SOUTH DAKOTA BOARD OF
MEDICAL AND OSTEOPATHIC EXAMINERS

IN THE MATTER OF MEDICAL DIRECTOR AND IMMUNIZATIONS	))))	FINDINGS OF FACT AND CONCLUSIONS OF LAW AND DECLARATORY RULING

This matter having come before the South Dakota Board of Medical and Osteopathic Examiners pursuant to SDCL 1-26-15 and ARSD ch. 20:78:02, and a petition from South Dakota State Medical Association requesting a declaratory ruling, dated August 31, 2012, regarding Immunizations and Standing Orders as follows:

1. Pursuant to SDCL 36-4-8, 36-4-8.1, 36-4-9, and 36-4-30(21)(22)

2. Whether a physician acting as a medical director may issue a standing order for immunizations, and if so, which immunizations are included in the standing order?

3. The precise inquiry asked is what immunizations, if any, may be given based on a standing order from a physician medical director for a clinic, lab, or other organization that allows a patient to enter the facility and request an immunization without a specific order or prescription for that patient.

FINDINGS OF FACT

1. SDCL 36-4-9 defines the "practice of medicine or osteopathy" as recommending, prescribing, or directing the use of any drug, medicine, apparatus, or other agency for the cure, relief, or palliation of any ailment or disease of the mind or body or the cure or relief of any wound, fracture, or bodily injury or deformity.

2. No person may engage in, offer, or hold him or herself out as qualified to provide diagnosis or treatment of any human illnesses unless that person possesses a legal and unrevoked license or certificate issued under the laws of South Dakota authorizing such person to practice the healing arts. SDCL 36-2-2.

3. No person may practice medicine or osteopathy without a license issued under SDCL ch. 36-4. SDCL 36-4-11.

4. Certain licensed professionals are authorized to prescribe medication to humans: Physicians (SDCL 36-4-8,-8.2,-9), Physician Assistants (SDCL 36-4A-22), Dentists (SDCL 36-6A-31), Optometrists (SDCL 36-7-1), Podiatrists (SDCL 36-8-1), and Certified Nurse Practitioners and Certified Nurse Midwives (SDCL 36-9A-12,13). *See* Exhibit 1.

5. Pharmacists have statutory authority to adopt rules for Drug Administration pursuant to SDCL 36-11-19.1.

6. Pharmacists have adopted rules that allow administration of influenza immunizations pursuant to ARSD 20:51:28.

7. Physicians, Physician Assistants and Certified Nurse Practitioners have been ordering or prescribing immunizations or other medicine as defined by their Board within the scope of their practice act.

8. Physician Assistants and Certified Nurse Practitioners are authorized to issue prescriptions for certain patients as set forth within the scope of their practice.[1]

9. Pharmacists have administered influenza immunizations as authorized by their Board through duly-adopted rules, within the scope of their practice act.

10. SDCL 36-4-8.1 prohibits a corporation from practicing medicine or osteopathy. A natural person must obtain a license pursuant to SDCL ch. 36-4 in order to practice medicine.

11. The officers, directors, and shareholders of a Medical Corporation subject to SDCL ch. 47-11 are required to be South Dakota licensed physicians under SDCL ch. 36-4. SDCL 47-11-3.

12. A medical director for a lab, clinic, organization, or office who is a "qualified medical director" as defined in SDCL 36-4C-1(4), 34-23A-58(5) and SDCL 58-17F-3, is required to be a South Dakota licensed physician under SDCL ch. 36-4.

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[1] Physician Assistants and Certified Nurse Practitioners agreements do not contain a list of medications for which they can write prescriptions.

13. Physicians or medical directors have issued standing orders or protocols for administration of immunizations or other preventative medicines.

14. Physicians or medical directors have issued standing orders or protocols for administration of immunizations or other preventative medicines only to licensed healthcare professionals who are authorized, within the scope of their practice, to perform injections after receiving delegation by a standing order or protocol. *See* Exhibit 2 for the list of healthcare professionals who may administer injections.

15. A protocol is a standardized plan for medical procedures or administration of medications with an outline of specific procedures and medications by which certain tasks are delegated to South Dakota licensed healthcare professionals whose scope of practice allows the performance of such tasks.

CONCLUSIONS OF LAW

1. The South Dakota Board of Medical and Osteopathic Examiners have authority under SDCL ch. 36-4, SDCL 1-26-15, and ARSD ch. 20:78:02, to issue declaratory rulings concerning the applicability of their statutory and regulatory provisions and the practice of medicine in the State of South Dakota.

2. A qualified medical director for a lab, clinic, organization, or office is, as defined in SDCL 36-4C-1(4), 34-23A-58 (5), and SDCL 58-17F-3, also a physician licensed pursuant to SDCL ch. 36- 4.

3. A physician with a valid South Dakota license pursuant to SDCL ch. 36-4 may act as a qualified medical director and issue standing orders or protocols authorizing the administration of immunizations or preventative medications by qualified healthcare professionals with valid South Dakota licenses who are authorized by their scope of practice to administer injections. *See* Exhibit 2.

4. The community medical standard in this State is the issuance of standing orders or protocols by a physician or qualified medical director authorizing and delegating the administration of certain immunizations and/or preventative medicines to a clinic, lab, or other organization, upon request by a patient entering the facility without a specific order or prescription for that particular patient.

5. This community medical standard is recognized and affirmed by the Board as a method of protecting the public health with few, if any, risks to the individual patients so long as the standing orders or protocols comply with the following:

(a) A physician or qualified medical director may only issue such

standing orders or protocols to licensed healthcare professionals who are authorized by the scope of their practice to accept delegation and administer injections.

(b) All physicians or qualified medical directors who issue standing orders or protocols ensure that the standing orders or protocols contain sufficient specification in terms of immunizations authorized, the practice authorized, and side-effects and other possible impacts to the health of the patient to be observed and, if noted, actions to be taken, so the healthcare professionals may properly administer the immunizations without a specific order or prescription for that patient.

(c) Physicians acting as medical directors may issue a standing order for immunizations or medications which can be administered by a standing order or protocol without a specific order or prescription to a patient, and which can be delegated to licensed healthcare professionals without undue risk to the patient.

Dated and signed this 12 day of September, 2013.

South Dakota Board of Medical &
Osteopathic Examiners

Exhibit 1

Prescribers and Prescribing Authority Approved by the South Dakota Board of Pharmacy

Prescribing of Controlled Substances Requires a DEA Registration Number

PRESCRIBER DRUG CLASS	MD/DO	OD[1] (Optometrist)	DDS (Dentist)	DPM (Podiatrist)	PA[2] (Physician Assistant Certified)	CNP[2] (Certified Nurse Practitioner)	PHARMACIST[3]	DVM[4] (Veterinarian)	CNM[2] (Certified Nurse Midwife)
C-II	YES	YES[1] ophthalmic only	YES for mouth only	YES for foot only	YES[2] 1 period of not more than 30 days	YES[2] 1 period of not more than 30 days	NO	YES[4]	YES[2] 1 period of not more than 30 days
CIII to V	YES	YES[1] ophthalmic only	YES for mouth only	YES for foot only	YES[2]	YES[2]	NO	YES[4]	YES[2]
Legend Drugs	YES	YES[1] ophthalmic only	YES for mouth only	YES for foot only	YES[2]	YES[2]	(see below)[3]	YES[4]	YES[2]
Contraception	YES	NO	NO	NO	YES[2]	YES[2]	NO	YES[4]	YES[2]
Nicotine Cessation	YES	NO	YES	NO	YES[2]	YES[2]	NO	NO	YES[2]
Anti-Anxiety	YES	NO	YES for dental visit only	YES for foot only	YES[2]	YES[2]	NO	YES[4]	YES[2]
Weight Loss	YES	NO	NO	NO	YES[2]	YES[2]	NO	YES[4]	YES[2]
Controlled substances for self	NO	NO	NO	NO	NO	NO	NO	NO	NO
Controlled substances for prescriber's spouse or children	YES discouraged	YES[1] discouraged	YES discouraged	YES discouraged	YES[2] discouraged	YES[2] discouraged	NO	NO	YES[2] discouraged

1. Optometrists are limited to prescribing for the eyes. Optometrists may prescribe, administer or dispense oral and topical pharmaceutical agents including analgesic and antibiotic agents rational to the diagnosis and treatment of the human eye and its appendages. They may not prescribe, administer or dispense any oral therapeutic agent to any child under 12 years of age, or any oral steroid to any person, without prior consultation with a licensed physician. They may not prescribe any injectables.
2. Physician Assistants, Nurse Practitioners, and Nurse Midwives may only prescribe medication specified by a practice agreement in collaboration with a sponsoring physician. To prescribe controlled substances these practitioners must have their own DEA registration. They may prescribe substances listed as Schedule II for one period of not more than 30 days.
3. Registered pharmacists may initiate or modify drug therapy by protocol or other legal authority established and approved within a licensed healthcare facility or by a practitioner authorized to prescribe drugs.
4. Veterinarians can only prescribe to treat non-human animals.

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Exhibit 2

The following persons in South Dakota may administer vaccinations:

Nurses[1] that hold a SD license or an out of state multi-state compact license:

Certified nurse midwifes (CNM)

Certified nurse practitioners (CNP)

Clinical nurse specialist (CNS)

Certified registered nurse anesthetist (CRNA)

Licensed practical nurses (LPN)

Registered nurses (RN)

SD licensed:

Paramedics[2]

Pharmacists[3]

Physicians (MD or DO)

Physician assistants (PA-C)

SD registered

Medical Assistants[4] (MA)

Footnotes:

1. Nurses may not delegate injectable medications to unlicensed med aides.

2. SD licensed Paramedics may administer medications with education/training as established by the Board of Medical and Osteopathic Examiners.

3. SD licensed pharmacists may administer influenza immunizations pursuant to ARSD 20:51:28.

4. SD registered Medical Assistants (MA) may administer medications with direct physician, CNP, CNM, or PA supervision; they may not calculate doses of medication, so the dose/amount of the vaccination must be calculated by supervising provider and they may not allowed to provide patient teaching. At the September 20, 1995 Joint Board Meeting, it was determined that: Medical Assistants are permitted to administer medications from either a single or multi dose vial as long as the supervising physician, CNP, CNM or PA assures appropriate training, competence, and assumes ultimate responsibility for administration of such drugs.