Full text of the adoption follows:

13:35-6.15 Continuing medical education

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

"Category I" and "Category II" mean the categories of medical education courses recognized by the American Medical Association as credited toward the Physician Recognition Award, and those categories of medical education courses recognized by the American Osteopathic Association or the American Podiatric Medical Association.

"Licensee" means a physician or podiatrist licensed and subject to regulation by the Board of Medical Examiners (the "Board").

(b) Except as provided in (b)1 and 2 and (c) below, a licensee applying for a biennial license renewal shall complete, in each biennial renewal period commencing with the biennial renewal period beginning on July 1, 2003, 100 continuing medical education credits in Category I or Category II courses, of which at least 40 of such credits shall be in Category I.

1. A licensee shall be required to complete 50 continuing medical education credits for the biennial renewal period beginning on July 1, 2003, if this section becomes effective on or before July 1, 2004, of which at least 20 credits shall be in Category I courses.

i. A licensee who completes credits in excess of the 50 continuing medical education credits required pursuant to (b)1 above may apply no more than 25 of the excess credits to the continuing medical education requirements for the following biennial period only.

2. A licensee shall be exempt from the continuing medical education requirements for the biennial renewal period beginning on July 1, 2003, if this section becomes effective after July 1, 2004.

(c) An applicant for initial licensure who has completed an accredited graduate medical education program within 12 months prior to licensure shall be exempt from the continuing medical education requirements of this section for the initial biennial period of licensure. Notwithstanding such exemption from the continuing medical education requirements, the applicant, once licensed by the Board, shall complete, within 24 months of becoming licensed, an orientation course which is presented or approved by the Board.

(d) A licensee shall certify on the application for biennial licensure renewal that he or she has completed the required number of continuing medical education credits. The Board may conduct random audits to determine licensee compliance with the continuing medical education requirements of this section.

(e) A licensee who completes credits in excess of the 100 continuing medical education credits required pursuant to this section may apply no more than 25 of the excess credits to the continuing medical education requirements for the following biennial period only.

(f) Licensees holding an inactive or retired license shall be exempt from continuing medical education requirements, except that any licensee holding an inactive or retired license, or whose license is suspended or revoked, who applies to resume practice shall provide proof of having attained 50 credits of continuing medical education for each year out of practice in New Jersey. At least 50 credits shall have been obtained in the year preceding the application to resume practice. At the time of application to resume practice, the licensee shall provide proof of the completed continuing medical education during the period while out of practice in New Jersey. The Board may accept such continuing medical education credits or require additional credits as a condition to return to practice.

(g) The Board may delineate specific topics of medical education which the Board deems necessary to address a particular issue or problem. Notification of the specific topic(s) shall be through the Board newsletter, the Division of Consumer Affairs website or by direct communication to licensees.

(h) To report continuing medical education credits, a licensee shall:

1. Certify, on the application for biennial renewal, completion of the required number of continuing medical education credits; and

2. Maintain all evidence of verification of continuing medical education requirements for a period of six years after completion of the credits and submit such documentation to the Board upon request.

(i) The Board may extend the time period for completion of continuing medical education requirements or may waive continuing medical education requirements on an individual basis for reasons of hardship, such as severe illness, disability or military service, consistent with the following:

1. A licensee seeking an extension and/or waiver of the continuing medical education requirements shall apply to the Board in writing and set forth in specific detail the reasons for requesting the extension and/or waiver. The licensee shall submit to the Board all documentation in support of the extension and/or waiver;

2. A licensee shall apply for an extension and/or waiver within 60 days of the expiration of the biennial renewal period. All requests shall be sent to the Board office, by certified mail, return receipt requested; and

3. An extension and/or waiver granted pursuant to this section shall be effective for the biennial licensure period in which the extension and/or waiver is granted. If the condition(s) which necessitated the extension and/or waiver continues into the next biennial period, the licensee shall apply to the Board for the renewal of such extension and/or waiver for the new biennial period.

(j) A licensee shall provide verification and proof of compliance with continuing medical education requirements for the prior biennial renewal period when appearing before an investigative committee of the Board or the Medical Practitioner Review Panel, or when required to do so pursuant to a Board Order, Directive or request.

(k) Failure to complete continuing medical education requirements or falsification of any information submitted on a renewal application shall provide cause for penalties and/or license suspension pursuant to N.J.S.A. 45:1-21.

(a)

DIVISION OF CONSUMER AFFAIRS

Administrative Rules of the Division of Consumer Affairs

New Jersey Uniform Prescription Blanks Program

Adopted New Rules: N.J.A.C. 13:45A-27

Proposed: September 15, 2003 at 35 N.J.R. 4172(a).

Adopted: January 8, 2004 by the Division of Consumer Affairs, Reni Erdos, Director.

Filed: May 27, 2004 as R.2004 d.238, **with substantive and technical changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:14-14.1 et seq.

Effective Date: June 21, 2004.

Expiration Date: October 20, 2005.

Summary of Public Comments and Agency Responses:

The Division received comments from the following:

1. The New Jersey State Board of Veterinary Medical Examiners;
2. Daniel Fechtner, M.D.;
3. The New Jersey State Board of Pharmacy; and
4. Richard J. Alampi, Executive Director, New Jersey Veterinary Medical Association.

COMMENT: The New Jersey Board of Veterinary Medical Examiners noted that the proposed new rules require pharmacists to consecutively file any written prescriptions, but impose less stringent filing requirements on prescriptions received electronically. The Board noted that under the new rules, electronically transmitted prescriptions "filed" at both in-State and out-of-State pharmacies would be exempt from the strict filing guidelines established in the new subchapter. The Board believes that if consumers are to be protected, pharmacists both inside and outside of the State should be required to file prescriptions in the same way, regardless of whether the prescription is received on a New Jersey Prescription Blank (NJPB) or electronically. The Board believes that a form similar to an NJPB should be utilized by all pharmacists for prescriptions transmitted electronically to record NJPB-required information, whether the prescription comes in by

telephone, facsimile or the Internet. The Board suggested the creation of a Uniform Electronic Prescription Form to be used for such purposes. Such forms would be filed consecutively, like written NJPBs. The Board also noted that out-of-State pharmacists who ship into the State should be required to follow the same regulations as in-State pharmacists. Failure to follow such regulations should result in the suspension of an out-of-State pharmacist's New Jersey license.

RESPONSE: Prescriptions transmitted verbally or electronically are exempt from the requirement of utilizing an NJPB under new rule N.J.A.C. 13:45A-27.3(e) because the Uniform Prescription Blanks Act, at N.J.S.A. 45:14-14.5, exempts such prescriptions from NJPB requirements. N.J.S.A. 45:14-14.5 and new rule N.J.A.C. 13:45A-27.3 authorize a licensed prescriber to verbally or electronically transmit a prescription to a pharmacist provided the prescriber provides the pharmacist with his or her license and DEA number at the time of prescription transmission. The Act does not authorize the creation of a uniform electronic prescription form as suggested by the commenter. In addition, the Division notes that N.J.A.C. 13:45A-27.3(e) requires a pharmacist to satisfy the requirements of Board of Pharmacy rules N.J.A.C. 13:39-5.8, 5.8A and 5.8B, regarding facsimile and electronically transmitted prescriptions. N.J.A.C. 13:39-5.8A and 5.8B require pharmacists to maintain facsimile and electronically transmitted prescriptions consistent with the requirements of N.J.S.A. 45:14-15. N.J.S.A. 45:14-15 of the Pharmacy Act provides that all prescriptions, regardless of the mode of transmission, must be consecutively numbered and filed by a pharmacist, and maintained for no less than five years. Therefore, the Division disagrees with the Board of Veterinary Medical Examiners' assertion that the new rules impose less stringent filing requirements on verbally or electronically transmitted prescriptions.

As to the commenter's concern regarding out-of-State pharmacists, the Division notes that the new rules cannot be made applicable to out-of-State pharmacies and pharmacists at this time. Currently, out-of-State pharmacies and pharmacists are not required to be licensed in New Jersey and, therefore, are not subject to the requirements of the uniform prescription blanks law. The Division notes, however, that bills have been introduced recently in the New Jersey Legislature that would require out-of-State pharmacies and pharmacists to become licensed in the State prior to transacting business in New Jersey.

COMMENT: The New Jersey State Board of Veterinary Medical Examiners objected to the requirement in the new rules whereby each time a doctor leaves a group practice, all the current NJPBs of the group practice must be destroyed, and new NJPBs must be ordered within 30 days. The cost to implement this and other requirements under the new rules will not be minimal and will be passed onto consumers. The Board suggested that the new rules be amended to allow a group practice to "strike through" with permanent ink the name of a departed doctor from the existing NJPBs for up to six months following the departure. The Board believes that new doctors in the group practice should have the privilege of hand-printing their name, and Drug Enforcement Administration (DEA) and license numbers on existing NJPBs of the group practice for up to six months. Such a change would minimize the costs associated with reprinting blanks due to staff changes.

RESPONSE: New rule N.J.A.C. 13:45A-27.5 does not require a group practice to utilize NJPBs which list multiple prescribers. Although a group practice may choose to utilize multiple prescriber NJPB pads, the rule provides that a group practice may utilize individual NJPB pads for each licensed prescriber affiliated with the group practice. Although the rule allows prescribers to choose individual prescriber or multiple prescriber NJPB pads, the Division recommends that group practices utilize individual prescriber NJPB pads. The Division believes that such pads are no more expensive than pads bearing multiple prescriber names because the same number of blanks will be utilized by a prescriber regardless of whether the prescription is issued on a single prescriber NJPB or a multiple prescriber NJPB. Using individual prescriber blanks could, in fact, save a group practice money because the departure of a prescriber affiliated with the practice would not require the destruction of any blanks other than those of that individual prescriber. The Division notes that the procedures recommended by the commenter whereby a group practice would "strike through" the name of a departed prescriber, and allow a newly affiliated prescriber to hand print his or her name on the group practice NJPB, would circumvent the security procedures instituted by the new rules. Such practices could lead to an increase in fraud and abuse. In addition, such practices would place an inordinate burden upon pharmacists filing prescriptions in the State. A pharmacist would have to independently verify each prescription emanating from a group practice in order to ensure that the prescription is, in fact, legitimate. For the foregoing reasons, the Division declines to amend N.J.A.C. 13:45A-27.5 as suggested by the State Board of Veterinary Medical Examiners.

COMMENT: The New Jersey State Board of Veterinary Medical Examiners believes that the new rules will not have a positive social impact upon consumers in light of the exemption provided for electronically transmitted prescriptions. Because of the administrative expenses, printing costs and clerical tasks associated with the use of written prescriptions under the new rules, the Board believes that more practitioners will choose to transmit prescriptions through electronic means. Because pharmacies do not have to process and file such prescriptions as diligently as written prescriptions, this could result in an increase in errors, fraud and abuse. The Board believes that requiring a pharmacist to get only DEA and license numbers for electronic prescriptions is not as secure as requiring the use of an NJPB.

RESPONSE: As noted above, the exemption from utilizing an NJPB for verbally or electronically transmitted prescriptions is based on the exemption provided in the Uniform Prescription Blanks Act, at N.J.S.A. 45:14-14.5. Under the Act, the use of the prescriber's DEA number and license number in connection with a verbally or electronically transmitted prescription is sufficient to authorize a pharmacist to fill the prescription. In addition, the Division disagrees with the commenter's assertion that the increased use of electronically transmitted prescriptions will result in an increase in errors, fraud and abuse. The increased use of electronically transmitted prescriptions, which are subject to the same filing requirements as written prescriptions pursuant to N.J.S.A. 45:14-15, will, in fact, benefit consumers by promoting the filling of prescriptions in a more efficient and timely manner. The Division also believes that the increased use of electronically transmitted prescriptions may result in a decrease in medication errors that are caused by misread or illegible prescriptions.

COMMENT: The New Jersey State Board of Veterinary Medical Examiners believe that the exemption from using an NJPB for electronically transmitted prescriptions under the new rules will result in an "unequal layering of regulatory weight" on smaller pharmacies. The Board believes that smaller pharmacies are more likely to receive written prescriptions, which must be filed according to the new rules, than would larger, on-line and potentially out-of-State pharmacies, which are more likely to receive electronic prescriptions. As a result, the Board believes that the new rules do not establish fair and equitable compliance guidelines for large and small pharmacies. The Board believes that the new rules create a business advantage for larger pharmacies and penalize smaller pharmacies.

RESPONSE: The Division disagrees with the Board of Veterinary Medical Examiners' assertion that the NJPB exemption for electronically transmitted prescriptions will have a greater impact upon smaller pharmacies in the State. The Division reiterates that electronically transmitted prescriptions are exempt from NJPB requirements under new rule N.J.A.C. 13:45A-27.3(e) because this exemption is provided in the Uniform Prescription Blanks Act at N.J.S.A. 45:14-14.5. The Division also notes that the commenter's assertion regarding the volume of written and/or electronic prescriptions that will be received by different pharmacies is speculative and is not supported by any objective data. The Division has no way of knowing at this time which pharmacies are more likely to receive each type of prescription. In addition, the Division disagrees with the Board of Veterinary Medical Examiners' assertion that the new rules create an unfair business advantage for larger pharmacies at the expense of smaller pharmacies by imposing unfair compliance guidelines on the two types of pharmacies. The new rules do not impose any differing compliance requirements upon pharmacies based upon the size of the business.

COMMENT: The New Jersey State Board of Veterinary Medical Examiners believes that the new rules will have a negative impact upon the agriculture industry. Large animal veterinarians will need to comply with the new rules. Increased regulatory costs for such veterinarians will be passed onto farmers and, eventually, onto the consumers of agricultural products.

RESPONSE: All prescribers have been required to comply with NJPB requirements since the passage of the Act in 1997. The Division notes that the new rules do not represent a significant change in existing policy but, rather, codify the NJPB program requirements imposed upon prescribers and vendors through the NJPB program contract specifications in effect since shortly after the passage of the Act. Therefore, the Division disagrees with the commenter's assertion that the promulgation of the new rules will have a negative impact upon the agriculture industry in New Jersey.

COMMENT: Daniel Fechtner, M.D., suggested that the new rule N.J.A.C. 13:45A-27.9(f)3, which provides that vendors must be capable of producing NJPBs on micro-perforated computer ready forms which are capable of being computer printed from a laser printer cassette tray, be amended to provide

that the forms should be capable of being computer printed from a laser or ink-jet printers, which may not require the use of cassette trays.

RESPONSE: The Division agrees with the commenter's suggestion that N.J.A.C. 13:45A-27.9(f)3 be amended to remove the reference to "cassette trays," but notes that N.J.A.C. 13:45A-27.9(f)4 already provides for the use of ink-jet printers. Therefore, N.J.A.C. 13:45A-27.9(f)3 is amended, on adoption, to provide that vendors shall be capable of producing computer ready NJPBs which are capable of being computer printed from a laser printer.

COMMENT: The New Jersey Board of Pharmacy recommended that new rule N.J.A.C. 13:45K-27.3 be amended to prohibit the issuance of a single NJPB with multiple drugs listed on it. The Board recommended that N.J.A.C. 13:45K-27.3(c), which provides that a separate NJPB shall be utilized for each prescription written for a controlled dangerous substance and that no other medication shall appear on the prescription, be amended to eliminate the reference to controlled dangerous substance, so as to make the requirements generally applicable to all prescriptions. Consistent with this suggestion, the Board recommended that N.J.A.C. 13:45K-27.3(d), which authorizes prescribers to utilize NJPBs which have been pre-printed with multiple drugs, be deleted.

RESPONSE: The Division has, in the past, considered prohibiting the issuance of a single NJPB with multiple, non-controlled drugs, listed on it, but has determined that such a prohibition would be very costly for prescribers, both in terms of the number of blanks that would be required and the amount of time needed to fill out individual blanks for each medication prescribed. In addition, the Division does not believe that this prohibition would substantially increase the protections against fraud and abuse already provided by the security requirements in the NJPB program as outlined in the new rules. As such, the Division declines to accept the Board of Pharmacy's suggestion to amend N.J.A.C. 13:45A-27.3.

COMMENT: The New Jersey Board of Pharmacy recommended that N.J.A.C. 13:45A-27.3(f), which provides that prescriptions for narcotic Schedule II substances for hospice patients, or prescriptions for any Schedule II substances for long-term care facility residents, are exempt from the requirements to use an NJPB if the prescriptions are transmitted or prepared in compliance with Federal DEA regulations, be amended to also include reference to prescriptions written for narcotic Schedule II substances compounded for direct administration to patients by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, in order to make the new rule consistent with the Federal DEA regulations set forth at 21 C.F.R. 1306.11(e). The Board recommends the same amendment to be made to N.J.A.C. 13:45A-27.3(f)1.

RESPONSE: The Division thanks the Board of Pharmacy for its suggestion and notes that the failure to include this category of exempt prescriptions in the proposal was an oversight by the Division. As a result, N.J.A.C. 13:45A-27.3(f) is amended, on adoption, to exempt from the NJPB requirements of the new rules licensed prescribers writing prescriptions for a Schedule II narcotic substance to be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, in order to make the new rule consistent with the Federal requirements set forth in 21 C.F.R. 1306.11. In addition, the Division notes that it is making several technical amendments to N.J.A.C. 13:45A-27.3(f) in order to make the terminology used in the section consistent with the terminology used in the Federal requirements.

COMMENT: Richard J. Alampi, on behalf of the New Jersey Veterinary Medical Association (the NJVMA), expressed concern over the security and recordkeeping requirements imposed upon prescribers pursuant to new rule N.J.A.C. 13:45A-27.4, noting that the costs of complying with these requirements will increase the cost of veterinary services, thereby diminishing the affordability of veterinary care.

RESPONSE: The Division notes that all prescribers have been required to comply with NJPB requirements since the passage of the Act in 1997, including security and recordkeeping requirements. The Division notes that the new rules do not represent a significant change in existing policy but, rather, codify the NJPB program requirements imposed upon prescribers and vendors through the NJPB program contract specifications in effect since shortly after the passage of the Act. Therefore, the Division disagrees with the commenter's assertion that the promulgation of the new rules will result in an increase in veterinary service costs.

COMMENT: The NJVMA expressed concern regarding new rule N.J.A.C. 13:45A-27.5, which will require a group practice to obtain new NJPBs whenever the composition of the group practice changes. The commenter noted that in light of significant turnover in veterinary practice, the new rule will require the frequent purchasing of new group NJPBs, or will require providing individual NJPBs for each veterinarian in the group practice, both of which will impose additional expense upon the practice. The NJVMA, therefore, recommended that the rule be amended to provide that group practice NJPBs contain a space to note the prescribers' name and license number.

RESPONSE: As noted above in response to the comment submitted by the New Jersey State Board of Veterinary Medical Examiners, new rule N.J.A.C. 13:45A-27.5 does not require a group practice to utilize NJPBs which list multiple prescribers. Although a group practice may choose to utilize multiple prescriber NJPB pads, the rule provides that a group practice may utilize individual NJPB pads for each licensed prescriber affiliated with the group practice. The Division disagrees with the commenter's assertion that providing individual NJPBs for each prescriber in a group practice will impose added expense upon a practice. Individual prescriber blanks are no more expensive then multiple prescriber blanks. The Division notes that the same number of blanks will be utilized by a prescriber regardless of whether the prescription is issued on a single prescriber NJPB or a multiple prescriber NJPB. Using individual prescriber blanks could, in fact, save a group practice money because the departure of a prescriber affiliated with the practice would not require the destruction of any blanks other than those of that individual prescriber. The Division notes that the procedure recommended by the commenter whereby a group practice blank would contain a blank space to note the prescriber's name and license number would circumvent the security procedures established in the new rules. Such a practice could lead to an increase in fraud and abuse. In addition, this practice would place an inordinate burden upon pharmacists filing prescriptions in the State. A pharmacist would have to independently verify each prescription emanating from a group practice to ensure that the prescription is, in fact, legitimate. For the foregoing reasons, the Division declines to amend N.J.A.C. 13:45A-27.5 as suggested by the New Jersey Veterinary Medical Association.

Summary of Agency Initiated Changes:

The Division has made a technical amendment to new rule N.J.A.C. 13:45A-27.7(e), on adoption, to correct the cross-reference provided in that subsection. As proposed, subsection (e) provides, in part, that the notice of withdrawal or termination submitted by a vendor who is leaving the NJPB program must include all information that is required to be maintained in the vendor database pursuant to N.J.A.C. 13:45A-27.8. The database requirements for vendors, however, are set forth in N.J.A.C. 13:45A-27.9(h). The Division has amended N.J.A.C. 13:45A-27.7(e) on adoption to refer to N.J.A.C. 13:45A-27.9(h).

In addition, the Division has amended N.J.A.C. 13:45A-27.8(n), on adoption, to correct the cross-reference provided in that subsection. As proposed, subsection (n) provides, in part, that vendors shall not produce NJPBs that contain ink that is of a different color than the colors specified in "(a) above." Subsection (a), however, does not contain any reference to the colors which may be used on an NJPB. Subsection (n) should have provided that a vendor shall not produce NJPBs that contain ink that is a different color than those colors specified throughout the section because several subsections of the rule reference permissible ink colors. The Division, therefore, has amended N.J.A.C. 13:45A-27.8(n), on adoption, to delete the reference to "(a) above" and has replaced it with a reference to "this section."

Federal Standards Statement

A Federal standards analysis is not required because the new rules are governed by N.J.S.A. 45:14-14.1 et seq., and are not subject to any Federal standards or requirements. Although the new rules in Subchapter 27 are not subject to any Federal requirements or standards, the Director has determined that licensed prescribers should comply with Federal DEA regulations concerning the transmission of prescriptions for narcotic substances for direct administration to patients by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, for Schedule II narcotic substances for hospice patients, and for Schedule II substances for long-term care facility residents, in order to ensure uniformity in the transmission of such prescriptions. Therefore, N.J.A.C. 13:45A-27.3(f) provides that licensed prescribers must comply with the relevant provisions of the DEA regulations set forth in 21 C.F.R. 1306.11.

Full text of the adoption follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

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 prescription 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 *[narcotic]* Schedule II *[controlled]* ***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 *[controlled]* 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 *[narcotic]* Schedule II *[controlled]* ***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 *[controlled]* 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-*[27.8]**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, exoept 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 *[(a) above]* ***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 *[cassette tray]*; 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, *[within 90 days following the effective date of this section]* ***by September 19, 2004*** and, thereafter, vendors shall apply for renewal of approved vendor status on a triennial basis.

(a)

DIVISION OF CRIMINAL JUSTICE

Administration of Victim Witness Advocacy Fund

Readoption: N.J.A.C. 13:78

Proposed: January 5, 2004 at 36 N.J.R. 15(a).

Adopted: May 20, 2004 by Jessica Oppenheim, Assistant Attorney General.

Filed: May 20, 2004 as R.2004 d.224, **without change.**

Authority: N.J.S.A. 2C:43-3.1a(6)(c) and N.J.S.A. 52:4B-43.1.

Effective Date: May 20, 2004.

Expiration Date: May 20, 2009.

Summary of Public Comment and Agency Response:

No public comments were received.

Federal Standards Statement

A Federal standards analysis is not required because the readopted rules are not under the authority of, or in order to implement, comply with, or participate in any program established under Federal law or a State law that incorporates or refers to Federal law, standards or requirements.

Full text of the readoption can be found in the New Jersey Administrative Code at N.J.A.C. 13:78.

TRANSPORTATION

(b)

DIVISION OF PROCUREMENT

Contracts for Architectural, Engineering and Land Surveying Services

Readoption with Amendments: N.J.A.C. 16:44A Adopted Repeal: N.J.A.C. 16:44A-4

Proposed: January 5, 2004 at 36 N.J.R. 20(a).

Adopted: May 24, 2004 by Jack Lettiere, Commissioner, Department of Transportation.

Filed: May 27, 2004 as R.2004 d.237, **without change.**

Authority: N.J.S.A. 27:1A-5, 27:1A-6 and 52:34-9.1 et seq.

Effective Dates: May 27, 2004, Readoption;
June 21, 2004, Amendments and Repeal.

Expiration Date: May 27, 2009.

Summary of Public Comment and Agency Response:

The Department received comments from James Hsu, Executive Director of the New Jersey State Board of Architects.

COMMENT: Mr. Hsu stated: "Please be advised that the New Jersey State Board of Architects, at its January 8, 2004 meeting, reviewed the rule proposal 16:44A 'Contracts for Architectural, Engineering and Land Surveying Services.' The Board would like to request that the DOT considers to include the certified landscape architects to the new rule proposal pursuant to **N.J.S.A. 45:3-1.1(f) Closely allied professional** 'means and is limited to licensed architects, professional engineers, land surveyors professional planners, certified landscape architects and persons that provide space planning services, interior design services, or the substantial equivalent thereof.'"

RESPONSE: The Department acknowledges this comment and feels that it has merit. To ensure that the current rule does not lapse, the Department is adopting the proposal without change. With the adoption of the current proposal, the Department will propose amendments to the rule to include landscape architects.

Federal Standards Statement

State law requires the promulgation of the readopted rules. The readopted rules are not subject to any Federal standards or requirements. Therefore, a Federal standards analysis is not required.

Full text of the readoption may be found in the New Jersey Administrative Code at N.J.A.C. 16:44A.

Full text of the adopted amendments follows:

SUBCHAPTER 3. CRITERIA FOR THE SELECTION OF THE MOST HIGHLY QUALIFIED PROFESSIONAL FIRMS

16:44A-3.1 Criteria for the selection of the most highly qualified professional firms

(a) Prior to the solicitation of technical proposals pertaining to the procurement of professional architectural, engineering, or land surveying services, the Department shall publicly advertise its need for such services. The advertisement shall conform to the requirements of N.J.S.A. 52:34-12(a) and (b), or be publicly advertised through electronic means. The advertisement shall either include a statement of the criteria by which the Department shall evaluate the technical qualifications of professional firms and determine the order of preference to be used in designating the