

VOLUME 46, ISSUE 4
ISSUE DATE: FEBRUARY 18, 2014
RULE ADOPTIONS

**LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
ADMINISTRATIVE RULES OF THE DIVISION OF CONSUMER AFFAIRS**

Adopted Amendments: N.J.A.C. 13:45A-27.1, 27.3, 27.4, 27.8, and 27.9

New Jersey Uniform Prescription Blanks Program

NJPB Printing Specifications

Proposed: November 5, 2012, at 44 N.J.R. 2453(a).

Adopted: August 16, 2013, by the Division of Consumer Affairs, Eric T. Kanefsky, Director.

Filed: November 1, 2013, as R.2014 d.033, **with substantial and technical changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: P.L. 2007, c. 244 (N.J.S.A. 45:14-59).

Effective Date: February 18, 2014.

Expiration Date: December 14, 2018.

Summary of Public Comments and Agency Responses follows:

The official comment period ended January 4, 2013. The Division received comments from the following:

1. Mark Cordes, President, Cordes Printing, Inc.
2. Arthur Meisel, Executive Director, New Jersey Dental Association
3. Helen Park, Product Engineer, Patterson Office Supplies
4. Kenneth O'Sperling, CDC, CPSS, President, Printco, Incorporated
5. Tony DePaola, Safeguard Business Systems
6. Drew Misuro, Corporate Vice President, and Vince Matthews, Esq., Associate Counsel on behalf of Barnabas Health
7. Lawrence Downs, Esq., Chief Executive Officer, Medical Society of New Jersey
8. Dan McCaffery, President, NationalRx Security
9. Tony Flaim, Owner/President, Target Printing & Graphics

10. Debra L. Wentz, Ph.D., Chief Executive Officer, New Jersey Association of Mental Health and Addiction Agencies, Inc.

11. Steven Klein, Senior VP Legal Counsel, Mediscripts

12. Joanna C. Jones, Operations Director, Triple i Prescriptions Pads, MediMedia Health [dba Triple i]

1. COMMENT: Four commenters expressed support for New Jersey's efforts to increase security measures for New Jersey Prescription Blanks (NJPBs) to make altering issued prescriptions and counterfeiting NJPBs more difficult.

RESPONSE: The Division thanks the commenters for their support.

2. COMMENT: Four commenters expressed concern with the amount of time to implement the proposed changes. Under proposed rules N.J.A.C. 13:45A-27.1(c) and (d), licensed health care practitioners and healthcare facilities would have six months from the effective date of the proposed amendments to issue written prescriptions on NJPBs purchased by them on or before three months from the effective date of the proposed amendments. Two of these commenters noted that three months is a very short period of time to use up existing stock for vendors that purchase their stock in large quantities. One commenter noted that it is important that NJPB vendors continue to keep NJPB blank inventory to fill doctor orders and not be placed in a position that once their inventory runs out, that they would not produce additional NJPB blanks until the new regulations come into effect. Another commenter noted that in 1998, when the initial NJPB program was launched, it took over one year to get sufficient quantities of NJPBs to all prescribers and suggested any implementation allow for the use of current NJPBs for at least nine months. One of the commenters noted that there are currently eight versions of the NJPBs and requested at least 120 days instead of 90 days to implement the proposed changes. The commenter suggested that increasing the amount of implementation time would help to keep costs down for the vendors. Another commenter suggested that healthcare facilities should have 12 months to use up NJPB blank inventory.

RESPONSE: The Division appreciates the commenters' concerns about the amount of time to implement the proposed changes. However, the abuse of prescription drugs has reached epidemic proportions nationwide and the increasing demand for controlled dangerous substance prescription drugs makes prescription blanks extremely valuable to black market dealers in these drugs. As observed in the July 2013 report from the State of New Jersey Commission of Investigation (SCI report), there has been a startling rise in the rate of patient admissions to drug addiction treatment centers:

The number of individuals who entered such facilities in New Jersey for opioid pill addictions tripled from 2006 to 2011, with more than 8,600 admissions in 2011 alone. Of those patients, nearly half were age 25 or younger . . . In 2011, the latest year for which such data is available, drug-related deaths statewide jumped to 1,008 - an increase of nearly 20 percent. Again, nearly three-quarters involved prescription drugs.

The SCI report stresses urgency in combatting prescription drug abuse. The SCI report also observes that unscrupulous individuals can manipulate prescription forms with readily available computer technology. In view of the urgency reflected in the SCI report, the Division believes it is critical to the health, safety, and well-being of the public to promptly begin use of the new blanks with additional security measures to make altering issued prescriptions and counterfeiting NJPBs more difficult. Accordingly, notwithstanding prior indications that there would be a change, due to the risk to the health, safety, and well-being of the public, the Division declines to change the operative date of this rulemaking.

3. COMMENT: One commenter expressed support for the Division's permissive pre-printing of the Drug

Enforcement Administration (DEA) registration number and leaving to the prescriber the decision whether to have the DEA number pre-printed. The commenter suggested modifying the language in proposed N.J.A.C. 13:45A-27.3(c) to include: "There shall be adequate space designated for the licensed prescriber's Federal DEA registration number: 'DEA #' and any prescription for a controlled dangerous substance shall bear the number." The Commenter also suggested modifying the language from "shall be pre-printed, legibly written . . ." to "may be pre-printed or legibly written . . ." Another commenter noted that some licensed dentists elect not to obtain a DEA registration number because they choose not to write prescriptions for controlled dangerous substances (CDS). This commenter suggested modifying the proposed amendment to include language to make it clear that the licensed prescriber's Federal DEA registration number must be affixed only if the prescription is for a controlled dangerous substance; otherwise, it is within the licensed prescriber's discretion whether to include it. One commenter indicated that there is contradictory language about whether the DEA number is to be pre-printed.

RESPONSE: The Division believes that existing N.J.A.C. 13:45A-27.3(b)4 and proposed N.J.A.C. 13:45A-27.3(c) clearly provide that only when the prescription is for CDS must the licensed prescriber provide a Federal DEA registration number. Proposed N.J.A.C. 13:45A-27.3(c) provides prescribers with the discretion to choose the manner in which the DEA registration number will be affixed to the prescription: whether to pre-print, legibly write, type, stamp, or otherwise affix it to the blank. The Division will display in the artwork the positioning of the DEA number and does not believe it is necessary to specify in the rule that there shall be adequate space designated for the DEA number. The Division declines to change the language as suggested by the commenters. However, upon adoption, the Division will make a technical change to N.J.A.C. 13:45A-27.3(b)4 to add "pre-printed" to be consistent with N.J.A.C. 13:45A-27.3(c).

4. COMMENT: One commenter requested clarification about the format with respect to the size of the electronic medical records version of the prescription blank and recommended that the Division remove the requirement in N.J.A.C. 13:45A-27.8(b) that each NJPB be four inches by five and one-half inches in size. The commenter noted that many states do not specify the size of the prescription form, which allows health care facilities to design larger sizes to accommodate their needs. The commenter also noted that those states that do mandate the size require the industry standard size of four and one-quarter inches by five and one-half inches. The commenter suggested that if the Division would not consider variable size then, alternatively, to change the prescribed [page=392] size of the form by one-quarter inch to conform to the industry standard to allow more room for the prescriber to write the prescription information without being any more expensive to produce.

RESPONSE: In accordance with N.J.S.A. 45:14-59, which requires that the format for New Jersey Prescription blanks be uniform, the Division must specify the size of the prescription blanks and cannot consider variable sizes for the prescriptions. The Division notes that the prescription blank has been four inches by five and one-half inches in size since the program's inception in 1998. At that time, the Division received comments in support of the current size. Moreover, in 2003, when the New Jersey Uniform Prescription Blanks Program was first proposed as new rules, the Division did not receive any objections to the proposed size of the prescription blanks. The Division further notes that it is not aware of general dissatisfaction with the size of the blanks. The Division declines to change the size of the prescription blanks specified in N.J.A.C. 13:45A-27.8(b).

5. COMMENT: One commenter expressed concern with the proposed change to N.J.A.C. 13:45A-27.8(c) with respect to switching ink colors such that blue will appear on the reverse side of the prescription blank and green will appear on the front. The commenter noted that the void feature works better with an ink color that is darker and has more black pigment. The commenter further noted that pigment-green 332 has no black pigment and, therefore, the void feature will not work as well and will be more difficult to manufacture.

RESPONSE: The Division agrees that the void feature works better with an ink color that is darker and has more black pigment. Accordingly, upon adoption the Division is changing proposed N.J.A.C. 13:45A-27.8(c) to specify PMS 336 green, rather than PMS 332 green as the ink color with an allowable variance no darker than PMS 337 green, rather than PMS 333 green. The change in the tint of the green color does not change the effect of this rule, which is to have the front side of the prescription blank appear in green; because the printer vendors will still need to purchase ink, the change does not increase the burden on printer vendors.

6. COMMENT: One commenter suggested removing the State seal pattern from the face of the prescription blank because it will not allow for a repeatable pattern to incorporate the void feature, making the void feature less effective. The commenter noted its belief that having the State seal solely on the reverse side of the prescription blank is sufficient for purposes of identifying the form specifically for New Jersey.

RESPONSE: The Division believes it is possible to incorporate a repeating pattern of the void feature in conjunction with the State seal pattern on the face of the prescription blank. Printer vendors will need to determine the appropriate line screen, tint percentage, and DPI (dots per inch) to produce a suitable hidden word feature. The Division notes that incorporating the State seal pattern on the face of the prescription has two purposes: to identify the form specifically for New Jersey and to function as an additional security feature. The Division declines to incorporate the commenter's suggestion to have the State seal solely on the reverse side of the prescription blank.

7. COMMENT: Five commenters raised concerns with the use of reverse type proposed in N.J.A.C. 13:45A-27.8(e)5. One commenter noted that reverse print of the prescriber's telephone number is not considered a security feature; such a requirement provides no value and will limit personalization options. Another commenter noted that reverse type is difficult to read and may create additional production issues that may cause the form to be less fraud resistant. The commenter suggested that, if the purpose is to make the phone number stand out, the prescriber's telephone number be in bold type. Another commenter expressed concerns with the additional space required for reverse print in the current prescription blank imprint area. Two commenters asked for clarification about the information to appear in reverse type and whether it would include information other than the prescriber's phone number, such as the prescriber's address or fax number. One commenter expressed concern that the State seal pantograph could interfere with the legibility of the phone number or that the imprint area for the phone number could obscure the State seal pantograph. The commenter suggested that the Division identify a static area within the pantograph that would always contain the reversed-out phone number.

RESPONSE: The Division shares the commenter's concern about the additional space required for reverse print of the prescriber's telephone number. The Division also recognizes that when blanks contain more than one prescriber telephone number the amount of available space would be further reduced. In addition, the Division believes that to have only one prescriber telephone number to be in reverse print would vitiate the benefit of this security feature. Accordingly, the Division is removing this requirement. Additional public notice of this change is not required because the reverse print was just one of the new security measures, the change does not increase the burden on printer vendors so as to destroy the value of the original notice.

8. COMMENT: One commenter requested clarification about the information that will still need to be printed on the electronic medical records version of the prescription blank.

RESPONSE: The Division did not change the existing rules regarding the information that must be printed on the electronic medical records version of the prescription blank. In accordance with N.J.S.A.

45:14-57 and proposed N.J.A.C. 13:45A-27.8(h), the practitioner's name, address, or NPI number or health care facility unique provider number may be imprinted using an electronic health records system; the electronic medical records version of the prescription blank must comply with all other requirements of N.J.A.C. 13:45A-27.8, including pre-printing the information specified in N.J.A.C. 13:45A-27.8(e).

9. COMMENT: One commenter requested clarification about the vendor's responsibility for documenting that a prescribing practitioner or health care facility uses an electronic health records (EHR) system. The commenter asked 1. how vendors will know which EHR systems are acceptable, 2. whether vendors will need to verify the prescriber's EHR system information on each order, and 3. the location of where vendors will be required to retain records for each prescriber.

RESPONSE: The Division does not prescribe the location where vendors maintain records, but recommends that vendors maintain this information on file with their practitioner records. In addition, in accordance with N.J.A.C. 13:45A-27.12, the Division requires that all records be maintained for five years following a vendor's termination or voluntary withdrawal from the NJPB program. The Division also does not prescribe which EHR systems may be used by a prescribing practitioner or health care facility. It is the vendor's responsibility to document that the practitioner or health care facility utilizes an EHR before manufacturing NJPBs without a practitioner's name, address, or National Provider Identifier (NPI) number or health care facility unique provider number. The Division reminds printer vendors that a short form to document that practitioners and health care facilities have an EHR is available on the Division's website at www.njconsumeraffairs.gov/drug/dchome.htm. The Division recommends as a best practice that whenever an order is placed for NJPBs to be used with an EHR system, printer vendors, at a minimum, verify that the prescribing practitioner or health care facility's EHR information is the same as previously documented.

10. COMMENT: One commenter expressed concerns with proposed new N.J.A.C. 13:45A-27.8(h), which permits a practitioner or health care facility to use an EHR system to print the prescriber's name, address, or NPI number or the unique provider number of the health care facility in lieu of having that information pre-printed on the prescription blank. The commenter noted that the new rule will create a potential security risk, as well as a financial burden. The commenter noted that the existence of an EHR at a health care facility does not necessarily mean that the health care facility also has the ability to print discharge prescriptions on some or all of the nursing units or outpatient areas of the hospital. The commenter further noted that health care facilities would incur substantial cost and time to remodel nursing areas to allow for installation of printers in a secure location, as well as storing and securing blank prescriptions. The commenter also noted that in most areas currently 10 to 20 prescription blanks are secured and stored in a Pyxis unit (automated medication dispensing system). The commenter expressed concerns with switching to printer paper because of current space limitations and security concerns resulting from the need, if prescriptions cannot be printed, for increased personnel to carry personalized blanks, which health care facility pharmacies could not control.

RESPONSE: Pursuant to N.J.A.C. 13:45A-27.4, all licensed healthcare facilities are required to have a security protocol for the [page=393] storage, maintenance, and distribution of NJPBs. The Division does not require healthcare facilities or prescribers who use an EHR to print prescriptions from the EHR system. N.J.S.A. 45:14-57 and N.J.A.C. 13:45A-27.8(h) permit, but do not require, prescription blanks to be printed without a practitioner's name, address, or NPI number or health care facility unique provider number if the healthcare facility or prescriber uses an EHR system to imprint this information.

11. COMMENT: One commenter noted that "hollow" void is not a widely used industry term and requested clarification as to what "hollow" means as it relates to void. The commenter also suggested changing the descriptive term to something more recognized by printers.

RESPONSE: The Division believes that "hollow" as used in N.J.A.C. 13:45A-27.8(i) is a descriptive term indicating that the selected word (for example, "VOID") is displayed in outline form. The Division also believes that using a hollow hidden word feature prevents obscuring vital prescription information, such as instructions and prescriber telephone number. The Division declines to change the descriptive term of "hollow" as suggested by the commenter. The Division has learned that hidden word is the generic term for the feature described in this subsection. Therefore, upon adoption, the Division is changing the reference in N.J.A.C. 13:45A-27.8(i) from "pantograph" to "hidden word feature."

12. COMMENT: Five commenters expressed concerns with the proposed change to N.J.A.C. 13:45A-27.8 to add a safety hollow "VOID" pantograph. Three commenters noted that there are several ways, with different technology and software, to create a "VOID" pantograph. One of these commenters noted that, based on its experience in printing such pantographs, each press or printing device used to print such pantograph must be tested to determine line screen, tint percentage, and DPI to produce the most suitable pantograph. Furthermore, these three commenters expressed the need for consistency and uniformity and requested guidance as to which technology should be used to meet the proposed requirements. One commenter noted that the "VOID" pantograph would have to be included in the artwork supplied or an area within the State seal pantograph would have to be knocked out to allow space for the precise printing of each printer's proprietary "VOID" pantograph. The commenter asked if each printer is supplying its own "VOID" pantograph artwork, whether there are additional requirements for printing the "VOID" pantograph, not set forth in the proposed changes, such as ink color. One commenter noted that Division's historical practice of providing a disk with the artwork is not a viable option with respect to the "VOID" pantograph because the void technology software must reside on the vendors' computers. Another commenter raised concerns that because the void imaging print processes may be proprietary, licensed, and patented they may not be available to all printer vendors and need to be confirmed as openly available to the trade. One commenter noted that some of these solutions are also very costly, with no guarantee of success in all situations. Another commenter noted that the proposed "VOID" pantograph feature may prove to be a bit costly for some of the smaller printers to include.

RESPONSE: The Division agrees with the commenters about the need to ensure consistency and uniformity and will display in the artwork provided to the printer vendors the position, type size, type style, and pattern for the hidden word feature. The printer vendors will need to test each press or printing device used to print the hidden word feature to determine the appropriate line screen, tint percentage, and DPI (dots per inch) for producing a suitable one. As noted in the Response to Comment 11, the Division upon adoption is changing the reference in N.J.A.C. 13:45A-27.8(i) from "pantograph" to "hidden word feature." In addition, upon adoption, the Division is changing N.J.A.C. 13:45A-27.8(i) to clarify that the hollow "VOID" shall appear in a repeating pattern. The Division believes that to deter counterfeiting it is common for the "VOID" to be printed in a repeated pattern. Further, the Division believes printer vendors use the same printing process whether the hidden word feature appears once or in a repeated pattern; therefore, this clarification does not increase the burden on printer vendors.

13. COMMENT: Two commenters noted that there is no "fail-safe" void technology. One commenter noted that no one "VOID" pantograph will work in each and every reproduction situation. Another commenter added that there is no void technology that cannot be overcome with enough knowledge and technology and suggested removing the word "cannot" from proposed N.J.A.C. 13:45A-27.8(i). One commenter noted that due to changing copier technology, a prescription could be duplicated on some photo copiers without the word "VOID" or other hidden messages showing up on the copy.

RESPONSE: The Division recognizes that there is no "fail-safe" void technology. However, the Division believes that each security feature provides an additional protection against the alteration or duplication of prescription blanks. In recognizing the practical limitations of current technology, the Division upon adoption is making a technical change to replace the words "cannot be replicated" with "is designed to

prevent replication" in proposed N.J.A.C. 13:45A-27.8(i).

14. COMMENT: Three commenters expressed concerns with the microprint described in proposed N.J.A.C. 13:45A-27.8(j). One commenter noted that the terminology for describing font sizes for microprint is "point" not "font." The commenter also noted that most micro printing is produced using 2 point for offset printing to as large as 3.5 point for digital printing. Two commenters requested confirmation that the micro printing feature will be included in the files provided by the Division. One commenter noted that having the microprinting feature provided by the Division will ensure that this security feature is uniform for all vendors rather than the vendors each determining which printing element (specific area, text, or line) to print in microprint.

RESPONSE: The Division thanks the commenter for bringing to its attention the correct terminology for describing microprint font sizes. The Division believes that 1 point for offset printing is common. The Division agrees with the commenters about the need to specify the microprint feature and confirms that the Division will display in the artwork the specific area and text or line to print in microprint. Upon adoption, the Division is changing N.J.A.C. 13:45A-27.8(j) to make a technical change from "font" to "point."

15. COMMENT: Two commenters expressed concern with the thermochromic (friction activated) ink security feature described in N.J.A.C. 13:45A-27.8(k). One of the commenters noted that there are several sources for thermochromic ink but few options as to ink color. The commenter asked, for consistency purposes, who will determine which ink/color will be used. Another commenter noted that thermochromic ink is expensive, but offers an extremely high level of security, and is only offered through one or two companies nationwide. The commenter suggested creating a NJPB Special set PMS color to be offered through a specific ink company and available only to approved vendors at a fixed cost.

RESPONSE: The Division agrees that thermochromic ink offers a high level of security. The Division also recognizes that there are few options as to color for thermochromic ink but does not believe it diminishes the security aspect of this feature. The Division confirms that it will specify in the artwork the thermochromic ink color to be used. The Division appreciates that thermochromic ink is more expensive than that of standard offset ink color, but notes that the specifications require the use of the ink in a small area requiring only a very small amount of the ink. The Division declines to create a special NJPB PMS color as the commenter suggested because the Division believes that it is cost-prohibitive to create a special NJPB PMS color.

16. COMMENT: Five commenters raised concerns with the tamper resistant coating security feature described in proposed N.J.A.C. 13:45A-27.8(l). Two of the commenters noted that they were unaware of any print-based coating that can accomplish this feature but there may be a paper-based solution. Two commenters noted that there is only one paper manufacturer that produces a paper with the chemical void feature as a standard item. One of these commenters noted that even if a paper based solution is available, it may not be practical for vendors to use in that it may only be available in rolls, not sheets. Two commenters noted that they were not aware of the existence of any erasure or abrasion activated "VOID" security feature. One commenter questioned how an erasure or abrasion attempt made in one portion of the prescription blank would produce a "VOID" in the area where the prescription information is written. Another commenter noted that the tamper resistant coating security feature is proprietary, licensed, and/or patented, and may not be available to all printers. One commenter noted that this feature may be costly for some of the smaller printers to include.

[page=394] RESPONSE: The Division believes that the commenters have valid concerns about the tamper resistant coating security feature described in proposed N.J.A.C. 13:45A-27.8(l). The Division is not adopting N.J.A.C. 13:45A-27.8(l) at this time and will reconsider this rule when the technology

becomes available.

17. COMMENT: Two commenters requested clarification about the list of security features described in N.J.A.C. 13:45A-27.8(m). One commenter asked whether the artwork for the list of security features will be provided and, if not, what guidelines the vendors will need to follow with respect to ink color. Two commenters asked about the location on the scripts for the list of security features. One commenter noted that the list could be placed on either side of the blank, but printing the list on the reverse side allows for a clearer definition of the features. The commenter noted that some prescribers' information is currently printed on the reverse side of the form, so placing the security list on the reverse side will limit the amount of available space. The commenter also noted that there is limited space on the face of the blank, which would require the shortening of the security list description.

RESPONSE: The artwork provided by the Division will display the list of security features described in N.J.A.C. 13:45A-27.8(m) on the reverse side of the prescription blank. The artwork will also include specific information about the position and color of the list of security features.

18. COMMENT: Seven commenters raised questions about the Code 39 barcode described in N.J.A.C. 13:45A-27.8(e)1. Two of these commenters raised concerns that the proposed 14-Digit Unique Identifier (14-DUI) consisting of a two-digit vendor prescriber identifier allows for a limited number of unique combinations, which is insufficient to uniquely identify the vendor's number for licensed prescribers. One of the commenters suggested that the 14-digit identifier be modified to allow for the use of at least nine digits for the vendor's prescriber identifier. The commenter also suggested that the Division retain the print date format of YYMMDD to allow for better tracking of orders. Another commenter suggested creating a unique two-digit identifier for a specific month and year and to use the remaining four digits to represent the unique orders per month. Two commenters raised concerns about ensuring consistency of the positioning of the barcode and suggested uniform positioning on each version of the NJPBs. Another commenter asked about the location of the barcode noting that the existing space for the imprint information is small and that the barcode will require a significant amount of space in that area of the prescription blank. One commenter suggested specifying that the barcode have visual characters printed below the barcode to allow for manual entry in the situation when a barcode is not functioning.

RESPONSE: The Division agrees with the commenters that a two-digit alphanumeric vendor prescriber identifier does not allow for a sufficient number of unique combinations for vendors to identify each of the licensed prescribers. Upon adoption, the Division is changing N.J.A.C. 13:45A-27.9(g) to specify a 15-digit identifier (rather than a 14-digit identifier) consisting of a three-digit vendor prescriber identifier. The Division, upon adoption, will also change N.J.A.C. 13:45A-27.4(a)3, 27.8(e)1, and 27.9(h) to change the reference from a 14-digit to a 15-digit identifier. The Division also clarifies that the vendor prescriber identifier consists of alphanumeric digits and that only capital letters will be used. The Division believes that by increasing the vendor prescriber identifier to three digits, there will be a sufficient number of unique combinations to uniquely identify the licensed prescribers and the commenter's suggestion to increase it to nine digits is not necessary. The increase to a 15-digit identifier, including an increase to a three-digit alphanumeric vendor prescriber identifier, does not increase the burden on printer vendors.

N.J.A.C. 13:45A-27.8(e)1 requires both a 14-digit identifier and a barcode that matches the 14-digit identifier (as noted, upon adoption changed to a 15-digit identifier). The Division believes it is clear that the barcode must have visual characters printed with the barcode that will allow for manual entry. Many commenters have raised concerns about ensuring consistency and uniformity of the blanks. The Division shares these concerns and will display in the artwork the positioning of the security features, including that of the barcode. The Division also agrees with the commenter that and, upon adoption, the Division is changing N.J.A.C. 13:45A-27.8(e)1 to specify a Code 128 linear barcode, which utilizes less space than that of a Code 39 barcode. The Division believes that the change in the specific Code of the barcode does

not increase the burden on printer vendors or those using a barcode scanner.

19. COMMENT: Three commenters were confused about the proposed 14-DUI. One commenter requested clarification whether the 14-DUI includes a two-digit vendor prefix, a six-digit order number, and a six-digit sequential number. Another commenter questioned whether each script within the batch will have a unique 14-digit identifier that is inclusive of a unique serial number or if each order will contain a 14-digit identifier separate from the serial number on each script within each order.

RESPONSE: As noted in the response to Comment 18, upon adoption, the Division is changing N.J.A.C. 13:45A-27.9(g) to specify a 15-digit identifier consisting of a three-digit alphanumeric vendor prescriber identifier. The Division clarifies that the 15-digit identifier consists of a two-digit alphabetic prefix assigned by the Division, which identifies the printer vendor, followed by a seven-digit order number consisting of three digits (alphabetic, only upper case, and numeric) for the vendor prescriber identifier and four digits representing the month and year of the printing order, and ending with a six-digit sequential serial number. The Division further clarifies that the serial number will be sequential within an entire order and continues for additional orders for the month. If a prescriber places multiple orders within the month, the orders within the month would continue the sequence.

20. COMMENT: One commenter questioned whether the bar coding with a unique identifier improves security over the current batch numbering.

RESPONSE: The Division introduced the unique identifier not only as a security measure to facilitate tracking from the vendor to the practitioner to the pharmacy, but also to facilitate reporting to the New Jersey Prescription Monitoring Program (NJMPMP). The NJMPMP is another important component of the Division's effort to halt the abuse and diversion of prescription drugs. Barcoding eliminates manual entry of the identifier number if the pharmacy has a barcode reader, thereby, improving accuracy.

21. COMMENT: One commenter expressed concerns with the imprinting technology needed to accommodate the proposed security features of barcodes and unique identifier. The commenter noted that there are two methods currently available that can reproduce variable data: toner-based technology and inkjet printing. The commenter noted that toner-based printing is fused to the paper at a given temperature and that many of the prescription forms produced are intended to be imprinted by the prescriber through a desktop laser printer, which operates at very high temperatures. The commenter noted that the net result is that the imprint information made by the vendor can be "re-melted" by the desktop printer and tracked down the sheet. The commenter noted that inkjet printing is extremely slow and costly or high-speed and very costly.

RESPONSE: The Division believes that the commenter's re-melting concerns that potentially arise only when prescribers imprint information using a desktop laser printer may be avoided by using 24- to 28-pound MOCR paper with a brightness of at least 75. In these limited circumstances, the Division will permit printer vendors whose customers request it, in response to problems or in anticipation of problems, to use 24- to 28-pound MOCR paper with a brightness of at least 75; any printer vendor who uses this alternate paper will be required to provide the Division with written notification. Accordingly, upon adoption, the Division is changing N.J.A.C. 13:45A-27.8(b)2. Providing printer vendors with a means of addressing re-melt problems associated with using a laser printer to imprint information will lessen their burden.

22. COMMENT: One commenter suggested reducing the number of versions of prescription blanks in order to reduce the cost of production of the forms. The commenter noted that New Jersey currently has eight versions of the NJPB and that no other state has more than one version. The commenter further noted that most states specify required security features but allow flexibility of how the form is designed.

The commenter recommended that if New Jersey continues to require standard versions that the State limits to two or three the number of versions in order to [page=395] reduce costs of production and inventory, and thereby lower the price to the prescriber.

RESPONSE: In accordance with N.J.S.A. 45:14-59, which requires a uniform format for the prescription blanks, the Division cannot allow printer vendors to vary the form's design. The Division notes that the different healthcare professionals with the authority to prescribe have specific rules governing the information required to be included on NJPBs they issue. Because of the differing regulatory requirements, the Division is unable to reduce to two or three, the number of versions of the prescription blanks. However, the Division is eliminating the "Combo Eye Wear/TPA Certified" prescription form, thereby, reducing the number of versions of the NJPBs from eight to seven. N.J.A.C. 13:45A-27.9 reflects this reduction in the number of versions of the blanks.

23. COMMENT: One commenter noted that there are three styles of forms that use "condensed or compressed" type styles, which make it difficult to read the printed copy. The commenter suggested that the different versions of the NJPB be consistent with regard to type styles used and that the Division not use compressed or condensed type styles as a requirement.

RESPONSE: The current NJPBs do not use condensed type styles, but rather some of the lines may have been condensed. The use of compressed type styles and condensing the lines permits the blanks to include necessary information while leaving adequate space for the prescription itself. The Division will continue to use compressed type styles.

24. COMMENT: One commenter suggested creating an online system to verify prescribers' licenses. The commenter noted that the current system of sending CDs is not effective because the CDs are not updated often enough and the information is often out-of-date as soon as the CDs are shipped because of production and shipping time. The commenter noted that because the information is out-of-date, the vendors have to take time to verify the prescribers' licenses, which slows down the process and adds costs to the production of the product. The commenter further noted that all other states that have mandated programs have online systems for vendors to verify prescribers' licenses. The commenter also noted that an online system allows vendors to immediately identify prescribers whose licenses have been revoked.

RESPONSE: In August, 2013, the Division launched an on-line tool to replace the prior system of providing printer vendors every three to six months with computer disks containing the names, license types and numbers, and updated addresses of practitioners eligible to order NJPBs. The on-line tool allows approved printer vendors to access and verify eligible practitioner information in a more timely and efficient manner. The Division will update the list of eligible practitioners and their addresses on a monthly basis, which approved vendors may download at their convenience. In addition, printer vendors may use the Division's online license verification system to verify prescribers' licenses. This system is available on the Division's website at <http://dcappsrvr.dca.lps.state.nj.us/12k/verification.jsp>.

25. COMMENT: Two commenters suggested incorporating an additional security feature, a hologram, into the NJPB. The commenters noted that a hologram is one of the most advanced security features and adding it would further ensure the security of the prescription blank. One commenter noted that its company uses the hologram as a common practice for its check printing and that the cost of pre-printing a hologram on each prescription blank would add less than one or two cents per sheet. A second commenter noted that it currently offers hologram prescription scripts.

RESPONSE: The Division thanks the commenters for their suggestion to enhance the security of the prescription blanks. The Division believes that including a hologram as a security feature is too costly for the benefit it offers and declines to incorporate this suggestion.

26. COMMENT: One commenter noted that as a paper supplier with advance print capabilities it can supply the secure stock and include the pre-printed pantographs, coatings, thermochromic ink, and holograms to all NJPB authorized printers for comparable or lower costs than currently incurred. The commenter further noted that authorized NJPB print vendors can then reduce costs by providing only the "black ink" printing that they currently provide. The commenter noted that, because of costs involved with proposed changes, the commenter's proposal has the benefit of providing a choice to each NJPB vendor to either incorporate the changes themselves or use the pre-printed security stock provided by a State-authorized vendor.

RESPONSE: The Division thanks the commenter for its suggestion. The Division notes that a future rule proposal will require a single manufacturer selected through the Request for Proposal process, to produce security document paper for NJPBs. The Division notes that the selected single paper supplier will not be permitted to print the prescription blanks.

27. COMMENT: To better meet the uniform control and economic benefits of the NJPB program, one commenter recommended that the Division require production and distribution of NJPBs within the State of New Jersey.

RESPONSE: The Division does not want to intentionally eliminate any existing printer vendors. Therefore, the Division declines to incorporate the commenter's suggestion.

28. COMMENT: Three commenters raised concerns with the financial impact of the proposed security feature changes. One commenter noted that health care facilities will incur costs associated with printers, dedicated lines, lock boxes, remodeling, and the development of security notification systems. Another commenter urged the Division to be mindful of the costs and that they cannot be passed onto patients. The commenter further noted that many physician practices are operating on slim margins and costs that cannot be passed on are increasingly difficult to absorb with falling reimbursement. One commenter noted that the recommended security features, such as void pantographs and tamper resistant coatings, may be costly for some of the smaller printers to include.

RESPONSE: As noted in the responses to comments above, the abuse of prescription drugs has reached epidemic proportions nationwide and the increasing demand for controlled dangerous substance prescription drugs makes prescription blanks extremely valuable to black market dealers in these drugs. Drug diversion, including altering and counterfeiting of prescription blanks, is a multi-billion business. The number of admissions to New Jersey addiction treatment programs due to prescription drug abuse tripled from 2006 to 2011. Moreover, the estimated cost of drug diversion and abuse to insurers is \$ 72.5 billion a year. The Division believes that the societal benefits of additional security measures to combat and deter the altering and counterfeiting of prescription blanks outweigh any cost increases resulting from those measures. In addition, as noted in the Response to Comment 16, as the Division is not adopting the tamper resistant coating, any cost increases associated with the adopted security features will be reduced. To the extent the commenters are discussing costs associated with an electronic health records system, as noted in the responses to other comments above, the Division does not require healthcare facilities or prescribers who use an EHR to print prescriptions from the EHR system.

29. COMMENT: Four commenters raised economic concerns with the Division's future proposal for a single manufacturer to produce security document paper for NJPBs. Three of these commenters expressed concern that having a single paper supplier will create an unfair price advantage and monopoly over the price for paper and prescription blanks. Two of the commenters expressed concern that the proposal will increase shipping costs. One commenter estimated an increase in costs of at least 40 percent and recommended a moratorium on such an expensive regulatory move by the State of New Jersey or,

alternatively, that the State provide New Jersey vendors with financial assistance by paying for the paper supplied by the single-sourced vendor. Two commenters noted concerns that the vendors have to make financial investments to implement the currently proposed print-based security features and then incur additional costly changes in a very short period of time.

RESPONSE: The Division notes that the selected single paper supplier will not be permitted to print the prescription blanks. At this time, the Division has no way of knowing the cost of paper supplied by a single-sourced vendor but believes it will be significantly less than a 40 percent increase. In addition, the Division believes that the societal benefit of deterring the alteration and counterfeiting of prescription blanks through its anticipated future proposal to use a single manufacturer to produce security document paper for prescription blanks outweighs any cost increase that results. See also the Response to Comment 28.

[page=396] 30. COMMENT: Four commenters raised logistical concerns with the Division's future proposal for a single manufacturer to produce security document paper for NJPBs. One commenter noted concerns about sheet sizes, availability, shipping costs, and run-ability of the paper. One commenter raised security concerns over the possibility of base stock being lost or stolen in transit from the one source supplier to the printing vendors. The commenter suggested requiring approved vendors to produce their own base stock to address these security concerns and to accommodate each printer vendor's different method for producing the prescription blanks. Another commenter noted that the proposal poses a risk if the paper chosen is not readily available for the suppliers as soon as the regulations become effective. One commenter asked about the anticipated time frame and notification process for the Division's Request for Proposal for the production of security document paper for NJPBs.

RESPONSE: The Division thanks the commenters for their feedback about its anticipated future proposal to use a single manufacturer to produce security document paper for prescription blanks. The Requests for Proposal (RFP) for a single approved paper supplier will include requirements to ensure an adequate supply of security document paper. The New Jersey Department of the Treasury's Division of Purchase and Property is the State's central procurement agency and is responsible for the RFP process. Because the Division of Purchase and Property will issue the RFP for a single approved paper supplier, the Division does not know the anticipated timeframe. Interested parties may enroll in the eRFP Notification Service at <https://wwwnet1.state.nj.us/treasury/dpp/ebid/NotificationUser/NotificationUserEnrollment.aspx> to receive email notifications on new and updated RFPs advertised by the Division of Purchase and Property.

31. COMMENT: One commenter noted the anticipated impact of the Federal Electronic Health Records (EHR) mandate on the number of prescription blanks sold. The commenter noted that the mandate requires physicians to move towards paperless workflow or face fiscal penalties. The commenter also noted that it anticipates a reduction by 80-90 percent of the number of blanks sold within the next two to three years. The commenter raised concerns that vendors may find proposed security feature changes combined with reduced volume of prescription blanks unjustifiable from a business perspective resulting in their dropping out of the NJPB program. The commenter suggested polling vendors as to their ability to incorporate the proposed changes and then adjust the proposed revisions based on the responses.

RESPONSE: The Division recognizes that the use of electronic prescriptions is becoming more prevalent. However, any decrease in the number of prescription blanks used does not lessen the need to try to deal with the prevalent problems of the counterfeiting and alteration of printed prescriptions. The Division does not believe it is necessary to poll the printer vendors because in 2011, the Division discussed and obtained input, which forms the basis for these proposed amendments, from the approved printer vendors about the proposed print-based security measures.

32. COMMENT: Three commenters made suggestions about the artwork supplied by the Division. One commenter suggested that the final artwork for the new features should take into consideration the proprietary nature of some print processes and be specific in print specifications, so as to create a uniform look. Another commenter suggested that, because the configuration of feature changes may present unforeseen difficulties with respect to content and placement, the Division provide vendors with exemplars. Two commenters asked about the elements that will be included in the artwork supplied by the Division.

RESPONSE: The Division agrees with the commenter about the need for uniformity and will provide the printer vendors with an electronic file displaying a visual representation of the new NJPB. The Division will display in the artwork the hidden word feature, barcode, the microprint feature, and list of security features.

33. COMMENT: One commenter asked whether vendors will be required to submit samples of the new base stock in order to remain a print vendor.

RESPONSE: In accordance with N.J.A.C. 13:45A-27.10(b), after the amendments are adopted and before the printer vendors are permitted to sell the new prescription blanks, the Division will require each printer vendor to provide a sample proof of the new prescription blank for review and approval.

34. COMMENT: One commenter suggested that the Division conduct a special committee meeting with the vendors, similar to the one held in 1997, to discuss in-person the proposed changes, provide expert input on the proposed changes, and ensure that all vendors and the Division are in agreement.

RESPONSE: The Division thanks the commenter for its suggestion. The Division held a meeting with approved printer vendors in 2011, and does not believe additional meetings are necessary. The information gleaned from that meeting forms the basis for these adopted changes.

Summary of Agency-Initiated Change

The Division is making a technical change to N.J.A.C. 13:45A-27.8(f) to reflect that the rectangle circumscribing the "Rx" graphic is to be printed in green ink consistent with the proposed change to the ink for body copy (line work) in N.J.A.C. 13:45A-27.8(c). In the notice of proposal, the Division changed the body copy (line work) from blue to green. The rectangle described in N.J.A.C. 13:45A-27.8(f) is line work and accordingly should have also been changed. Printer vendors were on notice that the body copy (line work) was changing from blue to green and the non-change to N.J.A.C. 13:45A-27.8(f) in the notice of proposal was an oversight.

Federal Standards Statement

A Federal standards analysis is not required because the adopted amendments are governed by P.L. 2007, c. 244, codified as N.J.S.A. 45:14-59, and are not subject to any Federal requirements or standards. However, the security measures required by the adopted amendments meet the Centers for Medicaid and Medicare Services (CMS) guidelines. CMS is a branch of the U.S. Department of Health and Human Services.

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)-(b) (No change)

(c) Until *[(six months from the effective date of these proposed amendments)]* ***August 18, 2014***, licensed healthcare practitioners authorized to write prescriptions for controlled dangerous substances, legend drugs, or other items shall be permitted to issue written prescriptions on NJPBs purchased by them on or before *[(three months from the effective date of these proposed amendments)]* ***May 18, 2014***.

(d) Until *[(six months from the effective date of these proposed amendments)]* ***August 18, 2014***, healthcare facilities licensed pursuant to N.J.S.A. 26:2H-1 et seq., that are authorized to issue prescription blanks shall be permitted to issue written prescriptions on NJPBs purchased by them on or before *[(three months from the effective date of these proposed amendments)]* ***May 18, 2014***.

13:45A-27.3 NJPB required for prescriptions

(a) (No change.)

(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.-3. (No change.)

4. If the prescription is for a controlled dangerous substance, the licensed prescriber's Federal Drug Enforcement Administration (DEA) registration number *[is]* ***shall be pre-printed,*** 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. The licensed prescriber's Federal DEA registration number shall be pre-printed, legibly written, typed, stamped, or otherwise affixed to the NJPB. No other medication shall appear on the prescription.

(d) (No change.)

[page=397] (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, DEA number, as appropriate to the particular prescription and NPI number, if the prescriber has obtained an NPI number, at the time of transmission of the prescription, and the pharmacist satisfies the requirements of N.J.A.C. 13:39-7.10, 7.11, or 9.27.

1. (No change.)

(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 CFR 1306.11(d), (e), (f), and (g), consistent with the requirements set forth at N.J.A.C. 13:39-7.10, 7.11, or 9.27.

1. (No change.)

13:45A-27.4 Recordkeeping, reporting, and security requirements for licensed prescribers, health-care 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.-2. (No change.)

3. The unique *[14-digit]* ***15-digit*** identifiers of the NJPB pads as provided in N.J.A.C. 13:45A-27.9(g);

4.-6. (No change.)

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

13:45A-27.8 NJPB printing specifications

(a) Vendors shall manufacture all NJPBs consistent with the requirements set forth in this subchapter and the printing specifications approved by the Division and supplied to each approved vendor. Vendors shall also manufacture all NJPBs using artwork disks supplied by the Division.

(b) Each NJPB shall be:

1. (No change.)

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. ***The Division will permit printer vendors whose customers request it to use 24- to 28-pound MOCR paper with a brightness of at least 75; the printer vendors shall notify the Division when they use this alternative paper.***

(c) The front side of each NJPB shall be printed with the body copy (line work) in PMS *[332]* ***336*** green overprinted on a background of five percent of the green (with an allowable variance no darker than PMS *[333]* ***337*** green).

(d) The background of the front side of each NJPB shall be a pantograph of the New Jersey State Seal reversed out of the green 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 following information, printed in black ink:

1. A unique *[14-digit]* ***15-digit*** identifier as provided in N.J.A.C. 13:45A-27.9(g), and a linear barcode (Code *[39]* ***128***) that matches the unique *[14-digit]* ***15-digit*** identifier for each blank;

Recodify existing 3. and 4. as 2. and 3. (No change in text.)

4. 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; ***and***

[5. The prescriber's telephone number in reverse print; and]

[6.] ***5.*** (No change in text.)

(f) The prescribing area of the front side of each NJPB shall contain an "Rx" graphic circumscribed within a rectangle, printed in *[blue]* ***green*** 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 299 blue screened down to five percent (with an allowable variance up to PMS 300 blue), 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) NJPBs may be printed without the practitioner's name, address, or NPI number, or the unique provider number of the health care facility, provided the practitioner or health care facility utilizes an electronic health records system to imprint such information on the blanks. Such blanks shall be pre-printed with all other information required to appear on an NJPB pursuant to (e) above, and shall comply with all other printing specifications set forth in this section.

1. Prior to manufacturing NJPBs without a practitioner's name, address, or NPI number or health care facility unique provider number, a vendor shall document that the practitioner or health care facility utilizes an electronic health records system. Such documentation shall include the name and manufacturer of the electronic health records system utilized by the practitioner or health care facility.

(i) A safety hollow "VOID" *[pantograph]* ***hidden word feature*** background that *[cannot be replicated]* ***is designed to prevent replication*** by a black and white or color copier or by a scanner is required on each NJPB. A ***repeating pattern of a*** hollow "VOID" shall appear on the face of the NJPB. Areas intended for data entry shall be in lighter tones to permit easy reading of information without compromising copy protection.

(j) Microprint shall be included on each NJPB. The print shall be in 0.5 *[font]* ***point*** or smaller and shall be readable when viewed at five times magnification or greater, but shall be illegible when photocopied or scanned.

(k) Each NJPB shall be printed with friction activated (thermochromic) ink, that shall appear in an Rx logo on the blank. The ink on the face shall change color or disappear when warmed (reacts to body heat). The ink should return to its original color when cooled.

(l) *[Each NJPB shall include a tamper evident coating containing a hidden void feature to prevent attempts to alter the prescription with acetone or other chemical agents. Under normal conditions, the feature is invisible. An erasure or abrasion attempt will activate the coating and the word VOID will appear and shall obscure the area where the prescription information is written.]* ***(Reserved)***

(m) Each NJPB shall be printed with a complete list of all security features incorporated into the prescription pad in order to minimize tampering. The security features shall be listed visibly in a box, band, or border on the prescription.

(n) Except as provided in (o) 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.-2. (No change.)

Recodify existing (i), (j), and (k) as (o), (p), and (q) (No change in text.)

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

1.-3. (No change.)

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

Recodify existing (n) and (o) as (t) and (u) (No change in text.)

13:45A-27.9 Vendor requirements

(a)-(e) (No change.)

(f) Vendors shall be capable of producing seven versions of NJPBs, each in the following forms:

1.-4. (No change.)

(g) Vendors shall assign and maintain a unique NJPB *[14-digit]* ***15-digit*** identifier for each order of NJPBs from a licensed prescriber or licensed healthcare facility. Re-orders of NJPBs shall contain a unique identifier sequentially greater than the unique identifier assigned to any previous order. The *[14-digit]* ***15-digit*** unique identifier shall consist of:

1. A two-digit alphabetic prefix assigned by the Division, which represents the identity of the vendor;

[page=398] 2. A six-digit order number, of which *[two]* ***three*** digits represent the vendor's prescriber identifier, and four digits that represent the month and year of the printing order; and

3. A six-digit sequential serial number, beginning with the number 1 and ending with 999,999. A zero shall be used as a placeholder for any unused digits to the left in the sequential serial number.

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

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

i.-v. (No change.)

vi. *[14-digit]* ***15-digit*** unique identifier;

vii.-x. (No change.)

2. (No change.)