

**PHARMACY LAW – 2017**  
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**SDPHA ANNUAL MEETING**  
**DEADWOOD, SD**  
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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 and evaluate recently-enacted state laws which are influencing pharmacy practice.
2. Summarize recent federal regulations which will influence pharmacy practice.
3. Identify federal and state laws and rules that may cause confusion in pharmacy practice.
4. Describe the potential impact that a proposed initiated measure in South Dakota could have on pharmacy practice.

Pharmacy Technician Learning Objectives:

1. Summarize the ways in which recently-enacted state laws are influencing pharmacy practice.
2. Name recent federal regulations which will influence pharmacy practice.
3. Identify federal and state laws and rules that may cause confusion for pharmacy technicians.
4. Describe the potential impact that a proposed initiated measure in South Dakota could have on pharmacy practice.

For multiple choice questions, circle all of the correct answers.

1. What are the limitations on a Nurse Practitioner (CNP) in South Dakota (SD) regarding writing prescriptions for non-controlled substances?
  - A. They may not write for over a 30-day supply.
  - B. Refills are limited to a maximum of one year.
  - C. Neither of the above.
  
2. What are the limitations on a Physician's Assistant (PA) in SD regarding writing prescriptions for non-controlled substances?
  - A. They may not write for over a 30-day supply.
  - B. Refills are limited to a maximum of one year.
  - C. Neither of the above.
  
3. What are the limitations on a CNP in SD regarding writing prescriptions for C-3 or C-4 controlled substances?
  - A. They may not write for over a 30-day supply.
  - B. Those prescriptions may not be refilled.
  - C. Neither of the above.
  
4. What are the limitations on a PA in SD regarding writing prescriptions for C-3 or C-4 controlled substances?
  - A. They may not write for over a 30-day supply.
  - B. Those prescriptions may not be refilled.
  - C. Neither of the above.
  
5. What are the limitations on a CNP in SD regarding writing prescriptions for C-2 controlled substances for a typical patient?
  - A. If the patient needs more of the drug, the patient must see another practitioner
  - B. They may not write for over a 30-day supply.
  - C. Neither of the above.

6. What are the limitations on a PA in SD regarding writing prescriptions for C-2 controlled substances for a typical patient?
  - A. If the patient needs more of the drug, the patient must see another practitioner
  - B. They may not write for over a 30-day supply.
  - C. Neither of the above.
7. A CNP in SD writes (1) a prescription dated 9/22/17 for Adderall XR 30mg #45 1 daily and (2) another prescription dated 9/22/17 for Adderall XR 30mg #45 1 daily and stating do not fill before November 6, 2017.
  - A. You may fill prescription #1
  - B. You may fill prescription #2 on November 6, 2017 or later
  - C. You may not fill either prescription.
8. A PA in SD writes (1) a prescription dated 9/22/17 for Adderall XR 30mg #45 1 daily and (2) another prescription dated 9/22/17 for Adderall XR 30mg #45 1 daily and stating do not fill before November 6, 2017.
  - A. You may fill prescription #1
  - B. You may fill prescription #2 on November 6, 2017 or later
  - C. You may not fill either prescription.
9. What are the limits to partially dispensing a prescription written by an MD for a C-2 drug for a terminally ill or nursing home (LTCF) patient in SD?
  - A. The quantity written on the prescription may be completely filled
  - B. Fill up to the quantity on the prescription, or a 30 days' supply whichever comes first
  - C. Fill up to the quantity on the prescription, or a 60 days' supply whichever comes first
10. A CNP in SD writes a C-2 controlled substance prescription "#240 tablets, one tablet QID," which will be partially dispensed for a patient in a LTCF.
  - A. You may not fill the prescription at all
  - B. You may partially fill the prescription up to a maximum of a 120 tablets/30-day supply
  - C. You may partially fill the prescription up to 240 tablets/60-day supply.
11. A PA in SD writes a C-2 controlled substance prescription "#240 tablets, one tablet QID," which will be partially dispensed for a patient in a LTCF.
  - A. You may not fill the prescription at all
  - B. You may partially fill the prescription up to a maximum of a 120 tablets/30-day supply
  - C. You may partially fill the prescription up to 240 tablets/60-day supply.
12. Regarding a CNP or NP in SD faxing a C-2 prescription for a LTCF patient to a pharmacy:
  - A. They may legally do so
  - B. They may legally do so as long as the pharmacy also gets a hard copy of the Rx
  - C. They may not legally do so
13. Which of the following meet the requirements for an emergency situation in order to have an emergency prescription for a C-2 controlled substance?
  - A. Immediate administration of the drug is necessary to properly treat the patient.
  - B. No appropriate alternative treatment is available, including administration of a drug which is not a C-2 controlled substance.
  - C. It is not reasonably possible for the prescriber to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.
14. What are the supply limits for an emergency prescription for a C-2 controlled substance?
  - A. 7 day supply
  - B. 72 hours' supply
  - C. None of the above
15. Legitimate emergency prescriptions for a C-2 controlled substance
  - A. May be partially filled
  - B. May be partially filled with certain restrictions
  - C. May not be partially filled

16. Other than for terminally ill patients, LTCF patients, and when a pharmacy does not have enough to fill the entire prescription, with restrictions the partial filling of C-2 controlled substances is:
  - A. allowed by federal law
  - B. allowed by South Dakota law
  - C. neither of the above
17. Practitioners may prescribe buprenorphine for analgesia
  - A. if they have a DEA number
  - B. if it is in their usual scope of practice
  - C. neither of the above
18. Specially trained practitioners meeting a number of guidelines may prescribe buprenorphine for office-based treatment of addiction. Those specially trained practitioners may include:
  - A. Physician Assistants
  - B. Nurse Practitioners
  - C. Neither of the above
19. 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
20. What are the restrictions for substituting one biosimilar for another without the prescriber's permission?
  - A. There are no restrictions
  - B. Biosimilars may not be substituted for each other without permission
  - C. Neither of the above
21. In SD, for most prescription drugs (not biosimilars), when substituting a generic product for a brand name product, a pharmacy
  - A. must notify the prescriber of the substitution
  - B. must notify the patient of the substitution
  - C. Neither of the above
22. DEA Form 222 for ordering C-2 controlled substances may only be signed
  - A. by the person who signed the pharmacy's most recent application for registration with the DEA
  - B. by any person given power of attorney to sign the form
  - C. by any staff pharmacist
23. For each controlled substance produced by a manufacturer
  - A. the DEA sets a quota for the maximum quantity of the drug which can be produced by that manufacturer
  - B. the manufacturer may not produce more than 10% more of that drug than produced the previous year
  - C. Neither of the above
24. A SD pharmacist who dispenses prescribed medications to a person who the pharmacist knows is planning to use those medications to commit suicide
  - A. could potentially be convicted of a felony
  - B. could potentially be convicted of a misdemeanor
  - C. neither of the above
25. A SD pharmacist who refuses to dispense prescribed medications to a person who the pharmacist knows is planning to use those medications to commit suicide
  - A. could potentially be convicted of a felony
  - B. could potentially be convicted of a misdemeanor
  - C. neither of the above

## REFERENCES

**“SDCL” refers to SD Codified Law. “ARSD” refers to the Administrative Rules of SD.**

**[http://sdlegislature.gov/statutes/Codified\\_Laws/](http://sdlegislature.gov/statutes/Codified_Laws/)**

**<http://sdlegislature.gov/Rules/default.aspx>**

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2, 4, 6, 8, SDCL 36-4A-26.1

9, 10 ARSD 44:58:08:18.01

11 <http://doh.sd.gov/boards/pharmacy/newsletter/July2016.pdf>

12, 13, 14 [https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306\\_11.htm](https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_11.htm)

15, 16 <https://www.law.cornell.edu/uscode/text/21/829>  
U.S Code > Title 21 > Chapter 13 > Subchapter I > Part C > § 829

17 , 18 <https://www.samhsa.gov/medication-assisted-treatment/qualify-nps-pas-waivers>  
<https://www.samhsa.gov/bupe/lookup-form>

19 <http://www.raps.org/Regulatory-Focus/News/2017/06/12/27881/US-Supreme-Court-No-Six-Month-Wait-for-Biosimilars-After-FDA-Approval/>

20 <http://www.raps.org/Regulatory-Focus/News/2017/06/26/27969/FDA-Interchangeable-Biosimilar-Approvals-Expected-Within-2-Years/>

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22 <https://www.deadiversion.usdoj.gov/21cfr/cfr/2105cfrt.htm>

23 <https://www.law.cornell.edu/uscode/text/21/826>

24 SDCL 22-16-37

25 SDCL 36-11-70  
<http://atg.sd.gov/docs/Ballot%20Explanen.Prescription%20of%20Life%20ending%20drugs.pdf>