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State of North Dakota
Doug Burgum, Governor

Mark J. Hardy, PharmD
Executive Director

ADMINISTRATIVE RULES COMMITTEE
11:05 PM - Wednesday – September 4, 2019 – Roughrider Room

Chairman Devlin, and members of the ND Legislative Management Administrative Rules Committee, I am Mark J Hardy, PharmD, Executive Director of the ND State Board of Pharmacy.

The extensive rule revision is brought on by the Board of Pharmacy's desire to review and modify any chapters that needed updating. Certainly, there are some rule revisions that have more immediate implications. However, you will note that many of these rule changes are simply modernizing to current standard of practice, and / or removing rules that have been deemed to be unnecessary. By removing some of these regulatory burdens over the top of the pharmacies we hope it streamlines some aspects of practice and ultimately leads to enhancements in care models.

It is of importance to note that the Board had proposed a new section 61-02-04-02 Handling of Hazardous Drugs (USP800 standards) overall for pharmacies. As we learned more of the applicability of this Chapter on pharmacies, the Board made the determination to not move this rule forward. For the record, many of the published analysis documents referenced the impact of this rule.

1. No rule changes are the result of any statutory changes made by the Legislative Assembly.
2. There are rules that are related to Federal statutes or regulatory changes. I highlight two areas:
   a) 61-02-01-03 the updating of Compounding Standards to United States Pharmacopeia [USP] Standards that will be effective December 1st 2019.
   b) 61-04-03-01 Destruction of Controlled Substances updated to be consistent with Drug Enforcement Administration [DEA] standards .

3. The Board went through an extensive rule making procedure. We had a public hearing at the North Dakota Pharmacist Association Convention, where the Board asked for the profession's input along with written comments to assure that we received as much input from the regulated community impacted by these rules. The Board always feels that having the opportunity to vet the proposed changes through the professionals who will be expected to adhere to these rules will lead to a clearer understanding and ultimately a better result for the regulated community and the public at large.

4. Included in this testimony is a "Consideration of Comments" based on the nature of having the public hearing at the NDPhA Convention, with nearly 100 professionals in attendance , there was understandably a number of comments and suggestions, most of which the Board agreed upon, by making adjustments or clarifications.

5. The approximate cost of the rule change process was $ 2,680.00.

6. I will briefly walk through each rule and explain the reason for the changes made:
   Page 145 61-01-01-01 Organization of Board of Pharmacy - is a simple correction that removes an email address that is no longer utilized. The current emails are available on the website.

   Page 146-154 61-02-01-03 Compounding Standards – this would update USP 795 which outlines the standards for non-sterile compounding, and USP797, which outlines the standards for sterile compounding to their newest revision. Also, starting on page 153, the Board updated the standards of compounding Hazardous Drugs to the new chapter USP800. We intentionally placed the effective date as December 1, 2019 to coordinate with each effective date of their newly revised USP chapters. Keeping the standards of care for compounding consistent with the long recognized USP chapters is certainly an important standard for the profession and safety of the public.

   Page 155 61-02-02-01 Building Standards for Pharmacies – this updates standards for storage of medications to ensure that there is enhanced monitoring in place, especially for those medications that are stored in a refrigerator or freezer. The advancements in therapy, including what pharmacies have available to them in specialty type medications that must be stored in cool, temperature controlled environments, has expanded tremendously over the past decade. This would require pharmacies to utilize continuous temperature monitoring devices, which can be purchased at a fairly minimal price. This not only provides assurance to the professionals and the public that the medications are appropriately stored, but allows the professionals to monitor the temperatures and any variations can be quickly identified for corrective actions before losing the expensive medications to an excursion. It is important to note that the average pharmacy reports that the inventory stored in a refrigerator can be upwards of $50,000 in a traditional retail pharmacy, which is why many pharmacies have this capability in place.

   Page 157 61-02-06-02 Computer Pharmacy Regulations –the Board felt it was no longer necessary to require manual printouts of summaries, as long as the pharmacy's software system has the ability to track controlled substances transactions and any adjustments to them. The pharmacy may continue to produce a hardcopy summary, if they chose.

   Page 158 starts three sections relative to Pharmacy Technician Standards
   61-02-07.1-03 Pharmacy Technician Education preparation – the Board removed the need to maintain national certification as a standard to maintaining registration as a Pharmacy Technician. Renewing certification requires the same number of Continuing Education credits that the Board requires to renew their registration. Other states are finally catching up to North Dakota in requiring educational and certification standards , however the need for a technician to pay to maintain the certification that is duplicated with our CE standards did not seem to benefit the public. We also expanded the options of the technician candidate to obtain certification, both from the Pharmacy Technician Certification Board [PTCB] and the National Health Career Association, which administers the ExCPT Exam. This should give further options to those needing to obtain certification as well as those that move into the state that may have the received ExCPT certification, easing the transition across state lines. The Board also added language to recognize a standard competency exam, similar to pharmacists, if one created.

Page 158 continued 61-02-07.1-04 Pharmacy Technician – adjusts the ratio of Pharmacists to Technicians – the Board had much deliberation on this rule and more comments than any of the other rules. With the expansion of the duties a Registered Pharmacy Technician may perform, we saw the need to expand the ratio to assure innovative models of care could be provided by each pharmacy location. There was a vigorous discussion as to whether a ratio is necessary at all, or if increased, to what level. The regulated community and the Board agreed on this change. We received more comments from the regulated community that do wish to see a ratio in place. The Board ultimately settled on increasing the ratio to 4 pharmacy technicians to 1 pharmacist in a retail and hospital pharmacy setting and increasing it to 5 technicians to 1 pharmacist in a closed-door pharmacy. The Board removed the language regarding Telepharmacy sites and supervision as that was enacted with the initial Telepharmacy rules. With the diversity of Telepharmacy sites, this has not proved to be a regulation that had merit.

Page 159 61-02-07.1-10 Pharmacy Technician Continuing Education –removes paper tracking requirements of Continuing Education. The implementation of the National Association of Boards of Pharmacy [NABP] CPE monitor allows us access for monitoring compliance. With accredited education credits for technicians, the Board no longer approves each program individually, thus the language in # 7 was removed.

Page 160-163 61-03-02-04 Consultant Pharmacist Regulations for LTC Facility- addresses controlled substance drug destruction, specifically unused substances in long-term-care facilities. The genesis of the rule is based on feedback from consultant pharmacists across the state, who felt that having unused controlled substances destroyed at the facility immediately upon discontinuation of the therapy was in the best interest of patient care and would reduce the chance for diversion of those medications. The consultant pharmacist would ultimately determine the policy and procedures for destruction. It is important to note that DEA regulations do not allow those medications to come back to a registered location, such as a pharmacy, and they must be destroyed at the facility.

Page 164 61-03-03.1-01 Internship – the goal of the Board was to provide clarity to the educational requirements for eligibility to become licensed as an Intern. This does not change the standards that are currently being administered.

Page 165 61-03-04-02 Pharmacist Continuing Education - removes paper tracking requirement of Continuing Education. The implementation of the National Association of Boards of Pharmacy [NABP] CPE monitor allows the Boards to review most professional's CE records, which eliminate the need for documenting them on paper forms.

Page 165 61-03-04-04 CE Advisory Board – With CE credits being nationally accredited, the Board no longer has a need for this Advisory Council and it has not met for a number of years.

Page 167 61-04-03-01 Destruction of Controlled Substances updates standards to be consistent with Drug Enforcement Administration [DEA] standards for destruction of controlled substance inventory on the DEA Form 41. Currently, facilities and pharmacies hold applicable inventory until the annual Board of Pharmacy Compliance visit with the Compliance Officer destroying them onsite. However, with the evolving model of controlled substance diversion, it is now a standard to destroy substances immediately instead of holding them for exposure to diversion. Now the substances are documented on DEA Form 41 by two staff

members and destroyed more frequently. With records maintained to prove destruction upon an inventory.

Page 168 61-08-01-08 Out-of-State Pharmacy – modifies Administrative Inspection requirements – the Board initiated this rule in 2014 and we have learned some important lessons on the best standards for states inspecting their pharmacies. With this knowledge, we have modified the requirement in 3 (a) for any pharmacy providing compounded products be inspected at least once every 24 months, with the option that if their state does not conduct a detailed inspections relative to compounding within that time period that they have the option of obtaining an in-depth Inspection through the National Association of Boards of Pharmacy [NABP] Verified Pharmacy Program . Inspections are important for us to understand the business operations of the pharmacy that wishes to ship their products to our citizens. It also provides assurance they are meeting the standards that are required to safely practice pharmacy for the public consistent with the standards North Dakota pharmacies are held to. The Board removed # 5 and # 6 on page 169 requiring background checks as we do not see that as a necessary standard. It is important to note that background checks are an option already given in #2 upon request, if we were to determine a need.

Page 169 61-08-01-09 Out-of-State Pharmacy – Prescription Records availability – As computerization and programs evolved Out-of-State Pharmacies can certainly provide records to the Board upon request. The need to separately stamp prescriptions is outdated and no longer applicable.

Page 170 61-12-01-03 Prescription Drug Monitoring Program [PDMP] – Operation of Program – The Board is reaffirming our standards in rule with the operation of the PDMP to allow a practitioner's delegate to access the PDMP under the practitioner's authority. Secondly, access to controlled substance records in the PDMP will be maintained for up to three years. These standards were developed with input from the PDMP Advisory Council and are consistent with many other state PDMP standards.

Page 170 61-12-01-04 Prescription Drug Monitoring Program [PDMP] – use for certain dispensing situations – The Board had a lengthy debate about revising the standards governing the pharmacist's need to look at the PDMP. This expands the standard for the pharmacist to review the PDMP report for a patient beyond the treatment of pain or anxiety. The Board determined with the advancements in the PDMP as well as the abuse in other types of controlled substances, pharmacists should look at PDMP reports on all controlled substances with the exception of Long-Term-Care and Hospice patients. This also updated the aggregate tool to the currently utilized, NARxCARE , which assists practitioners to better review PDMP Reports.

Page 172 61-13-01-03 Scheduling - Under the Controlled Substances Act, the Board of Pharmacy has the ability to do emergency scheduling of drugs. Back in 2012, the Board of Pharmacy in conjunction with the Attorney General's Office did an emergency scheduling of synthetic cannabinoids and bath salts which were causing extreme public harm and several deaths across the state of North Dakota. The Board followed up the emergency rule with the legislative scheduling in the 63rd Legislative Assembly to insert all these chemicals and

substances into the Chapter 19-03.1-05, Schedule I Controlled Substances, through House Bill 1070. With the additions to the law, the rule language of specific substances is not needed on page 178. The Board is requesting recognition of the DEA's exempt prescription product list. The DEA's exempt product list is a list of available drugs, which by the nature of each chemicals may be considered controlled substances, however based on their formulation have been deemed not to be habit forming. Thus, the DEA exempts them from scheduling. Examples would be Fiorcet Phenobarbital and Chlordiazepoxide. The Board has always taken the position that the exempt products would not be considered controlled substances in North Dakota due to their exclusion federally. However, this reaffirms this standard. Lastly, there is a reference to the Board's authority to schedule products as outlined in the North Dakota Century Code if needed for the public safety consistent with our authority granted by NDCC 19-03.1.-02.

7. A Regulatory Analysis was completed and a copy has been included. It is pertinent to note that this analysis was actually built largely upon the rule that the Board did not move forward with 61-02-04-02 Handling of Hazardous Drugs.

8. A Small Entity Economic Impact and Regulatory Statement, while technically not required of the Board, are included with my testimony as well.

9. We do not anticipate that these rules will have a fiscal impact on the operation of the Board, as most of the issues will be monitored for compliance and communicated to our regulated community through the Board of Pharmacy's Annual Compliance Visitations.

10. A takings assessment was not prepared as it is not applicable.

11. None of these rules were adopted as emergency rules.

I appreciate your time, if there are any questions or clarifications I would be happy to address them at this time.

Mark J. Hardy, PharmD

Board of Pharmacy Consideration of Comments regarding proposed administrative rule changes to:

61-01-01-01	Organization of Board of Pharmacy - removes out-dated email address
61-02-01-03	Pharmaceutical Compounding Standards – update to Compounding of Drugs to USP 795-797-800 standards
61-02-02-01	Building Standards for Pharmacies – updates Drug Storage areas
61-02-06-02	Computer Pharmacy Regulations –adds electronic tracking of prescriptions
61-02-07.1-03	Pharmacy Technician Education preparation – clarifies Certification Requirements
61-02-07.1-04	Pharmacy Technician – adjusts the ratio of Pharmacists to Technicians
61-02-07.1-10	Pharmacy Technician Continuing Education –removes paper tracking requirements
61-03-02-04	Consultant Pharmacist Regulations for LTC Facility- addresses controlled substance drug destruction process
61-03-03.1-01	Internship – clarifies educational requirements for eligibility
61-03-04-02	Pharmacist Continuing Education - removes paper tracking requirement
61-03-04-04	CE Advisory Board - repeal
61-04-03-01	Destruction of Controlled Substances – update to DEA standards
61-08-01-08	Out-of-State Pharmacy – modifies Administrative Inspection requirements
61-08-01-09	Out-of-State Pharmacy – Prescription Records availability
61-12-01-03	Prescription Drug Monitoring Program [PDMP] – Operation of Program
61-12-01-04	Prescription Drug Monitoring Program [PDMP] – use for certain dispensing situations
61-13-01-03	Controlled Substances Schedules – Remove codified substances scheduled in NDCC 19-03 by legislature in the 63rd assembly.

Information gathered at this hearing will be used by the Board of Pharmacy for its deliberation and final decision.

The Executive Director of the Board of Pharmacy is taking minutes of this meeting, and it is being recorded, so please identify yourself for the record before you speak.

Everyone present will be given an opportunity to speak. If you have a prepared statement, a written copy of your statement is appreciated and will be helpful.

At this point, I open the hearing for comments. We will begin with

61-01-01-01 Organization of Board of Pharmacy - removes out-dated email address

Dr. Hardy explained there are only changes to the Board e mail address and a new effective date for this rule.

It was moved by Public Member Fran Gronberg and seconded by Pharmacist Steve Irsfeld to approve 61-01-01-01 Organization of Board of Pharmacy with no changes.

61-02-01-03 Pharmaceutical Compounding Standards – update to Compounding of Drugs to USP 795-797-800 standards

Dr Hardy explained that this rule would updated the USP chapters to the most recent versions that would be effective on December 1st, 2019

Dr. Hardy explained there were similar written comments received from allergy specialists (Sanford and Trinity Health Physicians) who commented to this rule. The comments appear to be unrelated to this rule change but more references their ability to dispense allergy extracts made in their office to patients. Board member felt their comments are unaffected by this rule and furthermore dispensing is allowed per NDAC 61-04-02.

Pharmacist Elizabeth Skoy asked what the expectation was for the physicians compounding allergy extracts in their office.

Compliance Officer Dennis Delabarre RPh explained it was the expectation of the board and USP to use 797 principals for allergy extract compounding by allergists and to enforce the beyond use dates (BUD) as indicated in USP 797.

Dr. Hardy explained the other written request from RELX group requesting inclusion of the "Clinical Pharmacology" reference to 61-02-01-03 (8). Board members agreed to this addition and wish to modify accordingly.

Based on comments received from the National Community Pharmacist Association, board members requested that since the finalization of the rule may occur prior to the USP chapters becoming effective on December 1st, 2019.

It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Tyler Lannoye to approve 61-02-01-03 Pharmaceutical Compounding Standards with the addition of "Clinical Pharmacology" as a reference in section (8.) and the change of effect date to December 1, 2019 to mirror the effective date of USP Chapter 797, 795 and 800.

61-02-02-01 Building Standards for Pharmacies – updates Drug Storage areas

Dr. Hardy explained the purpose of this rule change in subsection 6 is to ensure medications are stored at manufacture recommended temperatures by requiring monitoring of the temperatures in the drug storage area, refrigerator or freezer with a monitoring device which records excursions which may occur. Also the drug storage units must be restricted to drugs only.

Pharmacist Carolyn Seehafer asked if medical grade refrigerators would be required. Dr. Hardy responded that medical grade was not required but that the continuous monitoring would be required.

Compliance Officer Dennis Delabarre related his experience with temperature monitoring

Pharmacist Gerald Finken reinforced the importance of monitoring.

Pharmacist Tim Carlson stressed that the room where room temperature storage occurs also needs to be monitored.

Board member Gayle Ziegler asked that the word "should" be changed to "shall" in both subsection 6 (a) and (b).

The Board agreed to make the change from "should" to "shall" in both places.

It was moved by Pharmacist Tyler Lannoye and seconded by Pharmacist Shane Wendel to approve 61-02-02-01 Building Standards for Pharmacies to accommodate the suggestion to change "should" to "shall" in three places in subsection (6) (a) and (b).

61-02-06-02 Computer Pharmacy Regulations –adds electronic tracking of prescriptions

Dr. Hardy explained the intent of this change is to make it easier to comply in the modern age without requiring saving a lot of paper.

Pharmacist Joel Aukes asked if the DEA required printouts.

Dr. Hardy responded that he did not believe they do, but promised to check.

It was moved by Pharmacist Steve Irsfeld and seconded by Technician Diane Halvorson to approve 61-02-06-02 Computer Pharmacy Regulations with no changes from the hearing.

61-02-07.1-03 Pharmacy Technician Education preparation – clarifies Certification Requirements

Dr. Hardy explained the purposes of this change being the technicians would no longer be required to maintain certification. This is much like education and testing of pharmacists, as they are not required to retest periodically.

The change allows acceptance of the ExCPT exam for initial certification requirements. He also explained the language and the board's vision, that NABP will eventually develop a national exam that all states can use and which will become the standard for initial registration.

Board member Diane Halvorson expressed her support for the changes in light of recent changes in the requirements for accreditation of technician programs.

Tracy Lindsey, RPhTech, NAPT Chairperson expressed that some employers may continue to require maintenance of certification.

Senior Compliance Officer Howard Anderson reinforced that the Continuing Education standards will not change.

Board member Tonya Schmidt indicated that individuals may choose to maintain certification as they work toward specialty certification goals.

Board member Diane Halvorson stated the board will continue to support the PTCB certification exam.

It was moved by Technician Diane Halvorson and seconded by Public Member Fran Gronberg to approve 61-02-07.1-03 Pharmacy Technician Education preparation with no changes from the hearing.

61-02-07.1-04 Pharmacy Technician – adjusts the ratio of Pharmacists to Technicians

Dr. Hardy discussed the changes in the ratio of pharmacists to technicians. He explained that there was much discussion and some disagreement on the board about whether to expand the numbers allowed or eliminate the ratio altogether.

Pharmacist Joel Aukes asked if technicians-in-training are to be considered in the ratio.

The board responded that it is their intention to include the technicians-in-training in the ratio.

Pharmacist Justin Heiser suggested that we strike to ratio altogether and leave it up to the pharmacist in charge. He felt the ratio is limiting and technicians are critical to the pharmacy operations.

Pharmacist Joel Aukes suggested we could get around the ratio in specific situations with pilot projects.

Pharmacist Heiser responded that he has had experience with Minnesota doing variances and would not suggest we follow that route.

Technician Board Member Diane Halvorson asked for a show of hands of those supporting the ratio in the proposed rule and those wishing to eliminate the ratio altogether.

Pharmacist Elizabeth Skoy asked to hear board member comments on the proposed change.

Board Member Tonya Schmidt stated she would prefer abolishing the ratio, pointing out tech-check-tech programs and other instances where the ratio was an impediment in her view. She stated she is licensed in 17 states and many have no established ratio.

Board member Gayle Ziegler has heard from employees that if the ratio is abolished employers may try to push the envelope and that may lead to inadequate staffing levels.

Pharmacist Earl Abrahamson has some experience with Idaho and discussed the history of the issue there.

Compliance Officer Judy Swisher asked about the ratio relative to Telepharmacy sites.

Board Member Steve Irsfeld suggested we abolish the ratio for Telepharmacy sites as they may be more than 4:1 now.

Board member Gayle Ziegler pointed out that pick-up sites (consultation sites) do not have technicians so the ratio would not apply to them.

It was apparent that the show of hands did not help resolve the issue.

Board member Tyler Lanouye felt that he is supporting the increase in the ratio but not abolishing it altogether.

Pharmacist Joel Aukes feels that a hard number is a good way for the board to maintain public safety when someone wants to tell the pharmacist what their staffing should be.

Pharmacist Kim Essler asked about the definition of functions a technician could perform as sometimes you have a technician who is working the cash register and not performing and technician functions.

Dr. Hardy said those technicians can be classified as supportive personnel when doing not-technician duties and then would not be counted in the ratio.

Dr. Hardy has received comments from NACDS supporting the modernization of the rule.

Pharmacist Kevin Oberlander discussed both sides of the issue.

Tracy from NDSHP said they struggle with this issue, wanting to trust their technicians and utilize them to the maximum.

Dr. Jordan Wolf asked if there were trends or research in the area and Dr. Hardy responded that he knew of no definitive research on the topic.

Pharmacist Earl Abrahamson asked if there were any comments from the technician organization.

Technician Diane Halvorson said that in their 2017 fall conference the majority supported the ratio although many struggle with a consensus, as well.

Dr Justin Heiser submitted written comments from Thrifty White in support of elimination of the ratio.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Steve Irsfeld to adjust the ratio in 61-02-07.1-04 Pharmacy Technician to 1 to 4 in the retail and hospital setting and 1 to 5 in the closed door pharmacy setting.

61-02-07.1-10 Pharmacy Technician Continuing Education –removes paper tracking requirements

Dr. Hardy explained that CE is easily tracked online with the NABP CPE monitor and maintenance of paper records on the board forms is no longer required.

There were no comments on this change.

It was moved Pharmacist Steve Irsfeld and seconded by Shane Wendel to approve 61-02-07.1-10 Pharmacy Technician Continuing Education without any changes.

61-03-02-04 Consultant Pharmacist Regulations for LTC Facility- addresses controlled substance drug destruction process

Dr. Hardy explained the intention of this change being that the facility will set the destruction policies along with the consultant pharmacist, although any two professionals may do the destruction.

Dr. Jordan Wolf pointed out that this mirrors what Minnesota has done.

Pharmacist Joe Litsey of Thrifty White, by email, stated that medications should not be returned to the pharmacy for the destruction but are allowed to be returned for credit.

Board members felt it was impractical for nursing facility staff to definitely determine what can be returned for credit. Policies and procedures set by the consultant pharmacist would be the best way to manage this at each individual facility

It was moved by Public Member Fran Gronberg and seconded by Technician Diane Halvorson to approve 61-03-02-04 Consultant Pharmacist Regulations for LTC Facility without any changes.

61-03-03.1-01 Internship – clarifies educational requirements for eligibility

Dr. Hardy explained the rule and the intention to make individuals eligible for an intern license upon being unconditionally accepted into a doctor of pharmacy program.

Pharmacist Joel Aukes suggested that we add general education diploma (GED) language in addition to the graduated from high school language.

The board was supportive of this addition and will make this change to add "or general education diploma (GED)".

It was moved by Pharmacist Steve Irsfeld and seconded by Pharmacist Tyler Lannoye to adopt 61-03-03.1-01 Internship including the change suggested by Joel Aukes to add "or obtained a general education diploma (GED)" in subsection (4.).

61-03-04-02 Pharmacist Continuing Education - removes paper tracking requirement

Dr. Hardy explained that this rule eliminates the paper tracking requirement.

There were no comments on this rule change.
It was moved by Pharmacist Shane Wendel and seconded by Public Member Fran Gronberg to approve 61-03-04-02 Pharmacist Continuing Education without any changes.

61-03-04-04 Advisory Council on Continuing Education
Dr. Hardy explained that this rule eliminates the Advisory Council on Continuing Education.

There were no comments on this rule change.
It was moved by Technician Diane Halvorson and seconded by Pharmacist Steve Irsfeld to approve the repeal of 61-03-04-04 CE Advisory Board without any changes.

61-04-03-01 Destruction of Controlled Substances – update to DEA standards
Dr. Hardy explained that this change will update our rule to the current DEA standards and allow onsite destruction by the pharmacy once the DEA 41 form has been sent to DEA electronically and permission to destroy received from DEA. The records must be made available to the board on request.
Dr. Hardy pointed out in response to question that destruction of consumer waste must be made by the ultimate user, thus the requirement that the consumer place the medication in the collection box themselves.
Dr Yin Li commented if the DEA Form 41 would be used for document destruction of a medication take back.
Dr Hardy indicated that it is used for destruction by collectors but not by the pharmacies in returning a mail back disposal program like the Board's offered MedSafe program. The language in the rule is specific to be consistent with DEA standards and only a pharmacy's inventory.
It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Steve Irsfeld to approve 61-04-03-01 Destruction of Controlled Substances without any changes.

61-08-01-08 Out-of-State Pharmacy – modifies Administrative Inspection requirements
Dr. Hardy explained we are updating the out-of-state inspection requirements to match what is done by NABP in their Verified Pharmacy Inspection Program, to move the requirement to be inspected to every two years and to make background check required only upon request of the board.

There were no comments on this rule change.
It was moved by Technician Diane Halvorson and seconded by Pharmacist Tyler Lannoye to approve 61-08-01-08 Out-of-State Pharmacy without any changes.

61-08-01-09 Out-of-State Pharmacy – Prescription Records availability

Dr. Hardy explained this rule change eliminates notations on the hard copy prescriptions as records are all maintained electronically and records must be available to the board upon request.

There were no comments on this rule change.
It was moved by Public Member Fran Gronberg and seconded by Technician Diane Halvorson to approve 61-08-01-09 Out-of-State Pharmacy without any changes.

61-12-01-03 Prescription Drug Monitoring Program [PDMP] – Operation of Program
Dr. Hardy explained this rule codifies the policy of access by delegates under the authority of those authorized by law to have access to patient records and sets a 3 year time frame for the PDMP to maintain patient records.

There were no comments on this rule change.
It was moved by Pharmacist Gayle Ziegler and seconded by Pharmacist Steve Irsfeld to approve 61-12-01-03 Prescription Drug Monitoring Program [PDMP]without any changes.

61-12-01-04 Prescription Drug Monitoring Program [PDMP] – use for certain dispensing situations
Dr. Hardy explained this rule as an update to match what our PDMP vendor, Appriss, is currently calling their risk measurement tool for PDMP profiles, NARxCARE. This also requires dispensers to review PDMP reports for all conditions in which controlled substances are dispensed.

Pharmacist Larry Larsen pointed out that most pharmacy software allows direct access to these risk assessment tools and suggested we eliminate the reference to a specific program and leave the language broad.
Board members thought by leaving the language to allow a "board-approved aggregate tool" they could manage future initiatives that may develop in the industry.
Board members requested Dr Hardy to look at the language in 61-12-01-04 (1) to clear any confusing provisions to ensure PDMP reports are run for patients initially receiving a controlled substance and subsequent reports run according to standards listed in the rule
It was moved by Technician Diane Halvorson and seconded by Public Member Fran Gronberg to approve 61-12-01-04 Prescription Drug Monitoring Program [PDMP] with these changes in subsection

(1.) ~~Prior to dispensing a prescription,~~. Each dispenser licensed by a regulatory agency in the state of North Dakota who dispenses a controlled substance to a patient, ~~for the treatment of pain of anxiety~~ shall, at a minimum, request and review a prescription drug monitoring report covering at least a one-year time period or another state's report, or both reports, when applicable and available prior to initially dispensing a prescription, with the exception of prescriptions for a

patient in a Skilled Long Term Care facility or a Hospice patient. Further reports shall be requested and reviewed if the dispenser becomes aware of a person currently:

61-13-01-03 Controlled Substances Schedules – Remove codified substances scheduled in NDCC 19-03 by legislature in the 63rd assembly.

Dr. Hardy explained that all of the items being eliminated from this rule have been added to the statutes by the legislature and the duplicate reference is no longer needed here.

Dr Hardy requested the addition of language to honor the Federal DEA Exempt Prescription Product List which is updated regularly to exempt a select few products containing primarily butalbital, phenobarbital, and chlordiazepoxide. We have administratively never considered these controlled substances as they are not labeled as such but clarity would be helpful for industry.

There were no public comments on this rule change.

It was moved by Technician Diane Halvorson and seconded by Pharmacist Shane Wendel to approve 61-13-01-03 Controlled Substances Schedules as proposed with the addition of the following sentence after 61-13-01-03 Scheduling. Substances on the Drug Enforcement Administration's published exempt prescription product list are not considered controlled substances.

State of North Dakota
Doug Burgum, Governor

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Mark J. Hardy, PharmD
Executive Director

February 13, 2019

NDCC 28-32-08 – Regulatory Analysis relative to amendments and creation of rules in NDAC 61

61-01-01-01	Organization of Board of Pharmacy
61-02-01-03	Pharmaceutical Compounding Standards
61-02-02-01	Building Standards for Pharmacies
61-02-04-02	Handling of Hazardous Drugs
61-02-06-02	Computer Pharmacy Regulations
61-02-07.1-03	Pharmacy Technician Education preparation
61-02-07.1-04	Pharmacy Technician
61-02-07.1-10	Pharmacy Technician Continuing Education
61-03-02-04	Consultant Pharmacist Regulations for LTC Facility
61-03-03.1-01	Internship
61-03-04-02	Pharmacist Continuing Education
61-03-04-04	CE Advisory Board
61-04-03-01	Destruction of Controlled Substances
61-08-01-08	Out-of-State Pharmacy
61-08-01-09	Out-of-State Pharmacy
61-12-01-03	Prescription Drug Monitoring Program [PDMP]
61-12-01-04	Prescription Drug Monitoring Program [PDMP]
61-13-01-03	Controlled Substances Schedules

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

The proposed rules 61-02-01-03-Pharmaceutical Compounding Standards and 61-02-04-02 - Handling of Hazardous Drugs USP 800 are expected to have an impact on the regulatory community as a whole in excess of $50,000. The regulated community consists of hospital pharmacies, retail pharmacies and any others, who handle, prepare and dispense hazardous drugs, either through compounding preparations or traditional dispensing mechanisms.

Many of our hospitals have already begun compliance with these rules and will be required by their accreditation agency to be in compliance with United States Pharmacopeia [USP] 795-797-800 standards.

Any modifications and installations of segregated compounding areas for hazardous drugs can amount to substantial amounts of money. It can certainly vary from facility to facility, depending upon their level of readiness and their plans for the future. Most of the hospitals have already begun modifications as it will be required to be in compliance with USP 795-797-800 standards for accreditation. Retail pharmacies will also have to make modifications to account for USP 800 Hazardous Drugs Handling and compliance dependent on the level and type of business they are conducting.

The Board of Pharmacy has determined to assist with the development of template forms, which can be modified to individual practices, to anticipate needs to comply with the standards in USP 800.

The cost directly to the North Dakota Board of Pharmacy will be fairly minimal. 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 develop the templates to bring each facility into compliance with the rule.

There should be no effect on state revenues with the rules. The other rules changes are not expected to have an impact on the regulatory community as a whole in excess of $50,000.

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NDCC 28-32-08.1 – Small Entity Economic Impact and Regulatory Statement Pertaining to adoption of NDAC 61-02-01-03 – Pharmaceutical Compounding Standards and 61-02-02-01 Building Standards for Pharmacies and 61-02-04-02 - Handling of Hazardous Drugs and

Although the Board of Pharmacy, as a professional or regulatory Licensing Board authority is exempt from the sections on Small Entity Economic Impact and Regulatory Analysis, I believe it is prudent to describe some potential impacts, so the regulated parties will understand the implications of the rules identified above.

The Board of Pharmacy is very aware of the impact on small entities to comply with these rules and have taken efforts to mitigate the impact.

All those who prepare compounded pharmaceutical products and those who handle hazardous pharmaceutical products will potentially be affected by this rule. These may include pharmacies, hospitals and some practitioner offices. Those benefiting from these rules are the patients who will receive these compounded preparations or will have them administered, or injected as in the case of sterile products. Also minimizing exposure to hazardous drugs to those working in medical facilities is important for long-term health.

Depending on the current progress of modification or remodeling of the pharmacy or compounding area, the impact may vary considerably. The Joint Commission and the Center for Medicare and Medicaid Services has moved towards requiring compliance with United States Pharmacopeia [USP] 795 -797 and 800 as a condition of their accreditation, mostly in hospital locations. For some pharmacies there will be almost no costs, for others who are just beginning the transition to USP compliant operations and need major remodeling, the costs could be quite high. Most of our hospitals in North Dakota have already begun compliance, if they desire, and many have completed the transition, comply with these standards. The impact for retail pharmacies will be low in regards to modifications or remodeling unless complex compounding is conducted. All pharmacies will need to develop a plan to comply which involves developing Policies and Procedures and best practices specific to their location. The Board of Pharmacy is providing resources for small pharmacies to create and adjust their procedures and trainings for compliance.

Specific to 61-02-02-01 Building Standards for Pharmacies, pharmacies will likely need to implement a continuous temperature monitoring system into their, both freezer and refrigeration and drug storage areas. These monitoring systems vary in price. However, a standard unit is around $300 to implement. It is important to note from our experience with pharmacies that the traditional pharmacy may have more than $50,000 in inventory stored in the refrigerator and freezer.

Some of our rule changes will ease the regulatory burden such as, 61-02-06-02 Computer Pharmacy Regulations 61-02-07.1-03 Pharmacy Technician Education preparation; 61-02-07.1-04 Pharmacy Technician; 61-02-07.1-10 Pharmacy Technician Continuing Education; 61-03-02-04 Consultant Pharmacist Regulations for LTC Facility; 61-08-01-08 and 61-08-01-09 Out-of-State Pharmacy; as well as 61-12-01-03 and 61-12-01-04 Prescription Drug Monitoring Program [PDMP]. Each relaxes some of the standards and can be viewed as deregulation with the input of our professional community. Others are just codifying language that was not clear in the regulations that the Board enforces.

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NDCC 28-32-08.2 – Fiscal Note Pertaining to adoption of NDAC
61-02-01-03 – Pharmaceutical Compounding Standards and
61-02-02-01 Building Standards for Pharmacies and
61-02-04-02 - Handling of Hazardous Drugs and

The Board of Pharmacy does not expect any fiscal impact on the operations of the Board in the adoption of these rules.

The compliance will be determined based on the regular annual Inspection that is provided the pharmacies.