**Statement by Richard Nance, LCSW**
**Director of Utah County's Department of Drug and Alcohol Prevention and Treatment**

on

**Combatting the Opioid Crisis: Helping Communities Balance Enforcement and Patient Safety**

before

**Committee on Energy & Commerce,**
**Subcommittee on Health**

**U.S. House of Representatives**
**February 28, 2018**

Chairman Burgess, Ranking Member Green, and Members of the Health Subcommittee, thank you for the opportunity to testify on an issue that is impacting community addiction and mental health treatment centers' ability to provide patients speedy and safe treatments for substance use disorder (SUD) and mental health conditions by utilizing telemedicine. Medically appropriate treatment for SUD and mental health conditions sometimes involves controlled substances. Unfortunately, today thousands of community addiction and mental health treatment centers across the country are unable to use telemedicine that results in the issuance of a prescription for a controlled substance due to the DEA's narrow interpretation of the Ryan Haight Online Pharmacy Consumer Protection Act (Ryan Haight Act).

I appreciate the opportunity to speak for the 2,900 National Council for Behavioral Health member organizations that provide front-line addiction and mental health treatment across the country. We deeply appreciate Congress's interest in creating a pathway to enable legitimate community addiction and mental health treatment centers to register with DEA such that they may provide treatment for Americans in need.

### *About the National Council for Behavioral Health*

The National Council for Behavioral Health is the unifying voice of America's health care organizations that deliver mental health and addictions treatment and services. Together with our 2,900 member organizations serving over 10 million adults, children and families living with mental illnesses and addictions, the National Council is committed to all Americans having access to comprehensive, high-quality care that affords every opportunity for recovery.

I am a Licensed Clinical Social Worker in Utah, and have been Director of Utah County's Department of Drug and Alcohol Prevention and Treatment (UCaDDAPT) since 1998. UCaDDAPT provides a comprehensive range of drug and alcohol prevention and treatment services, including medication-assisted treatment for substance use disorders (SUD), such as opiate addiction and abuse, as well as for co-occurring SUD and mental health disorders. UCaDDAPT also contracts for methadone treatment services. Utah County has a population of over 600,000, and UCaDDAPT serves over 2,000 people per year. Over 40% of these are now being seen for opiate use disorders, and at any given time about 30% of those are receiving MAT in addition to counseling services.

## LEGISLATION IS NEEDED TO ENABLE COMMUNITY ADDICTION AND MENTAL HEALTH TREATMENT CENTERS TO USE TELEMEDICINE TO PROVIDE TREATMENT INVOLVING CONTROLLED SUBSTANCES

### *The Problem*

Thanks to ever-expanding technological advances, telemedicine has the potential to improve access to care, while reducing costs and increasing patient and provider convenience. **Unfortunately, today my center and**

**many other legitimate community addiction and mental health treatment centers are unable use telemedicine to connect patients in our center with DEA-registered doctors.** Here is why:

The Controlled Substances Act, as amended by the Ryan Haight Act, allows for the issuance of a prescription for a controlled substance without a prior in-person patient medical evaluation in limited circumstances, known as telemedicine exceptions. The most common way for such telemedicine to be permitted is when the patient being treated is located in a DEA-registered hospital or clinic and is being treated by a DEA-registered provider located off-site. See 21 U.S.C. 829(e)(3)(A). In order to register, DEA requires that hospitals or clinics be licensed by a state. See *Appendix A*, DEA Registration Form 224, Section 4. The state licensure requirement is not in statute, rather is a result of DEA's administrative application of the Act. The problem is, many community addiction and mental health treatment centers are unable to use telemedicine that results in a prescription for a controlled substance because they are not "state-licensed" according to DEA's interpretation. Many community addiction and mental health centers are licensed, certified, or otherwise formally overseen and recognized by their state, county, or municipality but do not meet the DEA's narrow interpretation.

The National Council believes community mental health or addiction treatment facilities that are **licensed, operated, authorized, or otherwise recognized by a state, county or municipality** should be able to register with DEA for purposes of complying with the Ryan Haight Act.

**Especially given the opioid epidemic, the National Council continues to believe remote prescribing of controlled substances without a prior in-person medical evaluation should be limited to patients located in a DEA-registered facility, including community addiction and mental health treatment centers registered under the two draft bills sponsored by Representatives Harper and Matsui and by Representatives Carter and Bustos.** Our concerns with removing the registration requirement and/or allowing patients to receive prescriptions for controlled substances via telemedicine while at their home or otherwise not in a care setting as currently permitted under the Act are outlined later in this statement.

***About Community Addiction and Mental Health Treatment Centers***

In general, community addiction and mental health treatment centers are facilities that treat patients for mental health, substance use disorder, and other behavioral health needs. These centers, for the most part, do not dispense controlled substances.[1]

There is no federal definition of a community mental health center or of an addiction treatment center applicable in all 50 states to clinics that serve patients from all payer sources. Rather, states, counties, and in some cases municipalities determine what qualifies as a legitimate center and how to regulate them. Sometimes centers are required to have state licenses; sometimes states establish and run the centers themselves as parts of the government; in other cases, centers are regulated by county or municipal governments. For example:

1. **In Utah:** Community mental health and addiction treatment (MH/SUD) centers are overseen by the State Department of Human Services Office of Licensing. Utah has a county government-based addiction and mental health system, which means addiction and mental health services are services are delivered directly by county government, or are contracted out to one or more MH/SUD providers that are also under the purview of the state licensing department and are overseen by governing boards comprised of elected county government officials.
2. **In Texas –** Community mental health centers (known as Community Centers) are governmental entities authorized in Texas statute and required by Texas law to treat individuals with severe and

[1] While rare, we are aware of at least one center that does dispense: the Josephine County, Oregon Health Department is the local behavioral health authority, and they operate a licensed methadone program – thus dispense controlled substances.

persistent mental illness throughout Texas. In their capacity as units of Texas government they do not require any additional state license to perform their state-mandated tasks. These centers are a critical component of the Texas health care system and already meet the intent of registration by virtue of their statutory authorization to perform the functions of Community Mental Health Centers with regard to psychiatric medications. The Texas Council of Community Centers represents 39 centers across Texas that were established by Texas statute and has spent multiple years working with DEA on behalf of its membership to secure DEA registration, with no resolution to date. See *Appendix B* for a discussion of these efforts.

3. **In Georgia –** Community mental health centers (known as Community Service Boards) are quasi-governmental entities authorized in Georgia statute and required by Georgia law to treat individuals with severe and persistent mental illness. In their capacity as instrumentalities of Georgia government, they do not require any additional state license to perform their state-mandated tasks. These centers are a critical component of the Georgia health care system and they are already registered under Georgia law with regard to controlled substances. The CSBs of the Georgia Association of Community Service Boards are concerned about access to vital psychiatric services in schools (as delivered by school-based clinics in partnership with Community Service Boards) and rural areas.
4. **In Missouri –** Community mental health centers operate across 25 service areas reaching the entire state. These providers are non-profit entities serving in a quasi-governmental role as administrative agents of the state responsible for a comprehensive array of mental health and addiction services in their catchment area. Though these centers do not have a state licensure number, they are certified and monitored by the state, are subject to detailed administrative rules outlining their certification criteria and obligations, and are closely overseen by a system of regional managers.

The authorizing governmental body (e.g. states, counties) can determine the scope of services that are able to be provided in these centers and the professional qualification requirements of the centers' on-site staff.

1. **Types of Providers On-Site in Centers:** Community addiction and mental health treatment centers may not always have doctors or psychiatrists on-site at all times. In these cases, it is common for centers to be staffed by social workers, nurses, counselors and other state-licensed mental health or addiction professionals that do not have prescribing authority. Staff at community addiction and mental health treatment facilities are regulated by state and local laws, including any requirements for licensure (e.g. state nursing licenses, social worker licenses), education, and professional conduct.
2. **Scope of Services Provided in Centers:** The types of services provided by community addiction and mental health treatment centers vary, but we do know that roughly 75% of the National Council's 2,900 member organizations offer addiction treatment services. The number of organizations that strictly provide mental health treatment services without any addiction services is very slim.

   For example, Hill Country MHDD Centers serve 19 Texas counties and provide mental health, individual developmental disability, substance use disorder, and early childhood intervention services. These centers need the ability to register with DEA such they can bring in an addictionologist, addiction psychiatrist or child psychiatrist via telemedicine to prescribe to a patient on-site, when medically appropriate.

***The Impact on Patients During the Opioid Epidemic and Beyond***

**The inability of legitimate community addiction and mental health treatment centers to use telemedicine has a direct impact on the lives of Americans**. As this Committee understands, the demand for addiction and mental health services far exceeds current system capacity to serve patients. Telemedicine is a vital opportunity to extend both addiction and mental health treatment services to more patients, particularly those living in rural and frontier areas that lack qualified providers.

There are only four medications commonly used to treat opiate use disorders. One of these – naloxone – is only used for emergency reversal of opiate overdoses. Naltrexone – in oral or long acting injection form works well for some patients, but not for all. The other two – methadone and buprenorphine (also delivered as Suboxone, a formulation that includes buprenorphine combined with naloxone) – are controlled substances and a form of opiate medication themselves. Methadone is the longstanding gold standard for opiate addiction treatment, but methadone treatment programs are subject to tight licensing, accreditation, and DEA oversight standards. These standards make the establishment of methadone treatment programs in rural and frontier areas economically non-viable. Buprenorphine/Suboxone can be prescribed by DATA 2000 certified physicians, but for several reasons, there are few Suboxone prescribers in rural and frontier areas. In Utah, there are over 400 Suboxone prescribers on the DEA's list, however, many of these are not actively prescribing Suboxone. Of the remainder, many choose not to solicit new Suboxone patients, but only use their certification to prescribe to existing patients in their own practices. There are 506 registered buprenorphine prescribers in Utah and 28 American Board of Addiction Medicine (ABAM)-certified physicians in practice (however, some of these only do pain management). Only 72 Suboxone prescribers can be found on the Suboxone.com website for Utah.

**Here is a real-world example from my practice in Utah:** A patient at one of our rural county-licensed community mental health or addiction treatment centers is in crisis and needs addiction treatment involving a prescription for a controlled substance as part of his/her medication-assisted treatment (MAT). MAT is a highly effective, evidence-based treatment for opioid addiction that combines the use of medication with counseling and mental therapies.

As common with community addiction and mental health treatment centers, my center is staffed with social workers, nurses, counselors and other mental health professionals, including a full time ABAM certified addictionologist. Due to shortages of providers and the rural and frontier nature of most of the rest of the state, many other community addiction and mental health centers do not regularly have DEA-registered doctors or psychiatrists on site who are certified, competent, or willing to prescribe MAT for opiate use disorders.

But thanks to advances in technology, we do have the technical ability to connect the patient to a DEA-registered psychiatrist via telemedicine. The problem is that because my center is county-licensed (not state-licensed, as DEA requires), we are unable to register with DEA such that the Ryan Haight Act's telemedicine exception for "treatment in a hospital or clinic" would apply.

As such, we cannot provide the patient his/her needed care; rather we must wait for a DEA-registered doctor to "go on the road." If we take Bluff, Utah, as an example, it can take up to ten hours round-trip including an overnight stay – to do the required face-to-face physical evaluation of the patient prior to writing the prescription. If Suboxone treatment is indicated, this requires the patient to fill the prescription then return to the office for a medically supervised induction process that takes up to 4 hours. For Dr. Elina Chernyak in my office to provide this service, she must forego seeing up to 48 – 60 of our own patients to see one in the rural setting – if the patient actually keeps the appointment. People in active opiate addiction are often disorganized, physically ill, and cognitively impaired to the point that they may be unable to keep or even remember their appointment.

In the context of the opioid epidemic, the costs of this inefficiency can tragically be measured in lives lost from speedy access to MAT. We can also measure the cost in terms of dollars, as just for my Utah center alone we estimate it costs $490 in travel, lodging, and per diem and $1,400 in physician time to have Dr. Chernyak drive out to the center to do an in-person patient medical evaluation, prescribing, and Suboxone induction. In the winter in Utah, this could easily double or even have to be cancelled for safety reasons depending on road conditions. This is to see perhaps one patient, versus the 48 – 60 that she could see if she stayed in her office in Provo. Continuing care could be conducted via telemedicine procedures.

If the law were changed to permit our clinics to register with DEA, instead of this inefficient and high-cost workaround, we could provide consumers with more responsive, timely access to care. Currently, to evaluate

and initiate Suboxone treatment, Dr. Chernyak must drive often quite lengthy distances for the first face-to-face visit, with continuing patient care and consulting with the clinical staff being done via a secure HIPAA-compliant telehealth platform called Zoom.

In contrast, when Suboxone is prescribed via telemedicine, we would follow a version of Vermont's hub and spoke model. The hub would be our office in Provo where our DEA-certified addiction medicine doctor – Dr. Chernyak – has her full-time office. The spokes could be one or more rural or frontier community MH/SUD health center(s) or federally qualified health center sites. At present we have contracts with Northeastern Counseling Center and Mountainlands Community Health Center in Vernal and Roosevelt, Utah that could serve as the spokes in this model. In addition to counselors and therapists, both these centers employ nursing staff who can monitor patients' first use of the medication (known as "induction") and immediately address any adverse reactions in partnership with the prescribing physician via telemedicine. Having a medical professional in the room with the patient is the standard practice for first-time use, or induction, of Suboxone and is in accordance with national best practices and guidelines established by ASAM. This is the only way we would consider practicing addiction medicine using Suboxone. We would never consider it advisable to see a patient over a non-secure platform such as Facetime when the patient was using the Wi-Fi at Starbucks, for instance.

***National Council Support for Federal Legislation***

The National Council appreciates the efforts this Committee, including Representatives Carter, Harper and Matsui, for putting forward draft legislation that would support the ability of legitimate clinics to register with DEA for purposes of complying with the Ryan Haight Act. Benefits of this approach include:

1. Giving DEA transparency into and jurisdiction over the practices of health care locations not otherwise registered with the DEA under Section 303(f) but which nonetheless have patients on-site that need treatment via telemedicine involving the issuance of a prescription for a controlled substance.
2. Balancing the burden that is placed on the health care provider with a corresponding onus on the center where the patient is located. Providers already must be registered with DEA in order to prescribe controlled substances.
3. Continuing DEA jurisdiction over both parts of the treatment – the provider and the center – which both benefits the Agency's enforcement abilities and is consistent with the Ryan Haight Act's "belt and suspenders" approach of allowing telemedicine treatment in a hospital or clinic registered with the DEA.

As for how to accomplish this goal, we defer to Congressional leaders on the best approach but share some considerations:

1. Section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f) does not capture what community addiction and mental health treatment centers do. These centers typically do not dispense controlled substances and do not conduct research. Accordingly, we fear that the addition of community addiction and mental health treatment centers to Section 303(f) will not solve our problem.
2. As an alternative, Paragraph (54) of section 102 of the Controlled Substances Act (21 U.S.C. 102) could be amended to make clear that legitimate community addiction and mental health treatment centers shall be eligible to register with DEA just like state licensed hospitals and clinics currently can. For example:

*''(i) while the patient is being treated by, and physically located in—*
*''(I) a hospital or clinic registered under section 303(f); or*

*"(II) a community mental health or addiction treatment center registered for purposes of this subparagraph."*

Plus at the end:

"The Attorney General shall register community mental health or addiction treatment facilities that are licensed*, operated, authorized, or otherwise recognized by a State, county, or municipal government for purposes of treatment via the practice of telemedicine as described in subparagraph (A)"*

3. We appreciate the draft Harper/Matsui bill allows centers to use telemedicine to treat patients for all types of addiction and mental health conditions, not just SUD. While the opioid epidemic is the nation's most pressing public health issue and the subject of this hearing, the National Council wishes to emphasize the importance of allowing community addiction and mental health treatment centers to use telemedicine to treat other mental health conditions too, not just SUD. There are two reasons for this:
    a. There is a legitimate public health need to improve access to mental health services generally. According to federal health authorities, there are roughly 4,000 areas nationwide where there is only one psychiatrist for every 30,000 patients. Further, the American Academy of Child and Adolescent Psychiatrists, (AACAP) reports there are approximately 8,300 practicing child and adolescent psychiatrists in the U.S. — and over 15 million youths in need of one. Telemedicine can be part of the solution to this provided shortage, but currently the Ryan Haight Act limits mental health providers' ability to treat mental illness because of restrictions on stimulants that are commonly used in psychiatric treatment for both children and adults.
    b. Many treatment centers provide both addiction and mental health services, and not all states certify, recognize or otherwise authorize addiction and mental health treatment centers in the same way. In some states there are two separate certifications (one for mental health treatment services and another for addiction treatment services), while other states provide a single certification for community providers offering both types of services. Therefore, to be inclusive of the full universe of community providers who offer addiction treatment services, the legislation cannot narrow the scope to simply "addiction" providers as this would exclude many of the organizations who currently provide both addiction and mental health care.
4. We also support the approach outlined in the Carter/Bustos draft, which requires DEA to act swiftly to implement a "special registration" and note that we continue to believe that the patient who is being treated by telemedicine should be located in a DEA-registered facility. It is our hope that such a special process would be inclusive enough to apply to community addiction and mental health treatment clinics, though we fear that if the registration process is implemented too narrowly it could continue to exclude these treatment providers. It is possible that DEA could implement the "special registration" it in a way to still require "state licensure" of hospitals and clinics, or to otherwise draft regulations that would continue to exclude legitimate community addiction and mental health treatment centers from being able to use telemedicine for controlled substance treatment. If that were to occur, centers that are licensed, operated, authorized, or otherwise recognized by a State, county, or municipal government would still be shut out from being able to provide effective health care options to patients in need. The Carter/Bustos draft bill will have the most impact if enacted in conjunction with the Harper/Matsui draft bill that clearly specifies community mental health and addiction providers as a category of centers eligible to register with DEA.
5. We support requiring patients to be treated via telemedicine while located in a DEA-registered location (hospital, clinic, center). The draft Harper-Matsui bill simply makes clear that legitimate community addiction and mental health treatment centers shall be eligible to register with DEA just like hospitals and clinics.

Allowing patients to receive prescriptions for controlled substances via telemedicine outside of a legitimate care setting would erode the Ryan Haight Act and invite rogue online pharmacies posing as telemedicine providers into the market. The National Council worries rogue actors would see this as a market opportunity to offer controlled substances based on a prescription issued via "telemedicine," but instead of providing real patient care, rogue sites would simply sell prescriptions on demand for controlled substances. Such a result is opposite of Congress's intent, of course, and contrary to the Ryan Haight Act itself, but a foreseeable consequence of allowing online prescribing of controlled substances to patients outside of legitimate care settings. As true when the Ryan Haight Act was passed in 2008, illegal online dispensing/prescribing of controlled substances is still a problem today:

a. In February 2018 the National Association of Boards of Pharmacy (NABP) reported that 54% of the online pharmacy websites they surveyed were selling controlled substances. This is a substantial jump from the 13% of all sites NABP has reviewed and listed as "Not Recommended" in the past nine years that were selling controlled substances.

b. The Alliance for Safe Online Pharmacies estimates that there are roughly 30,000 active online drug sellers operating at any one time. If NABP's finding that 54% of sites sell controlled substances holds true for the full online pharmacy market, that would mean more than 15,000 sites offer controlled substances at any one time.

c. The U.S. Senate Permanent Subcommittee on Investigations January 2018 report evidences how easy it is to buy illicit, mail-order opioids online. Investigators for the Subcommittee posed as would-be online buyers, entering terms like "fentanyl for sale" into Google and used payment information to track more than 500 US-linked transactions from these illegal sites.

d. Just last week a group of Senators led by Ryan Haight Act sponsor Senator Feinstein and Judiciary Chairman Senator Grassley sent a letter to Google, Microsoft, Pinterest and Yahoo discuss the rise illegal online sale of controlled substances.

Therefore, the National Council urges Congress to not authorize online prescribing of controlled substances to patients not located in a DEA-registered facility—whether an existing DEA-registered facility or a center registered pursuant to the Harper/Matsui or Carter/Bustos bills—as such risks making the opioid epidemic worse.

***Conclusion***

Thank you again for considering my testimony in support of the draft Harper/Matsui and Carter/Bustos bills that would enable legitimate community addiction and mental health treatment centers to register with DEA to be able to use telemedicine that involves issuance of a prescription for a controlled substance. Changing this law will have immediate and measurable impact on the lives of countless Americans seeking treatment options for mental health conditions and substance use disorder. I appreciate your time and attention to this important public health issue.

***Appendices***

- Appendix A: DEA Registration Form 224, for hospitals and clinics
- Appendix B: Memo from Texas Council of Community Centers describing previous efforts to register community mental health centers with DEA, drafted April 2016

Form-224

# APPLICATION FOR REGISTRATION
## Under the Controlled Substances Act

APPROVED OMB NO 1117-0014
FORM DEA-224 (04-12)
FORM EXPIRES: 01/31/2016

**INSTRUCTIONS**

**Save time - apply on-line at *www.deadiversion.usdoj.gov***

1. To apply by mail complete this application. Keep a copy for your records.
2. Mail this form to the address provided in Section 7 or use enclosed envelope.
3. The "MAIL-TO ADDRESS" can be different than your "PLACE OF BUSINESS" address.
4. If you have any questions call 800-882-9539 prior to submitting your application.

IMPORTANT: DO NOT SEND THIS APPLICATION **AND** APPLY ON-LINE.

DEA OFFICIAL USE :

Do you have other DEA registration numbers?

☐ NO ☐ YES

**MAIL-TO ADDRESS** Please print mailing address changes to the right of the address in this box.

FEE FOR THREE (3) YEARS IS $731
**FEE IS NON-REFUNDABLE**



## SECTION 1 APPLICANT IDENTIFICATION

☐ **Individual Registration** ☐ **Business Registration**

Name 1 (Last Name of individual -OR- Business or Facility Name)

Name 2 (First Name and Middle Name of individual - OR- Continuation of business name)

PLACE OF BUSINESS Street Address Line 1

PLACE OF BUSINESS Address Line 2

City | State | Zip Code

Business Phone Number | Point of Contact

Business Fax Number | Email Address

**DEBT COLLECTION INFORMATION**

Mandatory pursuant to Debt Collection Improvements Act

Social Security Number (***if registration is for individual***)

**Provide SSN or TIN.** See additional information note #3 on page 4.

Tax Identification Number (***if registration is for business***)

**FOR Practitioner or MLP ONLY:**

Professional Degree : *select from list only*

Professional School :

Year of Graduation :

National Provider Identification:

Date of Birth (*MM-DD-YYYY*): M M - D D - Y Y Y Y

## SECTION 2 BUSINESS ACTIVITY

Check one business activity box only

- ☐ Central Fill Pharmacy
- ☐ Retail Pharmacy
- ☐ Nursing Home
- ☐ Automated Dispensing System (ADS)
- ☐ Practitioner (DDS, DMD, DO, DPM, DVM, or MD)
- ☐ Practitioner Military (DDS, DMD, DO, DPM, DVM, or MD)
- ☐ Mid-level Practitioner (MLP) (DOM, HMD, MP, ND, NP, OD, PA, or RPH)
- ☐ Euthanasia Technician
- ☐ Ambulance Service
- ☐ Animal Shelter
- ☐ Hospital/Clinic
- ☐ Teaching Institution

FOR Automated Dispensing System (ADS) ONLY:

DEA Registration # of Retail Pharmacy for this ADS

An ADS is automatically fee-exempt. Skip Section 6 and Section 7 on page 2. You must attach a notorized affidavit.

## SECTION 3 DRUG SCHEDULES

Check all that apply

- ☐ Schedule 2 Narcotic
- ☐ Schedule 2 Non-Narcotic (2N)
- ☐ Schedule 3 Narcotic
- ☐ Schedule 3 Non-Narcotic (3N)
- ☐ Schedule 4
- ☐ Schedule 5

☐ Check this box if you require official order forms - for purchase of schedule 2 controlled substances.

## SECTION 4

**STATE LICENSE(S)**

MANDATORY

Be sure to include both state license numbers

You MUST be currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the **state** or jurisdiction in which you are operating or propose to operate.

State License Number

Expiration Date / / MM - DD - YYYY

What state was this license issued in? _____

State Controlled Substance License Number

Expiration Date / / MM - DD - YYYY

What state was this license issued in? _____

## SECTION 5

**LIABILITY**

**IMPORTANT**

All questions in this section must be answered.

| | YES | NO |
|---|---|---|
| 1. Has the applicant ever been **convicted of a crime** in connection with controlled substance(s) under state or federal law, or been excluded or directed to be excluded from participation in a medicare or state health care program,or is any such action pending? Date(s) of incident MM-DD-YYYY: | ☐ | ☐ |
| 2. Has the applicant ever surrendered (for cause) or had a **federal** controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending? Date(s) of incident MM-DD-YYYY: | ☐ | ☐ |
| 3. Has the applicant ever surrendered (for cause) or had a **state** professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending? Date(s) of incident MM-DD-YYYY: | ☐ | ☐ |
| 4. If the applicant is a **corporation** (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been **convicted of a crime** in connection with controlled substance(s) under state or federal law, or ever surrendered, for cause, or had a **federal** controlled substance registration revoked, suspended, restricted, denied, or ever had a **state** professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation, or is any such action pending? Date(s) of incident MM-DD-YYYY: | ☐ | ☐ |

*Note: If question 4 does not apply to you, be sure to mark 'NO'. It will slow down processing of your application if you leave it blank.*

**EXPLANATION OF "YES" ANSWERS**

Applicants who have answered "YES" to any of the four questions above **must provide a statement to explain each "YES" answer.**

Use this space or attach a separate sheet and return with application

Liability question # _____ Location(s) of incident: _____

Nature of incident:

Disposition of incident:

## SECTION 6 EXEMPTION FROM APPLICATION FEE

☐ Check this box if the applicant is a federal, state, or local government official or institution. Does not apply to contractor-operated institutions.

Business or Facility Name of Fee Exempt Institution. **Be sure to enter the address of this exempt institution in Section 1.**

The undersigned hereby certifies that the applicant named hereon is a federal, state or local government official or institution, and is exempt from payment of the application fee.

**FEE EXEMPT CERTIFIER**

Provide the name and phone number of the certifying official

Signature of certifying official (**other than applicant**) Date

Print or type name and title of certifying official Telephone No. (required for verification)

## SECTION 7

**METHOD OF PAYMENT**

Check one form of payment only

☐ Check Make check payable to: **Drug Enforcement Administration**
See page 4 of instructions for important information.

☐ American Express ☐ Discover ☐ Master Card ☐ Visa

Credit Card Number Expiration Date

Sign if paying by credit card

Signature of Card Holder

Printed Name of Card Holder

*Mail this form with payment to:*

DEA Headquarter
ATTN: Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

**FEE IS NON-REFUNDABLE**

## SECTION 8

**APPLICANT'S SIGNATURE**

Sign in ink

I certify that the foregoing information furnished on this application is true and correct.

**Signature of applicant (sign in ink)** Date

Print or type name and title of applicant

WARNING: 21 USC 843(d), states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to a term of imprisonment of not more than 4 years, and a fine under Title 18 of not more than $250,000, or both.

## SECTION 4

**STATE LICENSE**

You MUST be currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the **state** or jurisdiction in which you are operating or propose to operate.

MANDATORY

State License Number

What state was this license issued in? _____

Expiration Date / / _____
MM - DD - YYYY

## SECTION 5

**LIABILITY**

**IMPORTANT**

All questions in this section must be answered.

| | YES | NO |
|---|---|---|
| 1. Has the applicant ever been **convicted of a crime** in connection with controlled substance(s) under state or federal law, or been excluded or directed to be excluded from participation in a medicare or state health care program,or is any such action pending? | ☐ | ☐ |
| Date(s) of incident MM-DD-YYYY: | | |
| 2. Has the applicant ever surrendered (for cause) or had a **federal** controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending? | ☐ | ☐ |
| Date(s) of incident MM-DD-YYYY: | | |
| 3. Has the applicant ever surrendered (for cause) or had a **state** professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending? | ☐ | ☐ |
| Date(s) of incident MM-DD-YYYY: | | |
| 4. If the applicant is a **corporation** (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been c**onvicted of a crime** in connection with controlled substance(s) under state or federal law, or ever surrendered, for cause, or had a **federal** controlled substance registration revoked, suspended, restricted, denied, or ever had a **state** professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation, or is any such action pending? | ☐ | ☐ |
| Date(s) of incident MM-DD-YYYY: | | |

*Note: If question 4 does not apply to you, be sure to mark 'NO'. It will slow down processing of your application if you leave it blank.*

**EXPLANATION OF "YES" ANSWERS**

Applicants who have answered "YES" to any of the four questions above **must provide a statement to explain each "YES" answer.**

Use this space or attach a separate sheet and return with application

Liability question # _____ Location(s) of incident: _____

Nature of incident:

Disposition of incident:

## SECTION 6 EXEMPTION FROM APPLICATION FEE

☐ Check this box if the applicant is a federal, state, or local government official or institution. Does not apply to contractor-operated institutions.

Business or Facility Name of Fee Exempt Institution. **Be sure to enter the address of this exempt institution in Section 1.**

The undersigned hereby certifies that the applicant named hereon is a federal, state or local government official or institution, and is exempt from payment of the application fee.

**FEE EXEMPT CERTIFIER**

Provide the name and phone number of the certifying official

Signature of certifying official (**other than applicant**) Date

Print or type name and title of certifying official Telephone No. (required for verification)

## SECTION 7

**METHOD OF PAYMENT**

Check one form of payment only

☐ Check Make check payable to: **Drug Enforcement Administration**
See page 4 of instructions for important information.

☐ American Express ☐ Discover ☐ Master Card ☐ Visa

Credit Card Number Expiration Date

Sign if paying by credit card

Signature of Card Holder

Printed Name of Card Holder

*Mail this form with payment to:*

DEA Headquarter
ATTN: Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

**FEE IS NON-REFUNDABLE**

## SECTION 8

**APPLICANT'S SIGNATURE**

Sign in ink

I certify that the foregoing information furnished on this application is true and correct.

**Signature of applicant (sign in ink)** Date

Print or type name and title of applicant

**WARNING: 21 USC 843(d), states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to a term of imprisonment of not more than 4 years, and a fine under Title 18 of not more than $250,000, or both.**

## SECTION 4

**STATE LICENSE(S)**

You MUST be currently authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the **state** or jurisdiction in which you are operating or propose to operate.

MANDATORY

TEM/Salud Numero ____ Expiration Date ___/___/___ MM - DD - YYYY

ASSMCA Numero ____ Expiration Date ___/___/___ MM - DD - YYYY

Colegio de Medicos Numero ____ Expiration Date ___/___/___ MM - DD - YYYY

## SECTION 5

**LIABILITY**

**IMPORTANT**

All questions in this section must be answered.

| | YES | NO |
|---|---|---|
| 1. Has the applicant ever been **convicted of a crime** in connection with controlled substance(s) under state or federal law, or been excluded or directed to be excluded from participation in a medicare or state health care program, or is any such action pending? | ☐ | ☐ |
| Date(s) of incident MM-DD-YYYY: __-__-____ | | |
| 2. Has the applicant ever surrendered (for cause) or had a **federal** controlled substance registration revoked, suspended, restricted, or denied, or is any such action pending? | ☐ | ☐ |
| Date(s) of incident MM-DD-YYYY: __-__-____ | | |
| 3. Has the applicant ever surrendered (for cause) or had a **state** professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending? | ☐ | ☐ |
| Date(s) of incident MM-DD-YYYY: __-__-____ | | |
| 4. If the applicant is a **corporation** (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been c**onvicted of a crime** in connection with controlled substance(s) under state or federal law, or ever surrendered, for cause, or had a **federal** controlled substance registration revoked, suspended, restricted, denied, or ever had a **state** professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation, or is any such action pending? | ☐ | ☐ |
| Date(s) of incident MM-DD-YYYY: __-__-____ | | |

*Note: If question 4 does not apply to you, be sure to mark 'NO'. It will slow down processing of your application if you leave it blank.*

**EXPLANATION OF "YES" ANSWERS**

Applicants who have answered "YES" to any of the four questions above **must provide a statement to explain each "YES" answer.**

Use this space or attach a separate sheet and return with application

Liability question # _____ Location(s) of incident: _____

Nature of incident:

Disposition of incident:

## SECTION 6 EXEMPTION FROM APPLICATION FEE

☐ Check this box if the applicant is a federal, state, or local government official or institution. Does not apply to contractor-operated institutions.

Business or Facility Name of Fee Exempt Institution. **Be sure to enter the address of this exempt institution in Section 1.**

The undersigned hereby certifies that the applicant named hereon is a federal, state or local government official or institution, and is exempt from payment of the application fee.

**FEE EXEMPT CERTIFIER**

Provide the name and phone number of the certifying official

Signature of certifying official (**other than applicant**) _____ Date _____

Print or type name and title of certifying official _____ Telephone No. (required for verification) _____

## SECTION 7

**METHOD OF PAYMENT**

Check one form of payment only

☐ Check Make check payable to: **Drug Enforcement Administration** See page 4 of instructions for important information.

☐ American Express ☐ Discover ☐ Master Card ☐ Visa

Credit Card Number _____ Expiration Date __ - __

Sign if paying by credit card

Signature of Card Holder _____

Printed Name of Card Holder _____

*Mail this form with payment to:*

DEA Headquarters
ATTN: Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

**FEE IS NON-REFUNDABLE**

## SECTION 8

**APPLICANT'S SIGNATURE**

Sign in ink

I certify that the foregoing information furnished on this application is true and correct.

**Signature of applicant (sign in ink)** _____ Date _____

Print or type name and title of applicant _____

WARNING: 21 USC 843(d), states that any person who knowingly or intentionally furnishes false or fraudulent information in the application is subject to a term of imprisonment of not more than 4 years, and a fine under Title 18 of not more than $250,000, or both.

SECTION 1. APPLICANT IDENTIFICATION - Information must be typed or printed in the blocks provided to help reduce data entry errors. A physical address is required in address line 1; a post office box or continuation of address may be entered in address line 2. Fee exempt applicant must list the address of the federal or state fee exempt institution.

Applicant must enter a valid social security number (SSN), or a tax identification number (TIN) if applying as a business entity. *Debt collection information is mandatory pursuant to the Debt Collection Improvement Act of 1996.*

The email address, point of contact, national provider id, date of birth, year graduated, and professional school are new data items that are used to facilitate communication or as required by inter-agency data sharing requirements. They are requested in order to facilitate communication or as required by inter-agency data sharing requirements.

Practitioner must enter one degree from this list: DDS, DMD, DO, DPM, DVM, or MD.
Mid-level practitioner must enter one degree from this list: DOM, HMD, MP, ND, NP, OD, PA, or RPH.

SECTION 2. BUSINESS ACTIVITY - Indicate only one. Practitioner or mid-level practitioner must enter the degree conferred, and are requested to enter the last professional school of matriculation and the year graduated.

Automated dispensing system (ADS) must provide current DEA registration number of parent retail pharmacy or hospital, and attach a notarized affidavit in accordance with 21 CFR Part 1301.17. Affidavit must include:

1. Name of parent retail pharmacy or hospital and complete address
2. Name of Long-term Care (LTC) facility and complete address
3. Permit or license number(s) and date issued of State certification to operate ADS at named LTC facility
4. Required Statement:
   *This affidavit is submitted to obtain a DEA registration number. If any material information is false, the Administrator may commence proceedings to deny the application under section 304 of the Act (21 U.S.C. 8224(a)). Any false or fraudulent material information contained in this affidavit may subject the person signing this affidavit, and the named corporation/partnership/business to prosecution under section 403 of the Act (21 U.S.C 843).*
5. Name of corporation operating the retail pharmacy or hospital
6. Name and title of corporate officer signing affidavit
7. Signature of authorized officer

SECTION 3. DRUG SCHEDULES - Applicant should check all drug schedules to be handled. However, applicant must still comply with state requirements; federal registration does not overrule state restrictions. Check the order form box only if you intend to purchase or to transfer schedule 2 controlled substances. Order forms will be mailed to the registered address following issuance of a Certificate of Registration. The following list of drug codes are examples of controlled substances for narcotic and non-narcotic schedules 2, 3, 4, and 5. Refer to the CFR for a complete list of basic classes.

| SCHEDULE 2 NARCOTIC | BASIC CLASS | SCHEDULE 3 NARCOTIC | BASIC CLASS | SCHEDULE 4 | BASIC CLASS |
|---|---|---|---|---|---|
| Alphaprodine (Nisentil) | 9010 | Buprenorphine (Buprenex, Temgesic, Subutex | 9064 | Alprzolam (Xanax) | 2882 |
| Anileridine (Leritine) | 9020 | Codeine combo product up to 90 mg/du (Empirin) | 9804 | Barbital (Veronal, Plexonal, Barbitone) | 2145 |
| Cocaine (Methyl Benzoylecgonine) | 9041 | Dihydrocodeine combo prod 90 mg/du (Compal) | 9807 | Chloral Hydrate (Noctec) | 2465 |
| Codeine (Morphine methyl ester) | 9050 | Ethylmorphine combo product 15 mg/du | 9808 | Chlordiazepoxide (Librium, Libritabs) | 2744 |
| Dextropropoxyphene (bulk) | 9273 | Hydrocodone combo product (Lorcet, Vicodin) | 9806 | Clorazepate (Tranxene) | 2768 |
| Diphenoxylate | 9170 | Morphine combo product 50 mg/100ml or gm | 9810 | Dextropropoxyphene du (Darvon) | 9278 |
| Diprenorphine (M50-50) | 9058 | Opium combo product 25 mg/du (Paregoric) | 9809 | Diazepam (Valium, Diastat) | 2765 |
| Ethylmorphine (Dionin) | 9190 | SCHEDULE 3 NON-NARCOTIC | BASIC CLASS | Diethylpropion (Tenuate, Tepanil) | 1610 |
| Etorphine Hydrochloride (M-99) | 9059 | Anabolic Steroids | 4000 | Difenoxin 1mg/25ug atropine SO4/du (Motofen) | 9167 |
| Glutethimide (Doriden, Dorimide) | 2550 | Benzphetamine (Didrex, Inapetyl) | 1228 | Fenfluramine (Pondimin, Dexfenfluramine) | 1670 |
| Hydrocodone (Dihydrocodeinone) | 9193 | Butalbital (Fiorinal, Butalbital w/aspirin) | 2100/2165 | Flurazepam (Dalmane) | 2767 |
| Hydromorphone (Dialudid) | 9150 | Dronabinol in sesame oil w/soft gelatin capsule | 7369 | Halazepam (Paxipam) | 2762 |
| Levo-alphacetylmethadol (LAAM) | 9648 | Gamma Hydroxbutyric Acid preps (Zyrem) | 2012 | Lorazepam (Ativan) | 2885 |
| Levorphanol (Levo-Dromoran) | 9220 | Ketamine (Ketaset) | 7285 | Mazindol (Sanorex, Mazanor) | 1605 |
| Meperidine (Demerol, Mepergan) | 9230 | Methyprylon (Noludar) | 2575 | Mebutamate (Capla) | 2800 |
| Methadone (Dolophine, Methadose) | 9250 | Pentobarbital suppository du & noncontrolled active ingred. (FP-3, WANS) | 2271 | Meprobamate (Miltown, Equanil) | 2820 |
| Morphine (MS Contin, Roxanol) | 9300 | Phendimetrazine (Plegine, Bontril, Statobex | 1615 | Methohexital (Brevital | 2264 |
| Opium, powdered | 9639 | Secobarbital suppository du & noncontrolled active ingredients | 2316 | Methylphenobarbital (Mebaral) | 2250 |
| Opium, raw | 9600 | Thiopental (Pentothal) | 2100/2329 | Midazolam (Versed) | 2884 |
| Oxycodone (Oxycontin, Percocet) | 9143 | Vinbarbital (Delvinal) | 2100/2329 | Oxazepam (Serax, Serenid-D)) | 2835 |
| Oxymorphone (Numorphan) | 9652 | | | Paraldehyde (Paral) | 2585 |
| Opium Poppy / Poppy Straw | 9650 | SCHEDULE 5 | BASIC CLASS | Pemoline (Cylert) | 1530 |
| Poppy Straw Concentrate | 9670 | Codeine Cough Preparation (Cosanyl, Pediacof) | 9050 | Pentazocine (Talwin, Talacen) | 9709 |
| Thebaine | 9333 | Difenoxin Preparation (Motofen) | 9167 | Phenobarbital (Luminal, Donnatal) | 2285 |
| SCHEDULE 2 NON-NARCOTIC | BASIC CLASS | Dihydrocodeine Preparation (Cophene-S) | 9120 | Phentermine (Ionamin, Fastin, Zantryl) | 1640 |
| Amobarbital (Amytal, Tuinal) | 2125 | Diphenoxylate Preparation (Lomotil, Logen) | 9170 | Prazepam (Centrax) | 2764 |
| Amphetamine (Dexedrine, Adderall) | 1100 | Ethylmorphine Preparation | 9190 | Quazepam (Doral) | 2881 |
| Methamphetamine (Desoxyn) | 1105 | Opium Preparation (Kapectolin PG) | 9809 | Temazepam (Restoril) | 2925 |
| Methylphenidate (Concerta, Ritalin) | 1724 | | | Triazolam (Halcion) | 2887 |
| Pentobarbital (Nemutal) | 2270 | | | Zolpidem (Ambien, Ivadal, Stilnox) | 2783 |
| Phencyclidine (PCP) | 7471 | | | | |
| Phenmetrazine (Preludin) | 1631 | | | | |
| Phenylacetone | 8501 | | | | |
| Secobarbital (Seconal) | 2315 | | | | |

SECTION 4. STATE LICENSE(S) - Federal registration by DEA is based upon the applicant 's compliance with applicable state and local laws. Applicant should contact the local state licensing authority prior to completing this application. If your state requires a separate controlled substance number, provide that number on this application.

SECTION 5. LIABILITY - Applicant must answer all four questions for the application to be accepted for processing. If you answer "Yes" to a question, provide an explanation in the space provided. If you answer "Yes" to several of the questions, then you must provide a separate explanation describing the date, location, nature, and result of each incident. If additional space is required, you may attach a separate page.

SECTION 6. EXEMPTION APPLICATION FEE - Exemption from payment of application fee is limited to federal, state or local government official or institution. The applicant's superior or agency officer must certify exempt status. The signature, authority title, and telephone number of the certifying official (other than the applicant) must be provided. The address of the fee exempt institution must appear in Section 1.

SECTION 7. METHOD OF PAYMENT - Indicate the desired method of payment. Make checks payable to "Drug Enforcement Administration". Third-party checks or checks drawn on foreign banks will not be accepted. FEES ARE NON-REFUNDABLE.

SECTION 8. APPLICANT'S SIGNATURE - Applicant MUST sign in this section or application will be returned. Card holder signature in section 7 does not fulfill this requirement.

Notice to Registrants Making Payment by Check

*Authorization to Convert Your Check:* If you send us a check to make your payment, your check will be converted into an electronic fund transfer. "Electronic fund transfer" is the term used to refer to the process in which we electronically instruct your financial institution to transfer funds from your account to our account, rather than processing your check. By sending your completed, signed check to us, you authorize us to copy your check and to use the account information from your check to make an electronic fund transfer from your account for the same amount as the check. If the electronic fund transfer cannot be processed for technical reasons, you authorize us to process the copy of your check.

*Insufficient Funds:* The electronic funds transfer from your account will usually occur with 24 hours, which is faster than a check is normally processed. Therefore, make sure there are sufficient funds available in your checking account when you send us your check. If the electronic funds transfer cannot be completed because of insufficient funds, we may try to make the transfer up to two more times.

*Transaction Information:* The electronic fund transfer from your account will be on the account statement you receive from your financial institution. However, the transfer may be in a different place on your statement than the place where your checks normally appear. For example, it may appear under "other withdrawals" or "other transactions." You will not receive your original check back from your financial institution. For security reasons, we will destroy your original check, but we will keep a copy of the check for record-keeping purposes.

*Your Rights:* You should contact your financial institution immediately if you believe that the electronic fund transfer reported on your account statement was not properly authorized or is otherwise incorrect. Consumers have protections under Federal law called the Electronic Fund Transfer Act for an unauthorized or incorrect electronic fund transfer.

ADDITIONAL INFORMATION

No registration will be issued unless a completed application has been received (21 CFR 1301.13).

In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The OMB number for this collection is 1117-0014. Public reporting burden for this collection of information is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information.

The Debt Collection Improvements Act of 1996 (31 U.S.C. §7701) requires that you furnish your Taxpayer Identification Number (TIN) or Social Security Number (SSN) on this application. This number is required for debt collection procedures if your fee is not collectible.

PRIVACY ACT NOTICE: Providing information other than your SSN or TIN is voluntary; however, failure to furnish it will preclude processing of the application. The authorities for collection of this information are §§302 and 303 of the Controlled Substances Act (CSA) (21 U.S.C. §§822 and 823). The principle purpose for which the information will be used is to register applicants pursuant to the CSA. The information may be disclosed to other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes, State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes, and persons registered under the CSA for the purpose of verifying registration. For further guidance regarding how your information may be used or disclosed, and a complete list of the routine uses of this collection, please see the DEA System of Records Notice "Controlled Substances Act Registration Records" (DEA-005), 52 FR 47208, December 11, 1987, as modified.

*Your Local DEA Office*

CONTACT INFORMATION
All offices are listed on web site
(800, 877, and 888 are toll-free)

INTERNET
www.deadiversion.usdoj.gov

TELEPHONE
HQ Call Center (800) 882-9539

WRITTEN INQUIRIES:
DEA
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, VA 22152-2639

Texas Council
of Community Centers

**BACKGROUND HIGHLIGHTS**

On April 15, 2014, the Texas Council was notified of an unfolding DEA issue at one of our Community Mental Health Centers (CMHCs) regarding a determination by a Drug Enforcement Agency (DEA) official that the Center's DEA registered psychiatrist was out of compliance with the Ryan Haight Act (RHA) relating to prescribing controlled substances via tele-medicine. This raised substantial concern not only for the cited CMHC, but for CMHCs across the state, the majority providing tele-psychiatry services.

Several attorneys surrounding the situation determined this DEA determination was a misunderstanding or misinterpretation of the RHA, noting the act exempts prescribing via tele-medicine. However, Texas Council legal counsel ultimately advised Texas CMHCs to accept the DEA determination and move toward resolution.

1. Following multiple communications and a June 24, 2014 meeting in East Texas with representatives from Texas CMHCs, Texas Department of Public Safety (TDPS) and the Drug Enforcement Agency (DEA), agreement was reached that Texas CMHCs should register their clinics with the DEA in order to realize the tele-medicine exemption cited in the RHA.

   NOTE: TDPS had previously determined that Texas CMHCs were exempt from registration requirements due to their governmental status, but in the course of deliberations with CMHCs and the DEA, they came to understand why the registration was necessary due to the negative impact on Texas tele-psychiatry practices as a result of the Ryan Haight Act.

2. As the registering authority in Texas, TDPS agreed to expedite Texas CMHC registrations and instructed the initial Texas CMHCs to register as Hospitals/Clinics on Form 224. On June 30, 2014, the first Texas CMHC submitted the registration as instructed by TDPS (see attached). In July, Mr. Richard Boyd, DEA Registration Section Chief, denied the registration with the stated reason that the "license" number provided on the application was "invalid and therefore DEA determined your application to be defective and is withdrawn. Please resubmit your application once you have the proper state authority".

   NOTE: the Texas Council was not able to obtain from DEA officials (or locate) a regulatory requirement for an entity to be licensed in order to receive DEA registration. In multiple exchanges with Mr. Boyd he referenced the need for evidence of "the state authority" for CMHCs. Texas Council legal counsel provided Mr. Boyd with the statutory authority of Texas CMHCs and advised him that TDPS conveyed this authority to the DEA by registering the Texas CMHCs, but this was not accepted by Mr. Boyd.

3. Another round of communications culminated in a September 9, 2014 meeting in Houston between Texas Council legal counsel, representatives of the Texas Health and Human Service Commission (HHSC), DEA representatives (Mr. Boyd joined by conference call) and other stakeholders impacted by the application of Ryan Haight Act on tele-psychiatry in Texas. From this meeting, Texas Council legal counsel understood the DEA would accept a letter from state officials describing the related authority of Texas CMHCs. Thus began a lengthy endeavor to

obtain a state agency letter describing the authority of Texas CMHCs, an endeavor that began with an educational process with Health and Human Services Commissioner and Department of State Health Services attorneys (who initially believed a registration path could be identified).

4. After several months of dialogue between Texas Council, HHSC officials, HHSC legal counsel (and, we understand, Mr. Boyd), on January 12, 2015 the HHSC Executive Commissioner issued a letter to the DEA describing the statutory authority of Texas CMHCs (see attached).

   Referenced Statute: http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.534.htm#534.001

5. The e-mail exchanges below, between Sonja Gaines, Texas HHSC Associate Commissioner for Mental Health Coordination, and Mr. Boyd, DEA Section Chief, begins with Mr. Boyd's response to the January 12, 2015 letter from Texas HHSC Executive Commissioner. As per this exchange, Mr. Boyd indicates that evidence of the "state authority" for Texas CMHC can only be met if the state puts in writing that Texas CMHCs are hospitals operating without a license (with licensure waived by the state). He would not accept that the Hospital/Clinic category was the closest category TDPS (as the DEA registering authority in Texas) had available in their on-line registration and that Texas CMHCs used this category to apply for registration of their tele-psychiatry clinics at the instruction of TDPS.

6. Although Mr. Boyd contends that he made clear all along that "state authority" meant licensed hospital, others involved in the various communications with Mr. Boyd never understood this was what he required in order to register the Texas CMHCs. This realization by the Texas Council effectively ended the quest for a letter from a state agency that would satisfy Mr. Boyd as the state agencies were clearly not in a legal position to state that Texas CMHCs are operating as "hospitals without licenses". This realization also effectively ended Texas Council hopes that we could register Texas CMHCs under current DEA regulations, as applied by Mr. Boyd.

7. On July 20, 2015 the Texas Council was notified that the DEA issued a notice of intent (excerpted below) to amend registration requirements to permit a special registration for "Practice of Telemedicine".

**Title:** ●Special Registration to Engage in the Practice of Telemedicine

**Abstract:**

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the Act) (Pub. L. 110-425) was enacted on October 15, 2008, and amended the Controlled Substances Act by adding various provisions to prevent the illegal distribution and dispensing of controlled substances by means of the Internet. Among other things, the Act required an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet, except in the case of practitioners engaged in the practice of telemedicine. The definition of the ''practice of telemedicine'' includes seven distinct categories that involve circumstances in which the prescribing practitioner might be unable to satisfy the Act's in-person medical evaluation requirement yet nonetheless has sufficient medical information to prescribe a controlled substance for a legitimate medical purpose in the usual course of professional practice. One specific category within the Act's definition of the ''practice of telemedicine'' includes ''a practitioner who has obtained from the [DEA Administrator] a special registration under [21 U.S.C. 831(h)].'' 21 U.S.C. 802(54)(E). The Act also specifies certain criteria that DEA must consider when evaluating an application for such a registration. However, the Act contemplates that DEA must issue regulations to effectuate this special registration provision. The DEA proposes to amend the registration requirements to permit such a special registration.

# SELECT E-Mail Exchanges

[Texas HHSC Associate Commissioner Sonja Gaines & DEA Section Chief, Richard Boyd]

**From:** Gaines,Sonja (HHSC) [mailto:Sonja.Gaines@hhsc.state.tx.us]
**Sent:** Friday, February 06, 2015 7:30 PM
**To:** Danette Castle <dcastle@txcouncil.com>; Carvan Adkins <cadkins@toase.com>
**Subject:** Fwd: New Pending app W15007375B

Mr. Boyd got back with me. The dialogue is very promising. HHSC attorneys are actively engaged and working through me to get to a resolution. You can see the dialogue about waiving centers as hospitals. That may not be viable - attorneys working on an alternative I can present to Boyd.

More next week!

**SONJA GAINES,MBA| ASSOCIATE COMMISSIONER**
Mental Health Coordination |4900 N. Lamar Blvd. | Austin, Texas 78751
Office: 512.487.3417 Cell: 512-720-2086| sonja.gaines@hhsc.state.tx.us

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**From:** "Gaines,Sonja (HHSC)" <Sonja.Gaines@hhsc.state.tx.us>
**Date:** February 6, 2015 at 11:31:09 AM PST
**To:** "Boyd, Richard A." <Richard.A.Boyd@usdoj.gov>
**Subject: Re: New Pending app W15007375B**

Great-we will work on a communication and hopefully get back with you by next week. Again, thank you so much for your clarification and assistance.

You have been a huge help.

**SONJA GAINES,MBA| ASSOCIATE COMMISSIONER**
Mental Health Coordination |4900 N. Lamar Blvd. | Austin, Texas 78751
Office: 512.487.3417 Cell: 512-720-2086| sonja.gaines@hhsc.state.tx.us

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On Feb 6, 2015, at 11:27 AM, "Boyd, Richard A." <Richard.A.Boyd@usdoj.gov> wrote:

Yes- we would be able to use that letter in lieu of state license for proof that the state understands they will be operating as a DEA registered hospital and the state license is waived.

Richard Boyd
Section Chief
DEA Registration and Program Support

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**From:** Gaines,Sonja (HHSC) [mailto:Sonja.Gaines@hhsc.state.tx.us]
**Sent:** Friday, February 06, 2015 2:24 PM
**To:** Boyd, Richard A.
**Subject:** Re: New Pending app W15007375B

Mr. Boyd,

Thanks so much for your assistance and the clarification.

Dr. Janek is the Executive Commissioner over DSHS as well as other state agencies. Would a communication from Dr.Janek regarding the referenced written waiver a a hospital ,meet the outcome you outlined below?

**SONJA GAINES,MBA| ASSOCIATE COMMISSIONER**
Mental Health Coordination |4900 N. Lamar Blvd. | Austin, Texas 78751
Office: 512.487.3417 Cell: 512-720-2086| sonja.gaines@hhsc.state.tx.us

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On Feb 6, 2015, at 10:53 AM, "Boyd, Richard A." <Richard.A.Boyd@usdoj.gov> wrote:

Ms.Gaines- thank you for your prompt response.

DEA issues a DEA registration predicated upon state authority (21USC 823). For hospitals in TX that requires a DPS license and a license from DSHS and if they have a pharmacy on the premises, than a state license from the BOP.

The Community Centers are attempting to register with DEA without the state licenses as state authorized hospitals in order to conduct telemedicine, which requires, as an exception to the initial face to face dr/patient consultation, for the telemedicine to be conducted in a DEA registered hospital.

This was all explained to them in the Sept video conference we had and DEA even offered that if they get DSHS to provide DEA with written waiver for getting a DSHS license as a hospital, DEA can use that as the state authority. I hope that helps

Richard Boyd
Section Chief
DEA Registration and Program Support

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-----Original Message-----
From: Gaines,Sonja (HHSC) [mailto:Sonja.Gaines@hhsc.state.tx.us]
Sent: Thursday, February 05, 2015 10:00 PM
To: Boyd, Richard A.
Subject: Re: New Pending app W15007375B

Mr. Boyd,

Thank you for your communication. Texas HHSC is committed to working with DEA to solve this registration dilemma. I have no doubt that the Texas Community Centers should be registered with DEA just as they are already registered with the Texas Department of Public Safety. You are correct that they are not hospitals, however, it is my understanding that DPS instructed the community centers to check the hospital box on the DPS form as that is the closest business activity label available on the DPS application.

These Community Centers are in fact governmental entities required by Texas law to treat individuals with severe and persistent mental illness throughout Texas. In their capacity as units of Texas government they do not require any additional state license in order to perform their state mandated tasks. These centers are a critical component of the Texas health care system and they are already registered under Texas law with regard to controlled substances. It is critical that they be registered with the DEA in order to comply with federal law. We just need to figure out how to make that happen.

You stated in your email communication that Commissioner Janek did not mention a waiver from the Texas hospital licensing requirements. As these centers are not required to be licensed as hospitals there is nothing to be waived by HHSC. I am unclear regarding your request for language waiving a requirement that does not exist under Texas law. HHSC is committed to working with DEA toward a viable solution to this registration dilemma, but I need your help in understanding why Commissioner Janek's January 12, 2015 letter was not sufficient for your purposes. Your assistance with what the letter needs to say is appreciated.

Thank you,

SONJA GAINES,MBA| ASSOCIATE COMMISSIONER Mental Health Coordination |4900 N. Lamar Blvd. | Austin, Texas 78751
Office: 512.487.3417 Cell: 512-720-2086| sonja.gaines@hhsc.state.tx.us

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-----Original Message-----
From: Boyd, Richard A. [mailto:Richard.A.Boyd@usdoj.gov]
Sent: Thursday, February 5, 2015 9:59 AM
To: Gaines, Sonja (HHSC)
Cc: Sullivan, Lisa D.; Carter, Ruth A.; Mullins, Robert E.; Giacoppo, Maureen; Adams, Carolyn B.
Subject: FW: New Pending app W15007375B

Ms. Gaines- your name was listed on Dr Janek's letter as the POC for the attached issue. After reading the attached , I believe some pertinent facts were omitted in the discussion surrounding the issuance of a DEA registration for the state MH/MR facilities.

Several MH/MR have submitted DEA applications as a hospital to obtain a DEA registration as a Texas hospital. All of these applications have been denied since there was no state licenses issued to those facilities by the DSHS, DPS and the BOP. All of the 1,378 hospitals in Texas have those licenses, including other state operated facilities.

The federal Controlled Substance Act 21 USC 823 requires that the entity registering with the DEA, for a DEA registration. to obtain state authority before the DEA can issue a registration. Numerous discussions /email have reiterated this requirement to the MH/MR facilities and their attorney. To date these facilities have not properly registered with the Texas authorities to recognize their authority to operate as a hospital under Texas law. Since these facilities have no state licensure, DEA cannot issue a DEA registration for the MH/MR as hospitals.

Dr Janek correctly pointed out that the MH/MR must comply with all applicable laws and regulatory requirements regarding controlled substances. To date MH/MR has failed to comply with both state and federal requirement to obtain a DEA registration. The attached letter contains no waiver of Texas requirements to be licensed as a hospital.

Please let me know if you have any other questions.

Richard Boyd
Section Chief
DEA Registration and Program Support