



OFFICE OF THE EXECUTIVE DIRECTOR
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FEB 22 2012

BOARD OF PHARMACY
State of North Dakota

E-mail= ndboph@btinet.net

www.nodakpharmacy.com

Jack Dalrymple, Governor

Mark J. Hardy, PharmD, R.Ph.
Assistant Executive Director
Howard C. Anderson, Jr, R.Ph.
Executive Director

February 21, 2012

Mr. John Walstad
Code Reviser
ND Legislative Council
600 E Blvd – Capitol Bldg
Bismarck ND 58505-0360

Dear Mr. Walstad:

As required by NDCC 28-32-10(1) enclosed are the Notice of Intent to Adopt or Amend Administrative Rules, the Regulatory Analysis, Fiscal Note and a copy of the proposed rules:

61-02-07-.1-03	Technician Education & Certification Requirements
61-04-06-02	Requirements of a prescription order for noncontrolled drugs.
61-04-06-03	Requirements of a prescription order for controlled drugs.
61-05-	Radiopharmaceutical Pharmacy Services
61-07-01-14 [new]	Pharmacist First Dose Review
61-09	Ambulance Services and prescription drugs (Tim Meyer)

Sincerely,

A handwritten signature in blue ink, reading "Howard C. Anderson, Jr, R.Ph.".

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

HCA/eh

Enclosure(s)

Full Notice

NOTICE OF INTENT TO [ADOPT, and AMEND ADMINISTRATIVE RULES

TAKE NOTICE that the North Dakota State Board of Pharmacy will hold a public hearing to address proposed new rules and amendments to, N.D. Admin. Code: 61-02-07.1 to codify the current board policy on education and certification requirements for pharmacy technician registration; 61-04-06-02 and -03 to bring the rule into compliance with Senate Bill 2122, adopted in the 2011 legislative session related to "brand medically necessary" requirements; 61-05 Radiopharmaceutical Services, to revise this 1983 rule to bring it into accordance with current radiopharmaceutical standards of practice and radiological health rules of the department of health; 61-07 Hospital Pharmacy to establish a requirement for protection of hospital patients by requiring a pharmacist to review all medication orders, before administration to the patient, except in limited circumstances; 61-09 prescription drug inventory of ambulance services, to allow the option of the ambulance service's medical director to obtain and supply the drugs for the ambulance service; at 10:30 AM on April 14, 2012, at The Jamestown Civic Center, 212 3rd Ave NE, Exchequer Room, Jamestown, ND 58401. The proposed rule in 61-07 Hospital Pharmacy may have an impact on the regulated community in excess of \$50,000 and the regulatory analysis explains that impact. The other rule changes are not expected to have an impact on the regulated community in excess of \$50,000.

The proposed rules may be reviewed at the office of the ND State Board of Pharmacy – 1906 E Broadway – Bismarck ND 58501. A copy of the proposed rules and/or a regulatory analysis may be requested by writing P O Box 1354 Bismarck ND 58502-1354, calling 701-328-9535, or by e mail at ndboph@btinet.net. The proposed rules and regulatory analysis are also on the board's web site at www.nodakpharmacy.com. Written or oral comments on the proposed rules sent to the above address, e mail or telephone number and received by May 1, 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 15th day of February, 2012.

Howard C. Anderson, Jr, RPh.
Executive Director



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NDCC 28-32-08.1 – Regulatory Analysis relative to amendment of rules in

NDAC 61 N.D. Admin. Code: 61-02-07.1 to codify the current board policy on education and certification requirements for pharmacy technician registration; **61-04-06-02 and -03** to bring the rule into compliance with Senate Bill 2122, adopted in the 2011 legislative session related to “brand medically necessary” requirements; **61-05 Radiopharmaceutical Services**, to revise this 1983 rule to bring it into accordance with current radiopharmaceutical standards of practice and the radiological health rules of the department of health; **61-09 prescription drug inventory of ambulance services**, to allow the option of the ambulance service’s medical director to obtain and supply the drugs for the ambulance service.

None of the above rules are expected to have an impact on the regulated community of \$50,000 or more.

61-07 Hospital Pharmacy: Specifically Chapter 61-07-01-14 – Pharmacist First Dose Review; to establish a requirement for protection of hospital patients by requiring a pharmacist to review all medication orders, before administration to the patient, except in limited circumstances;

Neither the Governor, nor any member of the Legislative Assembly has filed a written request for a Regulatory Analysis.

This proposed rule is expected to have an impact on the regulatory community as a whole in excess of \$50,000. The regulated community consists of hospital pharmacies some of which do not already have the tools and procedures in place to come into compliance.

Many of our larger hospitals and some critical access hospitals have already begun compliance, or are in compliance, with this rule, either on their own, or as required by their accreditation agency. It is well established that review by a pharmacist of medication orders before their administration to the patient provides an extra level of protection for the patient against medication misadventures. Therefore, the board of pharmacy feels it is time to complete the transition to this standard in all of our hospitals. North Dakota’s leadership in Telepharmacy with at least four hospital Telepharmacy providers currently working in our hospitals allows us to be a leader in the nation for this patient safety initiative. Initiation of Telepharmacy services to supplement the staff pharmacist or consultant pharmacist in providing first dose review can cost some money depending on the level of need and the current pharmacist staffing levels. This amount can vary significantly from facility to facility, based on their current level of readiness, adoption of electronic medical record systems and their plans for the future. Those facilities that are accredited by the Joint Commission on Accreditation of Health Care Facilities are in compliance, or nearly in compliance, with the intent of this rule, while many of our medium size and smaller facilities have begun preparations for compliance with this rule. We have 24 of our hospitals with sub-class K Telepharmacy licenses and six hospitals with 24/7 pharmacist coverage, so are well on our way to compliance. We have allowed a period of time to come into compliance, with the rule.

The cost for initial equipment set up can range from \$1,000 to \$20,000 depending on the equipment and connectivity choices made. The cost of pharmacist services can be based from \$250 per order reviewed, \$1000 per month, to an hourly rate up to \$20 per hour of coverage. We believe that all of our hospitals will need to move to this requirement eventually and want to afford North Dakota patients the protection afforded by this rule requirement, now that Telepharmacy tools are in place to make it work.

The cost directly to the North Dakota Board of Pharmacy will be minimal, as compliance will be checked when making our annual inspection visits. We will spend some time and energy in consulting with facilities and our inspectors will spend some additional time when visiting facilities during the annual inspection visit to assess the level of compliance and help bring each facility into compliance with the rule.

There should be no effect on state revenues with this rule.

The fiscal note to the board of pharmacy reflects no increase in revenue or costs, as we visit these licensees annually and this will be a part of that inspection.

The North Dakota State Board of Pharmacy has been working for nine years, through the North Dakota Telepharmacy Project, to put the tools in place to help our hospitals comply with this rule. We have consulted at state conventions and in numerous meetings involving stakeholders, primarily hospital pharmacists. We have attempted to write these rules to match expectations of accreditation bodies. First dose review has been proven to be valuable in patient care and it is time that North Dakota move forward with these rules to establish standards for patient care.

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



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Fiscal Note Required by NDCC 28-32-08.2 Relative to the adoption of:

61-02-07-.1-03	Technician Education & Certification Requirements
61-04-06-02	Requirements of a prescription order for noncontrolled drugs.
61-04-06-03	Requirements of a prescription order for controlled drugs.
61-05-	Radiopharmaceutical Pharmacy Services
61-07-01-14 [new]	Pharmacist First Dose Review
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It is not expected that any of these rules will have a significant impact on the finances of the North Dakota State Board of Pharmacy, as they do not directly increase revenue and although different in some respects, they will not change the process and procedure for investigating and inspecting pharmacies, or other licensees. Most activities will occur as part of our regular inspection process. In initial inspections, the time requirement might be increased slightly, but not significantly.

In the case of the Technician Certification rule it is anticipated that the time spent auditing pharmacy technicians will decrease slightly, as continuing education will be a component of their certification.

Of course, there are no effects on state generated revenue through the appropriation process, as the Board of Pharmacy does not receive or spend any appropriated dollars.

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