

STATE OF NEVADA

**ELECTRONIC
PEDIGREE PROGRAM
HANDBOOK**



NEVADA STATE BOARD OF PHARMACY

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1.0 Electronic Pedigree Program Overview

1.1 The Program

The Nevada State Board of Pharmacy (the Board) has been licensing and regulating the practices of pharmaceutical wholesalers in Nevada since 1967. In the 2005 Legislative Sessions, the Nevada Legislature passed substantial changes to the law related to the practices of pharmaceutical wholesalers licensed in Nevada. One of those changes, Nevada Revised Statutes (NRS) 639.540(3)(b)(2), requires that statements of prior sales (referred to herein as pedigrees) must be in “electronic form , if the transaction occurs on or after January 1, 2007.

As a result of the legislative directive of NRS 639.540(3)(b)(2), on May 4, 2006 the Board amended Nevada Administrative Code (NAC) 639.603 to add a new section 5 that provides:

5. Beginning February 15, 2007, a wholesaler shall transmit to the Board, on or before the 15th day of each month, the information collected pursuant to subsection 2 for all statements of prior sales made for the immediately preceding month regarding the sale of a prescription drug to:

- (a) Each customer in Nevada; and
- (b) Each wholesaler located in Nevada.

The information required by this subsection must be transmitted by electronic mail to the Board or to a website established by the Board in a format required by the Board.

The Electronic Pedigree Program (EPP) described and discussed in this document will implement NRS 639.540 and NAC 639.603.

1.2 The Requirement

A wholesaler must provide pedigree data to the EPP under the two conditions set out in NAC 639.603(5), namely: (1) for every pedigreed sale made by an out-of-state wholesaler to a customer in Nevada, or (2) for every pedigreed sale made by a wholesaler located in Nevada to any customer, regardless of who the customer is or where the customer is located.

Under Nevada law, a pedigree is required when one of two things is true:

- (1) The selling wholesaler is not an authorized distributor for the manufacturer of the drug, or
- (2) The selling wholesaler bought the drug from another wholesaler.

1.3 Collection of Data

The required pedigree data must be received by the Board’s Reno office no later than the 15th day of each month, beginning on February 15, 2007, for the pedigree data generated from the first day to the last day of the preceding month. The pedigree data can be

transmitted to the EPP either: (1) by e-mail addressed to ccramer@pharmacy.nv.gov or (2) by CD addressed to:

Nevada State Board of Pharmacy
Electronic Pedigree Program
431 West Plumb Lane
Reno, Nevada 89509

2.0 Prescription Data Required

2.1 Mandatory Data

The following data is required to be reported to the EPP for every pedigree:

- (a) Name, address, telephone number, and Nevada license number of the wholesaler making the pedigree;
- (b) Name and title of person certifying the pedigree's accuracy;
- (c) Invoice number and date for the transaction of which the pedigree is part;
- (d) Purchase order number and date for the transaction of which the pedigree is part;
- (e) Order number and date (if one) for the transaction of which the pedigree is part;
- (f) The business name, address, and telephone number of each preceding seller of the drug;
- (g) The business name, address, and telephone number of the customer to whom the reporting wholesaler sold the drug;
- (h) The date of each preceding or subsequent sale;
- (i) Name of the drug;
- (j) Strength of the drug;
- (k) Size of the container;
- (l) Number of containers;
- (m) Lot number of the drug;
- (n) Name of the manufacturer of the drug; and
- (o) NDC number for the drug (if the wholesaler captures or uses the number).

2.2 Record Layout

The data submitted must be in the format shown in Figure 2-1.

2.3 Definition of Each Data Element

A description of the data required in each field is presented in Figure 2-2.

3.0 Program Implementation Schedule

Effective Date of EPP Regulations:	May 4, 2006
Notification of Wholesalers Regarding EPP:	October 20, 2006
Initial Reporting Period:	January 1-31, 2007
Initial Reporting Deadline:	February 15, 2007

4.0 Submission of Data

4.1 Methods of Submission

Pedigree data must be submitted in Microsoft Excel format (an .xls file) either: (1) by e-mail addressed to ccramer@pharmacy.nv.gov; or (2) by mailing a CD containing the file along with an EPP Transmittal Form (*see* Section 4.3) addressed to: Nevada State Board of Pharmacy, Attn: EPP, 431 West Plumb Lane, Reno, Nevada 89509. The Excel file should contain all the pedigrees for the particular reporting period in a single file.

4.2 Certification and Rejection

4.2.1 Certification

Initial data submissions will be audited for compliance with the formats herein. If the electronic submission successfully passes the audit, that method of submission will be certified for all future reporting.

4.2.2 Rejection

Data will be rejected if it does not meet the data requirements specified herein. The submitting wholesaler will be notified of the reason for failure to be certified and in the case of CD, the media will be returned. Rejected data must be resubmitted within three business days upon notification of rejection. Because compliance with the EPP is mandatory for qualifying Nevada wholesalers, rejected data will be noted and may result in administrative, or even, disciplinary action if necessary to assure compliance.

4.3 Accounting for Submissions

All submissions by CD must be accompanied by an EPP Transmittal Form, a copy of which is included as Figure 4-1. The wholesaler should make a copy of the EPP Transmittal Form for its records and shall submit the original form along with the CD. In the case of an e-mail transmission, the wholesaler shall receive an acknowledgement by e-mail confirming receipt of the wholesaler's e-mail. If a wholesaler does not receive acknowledgement within five business days after transmitting data, it should contact the Board to determine whether the Board received the data.

5.0 Assistance and Support

5.1 Board of Pharmacy

Questions concerning interpretations of technical and compliance matters may be made by a telephone call to the Board at (775) 850-1440 or by e-mail addressed to pharmacy@pharmacy.nv.gov.

5.2 Software Vendors

Wholesalers are advised to contact their software vendors to obtain modification and instructions on compliance and participation in the EPP. Software vendors may direct their inquiries to the Board by a telephone call to the Board at (775) 850-1440 or by e-mail addressed to pharmacy@pharmacy.nv.gov.

6.0 Compliance

All qualifying wholesalers as discussed in Section 1.2 are required to report their pedigree data to the EPP in a timely and compliant manner. Because the Board has determined that the public health, safety, and welfare will be enhanced and promoted by the EPP, failure to submit timely and compliant pedigree data may result in administrative and/or disciplinary action by the Board to obtain compliance from a qualifying wholesaler.

7.0 Common Questions and Answers

7.1 *When must a wholesaler provide a pedigree?*

NAC 63 9.603(1) requires a wholesaler to provide a pedigree when one of two things is true:

- (1) The wholesaler is not an authorized distributor for the manufacturer of the drug, or
- (2) The wholesaler bought the drug from another wholesaler.

7.2 *Did the EPP program change when a pedigree is required or who is required to provide a pedigree?*

No.

7.3 *Is a wholesaler still required to make, keep, and provide paper pedigrees?*

Yes. Nevada hopes that the EPP will be a first step toward a fully implemented electronic pedigree system, but presently Nevada and other states still require that paper pedigrees be made, kept, and provided.

7.4 *What are the requirements for authorized distributor status in Nevada?*

To be an authorized distributor for a drug's manufacturer pursuant to NAC 639.594, a wholesaler must satisfy one of the following three conditions:

- (1) The wholesaler has a written franchise, license or other agreement with the manufacturer;
- (2) The wholesaler appears on the manufacturer's website as a recognized authorized distributor; or
- (3) The wholesaler has purchased at least 5,000 sales units of the drug directly from the manufacturer in the 12 months immediately preceding the transaction for which the wholesaler claims authorized distributor status.

7.5 *If a selling wholesaler claims to be an authorized distributor for the manufacturer of the drug, must the purchasing wholesaler receive a pedigree from the selling wholesaler?*

No. If the wholesaler selling a drug to a Nevada wholesaler is an authorized distributor for the drug's manufacturer and obtained the drug directly from the manufacturer, then a pedigree is not required. The purchasing wholesaler, though, is responsible and required to authenticate the selling wholesaler's claim of authorized distributor status.

7.6 *If a Nevada wholesaler is an authorized distributor for a drug's manufacturer, must the Nevada wholesaler make and provide a pedigree for a sale of that manufacturer's drug?*

No, if the wholesaler bought the drug directly from the manufacturer;
Yes, if the wholesaler bought the drug from anyone other than the drug's manufacturer.

7.7 *What data is mandatory?*

All of the information listed in Section 2.1 is mandatory. Data transmitted that omits any of the necessary information shall be deemed non-compliant.

7.8 *What do I do if I do not have Microsoft Excel or my system cannot produce an .xls file?*

A wholesaler is responsible to have whatever software needed to comply with the EPP's requirements. If you are unsure of whether you can comply, please contact the vendor of your software to ascertain what must be done to allow your computer system to produce a compliant .xls file.

7.9 ***What will happen if a wholesaler does not report required pedigree data to the EPP?***

Because pedigree data reporting is mandatory by Nevada law, a failure to report such data to the EPP will subject the wholesaler to disciplinary action by the Board which may include fines, fees and costs, and revocation of the wholesaler's license.

7.10 ***Are there criminal penalties regarding pedigrees?***

Yes. NRS 639.550 makes it a category C felony for a wholesaler who, with an intent to defraud or deceive:

- (1) Fails to deliver a pedigree when it is required;
- (2) Fails to acquire a pedigree when it is required; or
- (3) Falsely swears or certifies that the information in a pedigree is accurate and complete.

Additionally, NRS 639.555 makes it a category C felony for a wholesaler to knowingly:

- (1) Destroy, alter, conceal, or fail to maintain a pedigree when it is required;
- (2) Fail to authenticate information contained in a pedigree;
- (3) Forge, counterfeit, or falsely create a pedigree;
- (4) Make a false representation or assertion of any factual matter contained in a pedigree; or
- (5) Fail to record material information required to be recorded in a pedigree.

8.0 Statutes and Regulations

The following Nevada statutes relate to the practices of a pharmaceutical wholesaler licensed in Nevada:

NRS 639.233

NRS 639.234

NRS 639.500 – 639.595

The following Nevada regulations relate to the practices of a pharmaceutical wholesaler licensed in Nevada:

NAC 639.585 – 639.607

Copies of these specific statutes and regulations, or copies of the Board's entire law book that contains these statutes and regulations and others that may also be generally applicable to all licensees in Nevada, can be obtained free of charge at the Board's website, bop.nv.gov under the "Get a Law Book" link on the left side of the home page or under the "Nevada Statutes and Regulations" button on the home page. The Board must charge a fee for a paper copy of the law book to cover the Board's printing and mailing costs.

Figure 2-1 Record layout

Field Name	format	length
Wholesaler lic #	a/n	7
Wholesaler DEA#	a/n	9
Wholesaler name	a	30
Wholesaler addr	a/n	30
Wholesaler city	a	15
Wholesaler st	a	2
Wholesaler zip	n	5
Wholesaler phone	a/n	11
Lot#	a/n	10
Lot expire date	n	8
Invoice #	a/n	10
Invoice date	n	8
Order #	a/n	10
Order date	n	8
PO #	a/n	10
PO date	n	8
NDC number	n	11
Manufacturer	a	30
Product	a/n	30
Strength	a/n	10
Pkg size	a/n	10
Quantity	n	4
Certified by last	a	15
Certified by first	a	15
Certified by mi	a	1
Certified by title	a	20
Certified by date	n	8
customer sell date	n	8
customer lic#	a/n	10
customer DEA#	a/n	9
customer name	a	30
customer addr	a/n	30
customer city	a	15
customer st	a	2
customer zip	n	5
customer phone	a/n	11

Vendor #1 sell date	n	8
Vendor #1 lic#	a/n	10
Vendor #1 DEA#	a/n	9
Vendor #1 name	a	30
Vendor #1 addr	a/n	30
Vendor #1 city	a	15
Vendor #1 st	a	2
Vendor #1 zip	n	5
Vendor #1 phone	a/n	11
Vendor #2 sell date	n	8
Vendor #2 lic#	a/n	10
Vendor #2 DEA#	a/n	9
Vendor #2 name	a	30
Vendor #2 addr	a/n	30
Vendor #2 city	a	15
Vendor #2 st	a	2
Vendor #2 zip	n	5
Vendor #2 phone	a/n	11
Vendor #3 sell date	n	8
Vendor #3 lic#	a/n	10
Vendor #3 DEA#	a/n	9
Vendor #3 name	a	30
Vendor #3 addr	a/n	30
Vendor #3 city	a	15
Vendor #3 st	a	2
Vendor #3 zip	n	5
Vendor #3 phone	a/n	11
Vendor #4 sell date	n	8
Vendor #4 lic#	a/n	10
Vendor #4 DEA#	a/n	9
Vendor #4 name	a	30
Vendor #4 addr	a/n	30
Vendor #4 city	a	15
Vendor #4 st	a	2
Vendor #4 zip	n	5
Vendor #4 phone	a/n	11
Vendor #5 sell date	n	8
Vendor #5 lic#	a/n	10
Vendor #5 DEA#	a/n	9
Vendor #5 name	a	30

Vendor #5 addr	a/n	30
Vendor #5 city	a	15
Vendor #5 st	a	2
Vendor #5 zip	n	5
Vendor #5 phone	a/n	11
Vendor #6 sell date	n	8
Vendor #6 lic#	a/n	10
Vendor #6 DEA#	a/n	9
Vendor #6 name	a	30
Vendor #6 addr	a/n	30
Vendor #6 city	a	15
Vendor #6 st	a	2
Vendor #6 zip	n	5
Vendor #6 phone	a/n	11

Figure 2-2 Field Definitions for Pedigree Database

Field Name	Definition	Comments
Wholesaler lic#	License number assigned by the Nevada State Board of Pharmacy	WH####
Wholesaler DEA#	Number issued by DEA if wholesaler handles controlled substances	Ax#####
Wholesaler Name	Business name of the wholesaler submitting the data	Name should match name provided to the Board on application
Wholesaler addr	Business street address from which drugs were shipped	
Wholesaler city	Same	
Wholesaler State	Same	
Wholesaler zip	Same	5-digit only
Wholesaler phone	Business telephone for wholesaler submitting the data	
Lot Number	The lot number of an item.	Lot Number and Expiration Date are repeated for every Lot Number for one item
Lot Expire Date	The expiration date of the item. Each lot has its own expiration date.	See above
Invoice #	The unique number used by the wholesaler to identify the transaction by which the drug in the pedigree was sold	Form of number is left to the wholesaler
Invoice Date	Date of the underlying transaction by which the drug in the pedigree was sold	
Order #	The unique number assigned by the selling wholesaler at the time that it received the order for the drug subject to the pedigree	If the selling wholesaler makes this number, it must be reported. If the selling wholesaler does not make such a number, this field should contain a 0.
Order Date	Date that the selling wholesaler received the order for the drug subject to the pedigree	See above
PO#	The unique number used by the purchasing wholesaler to identify the purchase order underlying the transaction by which the drug in the pedigree was purchased	Form of the number is left to the wholesaler

Field Name	Definition	Comments
PO Date	Date that the purchasing wholesaler generated the purchase order	
NDC number	The National Drug Code number for the drug in the pedigree	If the selling wholesaler uses or captures this number in its computer system, it must provide the number to the EPP. If the selling wholesaler does not use or capture this number, this field should contain a 0.
Manufacturer	The manufacturer of the drug in the pedigree	
Product	The name of the drug in the pedigree	
Strength	The strength of the drug in the pedigree	
Package size	The quantity of the drug in a single package of the drug in the pedigree	
Quantity	The number of items (e.g., "eaches") of the NDC (Product Code above) and Lot Number that are part of the transaction.	
Certified by last	Last name of person certifying the accuracy of the data in the pedigree	
Certified by first	First name of person certifying the accuracy of the data in the pedigree	
Certified by mi	Middle Initial of person certifying the accuracy of the data in the pedigree	
Certified Title	Title of person certifying the accuracy of the data in the pedigree	
Certified Date	Date that certifying person certified the accuracy of the data in the pedigree	

Customer lic#	The license number of the person to whom the drug in the pedigree is being sold	If the wholesaler uses or captures this information in its computer system, it must provide this information. If the wholesaler does not use or capture this information, this field should contain a 0.
Customer DEA#	The DEA number for the person to whom the drug in the pedigree is being sold	See above.
Customer name	The name or business name of the person to whom the drug in the pedigree is being sold	
Customer addr	The street address for the person or business to whom the drug in the pedigree is being sold	
Customer city	Same	
Customer State	Same	
Customer Zip	Same	5-digit only
Customer phone	Same	
Vendor #x sell date	Date a preceding selling wholesaler sold the drug in the pedigree	
Vendor #x lic #	The preceding selling wholesaler's license number	If the preceding wholesaler provided this information on the pedigree, then the reporting wholesaler must provide the number. If the preceding wholesaler did not provide this information, then the field should contain a 0.
Vendor #x DEA#	DEA number for preceding selling wholesaler	Same
Vendor #x name	Business name of preceding selling wholesaler	
Vendor #x st addr	Street address of preceding selling wholesaler	
Vendor #x city	Same	
Vendor #x st	Same	
Vendor #x zip	Same	5-digit only
Vendor #x phone	Same	

Figure 4-2 EPP Transmittal Form

State of Nevada
Electronic Pedigree Program
EPP Transmittal Form

Date: _____	For the Month of: _____
Nevada License #:	
Name:	
Address:	
City, St., Zip:	
Phone: _____	Contact: _____

Number of Pedigrees Included:

Date Range: From: _____ To:

PLEASE COMPLETE THIS FORM AND
INCLUDE WITH YOUR CD

MAIL TO:
NEVADA STATE BOARD OF PHARMACY
ATTN: EPP
431 West Plumb Lane
RENO, NV 89509

**(Please keep a copy of this form for your records)
(Make copies for future use)**