Notice of Proposed Rule

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
Drugs, Devices and Cosmetics

RULE NO.: RULE TITLE:
61N-1.012 Records of Drugs, Cosmetics and Devices

PURPOSE AND EFFECT: The purpose and effect of the proposed rule is to amend the language to expand the return period of seven days for the exception to the pedigree documentation requirement for prescription drugs that are delivered in error to fourteen days.

SUMMARY: The proposed rule amends the language to expand the return period of seven days for the exception to the pedigree documentation requirement for prescription drugs that are delivered in error to fourteen days.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:
The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: The Department conducted an analysis of the proposed rule’s potential economic impact and determined that it did not exceed any of the criteria established in Section 120.541(2)(a), F.S.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 499.003, 499.05, 499.0121, 499.0122, 499.013, 499.014, 499.052 FS
LAW IMPLEMENTED: 499.01, 499.03, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 499.066, 499.067 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.


THE FULL TEXT OF THE PROPOSED RULE IS:

61N-1.012 Records of Drugs, Cosmetics and Devices.

(1) through (2) No change.

(3) Pedigree Papers.

(a)1. The pedigree papers required by Sections 499.01212, F.S., must include either the proprietary name or the generic name with the name of the manufacturer, repackager, or distributor as reflected on the label of the product; dosage form; strength; container size; quantity by lot number; the name and address of each owner of the prescription drug that is required to be identified on the pedigree paper; the name and address of each location from
which it was shipped if different from the owner’s; and the transaction dates. The pedigree paper must clearly identify the invoice to which it relates; however, if an invoice number has not been generated at the time the pedigree is prepared then an alternate reference number that is easily traceable to the invoice number may be used.

2. A copy of the pedigree paper must be maintained by each wholesaler distributor preparing a pedigree paper and by each recipient. This copy may be maintained in an electronic medium that is readily available and easily accessible to the wholesaler distributor preparing the pedigree paper; each recipient; and authorized federal, state, and local regulators or law enforcement. If a wholesaler distributor serves as the repository of its customer’s pedigree, the wholesaler distributor must specify on the customer’s invoice or other distribution document the method for immediately accessing all pedigrees associated with each prescription drug distributed and must enable access by the persons listed above for the duration of the applicable records retention period.

(b) If a wholesale distributor uses the statement contained in Section 499.01212, F.S., “This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer” the wholesale distributor must provide to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group must provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.

(c) Beginning July 1, 2006, “Pedigree Paper (Distribution History of Prescription Drugs),” either Form DH 2129 effective July 2006, which is incorporated by reference herein, or an electronic record that contains all the elements of Form DH 2129 must be used to comply with the requirement in Section 499.01212, F.S., for the distribution of a prescription drug. Beginning July 1, 2006, a repackager must use either “Prescription (legend) Drug Pedigree – Repackager” Form DH 2135 effective July 2006, which is incorporated by reference herein, or an electronic record that contains all the elements of Form DH 2135. A wholesaler distributor that further distributes a repackaged prescription drug must include in the pedigree the information related to the repacked drug contained in Form DH 2135 or the electronic record that contains all the elements of Form DH 2135. These forms may be used prior to July 1, 2006, to comply with the pedigree paper requirements of Section 499.01212, F.S., at the discretion of the wholesaler distributor. An electronic signature may be used on a pedigree paper. An electronic record must be easily readable or easily rendered in a readable format, and capable of being reproduced in a paper medium. Data on an electronic pedigree may be transmitted via the internet, data communications, a portable medium such as a CD-
Rom or smart card or similar devices. Additional information to that required by forms DH 2129 and DH 2135 may be included on a pedigree provided it does not detract from or confuse the history of the distribution of the drug.

(d) A copy of the pedigree paper must be maintained by each recipient. A copy of the pedigree paper provided to a wholesale distributor must be maintained by the wholesaler distributor providing the pedigree paper.

(e) Effective March 1, 2004, a pedigree paper under Section 499.01212, F.S., must trace a prescription drug back to the last authorized distributor of record. The department will maintain a database of authorized distributors of record. A prescription drug wholesaler distributor that receives or prepares a pedigree paper under Section 499.01212, F.S., and this chapter that traces the previous distributions of a prescription drug back to a prescription drug wholesaler distributor that is not listed on the department’s web site as an authorized distributor of record for the drug’s manufacturer for the date in which the transaction occurred must maintain and have available for inspection documentation that supports the fact the prescription drug wholesaler distributor is an authorized distributor of record in accordance with the criteria of Section 499.01212, F.S.

(f) Returns.

1. When a distribution of a prescription drug by a wholesaler distributor to an authorized recipient pharmacy or a health care entity, including a practitioner, licensed and authorized under Florida law to purchase and receive the prescription drug is the result of a mistake in ordering or shipment, the return of that shipment prescription drug by the authorized recipient to the wholesaler distributor need not be reflected in the pedigree paper. For purposes of this subparagraph, a mistake in ordering or shipment shall be deemed to have occurred if, within fourteen seven calendar days after the date of receipt of the original shipment:

   a. The authorized recipient ships the specific unit of the prescription drug back to the wholesaler distributor from which that specific unit was purchased; or

   b. The authorized recipient transmits a documented communication to the wholesaler distributor from which the prescription drug was purchased stating the authorized recipient’s intent to return the shipment in accordance with the wholesale distributor’s wholesaler’s prescribed written policies and procedures and the wholesaler distributor communicates authorization for return of the product.

2. Any returns to a wholesaler distributor by an authorized recipient that are not within the scope of subparagraph 1. shall be reflected in the pedigree paper trail for any subsequent wholesale further distributions of the returned drug product to the extent required by Section 499.01212, F.S.
3. An authorized recipient that returns a prescription drug shipment to the wholesaler distributor in accordance with subparagraph 1. or 2. shall verify by written declaration as set forth in Section 92.525(2), F.S., a written document submitted with the returned product,

a. That the specific unit (exact unit) being returned was purchased from the receiving wholesaler distributor (including the corresponding sales invoice number and the date of the sale from that wholesaler distributor to the authorized recipient); and

b. That the product was or was not stored and shipped in accordance with the requirements of Section 499.0121, F.S., and the rules adopted thereunder while in the purchaser’s custody and control.

c. The written declaration shall be printed or typed at the end of or immediately below the statements in sub-subparagraphs 3.a. and 3.b. and shall state: “Under penalties of perjury, I declare that I have read the foregoing and that the facts stated in it are true,” followed by the signature of the person making the declaration.

(g) For purposes of Section 499.003(31)(b), F.S., a manufacturer or repackager will have uniquely serialized an individual legend drug unit when the unit contains an electronic product code that meets industry standards for that type of legend drug unit. The department will adopt the industry standards for each type of legend drug unit when they are established. One pedigree record may be prepared for a group of serialized legend drugs, provided the only unique characteristic for the pedigree is the serialization codes.

(h) If a manufacturer initiates an electronic pedigree and transmits this information to a wholesaler distributor consistent with the standards in sub-subparagraph 61N-1.013(5)(d)1.f., F.A.C., (and that wholesaler distributor provides a pedigree to its customer consistent with the standards in sub-subparagraph 61N-1.013(5)(d)1.f., F.A.C., the wholesaler distributor must transmit the pedigree information initiated by the manufacturer in the pedigree the wholesaler distributor provides to its customer.

(i) A wholesaler distributor that purchases multiple units of a prescription drug from a manufacturer in one transaction, but receives these units from multiple distribution sites of the manufacturer or on multiple dates from the manufacturer, may reference the first occurrence of receipt in pedigree papers the wholesaler distributor prepares for subsequent wholesale distributions unless all applicable information is received from the manufacturer as set forth in paragraph (h) above.

(j) A contract distributor for the manufacturer is deemed an agent of the manufacturer and therefore is not required under Section 499.01212, F.S., to provide a pedigree paper upon distribution of the manufacturer’s
prescription drug provided the manufacturer retains title to the prescription drug and the contract distributor meets the requirements to be permitted under Chapter 499, F.S., as a non-resident prescription drug manufacturer based on its relationship with the manufacturer.

(k) Emergency Distributions. A wholesale distributor may distribute and a purchasing pharmacy or health care practitioner authorized by law to purchase prescription drugs may accept a prescription drug for which a pedigree that complies with Section 499.01212, F.S., is not available, when the prescription drug is required immediately to treat a specific patient with a life-threatening medical condition or a medical condition that will result in serious bodily harm. A pharmacist for the purchasing pharmacy, or the health care practitioner, shall supply a statement to the supplying wholesale distributor(s) that the emergency meets this rule paragraph’s requirements and the supplying wholesale distributor(s) must maintain such statement in compliance with the timeframes in Section 499.0121(6)(b), F.S. The supplying wholesale distributor must otherwise comply fully with all other applicable provisions of Sections 499.001 through 499.081, F.S., with respect to such drug.

(4) through (11) No change.

(12) An establishment permitted under Chapter 499, F.S., that shares a facility with another person or business shall keep all of its operational systems subject to Chapter 499, F.S., separate and distinct from the other person or business. A person permitted under Chapter 499, F.S., that also conducts other business activities not permitted under Chapter 499, F.S., shall keep all of its operational systems subject to Chapter 499, F.S., separate and distinct from the other business activities. For the purpose of this rule, those operational systems required to be kept separate and distinct shall mean all records, inventory, storage areas, repackaging operations, quarantine areas, and manufacturing operations, but this rule shall not require separate entrances to the establishment nor partitioning. A Retail Pharmacy Drug Wholesale Distributor wholesaler however, is not required to maintain its stock of prescription drugs which may be distributed through a wholesale transaction separate from the stock of prescription drugs which may be dispensed by a retail pharmacy.

(13) through (15) No change.

(16) Establishing an ongoing relationship pursuant to Sections 499.01212, F.S. A wholesale distributor that is not listed as an authorized distributor of record on the list submitted to the department by a prescription drug manufacturer may request the department add the wholesale distributor to the department’s web site of authorized distributors of record for a drug manufacturer for purposes of the pedigree paper requirements of Section 499.01212,
F.S., that become effective March 1, 2004, provided that such wholesale distributor satisfies the requirements of paragraph (a) or (b) below.

(a) A wholesale distributor or its affiliated group must submit the information in subparagraphs 1. and 2. below to document eligibility for inclusion as an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.01212, F.S. If the information submitted in subparagraphs 1. and 2. is based on the cumulative activity of an affiliated group, a wholesale distributor or its affiliated group must submit the information in subparagraph 3. below to document the eligibility of the individual wholesale distributor establishment that is a member of the affiliated group to be an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.01212, F.S.

1. To document total annual prescription drug sales of $100 million or more submit either:
   a. The most recent audited financial report that includes an Income Statement or Statement of Profit /Loss that indicates sales of prescription drugs of at least $100 million. (Note: the statement or notes in the audited financial report must clearly demonstrate the sales amount related to prescription drugs as opposed to other commodities), OR
   b. A signed attestation from a certified public accountant that the establishment or affiliated group, if applicable, had total annual prescription drug sales of $100 million or more in the most recent fiscal year, OR
   c. A computerized listing of prescription drug sales transactions during the period 10/1/02 – 9/30/03, or a 12-month period ending on the last day of the most recent calendar quarter, of at least $100 million. This report must be totaled. The detail should include the invoice number, invoice date, customer name, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least $100 million in prescription drug sales, excluding customer returns. AND

2. For each manufacturer for whom the wholesale distributor claims authorized distributor of record status, submit both subparagraphs a. and b. to document that the wholesale distributor annually purchases not less than 90%, based on dollar volume, of all of its purchases of a manufacturer’s prescription drug products directly from that manufacturer.
   a. A computerized listing of all of a manufacturer’s prescription drugs purchased by the wholesale distributor during the period 10/1/02 – 9/30/03, or a 12-month period ending on the last day of the most recent calendar quarter, regardless of the source of those prescription drugs. This report must be totaled. AND
   b.i. A computerized listing of all purchases of a manufacturer’s prescription drugs directly from the
manufacturer during the same time period. This report must be totaled. The detail should include the invoice number, invoice date, and total invoice amount related to prescription drugs. A statement must be provided that the report documents at least 90% of the wholesaler distributor’s purchases of a manufacturer’s prescription drug products directly from that manufacturer, excluding returns to the manufacturer. OR

ii. Copies of the manufacturer’s sales invoices of prescription drugs to the wholesaler distributor. An adding machine tape, or equivalent, must be included that lists each invoice, in order, and provides a total of all invoices submitted. A statement must be provided that the invoices document at least 90% of the wholesaler distributor’s purchases of a manufacturer’s prescription drug products directly from that manufacturer, excluding returns to the manufacturer.

3. Each wholesaler distributor establishment that applies to the department to be listed as an authorized distributor of record of a drug manufacturer based upon its affiliated group’s ongoing relationship with the manufacturer, or the affiliated group on behalf of each wholesaler distributor establishment, must submit the names and address of all member wholesaler distributor establishments of the affiliated group. In addition, each wholesaler distributor establishment must either:

a. Conduct its prescription drug wholesale activities under an establishment name that incorporates the same business name as the affiliated group upon which the eligibility criteria for the affiliated group was met, or

b. Hold a valid prescription drug wholesaler distributor permit or out-of-state prescription drug wholesaler distributor permit issued under Chapter 499, F.S.

(b) A wholesale distributor or its affiliated group must submit the information in subparagraphs 1. and 2. below to document eligibility for inclusion as an authorized distributor of record for a manufacturer of prescription drugs pursuant to Section 499.01212, F.S.

1. To document total annual prescription drug sales of $100 million or more submit either:

a. The most recent audited financial report that includes an Income Statement or Statement of Profit /Loss that indicates sales of prescription drugs of at least $100 million. (Note: the statement or notes in the audited financial report must clearly demonstrate the sales amount related to prescription drugs as opposed to other commodities), OR

b. A signed attestation from a certified public accountant that the establishment or affiliated group, if applicable, had total annual prescription drug sales of $100 million or more in the most recent fiscal year, OR

c. A computerized listing of prescription drug sales transactions during the period 10/1/02 – 9/30/03, or a 12-
month period based on the most recent calendar quarter, of at least $100 million. This report must be totaled. The
detail should include the invoice number, invoice date, customer name, and total invoice amount related to
prescription drugs. A statement must be provided that the report documents at least $100 million in prescription drug
sales, excluding customer returns.

2. For each manufacturer for whom the wholesale distributor claims authorized distributor of record status,
submit a., b., or c. to document that the wholesale distributor has a verifiable account number issued by the
manufacturer and has made at least 12 purchases of prescription drugs directly from that manufacturer using the
verifiable account number.

a. If the wholesale distributor is a member of an affiliated group and all purchases from that manufacturer are
made at a central location for the wholesale distributor, copies of at least 12 invoices dated during the previous 12
months from the date the information is submitted, which invoices document purchases of prescription drugs, at
least one unit of which on each invoice was not returned, under that central account number but shipped to the
wholesale distributor’s address for whom the authorized distributor of record status is claimed. A statement must be
provided that the invoices document purchases of prescription drugs for the wholesale distributor for whom the
authorized distributor of record status is claimed and that the wholesale distributor did not return to the
manufacturer at least one unit of the prescription drugs on each invoice.

b. If the wholesale distributor is a member of an affiliated group and all purchases from that manufacturer are
made at a central location and received at a central location for the wholesale distributor, copies of at least 12 invoices dated during the previous 12 months from the date the information was submitted, under the same account
number which is clearly assigned to the wholesale distributor at the permitted address. Each invoice must document
the purchase of prescription drugs, of which at least one unit identified on the invoice was not returned. A statement
must be provided that the invoices document purchases of prescription drugs by that central location and that the
central location or wholesale distributor for which the drugs were obtained did not return to the manufacturer at
least one unit of the prescription drugs on each invoice, and that the central location shipped at least 12 times to the
individual wholesale distributor for whom the authorized distributor of record status is claimed during the 12
months based on the fiscal year or designated timeframe.

c. For all other wholesale distributors, copies of at least 12 invoices dated during the previous 12 months from
the date the information was submitted, under the same account number that is clearly assigned to the wholesale
distributor at the permitted address. Each invoice must document the purchase of prescription drugs, of which at least one unit identified on the invoice was not returned. A statement must be provided that the invoices document purchases of prescription drugs by that wholesaler distributor and that the wholesaler distributor did not return to the manufacturer at least one unit of the prescription drugs on each invoice.

Rulemaking Authority 499.003, 499.05, 499.0121, 499.0122, 499.013, 499.014, 499.052 FS. Law Implemented 499.01, 499.003, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.028, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 499.066, 499.067 FS. History–New 1-1-77, Amended 12-12-82, 7-8-84, 1-30-85, Formerly 10D-45.53, Amended 11-26-86, 2-4-93, 7-1-96, Formerly 10D-45.053, Amended 1-26-99, 4-17-01, 10-7-03, 1-1-04, 6-15-04, 8-2-04, 1-19-06, 8-6-06, Formerly 64F-12.012, Amended ________.

NAME OF PERSON ORIGINATING PROPOSED RULE: R. Kathleen Brown-Blake, Assistant General Counsel, Office of the General Counsel, 1940 North Monroe Street, Suite 42, Tallahassee, Florida 32399, (850)717-1244
NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Ken Lawson, Secretary, Department of Business and Professional Regulation
DATE PROPOSED RULE APPROVED BY AGENCY HEAD: October 1, 2012
DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: August 3, 2012