DEPARTMENT OF SAFETY AND HOMELAND SECURITY

OFFICE OF THE SECRETARY

Statutory Authority: 16 Delaware Code, Section 4797(c)
(16 **Del.C.**, §4797(c))

PROPOSED

PUBLIC NOTICE

Regulations Governing the Statewide Authorized Tamper Resistant Prescription Forms

The Delaware Department of Homeland Security is promulgating rules and regulations pursuant to 16 Del. C. § 4797(c) of the Delaware Code affecting professionals licensed or registered under Title 24 and Title 16 of the Delaware Code having prescriptive authority. The proposed rules and regulations establish security requirements for a blank prescription form used by a prescriber or practitioner in this State. The primary objective of these rules and regulations is to reduce prescription fraud by decreasing the potential for forgery or alteration of a prescription form. The regulations shall be known as "Regulations Governing the Statewide Authorized Tamper Resistant Prescription Forms".

A public hearing will be held on July 13, 2011 at 9:00 a.m. in the second floor conference room B of the Cannon Building, 861 Silver Lake Boulevard, Dover before James L. Collins, Director of the Division of Professional Regulation, where members of the public can offer comments. The Director will also receive and consider input in writing from any person concerning the proposed regulations. Written comments should be submitted to James Collins, Director, Division of Professional Regulation, at the above address. The final date to submit written comments shall be at the public hearing. Anyone wishing to obtain a copy of the proposed regulations or to make comments at the public hearing should contact Shauna Slaughter, Administrative Specialist, at the above address or by calling (302) 744-4502.

The Department through the Director may consider promulgating the proposed regulations immediately following the public hearing.

Regulations Governing the Statewide Authorized Tamper Resistant Prescription Forms

1.0 Purpose.

To promulgate rules and regulations pursuant to Title 16, Section 4797 of the Delaware Code, that establish security requirements for a blank prescription form used by a prescriber or practitioner in this State. The primary objective of these rules and regulations is to reduce prescription fraud by decreasing the potential for forgery or alteration of a prescription form.

2.0 Scope and Applicability

2.1 Authority. These regulations are enacted pursuant to 16 **Del.C.** §4797. These regulations shall be known as "Regulations Governing the Statewide Authorized Tamper Resistant Prescription Forms".

2.2 Applicability. These regulations apply to any individual who is authorized by law to prescribe drugs in the course of professional practice and to any vendor in the business of manufacturing and selling tamper proof prescription forms to a Delaware practitioner or prescriber.

3.0 Definitions:

"**Controlled Substance**" shall mean a drug substance or immediate precursor in Schedules I through V as defined in 16 Del. C. Chap.47, Subchapter 2. There shall only be one controlled substance listed on each prescription form.

"**Division**" shall mean the Department of State, Division of Professional Regulation

"**Drugs**" shall mean drugs as defined in 16 Del. C. §4701(14) or 24 Del.C. § 2502(14).

"**Practitioner**" or "**Prescriber**" shall mean prescriber as defined in 24 Del. C. § 2502(20). It shall not include any practitioner or prescriber generating prescriptions within a licensed medical facility that results in the internal dispensing of prescription drugs or devices to any patient receiving treatment in that facility.

"**Provider ID #**" shall mean the unique identification number assigned by a vendor to any individual, group or organization authorized to purchase tamper resistant prescription forms pursuant to 24 Del. C. § 2502(20) and these rules and regulations. The Provider ID # shall be a suffix to the serial number on the prescription forms as described in section 6.11.

"**Tamper Resistant Prescription Form**" or "**Prescription Form**" shall mean a prescription form which has been authorized pursuant to 16 Del. C. § 4797 and meets the criteria established in these rules and regulations.

"**Vendor(s)**" shall mean any corporation, company, or entity in the business of manufacturing and selling tamper resistant prescription forms to authorized practitioners or prescribers and who has registered its name, address and telephone number to the Division of Professional Regulation and has been assigned a Vender ID number. All vendors registered with the Division of Professional Regulation are deemed to be in agreement that they shall abide by and comply with these rules and regulations.

"**Vendor ID #**" shall mean the unique identification number assigned by DPR to a registered vendor. Pursuant to 6.11, the Vendor ID # shall be displayed as a prefix to the serial number on the prescription form.

4.0 Authority of the Division of Professional Regulation:

4.1 In accordance with §4701(35) and §4731, Title 16 of the Delaware Code, the Director of the Division of Professional Regulation shall promulgate rules and regulations as they relate to tamper resistant prescription forms pursuant to 16 Del.C. §4797.

4.2 The Director shall establish and implement standards governing the production and issuance of authorized tamper resistant prescription forms pursuant to 16 Del. C. § 4797.

4.3 DPR may inspect facilities or records of vendors or require submission of information to demonstrate compliance with these rules.

4.4 Any enforcement actions pursuant to these rules and regulations shall be governed by the Administrative Procedures Act (Chapter 101, Title 29 of the Delaware Code)

5.0 Tamper Resistant Form Requirements.

5.1 Secure Stock. All paper utilized in the production of tamper resistant prescription forms must be manufactured under tightly controlled security conditions, restricted in its use and distribution, and not readily available on the open market(unavailable in retail stores or stored in unsecured print facilities).

5.2 Vendors will be required to set all new copy on each prescription design. There are multiple versions that require design. Placement of design elements and security features must be consistent across all versions.

5.3 General Composition. A safety hollow VOID pantograph background is required on each design (a solid void pantograph is not acceptable). The document shall include substantial protection against reproduction by color copiers. Preferred methods include darker and lighter gradually changing tones that provide significant color copy protection across a full range of copier settings. The word "VOID" shall appear on all copies made across a wide variety of copier settings. Areas intended for data entry shall be in lighter tones to permit easy reading of information without compromising copy protection.

5.4 Custom Imprinting. Custom imprinting of the Prescription Forms will be required for each practitioner, group practice or institution. Printing will include name, street, city, state zip code, telephone number, State of Delaware license number, and the United States Drug Enforcement Agency (DEA) number (at the practitioner's option) of the practitioner(s) or institution as requested. All custom imprinting must be printed in black ink that penetrates the paper fibers as a prescription fraud prevention requirement (Toner based imprinting is not permitted).

5.5 Prescription Forms (Two Types - Practitioner and Institution).

5.5.1 Size: 4-1/4 "x 5-1/2" overall, no bleeds.

5.5.2 Stock. The stock must be 24# white controlled safety paper. The paper must contain an invisible eradicator sensitive ink that shows the word "VOID" when tampering is attempted. A simple stain is not sufficient. The paper must react when alteration is attempted using the following list of chemicals: Acetone, Methyl Ethyl Ketone, Ethyl Acetate, Nail Polish Remover, Paint Remover, Benzyl Alcohol, Methyl Alcohol, N-Butyl Alcohol, Iso Propyl Alcohol, Ethyl Alcohol, Rubbing Alcohol, Hair Spray, 1-Methoxy-2-Propanol, Carbon Tetrachloride, Bleach, Tetrahydrofurane, Butyl Cellulose, 5% Hydrochloric Acid & Trichloroethylene.

5.5.3 Presswork/Ink.

5.5.3.1 FRONT: Prints 3 colors (black and other colors to be specified by DPR including a friction activated ink). The friction activated (thermochromic) ink on the face should be printed in blue and should change color or disappear when warmed (reacts to body heat). It should return to its original color (blue) when cooled. Must also contain color copy hollow VOID Pantograph as described under section 6.3, 6.5.2., and 7.1. There shall also be a tamper evident coating containing a hidden void feature. Under normal conditions, the feature is invisible. An erasure/ abrasion attempt will activate the coating and the word VOID will appear.

5.5.3.2 BACK: Prints 3 colors (gray, white fluorescent & a friction activated ink). "Enhanced" Laid lines - unevenly spaced and sized diagonal lines printed in gray ink across the back of each prescription. The back shall also contain an artificial watermark identifying the vendor responsible for manufacturing the prescriptions forms printed in white or transparent non-penetrating ink, which is visible to the human eye when viewed only at a 45 degree angle. This feature must also appear fluorescent green under a black light. A friction activated (thermochromic) ink must be present in several locations on the back of each prescription. The ink shall be printed in orange and should change color or disappear when warmed (reacts to body heat). It should return to its original color (orange) when cooled.

5.5.3 Construction/Bindery. Pads are edge glued in sets of 100 prescriptions for shipment to practitioners and institutions across Delaware. A chipboard backer is required for each pad.

5.6 Laser Sheets (1-Up Version).

5.6.1 Size: 8-1/2" x 11", no bleeds.

5.6.2 Stock. 24# white controlled safety paper. The stock utilized must be unavailable on the consumer market (unavailable in retail stores or stored in unsecured print facilities). The paper utilized must be designed and function effectively across a wide range of laser printing devices. The paper must contain an invisible eradicator sensitive ink that shows the word "VOID", as defined under section 6.3 and 7.1, when tampering is attempted. A simple stain is not sufficient. The paper must react when alteration is attempted using the following list of chemicals: (Acetone, Methyl Ethyl Ketone, Ethyl Acetate, Nail Polish Remover, Paint Remover, Benzyl Alcohol, Methyl Alcohol, N-Butyl Alcohol, Iso Propyl Alcohol, Ethyl Alcohol, Rubbing Alcohol, Hair Spray, 1- Methoxy-2-Propanol, Carbon Tetrachloride, Bleach, Tetrahydrofurane, Butyl Cellulose, 5% Hydrochloric Acid & Trichloroethylene).

5.6.3 Presswork/Ink:

5.6.3.1 FRONT: Prints 3 colors (black and other colors to be specified by DPR including a friction activated ink). The friction activated (thermochromic) ink on the face should be printed in blue and should change color or disappear when warmed (reacts to body heat). It should return to its original color (blue) when cooled. Must also contain color copy hollow VOID Pantograph as described under section 6.3, 6.6.2 and 7.1. An additional coating is required on the face to insure toner adhesion to the paper. This feature is commonly referred to as "toner grip" or "laser lock".

5.6.3.2 BACK: Prints 3 colors (gray, white fluorescent & a friction activated ink). "Enhanced" Laid lines - unevenly spaced and sized diagonal lines printed in gray ink across the back of each prescription. The back shall also contain an artificial watermark identifying the vendor responsible for manufacturing the prescription forms printed in white or transparent non-penetrating ink, which is visible to the human eye when viewed only at a 45 degree angle. This feature must also appear fluorescent green under a black light. A friction activated (thermochromic) ink must be present in several locations on the back of each prescription. The ink shall be printed in orange and should change color or disappear when warmed (reacts to body heat). It should return to its original color (orange) when cooled.

5.7 Laser Sheets (4-Up Version):

5.7.1 Size: Four individual 4-1/4" x 5-1/2" forms up on an 8-1/2" x 11" sheet, no bleeds.

5.7.2 Stock. 24# white controlled safety paper. The stock utilized must be unavailable on the consumer market (unavailable in retail stores or stored in unsecured print facilities). The paper utilized must be designed and function effectively across a wide range of laser printing devices. The paper must contain an invisible eradicator sensitive ink that shows the word "VOID", as defined under section 6.3 and 7.1, when tampering is attempted. A simple stain is not sufficient. The paper must react when alteration is attempted using the following list of chemicals: (Acetone, Methyl Ethyl Ketone, Ethyl Acetate, Nail Polish Remover, Paint Remover, Benzyl Alcohol, Methyl Alcohol, N-Butyl Alcohol, Iso Propyl Alcohol, Ethyl Alcohol, Rubbing Alcohol, Hair Spray, 1- Methoxy-2-Propanol, Carbon Tetrachloride, Bleach, Tetrahydrofurane, Butyl Cellulose, 5% Hydrochloric Acid & Trichloroethylene).

5.7.3 Presswork/Ink:

5.7.3.1 FRONT: Prints 3 colors (black plus colors to be specified by DPR including a friction activated ink). The friction activated (thermochromic) ink on the face should be printed in blue and should change color or disappear when warmed (reacts to body heat). It should return to its original color (blue) when cooled. Must also contain color copy hollow VOID Pantograph as described under section 6.3 and 7.1. An additional coating is required on the face to insure toner adhesion to the paper. This feature is commonly referred to as "toner grip" or "laser lock".

5.7.3.2 BACK: Prints 3 colors (gray, white fluorescent & a friction activated ink). "Enhanced" Laid lines - unevenly spaced and sized diagonal lines printed in gray ink across the back of each prescription.

The back shall also contain an artificial watermark identifying the vendor responsible for manufacturing the prescription forms printed in white or transparent non-penetrating ink, which is visible to the human eye when viewed only at a 45 degree angle. This feature must also appear fluorescent green under a black light. A friction activated (thermochromic) ink must be present in several locations on the back of each prescription. The ink shall be printed in orange and should change color or disappear when warmed (reacts to body heat). It should return to its original color (orange) when cooled.

5.7.4 Perforations: Laser cross perforations (full horizontal & full vertical) divide each sheet into 4 equal sections that measure 4-1/4"x 5-1/2". Perforations must be compatible with a laser printing environment the paper must feed effectively and operate trouble-free across a wide range of laser devices by various manufacturers.

5.8 Thermal Rolls:

5.8.1 Size: Individual form size is 4-1/4 "x 5-1/2", no bleeds.

5.8.2 Stock. A heavy weight, high sensitivity, direct thermal paper grade with an average basis weight of 20.4 lbs. (76.8 grams/m2). The thickness should be an average of 3.26 Mils (82.8 Microns). The grade should have an enhanced coating design with resistance to reasonable environmental conditions. The grade should provide a clear, dark image that is consistent and suitable for high quality bar code imaging. The optimum activation temperature at 194+/- 9 degrees F (90 +/- 5 degrees C) should result in a density reading of 1.3 ODU. The thermal grade should have an image stability or archivability rating such that after imaging with reasonable storage, the image will remain human readable for a minimum of 10 years.

5.8.3 Presswork/Ink:

5.8.3.1 FRONT: Prints 3 colors (black and other colors to be specified by DPR including a friction activated ink.). The friction activated (thermochromic) ink on the face should be printed in blue and should change color or disappear when warmed (reacts to body heat). It should return to its original color (blue) when cooled. Must also contain color copy hollow VOID Pantograph as described under section 6.3 and 7.1.

5.8.3.2 BACK: Prints 4 colors (gray, black, white fluorescent & a friction activated ink). "Enhanced" Laid lines - unevenly spaced and sized diagonal lines printed in gray ink across the back of each prescription. The back shall also contain an artificial watermark identifying the vendor responsible for manufacturing the prescription forms printed in white or transparent non-penetrating ink, which is visible to the human eye when viewed only at a 45 degree angle. This feature must also appear fluorescent green under a black light. A friction activated (thermochromic) ink must be present in several locations on the back of each prescription. The ink shall be printed in orange and should change color or disappear when warmed (reacts to body heat). It should return to its original color (orange) when cooled. Two timing marks must also be printed in black ink on the back of each individual prescription.

5.8.4 This is a direct thermal roll product that requires winding 500 prescriptions on each roll. Scripts are wound on a roll that utilizes a 1" plastic core. A core made of cardboard or other material is not acceptable.

5.9 Intermic Thermal Rolls.

5.9.1 Size: Individual form size is 4-1/4" x 5-1/2", no bleeds.

5.9.2 Stock. A heavy weight, high sensitivity, direct thermal paper grade with an average basis weight of 20.4 lbs. (76.8 grams/m2). The thickness should be an average of 3.26 Mils (82.8 Microns). The grade should have an enhanced coating design with resistance to reasonable environmental conditions, such as 24 hour immersion in water. The grade should provide a clear, dark image that is consistent and suitable for high quality bar code imaging. The optimum activation temperature at 194+/- 9 degrees F (90 +/- 5 degrees C) should result in a density reading of 1.3 ODU. The thermal grade should have an image stability or archivability rating such that after imaging with reasonable storage, the image will remain human readable for a minimum of 10 years.

5.9.3 Presswork/Ink:

5.9.3.1 FRONT: Prints 3 colors (black plus colors to be specified by DPR including a friction activated ink). The friction activated (thermochromic) ink on the face should be printed in blue and should change color or disappear when warmed (reacts to body heat). It should return to its original color (blue) when cooled. Must also contain color copy hollow VOID Pantograph as described under section 6.3 and 7.1.

5.9.3.2 BACK: Prints 4 colors (gray, black, white fluorescent & a friction activated ink). "Enhanced" Laid lines - unevenly spaced and sized diagonal lines printed in gray ink across the back of each prescription. The back shall also contain an artificial watermark identifying the vendor responsible

for manufacturing the prescription forms printed in white or transparent non-penetrating ink, which is visible to the human eye when viewed only at a 45 degree angle. This feature must also appear fluorescent green under a black light. A friction activated (thermochromic) ink must be present in several locations on the back of each prescription. The ink shall be printed in orange and should change color or disappear when warmed (reacts to body heat). It should return to its original color (orange) when cooled. A timing mark that extends horizontally across the back of each script shall be printed in black ink.

5.9.4 This is a direct thermal roll product that requires winding 500 prescriptions on each roll. Prescriptions are wound on a roll that utilizes a 1" plastic core. A core made of cardboard or other material is not acceptable. A full horizontal perforation is required between each prescription (every 5-1/2").

6.0 Two-Part Carbonless Form

6.1 Size: 4-1/4" x 5-1/2", no bleeds.

6.2 Stock:

6.2.1 Part 1 - Minimum of 20# White CB carbonless bond. The paper must contain an invisible coating that stains when bleach is applied.

6.2.2 Part 2 - Minimum of 20# Canary CF carbonless bond.

6.3 Presswork/Ink:

6.3.1 FRONT: Part 1 prints 3 colors (black plus colors to be specified by DPR including a friction activated ink). The friction activated (thermochromic) ink on the face should be printed in blue and should change color or disappear when warmed (reacts to body heat). It should return to its original color (blue) when cooled. Must also contain color copy hollow VOID Pantograph as described under section 6.3 and 7.1. An additional coating is required on the face to insure toner adhesion to the paper. This feature is commonly referred to as "toner grip" or "laser lock". Part 2 prints one color to be specified by DPR.

6.3.2 BACK: Part 1 prints 3 colors (gray, white fluorescent & a friction activated ink). "Enhanced" Laid lines - unevenly spaced and sized diagonal lines printed in gray ink across the back of each prescription. The back shall also contain an artificial watermark identifying the vendor responsible for manufacturing the prescription forms printed in white or transparent non-penetrating ink, which is visible to the human eye when viewed only at a 45 degree angle. This feature must also appear fluorescent green under a black light. A friction activated (thermochromic) ink must be present in several locations on the back of each prescription. The ink shall be printed in orange and should change color or disappear when warmed (reacts to body heat). It should return to its original color (orange) when cooled. The back of Part 2 is unprinted.

6.4 Numbering. A press or crash numbering methodology may be utilized to apply the crash numbering to part 2.

6.5 Construction and Bindery: Pads are edge glued in sets of 50 two-part prescriptions for shipment to practitioners and institutions across Delaware. A chipboard backer is required for each pad. An additional chipboard insert (size 4-1/4" x 5-1/2") is shipped with each pad. Since these are carbonless 2-part pads, the chipboard insert will be used to prevent writing through to other ply(s). An instruction sheet describing how to use the chipboard insert must also accompany STATE each shipment.

7.0 Mandatory Prescription Form Markers:

7.1 Hollow Void Pantograph: Outlined open letters spelling the word "VOID" when form is photocopied. A safety hollow VOID pantograph background is required on each design (a solid void pantograph is not acceptable) pursuant to Section 4.2 of these regulations.

7.2 Security Back Print: Text or images on back of forms stating that this is a security script;

7.3 Micro-printing: Very small font that is legible when viewed at 5 times magnification or greater, but illegible when copied;

7.4 Reverse "Rx": Visible "Rx" watermark that disappears when copied;

7.5 Watermarking: The back of the form shall contain an artificial watermark identifying the vendor responsible for manufacturing the prescription forms printed on the back of the prescription that can only be seen when viewed at an angle;

7.6 Solid colored background;

7.7 Quantity Check Boxes;

7.8 Refill Indicator;

7.9 Chemical Reactive Paper: The paper must react when alteration is attempted using the following list of chemicals: Acetone, Methyl Ethyl Ketone, Nail Polish Remover, Paint Remover, Benzyl Alcohol, Methyl Alcohol, Rubbing Alcohol, Hair Spray, 1-Methoxy-2-Propanol, Carbon Tetrachloride, Bleach;

7.10 List all Security Features on Back;

7.11 Serial Numbered: The serial number shall be prefaced by the Vendor ID # and the Provider ID # shall follow as a suffix to the serial number. The Vendor Id #, serial number and Provider ID # must also be displayed as a bar code pursuant to Section 6.13.2 of these regulations; and,

7.12 Heat Sensing (Thermochromic Ink) Imprint.

7.13 Serial Numbering/Bar Coding:

7.13.1 Vendors shall adhere to a base 31 numbering scheme to be developed and employed in the contract period. The numbering scheme shall include a code 39 barcode and be in a format that can be easily data entered by the dispensing pharmacy and shall be approved by the Division of Professional Regulation.

7.13.2 A unique human readable consecutive number (Alphanumeric) and matching linear barcode (code 39) must be applied to each individual prescription form in an established numbering scheme approved by the Division of Professional Regulation. Vendors must be able to guarantee no duplicate numbers across the entire range of product types (6 Items described herein). Each individual prescription must have a unique number and matching code 39 barcode printed in black. Forms held in storage for Delaware Practitioners shall be consecutive numbered/bar-coded to facilitate inventory accountability by the Vendor.

7.13.3 Only one copy of serially numbered set shall be produced. NO DUPLICATE OR MISSING NUMBERS ARE ACCEPTABLE.

7.13.4 The Vendor ID # shall appear as a prefix to the serial number and the Provider ID # shall appear as a suffix to the serial number. The Vendor ID # and Provider ID # shall also be included as part of the matching 39 barcode.

8.0 Requirements for Vendors

8.1 Secure Stock: Pursuant to section 6.1, all controlled paper utilized in the production of the Prescription Forms must be manufactured under tightly controlled security conditions, restricted in its use and distribution, and not readily available on the open market. Vendors must supply a list of the built in security features contained in their proposed security paper.

8.2 Document Security: Vendors must guard against the loss of forms during the process of manufacture, storage, imprinting and delivery to designated recipients. Vendors must provide document security measures including but not limited to:

8.2.1 Security of the area where prescriptions pads and paper are stored.

8.2.2 Destruction of sensitive material waste including but not limited to all samples and test documents.

8.2.3 Accessibility of the printing, handling, imprinting, packaging and distribution area.

8.2.4 Storage of all printing and imprinting plates including the maintenance of a plate log and destruction record of places.

8.2.5 Building security including but not limited to surveillance within and around the facility.

8.3 Technical Environment/Computer.

8.3.1 Vendors must provide system security including but not limited to:

8.3.1.1 Robust encryption management process for managing data transfers both internally and eternally.

8.3.1.2 Back up data process and recoverability.

8.3.1.3 Password policy.

8.4 Vendors shall guarantee that only one copy of each serially numbered set will be produced. NO DUPLICATE OR MISSING NUMBERS ARE ACCEPTABLE.

8.5 State of Delaware reserves the right to have DPR representatives enter a Vendor's premises without advance notice during stated hours of daily operation to inspect methods of production, storage and handling of forms, and to determine full compliance with all provisions of these regulations.

8.6 Any vendor manufacturing and selling tamper proof prescription forms to a Delaware licensed practitioner or prescriber shall contact the Division of Professional Regulation to:

8.6.1 Obtain, for purposes of accurate delivery of tamper proof prescription forms, the registered name, address and telephone number of the practitioner or prescriber;,

8.6.2 Register the company, contact person, address and telephone number; and,

8.6.3 The Division of Professional Regulation shall assign a Vendor ID # to a registered vendor, which shall then be included as a prefix to the serial number pursuant to 6.11.

8.7 Vendors must provide for the immediate disposal of all damaged or mutilated forms.

8.8 Vendors are required to furnish a toll free 800 number operated with the United States available to Practitioners for questions and order information.

8.8.1 Vendor staff and equipment must be capable of receiving and servicing all calls received daily.

8.8.2 Vendors must have the ability to track and report calls received, answered, abandoned, average speed of answer, average talk time, call reason, call resolution and call monitoring.

8.8.3 Vendors must have a contingency plan for equipment or service failure.

8.8.4 Vendor staff must have computer equipment capable of accessing the web-based ordering system, so that customer calls can be adequately serviced.

8.9 PAYMENT: Vendors must accept full payment by procurement (credit) card and/or conventional check and/or other electronic means.

8.10 Quality Assurance: Vendors must notify the DPR of any quality control problems as they occur.

8.11 Certified vendors must notify DPR in writing within 30 days of any material changes to its business, systems or processes related to compliance with these rules.

9.0 Order Processing:

9.1 Vendors must establish a system to directly receive, verify and process all orders for Prescription forms. Vendors must ensure that Prescriptions Forms are only to be issued to authorized practitioners and institutions. Such authorization shall include a registration process by which DPR registers authorized practitioners/institutions. All such systems, including computer information, shall be housed and maintained in a secure environment.

9.2 Vendors must establish a system for order processing that meets all applicable regulations.

9.3 Returned Prescriptions: Vendors are responsible for tracking all prescriptions that have been returned to the vendor as being undeliverable or that contain errors. The vendor must maintain a record of all returned prescriptions to include serial numbers, the date of delivery, and the name of the practitioner/institution. Such records shall be made available to the Division of Professional Regulation upon request. When vendors receive prescriptions that have been returned as being undeliverable, they shall notify the practitioner/ institution that placed the order immediately. Prescriptions containing errors or otherwise deemed undeliverable must be destroyed by the vendor.

9.4 All suspicious incidents involving returned prescriptions, as well as prescriptions that were lost in delivery must be immediately reported to the Division of Professional Regulation.

9.5 Tracers: Vendors are responsible for tracing orders not received, claims filed for non-receipt, and providing credit to registered practitioners for the cost of orders not received.

9.6 Suspicious Orders: Vendors must maintain records of all suspicious orders which shall be made available for review and inspection by the DPR upon request.

9.7 Rush Orders: Vendors shall establish and maintain a system capable of processing and shipping emergency orders overnight.

9.8 Ordering Procedure: Vendors are required to have either a local telephone number within the (302) area code, a toll free (800) number, or agree to accept collect calls. Each agency, practitioner or practitioner's authorized designee is responsible for placing their orders to the Vendor, which may be accomplished by written purchase order, telephone, fax or computer on-line systems. Vendors must accept full payment by procurement (credit) card and/or conventional check and/or other electronic means without imposing any additional fees, costs or conditions.

9.9 Order Management Requirements: The system must provide robust management information capabilities to the user such as Viewing Order History, Searching for an Order by various elements, Display of Previous Order Details including a PDF proof of the prescription layout, as well as the flexibility to place a Reorder based on a past order that is still viewable on the system. Previous Order History must be made available for a minimum of 2 years.

9.9.1 Order History - The system must be capable of maintaining order history for each Practitioner, Institution, and other authorized users. The system must present the user with a list of orders that can be sorted by order date, order number, or order status. A search engine should be deployed as part of the order history feature that allows user to search for an order by the above criteria. When an order is selected from the order history page, the details of the order must be presented. Details are to include the prescription numbers associated with that order, a shipping tracking number and estimated delivery date and the visible PDF proof of the actual order prescription information that was printed as part of the associated order.

9.9.1.1 Order Detail - When an order is selected from the order history page, the details of the order must be presented including the prescription numbers associated with that order, shipping tracking number and estimated delivery date and the visible PDF proof of the actual order script information that was printed as part of the associated order.

9.9.1.2 Reorder - The user must have the ability to repurpose past order data to place a reorder for any Practitioner order still active in their Order History Screen. All business rules, especially those relating to active practitioners and account status, need to be reapplied to a new order placed via the Reorder functionality.

9.9.2 Reorder forms.

9.9.2.1 A reorder form must accompany each shipped order.

9.9.2.2 Stock: 20# xerographic bond in colors specified by the DPR

9.9.2.3 Size: 8-1/2" x 11", no bleeds

9.9.2.4 Presswork/Ink: Prints black ink front and back.

9.9.2.5 Variable Information: Reorder forms to be personalized with individual practitioner's/institution's applicable contact information.

9.9.2.6 Perforation: a full horizontal perforation is required.

9.9.3 Mailing Container. All forms shall be wrapped in a secure manner suitable for mailing. All packaging must be of such strength, substance and construction suitable for mailing with a return address to vendor. Mailing container shall not contain any markers or labels to indicate that the contents are prescription forms.

10.0 Online Ordering

10.1 Data Transmission: Vendors shall provide authorized registered Practitioners with the order information in electronic format.

10.2 User Profile Requirements: Every Practitioner or designee connecting to the vendor provided software must be linked to a unique profile. The system must provide the capability to profile each user separately. This feature must enable the user to view his/her profile in the system and make modifications to user changeable fields such as password, telephone number, e-mail address. This screen also displays information that is not changeable by the user. These include spending limits, User ID, ship-to code, and user group affiliation (e.g., practitioner, Institutional user, etc.) and ship-to-address.

10.3 Input data validation

11.0 Data Interface Requirements.

Each business day, Vendors must retrieve profile account information about all practitioners and institutions that were added or changed during the current business day. This information shall be available in an electronic format to DPR upon request. Vendors will be provided a detailed field mapping and the associated exception processing that must be performed. The vendor's software must handle exception processing and must ensure all records are either transacted successfully or failed.

12.0 Drug Enforcement Agency (DEA).

Vendors must implement a technical solution for receiving and updating practitioner information from the DPR.

13.0 Delivery.

13.1 Forms shall be shipped via courier which provides a "protective signature service," or the vendor may make direct shipment from their factory by "For Hire" carrier or vendor's truck, provided shipment is made in locked vans and such vans are not left unlocked or unattended while making pickups and deliveries. Delivery may also be made by vendor's vehicles under similar security and delivery requirements. A printer's manifest must accompany the shipment.

13.2 Vendor Prescription Forms must be shipped within 3 days of receipt of order. Delivery must be made to the address approved by DPR. No deliveries will be made to a private residence unless a practitioner's office and business location are attached. A record of delivery must be maintained by the Vendor and shall consist of the name of the practitioner/institution, prescription serial numbers, date of delivery, and the name and signature of the person receiving the delivery. This information must be maintained for a period of at least 5 years. Orders which are not delivered shall be handled as detailed in the section titled "Returned Prescriptions".

14.0 Mandatory Insurance Requirements.

Vendors shall obtain at their own cost and expense and keep in force and effect comprehensive general liability insurance.

15.0 State of Delaware Business License Requirement.

Vendors shall provide proof of and shall maintain a valid State of Delaware Business Licensure. Failure to comply with the State of Delaware licensing requirements may subject the vendor to applicable fines and/or interest penalties.