PHARMACY LAW UPDATE – 2018
SDPHA ANNUAL MEETING
SIOUX FALLS, SD – SEPTEMBER 21, 2018
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I have had no financial relationship over the past 12 months with any commercial sponsor with a vested interest in this presentation.

Pharmacist Learning Objectives: 1. Identify a recently-enacted South Dakota law, and evaluate its influence on pharmacy practice in South Dakota; 2. Identify recently proposed federal rules and summarize their potential impact on pharmacy practice; 3. Describe issues related to other federal and state laws and rules that may cause confusion in pharmacy practice.
Pharmacy Technician Learning Objectives: 1. Identify a recently-enacted South Dakota law and explain its influence on pharmacy technician practice in South Dakota; 2. Identify recently proposed federal rules and describe their potential impact on pharmacy technician responsibilities; 3. Describe issues related to other federal and state laws and rules that may cause confusion for pharmacy technicians.

Pre-test/Post-test (Circle all of the correct answers – IF ANY)

1. Based on official definitions, which of the following definitions is/are true?
   A. "Pharmaceutical equivalents" -- are drug products containing the same active ingredients and are identical in strength or concentration, dosage form and route of administration.
   B. "Therapeutic Equivalents" -- are pharmaceutical equivalents expected to have the same therapeutic effects when administered under conditions specified in the labeling.

2. Which of the definitions in Q.1, if either, are used to mean “bioequivalent”?

3. According to the FDA, (simplistically) A-rated products are bioequivalent to each other and B-rated products are not bioequivalent to anything. TRUE FALSE

4. If a prescription is written for an A-rated brand name product in South Dakota, only an A-rated product may be substituted (if not prohibited by the prescriber). TRUE FALSE

5. A prescription for an A-rated, brand name product is considered substitutable in SD without the prescriber’s permission:
   A. unless the words “Brand Necessary” or words of similar meaning are on a written prescription.
   B. the prescriber or agent say “Brand Necessary” or words of similar meaning when telephoning a prescription to a pharmacy.

6. For question #5, for a written prescription, the words “Brand Necessary” or words of similar meaning must be handwritten, not preprinted, on the Rx blank. TRUE FALSE

7. When substitution takes place in SD, the patient must be informed of the substitution and has the right to refuse the substituted product. TRUE FALSE

8. Though it has been occurring for years, South Dakota law prohibits hospitals from interchanging non-bioequivalent products via policy or formulary. That is, dispensing the formulary proton pump inhibitor when a physician orders another PPI at the hospital is actually illegal. TRUE FALSE

9. Which of the following tells where to find out if a product is considered therapeutically equivalent to a brand name product?
   A. It is noted on the generic drug's label.
   B. Check on Google – you can find anything there.
   C. Look in the pharmacy's copy of the "Orange Book."
   D. Go to http://www.fda.gov/cder/ob/.
   E. None of the above.

10. In South Dakota the drug name must be on the prescription label unless otherwise requested by the prescriber. TRUE FALSE

11. When substitution has taken place:
   A. the brand name of the product used must go on the prescription label.
   B. the generic name of the product used must go on the prescription label.

12. It is legal to have the brand name of the product prescribed on the prescription label even if substitution with a generic has taken place. TRUE FALSE

13. If substitution has taken place, the file copy of the prescription must contain:
   A. the brand name of the product used, if it has a brand name.
   B. the name of the manufacturer, labeler, or distributor of the product used if it has no brand name.

14. Which, if any, of the following are considered biological products (using common brand names)?
   A. Neupogen B. Epogen C. Remicade
   D. Humira E. Enbrel

15. Biosimilars are generic versions of biological products. TRUE FALSE

16. Pharmacists may interchange a biosimilar on a prescription for the reference listed biological product without the prescriber's permission. TRUE FALSE

17. Which of the following tells where to find if a biosimilar is interchangeable with a reference listed biological product?
   A. It is noted on the biosimilar's label.
   B. Check on Google – you can find anything there.
   C. Look in the pharmacy's copy of the "Orange Book."
   D. Go to http://www.fda.gov/cder/ob/.
   E. None of the above.

18. A prescription for a brand name biologic is considered interchangeable with a biosimilar in SD without the prescriber's permission:
    A. unless the words "Brand Necessary" or words of similar meaning are on a written prescription.
    B. the prescriber or agent say "Brand Necessary" or words of similar meaning when telephoning a prescription to a pharmacy.

19. In the question above (#18), for a written prescription, the words "Brand Necessary" or words of similar meaning must be handwritten, not preprinted, on the prescription blank.
    TRUE FALSE

20. When interchange of biologics takes place in SD, the prescriber must be informed of the interchange. TRUE FALSE

21. When interchange of biologics takes place in SD, the patient must be informed of the interchange and has the right to refuse the interchanged product.
    TRUE FALSE

22. When biosimilar interchange has taken place:
    A. the brand name (proprietary name) of the product used must go on the prescription label.
    B. the proper name of the product used must go on the prescription label.

23. It is legal to have the brand name (proprietary name) of the product prescribed on the prescription label even if interchange with a biosimilar has taken place.
    TRUE FALSE

24. If interchange has taken place, the file copy of the prescription must contain:
    A. the brand name (proprietary name) of the product used, if it has a brand name (proprietary name).
    B. the proper name of the biologic product used.
    C. the name of the manufacturer of the biologic product used.

25. The interchange of biologics/biosimlars in hospitals must follow the requirements regarding:
    A. the prescriber noting "Brand Necessary" on the order.
    B. notifying the prescriber of the interchange.
    C. notifying the patient of the interchange.

26. When a biosimilar is approved by the FDA, how long must the manufacturer wait before marketing that biosimilar?
A. Six months. B. 30 days. C. There is no wait.

27. How often must a pharmacy take a controlled substances inventory for the DEA?
A. Once a year. B. Every six months. C. Once every two years.

28. What controlled substances must be included in that inventory?
A. All controlled substances that are in-date.
B. All controlled substances, whether in-date or expired.
C. All controlled substances that are in stock.
D. All controlled substances in stock and C-II drugs on order but not received.
E. All controlled substances, whether in stock or ready to be returned.

29. The controlled substance inventory must be taken before the open of business on the inventory date. TRUE FALSE

30. The printed inventory must be:
A. sent to the nearest DEA Regional Office.
B. sent to the state agency handling controlled substances activities.
C. sent to the state's Board of Pharmacy.

31. How long must the printed copy of the inventory be kept at the pharmacy?
A. Six months. B. Two years. C. Seven years.

32. If a physician practices in two different South Dakota (SD) communities, he/she must have a different DEA number for controlled substances prescriptions based on the clinic in which the controlled substance prescription is written.
TRUE FALSE MAYBE

33. A physician practices in South Dakota and Minnesota, the physician would use a different DEA number for controlled substances prescriptions written in South Dakota than the DEA number used to write controlled substances prescriptions written in Minnesota. TRUE FALSE MAYBE

34. What, if any, recordkeeping is required If a DEA-registered prescriber wants to get a C-II controlled substance from your pharmacy?
A. DEA Form-222 is used.
B. An invoice detailing the transaction is sufficient.
C. The pharmacy may not supply the C-II substance to the prescriber.

35. What is the procedure for the prescriber to use DEA Form 222 in ordering a C-II from your pharmacy:
A. Your pharmacy is considered the "supplier."
B. The prescriber keeps Copy 3 (the bottom copy) and sends the attached Copy 1 and Copy 2 to your pharmacy.
C. You keep Copy 1 and Copy 2 for a minimum of six months.

36. What is the procedure for your pharmacy to receive a C-III controlled substance from another pharmacy?
    A. Use DEA Form 222.
    B. Create an invoice.
    C. Use a sticky note which you discard when you pay the other pharmacy back.

37. Which of the following does not need to be on the invoice created regarding the C-III substance your pharmacy has received?
    A. Drug name. B. Dosage form. C. Strength.
    D. Quantity. E. Date transferred.

38. Which other information does not need to be on the invoice created regarding the C-III substance your pharmacy has received?
    A. Name of pharmacy from which you received the substance.
    B. Address of the pharmacy from which you received the substance.
    C. DEA Number of the pharmacy from which you received the substance.
    D. Name of the pharmacist or technician from the other pharmacy whom you spoke to about receiving the substance.
    E. Your name.

39. What is the maximum number of technicians that may be working at a South Dakota community pharmacy at any given time?
    A. Two. B. Two per pharmacist.
    C. Three. D. Three per pharmacist.
    E. It is up to the pharmacist in charge. F. It depends.

40. What is the maximum number of technicians that may be working at a South Dakota hospital pharmacy at any given time?
    A. Two. B. Two per pharmacist.
    C. Three. D. Three per pharmacist.
    E. It is up to the pharmacist in charge. F. It depends.

REFERENCES

The references do not always go in chronological order.
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