

PROPOSED AMENDMENT

SB 282 # 2

DIGEST

Compounding drugs and medical spas. Exempts: (1) hospitals, ambulatory outpatient surgical centers, and birthing centers; and (2) Category II pharmacies; from compounding limitations in the bill. Amends the definition of "compounding". Specifies when the Indiana board of pharmacy may request records. Amends language concerning bulk drug substance information in a certificate of analysis. Removes language exempting hospitals and ambulatory outpatient surgical centers from data reporting language. Applies definitions concerning pharmacies and pharmacists to the chapter on medical spas. Amends the definition of "medical spa". Changes information that must be included in an application for registration as a medical spa. Changes references from "responsible person" to "responsible practitioner". Specifies that a responsible practitioner who has prescriptive authority must be physically present at the medical spa. Allows for the suspension of a medical spa's registration in accordance with health professions' standard of practice statute.

- 1 Page 1, line 4, delete "IC 16-42-22.5-1." and insert "**IC**
- 2 **16-42-22.5-2.**".
- 3 Page 1, line 9, delete "IC 16-42-22.5-2." and insert "**IC**
- 4 **16-42-22.5-3.**".
- 5 Page 1, line 14, delete "IC 16-42-22.5-3." and insert "**IC**
- 6 **16-42-22.5-4.**".
- 7 Page 2, line 2, delete "IC 16-42-22.5-4." and insert "**IC**
- 8 **16-42-22.5-5.**".
- 9 Page 2, line 7, after "1." insert "**This chapter does not apply to the**
- 10 **following:**
- 11 **(1) An entity licensed under IC 16-21.**
- 12 **(2) A pharmacy regulated by the board that holds a Category**
- 13 **II permit as set forth in IC 25-26-13-17.**
- 14 **Sec. 2.**".
- 15 Page 2, line 11, delete "2." and insert "**3.**".
- 16 Page 2, line 19, delete "3." and insert "**4.**".
- 17 Page 2, line 25, delete "4." and insert "**5.**".
- 18 Page 2, line 27, delete "by:" and insert "**to create a drug.**".
- 19 Page 2, delete lines 28 through 33.
- 20 Page 2, line 34, delete "5." and insert "**6.**".
- 21 Page 2, line 34, after "compounding" insert "**under 21 U.S.C.**

- 1 **353a".**
- 2 Page 3, line 3, after "(ii)" insert **"if not a component of a drug**
- 3 **approved by the federal Food and Drug Administration,".**
- 4 Page 3, line 6, after "used" insert **"under subdivision (1)(B)(i)".**
- 5 Page 3, line 10, delete "." and insert **"for human use.".**
- 6 Page 3, line 14, delete "the following:" and insert **"any information**
- 7 **that the board requires through the adoption of rules under**
- 8 **IC 4-22-2.".**
- 9 Page 3, delete lines 15 through 21.
- 10 Page 3, line 23, delete "compounded drug" and insert **"compounded**
- 11 **drug.".**
- 12 Page 3, delete lines 24 through 32.
- 13 Page 3, line 35, delete "that:" and insert **"that is registered with the**
- 14 **federal Food and Drug Administration under 21 U.S.C. 360.".**
- 15 Page 3, delete lines 36 through 42.
- 16 Page 4, delete lines 1 through 3.
- 17 Page 4, line 17, after "pharmacy" insert **"during an inspection or**
- 18 **as part of the review of a license application or renewal".**
- 19 Page 4, line 24, delete "6." and insert **"7.".**
- 20 Page 4, line 29, delete "compounding and the risks posed by the
- 21 practice of".
- 22 Page 5, delete lines 8 through 9.
- 23 Page 5, line 19, delete "compounding" and insert **"compounded".**
- 24 Page 5, line 22, delete "drugs given the" and insert **"drugs.".**
- 25 Page 5, delete lines 23 through 26.
- 26 Page 5, line 35, after "1." insert **"The definitions in IC 25-26-13-2**
- 27 **apply to this chapter.**
- 28 **Sec. 2.".**
- 29 Page 6, line 4, delete "service," and insert **"services and**
- 30 **treatments,".**
- 31 Page 6, line 8, delete ";" and insert **"and dermal fillers;".**
- 32 Page 6, line 9, after "(iii)" insert **"hair loss;**
- 33 **(iv)".**
- 34 Page 6, line 10, delete "(iv)" and insert **"(v)".**
- 35 Page 6, line 13, delete "2." and insert **"3.".**
- 36 Page 6, line 22, delete "medical spa's license number." and insert
- 37 **"medical health care services intended to be provided at the**
- 38 **medical spa.**
- 39 **(4) The prescription drugs that are intended to be prepared,**

- 1 **administered, dispensed, or otherwise used at the medical spa,**
 - 2 **including whether the prescription drug is compounded."**
 - 3 Page 6, line 23, delete "(4)" and insert "**(5)**".
 - 4 Page 6, line 24, delete "person" and insert "**practitioner**".
 - 5 Page 6, line 24, delete "4" and insert "**5**".
 - 6 Page 6, line 26, after "spa" insert "**in an amount not to exceed five**
 - 7 **thousand dollars (\$5,000)**".
 - 8 Page 6, line 28, delete "3." and insert "**4.**".
 - 9 Page 6, line 30, delete "2(b)" and insert "**3(b)**".
 - 10 Page 6, line 37, delete "4." and insert "**5.**".
 - 11 Page 6, line 38, delete "person." and insert "**practitioner.**".
 - 12 Page 6, line 40, delete "person" and insert "**practitioner**".
 - 13 Page 6, line 42, delete "person" and insert "**practitioner who has**
 - 14 **prescriptive authority**".
 - 15 Page 7, line 4, delete "5." and insert "**6.**".
 - 16 Page 7, line 26, delete "6." and insert "**7.**".
 - 17 Page 7, line 34, delete "7." and insert "**8.**".
 - 18 Page 7, line 37, delete "if" and insert "**pursuant to the**
 - 19 **requirements set forth in IC 25-1-9-10.**".
 - 20 Page 7, delete line 38.
 - 21 Page 7, line 39, delete "8." and insert "**9.**".
- (Reference is to SB 282 as introduced.)