SUBCHAPTER 27. NEW JERSEY UNIFORM PRESCRIPTION BLANKS PROGRAM

13:45A-27.1 Purpose and scope

(a) The rules in this subchapter implement the provisions of P.L. 1996, c.154, the Uniform Prescription Blanks Act, supplementing N.J.S.A. 45:14-1 et seq., an act regulating the practice of pharmacy in the State of New Jersey.

(b) The rules of this subchapter shall apply to the following:

1. All licensed healthcare practitioners authorized to write prescriptions for controlled dangerous substances, legend drugs or other items;

2. All healthcare facilities licensed pursuant to N.J.S.A. 26:2H-1 et seq., that are authorized to issue prescription blanks;

3. All licensed pharmacies which fill prescriptions or medication orders pursuant to N.J.A.C. 13:39; and

4. All vendors authorized to manufacture and distribute New Jersey Prescription Blanks pursuant to N.J.A.C. 13:45A-27.7.

13:45A-27.2 Definitions

As used in this subchapter, the following words and terms have the following meanings unless the context clearly indicates otherwise:

"Address of record" means an address designated by a licensed prescriber which is part of the public record and which may be disclosed upon request. "Address of record" may be a licensed prescriber's home, business or mailing address, but shall not be a post office box.

"Division" means the New Jersey Division of Consumer Affairs.

"Licensed healthcare facility" means any facility licensed by the New Jersey Department of Health and Senior Services including hospitals, long-term care facilities, ambulatory care facilities, residential drug treatment facilities, and alcohol treatment facilities which have been, or are eligible to be assigned, a Division of Consumer Affairs uniform prescription blank unique provider number.

"Licensed prescriber" means any healthcare practitioner authorized by law to write prescriptions.

"New Jersey Prescription Blank (NJPB)" means a uniform, non-reproducible, non-erasable safety paper form developed by the Division pursuant to N.J.S.A. 45:14-14.6 which satisfies the specifications of N.J.A.C. 13:45A-27.8.

"Prescription" means an order for drugs or controlled dangerous substances, or any combination or mixture thereof, or other prescribed items, written or signed by a licensed prescriber for the diagnosis, treatment, prevention, or amelioration of disease, injury, pain, or physical condition in man or animals. For the purposes of this definition, the term "other prescribed items" includes eyewear, medical devices, orthotics and prosthetics, and syringes.

"Vendor" means any person authorized to manufacture and distribute NJPBs pursuant to the rules in this subchapter. For purposes of this definition, "person" means an individual, partnership, limited liability partnership, limited liability company, corporation or any other business entity.

13:45A-27.3 NJPB required for prescriptions

(a) A written prescription issued by a licensed prescriber shall appear on either the personal NJPB of the licensed prescriber or the NJPB of a licensed healthcare facility obtained from a vendor approved by the Division pursuant to this subchapter.

(b) A licensed prescriber affiliated with a healthcare facility licensed pursuant to P.L. 1971, c.136 (N.J.S.A. 26:2H-1 et seq.), may use the NJPB of the licensed facility provided that:

1. The prescription is written for a patient treated at that healthcare facility;

2. The name and license number of the licensed prescriber is legibly written, typed, stamped, or otherwise affixed to the NJPB;

3. The prescription contains the signature of the licensed prescriber; and

4. If the prescription is for a controlled dangerous substance, the licensed prescriber's Federal Drug Enforcement Administration (DEA) registration number is legibly written, typed, stamped, or otherwise affixed to the NJPB.

(c) A separate NJPB shall be utilized for each prescription written for a controlled dangerous substance. No other medication shall appear on the prescription.

(d) If a licensed prescriber utilizes an NJPB pre-printed with multiple drugs, the prescriber shall obliterate, by a cross-off procedure, any drug that is not being prescribed.

(e) A prescription transmitted verbally or transmitted electronically by telephone, facsimile, modem, or other means to a pharmacy by a licensed prescriber shall be exempt from the requirement of utilizing an NJPB if the licensed prescriber provides the pharmacist with his or her license number and DEA number, as appropriate to the particular prescription, at the time of transmission of the prescription, and the pharmacist satisfies the requirements of N.J.A.C. 13:39-5.8, 5.8A or 5.8B.

1. A prescriber licensed by the State Board of Medical Examiners who transmits a facsimile or electronic prescrip-

tion shall also comply with all requirements set forth in N.J.A.C. 13:35-7.4 and 7.4A.

(f) A licensed prescriber writing a prescription for a Schedule II narcotic substance to be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, or a prescription for a Schedule II narcotic substance for a hospice patient, or a prescription for any Schedule II substance for a long-term care facility resident, shall be exempt from the requirement of utilizing an NJPB if the prescription is transmitted or prepared in compliance with DEA regulations as set forth in 21 C.F.R. 1306.11(d), (e), (f) and (g), consistent with the requirements set forth at N.J.A.C. 13:39-5.8, 5.8A or 5.8B.

1. A prescriber licensed by the State Board of Medical Examiners writing a prescription for a Schedule II narcotic substance to be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, or a prescription for a Schedule II narcotic substance for a hospice patient, or a prescription for any Schedule II substance for a long-term care facility resident, shall also comply with all requirements set forth in N.J.A.C. 13:35-7.4 and 7.4A.

13:45A-27.4 Recordkeeping, reporting, and security requirements for licensed prescribers, healthcare facilities, and pharmacists

(a) Licensed prescribers and healthcare facilities shall maintain records indicating the ordering, receipt, storage, maintenance, and distribution of NJPB pads. Such records shall include, at a minimum, the following:

1. The name and address of the vendor supplying the NJPB pads;

2. The date of order and receipt;

3. The batch numbers of the NJPB pads;

4. The date, the quantity, and to whom the NJPB pads were distributed at a group practice office or healthcare facility, if applicable;

5. The designation of a person responsible for the ordering, receipt, storage, maintenance, and distribution of the NJPB pads. NJPB pads shall not be ordered, received, stored, maintained or distributed by anyone other than the licensed prescriber or healthcare facility, or persons employed by the licensed prescriber or healthcare facility; and

6. The designation of a secure storage area for the NJPB pads.

(b) All licensed prescribers and healthcare facilities shall establish and implement a security protocol for the storage, maintenance, and distribution of NJPBs.

(c) All licensed pharmacies shall establish and implement a security protocol for the storage and maintenance of prescriptions issued on NJPBs and shall consecutively number and file such prescriptions pursuant to N.J.S.A. 45:14-15.

(d) Licensed prescribers and healthcare facilities shall notify the Office of Drug Control in the Division as soon as possible but no later than 72 hours of becoming aware that any NJPB in their possession has been lost, stolen, or altered in any way. An incident report shall be filed in writing with the Office of Drug Control within seven days after such notification on a form provided by the Office of Drug Control.

13:45A-27.5 Group practice

(a) A group practice may utilize individual NJPB pads for each licensed prescriber affiliated with the practice, or may utilize NJPB pads listing multiple prescribers affiliated with the practice, provided that multiple prescriber NJPB pads contain check-off boxes to indicate which prescriber issued the prescription.

(b) A group practice using an NJPB listing multiple prescribers shall obtain new NJPBs within 30 days if the composition of the practice changes, except as provided in (c) below. Any remaining NJPBs of the former group practice shall be destroyed and the newly formed practice shall file an NJPB destruction form with the Office of Drug Control.

(c) If the composition of the group practice is changed through the addition of a licensed prescriber, the newly formed group practice may continue to use the NJPBs of the former group practice, provided that the licensed prescriber who becomes newly affiliated with the group obtains individual NJPBs with the information required pursuant to N.J.A.C. 13:45A-27.8.

13:45A-27.6 Vendor application

(a) An applicant to become an approved NJPB vendor shall submit an application on a form supplied by the Division, which shall include the following:

1. Documentary evidence of experience in large volume printing and distribution activity;

2. Organizational staffing plans;

3. Documentation that the applicant is financially viable;

4. A written description of the work output capacities of the physical plant(s), the size and location of the plant(s), the equipment list, and security measures;

5. The subcontractor company name, address, telephone number, ownership, and equipment list and the details regarding the subcontractor's production of any portion of the NJPB, including the security that will be provided, if an applicant intends to subcontract any portion of the NJPBs; and

6. The name and address of a designated agent in New Jersey for service of process, notices and/or orders.

(b) All information submitted by the applicant may be verified by on-site inspection by the Division or its authorized representative.

13:45A–27.7 Manufacture and distribution by approved vendors; withdrawal or termination from NJPB program

(a) NJPBs shall be manufactured and distributed by vendors approved by the Division pursuant to N.J.A.C. 13:45A–27.6. A vendor who has failed to comply with the requirements of this subchapter or the NJPB program contract specifications shall not be approved for the manufacture or distribution of NJPBs.

(b) A vendor may withdraw from the NJPB program upon 14 days written notice to the Division. A vendor that voluntarily withdraws from the program shall notify, in writing, at least 30 days prior to withdrawal, each licensed prescriber and healthcare facility that ordered NJPBs from the vendor within the previous six months.

(c) An approved vendor may be terminated by the Division upon 14 days written notice for any inability to comply with the requirements as set forth in this subchapter or the NJPB program specifications. The Division shall provide the vendor with the opportunity to respond in writing to any allegation of an inability to comply with NJPB program requirements. A vendor that is terminated by the Division shall notify, in writing, within seven days of such termination, each licensed prescriber and healthcare facility that ordered NJPBs from the vendor within the previous six months.

(d) A vendor that voluntarily withdraws from the NJPB program or is terminated by the Division shall either destroy or forward all materials, computer disks, plates, mechanicals, negatives, and other equipment related to the production or distribution of NJPBs to another approved vendor or the Division within seven days of notice of withdrawal or termination. If the vendor that withdraws or is terminated from the NJPB program does not forward all materials related to the production and distribution of NJPBs to the Division, the vendor shall provide to the Division a certification verifying the destruction or disposition of such materials.

(e) A vendor that voluntarily withdraws from the program or is terminated by the Division shall submit to the Division a list of all licensed prescribers and healthcare facilities that ordered NJPB pads from the vendor within the previous six months. The list shall be submitted within seven days of notice of withdrawal or termination and shall include all the information that is required to be maintained in the vendor database pursuant to N.J.A.C. 13:45A–27.9(h).

(f) Any person manufacturing or distributing NJPBs without approval by the Division shall be subject to prosecution for theft and/or forgery by appropriate criminal authorities pursuant to N.J.S.A. 2C:20–2 and 2C:21–1 et seq.

(g) Any person manufacturing or distributing NJPBs without approval by the Division shall be subject to an action to cease and desist, and any other action authorized by law.

13:45A–27.8 NJPB printing specifications

(a) Vendors shall manufacture all NJPBs utilizing artwork disks obtained from the Division.

(b) Each NJPB shall be:

1. Four inches by five and one-half inches in size; and

2. Printed on either 50–pound white offset smooth finish paper with a brightness of at least 85 or 20–pound paper with a brightness of at least 85.

(c) The front side of each NJPB shall be printed with the body copy (line work) in PMS 299 blue overprinted on a background of five percent of the blue (with an allowable variance no darker than PMS 300 blue).

(d) The background of the front side of each NJPB shall be a pantograph of the New Jersey State Seal reversed out of the blue screen and shall bleed on all four sides. A one and one-half inch State Seal shall be positioned centrally within the pantograph of State seals.

(e) The upper portion of the front side of each NJPB shall include the batch number, and the prescriber or healthcare facility name, the prescriber or healthcare facility address, which may be an address other than the address of record, but which shall not be a post office box, the license, certification or authorization number of the licensed prescriber, or the provider number of the healthcare facility, which shall all be printed in black ink.

(f) The prescribing area of the front side of each NJPB shall contain an "Rx" graphic circumscribed within a rectangle, printed in blue ink on the left hand side.

(g) The reverse side of each NJPB shall contain a pantograph of the New Jersey State Seal printed in PMS 332 green screened down to five percent (with an allowable variance up to PMS 333 green) which shall bleed on all four sides. A one and one-half inch State Seal shall be positioned centrally as on the front, except that it shall not be in reverse.

(h) Except as provided in (i) below, the front side of an NJPB may be imprinted with the name and license number of more than one licensed prescriber in the same licensing category provided that:

1. The name and license number of each licensed prescriber is printed in a seven point font or greater; and

2. The NJPB utilizes a printed method, such as a check-off box, to indicate which prescriber issued the prescription.

(i) NJPBs for physician assistants, certified nurse midwives and advanced practice nurses shall be imprinted only with the name and license number of the prescriber and his or her collaborating/ive physician.

(j) NJPBs for healthcare facilities shall be imprinted with sufficient space to allow a prescriber affiliated with the healthcare facility to write out his or her name, title, license number and collaborating/ive physician, if applicable, in the titlehead portion of the NJPB.

(k) At the request of a licensed prescriber or licensed healthcare facility, NJPBs may be pre-printed with the following:

1. Frequently used non-controlled prescription drugs. The prescription shall be printed in a seven point font or greater. The prescription may be pre-printed with several non-controlled drugs, delineated by check-off boxes, provided that separate directions for use, substitution, and refill instructions shall be clearly delineated for each drug prescribed;

2. A drug identifier bar code placed in the medication prescribing area, provided that the bar code shall not conceal any information contained in the medication prescribing area;

3. On the reverse side of the NJPB, any alternative practice address requested by the prescriber, with a check-off box to indicate the practice site at which the medication was prescribed. Vendors may utilize up to one half of the back of the NJPB to pre-print addresses, provided that at least three quarters of one inch remains at the top of the reverse side of the NJPB to permit the fastening of NJPB into pharmacy prescription binders;

4. The statement "NOT VALID FOR CONTROLLED SUBSTANCES" on the face of the NJPB in black ink;

5. DEA numbers; and

6. Consecutive numbers (serialized).

(*l*) In addition to the pre-printed requests set forth in (k) above, NJPBs may be printed to include the following special order requests in black ink only:

1. In the titlehead portion of the NJPB, the individual prescriber CDS or DEA numbers, Medicare Provider Numbers; Specialty Practice License numbers; fax numbers and/or more than one telephone number;

2. Special print, logotype lettering to designate the name of the healthcare facility or group practice on the first line of the NJPB titlehead; and

3. On the reverse side of the NJPB, a financial interest disclosure statement for licensees of the State Board of Medical Examiners, pursuant to N.J.A.C. 13:35–6.17.

(m) Any request for a pre-printed or special order NJPB not included in (k) or (*l*) above shall be approved by the Division before the NJPBs are produced.

(n) Vendors shall not produce NJPBs that contain logos, symbols, icons or graphics, or that contain ink that is of a different color than the colors specified in this section, or that contain pre-printed physician initials in the "Do Not Substitute" or "Substitution Permissible" portion of any NJPB.

(*o*) NJPBs shall be produced in prescription pads of 50 or 100 NJPBs per pad with chipboard backers.

13:45A–27.9 Vendor requirements

(a) A vendor may produce NJPB pads for a licensed prescriber or licensed healthcare facility consistent with the requirements of N.J.A.C. 13:45A–27.8, provided that:

1. The request for NJPBs is in writing and contains the original signature of the licensed prescriber; and

2. The vendor verifies that the prescriber's license is active and in good standing and the address of record in the Division's database or in notices sent to the vendors. The Division database shall be updated and provided to all authorized vendors on a quarterly basis.

(b) A vendor may produce NJPB pads for a group practice with the name and license number of more than one licensed prescriber, consistent with the requirements of N.J.A.C. 13:45A–27.8, provided that:

1. The request for NJPBs is in writing and contains the original signatures of all the licensed prescribers listed on the NJPB; and

2. The written request designates one licensed prescriber for receipt of the NJPB shipment.

(c) Vendors shall ensure the identity and authority of the prescriber or healthcare facility to utilize NJPBs prior to printing or delivering any order for NJPBs.

(d) Vendors shall deliver NJPBs within 14 days of receipt of an initial order, or seven days for a reorder, in sealed packets in minimum quantities of 500. Such deliveries shall be made to the address of record on file with a Division via a secure delivery service which is capable of tracking the shipment. Delivery of healthcare facility NJPBs shall be made only to the healthcare facility official designated as the responsible party when the order was placed, and only to the healthcare facility address. If a discrepancy exists between the order delivery information and the address which appears on file with the Division, the vendor shall verify the prescriber address information with the prescriber's licensing board. If a vendor is unable to deliver the NJPBs within the time specified above, the vendor shall immediately notify the licensed prescriber or the healthcare facility of the delay in the processing of the order.

(e) A licensed prescriber may pick up NJPBs at a vendor's place of business provided that:

1. The licensed prescriber provides documentation verifying his or her identity and licensure;

2. The vendor verifies the licensed prescriber's signature; and

3. The vendor remains responsible for the security of the NJPBs delivered in this manner.

(f) Vendors shall be capable of producing NJPBs in the following forms:

1. A single non-erasable NJPB form; and

2. A two-part carbonless NJPB form;

i. The top copy shall comply with the requirements of N.J.A.C. 13:45A-27.8;

ii. The second copy shall be yellow and may contain the prescriber information required pursuant to N.J.A.C. 13:45A-27.8;

3. Micro-perforated four inches by five and one half inches computer ready NJPBs imprinted with all the prescriber information required pursuant to N.J.A.C. 13:45A-27.8, which are capable of being computer printed from a laser printer; and

4. Micro-perforated four inches by five and one half inches continuous pin-fed NJPBs imprinted with all the prescriber information required pursuant to N.J.A.C. 13:45A-27.8, which are capable of being computer printed through the use of dot-matrix or ink-jet printers.

(g) Vendors shall assign and maintain a unique NJPB batch number for each order of NJPBs from a licensed prescriber or licensed healthcare facility. Re-orders of NJPBs shall contain batch numbers sequentially greater than the batch number assigned to any previous order. Batch numbers shall consist of:

1. An alphabetic prefix assigned by the Division which represents the identity of the vendor;

2. The date of printing in the following order: year, month, and day; and

3. A number sequentially assigned by the vendor.

(h) Vendors shall maintain an on-site computerized database which shall:

1. Include the following data fields for each licensed prescriber and healthcare facility:

i. Name;

ii. Name of the organization;

iii. Name of the person designated to receive shipment;

iv. Address;

v. License number;

vi. Batch number;

vii. Quantity ordered;

viii. Date ordered; and

ix. Date shipped and delivery service utilized; and

2. Be made available upon request by the Division on an ASCI format digital file.

13:45A-27.10 Vendor security requirements

(a) Vendors shall maintain secure production, storage, and distribution facilities. Security provisions shall include, at a minimum, the following:

1. All NJPBs are to be produced under tight security, in secure plants with access limited to authorized personnel. Any unfinished work related to the production of the NJPBs shall be stored under secure, controlled conditions.

2. NJPBs and materials used to produce NJPBs, including all disks, plates, negatives, and inventory goods, shall be stored at the vendor production site in a secure manner which protects against theft or loss;

3. Vendors shall not subcontract or assign any portion of the production of NJPBs without the prior approval of the Division;

4. If an applicant intends to subcontract any portion of NJPBs, the applicant shall provide the subcontractor company name, address, telephone number, ownership, and equipment list as part of the vendor's NJPB program application to the Division;

5. The subcontractor shall provide to the Division details regarding its production of any portion of the NJPBs and the security which will be provided. The vendor and the subcontractor shall sign and submit a completed form supplied by the Division which states that the parties understand and agree to the contract specifications and the regulations of this subchapter.

6. Vendors shall not add, transfer or discontinue the services of a subcontractor without prior approval by the Division. Vendors shall notify the Division of such changes in writing by mail, return receipt requested. Within 14 days of the discontinuance of the services of a subcontractor, an approved vendor shall retrieve all NJPB materials from the subcontractor and shall submit a certification to the Division verifying the retrieval;

7. Vendors shall assure that damaged NJPBs are destroyed and shall maintain records indicating the date and method of destruction; and

8. Vendors shall report to the Division any theft, loss, damage, alteration, or unauthorized use of NJPBs as soon as possible but no later than 72 hours of discovery.

(b) Vendors shall produce NJPB exemplar samples for review by the Division upon request.

13:45A-27.11 Confidentiality

(a) Vendors shall maintain the confidentiality of all data, documents, files and computer records received from, or access through, the Division, relating to the production, storage and distribution of NJPBs.

(b) Vendors shall certify, prior to being granted approved vendor status, that they will protect the confidentiality of all data related to prescribers and healthcare facilities for whom they print NJPBs, and all data collected in order to accomplish any NJPB related function.

(c) Vendors shall return all documents, files and records supplied by the Division, and all copies thereof, upon the vendor's termination or voluntary withdrawal from the NJPB program.

13:45A-27.12 Enforcement

(a) Vendors shall permit the Division or its authorized representative to inspect any facility utilized in the production, storage, or distribution of NJPBs. Inspections may be conducted for a period of five years following the withdrawal or termination of a vendor from the NJPB program.

(b) Vendors shall provide the Division or its authorized representative access to all records relating to the printing and distribution of NJPBs, including financial records. Such records shall be maintained for five years following a vendor's termination or voluntary withdrawal from the NJPB program.

(c) Failure to comply with any of the requirements of this subchapter or the contract specifications may result in suspension, the placement of conditions on, or the permanent termination of the vendor from the NJPB program consistent with the requirements of N.J.A.C. 13:45A-27.7.

13:45A-27.13 Renewal of approved vendor status

Vendors shall submit an application for renewal of approved vendor status, on a form supplied by the Division on a triennial basis.

Amended by R.2006 d.141, effective April 17, 2006.
See: 37 N.J.R. 4369(a), 38 N.J.R. 1760(a).
Deleted ", by September 19, 2004 and, thereafter, vendors shall apply for renewal of approved vendor status".

SUBCHAPTER 28. MOTOR VEHICLE LEASING

13:45A-28.1 through 13:45A-28.7 (Reserved)

13:45A-28.8 Credit check of lessee; right to review contract

(a)-(c) (Reserved)

(d) A lessee may waive his or her right to review the contract under N.J.S.A. 56:12-67b(1) provided the lessee obtains a waiver from the lessor which appears in 12-point Times Roman print (except for the document title "WAIVER" which shall appear in 14-point Times Roman print) and contains the following:

WAIVER

I HAVE BEEN ADVISED THAT UNDER THE NEW JERSEY CONSUMER PROTECTION LEASING ACT, N.J.S.A. 56:12-60 et seq., I AM ENTITLED TO REVIEW THE LEASE CONTRACT FOR ONE 24-HOUR BUSINESS DAY BEFORE SIGNING. I CHOOSE TO WAIVE THAT RIGHT AND SIGN THE LEASE NOW.

_____ _____.
LESSEE'S (CONSUMER'S) INITIALS
LESSOR'S (DEALER'S) INITIALS

_____
CO-LESSEE'S INITIALS

VEHICLE: Year _____ Make _____ Model _____

VIN Number _____

THE LESSOR (DEALER) HAS REVIEWED THE FOLLOWING ELEMENTS OF THE LEASE DISCLOSURE WITH ME:

$____ MSRP (New Vehicle Only)
$____ Total Cost of Options and Extras Not Included in MSRP
$____ Title and Registration Fees for: ____ First Year of Lease, or ____ Full Term of Lease
$____ Gross Capitalized Cost of Vehicle
$____ Capitalized Cost
$____ Acquisition Fee
$____ Security Deposit
$____ Optional Warranty or Insurance Charge

It has been explained to me that if I terminate this lease early, I may have to pay significant costs.