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Dear DEA representatives:

The American Civil Liberties Union (ACLU) of Nebraska respectfully submits this letter requesting that the United States Drug Enforcement Administration (DEA) investigate the matters set forth herein, and if the alleged violations are borne out by the investigation, to immediately notify the Nebraska State Penitentiary (NSP) that it may not use its current DEA Certificates of Registration issued to the NSP at 4201 South 14th Street, Lincoln, Nebraska (“the 14th Street address”) to administer controlled substances during lethal injection executions and to consider appropriate enforcement action against these registrations including but not limited to issuing an Immediate Suspension Order and Order to Show Cause (ISO/OTSC) pursuant to 21 USC 824(a)(1),(4), 824(d), and 823(f).

The 14th Street address is the location of the facility housing the death chamber where Nebraska intends to carry out lethal injection executions utilizing controlled substances as part of the execution protocol. The Nebraska Department of Correctional Services (NDCS) via Director Scott Frakes issued written notices



on November 9, 2017¹ and January 19, 2018², respectively, that it intends to carry out the executions of Jose Sandoval and Carey Dean Moore using a four-drug cocktail that includes Fentanyl Citrate, a Schedule II controlled substance, and Diazepam, a Schedule IV controlled substance. The executions are to be carried out at the NSP. *See* Neb. Rev. Stat. 83-964; Neb. Admin. Code, Title 69, Ch. 11.002.

The NSP does not possess a DEA COR to administer controlled substances to Mr. Sandoval and Mr. Moore during the lethal injection executions, and it does not meet the statutory and regulatory prerequisites under the Controlled Substances Act, 21 USC 801 *et seq.* (the CSA) and DEA regulations to be issued a COR for this purpose. Instead, the NSP apparently intends to unlawfully use the DEA registration for a purported hospital/clinic at the 14th Street address to administer controlled substances to Mr. Sandoval and Mr. Moore during the executions. As detailed below, that registration only authorizes the NSP to dispense controlled substances to patients of the hospital/clinic for medical treatment purposes, not for the purpose of executing individuals who are not patients of the hospital/clinic.

The ACLU of Nebraska has obtained documentary evidence indicating that the NSP's proposed unlawful dispensing in the pending executions may be the latest of several unlawful acts the NSP has committed in order to obtain controlled substances for lethal injection purposes. The documents indicate that the NSP may have committed repeated violations of the CSA and DEA regulations since 2011, and the latest of which occurred in or around November 2017 when it acquired Fentanyl Citrate using its Importer DEA COR.

If borne out by the DEA's investigation, the NSP's intended and committed violations would demonstrate that the NSP's continued registration is inconsistent with the public interest (21 USC 824(a)(4)), and constitutes "an imminent danger to the public health and safety" (21 USC 824(d)). The NSP's failure to comply with its obligations as a registrant has created a substantial likelihood that death, the executions of Mr. Sandoval and Mr. Moore, will occur in the absence of an immediate suspension of its DEA COR.

¹ Attached hereto as Exhibit 1 is the NDCS Letter to Jose Sandoval dated November 9, 2017 providing notice of substance to be used in execution by lethal injection. Mr. Sandoval currently has a pending habeas corpus action in the District Court of Madison County, Nebraska, Case No. CR02-238. As of the date of this letter, the state has not requested an execution warrant.

² Attached hereto as Exhibit 2 is the NDCS Letter to Carey Dean Moore dated January 19, 2018 providing notice of substance to be used in execution by lethal injection. Mr. Moore's 60 day notice will expire on or about March 21, 2018.



A. Factual Background

The NSP is one of several facilities that comprise the NDCS. The NSP is a state correctional facility located at the 14th Street address that has minimum, medium, and maximum security units housing prisoners aged twenty-one and over who have been sentenced to prison terms of varying lengths. *See* Homepage of NSP website, attached hereto as Exhibit 3. It also is the location where Nebraska carries out lethal injection executions. *See* Title 69, NE Admin. Code, Ch. 11.002. According to the Nebraska Department of Health’s license verification website, there is only one state-licensed health care facility located at the 14th Street address -- the “Nebraska State Penitentiary Hospital & Clinic.” According to the state license for that entity, license No. [REDACTED], it is a “Skilled Nursing Facility” authorized by the state of Nebraska to provide three limited services: physical therapy; respiratory therapy; and behavioral needs. Copies of the NSP’s Skilled Nursing Facility license and the licensure renewal application filed by the NSP on or about January 26, 2018, are attached hereto as Exhibit 4.

DEA has issued the NSP two controlled substances registrations at the 14th Street address: (1) an Importer registration, DEA # [REDACTED], which authorizes the NSP to import Schedule 3N and 4 controlled substances at that address through the expiration date of October 31, 2018; and (2) a “Hospital/Clinic” registration, DEA # [REDACTED], which authorizes the hospital or clinic located at that address (presumably, the Skilled Nursing Facility) to dispense Schedule 2-5 controlled substances through the expiration date of October 31, 2019. Copies of the NSP’s Importer and Hospital/Clinic DEA registrations are attached hereto, respectively, as Exhibits 5 and 6.

Another facility associated with the NDCS is the NDCS Pharmacy (the Pharmacy). It is located at 2620 W. Van Dorn Street, Lincoln, Nebraska, which is approximately four miles from the NSP. The Nebraska Department of Health has issued the Pharmacy a Community Pharmacy License, No. [REDACTED], which expires July 1, 2018. A copy of the Pharmacy’s state license is attached hereto as Exhibit 7.

B. Limits of the NSP’s Current DEA Registrations

As you are aware, DEA registers persons based on the controlled substances activity set forth in the registration application. 21 CFR 1301.13(e). Each activity is placed into one of the “groups of controlled substances activities” which DEA deems “to be independent of each other.” “Dispensing” is its own grouping, distinct from distributing or manufacturing, and includes the activities of, among others, a “Hospital/Clinic.” *Id.* *See also* 21 USC 822(a)(1), (2) (providing for separate registration requirements for manufacturers and distributors as compared to dispensers of controlled substances).



DEA regulations divide those individuals and entities authorized to engage in dispensing activities into two categories: “individual practitioner” and “institutional practitioner.” 21 CFR 1300.01. A hospital or clinic is an institutional practitioner, which is defined to mean “a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, . . .” 21 CFR 1300.01 (Emphasis added). A “dispenser,” according to DEA regulations, includes an “institutional practitioner . . . who dispenses a controlled substance.” *Id.* The NSP’s “Hospital/Clinic” registration, therefore, authorizes the hospital or clinic located at the 14th Street address, presumably the Skilled Nursing Facility, to dispense controlled substances “in the course of professional practice” and in accordance with the license it was issued by the state of Nebraska.

Thus, pursuant to its DEA registration, the Skilled Nursing Facility at the 14th Street address may “dispense” controlled substances to patients of that hospital/clinic. The Hospital/Clinic registration, however, does not authorize the hospital or clinic, or anyone else at that location, to administer controlled substances to individuals who are not patients of the hospital or clinic. The delivery of controlled substances to such individuals, therefore, would be beyond the authority conveyed by the DEA in the NSP’s Hospital/Clinic registration.

The Skilled Nursing Facility’s state license, moreover, effectively limits the NSP’s authority with respect to the dispensing of controlled substances to providing health care treatment to residents in the course of the practice of a medical or health care profession. A “skilled nursing facility” is a facility where medical care, skilled nursing care, rehabilitation, or related services and associated health care treatment are provided for a period of more than twenty-four consecutive hours to persons residing at such facility who are ill, injured, or disabled. 175 Neb. Admin. Code § 12-002 (2018). “Treatment” means a therapy, modality, product, device, or other intervention used to maintain well-being or to diagnose, assess, alleviate, or prevent a disability, injury, illness, disease, or other similar condition. *Id.* The Skilled-Nursing Facility License, therefore, does not authorize the NSP to administer lethal injection drugs to prisoners during executions. Rather, a nursing facility is explicitly required “to provide the necessary care and treatment to permit achievement and maintenance of optimal mental, physical, and psychosocial functional status” and independence in accordance with the comprehensive assessment and plan of care for each resident. 175 Neb. Admin. Code § 12-006.09D (2018) (emphasis added).

Similarly, under Nebraska law, a “Hospital” is defined to mean “a facility where diagnosis, treatment, medical care, obstetrical care, nursing care, or related services are provided . . . to persons who have an illness, injury, or deformity or



to aged or infirm persons requiring or receiving convalescent care.” *See* Neb. Rev. Stat. 71-419. Nebraska law defines a “health clinic” to mean “a facility where advice, counseling, diagnosis, treatment, surgery, care, or services relating to the preservation or maintenance of health” Neb. Rev. Stat. 71-416. As these definitions show, hospitals and health clinics, pursuant to Nebraska law, are facilities where person are to receive diagnosis and/or treatment related to some underlying medical conditions. Prisoners who are to be executed by lethal injection are not being diagnosed or treated, nor are they being provided any other form or medical care. As a result, they are clearly not patients of the Skilled Nursing Facility.

In fact, as discussed above, the Skilled Nursing Facility is only licensed to provide three limited services: physical therapy; respiratory therapy; and behavioral needs. *See* Exhibit 7. Thus, its DEA registration cannot be broadened to allow for the dispensing of controlled substances beyond the three services for which it has been licensed by the state.

Furthermore, the NSP’s Skilled Nursing Facility license does not authorize it to possess controlled substances for lethal injection purposes. Pursuant to Nebraska law, the possession of a controlled substance or prescription drug by a nursing facility is prohibited except as may be ordered by a medical practitioner by prescription for a resident. 175 Neb. Admin. Code § 12-006.12C1 (2018) (emphasis added). As discussed above, a prisoner awaiting an execution is not a “resident” of the Skilled Nursing Facility, and the state’s lethal injection laws do not require a “prescription” prior to the dispensing of controlled substances for execution.³ *See* Neb. Rev. Stat. 83-966(2). Consequently, the administration of controlled substances to these prisoners cannot be accomplished through the use of the NSP’s Hospital/Clinic registration. The NSP’s intention to use its Hospital/Clinic registration to administer controlled substances during lethal injection executions, therefore, constitutes an act for which it is not registered under the CSA/DEA regulations.

C. The NSP Fails to Satisfy the Legal Prerequisites For a DEA Dispenser COR

³ Nor could a Nebraska practitioner lawfully issue a controlled substance prescription under federal law for lethal injection purposes. Pursuant to 21 CFR 1306.04(a), a controlled substance prescription, “to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” As discussed below, Nebraska law states that the prescribing and dispensing of controlled substances for lethal injection purposes does not constitute the practice of medicine or any other health-related profession. *See* Neb. Rev. Stat. 83-966(1).



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As discussed above, pursuant to federal law, the NSP is not authorized to use its Hospital/Clinic registration to administer controlled substances in lethal injection executions, and instead is required to apply for and obtain a separate registration at the 14th Street address for this purpose. *See* 21 USC 822(a)(2) (“[e]very person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him”) (Emphasis added); *see also* 21 CFR 1301.11(a). However, as explained below, DEA cannot issue the NSP a dispenser registration for lethal injection purposes because the administration of controlled substances for lethal injection purposes does not constitute the dispensing of a controlled substance under the CSA/DEA regulations.

The term “dispense” is defined to mean the delivery of a controlled substance “to an ultimate user or research subject by, or pursuant to the lawful order of a practitioner.” 21 USC 802(10) (emphasis added). A “dispenser” is defined to mean “a practitioner who so delivers a controlled substance to an ultimate user or research subject.” *Id.* (emphasis added). A “practitioner” under the CSA includes a hospital or other person who is authorized by federal or state law to dispense and administer “a controlled substance in the course of professional practice or research.” 21 USC 802(21). *See also* 21 CFR 1300.01 (defining an institutional practitioner to include “a hospital or other person (other than an individual)” that is “licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice.” *Id.* (emphasis added).

The NSP is not a dispenser because neither it nor the Skilled Nursing Facility (the hospital or clinic located at the 14th Street address) is engaged in “professional practice” when it administers controlled substances for lethal injection purposes. Nebraska has enacted a law providing that administering lethal injection drugs does not constitute the practice of medicine or any other health-related practice. “Any prescription, preparation, compounding, dispensing, obtaining, or administration of the substances deemed necessary to perform a lethal injection shall not constitute the practice of medicine or any other profession relating to health care which is subject by law to regulation, licensure, or certification.” Neb. Rev. Stat. 83-966 (emphasis added). It is clear, therefore, that under Nebraska law, the administration of controlled substances during lethal injection executions is not “professional practice.” *See Joe W. Morgan, M.D.*, 78 FR 61961, 61964-65 (2013) (defining “professional practice” to mean “[t]he use of one’s knowledge in a particular profession” and “professional activities related to health care and the actual performance of the duties related to the provision of health care”(quoting Definitions.net)). Thus, in accordance with Nebraska law, anyone or any entity who administers controlled substances during lethal injection executions is not a “practitioner” under the CSA and DEA regulations, and is not a “dispenser.” DEA, consequently, cannot issue a dispenser registration for anyone or any entity



in Nebraska to perform lethal injection executions using controlled substances.

D. The NDCS Does Not Qualify For The Law Enforcement Exemption

Every person or entity who handles controlled substances must be registered with DEA or be exempt by regulation from registration. 21 USC 822; 21 CFR 1301.11. DEA's regulations provide for a limited exemption from the registration requirements for (1) law enforcement officials lawfully engaged in the enforcement of any federal laws relating to controlled substances, or (2) any officer or employee of any state, or any political subdivision or agency thereof, who is engaged in the enforcement of any state or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his/her official duties. 21 CFR 1301.24(a). The NDCS/NSP, however, does not qualify for the DEA regulations' law enforcement exemption from the CSA's registration requirements.

As an initial matter, the law enforcement exemption does not apply to an entire state agency or department. Rather, the exemption is for an individual "office or employee" who is engaged in "the enforcement of any state or local laws relating to controlled substances." *See* 21 CFR 1301.24(a). Officers or employees of the NDCS/NSP are not engaged in the enforcement of controlled substances laws in Nebraska. Under Nebraska law, the Division of Drug Control of the Nebraska State Patrol has been vested with "the duty . . . to enforce all of the provisions of the Uniform Controlled Substances Act and any other provisions of the law dealing with controlled substances . . .". Neb. Rev. Stat. 28-249.

Furthermore, NDCS/NSP correctional officers are not law enforcement officers under state law. Nebraska defines a "law enforcement officer" to mean any person who is responsible for the prevention or detection of a crime or the enforcement of the penal, traffic, or highway laws of the state or any political subdivision of the state for more than one hundred hours per year and is authorized by law to make arrests... but law enforcement officer shall not include employees of the Department of Correctional Services, probation officers under the Nebraska Probation System, parole officers appointed by the Parole Administrator..." 79 Neb. Admin. Code § 004.29 (2018) (Emphasis added). Consequently, the NDCS/NSP is not exempt from the requirement to obtain a DEA registration to procure, possess, and dispense controlled substances for carrying out lethal injection executions.

E. The NSP's Potential Unlawful Acquisition of Controlled Substances

Records obtained from the NSP show that on October 12, 2017, approximately two months after DEA completed an inspection of the 14th Street address and the NSP applied to renew its Importer registration, the NSP acquired 25 units of



fentanyl 2ml. A copy of the DEA's August 8, 2017, Inspection report, including DEA's Closing Inventory showing no controlled substances on-hand, is attached hereto as Exhibit 8. A copy of the NSP's September 1, 2017, renewal application is attached hereto as Exhibit 9. A copy of the NSP's October 12, 2017 DEA Perpetual Inventory (the Inventory) is attached hereto as Exhibit 10.

Fentanyl is a Schedule 2 controlled substance. *See* 21 USC 812(c), Schedule II (b)(6). The Inventory lists the NSP's Importer registration number, DEA # [REDACTED] at the top of the form, which indicates that the NSP acquired the fentanyl and has maintained it in stock pursuant to its DEA Importer registration. The NSP's DEA Importer registration, however, does not authorize the NSP to acquire Schedule 2 controlled substances. NSP is only authorized to import Schedule 3N and 4 controlled substances. *See* Exhibit 6 (NSP's current DEA Importer registration). Thus, if the NSP in fact imported the fentanyl, it violated federal law by importing a Schedule 2 controlled substance without a DEA registration to do so.⁴

F. The NSP Potential Material Misrepresentations in Applications to DEA

Upon information and belief, the NSP may have misled the DEA in order to obtain renewals of its Importer registration by falsely representing to the agency that it was licensed in Nebraska as a Community Pharmacy, and, therefore, eligible to obtain a DEA COR. As discussed above, the NSP and the Pharmacy are two different facilities located approximately four miles apart. In its November 2015, September 2016, and September 2017, applications to renew its Importer registration, DEA # [REDACTED], the NSP informed the DEA that it was licensed in Nebraska to handle controlled substances pursuant to state license number [REDACTED]. Copies of these renewals are attached hereto as Exhibit 11. That state license number, however, belongs to the Pharmacy, not the NSP. In fact, the Pharmacy has used that state license number [REDACTED], to apply in 2011 for its own DEA Importer registration. A copy of the Pharmacy's April 15, 2011, application for an Importer registration is attached hereto as Exhibit 12.

The NDCS, thus, may have used the existence of the Pharmacy and the Pharmacy's state license as a ruse to lure DEA into issuing an Importer registration so that the NSP could obtain controlled substances to administer to

⁴ The NSP is concealing from the public from whom it acquired the fentanyl. The ACLU submitted an Open Records request to the NSP seeking the source of this drug, and the NSP refused to provide the ACLU with records relating to this acquisition. There is pending litigation seeking to compel production of the records. *See Miller v. Frakes*, Case. No. CI17-4283, Lancaster County District Court of Nebraska



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prisoners during lethal injection executions, as opposed to acquiring the drugs to provide legitimate health care treatment at a state licensed facility located at the 14th Street address, as claimed on its application.

Moreover, the lethal injection executions for which the NDCS was effectively seeking the registration were not ever going to take place at the Pharmacy location. According to the Nebraska execution protocol, executions are conducted at the NSP. However, the NSP and the Community Pharmacy are distinct facilities overseen by different government departments. The NSP is a correctional facility under the management of the NDCS. The prisoner population includes maximum and medium security prisoners, and the facility includes three housing units with minimum security prisoners. Executions of condemned prisoners by lethal injection are performed at the NSP. 69 Neb. Admin Code §§ 1-10.

In contrast, the Pharmacy is under the management of the Nebraska Department of Administrative Services (NDAS). The license is issued only for the premises (2620 W. Van Dorn Street Lincoln, Nebraska) and persons named in the application. The license is not transferable or assignable. 175 Neb. Admin. Code §§ 8-003 and 8-004; *see also* 21 CFR 1301.52(b). Accordingly, the Pharmacy's authority to handle controlled substances would not extend to the NSP as a matter of law.⁵

The CSA authorizes DEA to revoke a controlled substance registration on a finding that the registrant "has materially falsified any application filed pursuant to" the CSA. 21 USC 824(a)(1). Also, the CSA provides that it is an unlawful act "to furnish false or fraudulent material information in, or omit any material information from, any application" required to be filed with DEA. 21 USC 843(a)(4)(A). DEA has held that "[t]he provision of truthful information on applications is absolutely essential to effectuating [the] statutory purpose" of determining whether the granting of an application is consistent with the public interest. *Peter A. Ahles, M.D.; Revocation of Registration*, 71 FR 50097, 50098 (Aug. 24, 2006); *see also Darby*, 75 FR at 26998. As DEA precedent states, "[s]ince DEA must rely on the truthfulness of information supplied by applicants in registering them to handle controlled substances, falsification cannot be tolerated." *Bobby Watts, M.D.; Revocation of Registration*, 58 FR 46995, 46995 (Sept. 3, 1993).

As detailed above, upon information and belief, the NSP may have provided false

⁵ Incorrect information is not limited to the NSP's Importer registration application. The NSP's application to renew its "Hospital/Clinic" registration erroneously lists a state license number, No. [REDACTED], that, according to the Nebraska Department of Health's license verification website, does not exist. *See* the NSP's September 14, 2016, application to renew its Hospital/Clinic registration, attached hereto as Exhibit 13.



information to the DEA in its renewal applications for the Importer Registration. See *Samuel Arnold, D.D.S.; Reprimand and Continuation of Registration*, 63 FR 8687, 8688 (Feb. 20, 1998). Moreover, the NSP’s alleged misrepresentations in its application would be material.

According to DEA administrative case law precedent:

The Supreme Court has held that “the most common formulation” of the concept of materiality is that “a concealment or misrepresentation is material if it ‘has a natural tendency to influence, or was capable of influencing, the decision of’ the decisionmaking body to which it was addressed.” *Kungys v. United States*, 485 U.S. 759, 770 (1988) (quoting *Weinstock v. United States*, 231 F.2d 699, 701 (D.C. Cir. 1956) (other citation omitted)) (quoted in *Samuel S. Jackson*, 72 FR 23848, 23852 (2007)); see also *United States v. Wells*, 519 U.S. 482, 489 (1997) (quoting *Kungys*, 485 U.S. at 770); *Arthur H. Bell*, 80 FR 50035, 50038 (2015). The Court has further explained that “[i]t has never been the test of materiality that the misrepresentation or concealment would more likely than not have produced an erroneous decision, or even that it would more likely than not have triggered an investigation.” *Kungys*, 485 U.S. at 771 (emphasis added). Rather, the test is “whether the misrepresentation or concealment was predictably capable of affecting, i.e., had a natural tendency to affect, the official decision.” *Id.*⁶

The NSP’s potential false statements in its renewal applications for the Importer registration would be material on the basis that the department intended this information to have a favorable effect on the agency’s decision to grant the registration.

G. Conclusion

As detailed above, it appears that the NDCS/NSP is intending to use the NSP’s existing importer and Hospital/Clinic DEA registrations to unlawfully administer controlled substances in upcoming lethal injection executions at the 14th Street address. This proposed action would contravene the authority granted the NSP by the DEA in those registrations. It also would constitute a violation of federal law, since the NSP is not eligible for a DEA dispenser registration to conduct lethal injection executions because it fails to satisfy the statutory and regulatory prerequisites to obtain such a registration. Additionally, the information obtained by the ACLU of Nebraska indicates that the NDCS/NSP may have misled the DEA about its state licensure status at the 14th Street address, in order to acquire

⁶ *Richard J. Settles, D.O.*, 81 FR 64940, 64946 (2016).



lethal injection drugs.

DEA must set aside the fact that the NDCS/NSP is a state agency and hold them to the same standards as any other DEA registrant. The public must have confidence that DEA is applying the federal controlled substances laws uniformly. The evidence shows that the NDCS/NSP may have previously violated these laws, and may be intending to engage in further violations. Accordingly, pursuant to 21 USC 824(a), (d), 21 USC 823(f), and 21 CFR 1301.36, the ACLU of Nebraska respectfully requests that DEA to further investigate the allegations set forth herein, if necessary, and commence proceedings to immediately notify the NSP that it may not use its current DEA Certificates of Registration to administer controlled substances during lethal injection executions and to consider appropriate enforcement action against these registrations including but not limited to suspending and revoking the NSP's registrations, and to place under seal any and all controlled substances in the NSP's possession that are intended to be used in a lethal injection execution.

A handwritten signature in blue ink, appearing to read "Amy Miller".

Amy A. Miller
Legal Director

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