

Bill No. CS for SB 926

Barcode 894412

CHAMBER ACTION

Senate

House

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31

Comm: WD
04/25/2006 09:53 PM

.
. .
. .
. .
. .
. .

The Committee on Judiciary (Campbell) recommended the following amendment:

Senate Amendment (with title amendment)

On page 1, line 14,

insert:

Section 1. Subsection (31) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in ss.

499.001-499.081.--As used in ss. 499.001-499.081, the term:

(31) "Pedigree paper" means:

(a) A document required pursuant to s. 499.0121(6)(d)

or (e); or

(b) Effective July 1, 2006:
~~7~~

1. A document or electronic form approved by the Department of Health and containing information that records each distribution of any given legend drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug; or
~~7~~

Bill No. CS for SB 926

Barcode 894412

- 1 2. A written statement under oath that:
- 2 a. If the establishment is not a member of an
- 3 affiliated group: "This establishment purchased the specific
- 4 unit of the prescription drug directly from the manufacturer";
- 5 or
- 6 b. If the establishment is a member of an affiliated
- 7 group: "This establishment or a member of my affiliated group
- 8 purchased the specific unit of the prescription drug directly
- 9 from the manufacturer."

10

11 The information required to be included on the form prescribed

12 by the Department of Health pursuant to subparagraph 1. a

13 ~~legend drug's pedigree paper~~ must at least detail the amount

14 of the legend drug; its dosage form and strength; its lot

15 numbers; the name and address of each owner of the legend drug

16 and his or her signature; its shipping information, including

17 the name and address of each person certifying delivery or

18 receipt of the legend drug; an invoice number, a shipping

19 document number, or another number uniquely identifying the

20 transaction; and a certification that the recipient wholesaler

21 has authenticated the pedigree papers. If the manufacturer or

22 repackager has uniquely serialized the individual legend drug

23 unit, that identifier must also be included on the form

24 prescribed by the Department of Health pursuant to

25 subparagraph 1. ~~pedigree~~. It must also include the name,

26 address, telephone number and, if available, e-mail contact

27 information of each wholesaler involved in the chain of the

28 legend drug's custody. The department shall adopt rules and a

29 form relating to the requirements of subparagraph 1. this

30 ~~paragraph~~ no later than 90 days after the effective date of

31 this act.

Bill No. CS for SB 926

Barcode 894412

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31

(Redesignate subsequent sections.)

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

And the title is amended as follows:

On page 1, line 2, after the semicolon,

insert:

amending s. 499.003, F.S.; redefining the term

"pedigree paper";