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RULE ADOPTIONS
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS

Readoption with Amendments: N.J.A.C. 8:65
Adopted Repeal and New Rule: N.J.A.C. 8:65-10.1
Adopted Repeals: N.J.A.C. 8:65-10.2 through 8:65-10.5

Controlled Dangerous Substances

Proposed: September 17, 2007 at 39 N.J.R. 3854(a).
Adopted: January 22, 2008 by Lawrence DeMarzo, Acting Director, Division of Consumer Affairs.
Filed: February 15, 2008 as R.2008 d.58, without change.
Authority: N.J.S.A. 24:21-3 and 24:21-9; P.L. 2007, c. 244.
Effective Date: February 15, 2008, Readoption;
March 17, 2008, Amendments, Repeals and New Rules.

Expiration Date: February 15, 2013.

The Department of Health and Senior Services (the Department), proposed the readoption of the rules in N.J.A.C. 8:65, concerning the registration of manufacturers, distributors and dispensers of controlled dangerous substances, as well as amendments and repeals of certain rules in the chapter, and new rule N.J.A.C. 8:65-10.1, in accordance with the authority then established under the "New Jersey Controlled Dangerous Substances Act," (the Act), N.J.S.A. 24:21-1 et seq. The Commissioner of the Department was authorized to administer the Act, including the authority to promulgate rules. Under a Memorandum of Understanding (MOU) between the Commissioner and the State Attorney General, the Division of Consumer Affairs in the Department of Law and Public Safety performed the administrative and technical functions connected with the registration of manufacturers, distributors and dispensers of controlled substances, and the Attorney General was responsible for coordinating the enforcement provisions of the Act.

Consistent with the MOU, the Department of Law and Public Safety, through the Division of Consumer Affairs, was involved in the review of the rules proposed for readoption, the proposed amendments and repeals and the proposed new rule prior to publication of the notice of proposal that appeared in the New Jersey Register on September 17, 2007, at 39 N.J.R. 3854(a). The Department shared with the Division the comment received on the notice, which is discussed below, in anticipation of the Department's adoption of the notice of proposal. On January 4, 2008, P.L. 2007, c. 244 was signed into law, transferring all authority to administer and enforce the provisions of the Act to the Director of the Division of Consumer Affairs, specifically the authority in N.J.S.A. 24:21-9 to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances within the State. Consequently, the authority to readopt the rules promulgated pursuant to the Act no longer resides with the Department of Health and Senior Services, but with the Division of Consumer Affairs. Therefore, the Acting Director of the Division of Consumer Affairs is readopting the rules in N.J.A.C. 8:65, the amendments, repeals and new rule. The Division notes that section 32 of P.L. 2007, c. 244 provides that all rules concerning the implementation of the New Jersey Controlled Dangerous Substances Act promulgated by the Department of Health and Senior Services prior to January 4, 2008, shall continue with full force and effect until amended or repealed by the Division of Consumer Affairs. The Division of Consumer Affairs will file a notice of administrative correction in the future to recodify the rules in N.J.A.C. 8:65 to Title 13 of the New Jersey Administrative Code, along with attendant technical changes to the text of the rules concerning cross-references, agency names and addresses, and the elimination of any rule provisions rendered redundant by the transfer of authority to the Division pursuant to P.L. 2007, c. 244.

Federal Standards Analysis

The readopted rules and adopted amendments, repeals and new rule meet the Federal standards for manufacturers, distributors and dispensers of controlled substances in most instances, with the exceptions set forth below. Manufacturers, distributors and dispensers of controlled substances must register with both the DEA, as required by the Federal Controlled Substances Act, 21 U.S.C. ßß801 et seq., (CSA), and with the Division, as required by the Act. The Federal registration requirements are contained at 21 CFR Part 1300 to 1399, while New Jersey's requirements are contained in N.J.A.C. 8:65. Therefore, manufacturers, distributors and dispensers of controlled substances in this State must comply with a dual system of registration.

Chapter 65 imposes the same inventory and recordkeeping requirements upon manufacturers and distributors that are imposed by the DEA, even though, unlike the Federal requirements, Chapter 65 does not subdivide manufacturers and distributors into separate categories of importer and exporter for purposes of registration.

N.J.A.C. 8:65-5.3(b) and (c) exceed the Federal requirements. The Federal rules permit doctors to prescribe or administer controlled substances in the course of their professional practice without keeping records. 21 CFR 1304.03(b)(c). N.J.A.C. 8:65-5.3(b) does not require practitioners to maintain records of the controlled substances they prescribe in the lawful course of their professional practice. But N.J.A.C. 8:65-5.3(b) and (c) do require that practitioners keep records of any controlled substances they administer or dispense. This requirement is needed to assure that all controlled substances are dispensed and accounted for properly. The Division does not believe that the manner in which a CDS is dispensed or administered lessens the need for recordkeeping.

N.J.A.C. 8:65-7.5(a) requires that prescriptions be filled within 30 days. This is not required by the Federal rules. This requirement is necessary to carefully monitor the progress of those individuals taking a controlled substance. The Division believes that this requirement is necessary to protect those using a controlled substance, and to avoid any potential for abuse of the controlled substance.

Adopted new rule N.J.A.C. 8:65-10.1(d) and (e) would require that Gamma Butyrolactone (GBL) and 1,4 Butanediol be designated as Schedule I substances even though they are not designated as Schedule I substances under Federal law. The Division believes that GBL and 1,4 Butanediol should be regulated as Schedule I substances because they can be used to produce the same effect as the date-rape drug Gamma hydroxybutyric acid (GHB). There are no other standards that exceed the Federal standards. The costs incurred by registrants as a result of the requirement that they maintain records for the controlled substances they administer derive from a CDS registrant's recordkeeping, and some of these costs may be passed to the patient or payor. The Division believes that any costs imposed on patients or payors because of the 30-day rule are outweighed by the need to prevent the abuse of controlled substances. The Division believes that the maintenance of public health through these more stringent New Jersey requirements is a benefit that outweighs the relatively minor additional costs incurred.

In addition, the adopted amendments regarding electronic orders and reverse distributors, and the addition and rescheduling of controlled substances would impose the same standards and requirements imposed by the Federal rules. Therefore, a Federal standards analysis is not required for these adopted amendments, repeals and new section.

Full text of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 8:65.

Full text of the adopted amendments and new rule follows:

SUBCHAPTER 1. GENERAL PROVISIONS; REGISTRATION

8:65-1.1 Registration fees

(a) (No change.)

(b) Distributors and reverse distributors of controlled dangerous substances shall pay an annual fee of $ 100.00 at the time of application for registration or for renewal of registration.

(c)-(g) (No change.)

8:65-1.1A Definitions

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise:

"Reverse distributor" means a person who receives controlled dangerous substances acquired from another person registered under this chapter for the purpose of:

1. Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or

2. Where necessary, processing such substances or arranging for processing such substances for disposal.

8:65-1.2 Registration requirements

(a) (No change.)

(b) Every person who distributes or proposes to distribute a controlled dangerous substance or substances, or who acts or proposes to act as a reverse distributor of a controlled dangerous substance or substances, unless specifically exempted by statute or specifically waived by the Commissioner, shall obtain a registration and shall obtain a renewal of the registration every year thereafter.

(c)-(e) (No change.)

(f) A separate application shall be made and a separate registration obtained for each place of business or professional practice, where the applicant manufactures, distributes, acts as a reverse distributor or dispenses controlled dangerous substances. A separate application shall be made and a separate registration obtained for each separate and distinct business entity, affiliated corporation, or subsidiary corporation that engages in such activities, but a single entity doing business at one location under more than one business name or trade name may obtain a single registration provided that all such business names or trade names are stated in the application.

(g)-(l) (No change.)

8:65-1.3 Activities requiring registration

(a) Registration under N.J.A.C. 8:65-1.2(a) or (b) shall be issued to authorize the registrant to manufacture, distribute or act as a reverse distributor of, respectively, specific controlled dangerous substances included in Schedule I or Schedule II, or to authorize the registrant to manufacture, distribute or act as a reverse distributor of, respectively, the controlled dangerous substances included in Schedules III, IV, or V. Any registrant authorized to manufacture, distribute or act as a reverse distributor of substances included in Schedules III, IV, or V may manufacture, distribute or act as a reverse distributor of, respectively, any controlled dangerous substance listed in the Schedule or Schedules for which he is registered.

(b) A person desiring to obtain a registration under N.J.A.C. 8:65-1.2(a) or (b) shall specify the controlled dangerous substances or the Schedules for which he wishes to obtain a registration in his application and may manufacture, distribute or act as a reverse distributor of, only those controlled dangerous substances authorized in his registration.

(c)-(g) (No change.)

(h) For purposes of registration, the following activities by a registrant shall not be deemed to require an additional registration for a separate location:

1. An office used by a registered manufacturer, distributor or reverse distributor or his agents or employees to solicit or make sales of controlled dangerous substances, provided that no such substances are contained in or distributed from such office.

2. (No change.)

(i) (No change.)

8:65-5.4 Maintenance of records and inventories

(a) (No change.)

(b) Each registered manufacturer, distributor, reverse distributor, importer, and exporter shall maintain inventories and records and controlled substances as follows:

1.-2. (No change.)

(c)-(e) (No change.)

8:65-5.10 Inventories of distributors

Except for reverse distributors subject to N.J.A.C. 8:65-5.11(a), each person registered or authorized under 21 U.S.C. ß823(b) or N.J.A.C. 8:65-1.3(a) to distribute controlled substances shall include in his inventory the same information required of manufacturers pursuant to N.J.A.C. 8:65-5.9(a)3 and 4.

8:65-5.11 Inventories of dispensers, researchers and reverse distributors

(a) Each person registered or authorized under 21 U.S.C. ß823(f) or N.J.A.C. 8:65-1.3(d) to dispense, conduct research or act as a reverse distributor with controlled substances and required to keep records pursuant to N.J.A.C. 8:65-5.3, shall include in his or her inventory the same information required of manufacturers pursuant to N.J.A.C. 8:65-5.9(a)3 and 4. In determining the number of units of each finished form of a controlled substance in a commercial container, which has been opened, the dispenser or reverse distributor shall do as follows:

1.-2. (No change.)

(b) (No change.)

8:65-5.16 Records for distributors and reverse distributors

(a) (No change.)

(b) Each person registered under this chapter to distribute controlled substances as a reverse distributor shall maintain records with the following information for each controlled substance:

1. For each controlled substance in bulk form, the following:

i. The name of the substance;

ii. The total quantity of the controlled substance to the nearest metric unit weight consistent with unit size;

iii. The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the controlled substance was received;

iv. The quantity returned to the original manufacturer of the controlled substance or the manufacturer's agent, including the date of and quantity of each distribution and the name, address and registration number of the manufacturer or manufacturer's agent to whom the controlled substance was distributed; and

v. The quantity disposed of including the date and manner of disposal and the signatures of two responsible employees of the registrant who witnessed the disposal; and

2. For each controlled substance in finished form, the following:

i. The name of the substance;

ii. Each finished form (for example, 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume or finished form in each commercial container (for example, 100-tablet bottle or three-milliliter vial);

iii. The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and registration number of the person from whom the containers were received;

iv. The number of commercial containers of each finished form distributed back to the original manufacturer of the substance or the manufacturer's agent, including the date of and number of containers in each distribution and the name, address, and registration number of the manufacturer or manufacturer's agent to whom the containers were distributed; and

v. The number of units or volume of finished forms and/or commercial containers disposed of including the date and manner of disposal, the quantity of the substance in finished form disposed, and the signatures of two responsible employees of the registrant who witnessed the disposal.

8:65-5.22 Reports of distributors, reverse distributors and exporters

(a) Every registered distributor and reverse distributor except any officer or agency of the Veteran's Administration or who or which is exempted from registration pursuant to 21 U.S.C. 822(c) and N.J.A.C. 8:65-1.3 and registered exporter shall submit a monthly report on D.E.A. Form 333 and its supplement accounting for all transactions involving narcotic controlled substances listed in Schedules I and II, including all receipts (D.E.A. Form 333) and dispositions (D.E.A. Form 333). The report shall be submitted to the Distribution Audit Branch, Department of Justice, Drug Enforcement Administration, Washington, DC 25037, on or before the 15th day of the month succeeding that for which the return is submitted.

(b) All narcotic controlled substances listed in Schedules I and II received by a distributor, reverse distributor or exporter shall be recorded on D.E.A. Form 333 in order and at the time of receipt. Where a record of D.E.A. Form 333, such form cannot, for any good and sufficient reason, be made immediately, the distributor or exporter shall have available for inspection such invoices, delivery or duplicate sales slips, or other papers or records as may be required to evidence any unrecorded purchase or receipt.

(c) (No change.)

(d) Each distributor, reverse distributor and exporter shall submit, as part of his December 31 month report on D.E.A. Form 333 and its supplements, any inventory on D.E.A. Form 333 of the narcotic controlled substances listed in Schedules I and II, which are in his possession on December 31 of each year. A separate entry shall be made for each narcotic substance as follows:

1.-3. (No change.)

(e) The distributor, reverse distributor and exporter shall report on D.E.A. Form 333 complete summary of transactions for the month.

SUBCHAPTER 6. ORDER FORMS

8:65-6.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the contents clearly indicate otherwise:

"Digital signature" means a digital signature as defined in 21 CFR 1311.02 and which is issued by the D.E.A. or the

D.E.A. certification authority.

"Electronic order" means an order signed with a digital signature and which complies with the requirements of Subpart C of 21 CFR Part 1305 (21 CFR 1305.21 through 1305.29) and Subparts A and B of 21 CFR Part 1311 (21 CFR 1311.01 through 1311.08 and 1311.10 through 1311.65), which are incorporated herein by reference as amended and supplemented.

8:65-6.3 Distribution requiring order forms; electronic orders

(a) An order form (DEA Form 222c) or an electronic order is required for each distribution of a controlled substance listed in Schedule I or II, except for the following:

1.-5. (No change.)

8:65-6.4 Persons entitled to obtain and execute order forms and to obtain digital signatures and execute electronic orders

(a)-(b) (No change.)

(c) Digital signatures may be obtained from the D.E.A. or the D.E.A. certification authority and shall be used in accordance with the provisions of Subparts A and B of 21 CFR Part 1311 (21 CFR 1311.01 through 1311.08 and 1311.10 through 1311.65), incorporated herein by reference, as amended and supplemented, and electronic orders may be used in accordance with the provisions of this chapter and Subpart C of 21 CFR Part 1305 (21 CFR 1305.21 through 1305.29), incorporated herein by reference, as amended and supplemented.

8:65-6.7 Power of attorney

(a) Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms, or to execute electronic orders, on his or her behalf by filing a power of attorney with records of the registrant.

(b)-(d) (No change.)

8:65-6.8 Persons entitled to fill order forms

(a) An order form or an electronic order for a Schedule I or II controlled dangerous substance may be filled only by a person registered as a manufacturer or distributor of controlled substances listed in Schedules I or II under 21 U.S.C. ß823 or as an importer of such substances under 21 U.S.C. ß958, except for the following:

1. A person registered to dispense such substances under 21 U.S.C. ß823, or to export such substances under 21 U.S.C. ß958, if he is discontinuing business or if his registration is expiring without reregistration may dispose of any controlled substances listed in Schedule I or II in his possession pursuant to order forms or an electronic order in accordance with N.J.A.C. 8:65-8.7;

2. A person who has obtained any controlled substance in Schedule I or II by order form or electronic order may return such substance, or portion thereof, to the person from whom he obtained the substance or the manufacturer of the substance, or to a registered reverse distributor pursuant to the order form or electronic order of the latter person; and

3. (No change.)

4. A person registered as a compounder of narcotic substances for use at off-site locations in conjunction with a narcotic treatment program at the compounding location, who is authorized to handle Schedule II narcotics, is authorized to fill order forms or electronic orders for distribution of narcotic drugs to off-site narcotic treatment programs only.

8:65-6.16 Special procedure for filling certain order forms

(a) (No change.)

(b) The supplier, upon determining that the purchaser is a veterinarian engaged in zoo and exotic animal practice, wildlife management programs and/or research and authorized by the D.E.A. to handle these substances, shall fill the order in accordance with the procedures set forth in 21 CFR 1305.13 except that:

1. Order forms or electronic orders for carfentanil, etorphine hydrochloride and diprenorphine shall only contain these substances in reasonable quantities; and

2. The substances shall only be shipped to the purchaser at the location printed by the D.E.A. upon such order forms or as specified in the electronic order under secure conditions using substantial packaging material with no markings on the outside, which would indicate the content.

8:65-8.4 Distribution by dispenser to another practitioner or reverse distributor

(a) A practitioner who is registered to dispense controlled substances may distribute (without being registered to distribute) a quantity of such substance to another practitioner for the purpose of general dispensing by the practitioner to his or her patients, or to a reverse distributor; provided, that:

1.-2. (No change.)

3. If the substance is listed in schedule I or II, an order form or electronic order is used as required in N.J.A.C. 8:65-6;

4. The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section during the 12-month period in which the practitioner is registered to dispense does not exceed five percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the 12-month period; and

5. The reverse distributor is registered to receive such substances.

(b) (No change.)

8:65-8.6 Distribution to supplier

(a) Any person lawfully in possession of a controlled substance listed in any Schedule may distribute (without being registered to distribute) that substance to the person from whom he or she obtained it or to the manufacturer of the substance, or, if designated, to the manufacturer's registered agent for accepting returns, provided that a written record is maintained, which indicates the date of transaction, the name, form and quantity of the substance, the name, address, and registration number, if known, of the supplier or manufacturer.

(b) In the case of returning a controlled substance listed in Schedule I or II, an order form shall be used in the manner prescribed in Part 305 of the Act and N.J.A.C. 8:65-6 and be maintained as the written record of the transaction. An electronic order may also be used to return a Schedule I or II controlled substance in accordance with this chapter and 21 CFR 1305.05. Any person not required to register pursuant to 21 U.S.C. ßß822(c), 957(b)1 or N.J.A.C. 8:65-1.3 shall be exempt from maintaining the records required by this section.

8:65-8.7 Distribution upon discontinuance or transfer of business

(a) Any registrant desiring to discontinue or transfer business activities altogether or with respect to controlled substances shall return his Federal Certificate of Registration, and any unexecuted order forms in his possession to the Drug Control Unit, as well as the State Certificate of Registration for cancellation. Any controlled substances in his possession may be disposed of in accordance with 21 CFR 1307.21 or N.J.A.C. 8:65-8.10 or by transfer to another registrant. If the registrant desires to transfer the substances to another registrant, he or she shall take an inventory, together with his or her name, address, and registration number, and the name, address, and registration number of the

proposed transferee and send them to the Special Agent in Charge of the District Office of the Drug Enforcement Administration in the region in which he is doing business at least 15 days in advance of the date of the proposed transfer. If the Special Agent in Charge does not notify the registrant that the transfer should be postponed or cancelled, the registrant may transfer the substances to the named transferee without being registered as a distributor. All controlled substances listed in Schedule I or II must be transferred pursuant to an order form in accordance with 21 U.S.C. ß828 and 21 CFR Part 1305 or N.J.A.C. 8:65-6. An electronic order may also be used to transfer a Schedule I or II controlled substance pursuant to this section, so long as such use of an electronic order is permitted by the D.E.A. Schedule III, IV and V substances will be transferred in accordance to the inventory prepared by the registrant and submitted to the Special Agent in Charge. If the Special Agent in Charge denies the registrant authority to make the proposed transfer, the registrant shall either dispose of the substances in accordance with N.J.A.C. 8:65-8.10 or transfer the substances to another registrant in accordance with this section and/or instructions of the Special Agent in Charge.

(b)-(c) (No change.)

8:65-8.8 Distribution to ocean vessels or aircraft

(a) Any registrant lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to a medical officer, master or first officer, of any ocean vessel engaged in international trade or in trade between points of the United States and any merchant vessel belonging to the United States Government; or to any aircraft operated by a carrier under a certificate of permit issued pursuant to the Federal Aviation Act of 1958 (49 U.S.C. ßß40101 - 49105) provided that:

1.-4. (No change.)

8:65-10.1 Schedules of controlled dangerous substances

(a) The Federal controlled dangerous substance Schedules I, II, III, IV and V at 21 CFR 1308.11 through 1308.15, as amended and supplemented, promulgated by the United States Attorney General pursuant to 21 U.S.C. ßß811 and 812, are incorporated herein by reference.

(b) Any reference in this chapter to controlled dangerous substance Schedules I, II, III, IV and V shall mean the Federal schedules promulgated at 21 CFR 1308.11 through 1308.15 and incorporated by reference pursuant to (a) above, unless the Commissioner objects to the inclusion, rescheduling or deletion of a substance in accordance with the provisions of N.J.S.A. 24:21-3 and N.J.A.C. 8:65-1.7.

(c) Any substance designated as an immediate precursor by the United States Attorney General pursuant to 21 U.S.C. ß811(e), or designated a controlled dangerous substance by temporary order issued by the United States Attorney General in accordance with and subject to the provisions of 21 U.S.C. ß811(d) or (h), as amended and supplemented, shall be subject to regulation under this chapter.

(d) Notwithstanding the provisions of (b) above, any substance that is an immediate precursor or that, when ingested, is metabolized or otherwise becomes a controlled dangerous substance, may be designated by the Commissioner as a controlled dangerous substance.

(e) In accordance with (d) above, the following substances shall be designated and controlled as Schedule I controlled dangerous substances:

1. Gamma Butyrolactone

2. 1,4 Butanediol

8:65-10.2 through 10.5 (Reserved)

8:65-11.7 Drugs used for treatment of narcotic addicts

The United States Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) regulations at 42 CFR Part 8, Treatment of opioid dependence with opioid medications, are incorporated herein by reference. All addiction treatment programs in New Jersey providing drugs used for treatment of narcotic addicts shall comply with these regulations and all the supplements and amendments thereto incorporated herein by reference.