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BOARD OF PHARMACY
State of North Dakota

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Jack Dalrymple, Governor

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

10:00 AM – Thursday – September 13, 2012
Roughrider Room – State Capitol

Chairman Koppelman, members of the Legislative Management's Administrative Rules Committee, for the record I am Mark J Hardy, PharmD., Assistant Executive Director of the North Dakota State Board of Pharmacy.

In response to the issues you enumerated in your hearing notification these rules are on pages 30-55 of your printed material:

1. The only rule that is a result in a statutory change made by the Legislative Assembly is the addition of the word Medically in the phrase "Brand Medically Necessary" originally Senate Bill 2122.

2. These rules are not related to any federal statue or regulation

3. A hearing was held on these rules and advertised for April 14, 2012 during the North Dakota Pharmacist Association Convention in Jamestown. There were over one hundred pharmacists and pharmacy technicians for this rule making process and express their concerns and comments. The Board enjoyed this process as we felt good for the people in the field to understand the implications of the rules and take that knowledge out into their work place with them.

4. I have included in this packet, a consideration of comments made relative to these rules. As you will notice in these comments there were questions relative to Chapter 61-07-01 and the First Dose Review on what is the intention of the rule and the Board's response as to why they felt the rule was the right step to enhance patient care. There were no written comments in disagreement on the other rules.

5. The approximate cost of giving public notice and holding the hearings was $3,378.68. The increase cost was due to having the Hearing outside of a regularly scheduled Board Meeting, but at the North Dakota Pharmacist Association Convention in Jamestown. The board felt this was a positive decision that leads to more educational awareness about the rules and Hearing process.

6. I would like to go through each of the five rules to explain the reason behind the change in the rule and provide an explanation of the subject matter:

a. **Educational Preparation for Pharmacy Technician NDAC 61-02-07.1-03 (Page 31-32)** This rule codifies the current Board of Pharmacy policy on the education and certification requirements for registration as a Pharmacy Technician in North Dakota. It places the PTCB, a Certification test for pharmacy technicians into the rule as an approved certification test. The Board had hoped to hear from other certification bodies to request that their tests also be included, but this did not happen and therefore the PTCB is the only test that was place into the rule.

b. **Requirements of a prescription order NDAC 61-04-06-02 & 61-04-06-03 (Page 33-34)** This language brings them into compliance with Senate Bill 2122 of the last legislative session which changes the term "Brand Necessary" to " Brand Medically Necessary" when a practitioner requests that a brand name drug be dispensed when a generic equivalent is available.

c. **Radiopharmaceutical Pharmacy Services NDAC 61-05 (Page 35-42)** The rule is intended to revive this 1983 rule to bring it into accordance with the current radiopharmaceutical standard of practice and radiological health rules of the Department of Health. It has been an extensive period of time since we have had a nuclear pharmacy located within North Dakota but we recently approved a nuclear pharmacy located in Bismarck providing nuclear medication to the medical communities in North Dakota. The rule was revised with the help of the Department of Health and pharmacists that specialize in this practice.

d. **Hospital Pharmacy NDAC 61-07-01 - specifically Pharmacist First Dose Review NDAC 61-07-01-14 (Page 51-52)** This rule addition establishes a requirement for the protection of hospital patients by requiring a pharmacist review all medication orders before administration to the patient; except in limited circumstances, such as when the patient would be compromised by the delay of care. The Board feels that putting this rule in place will provide for a higher level of patient care across the state. The Board has been considering this rule for an extensive period of time, but did not feel there were enough providers available for hospitals to choose from to comply with this requirement. Many of our large hospitals already comply with the standards set forward in the rule, with the availability of telepharmacy, the Board feels even the small rural hospitals now have a method to comply and provide this standard in their facility. The Board also feels national standards have been moving towards requiring first dose review, and research shows this to provide the best patient care. The Board has received multiple research papers that document this rule would provide a higher level of care. The Board has also received testimony from hospitals currently complying with this rule that multiple errors have been identified and telepharmacy services have been received by hospitals as a benefit to patient care. A little over half of our hospitals are providing this standard and the rest of them will be required to comply by the extended date of June 2015. This date will allow for the necessary planning and technological improvements to be implemented. This rule would create a proactive approach to pharmaceutical care and pharmacy services within all our hospitals instead of a reactive model currently practiced by some of our

facilities. The Board is very passionate about the improvements this rule will provide for North Dakota residents.

e. **Prescription Drug Inventory of Ambulance Services NDAC 61-09 (page 53-55)**. This rule allows the option of the ambulance services' medical director to obtain and supply the drugs for the ambulance service. The current rule is written in a way that mandated only a pharmacy could provide the medications for an ambulance. This rule change was at the request of the North Dakota Emergency Medical Services Association to deal with supply issues, especially as it pertained to the western part of the state.

7. We did prepare a regulatory analysis for 61-07-01 Hospital Pharmacy - specifically 61-07-01-14 Pharmacist First Dose Review. We did anticipate the impact on the regulatory community as a whole would be in excess of $50,000 updating hospital pharmacies across the state of North Dakota to comply with these requirements. With the initiation of telepharmacy services to supplement the staff 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 records system and their plans for the future. The initial cost for equipment setup can range from $1,000 to $20,000 depending on the equipment and connectivity choices made. The cost of pharmacist's services can be based from $250 per reviewed order, $1,000 per month, or an hourly rate of up to $20 per hour of coverage. We believe that our hospitals will need to make this move eventually and do want to provide North Dakota citizens this safeguard and level of care to their patients proved by this rule requirement. Now with the tool of Telepharmacy, a competitive amount of providers are in place to allow hospitals to choose a provider that fits the facility's needs.

   We do not anticipate any significant costs associated with any of the other four rules adopted.

8. The Board of Pharmacy is exempt from preparing a small entity regulatory and economic impact analysis.

9. These rules will not have any effect on state revenues and we do not expect any significant effect on Board of Pharmacy expenditures, as compliance with these rules will be ascertained during our regular pharmacy inspections.

10. No takings assessment was prepared as there is no private property being taken for the purpose of this rule.

11. These rules were definitely not adopted as any emergency rule. The Board of Pharmacy did not feel that there was any reason that would have required any emergency rule making.

In the printed version in your booklets, I inadvertently omitted two changes that the Board had intended to make in regards to NDAC 61-07-01-14 Pharmacist First Dose Review (page 51 and 52). The intentions of the board can be found in the consideration of comments document under my testimony.

1. Change the word "physician" to "practitioner" found on 3a. of the proposed rule (page 52).
2. Change the date from "2013" to "2015" found on 4 of the proposed rule (page 52).

I would appreciate if the committee would approve these two changes so they may be incorporated into the final rule that goes into code. Thanks for your consideration.

Sixty-second Legislative Assembly of North Dakota
In Regular Session Commencing Tuesday, January 4, 2011

SENATE BILL NO. 2122
(Human Services Committee)
(At the request of the State Board of Pharmacy)

AN ACT to amend and reenact subsections 3 and 4 of section 19-02.1-14.1 of the North Dakota Century Code, relating to electronic prescriptions.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. AMENDMENT. Subsections 3 and 4 of section 19-02.1-14.1 of the North Dakota Century Code are amended and reenacted as follows:

3. If a practitioner prescribes a drug by its brand name, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name and demonstrated therapeutical equivalency as the one prescribed for dispensing and sale to the patient unless the practitioner specifically indicates in the practitioner's own handwriting "brand medically necessary" on a written prescription or expressly indicates that an oral prescription is to be dispensed as communicated. If the prescription is created electronically by the prescriber, the required legend must appear on the practitioner's screen. The practitioner must take a specific overt action to include the "brand medically necessary" language with the electronic transmission. The pharmacist shall note the instructions on the file copy of the prescription, or maintain the digital record as transmitted if it is an electronic prescription. A reminder legend must be placed on all prescription forms or appear on the computer screen of the electronic prescribing system. The legend must state "In order to require that a brand name product be dispensed, the practitioner must handwrite the words 'brand medically necessary'.". The legend printed on the prescription form or appearing on the prescriber's computer screen must be in at least six-point uppercase print or font. The pharmacist may not substitute a generic name drug product unless its price to the purchaser is less than the price of the prescribed drug product. In addition, a pharmacist may not substitute drug products in the following dosage forms: enteric coated tablets, controlled release products, injectable suspensions other than antibiotics, suppositories containing active ingredients for which systemic absorption is necessary for therapeutic activity, and different delivery systems for aerosol and nebulizer drugs. In the event that any drug listed above is, subsequent to January 1, 1982, determined to be therapeutically equivalent, then the previously mentioned substitution ban is automatically removed for that drug. The pharmacist shall inform the person receiving the drug when a prescription for a brand name drug product does not require that the prescribed drug be dispensed and of the person's right to refuse a generic name drug product selected by the pharmacist. The pharmacy file copy of every prescription must include the brand name, if any, or the name of the manufacturer, packer, or distributor of the generic name drug dispensed. A pharmacist who selects and dispenses a therapeutically equivalent generic name drug product shall assume no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its generic name. The practitioner is not liable for the substitution made by a pharmacist.

4. In the case of a prescription for which a maximum allowable cost program for purposes of reimbursement has been established under title XIX of the federal Social Security Act, the following also apply:

   a. If the practitioner has instructed the pharmacist to dispense as written, the words "brand medically necessary" must also be written on the prescription in the practitioner's own handwriting, or appear as part of the electronic prescription as noted in subsection 3. The

Rule Hearing April 14th, 2012 - Consideration of Comments

61-02-07.1-03. Pharmacy Technician Educational Preparation

-Mary Pat Schwartz said that the other accredited programs should be listed in the rules if the PTCB exam is specifically listed in the rules. Sue Nelson stated that if a test is valid and accredited, then it should be mentioned in the rules.

Board Comments

The board felt the PTCB was the best written and administered exam and the most widely accepted certification exam for Technicians. They also felt if another exam meets the expectations of the board approval could be made by board action or by further rule hearing process.

61-04-06-02. Requirements of a prescription order for non-controlled drugs.

61-04-06-03. Requirements of a prescription order for controlled drugs.

No comments to address

61-05-01. Radiopharmaceutical Services.

No comments to address

61-07-01-14. Pharmacist First Dose Review.

- Joel Aukes stated that the rule is stricter than Joint Commission requirements. He expressed concerns with how the rule would affect medications in his automated dispensing machines.

Board Comments

The board feels that putting this rule into place would provide for a higher level of patient care across the state. With the availability of telepharmacy, small and rural hospitals now have a method to comply and provide this standard. The board also feels national standards are moving toward first dose review and research shows this to be the best patient care.

-Mark Hardy, Assistant Executive Director stated that the language of 3a should read "practitioner" or "prescriber" to include all prescribing professionals, and that the document needs to be corrected. Also Hardy asked for the board to change the effective date in section 4 to June 30, 2015 as previously discussed in conversations.

Board Comments

The board agrees with the changes presented by Hardy and requests the change in section 3a to "practitioner" instead of "physician" before final adoption. The board also agrees to change the date of implementation in section 4 to June 30, 2015.

- Mark Malzer questioned whether there have been patient safety problems with the current rules in place for patient safety in reviewing all orders.

Board Comments

The board has heard from hospitals currently complying with this rule that multiple errors have been caught and telepharmacy services have been received by hospitals as a benefit to patient care.

- Craig Lawler questioned if there were more errors caught using telepharmacy as compared to nurses checking nurses.

Board Comments

The board does not have a specific research article to point to on this comment but individual in the hearing provided anecdotal stories of errors and interventions that were made because of the pharmacist intervention thru telepharmacy. The board feels that the pharmacist is the best educated on drugs, so the first dose review should be their responsibility.

-Jordan Wolf questioned whether the language of section 3b could be used as a loophole for hospitals to avoid first dose review.

Board Comments

The board feels that the language is appropriate and the intent is clear as it is following the similar terminology of the JCAHO standards.

61-09-01. Prescription Drug Inventory of Ambulance Services.

-Maari Loy questioned how often ambulances would be asking to be restocked.

Board Comments

The board does not envision any large changes to the requests to restock medications. The board feels this will make it easier for ambulance service to keep their stock of medications needed for business purposes but still allowing the oversight and responsibility of the medical director. This change was requested by the ambulance association and supported by the state EMS director.

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April 19, 2012

North Dakota State Board of Pharmacy
Mr. Howard Anderson, Jr, R.Ph.
1906 East Broadway
Bismarck, ND 58501-4700

RE: ND Admin. Code 61-09-01, 61-09-02 amendment

Mr. Anderson:

The North Dakota Emergency Medical Services Association and the North Dakota State Board of Pharmacy have worked together since June of 2011 to amend the rules as it pertains to prescription drug inventory for licensed ambulance services in North Dakota. Our advocacy committee member, Tim Meyer, has appeared before you in support of changes to how ambulance services in North Dakota handle prescription drug inventory.

Over the past twenty-two years the EMS industry has evolved and it has become necessary to review the policies and make necessary changes. We thank you for working with us over the past nine months in drafting an amendment to Articles 61-09-01-01 and 61-09-01-02 in what will be a significant improvement in the prescription drug rules for our licensed ambulance services in North Dakota.

The North Dakota EMS Association fully supports the proposed amendments that went before a public hearing on April 14, 2012. We support the entire amendment, however most particularly the amendment in how prescription drugs must be obtained, the replenishment and disposal of prescription drugs, and the daily accounting of controlled substances. We sincerely appreciate your due diligence in the modification of these rules and as an Association will work hard to communicate these changes to the EMS industry once the amendments are fully adopted.

If you have any questions or need further clarification, please don't hesitate to contact our office or me personally at 701-710-0186.

Sincerely,

Curtis Halmrast

Curtis Halmrast, President
North Dakota Emergency Medical Services Association

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

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

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
61-09	Ambulance Services and prescription drugs (Tim Meyer)

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

American Society of Health-System Pharmacists

September 12, 2012

Howard C. Anderson, Jr.
Executive Director
North Dakota Board of Pharmacy
1906 East Broadway Avenue
Bismarck, ND 58501

RE: "Pharmacist First Dose Review," North Dakota Administrative Code 61-07-01-14

Dear Mr. Anderson:

On behalf of the American Society of Health-System Pharmacists (ASHP) and the North Dakota Society of Health-System Pharmacists (NDSHP), we are writing in support of the North Dakota Board of Pharmacy rule concerning "Pharmacist First Dose Review" (North Dakota Administrative Code 61-07-01-14), which will help ensure patient safety and prevent medication errors.

ASHP is the national professional organization whose nearly 40,000 members include pharmacists, pharmacy technicians, and pharmacy students who provide patient care services in acute and ambulatory settings, including hospitals, health systems, and clinics. For 70 years, the Society has been on the forefront of efforts to improve medication use and enhance patient safety. NDSHP promotes the professional interests of pharmacists practicing in hospitals and other organized health-care settings within North Dakota.

ASHP has developed policy positions and professional guidelines stating that – except in emergency situations – pharmacists must prospectively review medication orders before the administration of the first dose.[1] This may be accomplished by an on-site pharmacist or – where necessary – remotely via telepharmacy. Prospective pharmacist review of medication orders (1) helps ensure patient safety by intercepting prescribing errors; (2) helps ensure the right of every patient to 24-hour pharmacist access and care; and (3) helps ensure a minimum standard of care across all hospital settings.

In addition to ASHP policy, both the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission (TJC) have developed standards on pharmacist review of medication orders before the first dose is dispensed. TJC in its Hospital Program, Medication Management Chapter, Standard: MM.05.01.01 states:[2]

> A pharmacist reviews the appropriateness of all medication orders for medications to be dispensed in the hospital. Before dispensing or removing medications from floor stock or from an automated storage and distribution device, a pharmacist reviews all medication orders or prescriptions unless a licensed independent practitioner controls the ordering, preparation, and administration of the medication or when a delay would harm the patient in an urgent situation (including sudden changes in a patient's clinical status), in accordance with law and regulation.

CMS requires in its State Operations Manual:[3]

> All medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist before the first dose is dispensed.
> Review of medication orders should include:
> - Therapeutic appropriateness of a patient's medication regimen;
> - Therapeutic duplication in the patient's medication regimen;
> - Appropriateness of the drug, dose, frequency, route and method of administration;
> - Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;
> - Real or potential allergies or sensitivities;
> - Variation from organizational criteria for use
> - Other contraindications;

ASHP and NDSP support the adoption of this rule to help ensure patient safety, and we look forward to working with the board of pharmacy as it implements the rule.

Sincerely,

Brian Ament, R.Ph., Pharm.D., MBA
President
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[1] See **ASHP policy 0201, "Staffing for Safe and Effective Patient Care"** and **ASHP Policy 1023, "Scope and Hours of Pharmacy Services"** http://www.ashp.org/DocLibrary/BestPractices/policypositions2012.aspx (Accessed: 10 September 2012) See also **ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals.** In: Hawkins B, ed. Best practices for hospital and health-system pharmacy: positions and guidance documents of ASHP. 2011-2012 ed. Bethesda, MD: American Society of Health-System Pharmacists; 2011: 439. Available at: http://www.ashp.org/DocLibrary/BestPractices/SettingsGdlMinHosp.aspx (accessed 2012 Mar 06) and **ASHP Guidelines on Preventing Medication Errors in Hospitals**. In: Hawkins B, ed. Best practices for hospital and health-system pharmacy: positions and guidance documents of ASHP. 2011-2012 ed. Bethesda, MD: American Society of Health-System Pharmacists; 2011: 201-4. Available at: http://www.ashp.org/DocLibrary/BestPractices/MedMisGdlHosp.aspx (accessed 2012 Mar 06).

[2] **2012 Hospital Accreditation Standards** (Oakbrook Terrace, IL: The Joint Commission, 2012). Available at: http://www.jointcommission.org/standards_information/edition.aspx (Login required) (Accessed: 5 March 2012).

[3] **CMS State Operations Manual, Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals** http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf.