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The "Regulatory Fog" of Opioid Treatment

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Ready to restart her life with hope for recovery from her addiction to prescription opiates, a young woman spent her first day in her new town renting an apartment, attending a church service, walking on the beach, and making her initial visit to the local methadone clinic. Two days later she was dead of an overdose. The first day's standard clinic dose was increased on the second and third days without physician oversight, without any review of information from the drug test that was mandated on admission, and without confirmation from the state methadone registry that she was not enrolled elsewhere. With benzodiazepines still in her system, the addition of methadone suppressed her breathing. She had no counseling, and following a cursory physician visit on day one, saw no one on the second and third days other than an LPN, who observed her as she drank the methadone from a plastic cup. The clinic, which at that time was operating with a medical director without a medical license, did not report her death, suffered no negative ramifications or penalties imposed by state or federal regulators, and continues to be accredited by a private accrediting agency. In the two years since her death, it has been business as usual at the for-profit storefront opioid treatment center, where clients line up before daylight with cash in hand to receive the substances that reduce their cravings.

Over 300,000 people in the United States are dependent on the services of methadone clinics, more properly known as opioid treatment programs (OTPs). OTPs provide regular doses of methadone and other substitutes that enable most clients to continue to function in society despite their addictions. Regulation of OTPs is multi-layered and complex with uneven standards and enforcement across the country. OTPs are certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), which, since 2001, has required accreditation from a SAMHSA-approved accreditation body, (42 CFR Part 8) as well as compliance with SAMHSA standards. While SAMHSA determines rules concerning how opioid substitutes used for treatment may be distributed to OTP clients, the Food and Drug Administration is responsible for the manufacturing and labeling of methadone and specifies which drugs may be used in the course of treatment of addiction to heroin and, increasingly, as prescription abuse has grown, other opioid pain relievers. The Drug Enforcement Administration monitors methadone and other opioid treatment supplies through site visits and oversees the possible diversion of these controlled substances (Committee on Federal Regulation of Medicine, Institute of Medicine 1995, 2) for illicit purposes, including resale.

Less well understood are the role and effect of state regulation in the oversight of OTPs. Previous studies of state regulation of outpatient substance abuse programs have sometimes omitted OTPs because they are largely considered to be creatures of the federal certification process. This omission occurs despite the fact that state policies on substance abuse "may have significant public health implications" (Chriqui, Terry-McElrath, and McBride 2008, 18). In their description of the history of regulation of opioid agonist treatment in the United States, Jaffe and O'Keeffe describe the frustration of OTP clinicians with federal regulation considered by some to be "burdensome interference with the practice of medicine" (2003, 85), but they also point out that the matter is more complicated than just federal control:

> Although some of the criticism is valid, it often fails to distinguish between federal, state, and local regulatory burdens. State and local jurisdictions have also seen fit to enact legislation governing these programs, and some

> of those regulatory requirements are far more restrictive than federal ones. For example, some localities do not permit any take-home medication (Jaffe and O'Keeffe 2003, 85).

Even at the state level, multiple entities have a hand in regulation of OTPs. Licensure requirements for clinics in addition to SAMHSA mandates vary across the states. Compliance with regulations may be handled by the Opioid Treatment Authority, the state's mental health or substance abuse agency, or the licensing body. Prescription monitoring programs interact with OTPs in some states, which may also involve the state pharmacy board, while OTP physicians are licensed and disciplined by state medical boards. Clinic staff – nurses, social workers, and counselors – generally have their own licensing authorities. Data on reportable deaths related to OTPs may be maintained by the state's criminal investigation bureau or by the medical examiner or multiple medical examiners in separate locations, but not at the state's opioid treatment or licensing authority. In states that provide higher levels of Medicaid funding for methadone treatment, another layer of oversight is added. In addition, some local governments have instituted ordinances that limit the placement of methadone facilities or provide additional oversight related to public health (Committee on Federal Regulation of Medicine, Institute of Medicine 1995; Wallace 2011).

Fragmented Oversight Creates 'Regulatory Fog'

The complexities inherent in such fragmented oversight may lead to a condition that has been described by Warren and Wilkening as "regulatory fog, the phenomenon by which regulation obscures information regarding the value of counterfactual policies" (2012, 840). While these economist-authors focus on the persistence of regulation due to an inability to compare the need for regulation to an unregulated scenario, we borrow the term to describe the scenario in which many overlapping policies result in a fog in which regulation becomes separated from outcomes that the regulations were initially intended to control. In some circumstances, the regulation itself becomes the measuring stick rather than the appropriateness of the policies or even the outcomes associated with the OTPs. Jaffe and O'Keefe point out that criticisms of the current OTP regulatory process arise due to the fact that "regulatory oversight is concerned exclusively with process, although actual treatment outcome can be measured" (2003, 85). The purpose of this study is two-fold: to compare OTP regulations across the states to determine if stringency of regulation affects the number and type of clinics and patients and to determine if the "regulatory fog" created by the complexities of multi-agency governmental regulation obscures outcomes, as borrowed from the theory of Warren and Wilkening.

From Heroin to Prescription Opioids: The Changing Face of Addiction

Methadone as a medical treatment first gained acceptance in the United States in the late 1960s, thanks in large part to the work of researchers Marie Nyswander and Vincent Dole (Kleber 2008, 2303), who, in response to an epidemic of heroin use in the U.S., recommended the use of methadone as a long-term harm reduction strategy (Dole and Nyswander 1965). Prior to this research, U.S. policy – confirmed in a 1919 Supreme Court decision – prevented physicians from treating addictions with opioids (Center for Substance Abuse Treatment 2008, 8). The Dole-Nyswander work has been described as shifting addiction from its status as a social problem to a medical problem, in effect from "badness" to "sickness" (Rosenbaum 1995, 145). Since that time, however, methadone maintenance has been "demedicalized" (Rosenbaum 1995, 145). Though OTP practices vary from town to town and state to state,

methadone is often dispensed from strip mall clinics by nurses, with little physician oversight and out of the context of more mainstream health care services.

Berridge points out that while addiction treatment decisions have often been evidence-based, they have been, in part, political (2009). Though Kleber writes that "the benefits of long-term methadone maintenance are borne out by data" (2008, 2304), methadone maintenance is still controversial and underfunded. The maintenance approach, as differentiated from detoxification or abstinence, "has always struggled for acceptance against the forces of public opinion and politics" (Kuehn 2005, 887).

What began in the U.S. as a heroin problem has shifted dramatically to inappropriate use of prescription opiates. According to the National Drug Survey, in 2011, 620,000 or 2 percent of U.S. citizens ages 12 and older had used heroin in the past year compared to 11,143,000 or 4.3 percent who had nonmedical use of pain relievers (SAMHSA 2012b). About three times as many National Survey on Drug Use and Health respondents used Oxycontin® in 2011 than had used heroin (SAMHSA 2012b). Physician Susanna Duncan puts opioid use in layman's terms:

> Enough of these opiate-based drugs were prescribed last year to medicate every American adult with a dose of five mg of hydrocodone . . . taken every four hours, for a month, and have led to over 40,000 drug overdose deaths. Today there are more overdose deaths from opioid analgesics than heroin and cocaine combined (2012).

Methadone is responsible for about a third of opiate-related deaths, deaths ascribed to methadone 5.5 times as high in 2009 as in 1999 (Centers for Disease Control and Prevention 2012). As doctors prescribe inappropriately, including prescribing methadone for pain, and "pill mills" crop up in states without active prescription drug monitoring programs, addiction to opiates has soared. To meet the resultant higher demand of opioid addiction, the number of OTPs nearly doubled between 1996 and 2012, when there were 1270 facilities in the U.S. (Department of Health and Human Services 2012, 72753). Table 1 provides OTP data for 1996, 2002, and 2011.

Table 1. OTP Statistics 1996, 2002, 2011

	1996*	**2002****	**2011 ****
Number of OTP Clients	151,882	228,140	313,460
Number of OTP Facilities	688	1080	1189
Percentage of Private, For Profit OTPs	29%	43%	54%
Percentage of Private, Nonprofit OTPs	53%	42%	36%
Government (Local, State, Federal, Tribal)	18%	15%	10%
Median Number of Clients per Facility	177	180	200

(**SAMHSA N-SSATS 2003, 2013; *Levine et al. 2004, 15, 24)

Further changes may be in store for OTPs. Recent revisions announced by SAMHSA have relaxed the rules for take-home supplies of buprenorphine, allowing patients to take home a 30-day supply rather than mandating an "earned" right to take home medications as is the practice for methadone users, in part because deaths from buprenorphine have been significantly lower than those from methadone (Department of Health and Human Services 2012, 72753). SAMHSA's intention is to increase flexibility in the hope of achieving better

OTP client compliance, but the increased flexibility may also lead to increased diversion (Department of Health and Human Services 2012, 72758) for illicit purposes.

The Regulatory Environment for OTPs

According to the Institute of Medicine, at least part of complex nature of the OTP regulatory system stems from a long history of judgmental attitudes reflected in the often-heard expressions that methadone users are simply "substituting one addiction for another" and that clinics are "legal drug dealers" (Committee on Federal Regulation of Medicine, Institute of Medicine 1995). The Institute of Medicine's (IOM) landmark 1995 publication on federal regulation of methadone treatment was influential in shifting attitudes toward methadone maintenance treatment:

> Methadone-maintained patients show improvement in a number of outcomes, after an adequate dose (usually 60 -120 mg per day) is established. Consumption of all illicit drugs, especially heroin, declines. Crime is reduced, fewer individuals become HIV positive, and individual function is improved. These outcomes reflect the three objectives of methadone treatment: assisting the individual addict, enhancing public safety, and safeguarding the public health. Outcomes serving these objectives are realized most often by the combined effects of the medication and the counseling provided by good treatment programs. The two factors limiting methadone's effectiveness are the multiple health and social problems of methadone maintenance patients, and the variability in quality of treatment programs (1).

The move to accreditation reflected the philosophy expressed in the IOM report and was implemented as a means of regulation based, in part, on efforts to ensure quality and to reduce the stigma often associated with drug treatment. SAMHSA's desire to "position methadone maintenance treatment more closely within mainstream health care," thereby "potentially . . . expand[ing] the availability of treatment within hospitals and health plans of all kinds – entities that are experienced with meeting accreditation standards" was an unmet goal, since the majority of non-governmental OTP clinics are stand-alone or chain clinics devoted to opioid treatment only (Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment 2000). In 2004, three years after the accreditation process was substituted for the survey process, researchers found that about a third of states had either reduced or modified survey requirements for accredited OTP facilities and determined that "quality of communications between states and accrediting bodies is uneven" (Podus, Prendergast, and Rawson 2004). Complicating the regulatory environment is that accreditation agencies (unless the state is the accrediting body) do not make public their findings about OTP violations. In fact, the private accreditors who survey only periodically may not be aware of even the most egregious violations, since many state licensing authorities have no responsibility to report to them or vice-versa. One SAMHSA official admitted, "We have trouble getting information from the accrediting agencies" (Anonymous, Personal Interview, April 19, 2013).

Some criticisms of OTPs derive from the fact that the majority of clinics in the U.S. are for-profit entities, where clients must pay for services up-front, often on a daily basis, and may be turned away for lack of payment. Others decry the disproportionate share of poor people who use the clinics, but whether this reflects the "last resort" nature of the clinics or the effect of opioid addiction is unclear. It is clear, however, that deaths from methadone

overdose – not necessarily related to OTPs - occur disproportionately in poor communities. A Pulitzer Prize-winning study of methadone in the *Seattle Times* found that "accidental methadone overdoses [not those directly related to OTPs] across the Puget Sound area . . . occur in low-income areas at a rate three times higher than that of high-income areas" (Berens and Armstrong 2011). Critics allege that for-profit clinics strive to keep overhead low through limited hours of service, to attract long-term maintenance rather than detox clients, and to increase the number of take-home doses to reduce office hours for their own economic well-being (Freedberg 2013; Anonymous 2010).

While take-home dosing may also encourage compliance with program goals and client desire to continue in the program, it also provides opportunities for drugs to be illegally diverted to the black market. A small study of methadone maintenance clients in Canada found that "seven of the nine MMT [methadone maintenance treatment] patients returned lower than expected quantities of methadone, while one patient returned more than the expected quantity" (Varenbut et al. 2007). A 2005 study that compared diversion rates across Australian states found that "[t]hose states with the most restrictive take-away policies have the lowest reported prevalence of methadone injection and methadone use in the previous six months and those states with the most liberal take-away policies have the highest" (Ritter and Di Natale 2005, 350). Because of the potentially lethal nature of misappropriated methadone, in order to reduce diversion, SAMHSA advises clinics to require "random call-backs, asking patients to return to the facility before their scheduled appointments and bring with them the remainder of their take-home medication" (2009, 6). Since the DEA is required to conduct only biennial reviews of inventory records, diversion may go unnoticed if the clinic is not monitoring closely or if the clinic is not required to report missing supplies to the state regulatory authority.

While prescription methadone is widely viewed as the principal driver of methadone-related deaths due to the increase in methadone prescriptions for pain (Paulozzi, Mack, and Jones 2012; SAMHSA 2010a; Centers for Disease Control and Prevention 2012; Stahl and Webster 2012; United States General Accountability Office 2009), there is no credible, documented source of unprescribed methadone-related deaths. A 2009 SAMHSA report states that "it is difficult to obtain enough data to confirm whether methadone deaths are linked more to OTPs or to pain treatment situations" (SAMHSA 2009, 2).

Deaths of OTP patients are not well documented at the state or federal levels. A Virginia study using 2004 data (Weimer et al. 2011) and a Vermont study with data from 2001 to 2006 (Madden and Shapiro 2011) both determined that 67 percent of methadone deaths were due to illicit - not prescribed - methadone, though neither study found high mortality rates among OTP clients. A 2003 review of methadone deaths in a Minnesota county from 1992-2002 found that almost 35 percent were opioid therapy clients (Gagajewski and Apple 2003). A federal effort to document OTP-related deaths was halted in 2009 "due to concerns about privacy," forcing SAMHSA "to destroy all records" (Anonymous, Personal Interview, April 19, 2013). The subject of mortality among OTP patients is complex, since many patients in methadone treatment have both physical and psychiatric comorbidities, and deaths of clinic patients may go unreported or not be associated with their treatment. Few centers track deaths of OTP family members or their associates. The source of diverted methadone is generally unknown to the medical examiner, and responsibility for tracking deaths varies widely from state to state.

A GAO report confirms that "circumstances of methadone associated overdose deaths vary by state," (2009, 23) the deaths of "patients in OTPs ranging from 4 percent to 50 percent" of total methadone deaths (SAMHSA 2010a, 18). According to a SAMHSA 2010

mortality report, of the 406 deaths of OTP patients that were voluntarily reported, 27 percent were in early treatment phases and 32 percent of patients were taking benzodiazepines in addition to methadone (SAMHSA citing Maxwell 2010a, 20). OTP deaths often occur "during the first weeks of medically supervised treatment and at the time of dose adjustments" (SAMHSA 2010a, 5), but diversion of methadone resulting in death, while lower than deaths from prescription methadone, is also widely reported (Freedberg 2013; National Drug Intelligence Center 2007; Anonymous 2012a).

According to SAMHSA, risk of death is greatest due to the following factors:

- Simultaneous patient abuse of substances such as benzodiazepines, other opioids, cocaine, or alcohol; . . .
- interactions between prescribed medications; . . .
- methadone accumulation in the body; . . .
- methadone's peak respiratory depressant effects; . . .
- poor clinical practice during the start of treatment (induction dosing phase); . . .
- [lack of] cardiac screening; . . . [and]
- poisoning that occurs when methadone is diverted for nonmedical use [or ingested by children] (2009, 3-4).

While hundreds of medical studies provide strong evidence that methadone maintenance is cost-effective, state-by-state and clinic-by-clinic outcomes for policy review are largely inaccessible because of the large number of overseers, the separation of regulation and outcomes, and the proprietary nature of the accreditation process. Fears of violation of patient privacy laws and the lack of a reliable database or dependence on a paper database limit some state agencies' ability or willingness to provide even aggregated information on numbers of clients, length of stay, and other outcomes. When state regulations do not require collection of such data, the responsibility is left to the accrediting agencies, which do not release reports to the public. Licensure surveys, which may be publicly reported, are often infrequent, unavailable, or lack detail. In Georgia, for example, in February 2013, licensure reports were not available for 23 of 56 opioid treatment programs then operating, since there are no statutory obligations to survey on a set schedule. As a result, many inspections in Georgia, as in other states, are driven by complaints, not through the routine regulatory process. Two Georgia OTPs closed in March and April 2013, and reports were not publicly available afterwards for either on the state's facility regulation website. At least one of those facilities remained on the list of CARF International-accredited programs after closure, further evidence of a communications disconnect among the regulatory bodies.

Methods

Many scholars have studied the effectiveness of state regulation. Among these studies are the relationships between state-required training of certified nursing assistants and improved nursing home resident outcomes (Trinkoff et al. 2013); regulation of tattoo parlors and public health (Carlson, Lehman, and Armstrong 2012); state licensure of marriage and family therapists and preparation for practice standards (West and Hinton 2013); regulation of physical therapy and patient outcomes (Resnik, Feng, and Hart 2006); and "state regulatory stringency on nursing home quality" (Mukamel et al. 2012). It must be noted, however, that regulation is only as effective as those agencies charged with oversight, the degree of authority of agencies charged with oversight, whether violations of policy are linked to sanctions, and whether regulations are based on or linked to outcomes. While rules may exist,

this research does not attempt to address the effectiveness or performance of states in implementation of regulatory policy. The focus is on state regulation of OTPs in the context of oversight from multiple federal agencies and private accreditation agencies. Two basic research questions are asked:

- *Does state regulation matter?* The lack of patient outcomes data at all levels limits the researchers' ability to link state regulations directly to patient outcomes. As a result, this research seeks to determine whether there is a relationship between the degree of state regulatory authority and the number of patients, the number of OTPs, and the for-profit or nonprofit status of OTPs with the following hypotheses:
    - H_1: Responding states with more stringent regulations have fewer OTPs.
    - H_2: Responding states with the fewest regulations have the greatest number of patients per capita.
    - H_3: States with higher percentages of for-profit OTPs have more OTP patients per capita.

- *Is state regulation mainly about process and less about outcomes?* Given that outcomes data, including sentinel events and death, are not readily available from federal overseers or accreditation agencies, this research seeks to determine to what degree states fill that void. A survey tool was employed to ask whether OTP performance measures and outcomes data are an expectation of state OTP regulatory authorities with the following hypotheses:
    - H_4: There is wide variation in regulatory environments across the states.
    - H_5: OTP performance measures and outcomes are not widely reported or publicly available from the states.
    - H_6: Performance measures emphasize process and outputs, not outcomes.
    - H_7: The "regulatory fog" of multi-layered oversight limits the ability of citizens, potential clients, and the regulators themselves to determine the safety and effectiveness of OTP programs.

State opioid authorities and state substance abuse agencies were invited to answer questions about a set list of common state regulations based on federal regulations and a separate review of regulatory policy in several states. Table 2 summarizes the questions included on the survey. All questions required Yes/No answers regarding state OTP policies.

Table 2. Survey Questions by Category of Regulation
(Total Measures per Category)

Administrative Regulations (12)	Clinic must be non-profit Clinic must be physician-owned Clinic requires certificate of need Licensing authority or other state authority must inspect annually Licensing authority or other state authority must inspect every two years Minimum number of hours open set by state Required use of state Prescription Monitoring Program or similar Requirement to be open 7 days/week State has performance measures for all OTPs State inspection results available on website State inspections unannounced State must report survey violations/complaint violations to accrediting body
Patient Admission, Care, Counseling, Discharge, Drug Testing (15)	Annual physical for clients Clients must be discharged after 4 or fewer positive drug screens Clinic must establish progressive sanctions for clients with positive drug screens Clinic must receive OK from central registry prior to first dosing Clinics must establish specific parameters for acceptance into the OTP Discharge plan implemented as part of treatment plan Initial drug tests must be completed and results returned prior to first dosing Initial orientation and counseling section mandated Initial physical exam required prior to dosing Initial plan of care completed within 7 days OTPs required to have additional screening/counseling during clients' first two weeks in program Spot checks for take-home medications required State rules govern clients driving to and from clinics Treatment plan on chart within 2 weeks Treatment plan revised at least quarterly
Reporting Requirements (16)	Required annual or semi-annual reporting to state Required annual reporting of length of client stay for each client Required reporting of annual or more frequent inventories Required reporting of discharges Required reporting of frequency distribution of clients by dosing level Required reporting of inventory issues Required reporting of known diversions Required reporting of law enforcement calls to clinic Required reporting of methadone/drug-related client deaths Required reporting of methadone-related death of client household members Required reporting of number/percentage of clients with take-home privileges by category Required reporting of OTP clients involved in criminal activity Required reporting of OTP clients involved in diversion Required reporting of spot-checks for take-homes Required reporting of state of residence of OPT clients Required reporting of suspected diversions

Staffing Requirements (4)	Clinic doctor must be at clinic a set percentage of time Clinic must have RN present during all dosing hours Minimum education for counselors set On-site physician must be addiction specialist

In addition, responding state agencies were asked to provide demographic and outcomes data, including number of OTPs, profit or nonprofit status of OTPs, number of patients, deaths and other sentinel events, and survey and reporting requirements. A link to an online survey tool was sent to all State Opioid Treatment Authorities in the United States in February 2013. Response was inadequate and the same survey was sent as a follow up via email to all State Substance Abuse Agencies. Twenty-two states with Opioid Treatment Programs completed the survey portion that included questions concerning regulations. Fewer responses were received on outcomes and trends, according to respondents due to poor record keeping, lack of electronic records, lack of historical data collection, and the fact that many of the responding agencies are not responsible for collecting such information or state reporting requirements are minimal.

Respondents provided yes or no responses about the existence of specific regulations in their states. Forty-seven yes/no answers were captured for statistical purposes with responses converted to ones and zeros in order to quantify the responses as a measure of the degree of and variation in regulation. Questions to which all answers were no or yes were omitted, as the intent of the data collection was to differentiate among the states. While the authors recognize that all regulations should not be weighted equally, all queries about regulations reflect common practice at the federal level and in many states. The authors also examined the role of regulation across the respondent states by category of regulation, including administrative regulations, reporting regulations, staffing regulations, and patient care and discharge regulations.

Though some outcomes data was available from select states, responses were inconsistent. The lack of outcomes data limited the ability of the authors to directly compare regulation with outcomes. Other public data sources include information from SAMHSA, but a significant lag time in federal reporting must be noted as a limitation. Statistical analysis includes descriptive statistics and regression analysis to determine the relationship between regulation, numbers of clinics and patients, and certain outcomes.

Results

Does state regulation matter?

Based on Yes/No responses to 47 questions for which answers varied, there is significant variation in the degree of regulation and reporting requirements across the states. Table 2 illustrates the total points and statistics for patients and clinics in participating states.

Table 3. State Data: Total OTPs, OTPs per 100,000 Population (U.S. Census 2010, SAMHSA 2012b).

Total Regulation Points, and Regulation Points by Category

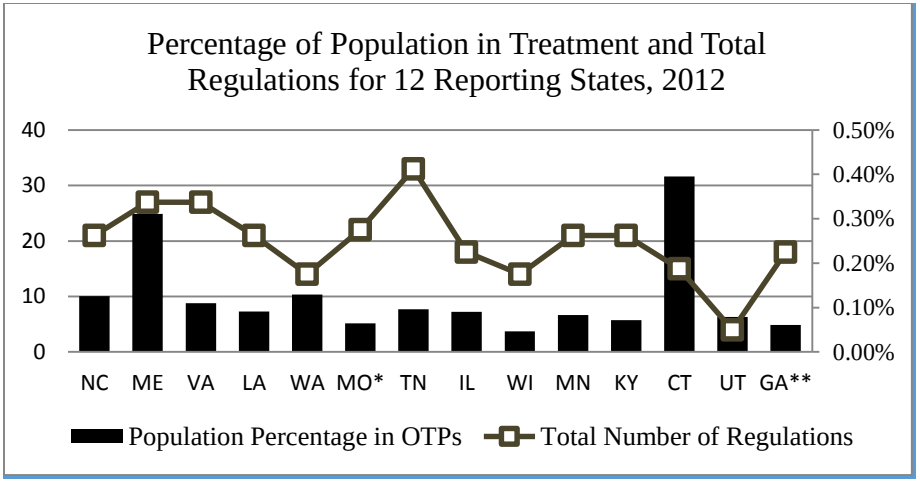
Regulation Points: Mean = 20.09; Median = 21; Mode = 21; St. Dev. = 7.62 Range = 29

	OTPs	CLI.	Total	Categories of Regulation

State				Points for Administrative Regulations	Points for Patient Admission, Care, Counseling, Discharge Drug Testing	Points Assigned for Reporting Requirements	Points Assigned for Staffing Requirements
Questions in Category	--	--	47 Possible	12 Possible	15 Possible	16 Possible	4 Possible
Utah	12	.43	4	1	1	1	1
Oregon	14	.37	9	1	5	2	1
Wisconsin	15	.26	14	1	10	2	1
Washington	21	.31	14	3	6	4	1
Connecticut	23	.64	15	3	4	7	1
Michigan	35	.35	16	3	9	0	3
Georgia	56	.58	18	1	10	4	3
Illinois	62	.48	18	0	8	9	1
Iowa	4	.13	17	2	10	4	1
North Carolina	47	.49	21	5	8	6	1
Louisiana	10	.22	21	3	9	8	1
Minnesota	14*	.26	21	5	8	5	2
Kentucky	11	.25	21	4	8	7	2
California	146*	.39	22	4	6	10	1
Missouri	11	.18	22	4	10	7	1
Montana	3	.30	24	4	10	8	2
Maine	9	.68	27	3	10	11	2
Virginia	23	.29	27	5	10	9	2
Arkansas	5	.17	30	5	13	7	4
Delaware	6*	.67	33	8	11	13	2
South Carolina	16	.35	33	8	9	11	4
Tennessee	12	.19	33	8	11	10	3

H_1 incorrectly predicts that states with more stringent regulations will have fewer clinics per capita. Using data provided by the states or filling in missing data with 2010 OTP "State Profiles" statistics from SAMHSA (2010b; 2011) for a multiple regression analysis, there is no statistically significant relationship between total number of regulations or specific areas of regulation and clinics per capita. In fact, respondent states that require a Certificate of Need for OTPs, perhaps the most stringent regulatory hurdle for opening an OTP, have slightly higher OTPs per capita than those that do not require a Certificate of Need, but the t-test for difference in means is not statistically significant.

Figure 1. OTP Clients and Regulatory Stringency (U.S. Census 2012)



Missouri data is from voluntary OTP reports only; Georgia data is an approximation

Fourteen states reported data or partial data on clients in treatment from 2008 through 2012. The percentage of state population in treatment at OTPs in reporting states in 2012 ranged from a high of .4 percent in Connecticut to a low of .05 percent in Wisconsin. (U.S. Census 2012) H_2 incorrectly predicts that states with the fewest regulations will have the greatest number of patients per capita. H_3 is unsubstantiated as there is no correlation between percentage of for-profit OTPs and OTP patients per capita. As a means of validating data, patient and facility statistics from SAMHSA's State Profiles from 2010 were used for all responding states (SAMHSA 2011). There was no correlation between the stringency of regulation and the number of patients, the number of clinics, or for-profit/nonprofit status.

Is state regulation mainly about process, not outcomes?

H_4 correctly predicts the presence of wide variation in state regulatory environments. Of 47 regulations, the mean number of regulations per state is 20.9 with a standard deviation of 7.6. The subset of state-required reporting requirements also indicates a high level of variation. (See Tables 3 and 4.) It is also unclear whether data collected is accurate or is even analyzed at the state level, given that some states that indicated on the survey required reporting of certain data could not produce that same data.

Table 4. State Requirements for Reporting
Mean = 39 Standard Deviation = 22.7

Type of Report	Percentage of States That Require
Annual or semi-annual reporting to state	59%
Required annual reporting of length of client stay for each client	32%
Required reporting of discharges	59%
Required reporting of number/percentage of clients with take-home privileges by category	32%

Required reporting of methadone/drug-related client deaths	86%
Required reporting of methadone-related death of client household members	32%
Required reporting of OTP clients involved in criminal activity	36%
Required reporting of frequency distribution of clients by dosing level	5%
Required reporting of suspected diversions	36%
Required reporting of known diversions	55%
Required reporting of spot-checks for take-homes	23%
Required reporting of inventory issues	50%
Required reporting of annual or more frequent inventories	4%

While 19 of 22 states state that they require OTPs to report deaths, fewer than half of respondents could provide the number of methadone or other drug related deaths of OTP clients in the past year. There is no way to check reliability of death reports due to privacy in accreditation agencies, (with the exception of states that serve as the accrediting bodies), a dearth of publicly reported state data, and the lack of mortality data collection by federal agencies. Conflicting reports also reduce reliability. One responding Opioid Treatment Authority reported three deaths at OTPs in 2012, information that was contradicted by the state licensing agency, which indicated 13 deaths of OTP clients during the same time period.

H_5 correctly predicts that OTP performance measures and outcomes are not widely reported or publicly available from the states. Of the 22 states responding to the survey, only three report any specific performance measures in place, though some states indicated that they plan to have performance measures in the future and one state stated that performance measures are included in state regulations. Of responding states, Connecticut has the most sophisticated measures of performance with specific targets for performance. North Carolina maintains demographic and outcomes data in an attractive, useful, and publically accessible format. Table 5 illustrates measures listed by the three states.

Table 5. Performance Measures Described by Three States

Outputs	Outcomes – Specific levels of performance may apply
Number of consumers enrolled Number of drug screens performed Reporting requirements met in a timely manner Contractor meets expected utilization rate Percentage of patients in treatment for 12 month minimum	Drug and alcohol abstinence Clients employed or in school Lack of criminal activity Outcomes of drug screens Drug-free babies born Client satisfaction Clients maintain level of function Clients improve their living situation Clients maintain or improve social supports Clients discharged have successfully completed objectives on plan of treatment

While Kentucky indicated on the survey that they have no performance measures, they do have access to a thorough evaluation of OTP outcomes created by the University of

Kentucky. The 2012 report on OTP outcomes demonstrated measurable reductions in alcohol and substance abuse, increase in income, improvements in education and employment, less criminal activity and jail time, and increased use of socials supports (Logan et al. 2012). Maine's Office of Substance Abuse published an evaluation of medication-assisted therapy in March 2010, which included recommendations to improve outcomes (McAuley et al. 2010).

States were also asked to describe how they measure success of OTPs. Responses indicate that states without defined performance measures may provide oversight in other ways. Arkansas, for example, looks at "employment, number of arrests, and number of relapses" but does not have a formal performance management program. Other state responses indicate a disconnect between "success of OTPs" and client outcomes, in most cases deferring evaluation to others, including the licensure accreditation bodies and even to the OTPs themselves. One state responded to a survey question about measuring success that "all clinics are privately owned." Another says that the "OTPs themselves define if the client was 'successful,'" and another commented that individual programs are required to create their own outcomes measures. Three of the responding states measure OTP success in terms of compliance with accreditation standards. Others base success on the number of admissions and discharges, giving credence to H_6, which predicts that states collect data that focuses largely on outputs, not on outcomes.

H_6 is further supported in both the lack of performance measures across the states and the absence of reportable data concerning outcomes. Only two states could provide data on client time in treatment, although about a third say that they collect such data. While 59 percent of states report that they require reporting of discharges, almost 37 percent could not explain the reasons for discharge, since discharges may be at the discretion of another agency, lack of ability to pay, or the OTP's own rules, including noncompliance and diversion. Only twelve states require OTPs to report known diversions of methadone, and only five states are required to report to states the results of spot-checks for take-home medications. Just half of the responding states require the OTP to report known methadone inventory problems to the state authority. The absence of data on deaths, as indicated earlier, is a primary missing outcome. There are investigational studies of data from individual states or clinics that support the 1995 IOM report that methadone maintenance can improve quality of life for clients, but there is no updated, comprehensive, reliable source of data about patient outcomes to support the 1995 study.

H_7 predicts that the "regulatory fog" of multi-layered oversight limits the ability of citizens, potential clients, and the regulators themselves to determine the effectiveness and safety of OTP programs. Only six of 22 responding states report that licensure surveys are posted on public websites. Fewer than one-third of responding agencies are required to report to accrediting bodies, and accrediting bodies are not generally compelled to report to state and federal agencies. Five states of 22 responding report having closed a facility since 2008, and four of those closures were in 2012. One such closure was a facility licensed by the state's Health Facility Regulation, overseen by the State Opioid Authority, with a current three-year CARF International accreditation. In early 2013, this clinic was sanctioned by the DEA for "methadone overages in 2011 and a 2012 shortage of about 460,000 milligrams of methadone" and fined $12,500 (United States Attorneys Office 2013). In another case reported on a state public website, a facility received a remediable deficiency but without substantive sanctions for giving free doses of methadone to current clients who successfully recruited new "customers." Minnesota's Lake Superior Treatment Center was given "high marks, finding that the clinic met or exceeded standards" and reaccredited for three years by

CARF International just before the state authority found 56 violations and closed the clinic (Anonymous 2012b). In some states, OTP owners or managers serve as part-time surveyors for accreditation agencies, which raises the specter of conflict of interest when the surveyors' own facilities may be surveyed by members of their own associations.

The survey also indicates that there are also missed opportunities for improved care. Only half of the states participate in prescription drug monitoring programs. Only 55 percent of states require OTPs to have initial drug screens on the charts prior to the first dosing, a best practice, and only four require approval from the state's central registry before initiation of treatment. The first two weeks of treatment are especially high-risk and coordinating care with other health care providers and the state could improve safety.

Discussion and Conclusions

A review of literature that describes the benefits of opioid replacement therapy supports a place for Opioid Treatment Programs within the health care system. Instead, many OTPs are managed by laypersons with little professional medical oversight in for-profit, non-medical facilities with limited hours of service, often five hours or fewer on weekdays and two hours or less on weekends. Only six of 22 responding states require clinics to be open seven days a week, and only two set minimum hours for clinics. Six states require defined hours for physicians to be on-site, and only nine of 22 require the presence of a registered nurse during dosing hours. Fewer than half of the states responding require a minimum amount of time in patient counseling. Many OTPs operate with a "dose and go" philosophy and little mandated counseling, despite the fact that counseling as part of detoxification is considered a best practice (Veilleux et al 2010; Kraft et al. 1997). Although there are newer and more effective substitutes that could help more patients work toward detoxification and simultaneously reduce their risk of harm, nearly all clients in the U.S. are considered long-term methadone maintenance clients (SAMHSA 2012b). This fact warrants a new look at expectations and outcomes.

The failure of the health system to incorporate and advance opioid treatment may reflect societal attitudes that demonstrate little empathy for those addicted to opiates, despite the fact that these drugs are increasingly initially attained by legitimate prescription rather than heroin, which was the primary substance for which methadone clinics were founded. Poverty may also be a factor, that is, there are few to speak for the economically marginalized outside of the OTPs who serve them. The decline in government-operated facilities from 18 percent in 1996 to ten percent in 2011 and the subsequent growth in for-profit clinics and clients per clinic are further indications of a shift in policy that may not portend a focus on best practices (SAMHSA N-SSAT 2003; SAMHSA N-SSATS 2012b). OTP businesses are considered "one of the most lucrative sectors in health care because of its cash-only nature and high profit margin" (Swisher 2013). The focus on profits – not patients – and continued demedicalization of OTP services have potential to further ostracize OTPs from mainstream health care.

The deliberate decision of federal agencies to shift direct oversight of OTPs to accreditation agencies and, by default, to state licensure bodies or substance abuse authorities has resulted in a focus on regulations and process to the detriment of performance measures and outcomes. Though this shift to accreditation initially reflected the federal government's intent to improve quality and mainstream methadone maintenance, the effective abdication of governmental authority has reduced transparency, allowing even the worst clinics to obtain the accreditation "seal of approval." This hand-off of authority also raises concerns due to the fact that the increasingly for-profit OTP providers are operating in a customer-vendor

relationship with the private accreditation agencies, which are not forthcoming with information about outcomes, even to federal regulators (Anonymous, Personal Interview, April 20, 2013) and which sometimes hire other OTP managers as surveyors. The ability of clients to compare clinics for quality is virtually impossible due to the proprietary nature of the private accrediting bodies and the lack of publically available outcomes data from state or local governments.

In fairness to government regulators, the addition of 200 new methadone clinics and nearly 100,000 clients in the United States in the past decade (Swisher 2013) has increased demand, perhaps diluting the strength of oversight. The absence of performance data obvious in this survey may also be associated with declining state revenues that have caused regulatory bodies to ration their services or to further punt responsibility to other agencies like the accrediting bodies. In effect, the government overseer has become little more than a middleman serving in a pass-through role. A more coordinated approach to regulation, enhanced mandatory reporting with verification, a uniform system of sanctions, or even a wholesale reconsideration of the current system of regulatory authority could improve outcomes and make the system more transparent. The number of deaths and the growth in long-term methadone maintenance are a call to revisit the regulators' dependence on accreditation as the solution.

The effort to quantify regulations for comparison purposes obscures the importance of certain regulations, including those for patient protection, and while this is a study limitation, the methodology does provide a means of comparison across the states. The study is also limited by the fact that data are self-reported with a near total absence of meaningful outcomes to compare with regulatory stringency. The data derived from the participating states in this study indicate wide variation in regulatory policy and management and, by extension, OTP performance and client outcomes. The "regulatory fog" of multi-layered oversight and the focus on rule and process as the end, not the means, obfuscates the vital information required for evaluation by methadone clinic clients, the general public, the OTPs, and even the regulators themselves.

Many professional journal articles proclaim the harm-reduction benefits of methadone maintenance, but few explore a world without methadone maintenance clinics as they are currently known. Further study of OTP client outcomes by non-clinic researchers across the country could provide valuable insights into the work of these facilities and allow health scientists to determine if the "regulatory fog" that current policy represents is, in fact, "counterfactual" (Warren and Wilkening 2012, 840). At a time when opioid addiction is growing, a fresh look at alternatives could ultimately provide opportunities to identify best practices that could return medication-assisted treatment to the health care fold and improve outcomes for persons addicted to opioids.

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