In 2017, 47,000 Americans died of opioid overdose that includes: opioid prescriptions, heroin, and illicit fentanyl.\(^1\) That same year, the U.S. Department of Health and Human Services (HHS) declared a public health emergency associated with opioid drug abuse.\(^2\) HHS published the graph below to highlight the statistics associated with the “Opioid Crisis.”

Hereby labeled “Chart 1”

The “Opioid Crisis” has brought back the importance of prescription drug abuse enforcement and regulation. The public outcry against the epidemic caused states to create their own regulations and laws handling prescription drug abuse and opioids. After states enact


regulations and laws governing the practice of medicine, agencies known as State Medical Boards (SMB) interpret and enforce their state’s medical laws. Furthermore, the state laws specify the responsibilities of the SMB. The main mechanism through which SMB’s enforce and govern physicians is licensing.

Physicians are subjected to multitudes of standards and regulations. For instance, physicians must comply with SMBs, The Controlled Substance Act (CSA), and Drug Enforcement Agency (DEA) registrations. This paper examines how the various levels of regulation impact physicians while examining whether a circuit split exists in the standard applied to analyzing physician prescribing of opioids. The following sections break down both state and federal regulations. This paper will start on the state level and compare states with “stricter” laws to states with “looser” laws as to impact on physicians and patients. Regarding federal laws, this paper will investigate whether there is a split in standards between the Circuit courts.

**State Laws/Regulations and the State Medical Boards:**

States can create their own laws regarding the management of physicians within their own borders. For the most part, these state laws and regulations are enforced and carried out by SMBs. SMBs are the state created agency that enforce and carry out the state laws and

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4 Id at 5
5 Id at 7
regulations that pertain to physicians and other healthcare providers. SMBs are compiled of various individuals, including some professionals and some ordinary citizens, but can vary based on the state. However, SMBs do not operate like police departments, rather, SMBs react to complaints from individuals, organizations, or the state. The purpose of SMBs are to protect the public and ensure that physicians are acting in accordance with proper treatment. Therefore, SMBs has broader range to act compared to Federal agencies. For instance, SMBs can investigate and reprimand physicians if a complaint suggests that the physician is acting carelessly/recklessly or if the physician’s ability is compromised. A careless/reckless physician is a physician that constantly deviates from the professional standard of care. These physicians are considered “bad doctors,” because of their constant deviations, however, they do not rise to the category of corrupt, because they are not abandoning the standard of care for personal or financial gain. These physicians are disciplined by SMBs but not by federal agencies.

Physicians that are compromised are ones that overprescribe or mis-prescribe, because of some factor that impairs their judgement. Factors include but are not limited to: age, mental illness, mental abilities, other illnesses, and being gullible. These physicians are disciplined by SMBs but not federal agencies as well. Practically, disciplining these physicians through SMBs and not through federal agencies makes sense, because they are not criminals, but do present a possible danger to the public. It does not appear to be unsettling or disconcerting to discipline

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7 Id
8 Id
10 Id at 41
11 The Role of State Medical Boards
12 Dineen at 33
13 Id
14 Id
15 Id at 34
16 Id at 20
careless or compromised physicians through SMB sanctions, but it would be unsettling and disconcerting to subject those physicians to criminal convictions.

Prior to 2012, disciplinary hearings against physicians were low.\textsuperscript{17} Since then, the number of physicians being disciplined has increased and continues to increase today.\textsuperscript{18} SMBs investigations are triggered by the filing of a complaint.\textsuperscript{19} In response to the complaints SMBs receive, the state agency can reprimand the physician, for instance, suspension, or the state agency can completely revoke the physicians license, thereby preventing the physician from practicing within their borders.\textsuperscript{20} SMBs reprimand physicians after investigating a complaint the state agency receives.\textsuperscript{21} All states allow for voluntary complaints, meaning complaints that are usually filed by individuals or corporations.\textsuperscript{22} In addition to voluntary complaints, SMBs investigations are triggered by mandatory reporting.\textsuperscript{23} Mandatory reporting to SMBs includes criminal investigations and charges, criminal prosecutions, convictions of felony, and convictions involving controlled substance (i.e. conviction under CSA).\textsuperscript{24} Additionally, in many states, complaints involving over-prescribing are mandatory reporting.\textsuperscript{25}

Since 2017, at least seventeen states have enacted rules to limit the number of painkillers physicians can prescribe to the patient before the patient has to return to the physician to acquire more.\textsuperscript{26} Most of these opioid prescription drug laws have stemmed from the opioid epidemic that

\footnotesize{\textsuperscript{17} Aaron Young et al., A Census of Actively Licensed Physicians in the United States, 2014, 101 Journal of Medical Regulation 7–22 (2015).}
{\textsuperscript{18} Id at 12}
{\textsuperscript{19} Dineen at 25}
{\textsuperscript{20} Id at 99}
{\textsuperscript{21} Id at 101}
{\textsuperscript{22} Id at 28}
{\textsuperscript{23} Id at 31}
{\textsuperscript{24} Id at 35}
{\textsuperscript{25} Id at 40}
{\textsuperscript{26} Katie Zezima, With drug overdoses soaring, states limit the length of painkiller prescriptionsThe Washington Post(2017), https://www.washingtonpost.com/politics/with-drug-}
has developed within the United States. Some states, including New Jersey, Massachusetts, Connecticut and Delaware have limited the initial opioid prescription amount to five or seven days.\textsuperscript{27}

For example, New Jersey was the first state to limit the initial opioid prescription amount to five days.\textsuperscript{28} In addition, New Jersey is considered to be an example of a state with strict rules on opioid prescribing.\textsuperscript{29} NJ allows for physicians to renew the prescription on the fourth day if the patient’s pain has not subsided.\textsuperscript{30} The goal of this NJ law is to limit the number of pills in the public.\textsuperscript{31} This law does not apply to long-term care facilities, chronic pain, hospice or cancer patients.\textsuperscript{32} Then Governor Chris Christie stated, "Today, we are taking action to save lives," in reference to this state law passing.\textsuperscript{33}

States that have limited the amount of initial days to opioid prescriptions appear to be following the guidance of a 2016 Center for Disease Control and Prevention (CDC) study finding that patients that use painkillers for longer than seven days increase their chance of opioid addiction.\textsuperscript{34} However, this study does not shed light on what timeframe is necessary to remedy a patient’s pain. It is unclear as to how many days are appropriate for opioid

\begin{flushleft}
\textsuperscript{27} Id
\textsuperscript{29} Id
\textsuperscript{30} Id
\textsuperscript{31} Id
\textsuperscript{32} Id
\textsuperscript{33} Id
\textsuperscript{34} Morbidity and Mortality Weekly Report (MMWR), Centers for Disease Control and Prevention (2017), https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm (last visited Mar 24, 2019).
\end{flushleft}
prescriptions, but one study published by JAMA in 2018 found that four to nine days following general surgery is typical.\(^{35}\) Additionally, the researchers found that procedures such as hip and knee replacement average between six and fifteen days, while women’s health procedures generally require anywhere between four and thirteen days.\(^{36}\)

While most states set mandatory limits on initial days, few states have yet to set any. For instance, Oregon, Iowa and Maryland do not have initial day limitations for prescription drugs.\(^{37}\) However, Oregon and Maryland do set limitations for minors.\(^{38}\) Oregon, instead of initial day limitations, requires physicians to use their judgment to prescribe the lowest dose that will still be effective for the patient.\(^{39}\) Physicians are encouraged to prescribe opioids for acute pain only if it is necessary.\(^{40}\) Like Oregon, Maryland passed a law that does not set initial day limitations but requires physicians/prescribers to prescribe the lowest effective dose of opioid prescription.\(^{41}\) On the other hand, Iowa requires physicians to register for monitoring programs, and to proactively “investigate” whether a patient is a high-risk for opioid abuse and addiction.\(^{42}\) Iowa defers to the judgment of the physician/prescriber as to whether a patient requires opioid


\(^{36}\) Id at 37


\(^{38}\) Id


\(^{40}\) Id


prescription and how much they need. Iowa Governor Kim Reynolds stated, “And like I said in my Condition of the State address, this will not end until we take action. With this legislation, we are taking the first step to reverse this heart-wrenching trend.” Additionally, Maryland Governor Larry Hogan states:

These critical initiatives will help us continue to lead the charge against Maryland’s heroin and opioid crisis in our state. Our administration remains committed to treating this crisis like the emergency that it is, and I thank the legislature for working with us to provide additional tools to save the lives of Marylanders – before it’s too late.

It is unclear why Oregon, Iowa and Maryland decided not to set any initial day limitations on opioid prescriptions. Potentially, it could be that they are giving physicians more discretion to combat the opioid epidemic.

It is likely that States inform their decisions through studies and articles written by researchers and medical professionals. The main distinction between proponents and opponents of initial day limitations involves the likelihood of addictions verses ability to manage pain. Proponents agree with the CDC that a limited supply of opioid prescriptions is sufficient to manage pain; additionally, prescribing more opioid prescriptions increases the likelihood of addiction. On the other hand, opponents rely on the claims that limiting opioid prescriptions both harm patients and will increase heroin use. Essentially, opponents of limiting opioid prescriptions believe that it will destabilize patients that rely on opioid prescriptions, mainly chronic but also acute, leading them to turn to alternatives, such as heroin. For instance, one article states:

43 Iowa
44 Governor Larry
45 Ballotpedia
46 Id
47 Ballotpedia
48 Id
While doing so [discontinuing opioids] could help some, it will destabilize others and likely promote the use of heroin or other drugs. ... We cannot be surprised by a flurry of reports, in the press, social media, and the medical literature describing pain patients entering acute withdrawal, losing function, committing suicide, or dying in jail.\textsuperscript{49}

The data supporting these findings are unclear, but rather speculative via anecdotes from professional and other experts within the practice. The accuracy of these claims will be revealed within the next few years after the opioid prescription initial day limitations have integrated within the United States.

Regardless of which route a state takes in tackling prescription opioid abuse and addiction, it is the job of the SMBs to investigate complaints and enforce the state laws passed that regulate medical professionals. Medical professionals are required to understand and comply with the laws and regulations within the state that they practice in while understanding and complying with The CSA. The following section dives into the caselaw regarding The CSA. Afterwards, a discussion about how The CSA caselaw and various state regulations applies to hypotheticals.

\textbf{The CSA and Subsequent Caselaw:}

This section will discuss the various judicial interpretations of The CSA and examine how these various interpretations effect physicians within the circuit/area. Based on reading the cases within several jurisdictions/circuits, it appears that there is a split in the standard used to convict a physician under The CSA. The focus on these cases look at the meaning of \textit{outside the}

usual course of professional practice that was established by U.S. v. Moore. Some circuits believe that this statement includes without a legitimate medical purpose as utilized in cases in line with U.S. v. Tighe. On the other hand, some circuits interpret the standard to mean outside the usual course of professional practice and without a legitimate medical purpose as seen within U.S. v. Feingold. To begin, for a person to be convicted under The CSA, they must knowingly or intentionally: (1) manufacture, distribute, or dispense, or possess with the intent to manufacture, distribute, or dispense, a controlled substance; or (2) create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance. The “standards” that the caselaw interprets can be seen within the notes of 21 U.S.C.S. § 841. Ultimately, the interpretations that stem from these case can be reduced to whether the physician should be subjected to increased protections. The following paragraphs will examine Moore and the standard it sets forth.

U.S. v. Moore, involves the prosecution and conviction of a physician under §841 of The CSA. The physician was caught unlawfully distributing and dispensing methadone. Methadone is an extremely addictive substance that is typically used to treat heroin addicts due to the similar “euphoric highs” that one gets from heroin. The use of methadone requires proper supervision and control to be effective and not harmful. The two most common methods to treating heroin addicts with methadone is through a maintenance method, which requires

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50 United States v. Moore, 423 U.S. 122 (1975)
51 United States v. Tighe, 551 F.2d 18 (3rd Cir. 1977)
52 United States v. Feingold, 454 F.3d 1001 (9th Cir. 2006)
53 21 U.S.C.S. § 841
54 Id
55 U.S. v. Moore, 423 U.S. at 124
56 Id
57 Id at 125
58 Id
authorization from Food and Drug Administration (FDA), and a *detoxification* method.\(^{59}\) The concept under *maintenance* is to give a heroin addict a fixed amount of methadone for an indefinite amount of time to keep the urge of using heroin minimal.\(^{60}\) Under a *detoxification* method, an addict is given a large amount of methadone during the beginning of the treatment to minimize withdrawal symptoms and will taper off as time goes on.\(^{61}\) Dr. Moore previously had authorization from the FDA revoked but that did not stop him.\(^{62}\) Between September 1971 and mid-February 1972, three pharmacies within the District of Columbia area filled 11,169 prescriptions that were written by Dr. Moore.\(^{63}\) Roughly 800,000 methadone pills were prescribed during this time.\(^{64}\) Additionally, during a fifty-four-day period, Dr. Moore filled over 100 prescriptions a day while making over $260,000 during the five and a half months.\(^{65}\) Dr. Moore was paid via a “sliding-scale” that ranged from $15 for a fifty-pill prescription to $50 for a 150 pill prescription.\(^{66}\) The defendant conceded that he did not observe the generally accepted medical practices.\(^{67}\) It was clear to the Court that the defendant acted *outside the usual course of professional practice*. The Court stated that Dr. Moore was acting as a “pusher” instead of a physician.\(^{68}\) The Court found that Dr. Moore gave inadequate examinations to patients if they got one at all.\(^{59}\) He ignored or did comply with test results he conducted.\(^{70}\) He had no precautions to prevent misuse of methadone by the patients.\(^{71}\) He did not restrict the dosage patients received

\(^{59}\) Id at 126  
\(^{60}\) Id  
\(^{61}\) Id  
\(^{62}\) Id  
\(^{63}\) Id at 127  
\(^{64}\) Id  
\(^{65}\) Id  
\(^{66}\) Id at 128  
\(^{67}\) Id at 135  
\(^{68}\) Id at 137  
\(^{69}\) Id  
\(^{70}\) Id  
\(^{71}\) Id at 140
and frequently prescribed the amount the patient requested.\textsuperscript{72} As previously stated, he adjusted his fees based on the number of pills he prescribed to his patients.\textsuperscript{73} The Court found that the legislative history of 21 U.S.C.S. § 841 indicated that the concern of Congress was the nature of the drug transaction and not the title of the person who is conducting the transaction.\textsuperscript{74}

\textit{U.S. v. Moore} is the bedrock case involving prosecutions of physicians under 21 U.S.C. § 841 for the prescribing of opioids that was first addressed by the Supreme Court. Since then, the Supreme Court has not further discussed 21 U.S.C. § 841 and \textit{Moore}. \textit{U.S. v. Moore} provided the standard that has been used by Circuit Courts since then, including two years later when the Third Circuit considered \textit{U.S. v. Tighe}.

In \textit{Tighe}, the defendant, Dr. Patrick Tighe, was a licensed physician within Pennsylvania.\textsuperscript{75} Between November 26, 1973 and May 29, 1974, two DEA agents visited Dr. Tighe at his office and at his home.\textsuperscript{76} During these visits by the DEA agents, eighteen unfilled prescriptions for biphetamines were found in his office, presumably to be given to someone who desires copious amounts of drugs.\textsuperscript{77} The facts of the case do not specify the reason as to why Dr. Patrick Tighe had unfilled prescriptions for biphetamines laying around his home and office, but it is believed that he was dispensing biphetamines outside his practice.\textsuperscript{78} Nevertheless, Dr. Patrick Tighe was convicted under The CSA, because he acted \textit{outside the usual course of professional practice}.\textsuperscript{79} \textit{Tighe} takes the \textit{Moore} approach by including \textit{without a legitimate

\begin{itemize}
\item \textsuperscript{72} Id at 125
\item \textsuperscript{73} Id
\item \textsuperscript{74} Id at 130
\item \textsuperscript{75} United States v. Tighe, 551 F.2d at 19
\item \textsuperscript{76} Id
\item \textsuperscript{77} Id
\item \textsuperscript{78} Id at 20
\item \textsuperscript{79} Id
\end{itemize}
medical purpose within using outside the usual course of professional practice.\textsuperscript{80} It was clear that there was no legitimate medical purpose to have eighteen unfilled prescriptions for biphethamines within your office. The Third Circuit in this case took the position that there is no other requirement to 21 U.S.C.S. § 841 besides what is stated within the statute. It is plain to see that having multiple unfilled prescriptions of a schedule II drug is outside the usual course of professional practice.

\textit{United States v. Rottschaefer}, continued this idea that outside the usual course of professional practice and without a legitimate medical purpose are the same\textsuperscript{81}. Dr. Rottschaefer was convicted under The CSA for unlawful distribution of controlled substances.\textsuperscript{82} At trial, his patients testified that Dr. Rottschaefer prescribed them Xanax, Oxycontin and other addictive painkillers to feed their prescription drug addictions.\textsuperscript{83} Additionally, four out of five testifying patients stated that they had to perform sexual favors as payment for their prescription.\textsuperscript{84} Dr. Rottschaefer argued that he was improperly convicted under a medical malpractice or negligence standard rather than the higher burden The CSA requires.\textsuperscript{85} Throughout the trial, the prosecutor used without a legitimate medical purpose instead of using outside the usual course of professional practice.\textsuperscript{86} The Third Circuit examined whether the use of without a legitimate medical purpose was proper.\textsuperscript{87} Based on the text from The CSA, the Third Circuit held that physicians will be held criminally liable if they prescribe and dispense prescription drugs outside the usual course of professional practice.\textsuperscript{88} Furthermore, the physician must prescribe the drug

\begin{itemize}
\item \textsuperscript{80} Id
\item \textsuperscript{81} \textit{United States v. Rottschaefer}, 178 Fed. Appx. 145 (3\textsuperscript{rd} Cir. 2006)
\item \textsuperscript{82} Id at 146
\item \textsuperscript{83} Id
\item \textsuperscript{84} Id at 149
\item \textsuperscript{85} United States v. Rottschaefer, 178 Fed. Appx. at 150
\item \textsuperscript{86} Id
\item \textsuperscript{87} Id
\item \textsuperscript{88} Id at 149
\end{itemize}
with legitimate medical purpose by the physician acting within the usual course of professional practice. If the prescription drug is knowingly given for ineffective reasons/purposes, the physician is subjected to the penalties of law. Therefore, the court determined that The CSA can use legitimate medical purpose when prosecuting a defendant. The Third Circuit further stated that the prosecutor using without a legitimate medical purpose was not a medical malpractice or a negligence standard that Dr. Rottschaefer argues. Next, the court examined whether there is a distinction between outside the usual course of professional practice and without a legitimate medical purpose. Using the Fifth, Sixth, and Tenth Circuits, the Third Circuit agreed that there is no difference between the two. The Third Circuit ultimately agrees with the Fifth and Fourth Circuit holdings that if there was a distinction, it is of no importance within the context of The CSA.

In United States v. Smith, the Eighth Circuit used similar reasoning as seen in United States v. Rottschaefer by claiming that outside the usual course of professional practice includes without a legitimate medical purpose to inform and meet the criteria of The CSA. Smith, did not involve a physician, but a businessman that was convicted of selling millions of dollars’ worth of prescription drugs online without valid prescriptions. Nevertheless, The CSA still applies, because it is not limited to the profession of the individual that dispenses, distributes or prescribes prescription drugs. Smith started distributing and selling prescription drugs online in 2004. Smith’s website had several names over the period it operated but the one thing that remained constant was the questionnaire that Smith required all customers to fill out prior to

89 Id at 148
90 Id at 147
91 Id at 150
92 United States v. Smith, 573 F.3d 639 (8th Cir. 2009)
93 Id at 640
94 21 U.S.C.S. § 841
95 United States v. Smith, 573 F.3d at 640
purchasing the prescription drugs. The questionnaire only required the customer to submit information regarding their name, address, date of birth, phone number, height, and weight; however, there was a spot for the customer to write in their medical condition/reason for the need of prescription. After some time of being open, Smith hired Dr. Phillip Mach to help issue prescriptions. Dr. Mach would review the submissions from the customers and either approve or deny the request for prescription drugs. Yet, if Dr. Mach denied a request, Smith would have that submission reviewed again by another employee, who would ultimately approve the request, because Smith’s company was under a “sell sell sell” mentality. Furthermore, in case the customer did not have internet access, Smith also established call centers within the United States for customers to call to purchase prescription drugs over the phone. Despite the allege requirement of needing necessary information to fill the prescription, Smith and Dr. Mach filled most requests get approved regardless of amount of adequate information given or whether the injury requires prescription drugs. In fact, the FDA found that most requests did not provide enough information for a physician to adequately decide whether the patient required prescription drugs. During the investigation into the business, undercover FDA agents made six requests for prescription drugs with false information through defendants and none of the requests were verified by the defendants regarding the accuracy of their information. Throughout the year that the website was open, Dr. Mach approved about 72,000 orders per day

96 Id at 641
97 Id
98 Id
99 Id at 642
100 Id at 644
101 Id at 643
102 United States v. Smith, 573 F.3d at 644
103 Id
104 Id
for pharmaceutical companies while the total amount sold was worth about $24 million.\textsuperscript{105} Smith’s business model preyed upon smaller pharmacies that were economically dependent on Smith’s company.\textsuperscript{106} To soothe the concerns these pharmacies had, Smith stated within their contracts that their business model was FDA approved.\textsuperscript{107} Smith and Dr. Mach’s highest selling drug was hydrocodone, which they sold over four-million tablets.\textsuperscript{108} In May 2005, a preliminary injunction was filed against Smith and his business.\textsuperscript{109} In response, Smith fled the United States to Dominican Republic where he was arrested when he returned to the US some time later.\textsuperscript{110} On November 22, 2006, a jury found Smith guilty on various accounts, one being The CSA.\textsuperscript{111} Smith argues that the court used a medical malpractice standard and not The CSA standard.\textsuperscript{112}

The 8\textsuperscript{th} Circuit disagreed with Smith on both points, because the jury instruction conforms with Moore.\textsuperscript{113} To start, \textit{within the usual course of professional practice} is not a medical malpractice standard but the proper standard for The CSA, because, according to the 8\textsuperscript{th} Circuit, it conforms with Moore.\textsuperscript{114} The 8\textsuperscript{th} Circuit relies on the fact that Moore considers \textit{within the usual course of professional practice} to incorporate without a legitimate medical purpose.\textsuperscript{115} Similar to Moore, the 8\textsuperscript{th} Circuit finds it hard to imagine a scenario where a physician is acting \textit{within the usual course of professional practice} while acting without a legitimate medical purpose.\textsuperscript{116} Therefore, the 8\textsuperscript{th} Circuit finds that the district court was correct in interpreting the

\begin{flushright}
\textsuperscript{105} Id \\
\textsuperscript{106} Id at 645 \\
\textsuperscript{107} Id \\
\textsuperscript{108} Id \\
\textsuperscript{109} Id \\
\textsuperscript{110} Id at 646 \\
\textsuperscript{111} Id \\
\textsuperscript{112} Id \\
\textsuperscript{113} Id at 646 \\
\textsuperscript{114} Id at 659 \\
\textsuperscript{115} Id \\
\textsuperscript{116} Id
\end{flushright}
standard to be *within the usual course of professional practice* of The CSA.\textsuperscript{117} Regarding Dr. Mach’s conduct, the 8\textsuperscript{th} Circuit stated that the totality of the acts taken by Dr. Mach succeeds on this element.\textsuperscript{118} For instance, Dr. Mach approved of many requests that lack enough information to indicate whether that patient required prescription drugs or not.\textsuperscript{119} In other words, Dr. Mach was prescribing *without legitimate medical purpose* when he routinely prescribed prescription drugs to patients that did not provide adequate medical information or included injuries that did not require prescription drug usage for recovery and treatment.\textsuperscript{120} It is possible that if Dr. Mach verified the information he received or requested more that the 8\textsuperscript{th} Circuit would have allowed Dr. Mach to meet this element of The CSA, but that seems unlikely due to the fact that Dr. Mach was prescribing about 72,000 orders a day. All in all, the 8\textsuperscript{th} Circuit claims that considering *outside the usual course of professional practice* and *without legitimate medical purpose* to be one-in-the-same, because the difficulty to have one without the other.\textsuperscript{121} This is not different from the 3\textsuperscript{rd} Circuit, because the 8\textsuperscript{th} Circuit believe that the two are the same. One cannot exist without the other, therefore, the 8\textsuperscript{th} Circuit believes that the test includes both, not separate them.

The last case involving circuit courts considering *without legitimate medical purpose* to be within *outside the usual course of professional practice* is *U.S. v. Armstrong*.\textsuperscript{122} Armstrong was a registered nurse who owned and operated some clinics and pharmacies.\textsuperscript{123} In the beginning, her clinics and pharmacies focused primarily on weight loss from 1998-2000.\textsuperscript{124} During this time, her clinics and pharmacies did prescribe controlled substances for the

\textsuperscript{117} Id \textsuperscript{118} Id at 660 \textsuperscript{119} Id \textsuperscript{120} Id \textsuperscript{121} Id at 659 \textsuperscript{122} United States v. Armstrong, 550 F.3d 382 (5\textsuperscript{th} Cir. 2008) \textsuperscript{123} Id at 386 \textsuperscript{124} Id
management and loss of weight. However, in or around August 2000, Armstrong switched the primary focus towards pain management. At this point, the clinics and pharmacies started prescribing off-brand versions of the “trinity drugs.” The drugs that make up the “trinity drugs” are hydrocodone, alprazolam/diazepam, and carisoprodol. Regardless of whether the actual “trinity drugs” are stocked and sold or if the pharmacy stocks and sells generic versions, they are highly addictive. In April 2005, agents of the DEA shut down Armstrong’s clinics and pharmacies for conspiring to dispense controlled substances in violation of The CSA. The DEA also found that the following defendants were involved in knowingly and intentionally dispensing controlled substances. The facts of the case do not specifically mention what the conduct of the defendants were, nevertheless, they were convicted for conspiracy under The CSA.

The defendants in this case challenged the jury instruction, because it only had outside the usual course of professional practice. The 5th Circuit found that the jury instruction was grounded in previous instructions and cases (see Moore). This court stated that outside the usual course of professional practice was intended to include without legitimate medical purpose and agreed with the district court that behavioral examples of one can meet the other. Similar to how other courts consider the two, the 5th Circuit considers the two to be one in the same. The 5th Circuit believes and agrees without circuits (such as the 3rd and the 8th) that a logical reading

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125 Id
126 Id
127 Id
128 Id
129 Id
130 Id
131 Id at 387
132 Id
133 Id at 395
134 Id
135 Id
of Moore indicates that both are the same rather than separate elements of The CSA.\textsuperscript{136} Once again, circuit courts are interpreting The CSA to have only three elements.\textsuperscript{137}

The circuits that were previously discussed take the approach that to be convicted under The CSA, a person must dispense, distribute, or prescribe controlled substance either \textit{outside the usual course of professional practice} or \textit{without legitimate medical purpose}. All the circuit courts rely on a belief that there are no scenarios where a physician/person could act with \textit{legitimate medical purpose} but \textit{outside the usual course of professional practice} or vice versa. In other words, these circuits believe that if you meet one, you meet the other, or if you fail one, you fail the other. Whether this is the case will be discussed later in the paper. The subsequent paragraphs will illustrate the circuit court cases that have the other interpretation of The CSA.

Moving onto the interpretation, circuit courts that align themselves within this camp typically believe that The CSA requires something a bit more than \textit{outside the usual course of professional practice}. Some circuit courts consider \textit{without legitimate medical purposes} to be a \textquotedblleft 4\textsuperscript{th} element\textquotedblright{} within The CSA.\textsuperscript{138}

\textit{U.S. v. Tran Trong Cuong} involves a physician that practiced in the Commonwealth of Virginia who was registered with the DEA and properly authorized to prescribe controlled substances under The CSA.\textsuperscript{139} Between April 1989 and January 1992, Dr. Tran prescribed approximately 1,711 controlled substances, such as Percodan, Vicodin, Valium and Zanax, to thirty patients.\textsuperscript{140} Around 1990, a pharmacist and an inspector from the Virginia Department of

\begin{flushleft}
\textsuperscript{136} Id
\textsuperscript{137} Id
\textsuperscript{138} United States v. Tran Trong Cuong, 18 F.3d 1132 (4\textsuperscript{th} Cir. 1994)
\textsuperscript{139} Id at 1133
\textsuperscript{140} Id
\end{flushleft}
Health, were concerned about the amount and manner that Dr. Tran was prescribing.\textsuperscript{141} For instance, the pharmacist informed Dr. Tran that one of his patients was receiving prescription drugs from other physicians while Jennings, the inspector, contacted Dr. Tran to warn him that he was being “conned” into prescribing drugs that were known drug abusers.\textsuperscript{142} The government had several former patients testify that they reported fake symptoms to Dr. Tran to receive prescription drugs.\textsuperscript{143} Additionally, some asked for specific drugs from Dr. Tran.\textsuperscript{144} In response, Dr. Tran frequently reminded his patients that he could not prescribe them drugs without the patients informing him that they were in pain.\textsuperscript{145} To help them, Dr. Tran also advised the patients to fill their prescriptions at multiple pharmacies.\textsuperscript{146} On one occasion, Dr. Tran accepted office repair work from a patient in return for prescription drugs.\textsuperscript{147} At one point, the DEA obtained a search warrant to investigate Dr. Tran’s office.\textsuperscript{148} The DEA found records indicating that Dr. Tran charged patients $35 for non-refillable prescriptions.\textsuperscript{149} Furthermore, the DEA obtained testimony from Dr. Tran’s patients stating that Dr. Tran would advise and suggest that the patient needed to have different complaints of pain, such as location and severity, to avoid suspicion of prolonged pain.\textsuperscript{150} Sometime during 1991, the DEA sent two undercover agents to Dr. Tran’s office where the agents asked to see Dr. Tran when they did not have appointments to seek prescription drugs.\textsuperscript{151} Dr. Tan saw one of the two undercover agents eight times over two months during the early part of 1991, and on each visit, Dr. Tan saw the undercover agent for less than

\begin{footnotes}
\footnotesize
\item[141] Id at 1134
\item[142] Id
\item[143] Id
\item[144] Id
\item[145] Id at 1135
\item[146] Id
\item[147] Id
\item[148] Id at 1134
\item[149] Id
\item[150] Id
\item[151] Id
\end{footnotes}
five minutes and prescribed prescription drugs on each visit. The agents testified that Dr. Tran never performed any medical evaluations on them; additionally, one of the agents testified that he/she advised Dr. Tran that he/she would like to “feel a little mellowed out.” The other officer, dressed very shabbily and with bourbon whiskey spilt all over his clothes, testified that he asked Dr. Tran for Percodan to get through winter as a construction laborer. However, Dr. Tran refused to prescribe the undercover agent Percodan, but agreed to prescribe Vicodin.

The 4th Circuit reversed and remanded the case on some counts for issues regarding the manner of witness testimony, however, for the purpose of this paper, we are examining the standard used within the jury instruction. Dr. Tran contended that the district court used a medical malpractice standard rather than the criminal standard set forth in Moore. The defendant’s claim relies on the court advising witnesses that the “standard is whether a reasonably prudent physician would do it,” and “whether it is within the standard of care of a family practitioner,” and “whether in the usual course of treating a patient by the average family practitioner.” The 4th Circuit agreed that the statements from the district court reflected a negligence standard and not a criminal standard, but found that the instruction given to the jury contained the sufficient burden threshold. The jury instruction contained the following:

The third element, no legitimate medical purpose. The final element the government must prove beyond a reasonable doubt is that the defendant prescribed the drug other than for legitimate medical purpose and not in the usual course of medical practice.

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152 Id
153 Id
154 Id at 1135
155 Id
156 Id at 1137
157 Id
158 Id
159 Id at 1138
160 Id at 1137
The 4\textsuperscript{th} Circuit found that this instruction was satisfactory based on the definitions within The CSA.\textsuperscript{161} In addition, the 4\textsuperscript{th} Circuit stated that \textit{without legitimate medical purpose} was stricter than what was intended by \textit{Moore} and was therefore beneficial to Dr. Tran.\textsuperscript{162} The “stricter standard” used by the district court was not explicitly utilized to benefit the defendant but did on some counts.\textsuperscript{163} For example, 80 counts (1-8, 25-64, 69-96, 101-112) did not meet the threshold of the third element within The CSA.\textsuperscript{164} Some counts involved the government’s claim that patients requesting specific drugs by name are “red flags” to a doctor, therefore, the doctor acted \textit{outside the usual course of professional practice}.\textsuperscript{165} The 4\textsuperscript{th} Circuit agrees that this does inform the jury of the possibility of Dr. Tran acting inappropriately, but it is not sufficient to meet the criminal standard set forth by The CSA.\textsuperscript{166} The 4\textsuperscript{th} Circuit found that prescribing prescription drugs to patients that requested said drug by name does not, by itself, reach the standard of acting \textit{outside the usual course of professional practice and without legitimate medical purpose}.\textsuperscript{167} The \textit{Tran} case does not endorse that view that courts need to enact a stricter standard than what \textit{Moore} intended, but it does lay the foundation for rationale that other courts use to support a “stricter standard.” The next cases illustrate how the \textit{Moore} standard changed to require additional material.

The one case that benchmarks the approach of additional material for The CSA is \textit{United States v. Feingold}.\textsuperscript{168} Dr. Jeffery Feingold was a naturopathic physician licensed by Arizona that

\begin{verbatim}
\textsuperscript{161} Id at 1138
\textsuperscript{162} Id
\textsuperscript{163} Id
\textsuperscript{164} Id
\textsuperscript{165} United States v. Chin, 795 F.2d 496 (5th Cir. 1986)
\textsuperscript{166} Id
\textsuperscript{167} Id at 1137
\textsuperscript{168} United States v. Feingold, 454 F.3d at 1003
\end{verbatim}
was convicted of illegally distributing controlled substance in violation of The CSA.\textsuperscript{169} Dr. Feingold moved to Arizona and opened his own practice in 1990.\textsuperscript{170} Arizona granted all naturopathic physicians the authority and ability to prescribe Schedule II, III, IV, and V controlled substances in 2000.\textsuperscript{171} However, in 2002, Arizona revised this and revoked their ability to prescribe Schedule II, outside morphine.\textsuperscript{172} During this time, Dr. Feingold obtained the proper licensing and authority from the DEA to prescribe controlled substances.\textsuperscript{173} At trial, the government called many former patients to testify against Dr. Feingold regarding his behavior and actions of prescribing controlled substances.\textsuperscript{174} For instance, some patients testified that they received controlled substances from Dr. Feingold despite never seeing him, being physically examined or recording reasons for the prescription.\textsuperscript{175} Other patients testified that Dr. Feingold prescribed them controlled substances notwithstanding the fact that he knew they were drug addicts.\textsuperscript{176} Further, one patient testified Dr. Feingold prescribed him controlled substance in exchange for having painted Dr. Feingold’s house.\textsuperscript{177} Additionally, Dr. Feingold continued prescribing Schedule II controlled substances in spite of Arizona revoking that authority.\textsuperscript{178} Lastly, the DEA sent two undercover agents to obtain prescriptions from Dr. Feingold and the undercover agents were able to obtain the prescriptions in a manner that was identical to how his former patients testified.\textsuperscript{179}
Dr. Feingold challenged the jury instruction claiming it did not reach the criminal standard set forth by Moore, but rather indicated the threshold was incompetency.\textsuperscript{180} The 9\textsuperscript{th} Circuit disagreed with Dr. Feingold but did remand for resentencing.\textsuperscript{181} Throughout the trial, Dr. Feingold conceded that his conduct regarding the complaint was \textit{outside the usual course of professional practice}, but Dr. Feingold contested that he was acting \textit{with legitimate medical purpose}, because his patients were in pain.\textsuperscript{182} In other words, Dr. Feingold argued that the jury instruction lacked a mens rea or intent component that The CSA contains.\textsuperscript{183} The 9\textsuperscript{th} Circuit agrees with Dr. Feingold’s arguments, because a physician acting with \textit{good faith for a legitimate medical purpose} is generally a defense against a criminal conviction under The CSA.\textsuperscript{184} The 9\textsuperscript{th} Circuit interprets Moore and The CSA to allow doctors to refute the claims against them if they can show they acted \textit{within the usual course of professional practice} or acted in \textit{good faith for a legitimate medical purpose}.\textsuperscript{185} Furthermore, the 9\textsuperscript{th} Circuit interprets Moore to impose a much higher burden for criminal convictions compared to medical malpractice/negligence.\textsuperscript{186} To summarize, to convict a physician under The CSA, the physician must cease to be a physician and simply not be negligent.\textsuperscript{187} Now, taking Dr. Feingold’s case, the 9\textsuperscript{th} Circuit affirmed the district court’s conviction, because the record did not contain any information that Dr. Feingold acted in \textit{good faith for a legitimate medical purpose}.\textsuperscript{188} Rather, the record reflected that Dr. Feingold’s argument to refute The CSA claim was that he was simply incompetent and honestly

\begin{itemize}
\item \textsuperscript{180} Id at 1006
\item \textsuperscript{181} Id
\item \textsuperscript{182} Id at 1009
\item \textsuperscript{183} Id
\item \textsuperscript{184} Id
\item \textsuperscript{185} Id
\item \textsuperscript{186} Id
\item \textsuperscript{187} Id
\item \textsuperscript{188} Id at 1010
\end{itemize}
wanted to help his patients despite being unfamiliar with controlled substances.\textsuperscript{189} Additionally, Dr. Feingold asserted that he did not know that his patients were abusing the prescriptions due to his lack of training, and that he never intended to “flout” professional protocol.\textsuperscript{190} Therefore, based on the record, the 9\textsuperscript{th} Circuit concluded that any reasonable jury could find that Dr. Feingold violated The CSA by intentionally acting outside the usual course of professional practice.\textsuperscript{191} The 9\textsuperscript{th} Circuit here diverts from other circuits by setting up another component in the CSA claims by allowing physicians to shield themselves by proving they were acting in good faith for a legitimate medical purpose. This was not seen in the circuits that consider legitimate medical purpose to be included within outside the usual course of professional practice.

The last case that will be discussed in the paper is \textit{United States v. Wexler}.\textsuperscript{192} On March 17, 2006, Dr. Wexler, a dermatologist in Manhattan, was convicted of conspiracy to distribute, and possession with intent to distribute Dilaudid, Percocet, Vicodin and Xanax, in violation of The CSA.\textsuperscript{193} The evidence presented at trial suggested that Wexler prescribed the listed controlled substances, as painkillers, to addicted patients.\textsuperscript{194} One such patient was Barry Alber, who resold said prescriptions to other addicts and later died of an overdose.\textsuperscript{195} Additionally, Wexler caused two others to become addicted to painkillers by prescribing controlled substances.

\textsuperscript{189} Id at 1008  
\textsuperscript{190} Id  
\textsuperscript{191} Id  
\textsuperscript{192} United States v. Wexler, 522 F.3d 194 (2\textsuperscript{nd} Cir. 2008)  
\textsuperscript{193} Id at 197  
\textsuperscript{194} Id at 198  
\textsuperscript{195} Id
without evaluating them.\textsuperscript{196} An expert witness testified for the government indicating that the records kept by Dr. Wexler were so incomplete that they were not medical charts at all.\textsuperscript{197}

Dr. Wexler challenged the jury instruction, because it lacked the phrase “good intentions,” but only had “good faith.”\textsuperscript{198} Since the district did not include “good intentions,” Dr. Wexler contends that the standard resembled a gross mistake or malpractice standard instead of the criminal standard.\textsuperscript{199} The 2\textsuperscript{nd} Circuit disagrees with Dr. Wexler, because they consider “good intentions” to be part of “good faith.” Therefore, the district court did not err in omitting Dr. Wexler’s request.\textsuperscript{200} Dr. Wexler raised that challenge, because he felt that the jury instruction misleads the jury in considering his “good faith” defense of prescribing the painkillers for a legitimate medical purpose.\textsuperscript{201} The 2\textsuperscript{nd} Circuit agrees with Dr. Wexler that he deserves a chance to refute the government’s claim by providing a defense, but the court disagrees that the specific wording of the jury instruction is critical within the context of The CSA compared to other laws.\textsuperscript{202} In fact, the 2\textsuperscript{nd} Circuit cites Feingold to justify the use of good faith with a legitimate medical purpose defense.\textsuperscript{203} Furthermore, the 2\textsuperscript{nd} Circuit cites Moore to illustrate that the purpose of The CSA is to punish physicians that do not act like physicians but act as a “pusher.”\textsuperscript{204}

In conclusion, there appears to be two approaches to interpreting and utilizing The CSA. On one hand, some courts look at the evidence and determine whether the person was acting

\textsuperscript{196} Id at 199  
\textsuperscript{197} Id  
\textsuperscript{198} Id at 205  
\textsuperscript{199} Id  
\textsuperscript{200} Id  
\textsuperscript{201} Id  
\textsuperscript{202} Id at 206  
\textsuperscript{203} Id  
\textsuperscript{204} Id
outside the usual course of professional practice. On the other hand, some courts look at the evidence and determine whether the person was outside the usual course of professional practice and without a legitimate medical purpose. The former group considers without a legitimate medical purpose to be incorporated within outside the usual course of professional practice. The latter group believes that good faith plays a larger role within The CSA claims. A good faith defense involves whether the physician had a legitimate medical purpose for providing the treatment he/she decided to conduct. The following section of the paper will analyze the cases and examine whether there are different standards. Additionally, if there are multiple standards, how they impact physicians and prescribers.

Analysis:

The following section will examine the impact of the standards on physicians and the potential implications of having multiple standards for The CSA. Afterwards, the section will discuss how state laws coincide with federal law.

According to the cases, there is a circuit split regarding the mens rea component of The CSA. Some courts prefer to provide more protections for physicians through adding a good faith element and/or by separating without a legitimate medical purpose from outside the usual course of professional practice. The importance of this split involves how the jury will utilize these varying instructions. The circuit courts do not believe the distinction is of any importance, because the courts find it difficult to imagine a situation where a physician was acting outside the usual course of professional practice but had a legitimate medical purpose. However, juries could imagine a situation, because they are, generally, more sympathetic towards defendants and plaintiffs. For instance, a physician that works hard as a solo-practitioner provides extra
prescriptions for his/her patients that are physically unable to make appointments to renew their prescriptions. This act would be outside the usual course of professional practice, but a skillful attorney could convince a jury that there is good faith and the physician acted with legitimate medical purpose. Practically speaking, the added defense for a physician can be the difference between being convicted and being acquitted.

The caselaw would beg to differ on that point, but the facts of those cases do not shed light on the point. Going back to the example brought up above, two physicians that do the exact same thing could, in theory, have different outcomes. One would be convicted under The CSA, because he/she was acting outside the usual course of professional practice. However, the other physician would not be convicted because he/she had a legitimate medical purpose. This does not seem to be the national standard that Moore indicated was needed for The CSA. Laws are supposed to be predictable, so people know how to act to avoid being sued and/or going to jail. The CSA is one of the most important law for a physician to abide by.

In addition to The CSA, physicians must follow state laws and regulations to remained licensed within their state. As we have seen, some states, like New Jersey, are strict while others, like Oregon, are lenient with their laws and regulations. The stricter states prefer to control the physicians rather than the lenient states. For example, strict states require physicians to only prescribe a few days’ worth of opioids. On the other hand, lenient states allow physicians to use their judgment to determine the amount. Regardless of the state the physician is licensed in, said physician must comply with both state laws and regulations along with the federal law. There can be scenarios in which a physician can be compliant in one state, but potential violate The CSA. For instance, the physician lives in Oregon and prescribes a month’s worth of opioids for a patient, because the patient is traveling for the next month and requires the prescription to function, additionally, assume that the patient is taking the prescription and not doing anything
nefarious with the prescription. In Oregon, this would be within the bounds of the physician. Obviously, this is not within the bounds of New Jersey or New York. Nevertheless, this could violate The CSA depending on which circuit the physician was in. On one hand, this is clearly outside the usual course of professional practice, but one can argue that the physician was acting with a legitimate medical purpose.

**Conclusion:**

There are two instructions that are given to juries for a case involving The CSA. One instruction provides more affordance for a physician while the other does not. There are scenarios that illustrate that division between the instructions. Conforming states to have similar laws would be extremely difficult for multiple reasons, such as state sovereignty. Therefore, the focus should be on setting a national standard for The CSA. This would prevent certain groups of physicians from being convicted while others are not. Ultimately, The CSA was designed to prevent physicians from pushing drugs and to protect patients from opioid addictions.