



312402

LEGISLATIVE ACTION

Senate

.

House

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Floor: 1/AD/2R

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04/23/2009 04:28 PM

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Senator Peaden moved the following:

Senate Amendment (with title amendment)

Delete lines 936 - 1262

and insert:

Section 6. Paragraph (e) of subsection (6) of section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug



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13 distribution records.

14 (6) RECORDKEEPING.—The department shall adopt rules that
15 require keeping such records of prescription drugs as are
16 necessary for the protection of the public health.

17 (e) When pedigree papers are required by this part, a
18 wholesale distributor must maintain the pedigree papers separate
19 and distinct from other records required under this part
20 ~~chapter~~.

21 Section 7. Paragraph (b) of subsection (2) of section
22 499.01212, Florida Statutes, is amended to read:

23 499.01212 Pedigree paper.—

24 (2) FORMAT.—A pedigree paper must contain the following
25 information:

26 (b) For all other wholesale distributions of prescription
27 drugs:

28 1. The quantity, dosage form, and strength of the
29 prescription drugs.

30 2. The lot numbers of the prescription drugs.

31 3. The name and address of each owner of the prescription
32 drug and his or her signature.

33 4. Shipping information, including the name and address of
34 each person certifying delivery or receipt of the prescription
35 drug.

36 5. An invoice number, a shipping document number, or
37 another number uniquely identifying the transaction.

38 6. A certification that the recipient wholesale distributor
39 has authenticated the pedigree papers.

40 7. The unique serialization of the prescription drug, if
41 the manufacturer or repackager has uniquely serialized the



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42 individual prescription drug unit.

43 8. The name, address, telephone number, and, if available,
44 e-mail contact information of each wholesale distributor
45 involved in the chain of the prescription drug's custody.

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47 When an affiliated group member obtains title to a prescription
48 drug before distributing the prescription drug as the
49 manufacturer under s. 499.003(31)(e), information regarding the
50 distribution between those affiliated group members may be
51 omitted from a pedigree paper required under this paragraph for
52 subsequent distributions of that prescription drug.

53
54 ===== T I T L E A M E N D M E N T =====

55 And the title is amended as follows:

56 Delete lines 14 - 30

57 and insert:

58 clarifying that a wholesale distributor is required to
59 maintain pedigree papers separately from other records
60 of prescription drugs under certain circumstances;
61 amending s. 499.01212, F.S.; revising requirements for
62 a pedigree paper;