ARTICLE 20:78

BOARD OF MEDICAL AND OSTEOPATHIC EXAMINERS

Chapter

CHAPTER 20:78:06

OPIOID OVERDOSE PREVENTION

Section

20:78:06:01 Definitions. Terms used in this chapter mean:

(1) "Board," the South Dakota Board of Medical and Osteopathic Examiners;

(2) "First responder training," a training program that meets the criteria established by the board in §20:78:06:02;

(3) "Protocols," a standardized plan for medical procedures or administration of nasal or auto-injector medications;

(4) "Opioid overdose," a medical condition that causes depressed consciousness and mental functioning, decreased movement, depressed respiratory function, and the impairment of vital functions as a result of ingesting opioids in any amount larger than can be physically tolerated;

(5) "Standing order," an ongoing authorization for a first responder to obtain, possess, and administer opioid antagonists.

Source:

General Authority: SDCL 34-20A-102

Law Implemented: SDCL 34-20A-100

20:78:06:02. Criteria for training a first responder. Training programs shall meet the following criteria:

Each first responder training program shall include:

(1) The signs and symptoms of an opioid overdose;

(2) The protocols and procedures for administration of an opioid antagonist;

(3) The signs and symptoms of an adverse reaction to an opioid antagonist;

(4) The protocols and procedures to stabilize the patient if an adverse response occurs;

(5) Opioid antagonist duration;

(6) The protocols and procedures for monitoring the suspected opioid overdose victim and re-administration of opioid antagonist if necessary for the safety and security of the suspected overdose victim;

(7) The procedures for storage, transport, and security of the opioid antagonist; and

(8) The method of opioid antagonist administration being taught.

Each first responder training program shall be overseen by a physician licensed pursuant to SDCL chapter 36-4. The employer of a first responder may provide the training for a first responder if the training meets each requirement listed in this section.

A first responder trained to possess and administer opioid antagonists must complete a first responder training program at least every three years.

Source:

General Authority: SDCL 34-20A-102

Law Implemented: SDCL 34-20A-101

20:78:06:03. Standing order. A physician licensed under SDCL chapter 36-4 may issue a standing order to a first responder authorizing a prescription for the possession of an opioid antagonist. The standing order:

(1) Authorizes a first responder who has completed a first responder training program to possess and administer opioid antagonists;

(2) Shall specify the method of opioid antagonist administration that is compatible with the education and training of the person administering the antagonist; and

(3) Shall be kept on file by the first responder, the issuing physician, and the first responder's employer.

The standing order expires three years after the date it is issued.

Source:

General Authority: SDCL 34-20A-102

Law Implemented: SDCL 34-20A-98

20:78:06:04. Protocols. The issuing physician and the first responder shall each maintain one copy of the issuing physicians' written protocol.

Source:

General Authority: SDCL 34-20A-102

Law Implemented: SDCL 34-20A-101

South Dakota Board of Medical and Osteopathic Examiners
BOARD MEETING AND PUBLIC RULES HEARING

Thursday, December 4, 2015
9:00 am (central time)/8:00 am (mountain time)

To participate by:

DDN Sites: Pierre: CAP A, 500 E. Capitol, Pierre, SD 57501
Rapid City: Rapid City University Center, Room 113, 4300 Cheyenne Blvd. Rapid City, SD
In person: Board Conference Room, 101 N. Main Ave., Suite 215 (on 2nd floor), Sioux Falls, SD

Unapproved Draft Minutes[i]

South Dakota Board of Medical and Osteopathic Examiners Meeting and Public Rules Hearing 9:00 am (CT) Thursday, December 4, 2015

Boards Members Present: Kevin Bjordahl, MD, Ms. Deb Bowman, Laurie Landeen, MD; Brent Lindbloom, DO; Mr. David Lust; Jeffrey Murray, MD

Boards Members Absent: Walter Carlson, MD; Mary Carpenter, MD; David Erickson, MD

Board Staff Present: Margaret Hansen, PA-C; Mr. Tyler Klatt; Ms. Jane Phalen; Ms. Misty Rallis

Board Counsel: Steven Blair

Staff Counsel: William Golden

1. Dr. Kevin Bjordahl, vice president of the Board, called the meeting to order at 9:00 am. Roll was called and a quorum was confirmed.

2. The scheduled Public Hearing on Administrative Rule ARSD Chapter 20:78:06: Opioid Overdose Prevention was called to order at 9:00 am by Mr. Steven Blair. The proposed administrative rules were introduced by Mr. Tyler Klatt. Written comments from Dr. Timothy Ridgway, president of the South Dakota State Medical Association, were presented and accepted into the record. Mr. Blair called for testimony from proponents of the proposed rule, but there were no proponents present at the meeting to present testimony. Mr. Blair called for testimony opposing the proposed rule. Attorney Timothy Engel, on behalf of the South Dakota State Medical Association, and Mr. Mark East, on behalf of the South Dakota State Medical Association, presented testimony in opposition to the proposed rule which was accepted into the record. Mr. Engel clarified, that he characterized not as opposition, but as suggestions to improve the rules. Staff then presented responses to the questions and recommendations brought by Mr. Engel and Mr. East, and this was accepted into the record. Discussion was held resulting in the following amendments to the proposed administrative rule:
    i. ARSD 20:78:06:01(3): amend the language as follows: “Protocols, a standardized plan for medical procedures or administration of ~~medications~~ nasal or auto-injector medication;”

ii. ARSD 20:78:06:02: add as follows:
    1. (5) Opioid antagonist duration
    2. (6) The protocols and procedures for monitoring the suspected overdose victim and re-administration of opioid antagonist if necessary for the safety and security of the suspected overdose victim
iii. ARSD 20:78:06:03(2): amend the language as follows: "Shall specify the method of opioid antagonist administration that is compatible with the education and training of the person administering the antagonist;"

3. There being no further questions or comments from the Board members, Dr. Landeen moved that the public hearing for the proposed administrative rules 20:78:06 be concluded. The motion was seconded and unanimously approved.

[i] 1-27-1.17. Draft minutes of public meeting to be available--Exceptions--Violation as misdemeanor. The unapproved, draft minutes of any public meeting held pursuant to § 1-25-1 that are required to be kept by law shall be available for inspection by any person within ten business days after the meeting. However, this section does not apply if an audio or video recording of the meeting is available to the public on the governing body's website within five business days after the meeting. A violation of this section is a Class 2 misdemeanor. However, the provisions of this section do not apply to draft minutes of contested case proceedings held in accordance with the provisions of chapter 1-26.

SOUTH DAKOTA STATE MEDICAL ASSOCIATION

Values. Ethics. Advocacy.

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Sioux Falls, SD 57117-7406
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www.sdsma.org

November 24, 2015

Walter Carlson, M.D., Board President
South Dakota Board of Medical & Osteopathic Examiners
101 N. Main Avenue, Ste 301
Sioux Falls, SD 57104-6411

RE: Opioid Overdose Prevention

Dear Dr. Carlson:

As President of the South Dakota State Medical Association (SDSMA), I am writing to express our appreciation for the South Dakota Board of Medical & Osteopathic Examiners' (SDBMOE) efforts to develop guidelines for first responder possession and administration of opioid antagonists to combat opiate overdose and death.

On behalf of the SDSMA, I present the following concerns:

1. Proposed Rule 20:78:06:01 (3). The definition of "protocols" includes, "a standardized plan for medical procedures or administration of medications." Can the SDBMOE define, "administration of medications?" The SDSMA is concerned that as proposed, this rule would grant "first responders" the authority to give injections, while many are not licensed or authorized to do so. Many states limit the "administration of medications" by first responders to that of the administration of Narcan (naloxone) via nasal spray – which was recently approved by the Food and Drug Administration (FDA).

2. Proposed Rule 20:78:06:02 (1). The SDSMA recommends that first responder course content include information and education regarding naloxone duration as its effect is shorter than most opiates and therefore, the patient must be monitored continuously for the return of life-threatening symptoms and the onset of violent behavior.

3. We also believe while that any first responder who administers naloxone shall be immune from liability per SDCL 20-9-3 or 20-9-4, we recommend the inclusion of language that specifically states immunity from liability for anyone who fails to administer naloxone. We believe the precedence for this protection was set

with SDCL 20-9-4.4, which grants civil immunity for emergency use or nonuse of an AED.

On behalf of the SDSMA, I present the following questions for clarification:

1. Proposed Rule 20:78:06:03. "The standing order shall expire three years after the date it is issued." Typically, standing orders are not time limited and we question the need for the three-year duration. We would also ask if the rule should include guidelines regarding proper storage and maintenance of supplies to ensure naloxone efficacy.

2. Proposed Rule 20:78:06:04. Please define or provide additional clarification to this protocol maintenance requirement which states, "One copy of the physician's written protocol shall be maintained by each of the following persons or parties: 1) the issuing physician; 2) the first responder.

In closing, we thank you for the opportunity to express our concerns and look forward to hearing from you in regard to our suggestions on the proposed administrative rules on opioid overdose prevention.

Sincerely,

Tim M. Ridgway, M.D.
President

cc: Margaret Hansen, Executive Director, SDBMOE
Barbara Smith, CEO, SDSMA

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BOARD OF MEDICAL AND OSTEOPATHIC EXAMINERS

Chapter

CHAPTER 20:78:06

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20:78:06:01 Definitions. Words used in this section mean:

(1) "Board," the South Dakota Board of Medical and Osteopathic Examiners;

(2) "First responder training," a training program that follows the criteria set by the Board;

(3) "Protocols," a standardized plan for medical procedures or administration of nasal or auto-injector medications;

(4) "Opioid overdose," means a medical condition that causes depressed consciousness and mental functioning, decreased movement, depressed respiratory function, and the impairment of vital functions as a result of ingesting opioids in any amount larger than can be physically tolerated;

(5) "Standing order," ongoing authorization for a first responder to obtain, possess, and administer opioid antagonists.

Source:

General Authority: SDCL 34-20A-102

Law Implemented: SDCL 34-20A-100

20:78:06:02. Criteria for training a first responder. Training programs shall meet the following criteria:

(1) Course content includes:

a. The signs and symptoms of an opioid overdose;

b. The protocols and procedures for administration of an opioid antagonist;

c. The signs and symptoms of an adverse reaction to an opioid antagonist;

d. The protocols and procedures to stabilize the patient if an adverse response occurs;

e. Opioid antagonist duration

f. The protocols and procedures for re-administration of opioid antagonist if necessary for the safety and security of the suspected overdose victim

g. The procedures for the transport and security of a suspected overdose victim

h. The procedures for storage, transport, and security of the opioid antagonist.

(2) The method of opioid antagonist administration being taught.

(3) Training will be overseen by a physician licensed pursuant to SDCL chapter 36-4.

(4) Subject to the oversight required in section (3) of this rule, training may be provided by the employer of the first responder.

(5) First responders trained to possess and administer opioid antagonists must be retrained at least every three years.

Source:

General Authority: SDCL 34-20A-102

Law Implemented: SDCL 34-20A-101

20:78:06:03. Standing order. A physician licensed under SDCL chapter 36-4 may issue a standing order to first responders authorizing a prescription for the possession of an opioid antagonist. The standing order shall:

(1) Authorize a first responder who has completed training as listed in section 2 to possess and administer opioid antagonists;

(2) Determine the method of opioid antagonist administration that is compatible with the scope of practice of the person administering the antagonist;

(3) Be kept on file by the first responder, the issuing physician, and the first responder's employer.

The standing order shall expire three years after the date it is issued. First responders must complete the retraining requirements pursuant to ARSD 20:78:06:02.

Source:

General Authority: SDCL 34-20A-102

Law Implemented: SDCL 34-20A-98 4

20:78:06:04. Protocols. One copy of the physician's written protocol shall be maintained by each of the following persons or parties:

(1) The issuing physician;

(2) The first responder.

Source:

General Authority: SDCL 34-20A-102

Law Implemented: SDCL 34-20A-101

~~**20:78:06:05.** Civil immunity for emergency use or nonuse of opioid antagonist. Any person, who in good faith uses, attempts to use, or chooses not to use an opioid antagonist in providing emergency care or treatment, is immune from civil liability for any injury as a result of such emergency care or treatment or as a result of an act or failure to act in providing or arranging such medical treatment.~~

~~**Source:**~~

FORM 14

SMALL BUSINESS IMPACT STATEMENT FORM

See SDCL 1-26-2.1

(NOTE: This form must be signed by either the head of the agency or the presiding officer of the board or commission empowered to adopt the rules. Check your statutes to see who is authorized to promulgate rules. A small business is defined as any business with 25 or fewer full-time employees. When a set of rules is proposed, a general summary shall be provided; each proposed rule amendment shall also be explained thoroughly. In the case of a large set of proposed rules which all have a single purpose and impact, one explanation is sufficient. The law makes it clear that agencies or commissions shall use readily available information and existing resources to prepare the impact statement.)

1. Our agency has determined that the rule/s we are proposing have the following type of impact on small businesses:
   - ☐ Direct impact *(please complete remainder of form)*
   - ☐ Indirect impact *(please provide a brief explanation, then sign, date, and submit form. Questions 2 through 8 do not need to be answered)*
   - **X** No impact *(please provide a brief explanation, sign, date, and submit form - Questions 2 through 8 do not need to be answered)*

     The proposed rules focus on administrative procedures and do not create or change any requirements related to small businesses.

2. A general narrative and overview of the effect of the rule(s) on small business - written in plain, easy to read language:

3. What is the basis for the enactment of the rules(s)?
   - ☐ Required to meet changes in federal law
   - ☐ Required to meet changes in state law
   - ☐ Required solely due to changes in date (i.e. must be changed annually)

   Other: _____

4. Why is the rule(s) needed?

5. What small businesses or types of small businesses would be subject to the rule?

6. Estimate the number of small businesses that would be subject to the rule.
   ☐ 1-99 ☐ 100-499 ☐ 500-999 ☐ 1,000-4,999 ☐ More than 5,000
   ☐ Unknown - please explain _____

7. Are small businesses required to file or maintain any reports or records under this rule?
   ☐ Yes ☐ No

   a. If "yes," how many reports must a small business submit to the state on an annual basis?

   b. If "yes," how much ongoing recordkeeping within the business is necessary?

   c. If "yes," what type of professional skills would be necessary to prepare the reports or records?

      ☐ The average owner of a small business should be able to complete the reports and/or records with no assistance
      ☐ It is likely that a bookkeeper for a small business should be able to complete the reports and/or records
      ☐ It is likely that a small business person would need the assistance of a CPA to complete the reports and/or records
      ☐ It is likely that a small business person would need the assistance of an attorney to complete the reports and/or records
      ☐ Other _____
      ☐ Unknown - please explain _____

8. Are there any less intrusive or less costly methods to achieve the purpose of the rule (i.e. fewer reports, less recordkeeping, lower penalties)?
   ☐ No - please explain _____
   ☐ Yes - please explain _____

10/30/2015
Dated

Margaret B. Hansen
Authorized Signature

Board of Medical and Osteopathic Examiners
Name of Agency

(NOTE: A copy of this form may be obtained from the Bureau of Finance and Management. If your rules have a negative fiscal impact on a local government, such as a county or a school district, you must direct the Bureau of Finance and Management to send a copy of its fiscal note to the organizations listed in SDCL 1-26-4.2.)

ADMINISTRATIVE PROCEDURES ACT
FISCAL NOTE
Prepared by Submitting Agency

	CODE	NAME
DEPARTMENT	*09*	*Health*
DIVISION	*2*	*Boards*
PROGRAM	*05*	*Board of Med & Osteo*

PROPOSED RULE: §§ 20:78:06

Hearing Date: December 3, 2015

FISCAL IMPACT STATEMENT:
Pursuant to SDCL 1-26-4.2, these rules have minimal impact on all entities. No additional staffing or resources are required.

FISCAL NOTE SUMMARY:
The proposed rules provide administrative procedures and clarifications. No governmental subdivisions will be impacted.

COST INCREASES (DECREASES)

State Agencies:	***First-Year Impact***	***Continuous-Yearly Impact***
TOTAL		*$0*
Local Subdivisions:		
TOTAL		*$0*
Small Business Increases (Decreases)		
TOTAL		*$0*

REVENUE INCREASES (DECREASES)

Revenue Increases (Decreases) State, Local & Small Business :		
TOTAL		*$0*

APPROVED Margaret B. Hansen *DATE* 10/30/2015
Signature Department Secretary or Board or Commission Chairman

ATTACH: *Copy of proposed rules; separate sections for: 1) explanation of rules effect, i.e. what procedures, schedules, activities, etc. will change with its adoption 2) statistics used, and their source, 3) assumptions that were made to arrive at fiscal impact, 4) computations that were made, and 5)small business impact statement*

Revised June 2004