

Second, the Show Cause Order alleged that on June 25, 2012, Dr. Unger submitted an application to renew his DEA registration. *Id.* The Order alleged that notwithstanding that his New York State dental license had expired on June 30, 2010, Dr. Unger falsely stated that his license did not expire until June 30, 2013. *Id.* The Order thus alleged that this constituted a material falsification of the application and was ground to revoke the registration under 21 U.S.C. 824(a)(1).

Third, the Show Cause Order alleged that notwithstanding his lack of state authority to dispense controlled substances, “between December 2010 and November 2012,” Dr. Unger “issued at least seven controlled substance prescriptions” to L.B. and M.N., for drugs which included hydrocodone 10/325mg, Ambien 10mg, and Percocet 5/325mg. *Id.* The Order further alleged that Dr. Unger violated federal law by authorizing six refills for two of the hydrocodone prescriptions and twelve refills for an Ambien prescription. *Id.* (citing 21 U.S.C. 829(b) and 21 CFR 1306.22(a)). Finally, the Order alleged that Dr. Unger violated federal law which prohibits the refilling of a schedule II prescription when he authorized two refills of a Percocet prescription. *Id.* at 3 (citing 21 U.S.C. 829(a) and 21 CFR 1306.12(a)). The Order thus alleged that Dr. Unger had committed acts rendering his registration “inconsistent with the public interest.” 21 U.S.C. 824(a)(4).

The Show Cause Order also notified Dr. Unger of his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedure for electing either option, and the consequence of failing to elect either option. GX 1, at 3 (citing 21 CFR 1301.43). On March 11, 2014, a DEA Diversion Investigator (DI) personally served the Show Cause Order on Dr. Unger who was then incarcerated at the Rennselaer County Jail. GX 3.

Since the date of service, thirty (30) days have now passed and neither Dr. Unger, nor anyone purporting to represent him, has requested a hearing on the allegations or submitted a written statement in lieu of a hearing. I therefore find that Dr. Unger has waived his right to a hearing or to submit a written statement and issue this Decision and Order based on evidence contained in the Investigative Record submitted by the Government. 21 CFR 1301.43(d) & (e). I make the following findings of fact.

Findings

Dr. Unger was licensed as a dentist by the State of New York between July 16, 1976 and June 30, 2010, at which point

he became unregistered to practice dentistry. GX 4. Dr. Unger remains unregistered by the State as of the date of this order.

Dr. Unger also previously held DEA Certificate of Registration FU1504477, pursuant to which he was authorized to dispense controlled substances as a practitioner in schedules II through V. GX 6. While this registration apparently expired in May 2012, on June 22, 2012, a renewal application was submitted for this registration. *Id.* The application listed Dr. Unger’s former New York State license number and provided an expiration date of June 30, 2013. *Id.* at 2; GX 5, at 1. The application was not, however, signed by Dr. Unger but by a person named “Nathan Green.” GX 5, at 2.

Notably, the Application contains the following statement immediately above the signature line: “Name of Applicant (For Individual registrants, the registrant themselves MUST complete this E-Signature).” *Id.* Moreover, immediately below the E-Signature line, the Application contains the following statement: “This electronic application/DEA form must be certified by the applicant/registant, if an individual” *Id.*

Discussion

Under DEA regulations:

[e]ach application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual. . . . An applicant may authorize one or more individuals, who would not otherwise be authorized to do so, to sign applications for the applicant by filing with the Registration Unit of the Administration a power of attorney for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this paragraph and shall contain the signature of the individual being authorized to sign applications.

21 CFR 1301.13(j).

As found above, Dr. Unger did not sign the application. Moreover, according to the registration records of the Agency (of which I take official notice, *see* 5 U.S.C. 556(e)), Dr. Unger has not submitted a power of attorney designating any person as authorized to sign his application. Accordingly, I find that the June 22, 2012 application was defective and should not have been accepted for filing. I further declare that DEA Certificate of Registration FU1504477 issued to Dr. Glenn R. Unger on June 25, 2012, was void *ab initio* and order that the registration be terminated. *See id.* § 554(e). There being no application to act upon or registration to revoke, I further order that the Order to Show Cause be dismissed.

It is so ordered.

Dated: August 7, 2014.

Thomas M. Harrigan,
Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–396]

Electronic Prescriptions for Controlled Substances Notice of Approved Certification Process

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice.

SUMMARY: The Drug Enforcement Administration (DEA) is announcing one new DEA-approved certification process for providers of Electronic Prescriptions for Controlled Substances (EPCS) applications. Certifying organizations with a certification process approved pursuant to 21 CFR 1311.300(e) are posted on DEA’s Web site upon approval.

FOR FURTHER INFORMATION CONTACT:

Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or the “CSA” for the purpose of this notice. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

The CSA and DEA’s implementing regulations establish the legal

requirements for possessing and dispensing controlled substances, including the issuance of a prescription for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 CFR 1306.04(a). A prescription serves as a record of the practitioner's determination of the legitimate medical need for the drug to be dispensed. The prescription also provides a record of the actual dispensing of the controlled substance to the ultimate user (the patient) and, therefore, is critical to documenting that controlled substances held by a pharmacy have been dispensed. The maintenance of complete and accurate records is an essential part of the closed system of distribution established by Congress.

Electronic Prescriptions for Controlled Substances

Historically, where federal law required that a prescription for a controlled substance be issued in writing, that requirement could only be satisfied through the issuance of a paper prescription. Given advancements in technology and security capabilities for electronic applications, DEA amended its regulations to provide practitioners with the option of issuing electronic prescriptions for controlled substances in lieu of paper prescriptions. DEA's Interim Final Rule for Electronic Prescriptions for Controlled Substances was published on March 31, 2010, at 75 FR 16236–16319, and became effective on June 1, 2010.

Update

Certifying Organization With a Certification Process Approved by DEA Pursuant to 21 CFR 1311.300(e)

The Interim Final Rule and the DEA's Electronic Prescriptions for Controlled Substances Clarification (76 FR 64813) provides that, as an alternative to the third-party audit requirements of 21 CFR 1311.300(a) through (d), an electronic prescription or pharmacy application may be verified and certified as meeting the requirements of 21 CFR part 1311 by a certifying organization whose certification process has been approved by DEA. The preamble to the Interim Final Rule further indicated that, once a certifying organization's certification process has been approved by DEA in accordance with 21 CFR 1311.300(e), such

information will be posted on DEA's Web site. 75 FR 16243 (March 31, 2010). On July 25, 2014, DEA approved the certification process developed by ComplySmart, LLC. Relevant information has been posted on DEA's Web site at <http://www.DEAdiversion.usdoj.gov>.

Dated: August 11, 2014.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: United States Pharmacopeial Convention

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.34(a) on or before September 19, 2014. Such persons may also file a written request for a hearing on the application pursuant to 21 CFR 1301.43 on or before September 19, 2014.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of importers, of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control ("Deputy Assistant Administrator") pursuant to section 7 of 28 CFR pt. 0, subpt. R, App.

In accordance with 21 CFR 1301.34(a), this is notice that on February 10, 2014, United States Pharmacopeial Convention, 12601 Twinbrook Parkway, Rockville, Maryland 20852, applied to be

registered as an importer of the following basic classes of controlled substances:

Controlled substance	Schedule
Cathinone (1235)	I
Methaqualone (2565)	I
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
4-Methyl-2,5-dimethoxyamphetamine (7395).	I
3,4-Methylenedioxyamphetamine (7400).	I
Codeine-N-oxide (9053)	I
Difenoxin (9168)	I
Heroin (9200)	I
Morphine-N-oxide (9307)	I
Norlevorphanol (9634)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Phenmetrazine (1631)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Secobarbital (2315)	II
Glutethimide (2550)	II
Phencyclidine (7471)	II
4-Anilino-N-phenethyl-4-piperidine (8333).	II
Phenylacetone (8501)	II
Alphaprodine (9010)	II
Anileridine (9020)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Hydrocodone (9193)	II
Levomethorphan (9210)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Thebaine (9333)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Sufentanil (9740)	II

The company plans to import reference standards for sale to researchers and analytical labs.

The company plans to import the listed controlled substances in bulk powder form from foreign sources for the manufacture of analytical reference standards for sale to their customers.

Dated: August 11, 2014.

Joseph T. Rannazzisi,
Deputy Assistant Administrator.

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