

**BOARD OF PHARMACY**State of North Dakota

Jack Dalrymple, Governor

OCT 1 1 2011

OFFICE OF THE EXECUTIVE DIRECTOR 1906 E Broadway Ave Bismarck ND 58501-4700 Telephone (701) 328-9535 Fax (701) 328-9536

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Bismarck, Assistant Executive Director

October 10, 2011

Mr. John Walstad Code Revisor ND Legislative Council 600 E Blvd – 2<sup>nd</sup> Floor Bismarck ND 58505-0360

Dear Mr. Walstad:

The Notice of Intent to Adopt and Amend Administrative Rules and a copy of the proposed rule changes, amendments and additions to them are enclosed as required by NDCC 28-32-10 (1).

The hearing is to address proposed N.D. Admin. Code Article 61; 61-02-01-03 Pharmaceutical Compounding Standards.

Sincerely,

Howard C. Anderson, Jr, R.Ph. Executive Director

HCA/eh

Enclosure(s)

## **Full Notice**

## NOTICE OF INTENT TO [ADOPT, AMEND, OR REPEAL] ADMINISTRATIVE RULES

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address proposed N.D. Admin. Code Article 61; 61-02-01-03 Pharmaceutical Compounding Standards. The Hearing will be held at 10:00 AM on Thursday, November 17, 2011, at the Board of Pharmacy Office – 1906 East Broadway in Bismarck ND 58501.

The purpose of these proposed rule in 61-02-01-03 are to set standards for both non-sterile and sterile compounding [United States Pharmacopeia guidelines have been in place since June 2008]. This rule, once adopted, will give specificity to those individuals and entities in North Dakota wishing to compound pharmaceuticals, both non-sterile and sterile. This rule will give North Dakota entities a basis for coming into compliance with professional standards and a timeline for doing so.

The proposed compounding rules may have an impact on the regulated community in excess of \$50,000. The regulatory analysis can be obtained at the location bellow.

The proposed rules may be reviewed at the office of the ND State Board of Pharmacy – 1906 E Broadway – Bismarck ND 58501 or Board website <a href="www.nodakpharmacy.com">www.nodakpharmacy.com</a>. A Copy of the proposed rules and/or a regulatory analysis may be requested by writing P O Box 1354 Bismarck ND 58502-1354; emailing <a href="mailto:ndboph2@btinet.net">ndboph2@btinet.net</a> or calling 701-328-9535. Written or oral comments on the proposed rules sent to the above address or email address and received by January 2, 2012 will be fully considered.

If you plan to attend the public hearing and will need special facilities or assistance relating to a disability, please contact the ND State Board of Pharmacy at the above telephone number or address at least two weeks (14 days) prior to the public hearing.

Dated this 11th day of October 2011.

Howard C. Anderson, Jr, RPh. Executive Director

## NOTICE OF INTENT TO [ADOPT, AMEND, OR REPEAL] ADMINISTRATIVE RULES RELATING TO THE PRACTICE OF PHARMACY, INCLUDING PHARMACEUTICAL COMPOUNDING STANDARDS

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address proposed N.D. Admin. Code Article 61; 61-02-01-03 Pharmaceutical Compounding Standards. The Hearing will be held at 10:00 AM on Thursday, November 17, 2011, at the Board of Pharmacy Office – 1906 East Broadway in Bismarck ND 58501.

The proposed rule may be reviewed at the office of the ND State Board of Pharmacy – 1906 E Broadway – Bismarck ND 58501 or Board website <a href="www.nodakpharmacy.com">www.nodakpharmacy.com</a>. A Copy of the proposed rules and/or a regulatory analysis may be requested by writing P O Box 1354 Bismarck ND 58502-1354; emailing <a href="mailto:ndboph2@btinet.net">ndboph2@btinet.net</a> or calling 701-328-9535. Written or oral comments on the proposed rules sent to the above address or email address and received by January 2<sup>nd</sup> 2012 will be fully considered.

If you plan to attend the public hearing and will need special facilities or assistance relating to a disability, please contact the ND State Board of Pharmacy at the above telephone number or address at least two weeks (14 days) prior to the public hearing.

Dated this 11th day of October 2011.

Howard C. Anderson, Jr, RPh. Executive Director