Tackling the Opioid Crisis: Navigating the Regulatory, Legislative and Ethical Maze, Including How-To's on Becoming a Substance Abuse Treatment Center in New York

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I. Intro

America faces an opioid epidemic.[1] According to the CDC, "[d]rug overdose deaths continue to increase in the United States. From 1999 to 2016 more than 630,000 people have died from a drug overdose. Around 66% of the more than 63,600 drug overdose deaths in 2016 involved an opioid."[2] Furthermore, "[i]n 2016, the number of overdose deaths involving opioids (including prescription opioids and illegal opioids like heroin and illicitly manufactured fentanyl) was 5 times higher than in 1999."[3] The CDC states that "[o]n average, 115 Americans die every day from an opioid overdose."[4]

While America looks to navigate the ever-increasing web of issues associated with the opioid epidemic, alternative forms of treatment are at the forefront of the discussion on remedial measures to the crisis. However, alternative forms of treatment often run afoul of existing statutes and subsequently place attorneys - retained to assist in the establishment of treatment centers – in unchartered or problematic ethical territory. Many questions, not all of which have been answered or are easily navigable, present themselves. Therefore, as federal preemption is the jumping off point for many discussions on alternative or non-traditional forms of substance abuse treatment, any discussion on treatment centers, looking to utilize non-traditional methods to combat opioid dependence, must begin by addressing the governing federal law on controlled substances: The Controlled Substances Act (CSA).

[1] CDC, Centers for Disease Control and Prevention, Understanding the Epidemic, https://www.cdc.gov/drugoverdose/epidemic/index.html, last visited Dec. 11, 2018.
[2] *Id.*
[3] *Id.*
[4] *Id.*

II. CSA

International and federal regulation of drug use is predicated primarily on punishment-based models. The CSA, the governing federal law on controlled substances in the United States, "regulates the manufacture, importation, possession, use and distribution of most psychoactive substances, except for three legal substances: caffeine, tobacco, and alcohol."[5] The Controlled Substances Act/CSA, or Title 21 United Sates Code (USC) Controlled Substances Act, schedules substances based on the substance's alleged propensity for abuse, accepted medical use in the United States, and accepted safety for use under medical supervision.[6] The CSA has five (5) schedules, with schedule I including those drugs that are the most dangerous and have no accepted safe medical use.[7] Schedule I substances, those with no currently accepted medical use and a high potential for abuse, include heroin, LSD, and cannabis (marihuana).[8] 21 U.S.C. § 812(c), Schedule I (b)(10); 21 U.S.C. § 812(c), Schedule I(c)(9) and (c)(10).

Given current trends towards the legalization of cannabis, especially in the use of cannabis for medicinal purposes, many questions are presented over the current scientific accuracy of the Controlled Substances Act, which was signed by President Richard Nixon in 1970. For example, in 2018, Wiese and Wilson-Poe published Emerging Evidence for Cannabis' Role in Opioid Use Disorder.[9] This article reviewed emerging evidence that suggested cannabis (marihuana, Schedule I), could "play a role in ameliorating the impact of OUD [opioid use

[5] *Charting A Wiser Course: Human Rights and the World Drug Problem,* A Report of the Special Committee on Drugs and the Law of the New York City Bar Association (2016).
[6] U.S. Department of Justice, DEA, Diversion Control Division, https://www.deadiversion.usdoj.gov/21cfr/21usc/812.htm (last visited Dec. 11, 2018).
[7] *Id.*
[8] DEA, Drug Scheduling, https://www.dea.gov/drug-scheduling (last visited Dec. 11, 2018).
[9] Emerging Evidence for Cannabis' Role in Opioid Use Disorder, Wiese and Wilson-Poe, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6135562/ (2018).

disorder]."[10] This article is specific to cannabis's usage in the treatment of opioid use disorder. There are an increasing numbers of scientific publications on the use of cannabis as a pain killer/analgesic. This body of literature calls into question the wisdom of the CSA's scheduling of cannabis, as having no accepted medical use.

Next, the CSA, Schedule II, includes many opioid/opiate drugs, including fentanyl-fentanyl is 50 to 100 times more potent than morphine.[11] Despite varying reports and mixed research on the safety and dependency forming properties of cannabis, to date, cannabis touts no confirmed fatal overdose. It can therefore be extrapolated that cannabis, though not harmless, is less harmful than prescription and other opioids/opiates, which, when improperly administered or abused, can easily lead to fatalities and are highly dependency forming. Therefore, the wisdom of current scheduling of cannabis under the CSA is called into question.

Notably, the origins of cannabis prohibition, or more aptly named, the War on Drugs, trace, in part, back to Harry Anslinger, who served as U.S. commissioner of Narcotic Drugs.[12] Anslinger is reported to have said "'[t]here are 100,000 total marijuana smokers in the US, and most are Negroes, Hispanics, Filipinos and entertainers. Their Satanic music, jazz and swing result from marijuana use. This marijuana causes white women to seek sexual relations with Negroes, entertainers and others.'"[13] The Drug Policy Alliance provides a succinct summary of the racist origins of the United States War on Drugs – a war, that when parsed, is laced with racist rhetoric – both latent and blatant – and has historically been a war on people – mostly

[10] *Id.*
[11] CDC, Opioid Overdose, Fentanyl, https://www.cdc.gov/drugoverdose/opioids/fentanyl.html (last visited Dec. 11, 2018).
[12] H.J. Anslinger papers, 1835-1975, Collection Overview, https://libraries.psu.edu/findingaids/1875.htm (last visited Dec. 12, 2018).
[13] "Marijuana: is it time to stop using a word with racist roots?", The Guardian, https://www.theguardian.com/society/2018/jan/29/marijuana-name-cannabis-racism

individuals of color, the poor, and the hippies of the 1960s and 1970s counter-culture.[14] It should be noted that the racism at the roots of the drug war predates Anslinger, though drug policy activists frequently cite to him in order to highlight the cruelty of our country's Drug War.

> The first anti-opium laws in the 1870s were directed at Chinese immigrants. The first anti-cocaine laws in the early 1900s were directed at black men in the south. … Today, Latino and especially black communities are still subject to wildly disproportionate drug enforcement and sentencing practices.[15]

Any discussion of the current opioid crisis cannot be academically honest if it excludes at least some history, including the evolution of, the United States' War on Drugs, from its origins to its expansions by the Nixon and Reagan Administrations. Interestingly, the demographics impacted by the current opioid crisis are different from those impacted by the crack/cocaine scare from the 1980s. Notably, the 1980s gave birth to a new wave of draconian drug laws, which created a gap in harsher sentences for the smokeable form of cocaine - crack.[16] Additionally, in the 1980s, harm reduction methods – such as syringe exchange programs – which could have prevented the spread of HIV/AIDS were blocked.[17] Drugs and drug users have historically been vilified and stigmatized. As America faces the devastation of the opioid epidemic, a shift in our cultural narrative, from stigma and punishment of the drug user/abuser to a more treatment-centric approach, is transpiring.

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[14] A Brief History of the Drug War, http://www.drugpolicy.org/issues/brief-history-drug-war, (last visited Dec. 12, 2018).

[15] *Id.*
[16] *Id.*
[17] *Id.*

> Public opinion has shifted dramatically in favor of sensible reforms that expand health- based approaches while reducing the role of criminalization in drug policy.
>
> Marijuana reform has gained unprecedented momentum throughout the Americas. Alaska, California, Colorado, Nevada, Oregon, Maine, Massachusetts, Washington State, and Washington D.C. have legalized marijuana for adults. In December 2013, Uruguay became the first country in the world to legally regulate marijuana. In Canada, Prime Minister Justin Trudeau plans legalize marijuana for adults by 2018.
>
> In response to a worsening overdose epidemic, dozens of U.S. states passed laws to increase access to the overdose antidote, naloxone, as well as "911 Good Samaritan" laws to encourage people to seek medical help in the event of an overdose.[18]

Unfortunately, the current political climate is leading to further uncertainty in the realm of drug policy and drug laws. Though more states move towards the legalization of the adult use of cannabis, cannabis remains prohibited at the federal level – curtailing the ability to study its effects, whether they be positive or negative, and leading to a maze of legal issues for attorneys representing individuals looking to use certain harm reduction methods to ameliorate the harms associated with the current opioid epidemic.

[18] *Id.*

III. Alternative Forms of Treatment

Many forms of substance abuse treatment are legal and face only the typical legal and business obstacles that health care facilities face when setting up practice. Many issues presented in the realm of the ethics of treatment centers focus on so-called less traditional approaches to treatment, that may run afoul of state and/or federal law.

a. Harm Reduction and Your Client

Cannabis as a treatment for opioid use disorder, or a replacement for prescription opioids, falls under the umbrella of harm reduction. Harm reduction is a school of thought in public health that centers around accepting the realities of the world in which we live – that people will use and abuse drugs – and instead of punishing the drug user or abuser seeks to reduce the harms associated by the conduct at issue.

New York had medical marihuana pursuant to the Compassionate Care Act. McKinney's Public Health Law § 3362, provides for the lawful medical use of medical marihuana, subject to limitation. McKinney's Public Health Law § 3369(1), Protections for the medical use of marihuana, provide that

> Certified patients, designated caregivers, practitioners, registered organizations and the employees of registered organizations shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including but not limited to civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, solely for the certified medical use or manufacture of marihuana, or for any other action or conduct in accordance with this title.

A potential hypothetical for a substance abuse treatment center is one in which cannabis is used to help patients with some of the unpleasant symptoms associated with prescription or other opioid/opiate withdrawal. Treatment centers often facilitate detoxification, a series of symptoms that transpire during the acute withdrawal phase from many dangerous drugs, such as alcohol, heroin, and prescriptions pain killers.

The NY State Department of Health provides information on The New York State Medical Cannabis Program.[19] Notably,

> Medical marijuana is available in New York for patients with the following severe debilitating or lifethreatening conditions: cancer, HIV infection or AIDS, amyotrophic lateral sclerosis (ALS), Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, chronic pain, Post-Traumatic Stress Disorder (PTSD) and as a replacement to prescription opioids. Chronic pain was added by NYSDOH as a qualifying condition through regulations adopted on March 22, 2017. PTSD was added through legislation on November 11, 2017. Most recently, NYSDOH introduced emergency regulations, which went into effect on July 12, 2018, adding any condition for which an opioid may be prescribed. In addition to a severe debilitating or life-threatening condition, patients must also have one of the following clinically associated or complicating conditions: cachexia or wasting syndrome, severe or chronic pain resulting in substantial limitation of function, severe nausea, seizures, severe or persistent muscle spasms, PTSD, or opioid use disorder, but

[19] The New York State Medical Marijuana Program, https://www.health.ny.gov/regulations/medical_marijuana/ (Dec. 18, 2018).

only if enrolled in a treatment program certified pursuant to Article 32 of the Mental Hygiene Law.[20]

The fact that New York State includes replacement for prescription opioids and opioid use disorder as conditions qualifying for medical cannabis prescription speaks volumes. If a state, such as New York, has taken the step to use cannabis to treat opioid use disorder, or as a replacement for prescription opioids, it is arguably time to revisit the scheduling of cannabis under the CSA.

An ethics opinion, NY Eth. Op. 1024 (N.Y.St.Bar.Assn.Comm.Prof.Eth.), 2014 WL 12811305, advises that "[l]awyers may advise clients about the lawfulness of their proposed conduct and assist them in complying with the law, but lawyers may not knowingly assist client in illegal conduct." *Id.* at 1. The opinion cites to Rule 1.2(d), stating

> "A lawyer shall not counsel a client to engage, or assist a client, in conduct that the lawyer knows is illegal or fraudulent, except that the lawyer may discuss the legal consequences of any proposed course of conduct with a client." Disciplinary Rule 7-102(A)(7), contained in the pre-2009 Code of Professional Responsibility, was to the same effect. As this Committee has observed, if a client proposes to engage in conduct that is illegal, "then it would be unethical for an attorney to recommend the action or assist the client in carrying it out." N.Y. State 769 (2003); *accord* N.Y. State 666 (1994).

Additionally, this opinion goes on to state that

[20] Medical Use of Marijuana Under the Compassionate Care Act, 6 of 16, https://www.health.ny.gov/regulations/medical_marijuana/docs/two_year_report_2016-2018.pdf

The difficult question arises if the lawyer *knows* that the client's proposed conduct, although consistent with state law, would violate valid and enforceable federal law. Ordinarily, in that event, while the lawyer could advise the client about the reach of the federal law and how to conform to the federal law, the lawyer could not properly encourage or assist the client in conduct that violates the federal law. That would ordinarily be true even if the federal law, although applicable to the client's proposed conduct, was not rigorously enforced and the lawyer anticipated that the law would not be enforced in the client's situation. *See* Charles W. Wolfram, Modern Legal Ethics 703 (1986) ("on the whole, lawyers serve the interests of society better if they urge upon clients the desirability of complying with all valid laws, no matter how widely violated by others they may be"); *cf.* Restatement (Third) of the Law Governing Lawyers § 94, Cmt. f (2000) ("A lawyer's advice to a client about the degree of risk that a law violation will be detected or prosecuted [is impermissible when] the lawyer thereby intended to counsel or assist the client's crime, fraud, or violation of a court order."). But the situation is different where the state executive branch determines to implement the state legislation by authorizing and regulating medical marijuana, consistent with current, published federal executive-branch enforcement policy, and the federal government does not take effective measures to prevent the implementation of the state law. ***In that event, the question under Rule 1.2(d) is whether a lawyer may assist in conduct under the state medical marijuana law that the lawyer knows would violate federal narcotics law that is on the books but deliberately unenforced as a matter of federal executive discretion***. (Emphasis added).

The opinion concluded that "the New York Rules of Professional Conduct permit lawyers to give legal assistance regarding the CCA that goes beyond a mere discussion of the legality of the client's proposed conduct." *Id.* at 9. Furthermore, "[i]n general, state professional conduct rules should be interpreted to promote state law, not to impede its effective implementation." *Id.*

> In light of current federal enforcement policy, the New York Rules of Professional Conduct permit a lawyer to assist a client in conduct designed to comply with state medical marijuana law, notwithstanding that federal narcotics law prohibits the delivery, sale, possession and use of marijuana and makes no exception for medical marijuana. *Id.*

The opinion ultimately reached its conclusion by centering the question around federal non-enforcement policy of the CSA. Notably, this opinion was written in 2014, during the Obama years. Despite the shift in the occupant of The White House, and former Attorney General Jeff Sessions' statements against cannabis legalization efforts, no major change in federal enforcement policy has taken place as a matter of fact. Therefore, the above-cited opinion, from 2014, counsels New York attorneys on the ethics of advising clients on the newly enacted state legalized cannabis policy when federal law prohibits the conduct engaged in. It is important to note that the above-cited opinion hinges on the federal government's policy and that the policy can change on a whim of politicians, though there would be an imaginably large amount of political backlash if federal non-enforcement policy were to shift.

For lawyers, governed and sworn to the rule of law, the fact may be less than comforting. Though it is likely that federal non-enforcement will continue, no one has a crystal ball. The future is unwritten but the law is clear: there is a conflict between federal and the laws of many

states now, which arguably places attorneys – merely seeking to best advise their clients - in a slightly unstable position. Ultimately, in order to ensure less dependence on federal non-enforcement policy and ensure clarity for licensed practitioners, the CSA schedules need to be updated to reflect the science available to us in the twenty-first century and not to embody 20th century prejudices.

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MEMORANDUM

TO: NYSBA, Health Law Section

FROM: Daniel M. Meier

DATE: December 13, 2018

SUBJECT: Tackling the Opioid Crisis: Navigating the regulatory, legislative and ethical maze, including how-to's on Becoming a Substance Abuse Treatment Center in New York

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I. Medicare Benefit Manual Chapter 15

A. "When the therapist who has a Medicare NPI is employed in a physician's/NPP's office the services are ordinarily billed as services of the therapist, with the therapist identified on the claim as the supplier of services. However, services of the therapist who has a Medicare NPI may also be billed by the physician/NPP as services incident to the physician's/NPP's service. (See §230.5 for rules related to therapy services incident to a physician.) In that case, the physician/NPP is the supplier of service, the NPI of the supervising physician/NPP is reported on the claim with the service and all the rules for both therapy services and incident to services (§230.5) must be followed."

II. Stark Law Preamble, 69 Fed. Reg. 16054, 16071-16072 (March 26, 2004)

A. "As explained in the Phase I preamble (66 FR 885–886), we have concluded that section 1877 of the Act should not subject physicians to supervision standards that differ from the standards for Medicare payment and coverage for the services provided. Thus, for example, services billed ''incident to'' will require the level of supervision applicable under the ''incident to'' rules. Services that require only low-level general supervision are subject to that lower level of supervision for purposes of section 1877 of the Act. As noted above, these regulations under section 1877 of the Act do not, in the first instance, establish the supervision requirements applicable to particular services, nor are they an appropriate vehicle for doing so."

III. Stark Law Preamble, 69 Fed. Reg. 16054, 16076 (March 26, 2004)

A. "A professional association for physical therapists asked the following questions:

1. If a physical therapist employed by a physician practice furnishes services, bills using the physical therapy provider number, and then reassigns payment to the group practice, are the billing requirements met?

2. Would a rehabilitation agency, which is owned by physicians, and has its own billing number, be considered a wholly owned entity for billing purposes?

3. Can physicians own a physical therapy private practice office and bill through the provider number of that office?

4. When a designated health service is billed by an entity wholly owned by a group practice, do the Medicare conditions of participation applicable to the wholly owned entity determine the applicable level of supervision or do the supervision requirements related to group practice billing apply."

B. "With respect to the first question, we assume it is directed at services provided after March 1, 2003, as prior to that date, services by an employed physical therapist had to be billed as ''incident to'' services. Billing by a physical therapist under his or her own billing number does not satisfy the billing requirement of section 1877(b)(2)(B) of the Act, which requires that the service be billed by the performing physician, the supervising physician, the group practice using a number assigned to the group, or an entity wholly owned by the performing or supervising physician or the group practice. However, **if the physical therapist reassigns his or her right to payment to the group, and the group bills using its own billing number (with the physical therapist's number indicated on the bill), then the billing requirement would be met. . . With respect to the last question, the supervision must meet the requirements applicable to the billing submitted to the Medicare program.**

IV. Physician Self-Referral (Stark) Law, 42 U.S.C. §1395nn

A. Prohibits any financial relationship -- including arrangements for compensation -- between a physician (or immediate family member) and an entity with which the physician (or immediate family member) refers patients for designated health services ("DHS"), defined by the statute.

B. Examples of DHS

1. Prohibits any financial relationship -- including arrangements for compensation -- between a physician (or immediate family member) and an entity with which the physician (or immediate family member) refers patients for designated health services ("DHS"), defined by the statute.

C. Strict Liability Statute

1. Refund any amounts collected for services provided pursuant to a prohibited referral.

D. Civil Monetary Penalties ("CMP") if a violation is found

1. Improper claims or failure to refund money.

2. Circumvention Scheme - DHS entity knows/should know an arrangement has a general purpose of assuring referrals to DHS entity that if made directly to DHS entity, would violate Stark.

E. Exclusion from federal health care programs

F. Potential False Claims Act liability

1. Knowingly presenting or causing to be presented a false or fraudulent claim to the U.S. government for payment.

G. Exceptions

1. The only circumstance in which a physician and an entity to which the physician refers can escape the prohibition is through meeting an applicable exception to the statute, such as:

   a. Personal Services.

   b. Employment.

   c. Group practice.

   d. In-office ancillary services.

V. <u>Group Practice Exception to Stark Law</u>

A. Group practice means a single legal entity of two or more physicians legally organized as a partnership, professional corporation, faculty practice plan or similar association where:

1. Each physician member provides substantially the full range of services that physician routinely provides (including medical care, consultation, diagnosis or treatment).

2. Professional services provided through the joint use of shared office space, facilities, equipment and personnel.

B. ***Substantially all*** **(at least 75%) of each physician member's patient care services:**

1. Are provided through the group

    a. Document through time cards, personal schedules, etc.

    b. Must meet within 12 months of formation or 12 months of new physician relocating (25 miles+) to join group.

2. Are billed under group's billing number.

3. Have all income treated as receipts of group.

4. Have overhead expenses and income from the practice distributed in accordance with previously determined methods.

C. No physician in the group may directly or indirectly receive compensation based on the volume or value of referrals by the physician.

1. Exception: Group physicians may be paid a share of overall profits or a productivity bonus (for personally performed or "incident to" services) if not directly related to DHS referrals.

D. Productivity Bonus

1. Not the same as productivity bonus in the employment context.

2. A physician in the group may be paid a productivity bonus based on services that he or she has personally performed, services "incident to" such personally performed services, or both.

3. May not be determined in any manner that is directly related to the v/v of DHS referrals by the physicians (except for the "incident to" services).

E. Productivity bonus will not be considered directly related to volume or value of referrals if one of the following conditions is met:

1. The bonus is based on the physician's total patient encounters or RVUs;

2. The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payor; or

3. DHS revenues for group practice are less than 5% of group practices' total revenue and the allocated portion to each physician in the group is 5% or less of the physician's total compensation from the group.

VI. In-Office Ancillary Services Exception to Stark law

A. For provision of DHS when ancillary to the office-based practice of medicine (even if not really ancillary).

B. Definition of "group practice" is key.

1. Fully integrated, not a loose confederation of physicians designed to profit from DHS referrals.

2. Financial incentives to make DHS referrals are attenuated.

C. Who may provide services?

1. Referring physician;

2. Physician who is member of same group practice as referring physician;

3. Individuals who are directly supervised by physician or another physician in same group practice; and

4. Physicians in the group practice, such as employees and independent contractors of group practice.

D. Where are services provided?

1. Same building where the referring physician (or others in group) furnish services unrelated to the furnishing of DHS; must meet one of 3 tests:

   a. Office is open to the group's patients for medical services at least 35 hours per week and a member of the group provides physician services (including non-DHS services) to patients at least 30 hours per week.

   b. Referring physician's group owns or rents an office that is normally open to patients for medical services at least 8 hours per week and referring physician provides physician services (include non-DHS services) to patients at this office at least 6 hours per week.

   c. Referring physician's group owns or rents an office that is normally open to patients for medical services at least 8 hours per week, either referring physician orders DHS services while seeing the patient on the premises or a member of referring physician's group practice is on premises when DHS is performed and referring physician or member of group practices at site at least 6 hours per week.

2. Centralized building which means all or part of a building that is owned or leased on a full-time basis by a group practice, including a mobile vehicle, van or trailer where some or all of the group practice's DHS is provided; must meet one of 3 tests

    a. Office is open to the group's patients for medical services at least 35 hours per week and a member of the group provides physician services (including non-DHS services) to patients at least 30 hours per week.

    b. Referring physician's group owns or rents an office that is normally open to patients for medical services at least 8 hours per week and referring physician provides physician services (include non-DHS services) to patients at this office at least 6 hours per week.

    c. Referring physician's group owns or rents an office that is normally open to patients for medical services at least 8 hours per week, either referring physician orders DHS services while seeing the patient on the premises or a member of referring physician's group practice is on premises when DHS is performed and referring physician or member of group practices at site at least 6 hours per week.

3. How are services billed?

    a. By the physician performing or supervising services;

    b. By the group practice of which such physician is a member, employee or independent contractor under a billing number assigned to the group practice; or

    c. By an entity that is wholly owned by such physician or such group practice.

DMM

Tackling the Opioid Crisis: Navigating the regulatory, legislative and ethical maze, including how-to's on Becoming a Substance Abuse Treatment Center in New York

Edward Rebenwurzel, Esq., Triumph Treatment

1. **How to Become an Opioid Treatment Program in New York?**
    a. There are a number of regulatory hurdles to overcome and licenses to obtain:
        i. New York State Office of Alcoholism and Substance Abuse Services (OASAS)
        ii. Substance Abuse and Mental Health Services Administration (SAMHSA)
        iii. Drug Enforcement Administration (DEA)
        iv. Accrediting body (e.g., CARF International, The Joint Commission, Council on Accreditation)
    b. We will focus on the OASAS piece

2. **OASAS Certification Process**
    a. A prospective provider of substance use disorder services is required to obtain the prior approval of the Commissioner of OASAS before establishing, incorporating and/or constructing a facility or offering a service

3. **Meeting with Local Governmental Unit and Regional Office and "Attachment #1A"**
    a. The first step in the application process is for prospective applicants to contact the Local Governmental Unit (LGU) and OASAS Regional Office (RO) in the jurisdiction where services are to be offered
        i. Applicants must arrange for a discussion of the conceptual basis for the application and its relationship to the service needs expressed in the LGU's Local Services Plan (if applicable)
    b. Prior to the meeting, applicant must submit a "Certification Proposal – Prior Consult Form" also known as "Attachment #1A"
    c. At the conclusion of these discussions, the RO and LGU render a recommendation on the applicant's proposal

i. If the applicant receives the recommendation from the RO and LGU to move forward, a full application ("PPD-5") must be submitted

4. A Closer Look at Attachment #1A

a. Attachment #1A addresses a number of key elements of the proposed program including:
   i. Type of entity
      1. Individual Proprietorship
      2. Partnership
      3. Limited Liability Partnership
      4. Not-for-Profit Corporation
      5. Business Corporation
      6. Limited Liability Company
   ii. Outreach to the local community
      1. Community Boards, Planning Boards, Neighborhood Coalitions, other local municipalities, politicians, etc.
   iii. Community input, including any existing or likely concerns
   iv. Proposed location of the program
      1. OASAS assesses
         a. whether location is suitable for a chemical dependency treatment program
         b. accessibility of public transportation and adequate parking
         c. any other potential impact on the community environment
   v. Need for the proposed services in the service area
   vi. Staffing pattern
   vii. Applicant's approach/philosophy regarding the treatment of chemical dependence
      1. e.g., use of self-help services, medication, individual/group counseling, and other treatment techniques
   viii. Experience in chemical dependence services
      1. Per Section 810.7(a)(6) of the OASAS Operating Regulations, owners or principals of the applicant must demonstrate and substantiate prior experience providing or managing substance use disorder treatment services
   ix. Proposed operating budget (pre-/post-operational)
b. LGU and FO sign and add comments

5. **The Chemical Dependence Certification Application (PPD-5)**
    a. If applicant receives clearance to proceed, a PPD-5 application may be submitted
    b. Attachment #1A is submitted along with the PPD-5 as proof of prior consultation with the LGU and FO
    c. Many of the items covered in the Local Governmental Unit and Regional Office Meeting/Attachment #1A are explored in greater detail. There are also a number of additional required elements:
    d. Site drawings and photographs
        i. OASAS conducts a physical plant inspection of the proposed premises
    e. Zoning classification, building classification, certificate of occupancy
    f. A copy of the existing or proposed lease
        i. Lease terms must be for a term sufficient to ensure program continuity with an option to renew for an additional term of years
            1. Longer terms may be required if financial support is provided for a capital project by OASAS
        ii. Pursuant to Section 810.7 (d), the lease agreement must contain the following clause:
            1. "The landlord acknowledges that the rights of re-entry into the premises as set forth in this lease do not confer on the landlord the authority to operate an alcoholism, substance abuse, or chemical dependence facility. The landlord agrees to give the New York State Office of Alcoholism and Substance Abuse Services at least thirty days notice by certified mail of an intent to re-enter the premises or to initiate dispossess proceedings and at least sixty days notice of expiration of the lease."
    g. Capital investment needs of property
    h. Shared space issues
        i. If applicant will share space with other providers of human services, must describe plans to assign discrete space for chemical dependence services as well as plans for utilizing shared space (e.g., through scheduling, etc.)
    i. Details regarding how the services will function within the network of chemical dependence providers in the area
    j. Assessment of need, including the following information as support:
        i. Description of the relationship of the proposed services to the applicant's long-range service development plan

ii. a chart or narrative describing the demographic characteristics of the area to be served including age, sex, ethnicity, level of disability
iii. an assessment of the availability of similar services in the targeted geographic area
iv. a description of how the applicant will address the special needs of disabled people
v. a description of the relationships and impact of the proposed services on the area's existing health care system and on its other support services
vi. an assessment of the availability of resources (e.g., support services) needed to provide the proposed services
vii. a description of the methodology used to determine need for the targeted service area accompanied with supporting calculations

k. Special populations served
l. Operational policies and procedures
    i. applicant must develop and submit an array of detailed chemical dependence operational policies and procedures
m. List of key opioid program staff
n. Plans to assure the smooth integration of services in the community, including addressing potential loitering by patients in the neighborhood
o. Full review of the financial condition of the applicant
p. Character and competence review of the applicant along with a criminal background check

6. Corporate Entities

a. Section 32.31 of the Mental Hygiene Law, Section 406 and Section 407 of the Business Corporation Law and Section 404(u) of the Not-for-Profit Corporation Law require OASAS approval of any Certificates of Incorporation (or Amendments) which has among its purposes the establishment or operation of any facility proposing to provide chemical dependence, alcoholism or substance abuse services or to solicit contributions for any such purpose
b. Upon receiving OASAS consent to file, applicant forwards the amended incorporation papers to the New York State Department of State for filing
c. OASAS requires that corporate entities include the following statement of purpose in their amended incorporation papers:

i. “To operate chemical dependence, alcoholism and/or substance abuse services, within the meaning of Articles 19 and 32 of the Mental Hygiene Law and the Rules and Regulations adopted pursuant thereto as each may be amended from time to time, which shall require as a condition precedent before engaging in the conduct of any such services an Operating Certificate from the New York State Office of Alcoholism and Substance Abuse Services.”

7. Post-Submission

a. OASAS Bureau of Certification and Systems Management (BoC) conducts extensive reviews
b. Threshold Review is conducted to verify that no components of the application are missing
c. If the submission is found acceptable, an acknowledgement is sent and a Completeness Review is conducted next
    i. The content of the application is assessed and if necessary, applicant is notified of the need to submit additional information within a reasonable timeframe
    ii. According to the standards in Mental Hygiene Law § 32.09, applicant must be found to have:
        1. character and competence
        2. financial feasibility
        3. the potential for compliance with applicable law and regulations
    iii. In its review, BoC staff incorporates recommendations from:
        1. Field Office
        2. LGU
        3. Other OASAS recommendations
        4. Other NYS agency recommendations
d. Next, a Full Review is conducted per §810.5
    i. The LGU is provided with copies of the completed application and accompanying documents and given a reasonable time to review and submit its recommendations to OASAS

8. Behavioral Health Services Advisory Council Review

a. Once the Full Review has been successfully completed, the proposal is considered by the Behavioral Health Services Advisory Council

("Advisory Council") for review and recommendation to the Commissioner

i. The Commissioner makes a decision on the application within a reasonable time after his or her receipt of the Advisory Council's recommendations

1. If approved, OASAS issues an operating certificate

9. Standards for approval of an application requiring Full Review

a. Per §810.7(a), to approve a project requiring Full Review, OASAS must find the application meets all of the following:

i. that there is a public need for the services at the time and place and under the circumstances proposed

ii. that there are no facilities or services available which serve as alternatives or substitutes, for the services and facilities proposed

iii. that there are no substantiated negative findings as to the character, competence and standing in the community of the applicant

iv. that the available financial resources and the sources of future revenues are adequate to meet all necessary and proper capital and operating expenses

v. that services will be provided in compliance with applicable laws and regulations

vi. that the owners or principals of the applicant have demonstrated, and can substantiate, prior experience providing or managing substance use disorder treatment services

vii. that the owners or principals of the applicant have received a criminal history information review pursuant to provisions of Part 805 of this Title, and the applicant has been subsequently approved by OASAS

b. In determining whether the aforementioned requirements are met, OASAS considers the extent to which:

i. the services and facilities conform to local and statewide plans, including but not limited to plans for Medicaid managed care

ii. the services and facilities will meet the particular needs of the community to be served, including identified target populations such as women, minorities, persons with low income,

uninsured and underinsured persons, and other underserved groups

iii. existing like services are able to meet or exceed regulatory compliance

iv. there exist any other matters determined to be in the public interest

OASAS Regional Offices

ZONE	REGION	COUNTIES SERVED
UPSTATE	Western	Allegany, Cattaraugus, Chautauqua, Chemung, Erie, Genesee, Livingston, Monroe, Niagara, Ontario, Orleans, Schuyler, Steuben, Wayne, Wyoming, Yates
UPSTATE	Central	Broome, Cayuga, Chenango, Cortland, Delaware, Herkimer, Jefferson, Lewis, Madison, Oneida, Onondaga, Oswego, Otsego, Seneca, St. Lawrence, Tompkins, Tioga
UPSTATE	Hudson	Albany, Clinton, Columbia, Dutchess, Essex, Franklin, Fulton, Greene, Hamilton, Montgomery, Orange, Putnam, Rensselaer, Rockland, Saratoga, Schenectady, Schoharie, Sullivan, Ulster, Warren, Washington, Westchester
DOWNSTATE	New York	Bronx, New York, Richmond (Staten Island), Kings (Brooklyn), Queens
DOWNSTATE	Long Island	Nassau, Suffolk