

FIRST SUPPLEMENT TO THE NEVADA ELECTRONIC PEDIGREE PROGRAM HANDBOOK

(Version 12/28/06)

Since the publication of the Electronic Pedigree Program Handbook in October 2006, we have received a number of questions regarding the EPP and its implementation. We are providing the following information as a supplement to the Handbook to answer or address the questions we have received. Please review this Supplement carefully because it is considered part of the Handbook and, thus, provides information with which we will expect a wholesaler to comply.

Is Nevada's requirement for pedigrees a new requirement?

No. Nevada has required paper pedigrees for pharmaceutical wholesale transaction since 1991.

What is new about Nevada's pedigree laws?

Beginning January 1, 2007, Nevada is requiring something new, namely participation in the Electronic Pedigree Program (EPP). The EPP laws did not change when a pedigree is needed or who needs to provide a pedigree. Instead, the EPP requires that once a month, a wholesaler who provided pedigrees for wholesale transactions into or from Nevada must provide the same pedigree information in an electronic file to the Board at an e-mail address established solely for the EPP, namely EPP@govmail.state.nv.us.

Can I provide the data in a format other than an .xls file?

Yes. After consulting with our information technology staff, we have determined that, we can accept any file that readily loads into Excel such as .csv files and flat files. If a wholesaler transmits a file that cannot be readily loaded into Excel, we will notify the wholesaler of the rejection of the file and will ask that a compliant file be provided.

How do you want the date fields to be formatted?

We would like the date fields to be formatted mm/dd/yyyy.

Do I have to provide data I do not have?

We are aware that pedigrees vary as to the completeness of the information provided, and thus, that a wholesaler may not have some of the data that we are seeking. We are asking that a wholesaler provide all of the data in the possession of the wholesaler, but that a wholesaler may leave any field blank if it does not have the information. For example, a wholesaler may receive a pedigree that contains only a purchase order number, but may lack an invoice number or an order number. The wholesaler must provide the purchase order number it has, but need not provide the other numbers that it lacks. Please be aware that some information is mandatory by law and that a wholesaler should not accept a drug with a pedigree that lacks such mandatory elements.

Can a pedigree be passed between two wholesalers electronically and without an accompanying paper pedigree?

Yes. In the Handbook, we stated that the EPP did not eliminate the need for trading partners to continue to provide each other with paper pedigrees. Since we published the Handbook, we have become aware that electronic pedigree software is presently in use in the wholesale industry and that some trading partners are providing pedigrees between themselves solely by electronic means. Nevada law allows such fully electronic pedigrees as long as all of the electronic pedigree contains all data and information required by Nevada law, the electronic pedigree system can transmit the data to the EPP in an acceptable form, the electronic record is kept for at least three years, and the electronic pedigree can be produced upon request by Board Staff.

Is a wholesaler required to provide a pedigree to a non-wholesaler customer?

No. Presently, we are not requiring that a pedigree be provided by a wholesaler to an end-user customer such as a pharmacy, practitioner, hospital, ambulance services, etc. An end-user customer has the right to request a pedigree and it must be provided, but absent such a request, a wholesaler is not required to provide a pedigree to an end-user, non-wholesaler customer.

Is a wholesaler required to receive a pedigree from a manufacturer?

No.

Is a wholesaler required to receive a pedigree from a wholesaler who is an authorized distributor for the manufacturer of the drug?

It depends. In most cases, the authorized distributor (ADR) has purchased the drug directly from the manufacturer. In such a case, the ADR is not required to provide a pedigree. Occasionally, a wholesaler will acquire from another wholesaler a drug for which the wholesaler is an ADR for the drug's manufacturer. In such a case, a pedigree is required. In Nevada, a pedigree is not required only in the case where the wholesaler

is an ADR for the drug **AND** the wholesaler purchased the drug directly from the manufacturer.

Will the requirements for the EPP change if an industry standard for electronic pedigrees is created?

Yes. We are aware that work has been ongoing on a uniform set of data requirements for electronic pedigrees. When the standard is published (we hope sometime in the first half of 2007), we will examine it and may alter the EPP requirements as appropriate. Of course, if such a change is made, we will notify all Nevada-licensed wholesalers of the change.

Are there any resources on the Board's website to assist wholesalers?

Not presently. We intend in the near future to add a page or pages especially to provide information regarding Nevada's pharmaceutical wholesaler laws, interpretations and applications of those laws, and the operation of the EPP. Presently, you may correspond directly with the EPP through its dedicated e-mail address: EPP@govmail.state.nv.us. Please keep checking our website, bop.nv.gov (no www. please) for further information.