

DURABLE MEDICAL EQUIPMENT [DME] LICENSURE IN NORTH DAKOTA December 2011

I have recently received many questions about medical supply licensure and durable medical equipment licensure [DME] in North Dakota. This is particularly relevant to the recent bid opening for these items in the new health care reform proposals. I have answered this question many times over the phone and have tried to set the record straight, in this interpretation.

North Dakota's wholesale licensing statute currently speaks to legend drugs. It does not currently have a licensure provision, at wholesale, for durable medical equipment or medical supplies. Additionally, a wholesale licensee specifically may ship only to other licensees. There is no provision in the wholesale act to sell directly to consumers or patients.

The North Dakota pharmacy licensure statute and the practice of pharmacy clearly speaks to the ability of a licensed in-state or out-of-state pharmacy to dispense legend drugs, durable medical equipment or medical supplies, on prescription.

Under the North Dakota Food, Drug and Cosmetic Act NDCC 19-02.1 subsection 7 reads as follows:

"Device", except when used in the first paragraph following subsection 21 of this section and in subsection 10 of section 19-02.1-02, subsection 6 of section 19-02.1-10, subsections 3 and 16 of section 19-02.1-14, and subsection 3 of section 19-02.1-18, means instruments, apparatus and contrivances, including their components, parts, and accessories, intended:

- a. For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or
- b. To affect the structure or any function of the body of man or other animals.

This is a very broad definition and includes devices and medical supplies which require prescriptions. This is consistent with federal definitions and points out the difference between an over-the-counter device and the same device, which is prescribed because it meets the definition of this section.

Additionally, NDCC 43-15-01 subsection 7 defines: "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, which is required under federal or North Dakota law to be prescribed by a practitioner and dispensed by a pharmacist.

This is interpreted to mean that if the device meets the requirements of 19-02.1, it then must be prescribed by a practitioner and dispensed by a pharmacist and thus the requirement for a prescription, if the seller is to get paid for these devices and medical supplies under Medicare regulations.

To follow up with NDCC 43-15-01, subsection 8 which defines: "Dispense" or "dispensing" means the preparation and delivery of a prescription drug, pursuant to a lawful order of a practitioner or a nurse licensed under chapter 43-12.1 who is authorized by the practitioner to orally transmit the order that has been reduced to

writing in the patient's record, in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

In addition, the practice of pharmacy is defined in part under NDCC 43-15-01 subsection 24 – “Practice of pharmacy” means the interpretation, evaluation, and monitoring of prescription orders and patient drug therapy; the compounding, dispensing, labeling of drugs and devices except labeling by a manufacturer, packer, or distributor of nonprescription drugs and commercially packaged legend drugs and devices;

Under subsection 26 which clearly includes drugs or medical supplies: “ Prescription” means any order for drugs or medical supplies, if such order is written or signed or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed physician, optometrist, dentist, veterinarian, or other practitioner, licensed by law to prescribe and administer such drugs or medical supplies intended to be filled, compounded, or dispensed by a pharmacist or any order for drugs or medical supplies transmitted orally by a nurse licensed under chapter 43-12.1 as written and signed by such a duly licensed physician, optometrist, dentist, veterinarian, or other practitioner.”

This dispensing of legend devices or medical supplies might be done by pharmacists, physicians, nurse practitioners or physician assistants for the broadest range of drugs and devices. More specifically, other practitioners such as podiatrists, veterinarians, optometrists, dentists, physical therapists, respiratory therapists, and perhaps a few others that are authorized by their specific practice acts to perform these functions for patients, can also do so.

In summary, since North Dakota does not have specific licensure requirements, other than a licensed pharmacy, to dispense legend devices or medical supplies directly to patients, it is our interpretation that only pharmacies or those North Dakota licensed individuals specifically authorized by their practice act to prescribe or dispense those devices, are authorized to do so for patients in North Dakota.

Therefore, a company that wishes to furnish these devices, on the prescription of a practitioner, directly to a consumer, must either hold a pharmacy license, employ or contract with one of these specific individuals who is licensed in North Dakota, to represent the patient for the particular devices that are being sold on prescription.

Having said all of these things, it is our intention to clear this up in the next North Dakota legislative session, by asking the legislature to require licensure of wholesalers of Durable Medical Equipment and supplies and make clear in the statute what I have said above about who may dispense them to patients, or to disagree with me and codify that position.

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