictions requiring OTAs exclude from their requirements patients with cancer or noncancer terminal conditions who would otherwise qualify (with some unclarity in Massachusetts's statute on this subject). This is so even though such patients could also engage in opioid misuse or diversion and would benefit from any shared decision-making role that OTAs ostensibly serve.[9–11,99–101] Indeed, some clinicians have specifically recommended the use of OTAs with patients with cancer.[102] The combination of requiring OTAs only for long-term opioid therapy and exempting patients with cancer or noncancer terminal conditions who receive long-term opioid therapy thus might suggest that the OTA statutes and regulations consistently target certain groups of patients for reasons other than these patients being at greatest risk. That is, this structure to the laws and regulations may reflect the ways in which patients receiving long-term opioid therapy are stigmatized, particularly when their chronic pain is not caused by cancer or a terminal illness,[103,104] rather than solely reflecting judgments about which patients would benefit most from OTAs.

The differences of the ways OTA laws and regulations apply to different kinds of patients with chronic pain, in turn, offer an opportunity for health policymakers to reevaluate the aims of OTA requirements and to reconsider who, if anyone, stands to benefit from these requirements. This reevaluation is made more salient when we compare our data related to statutory and regulatory requirements with our data related to court case outcomes. All four of the patient-defendant criminal cases took place in jurisdictions where OTAs were required, and in each of the cases, the presence of the OTA was cited as evidence that supported criminal conviction. At the same time, it is possible that in each of these cases, there may have been other evidence that would have led to criminal conviction. However, insofar as the laws and regulations requiring OTAs target patients for reasons other than who is at greatest risk of opioid misuse, these laws may expose certain patients, who are already stigmatized, to criminal liability unfairly. Even if exemptions for patients with cancer were dropped, given the lack of evidence of the effectiveness of OTAs, health policymakers should consider whether people who are at greatest risk of opioid misuse deserve disproportionate criminal liability.

Variability and Discretion in OTA Requirements

Apart from linking the OTA requirement to the duration of prescribing, there is substantial variation between jurisdictions' statutory and regulatory requirements for OTA use. At a minimum, clinicians and health care institutions should be aware of whether OTA use is legally required in their jurisdiction and, if so, what specifically is required.

Understanding the statutory and regulatory requirements is also important for enabling clinicians and health care institutions to identify when they have flexibility to implement OTAs in ways that could enhance the clinician–patient relationship

and better serve patients. And generally, clinicians and health care institutions have substantial discretion to decide how to use OTAs. For those jurisdictions that do not require OTA use, there is, of course, quite a bit of flexibility in how a clinician or a health care institution might choose to write and use OTAs in their practice. Even those jurisdictions that do require OTAs, however, give clinicians and health care institutions discretion in how those requirements are implemented. For example, some jurisdictions mandate very few or no terms that must be included in an OTA, leaving room for clinicians or, more likely, health care institutions to determine the appropriate provisions to include in an OTA. Moreover, for the jurisdictions that require a relatively long list of terms to be included—such as Washington, which lists eight mandatory provisions—the statutes and regulations do not prohibit adding more terms or language that might help frame an OTA as a shared decision-making tool, nor do they specify particular procedures or conversations that must be used when introducing an OTA to a patient.

Given that OTAs are increasingly required by various statutes and regulations, we hope that clinicians and health care institutions will identify and use whatever flexibility those requirements offer to promote the values often described as the aims of OTA use: to strengthen clinician–patient relationships and promote public health (e.g., by facilitating a conversation between the patient and clinician about the goals and expectations of treatment) and mitigate potential harms (e.g., stigma connected to receiving opioids, additional barriers to access pain management).

OTAs as Legal Protection and Implications for the Clinician–Patient Relationship

Against this background of discretion, clinicians and health care institutions should also be aware that whatever norms are in place with respect to OTA use, or whatever terms are elected for inclusion in the OTA, may impact how a court will assess patient or clinician conduct if a lawsuit arises. Clinicians perceive OTAs to be legally protective,[27,28] and our analysis of written judicial opinions confirms that OTAs can provide evidence that supports clinicians' decisions under some circumstances. For example, in two cases in which patients alleged that clinicians or clinics acted negligently (among other claims), courts concluded that the patient's failure to follow the terms of the OTA provided evidence that the clinician or clinic was justified in discontinuing prescribing (*Franson v United States*[72]) or was justified in discontinuing the therapeutic relationship altogether (*Wecker v Salem Clinic*[97]). This sort of shield from liability is precisely the kind of legal protection that clinicians may envision OTAs providing and does not appear to depend on a jurisdiction requiring OTA use by statute or regulation.[28]

Yet OTAs are not always legally protective for clinicians. In cases in which there are allegations that a clinician has acted improperly, courts may view the clinician's failure to use an OTA or failure to enforce the terms of an OTA against a patient (e.g., by continuing to prescribe to patients who do not comply with an OTA) as evidence supporting the allegations against the clinician. For instance, in *State v Christensen*,[88] the court cited the physician's failure to use an OTA as a piece of evidence supporting the physician being convicted of drug-related crimes, even though the relevant conduct occurred in Idaho and Montana, where OTA use is not required by statute or regulation. As another example, in *Osborne v Arizona Medical Board*,[83] the court cited a physician's failure to address patient violations of OTA terms as evidence that supported the medical board's finding that the physician violated a regulation prohibiting "conduct or practice that is or might be harmful or dangerous to the health of the patient or the public."

It should be noted that of the judicial decisions in which OTAs shielded clinicians from liability, they all related to cases in which the clinician chose to either end opioid therapy or the therapeutic relationship altogether. In the judicial decisions in which OTAs did not provide evidence supporting the clinician's position, often a court pointed to a clinician's failure to enforce the terms of the OTA against a patient, or failure to use an OTA at all, as evidence that supported a civil or criminal claim against the clinician. In other words, the ways OTAs are influencing judicial decision making seems likely to encourage clinicians to use OTAs, be conservative in their understanding of the terms of OTAs, and use their discretion to disproportionately cut off long-term opioid therapy for patient infractions of the OTA terms, even if they would judge the treatment to continue to be clinically indicated absent an OTA. This outcome would lend support to concerns that OTA use can undermine clinician–patient relationships.

Moreover, OTAs can support patients' positions, or be used against patients, as well. For example, in *Davis v High Desert State Prison*,[69] an incarcerated patient's compliance with the terms of the OTA was cited as evidence that the patient's pain medications were discontinued arbitrarily. Conversely, in *Estate of Watson v King*,[71] the court cited the patient's failure to comply with the OTA as evidence that the patient negligently contributed to their own overdose. Additionally, in all four criminal cases involving a patient defendant, the patient's failure to follow OTA provisions was cited as evidence supporting the patient's criminal conviction. Similar to the ways OTAs appear to influence judicial views of clinicians' conduct, courts appear to expect that patients can and will comply with all terms of an OTA.

Accordingly, clinicians and health care institutions should be aware that how they choose to use the discretion available to them, particularly when they choose to use OTAs and what terms they choose to include in OTAs, might impact lawsuits' outcomes both for themselves and for their patients. This includes legal actions, such as criminal prosecutions in which patients are defendants and clinicians and health care

institutions are not parties to the case and have no formal stake in the outcomes. Failing to use an OTA or failing to enforce its terms against a patient might be cited by courts as evidence of clinician wrongdoing, which could drive clinicians and health care institutions to adopt more rigid OTA policies and enforce those policies more strictly. Rather than that outcome, however, we hope these findings add nuance to clinicians' understanding of how OTA use arises in lawsuits. In particular, clinicians' perceptions that OTAs are legally protective for them may be part of what drives clinicians to report that OTAs are useful even while reporting doubts about OTAs' effectiveness at reducing opioid misuse and diversion.[27] These findings, thus, may be cause for clinicians and health care institutions to reevaluate the legal value of OTAs for both them and their patients.

Conclusions

Taken together, our analyses support the view that, notwithstanding controversy regarding the benefits and risks of OTA use, OTA use has become legally required in many jurisdictions and, even in jurisdictions where they are not required, their implementation may be expected by courts as a matter of professional duty. In our analysis, we found wide variability in the language of OTA requirements and the ways that OTAs end up being used as evidence in judicial decisions. However, some concerning trends did emerge that would benefit from further research and normative assessment. First, the structure to the laws and regulations may reflect the ways in which patients receiving long-term opioid therapy are stigmatized rather than solely reflecting judgments about which patients would benefit most from OTAs. Second, OTAs may not provide the robust safeguards against legal liability that they are perceived to be providing. Even in jurisdictions where OTAs are not required, an OTA can be cited as evidence against both patients and physicians in criminal cases. These trends give urgency for further research into how these legal requirements are affecting practice.

Given these trends, further research should explore numerous topics. First, research could investigate the ways in which clinicians and health care institutions are operationalizing these requirements. How are clinical discretion and flexibility being incorporated into these policies, if at all? To what degree are the jurisdictions' legal requirements being balanced with the local needs of specific patient populations, including protecting access to comprehensive pain management?

As a second example, future research could seek to identify whether there can be a model state statute. Without strong evidence that OTAs yield improvements in patient care or reductions in opioids' harms, we stopped short of offering a model statute. However, various statutory and regulatory requirements, depending on how they are implemented, could have the potential to facilitate productive discussions

and reinforce the clinician–patient relationship to varying degrees. Further qualitative analysis of these requirements may begin to shed light on best practices that jurisdictions could consider as they decide whether and how to include OTAs in opioid prescribing requirements.

Third, other recent studies of public health laws have found significant concurrence in the language of new statutes, especially in health matters of high public interest.[105–108] Given the variability of the legal requirements related to OTAs, it appears that these legislative and regulatory initiatives may not have been the result of polarized networks drafting and lobbying for model bills across the different jurisdictions. Why this convergence on OTA requirements has not occurred when we have seen it in other contexts should be further explored, particularly given the public salience of the drug overdose crisis.

As a final example, future research can use our data set to explore the potential differences between the legal requirements imposed by statutes versus those imposed by regulations. Are there material differences among such OTA requirements? How do any fundamental differences in drafting and enactment processes affect the content and language of OTA requirements?

Although OTAs are only one piece of a complicated web of legal and policy structures related to the drug overdose crisis, studying the legal environment in which OTAs are used, and the best practices for OTA use, are important public health goals. Ultimately, better understanding all aspects of the legal environment for opioid use and prescribing will help us see the ways in which the law can shape the ongoing drug overdose crisis and design legal requirements to help, rather than harm, people. Moreover, if additional research does not resolve the current level of uncertainty regarding the benefits of OTAs, then policymakers in jurisdictions where they are required should consider eliminating OTA mandates or, at least, providing flexibility in the legal requirements to make room for clinicians and health care institutions to implement best practices.

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