

SENATE COMMITTEE OF REFERENCE REPORT

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Chairman of Committee

February 18, 2010

Date

Committee on Health and Human Services.

After consideration on the merits, the Committee recommends the following:

SB10-126 be amended as follows, and as so amended, be referred to the Committee on Appropriations with favorable recommendation:

- 1 Amend printed bill, page 3, line 18, after "(3)" insert "(a)".
- 2 Page 3, line 21, strike "SUPPLY." and substitute "SUPPLY THAT HAS BEEN
- 3 APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.
- 4 (b) "GROUP PURCHASING ORGANIZATION" MEANS AN
- 5 ORGANIZATION THAT ENGAGES IN THE ACTIVITIES DESCRIBED IN
- 6 PARAGRAPH (a) OF THIS SUBSECTION (3) IN CONNECTION WITH A COVERED
- 7 DRUG, MEDICAL DEVICE, BIOLOGICAL PRODUCT, OR MEDICAL SUPPLY THAT
- 8 IS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION
- 9 ON OR AFTER THE EFFECTIVE DATE OF THIS PART 4, AND SUCH GROUP
- 10 PURCHASING ORGANIZATION SHALL BE SUBJECT TO THE REPORTING
- 11 REQUIREMENTS OF THIS PART 4 ONE YEAR AFTER THE YEAR IN WHICH
- 12 APPROVAL FROM THE UNITED STATES FOOD AND DRUG ADMINISTRATION
- 13 IS OBTAINED."
- 14 Page 3, line 25, after "LICENSED" insert "IN COLORADO".
- 15 Page 4, line 17, strike "SUPPLY." and substitute "SUPPLY THAT HAS BEEN
- 16 APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.
- 17 (b) "MANUFACTURER" INCLUDES A PERSON WHO ENGAGES IN THE
- 18 ACTIVITIES DESCRIBED IN PARAGRAPH (a) OF THIS SUBSECTION (6) IN
- 19 CONNECTION WITH A COVERED DRUG, MEDICAL DEVICE, BIOLOGICAL

1 PRODUCT, OR MEDICAL SUPPLY THAT IS APPROVED BY THE UNITED STATES  
2 FOOD AND DRUG ADMINISTRATION ON OR AFTER THE EFFECTIVE DATE OF  
3 THIS PART 4, AND SUCH MANUFACTURER SHALL BE SUBJECT TO THE  
4 REPORTING REQUIREMENTS OF THIS PART 4 ONE YEAR AFTER THE YEAR IN  
5 WHICH APPROVAL FROM THE UNITED STATES FOOD AND DRUG  
6 ADMINISTRATION IS OBTAINED."

7 Reletter succeeding paragraph accordingly.

8 Page 5, line 2, after "(a)" insert "(I)".

9 Page 5, after line 6 insert:

10 "(II) "PAYMENT OR OTHER TRANSFER OF VALUE" DOES NOT  
11 INCLUDE A TRANSFER OF ANYTHING OF VALUE THAT IS MADE INDIRECTLY  
12 TO A HEALTH CARE PRACTITIONER THROUGH A THIRD PARTY, OTHER THAN  
13 THE APPLICABLE MANUFACTURER, IN CONNECTION WITH AN ACTIVITY OR  
14 SERVICE IN THE CASE WHERE THE APPLICABLE MANUFACTURER IS  
15 UNAWARE OF THE IDENTITY OF THE HEALTH CARE PRACTITIONER."

16 Page 9, line 14, strike "THE" and substitute "OR COMPLIANCE WITH ONE OF  
17 THE FOLLOWING CODES, AS APPLICABLE:

18 (I) THE".

19 Page 9, after line 21 insert:

20 "(II) THE CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE  
21 PROFESSIONALS, REVISED AND RESTATED, EFFECTIVE JULY 1, 2009, OR ITS  
22 SUCCESSOR CODE, ADOPTED BY THE ADVANCED MEDICAL TECHNOLOGY  
23 ASSOCIATION (ADVAMED), OR ITS SUCCESSOR ASSOCIATION, INCLUDING  
24 PROCEDURES TO ENSURE EFFECTIVE COMPLIANCE WITH THE CODE; OR

25 (III) THE REVISED CODE OF CONDUCT ON INTERACTIONS WITH  
26 HEALTH CARE PROVIDERS, ADOPTED JULY 1, 2009, OR ITS SUCCESSOR  
27 CODE, ADOPTED BY THE MEDICAL DEVICE MANUFACTURERS ASSOCIATION  
28 (MDMA), OR ITS SUCCESSOR ASSOCIATION, INCLUDING IMPLEMENTATION  
29 OF AN EFFECTIVE COMPLIANCE PROGRAM."

30 Page 9, line 23, before "CODE" insert "APPLICABLE".

1 Page 9, line 25, strike "PhRMA" and substitute "PhRMA, ADVAMED, OR  
2 MDMA" and strike "SITE" and substitute "SITE, OR IS SELF-IDENTIFIED ON  
3 ITS OWN WEB SITE,".

4 Page 9, line 26, before "CODE" insert "APPLICABLE".

5 Page 10, after line 13 insert:

6 "(6) A MANUFACTURER THAT DISCLOSES THE INFORMATION  
7 REQUIRED BY THIS SECTION, OR SUBSTANTIALLY SIMILAR INFORMATION,  
8 ON ITS WEB SITE COMPLIES WITH THIS SECTION IF THE MANUFACTURER  
9 PROVIDES TO THE SECRETARY, BY MARCH 31, 2011, AND BY EACH MARCH  
10 31 THEREAFTER, A CURRENT, FUNCTIONING LINK TO THE INFORMATION ON  
11 ITS WEB SITE."

12 Page 11, after line 11 insert:

13 "(3) A MANUFACTURER OR GROUP PURCHASING ORGANIZATION  
14 THAT DISCLOSES THE INFORMATION REQUIRED BY THIS SECTION, OR  
15 SUBSTANTIALLY SIMILAR INFORMATION, ON ITS WEB SITE COMPLIES WITH  
16 THIS SECTION IF THE MANUFACTURER OR GROUP PURCHASING  
17 ORGANIZATION PROVIDES TO THE SECRETARY, BY MARCH 31, 2011, AND  
18 BY EACH MARCH 31 THEREAFTER, A CURRENT, FUNCTIONING LINK TO THE  
19 INFORMATION ON ITS WEB SITE."

20 Page 12, strike line 9 and substitute:

21 "(3) IF A MANUFACTURER OR GROUP PURCHASING ORGANIZATION  
22 DISPUTES A FINE IMPOSED PURSUANT TO SUBSECTION (1) OR (2) OF THIS  
23 SECTION, THE".

24 Page 12, line 24, strike "24-21-404. THE" and substitute "24-21-404 IN AN  
25 ELECTRONIC FORMAT IN".

26 Page 12, strike line 25.

27 Page 12, line 27, after "(b)" insert "(I)".

28 Page 13, line 7, strike "(I)" and substitute "(A)".

29 Page 13, line 9, strike "(II)" and substitute "(B)".

1 Page 13, line 16, strike "(III)" and substitute "(C)".

2 Page 13, line 18, strike "(IV)" and substitute "(D)".

3 Page 13, line 22, strike "(V)" and substitute "(E)".

4 Page 13, line 24, strike "(VI)" and substitute "(F)".

5 Page 14, line 3, strike "(VII)" and substitute "(G)".

6 Page 14, line 5, strike "(VIII)" and substitute "(H)".

7 Page 14, after line 7 insert:

8           "(II) IF THE SECRETARY DETERMINES THAT PROVIDING THE  
9 INFORMATION SUBMITTED PURSUANT TO SECTIONS 24-21-403 AND  
10 24-21-404 ON A WEB SITE IN THE MANNER DESCRIBED IN  
11 SUB-SUBPARAGRAPHS (B), (C), AND (F) OF SUBPARAGRAPH (I) OF THIS  
12 PARAGRAPH (b) IS COST PROHIBITIVE, THE SECRETARY'S PROCEDURES MAY  
13 REQUIRE MANUFACTURERS AND GROUP PURCHASING ORGANIZATIONS TO  
14 SUBMIT THE REQUIRED INFORMATION IN AN ELECTRONIC, DOWNLOADABLE  
15 DOCUMENT THAT THE SECRETARY CAN POST ON THE WEB SITE."

16 Page 14, after line 26 insert:

17           **"24-21-407. Effect of federal legislation - compliance with part.**  
18 IF THE UNITED STATES CONGRESS ENACTS AND THE PRESIDENT SIGNS  
19 LEGISLATION KNOWN AS THE "PHYSICIAN PAYMENTS SUNSHINE ACT OF  
20 2009" OR SIMILAR LEGISLATION THAT REQUIRES MANUFACTURERS AND  
21 GROUP PURCHASING ORGANIZATIONS TO DISCLOSE INFORMATION  
22 CONSISTENT WITH OR SIMILAR TO THE INFORMATION REQUIRED BY  
23 SECTIONS 24-21-403 AND 24-21-404, A MANUFACTURER OR GROUP  
24 PURCHASING ORGANIZATION MAY COMPLY WITH THIS PART 4 BY  
25 PROVIDING TO THE SECRETARY BY MARCH 31 OF THE YEAR IN WHICH THE  
26 MANUFACTURER OR GROUP PURCHASING ORGANIZATION IS REQUIRED BY  
27 THE FEDERAL LEGISLATION TO SUBMIT INFORMATION, AND BY EACH  
28 MARCH 31 THEREAFTER, A LINK TO THE WEB SITE ON WHICH THE  
29 MANUFACTURER'S OR GROUP PURCHASING ORGANIZATION'S DISCLOSURES  
30 ARE AVAILABLE."

31 Renumber succeeding C.R.S. section accordingly.

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