ADOPTED REGULATION OF THE

BOARD OF MEDICAL EXAMINERS

LCB File No. R057-14

Effective June 26, 2015

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §1, NRS 630.130 and 630.275.

A REGULATION relating to single-use medical devices; prohibiting a physician or a physician assistant from using or allowing another person under his or her control or supervision to use a single-use medical device more than once, for more than one patient, or in a manner inconsistent with the manufacturer's instructions; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing regulations prohibit certain actions by a person licensed as a physician or physician assistant; for example, the falsification of records of health care, the rendering of professional services while under the influence of alcohol or any controlled substance and the acquisition of any controlled substance by misrepresentation, fraud, deception or subterfuge. (NAC 630.230) This regulation prohibits a person licensed as a physician or physician assistant from administering or using, or allowing a person under his or her supervision, direction or control to administer or use, a single-use medical device for more than one procedure, for more than one patient, or in a manner that is inconsistent with the manufacturer's packaging instructions or directions included with the single-use medical device. The regulation defines "single-use medical device" as a medical device that is intended for one use or on a single patient during a single procedure and includes, without limitation, a blade, clip, catheter, implant, insufflator, lancet, needle, sleeve, syringe and a single-dose vial of medication.

Section 1. NAC 630.230 is hereby amended to read as follows:

630.230 1. A person who is licensed as a physician or physician assistant shall not:

(a) Falsify records of health care;

(b) Falsify the medical records of a hospital so as to indicate his or her presence at a time when he or she was not in attendance or falsify those records to indicate that procedures were performed by him or her which were in fact not performed by him or her;

(c) Render professional services to a patient while the physician or physician assistant is under the influence of alcohol or any controlled substance or is in any impaired mental or physical condition;

(d) Acquire any controlled substances from any pharmacy or other source by misrepresentation, fraud, deception or subterfuge;

(e) Prescribe anabolic steroids for any person to increase muscle mass for competitive or athletic purposes;

(f) Make an unreasonable additional charge for tests in a laboratory, radiological services or other services for testing which are ordered by the physician or physician assistant and performed outside his or her own office;

(g) Allow any person to act as a medical assistant in the treatment of a patient of the physician or physician assistant, unless the medical assistant has sufficient training to provide the assistance;

(h) Fail to provide adequate supervision of a medical assistant who is employed or supervised by the physician or physician assistant, including, without limitation, supervision provided in the manner described in NAC 630.810 or 630.820;

(i) If the person is a physician, fail to provide adequate supervision of a physician assistant or an advanced practitioner of nursing;

(j) Fail to honor the advance directive of a patient without informing the patient or the surrogate or guardian of the patient, and without documenting in the patient's records the reasons for failing to honor the advance directive of the patient contained therein; ~~[or]~~

(k) Engage in the practice of writing prescriptions for controlled substances to treat acute pain or chronic pain in a manner that deviates from the policies set forth in the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* adopted by reference in NAC 630.187 ~~[.]~~ ***; or***

(l) Administer or use, or allow any person under his or her supervision, direction or control to administer or use, a single-use medical device:

(1) For more than one procedure;

(2) For more than one patient; or

(3) In a manner inconsistent with the manufacturer's instructions or directions included on or with the single-use medical device.

2. As used in this section:

(a) "Acute pain" has the meaning ascribed to it in section 3 of the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* adopted by reference in NAC 630.187.

(b) "Chronic pain" has the meaning ascribed to it in section 3 of the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* adopted by reference in NAC 630.187.

(c) "Single-dose vial" means a vial, including, without limitation, a sealed sterile vial, which may be accessed by insertion of a needle and which, according to the manufacturer's instructions:

(1) Contains only one dose of a medication; and

(2) May be used for only one patient.

(d) "Single-use medical device" means a medical device that is intended for one use or on a single patient during a single procedure and includes, without limitation, a blade, clip, catheter, implant, insufflator, lancet, needle, sleeve, syringe and a single-dose vial.

REGULATION ADOPTED BY THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS
LCB File No. R057-14

INFORMATIONAL STATEMENT

Pursuant to the provisions of NRS 233B.066, the following informational statement is submitted:

DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED
SUMMARY OF THE PUBLIC RESPONSE
EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN
A COPY OF THE SUMMARY

How public comment was solicited:

The Nevada State Board of Medical Examiners (Board) published a Notice of Intent to Act Upon Regulation to solicit comments on proposed changes to the regulation. The hearing was to be conducted in Reno on Wednesday, September 17, 2014, at the hour of 11:00 o'clock a.m., at the Board office located at 1105 Terminal Way, Suite 301, Reno, Nevada, and videoconferenced to the Las Vegas Board office located at 6010 S. Rainbow Blvd., Bldg. A., Suite 1, Las Vegas, Nevada.

In the notice the public was notified that a copy of the proposed regulation was on file at the State Library, 100 Stewart St., Carson City, Nevada; available at the offices of the Board at 1105 Terminal Way, Suite 301, Reno, Nevada; in all counties in the state of Nevada in which the Board does not maintain an office, at the main public library; in the State of Nevada Register of Administrative Regulations which is prepared and published monthly by the Legislative Counsel Bureau pursuant to NRS 233B.0653; and on the Internet at http://www.leg.state.nv.us., as well as posted at the following locations:

Washoe County Courthouse	**Reno, Nevada**
Carson City Library	**Carson City, Nevada**
Clark County District Library	**Las Vegas, Nevada**
Churchill County Library	**Fallon, Nevada**
Douglas County Library	**Minden, Nevada**
Elko County Library	**Elko, Nevada**
Esmeralda County Library	**Goldfield, Nevada**
Humboldt County Library	**Winnemucca, Nevada**
Lander County Library	**White Pine, Nevada**
Lincoln County Library	**Pioche, Nevada**
Lyon County Library	**Yerington, Nevada**
Mineral County Library	**Hawthorne, Nevada**
Tonopah Library	**Tonopah, Nevada**
Pershing County Library	**Lovelock, Nevada**
Storey County Library	**Virginia City, Nevada**
White Pine County Library	**Ely, Nevada**

Attached hereto and made parts hereof, are copies of certifications of posting from many of the above named.

A clear and concise statement of the need for the regulation:

Regulation R057-14 is an addition to Nevada Administrative Code 630.230 and is designed to ensure public safety relative to the practice of medicine. R057-14 prohibits licensed physicians and physician assistants from allowing single-use medical devices to be used in more than one instance or on more than one patient. This regulation can assist in reducing negative medical outcomes.

Summary of the public response:

The response to the proposed regulation R057-14 could be summarized with a general concern about adding additional costs to health care providers. There was also a concern about Nevada law not being in alignment with federal regulations, specifically the requirements of the United States Food and Drug Administration (FDA). In response to the concerns bought forth, the Nevada State Board of Medical Examiners agreed to include language that would allow these single-use medical devices to be reprocessed as specified under federal regulation. The additional language is as follows:

However, nothing in this regulation shall limit the right or ability of a physician or physician assistant to purchase and use commercially available reprocessed single-use medical devices, reprocessed by entities registered with the United States Food and Drug Administration pursuant to 21 U.S.C. § 360, in accordance with applicable requirements of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et. seq., and applicable implementing regulations promulgated by the FDA.

How other interested persons may obtain a copy of the public response to the regulations:

On file with the Board at the offices of the Board at 1105 Terminal Way, Suite 301, Reno, Nevada, is a complete transcript of the hearing conducted on the regulation change.

Any member of the public may visit the offices of the Board and may review any or the entire transcript referred to above. Also, any member of the public may request copies of the transcript of all the public comment by contacting the court reporter and requesting a copy.

The court reporter may be contacted at:

Litigation Services
(800) 330-1112

Persons who attended the workshop and hearing:

Grayson Wilt with Nevada State Medical Association attended the workshop in Reno.
Joanna Jacob, Esq. with Ferrari Public Affairs attended the workshop in Reno.
Kathleen Conalsy with Nevada Othro Society attended the workshop in Reno.
Robert Haze with Institute of Orthopaedic Surgery attended the workshop in Las Vegas.
Tracy Wale with Compliance Alliance attended the workshop in Las Vegas.
Janette Atkins with Compliance Alliance attended the workshop in Las Vegas.

Marissa Brown with Nevada Hospital Association attended the hearing in Reno.
Joanna Jacob, Esq. with Ferrari Public Affairs attended the hearing in Reno.
Lindsay Knox with McDonald Carano Wilson attended the hearing in Reno.
Stacy Woodbury with Nevada State Medical Association attended the hearing in Reno.
Leo Basch attended the hearing in Las Vegas.

Persons who testified at the workshop or public hearing:

Marisa Brown with Nevada Hospital Association.
Leo Basch, pharmacist.
Stacy Woodbury with Nevada State Medical Association.

The number of persons who submitted written statements:

The Nevada State Board of Medical Examiners received in written comments from the following:

Nevada State Medical Association
Association of Medical Device Reprocessors
American Association of Orthopaedic Surgeons
Nevada Hospital Association
Leo Basch PharmD RPh

ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH THE BOARD REGULATES AND ON THE PUBLIC

The Nevada State Board of Medical Examiners solicited any potential impacted businesses by reaching out to various business chambers and associations. Correspondence was sent to the following organizations:

- Las Vegas Metro Chamber of Commerce
- Better Business Bureau of Southern Nevada, Inc.
- Reno/Sparks Chamber of Commerce
- City of Winnemucca
- Elko Great Basin College
- Better Business Bureau of Northern Nevada, Inc.
- Pahrump Rural Nevada Development Corp.
- Ely Rural Nevada Development Corp.
- Churchill County Economic Development Authority

The Board did not receive any communication back from these organizations relative to any potential economic impact regarding regulation R057-14.

The economic effect of the regulation on the medical profession:

There will be no economic effect to the medical profession by adoption of this regulation.

The economic effect of the regulation on the general public:

There will be no economic effect to the general public by adoption of this regulation.

The estimated cost to the Nevada State Board of Medical Examiners to enforce the proposed regulation:

The Nevada State Board of Medical Examiners estimates that there will be no additional cost to itself to enforce the proposed regulation.

THE REGULATION OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS DOES NOT OVERLAP OR DUPLICATE ANY REGULATIONS OF ANY OTHER STATE OR GOVERNMENTAL AGENCIES, INCLUDING THE FEDERAL GOVERNMENT.

THE REGULATION OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS DOES NOT INCLUDE PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY.

THE NEW REGULATION DOES NOT PROVIDE OR INVOLVE A NEW FEE.

THE REGULATION WAS ADOPTED IN ENCLOSED FORM.

I hereby certify to the best of my knowledge or belief a concerted effort was made to determine the impact of the proposed regulation on small businesses and that this statement was properly prepared and the information contained herein is accurate.

/s/
Todd C. Rich
Deputy Executive Director
Nevada State Board of Medical Examiners