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LEGISLATIVE ACTION

Senate

House

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Floor: 14/AD/2R
04/28/2011 02:42 PM

Senator Fasano moved the following:

Senate Amendment (with title amendment)

Delete lines 1989 - 2035

and insert:

Section 26. Subsection (9) is added to section 465.025,
Florida Statutes, to read:

465.025 Substitution of drugs.—

(9) The board shall establish by rule a list of opioid
drugs that incorporate tamper-resistant technology. Inclusion of
a drug on the list does not require that the drug bear a
labeling claim with respect to reduction of tampering, abuse, or
abuse potential at the time of listing. The board shall make a
determination whether to include a drug on the list based on a



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14 submission of evidence by the drug manufacturer or distributor
15 that the drug:

16 (a) Incorporates a tamper-resistance technology; and

17 (b) Has been approved by the United States Food and Drug
18 Administration pursuant to an application that includes at least
19 one study on human tampering or abuse potential or a laboratory
20 study comparing the tamper-resistant or abuse-resistant
21 properties of the drug to one or more opioid drugs that has been
22 approved by the United States Food and Drug Administration and
23 serves as a positive control.

24
25 Notwithstanding subsection (2), a pharmacist may not substitute
26 an opioid analgesic drug, either the brand name drug or generic
27 drug, for an opioid analgesic drug incorporating a tamper-
28 resistance technology which was originally prescribed and is
29 listed by the board pursuant to this subsection.

30
31 ===== T I T L E A M E N D M E N T =====

32 And the title is amended as follows:

33 Delete lines 222 - 225

34 and insert:

35 clinic may be declared a public nuisance; amending s.
36 465.025, F.S.; requiring the Board of Pharmacy to
37 create a list of opioid analgesic drugs; providing
38 requirements for the list of opioid analgesic drugs;
39 prohibiting a pharmacist from substituting an opioid
40 analgesic drug for an opioid analgesic drug that
41 incorporates a tamper-resistant technology;