ENABLING PHARMACISTS TO RESPOND TO THE HEALTH NEEDS OF MINNESOTA COMMUNITIES

Recommendations for the modernization of MN Statutes, Chapter 151

WORKING GROUP ON THE PHARMACY PRACTICE ACT
CENTER FOR LEADING HEALTHCARE CHANGE
COLLEGE OF PHARMACY, UNIVERSITY OF MINNESOTA

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WORKING GROUP ON MINNESOTA PHARMACY PRACTICE ACT

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CHAPTER 1
INTRODUCTION

Session Law, Chapter 354, 1937 Section 1. Definitions. —
As used in this Act.
(a) The term "pharmacy" shall mean a drug store or other
established place regularly registered by the State Board of Pharmacy,
in which prescriptions, drugs, medicines, chemicals and poisons
1. are compounded, dispensed, vended or sold at retail.
(b) The term "pharmacist" shall mean a natural person licensed
by the State Board of Pharmacy to prepare, compound, dispense
and sell drugs, medicines, chemicals, and poisons.

The practice of pharmacy has changed far beyond that which was envisioned in the 1937
Practice Act. At that time the demands on pharmacists were restricted to the preparation,
compounding, dispensing and selling of drugs, medicines, chemicals and poisons. Our
current practice act and the supporting rules and additional statutes that govern the
distribution of medicines and the practice of pharmacy have built on the limited 1937
concept of practice.

In the intervening three-quarters of a century the Minnesota Board of Pharmacy,
Minnesota Pharmacists Association and Minnesota Society of Health-Systems
Pharmacists have periodically sought amendments to the Act in efforts to provide a
contemporary underpinning to the distribution of medicines and practice of pharmacy.
The Legislature has also initiated changes in the Act in response to a variety of interest
groups.

In spite of these changes, however, the practice Act and its penumbra of Acts and
rules still approach pharmacy practice from the viewpoint of pharmacists as
dispensers of medicines who may also provide clinical services. The changing
consumer and system demands on pharmacists would dictate the emphasis should
be the reverse: pharmacist practitioners who provide medications related clinical
services who may also manage the medication supply and distribution.

The market, and the society that it reflects, is driving changes in the roles of
pharmacists faster than either the profession or the Board can keep up with. It is
impossible to anticipate the direction that many of these changes will take in light of
the many constituencies represented in the reform debate. It is certain, however,
that constant change will be with us for the foreseeable future – and beyond. The
competing forces of public policy, legislation, consumer/voter and payer demands,
professional aspirations and resistance, and financial constraints work together in
such strange and mysterious ways as to make strategic planning difficult. Likewise it is a challenge to regulators to fulfill their statutory mandates while allowing those that they regulate to respond to these changing markets.

The current law in many ways restricts the pharmacist practitioner to practice in a manner not that different from the manner anticipated in the 1937 Act. It is the belief of the Working Group that the current restrictions and requirement make it difficult for pharmacists to fully participate in developing new healthcare delivery systems.

That having been said, it is then important to free the pharmacist practitioner to be responsive in delivering services while still protecting the public health.

**COMPOSITION OF THE WORKING GROUP**

The members of the group were chosen because of their understanding of their practice specialty, understanding of the needs of Minnesotan in the context of the progress of health-reform initiatives, and capabilities and aspirations of the profession and its practitioners. Obviously, there are many pharmacists in Minnesota who meet these criteria. In the interest of management of the Working Group it was limited to twelve pharmacist members and a chairman.

The Working Group was brought together under the leadership of the Center for Leading Healthcare Change of the College of Pharmacy, University of Minnesota as part of its mission to advance the practice of pharmacy.

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<tr>
<th>Member</th>
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<td>Lowell Anderson, Chairman†</td>
<td>Center for Leading Healthcare Change</td>
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* moved before completion
† previous membership on Board of Pharmacy

Meghan Kelly, PharmD and a graduate student in SAPH program served as staff to the group.

*Working Group on Minnesota Pharmacy Practice Act, 2012*
GOALS OF THE WORKING GROUP

In considering MS Chapter 151, the Working Group reviewed each section by comparing it with contemporary pharmacy practice or with practice after reasonable assumptions of changes that may occur. More importantly, the Working Group considered the inherent barriers to practice development that might be imbedded within the sections. The Working Group’s desire is that the report provide guidance for the profession and the Board of Pharmacy on updating the Act so as to allow the pharmacists to fully use the knowledge and skills gained in their education, ongoing continuing education and practice experience to improve quality and accessible pharmacists services.

A number of concepts that were key to the discussions in which existing sections and proposed concepts were measured:

• Does/will it maintain assurances of patient and consumer safety
• Will it enable pharmacists to respond to consumer needs and market opportunities, particularly in the management of medication use
• Does/will it provide opportunities for pharmacists to fully participate in new multi-disciplinary delivery systems such as health homes and accountable-care organizations (ACOs)
• Does/will it allow pharmacists to share in both the risks and the rewards of ACOs and health homes
• Does/will it enhance the ability of the pharmacist to provide pharmacist services wherever there are patient/consumer needs – whether from a pharmacy or outside a pharmacy
• Will it remove historical accretions that impede pharmacists’ innovations

CONSIDERATIONS BY THE WORKING GROUP

Beginning with an initial meeting in November 2010, there were eight meetings of the Working Group in which it considered the content of Chapter 151. The Working Group spent several sessions on the Definitions (§151.01) because of the criticality of definitions to the understanding and direction of the body of §151 itself.

In §151 there are many definitions and sections that do not directly affect the practice of pharmacy and, therefore, are not related to the mission of the Working Group. After they were reviewed, we did not recommend any changes to these definitions.

Those sections that did impact the pharmacists’ abilities to practice in a responsible and responsive manner were discussed, and this report will provide the thinking and recommendations resulting from those discussions.

Alternative language is provided where it serves to describe our intent more clearly.

FUTURE DIRECTION
It is the intent of the Working Group that the Minnesota pharmacist community broadly engages in the discussions on the report. The Working Group will seek to discuss the report with the relevant professional and trade associations that have a presence in Minnesota, and interested faculty members and students at the College of Pharmacy. It will also be discussed with the members of the Board of Pharmacy and its staff.

Recognizing that health systems are moving toward multi-disciplinary health practices, the Working Group urges the community of interests to seek audiences with leaders in allied health professions -- notably medicine and nursing for the purpose of garnering support for the changes and their seeking similar updates to their Acts.

To achieve the goal of professionals who can respond to the full panoply of medication use and related needs and demands, the pharmacy profession in Minnesota must agree that significant changes need to occur in the pharmacy practice Act and related Acts and rules in order to ensure that pharmacists are an integral part of health-care delivery. Further, the consensus for needed modernization of the statutory and regulatory underpinnings of practice will need to be translated into action by the profession and support of such action by the members of the profession.

Beyond the development of agreement and support by the pharmacist and allied-health community, the consensus developed will need to be expressed in language that can be the content of bills submitted to the legislature. This difficult work will need to be done by others than the members of the Working Group -- most obviously the Board of Pharmacy, MSHP and MPhA.

Ultimately, the NABP and the national professional associations must also provide leadership in the modernization of the practice acts of each of the fifty states. National leadership in this matter can serve to improve the quality of services provided by pharmacist practitioner by allowing them to practice at the limits of their education and to the fullest extent of patients’ and consumers’ medication-use needs.
CHAPTER 2
DEFINITIONS

151.01 DEFINITIONS.

Subdivision 1. Words, terms, and phrases. Unless the language or context clearly indicates that a different meaning is intended, the following words, terms, and phrases, for the purposes of this chapter, shall be given the meanings subjoined to them.

Current: Subd. 2. Pharmacy. "Pharmacy" means an established place of business in which prescriptions, drugs, medicines, chemicals, and poisons are prepared, compounded, dispensed, vended, or sold to or for the use of patients and from which related clinical pharmacy services are delivered.

Discussion: The terminology used in this definition, which dates substantially from the 1937 Chapter 354 language, needs to be updated to reflect contemporary practice and usage. In contemporary pharmacist usage “drug” and “medicines” are used interchangeably and lay usage applies a negative connotation to “drug.” The term of art should be “medicine.” Further, all medicines are “chemicals” and “poisons” so inclusion is redundant. Similarly, the use of “vended” is dated.

Clinical pharmacy services have not been defined. Removing the phrase ‘from which related clinical pharmacy services are delivered’ removes the constraints on clinical services to being delivered outside a pharmacy setting, which would include medication management services or pharmacist consulting services generally.

Recommended: Subd. 2. Pharmacy. "Pharmacy" means an established place of business in which prescriptions or orders for drugs or medicines, chemicals, and poisons are prepared, compounded, or dispensed, vended, or sold to or for the use of patients and from which related clinical pharmacy services are
**Current: Subd. 3. Pharmacist.** The term "pharmacist" means an individual with a currently valid license issued by the Board of Pharmacy to practice pharmacy.

**Discussion:** The definition of “Pharmacist” should clearly state that practice is not tied to the location from which a pharmacist provides a service. Clearly, contemporary societal needs for pharmacists’ services extend to sites beyond a licensed pharmacy. The NABP Model Act language more appropriately answers the needs of contemporary society and practice.

**Recommended: Subd. 3 Pharmacist.** “Pharmacist” means an individual currently licensed by this State to engage in the Practice of Pharmacy. A Pharmacist may engage in the Practice of Pharmacy, as defined in this Chapter, within or outside of a licensed Pharmacy, as defined in the Rules of the Board

**Current: Subd. 5. Drug.** The term "drug" means all medicinal substances and preparations recognized by the United States Pharmacopoeia and National Formulary, or any revision thereof, and all substances and preparations intended for external and internal use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals, and all substances and preparations, other than food, intended to affect the structure or any function of the bodies of humans or other animals.

**Current: Subd. 6. Medicine.** The term "medicine" means any remedial agent that has the property of curing, preventing, treating, or mitigating diseases, or that is used for that purpose.

**Discussion:** These definitions “Drug” and “Medicine” come forward from the 1937 Act, unchanged. Contemporary professional usage makes little distinction between the two. However, lay usage ascribes a negative connotation to “drugs.” Since even the USP considers them to be the same the definitions should be combined.
Future considerations: Drugs still under IND may need to be defined or included in a separate section of 151. Supplemental labeling and other label requirements by the BOP may interfere with study design.

**Recommended: (Combine Subd 5 & 6) Drug or Medicine.** The terms "drug" and "medicine" means articles recognized as Drugs or Medicines by the United States Pharmacopoeia, or any other official compendium, or supplement, for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and articles intended for use as a component of any articles specified in clause above in this definition.

**Current:** Subd. 7. Poisons. The term "poisons" means any substance which, when introduced into the system, directly or by absorption, produces violent, morbid, or fatal changes, or which destroys living tissue with which it comes in contact.

**Current:** Subd. 8. Chemical. The term "chemical" means all medicinal or industrial substances, whether simple or compound, or obtained through the process of the science and art of chemistry, whether of organic or inorganic origin.

**Discussion:** Since the definitions of "Poisons" and "Chemicals" are not unique to the practice of pharmacy, nor are they customarily distributed in contemporary pharmacy practice and further, all drugs and medicines are chemicals, and poisons when used in excessive dose; the inclusion of these definitions in this document appears redundant.

**Recommended:** Strike both 7 & 8

**Discussion:** The language in the NABP Model Act appears to be more contemporary, therefore it is recommended that it be changed to the NABP language, or the definition
struck entirely as the term is adequately described and understood in legal parlance.

**Recommended (if retained):** “Person” means an individual, corporation, subsidiary, partnership, association, organization, affiliate organization, or any other legal entity, including government.

Subd. 12. Wholesale. **NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.**

Subd. 13. **NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.**

Subd. 14. Manufacturing. **NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.**

**Current: Subd. 15. Pharmacist intern.** The term "pharmacist intern" means (1) a natural person satisfactorily progressing toward the degree in pharmacy required for licensure, or (2) a graduate of the University of Minnesota College of Pharmacy, or other pharmacy college approved by the board, who is registered by the State Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist, or (3) a qualified applicant awaiting examination for licensure.

**Discussion:** It was noted that the current rule does not address foreign graduates and since the NABP Model act definition does, it is recommended that the model language be used.

There is a concern that the language should allow delegation and not require constant direct supervision of a pharmacist.

Students receive internship credit through the College of Pharmacy experiential program and may have non-pharmacist preceptors. The College of Pharmacy supervises these experiences and the preceptors. Internship hours not through the COP, e.g., summer internships, would be subject to Board supervision. There is also concern that the current language restricts activities of postgraduate interns or residents.
**Recommended: Subd. 15. Pharmacist intern.** The term "pharmacist intern" means (1) an individual enrolled in an accredited professional-pharmacy degree program who is working with a licensed pharmacist and who is registered by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist; or (2) an individual enrolled and participating in the experiential education portion of an accredited professional pharmacy degree program, for which internship credit will be applied toward requirements of a pharmacist license; or (3) a graduate of the accredited professional degree program of a school or college of Pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certificate, who is currently registered by the Board of Pharmacy for the purpose of obtaining practical experience as a requirement for licensure as a Pharmacist; or (4) a qualified applicant awaiting examination for licensure or meeting Board requirements for re-licensure.

**Current: Subd. 15a. Pharmacy technician.** The term "pharmacy technician" means a person not licensed as a pharmacist or a pharmacist intern, who assists the pharmacist in the preparation and dispensing of medicines by performing computer entry of prescription data and other manipulative tasks. A pharmacy technician shall not perform tasks specifically reserved to a licensed pharmacist or requiring professional judgment.

**Discussion:** As long as it explicitly states that the technician is not to enter into professional judgments restricted to pharmacists the elaboration in sentence one serves no purpose as it does not describe the functions of a technician. There is also a need for defining accountability. In situations where there are multiple pharmacists present, which pharmacist is accountable?

(*PTCB definition: Pharmacy technicians assist pharmacists in dispensing medications and are accountable to the supervising pharmacist who is legally responsible through state licensure for the care and safety of patients served by the pharmacy. Pharmacy technician job duties include providing medication and other health care products to patients and working with third party and doctors' offices in resolving adjudication of patients' insurance or state program. Pharmacy technicians often do the routine tasks associated with preparing prescribed medication and providing drugs to patients, but may also do compounding of medications, verbal prescriptions, doctor calls, expense and medication orders, returns and expired credits, and non-licensed pharmacy*
Recommended: Subd. 15a. Pharmacy technician. The term "pharmacy technician" means a person not licensed as a pharmacist or a pharmacist intern who is registered with the Board as a Technician, who assists the pharmacist and is accountable to a pharmacist, in the preparation and dispensing of medications by performing computer entry of prescription data and other manipulative tasks. A pharmacy technician shall not perform tasks specifically reserved to a licensed pharmacist or requiring professional judgment of a pharmacist.

Current: Subd. 16. Prescription. The term "prescription" means a signed written order, or an oral order reduced to writing, given by a practitioner licensed to prescribe drugs for patients in the course of the practitioner's practice, issued for an individual patient and containing the following: the date of issue, name and address of the patient, name and quantity of the drug prescribed, directions for use, and the name and address of the prescriber.

Discussion: The NABP Model act defines “prescription” as: “Prescription Drug Order” means a lawful order from a Practitioner for a Drug or Device for a specific patient, including orders derived from Collaborative Pharmacy Practice, where a valid Patient-Practitioner relationship exists, that is communicated to a Pharmacist in a licensed Pharmacy.

MN Rule 6800.0100 Subd. 11. Defines it as: Prescription drug order. "Prescription drug order" means a lawful written, oral, or electronic order of a practitioner for a drug for a specific patient.

Further, Subd. 11b defines Chart order Subd. 11b. Chart order. "Chart order" means a prescription drug order for a drug that is to be dispensed by a pharmacist, or by a pharmacist-intern under the direct supervision of a pharmacist, and administered by an authorized person only during the patient's stay in a hospital or long-term care facility. The chart order shall contain the name of the patient, another patient identifier such as a birth date or medical record number, the drug ordered, and any directions as the practitioner may prescribe concerning strength, dosage, frequency, and route of administration. The manual or electronic signature of the practitioner must be affixed to the chart order at the time it is written or at a later date in the case of verbal chart orders.

The distinction of an order in a hospital from a prescription in an ambulatory-patient setting is significant. Although addressed in the Rules, consideration should be given to including in the statute. The Working Group was of mixed opinion in this matter.
**Recommended: subd. 16.**

The term "prescription" means a lawful order of a practitioner for a medicine or device for a specific patient, where a valid patient-practitioner relationship exists, that is communicated to a pharmacist, or designee, in a licensed pharmacy.

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Subd. 17. Legend drug **NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.**

**Current: Subd. 18.**

"Label" means a display of written, printed, or graphic matter upon the immediate container of any drug or medicine; and a requirement made by or under authority of Laws 1969, chapter 933 that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such drug or medicine, or is easily legible through the outside container or wrapper.

**Discussion:** This definition appears to be rather wordy and the reference to “Laws 1969, chapter 933” is confusing. The NABP Model act defines Label as: “Label” means a display of written, printed, or graphic matter upon the immediate container of any Drug or Device. The NABP definition would seem to cover the needs for a proper definition.

**Recommended: Subd. 18 Label:** "Label" means a display of written, printed, or graphic matter upon the immediate container of any Drug or Device.

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Subd. 19. Package. **NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.**

**Current: Subd. 20.**

"Labeling" means all labels and other written, printed, or graphic matter (a) upon a drug or MEDICINE or any of its containers or wrappers, or (b) accompanying such article.

**Discussion:** NABP defines Labeling as: “Labeling” means the process of preparing and affixing a label to any Drug container exclusive, however, of the Labeling by a Manufacturer, packer, or Distributor of a Non Prescription Drug or commercially
packaged Legend Drug or Device. Any such label shall include all information required by Federal and State law or rule.

Recommended: Subd. 20 Labeling: "Labeling" means all labels and other written, printed, or graphic matter (a) upon a drug or medicine or any of its containers or wrappers exclusive of labeling by a manufacturer, packer, or distributor of a non prescription drug or commercially packaged legend drug or device.

Subd. 21. Federal act. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.

Current: Subd. 22. Pharmacist in charge. "Pharmacist in charge" means a duly licensed pharmacist in the state of Minnesota who has been designated in accord-ance with the rules of the State Board of Pharmacy to assume professional responsibility for the operation of the pharmacy in compliance with the requirements and duties as established by the board in its rules.

Discussion: The use of the term “operation” refers to the business entity and the way business is conducted. Unless the PIC is also the owner of the pharmacy (increasingly unusual) he/she does not control the operation of the business entity. The PIC does however, and should, have major say in the professional aspects of the pharmacy, which may reach the level of control. Therefore, we recommend that “operation” be changed to “practice.”

Current language would appear to include the need for a PIC at an MTM practice that is not attendant to a licensed pharmacy. Does this mean each “clinic” would need to be licensed as a pharmacy and have one pharmacist designated as the PIC at each clinic? Would licensing the pharmacist rather than the practice be a use of the limited license that’s in the new rules? Since each licensed pharmacist is responsible for his/her work, and accountable to the board it could be asked if we even define PIC in statute?
**Recommended: Subd. 22. Pharmacist in charge.** "Pharmacist in charge" means a duly licensed pharmacist in the state of Minnesota who has been designated in accordance with the rules of the State Board of Pharmacy to assume professional responsibility for the practice of pharmacy in a licensed pharmacy in compliance with the requirements and duties as established by the board in its rules.

Current: Subd. 23. Practitioner. "Practitioner" means a licensed doctor of medicine, licensed doctor of osteopathy duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian. For purposes of sections 151.15, subdivision 4; 151.37, subdivision 2, paragraphs (b), (e), and (f); and 151.461, "practitioner" also means a physician assistant authorized to prescribe, dispense, and administer under chapter 147A, or an advanced practice nurse authorized to prescribe, dispense, and administer under section 148.235. For purposes of sections 151.15, subdivision 4; 151.37, subdivision 2, paragraph (b); and 151.461, “practitioner” also means a dental therapist authorized to dispense and administer under chapter 150A.

**Discussion:** For the pharmacist to be fully integrated into the new concepts of care delivery the pharmacist should be considered as a practitioner just as the physician assistant and advanced practice nurse. Alternatively, the pharmacist could be recognized in the group with PA, NP, etc.
**Recommended:** Subd. 23. **Practitioner.** “Practitioner” means a licensed doctor of medicine, licensed doctor of osteopathy duly licensed to practice medicine, licensed doctor of dentistry, licensed doctor of optometry, licensed podiatrist, licensed veterinarian. For purposes of sections 151.15, subdivision 4; 151.37, subdivision 2, paragraphs (b), (e), and (f); and 151.461, “practitioner” also means a physician assistant authorized to prescribe, dispense, and administer under chapter 147A, or an advanced practice nurse authorized to prescribe, dispense, and administer under section 148.235, or licensed pharmacist authorized to prescribe and administer under section 151.01 sub27 For purposes of sections 151.15, subdivision 4; 151.37, subdivision 2, paragraph (b); and 151.461, “practitioner” also means a dental therapist authorized to dispense and administer under chapter 150A.

Subd. 24.Brand name. **NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.**

Subd. 25.Generic name. **NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.**

Subd. 26.Finished dosage form. **NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.**

**Current:** Subd. 27. **Practice of pharmacy.** "Practice of pharmacy" means:

1. interpretation and evaluation of prescription drug orders;
2. compounding, labeling, and dispensing drugs and devices (except labeling by a manufacturer or packager of nonprescription drugs or commercially packaged legend drugs and devices);
3. participation in clinical interpretations and monitoring of drug therapy for assurance of safe and effective use of drugs;
4. participation in drug and therapeutic device selection; drug administration for first dosage and medical emergencies; drug regimen reviews; and drug or drug-related research;
5. participation in administration of influenza vaccines to all eligible individuals ten years of age and older and all other vaccines to patients 18 years of age and older under standing orders from a physician licensed under chapter 147 or by written protocol with a physician provided that:
   (i) the pharmacist is trained in a program approved by the American Council of Pharmaceutical Education for the administration of immunizations or graduated from a
college of pharmacy in 2001 or thereafter; and
(ii) the pharmacist reports the administration of the immunization to the patient's primary
physician or clinic;
(6) participation in the practice of managing drug therapy and modifying drug therapy,
according to section 151.21, subdivision 1, according to a written protocol between the
specific pharmacist and the individual dentist, optometrist, physician, podiatrist, or
veterinarian who is responsible for the patient's care and authorized to independently
prescribe drugs. Any significant changes in drug therapy must be reported by the
pharmacist to the patient's medical record;
(7) participation in the storage of drugs and the maintenance of records;
(8) responsibility for participation in patient counseling on therapeutic values, content,
hazards, and uses of drugs and devices; and
(9) offering or performing those acts, services, operations, or transactions necessary in
the conduct, operation, management, and control of a pharmacy.

Discussion: The focus of pharmacy practice is changing, as has been previously noted,
from primarily a dispensing function to a clinical services function. Therefore, the
definition should reflect the training and competencies of the pharmacist. The
definition should reflect the need for the pharmacist to oversee the management of the
product distribution function, but the focus should be the on the service side.

Further, the definition of practice should allow for innovation and full participation in
emerging delivery systems. E.g., accountable-care organizations, health homes

The use of the term “patient centered” is a cliché that has little real meaning and should
be removed from statute.

Even though the process of collaborative practice is currently defined in this section
Subd 27 (6), functionally it will most likely change, as ACOs and health homes become a
standard for delivery of services. There is strong possibility that these new entities will be
given authority to define collaborative practice, as they need for the populations for
which they are responsible. Therefore, these entities will obviate the need to prescribe the
manner in which an agreement will be reached. There is concern that until such time, the
current language be maintained.
Recommended: Subd. 27. Practice of Pharmacy. “Practice of pharmacy” means the practice in which a pharmacist accepts responsibility for a consumer’s drug or medicine-related needs, which may include but not be limited to:

(1) the management of drug or medicines-related consumer and patient needs, which may include but is not limited to
   (a) modify, initiate, and discontinue medications,
   (b) order and collect information to inform medication management,
   (c) document appropriately
(2) the control, dispensing, preparation, and compounding of drugs or medicines
(3) collaboration with other practitioners in the management of the care of a consumer or patient
(4) administration of drugs or medicines

It is unlawful for any person to practice pharmacy as defined in subdivision 27 in this state unless the person holds a valid license issued according to this chapter.

Subd. 28. Veterinary legend drug. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.
Subd. 29. Legend medical gas. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.
Subd. 30. Dispense. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.
Subd. 31. Central service pharmacy. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.
Subd. 32. Electronic signature. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.
Subd. 33. Electronic transmission. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.

Subd. 34 Collaborative Practice (no current definition)

Discussion: The current requirements for the pharmacists to enter into a collaborative practice agreement appears in §151.0, Subd. 27(6). Conceptually, collaborative practice should be seen as encompassing any mutually agreed upon tasks that the participating providers, by virtue of education and training, are competent to provide. Therefore, a pharmacist could adjust doses, order and prescribe medication, order lab tests, etc: in short the pharmacist acting in a liberal collaborative practice environment
could practice in much the same way as those who practice under “advanced practice” certifications in some jurisdictions.

This level of practice will be particularly feasible under the umbrella of ACOs and health homes. See further discussion in §151.21 (page 19) and §151.01, Subd27 (6), (page 15). The functional definition of collaborative practice as it relates to the pharmacist and dentist, optometrist, physician, podiatrist, or veterinarian is a policy discussion of strategic importance to the profession and pharmacist practitioners and should be joined by all elements of the profession for a consensual resolution while the opportunities exist under the health-reform movement.

Subd. 34, Collaborative Practice. “Collaborative Practice” means a pharmacist and other practitioner(s) practicing together within the framework of their respective professional scopes of practice. This collaborative agreement reflects both independent (E.g., adjust doses, order, prescribe) and cooperative decision-making and is based on the preparation and ability of each participant.
Sections are re-ordered so that related topics are considered together.

**BOARD: DESCRIPTION & ADMINISTRATION**

151.02 STATE BOARD OF PHARMACY.
151.03 MEMBERSHIP.
151.04 RECOMMENDED NAMES.
151.05 ELECTION OF OFFICERS.
151.06 POWERS AND DUTIES.

The above sections pertain to the functioning of the Board, its nomination & appointment, and powers and duties. Although these functions ultimately having bearing on the practice of pharmacy, it is indirect and therefore no recommendations are offered for consideration. Similarly, the Working Group did not comment on other sections and subdivisions that in our judgment did not directly affect practice.

**PRACTICE**

**Discussion and Recommendations:** It is notable that there appears to be no specific section, other than in the definitions that address pharmacy practice.

**COMPOUNDING**

151.15 COMPOUNDING DRUGS UNLAWFUL UNDER CERTAIN CONDITIONS. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION.
151.21 SUBSTITUTION.

Subdivision 1. Generally.

Except as provided in this section, it shall be unlawful for any pharmacist or pharmacist intern who dispenses prescriptions, drugs, and medicines to substitute an article different from the one ordered, or deviate in any manner from the requirements of an order or prescription without the approval of the prescriber.

Discussion & Recommendations The pharmacist is competent by training to choose the appropriate medication for use by a given patient when the pharmacist has access to the medical record including protected health information. Particularly so in a collaborative practice (see §151.01, Subd 27). In effect, and in fact, each health home is a collaborative practice team and should be free to define within the team the relative functions of each member. This reality should be captured in the Section. Also, this important section should be recast into positive statement.

Subd. 2. Brand name specified.

NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

Subd. 3. Brand name not specified.

When a pharmacist receives a paper or hard copy prescription on which the prescriber has not personally written in handwriting "dispense as written" or "D.A.W.," a prescription sent by electronic transmission on which the prescriber has not expressly indicated in a manner consistent with the standards for electronic prescribing under Code of Federal Regulations, title 42, section 423, that the prescription is to be dispensed as transmitted and which bears the prescriber's electronic signature, or an oral prescription in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated, and there is available in the pharmacist's stock a less expensive generically equivalent drug that, in the pharmacist's professional judgment, is therapeutically equivalent and safely interchangeable with the prescribed drug, then the pharmacist shall, after disclosing the substitution to the purchaser, dispense the generic drug, unless the purchaser objects.

A pharmacist may also substitute pursuant to the oral instructions of the prescriber. A pharmacist may not substitute a generically equivalent drug product unless, in the pharmacist's professional
judgment, the substituted drug is therapeutically equivalent and interchangeable to the prescribed drug. A pharmacist shall notify the purchaser if the pharmacist is dispensing a drug other than the brand name drug prescribed.

Discussion & Recommendations The working group believes that the section would be enhanced by recognizing therapeutic equivalence in addition to generic equivalence. Further, the substitution of a generically equivalent product is often driven by a person’s health plan and its copayment formula and the patient has little effective say in whether or not they will accept a generic. Any changes should be communicated to the prescriber.

(The struck portion is not seen to be necessary.)

Subd. 3a. Prescriptions by electronic transmission.

Nothing in this section permits a prescriber to maintain "dispense as written" or "D.A.W." as a default on all prescriptions. Prescribers must add the "dispense as written" or "D.A.W." designation to electronic prescriptions individually, as appropriate.

Discussion & Recommendations This section might be improved by explicitly saying that when this occurs the DAW is invalid.

Subd. 4. Pricing.

A pharmacist dispensing a drug under the provisions of subdivision 3 shall not dispense a drug of a higher retail price than that of the brand name drug prescribed. If more than one safely interchangeable generic drug is available in a pharmacist's stock, then the pharmacist shall dispense the least expensive alternative, which in the pharmacist’s professional judgment is therapeutically equivalent. Any difference between acquisition cost to the pharmacist of the drug dispensed and the brand name drug prescribed shall be passed on to the purchaser.

Discussion & Recommendations This section could be relevant and could be retained by adding to the beginning of the section: “In those instances where the prescription is not paid by a third party...” Alternatively it could be considered that pricing issues do not have a place in a professional practice act. The Working Group recommends the deletion of Subd 4, 5, 6 & 7 so the act would be in conformity with other Minnesota professional practice acts and conforming to the development of accountable-care organizations.
In the current prescription market there is no “retail” price for prescriptions, due to the fact that reimbursement and patient costs are directed by the health plans for virtually all consumers in Minnesota. Use of “cost” is not an alternative for the same reason. For related reasons the cost differential is determined by reimbursement formulae and are not by contract passed on to the consumer.

Subd. 4a. Sign.

A pharmacy must post a sign in a conspicuous location and in a typeface easily seen at the counter where prescriptions are dispensed stating: "In order to save you money, this pharmacy will substitute whenever possible an FDA-approved, less expensive, generic drug product, which is therapeutically equivalent to and safely interchangeable with the one prescribed by your doctor, unless you object to this substitution."

Discussion & Recommendations Because of the predominance of third-party control over the calculation of medication prices and reimbursement this section is irrelevant and should be deleted.

Subd. 5. Reimbursement.

Nothing in this section requires a pharmacist to substitute a generic drug if the substitution will make the transaction ineligible for third-party reimbursement or the reimbursement would cause the pharmacy to lose money on the transaction.

Discussion & Recommendations In many instances the current law and third-party contracts put the pharmacy into a position of taking a loss on a transaction. The statute should recognize this and give the pharmacist the authority to over-ride the reimbursement of the third party.

Subd. 6. Disclosure.

When a pharmacist dispenses a brand name legend drug and, at that time, a less expensive generically equivalent drug is also available in the pharmacist’s stock, the pharmacist shall disclose to the purchaser that a generic drug is available.

Discussion & Recommendations Current product management practice of managed care makes this unnecessary and it is recommended to delete this section.
Subd. 7. Drug formulary.

This section does not apply when a pharmacist is dispensing a prescribed drug to persons covered under a managed health care plan that maintains a mandatory or closed drug formulary.

Discussion & Recommendations This provision is not generally understood. This section would not be needed if Subd 4 were amended by the addition of: “In those instances where the prescription is not paid by a third party . . .”

Subd. 8. List of excluded products.

The Drug Formulary Committee established under section 256B.0625, subdivision 13, shall establish a list of drug products that are to be excluded from this section. This list shall be updated on an annual basis and shall be provided to the board for dissemination to pharmacists licensed in the state.

Discussion & Recommendations This section should be amended to show that it refers to DHS only.

It is recommended that another subdivision under §151.21 be added that addresses the transparency of formulary development: Subd. 9. Managed-care organizations shall have systems in place that ensure formulary-committee members disclose relationships with manufacturers or other organizations that may represent the potential for conflicts of interest. Managed-care organizations must be responsible for managing conflicts of interest among formulary-committee members. Such disclosures shall be available to the public on request.

151.211 Records of prescriptions. No recommendations are offered for this section

151.212 Label of prescription drug containers. No recommendations are offered for this section

151.213 Copies of prescriptions. No recommendations are offered for this section

151.214 Payment disclosure.

Subdivision 1. Explanation of pharmacy benefits.
A pharmacist licensed under this chapter must provide to a patient, each prescription dispensed where part or all of the cost of the prescription is being paid or reimbursed by an employer-sponsored or health plan company, or its contracted pharmacy benefit manager, patient's co-payment amount and the pharmacy's own usual and price of the prescription or the amount the pharmacy will be paid the prescription drug by the patient's employer-sponsored plan or plan company, or its contracted pharmacy benefit manager.

**Discussion & Recommendations** As noted elsewhere, “usual and customary” is an artifact in that nearly all prescriptions are covered by some entity and is only around because PBMs require a figure. Recommend that reference to usual and customary be stricken from the statute.

Subd. 2.No prohibition on disclosure. **NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION**

151.215 **CERTIFICATION. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION**

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**DRUG PRODUCT**

151.22 **LIABILITY FOR QUALITY OF DRUGS.**

Every pharmacist in charge or proprietor of a pharmacy shall be responsible for the quality of all drugs, medicines, chemicals, and poisons procured for use and sold therein, except proprietary medicines or other articles sold in the original package of the manufacturer.

**Discussion & Recommendations** It is a stretch for the pharmacist/proprietor in today's international pharmaceuticals market to be responsible, or liable, for the quality of all drugs. The pharmacist can neither analyze the product nor be certain of the supply chain.

Unless this section is extended to the entire supply chain -- each is responsible for assuring the next person in the chain of the quality of the product – we recommend its deletion.

151.23 **POISONS MUST BE LABELED.**
151.24 SALE OF POISONS MUST BE RECORDED.

It shall be unlawful:

(1) for any person, either acting independently or while in the
of another, to sell or give away any poison, as designated by the
board, without first recording in a book to be kept for that purpose
indelible pencil or ink the date, the name and address of the person
whom, and the amount and kind of poison, delivered, except when such
poison is sold on the written prescription of a physician;

(2) to give a false name to be recorded;

(3) for any person having custody of any such record book to refuse
produce it on demand for the inspection of any authorized agent of
board or other duly authorized officer.

Discussion & Recommendations The Working Group wonders
about the currency of poison related language, as pharmacies no
longer sell poisons.

151.33 CARELESS DISTRIBUTION OF DRUGS.

Subdivision 1. Prohibited.

No person, directly or indirectly, by agent or otherwise, shall
scatter, distribute, or give away any samples of any medicine,
drugs, or medical compounds, salve, or liniment of any kind unless
the same is delivered into the hands of an adult person, or mailed
to such persons through the regular mail service.

Subd. 2. Penalty.

Any person violating any provision of this section shall be guilty
of a misdemeanor.

Discussion & Recommendations The Working Group believes
that terminology in this subdivision: specifically “scatter,” “Salve,”
“liniment,” “medical compound” could be updated. Also, “mail
service” should be expanded to “regular commercial delivery
systems.”

151.34 PROHIBITED ACTS.

It shall be unlawful to:

(1) manufacture, sell or deliver, hold or offer for sale any drug
that is adulterated or misbranded;
(2) adulterate or misbrand any drug;

(3) receive in commerce any drug that is adulterated or misbranded, and to deliver or proffer delivery thereof for pay or otherwise;

(4) refuse to permit entry or inspection, or to permit the taking of a sample, or to permit access to or copying of any record as authorized by this chapter;

(5) remove or dispose of a detained or embargoed article in violation of this chapter;

(6) alter, mutilate, destroy, obliterate, or remove the whole or any part of the labeling of, or to do any other act with respect to a drug, if such act is done while such drug is held for sale and results in such drug being adulterated or misbranded;

(7) use for a person’s own advantage or to reveal other than to the board or its authorized representative or to the courts when required in any judicial proceeding under this chapter any information acquired under authority of this chapter concerning any method or process which is a trade secret and entitled to protection;

(8) use on the labeling of any drug any representation or suggestion that an application with respect to such drug is effective under the federal act or that such drug complies with such provisions;

(9) in the case of a manufacturer, packer, or distributor offering legend drugs for sale within this state, fail to maintain for transmittal or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal act. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under provisions of this chapter;

(10) conduct a pharmacy without a pharmacist in charge;

(11) dispense a legend drug without first obtaining a valid prescription for that drug;

(12) conduct a pharmacy without proper registration with the board;

(13) pharmacy without being licensed to do so by the board; or

(14) sell at retail federally restricted medical gases without proper registration with the board except as provided in this chapter.

**Discussion & Recommendations** This subdivision relates to the physical pharmacy and the dispensing function. There are
elements of clinical practice that can/should be addressed in a companion section. Consideration should be given to including the individual pharmacists discipline as in physicians in 147.091 and nurses in 148.261. This should not get into the level of detail that would dictate such inappropriate items as the size of a room, nor should it address issues that directly impact judgments in clinical practice.

151.35 DRUGS, ADULTERATION. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.36 DRUGS, MISBRANDING. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.361 MANUFACTURER DISCLOSURE.


The manufacturer, packager, or distributor of any human use legend drug sold, delivered, or offered for sale in the state of Minnesota after January 1, 1976 must have printed on the label on the immediate container of the drug the name and address of the manufacturer of the finished dosage form of the drug.

Discussion & Recommendations If this requirement is retained, the implementation date language should be removed. However, it appears that this is not enforced by the BOP and it is the belief of the Working Group that it should be because by enforcing this provision the practitioner would have an additional tool in assessing the quality of the medication supply.


(a) No legend drug in solid oral dosage form may be manufactured, packaged or distributed for sale in this state after January 1, 1983 unless it is clearly marked or imprinted with a symbol, number, company name, words, letters, national drug code or other mark uniquely identifiable to that drug product. An identifying mark or imprint made as required by federal law or by the federal Food and Drug Administration shall be deemed to be in compliance with this section.

(b) The Board of Pharmacy may grant exemptions from the requirements of this section on its own initiative or upon application of a manufacturer, packager, or distributor indicating size or other characteristics which render the product impractical for the imprinting required by this section.
(c) The provisions of clauses (a) and (b) shall not apply to any of the following:

(1) Drugs purchased by a pharmacy, pharmacist, or licensed wholesaler prior to January 1, 1983, and held in stock for resale.

(2) Drugs which are manufactured by or upon the order of a practitioner licensed by law to prescribe or administer drugs and which are to be used solely by the patient for whom prescribed.

Discussion & Recommendations Remove the language as to implementation dates.

Subd. 3. Penalty. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.38 EMBARGOES. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.39 DISTRESSED DRUGS. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.40 POSSESSION AND SALE OF HYPODERMIC SYRINGES AND NEEDLES.

Subdivision 1. Generally.

Except as otherwise provided in subdivision 2, it is unlawful for person to possess, control, manufacture, sell, furnish, dispense, or otherwise dispose of hypodermic syringes or needles or any instrument or implement which can be adapted for subcutaneous injections, except by the following persons when acting in the course of their or employment: licensed practitioners, registered pharmacies and their employees or agents, licensed pharmacists, licensed doctors of veterinary medicine or their assistants, registered nurses, registered medical technologists, medical interns, licensed drug wholesalers, their employees or agents, licensed hospitals, licensed nursing homes, bona fide hospitals where animals are treated, licensed morticians, syringe and needle manufacturers, their dealers and agents, persons engaged in animal husbandry, clinical laboratories, persons engaged in bona fide research or education or industrial use of hypodermic syringes and needles provided such persons cannot use hypodermic syringes and needles for the administration of drugs to human beings unless such drugs are prescribed, dispensed, and administered by a person lawfully authorized to do so, persons who administer drugs pursuant to an order or direction of a licensed doctor of medicine or of a licensed doctor of osteopathy duly licensed to medicine.

Subd. 2. Sales of limited quantities of clean needles and syringes.

(a) A registered pharmacy or its agent or a licensed pharmacist may sell, without a prescription, unused hypodermic needles and syringes in quantities of ten or fewer, provided the pharmacy or pharmacist complies with all of the requirements of this subdivision.
(b) At any location where hypodermic needles and syringes are kept for retail sale under this subdivision, the needles and syringes shall be stored in a manner that makes them available only to authorized personnel and not openly available to customers.

(c) No registered pharmacy or licensed pharmacist may advertise to the public the availability for retail sale, without a prescription, of hypodermic needles or syringes in quantities of ten or fewer.

(d) A registered pharmacy or licensed pharmacist that sells hypodermic needles or syringes under this subdivision may give the purchaser the materials developed by the commissioner of health under section 325F.785.

(e) A registered pharmacy or licensed pharmacist that sells hypodermic needles or syringes must certify to the commissioner of health participation in an activity, including but not limited to those developed under section 325F.785, that supports proper disposal of used hypodermic needles or syringes.

Discussion & Recommendations The Working Group is of the opinion that the entire §151.40 relating to possession and sale of syringes should be removed. This is because syringes are distributed in various quantities by many social agencies outside the constraints of this Section. Further, it restricts the pharmacists' activities in meeting the needs of consumers that are entirely legal or sanctioned by contemporary society.

**LONG-TERM CARE**

**LONG-TERM CARE RESIDENT ACCESS TO PHARMACEUTICALS ACT**

**151.415** LONG-TERM CARE RESIDENT ACCESS TO PHARMACEUTICALS ACT.

**NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION**

**PRESCRIBING AND FILLING**

**151.37 LEGEND DRUGS, WHO MAY PRESCRIBE, POSSESS.**
Subdivision 1. Prohibition.

Except as otherwise provided in this chapter, it shall be unlawful for any person to have in possession, or to sell, give away, barter, exchange, or distribute a legend drug.

Subd. 2. Prescribing and filing.

(a) A licensed practitioner in the course of professional practice only, may prescribe, administer, and dispense a legend drug, and may cause the same to be administered by a nurse, a physician assistant, or medical student or resident under the practitioner’s direction and supervision, and may cause a person who is an appropriately certified, registered, or licensed health care professional to prescribe, dispense, and administer the same within the expressed legal scope of the person’s practice as defined in Minnesota Statutes. A licensed practitioner may prescribe a legend drug, without reference to a specific patient, by directing a nurse, pursuant to section 148.235, subdivisions 8 and 9 physician assistant, medical student or resident, or pharmacist according to section 151.01, subdivision 27, to adhere to a particular practice guideline or protocol when treating patients whose condition falls within such guideline or protocol, and when such guideline or protocol specifies the circumstances under which the legend drug is to be prescribed and administered. An individual who verbally, electronically, or otherwise transmits a written, oral, or electronic order, as an agent of a prescriber, shall not be deemed to have prescribed the legend drug. This paragraph applies to a physician assistant only if the physician assistant meets the requirements of section 147A.18

Discussion & Recommendations Subd.2 (a) allows a practitioner to direct administration to “…medical student or resident.” It should also allow any professional student/resident (e.g. nursing, pharmacy), acting within their scope of practice to administer medication.

(b) The commissioner of health, if a licensed practitioner, or a person designated by the commissioner who is a licensed practitioner, may prescribe a legend drug to an individual or by protocol for mass dispensing purposes where the commissioner finds that the conditions triggering section 144.4197 or 144.4198, subdivision 2 </statutes?id=144.4198#stat.144.4198.2>, paragraph (b), exist. The commissioner, if a licensed practitioner, or a designated licensed practitioner, may prescribe, dispense, or administer a legend drug or other substance listed in subdivision 10 to control tuberculosis and other communicable diseases. The commissioner may modify state drug labeling requirements, and medical screening criteria and documentation, where time is critical and limited labeling and screening are most likely to ensure legend drugs reach the maximum number of persons in a timely fashion so as to reduce morbidity and mortality.
(c) A licensed practitioner that dispenses for profit a legend drug that is to be administered orally, is ordinarily dispensed by a pharmacist, and is not a vaccine, must file with the practitioner's licensing board a statement indicating that the practitioner dispenses legend drugs for profit, the general circumstances under which the practitioner dispenses for profit, and the types of legend drugs generally dispensed. It is unlawful to dispense legend drugs for profit after July 31, 1990, unless the statement has been filed with the appropriate licensing board. For purposes of this paragraph, "profit" means (1) any amount received by the practitioner in excess of the acquisition cost of a legend drug for legend drugs that are purchased in prepackaged form, or (2) any amount received by the practitioner in excess of the acquisition cost of a legend drug plus the cost of making the drug available if the legend drug requires compounding, packaging, or other treatment. The statement filed under this paragraph is public data under section 13.03. This paragraph does not apply to a licensed doctor of veterinary medicine or a registered pharmacist. Any person other than a licensed practitioner with the authority to prescribe, dispense, and administer a legend drug under paragraph (a) shall not dispense for profit. To dispense for profit does not include dispensing by a community health clinic when the profit from dispensing is used to meet operating expenses.

**Discussion & Recommendations** The Working Group recognizes the import of this section but questions the definition of “profit” and the exclusion of community health clinics. Further, does BOP have any information as to the MD registration under this section with BMP?

(d) A prescription or drug order for the following drugs is not valid, unless it can be established that the prescription or order was based on a documented patient evaluation, including an examination, adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment:

**NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION**

Subd. 2a. Delegation.
Subd. 3. Veterinarians.
Subd. 4. Research.
Subd. 5. Exclusion for course of practice.
Subd. 6. Exclusion for course of employment.
Subd. 7. Exclusion for prescriptions.
Subd. 8. Misrepresentation.
Subd. 9. Exclusion for course of laboratory employment.
Subd. 10. Purchase of drugs and other agents by commissioner of health.
Subd. 11. Complaint reporting.

**NO RECOMMENDATIONS ARE OFFERED FOR THESE SECTIONS**
Discussion & Recommendations It is the belief of the Working Group that there should be a statutory responsibility to assure the pharmacies that the product they distribute is not counterfeit, adulterated or contaminated. Since there is a similar requirement of the pharmacy, this is an appropriate action.

WHOLESALE DRUG DISTRIBUTION LICENSING ACT: OTHER THAN AS NOTED ABOVE, NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.45 WHOLESALE DRUG DISTRIBUTOR ADVISORY TASK FORCE. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

The board shall appoint a Wholesale Drug Distributor Advisory Task

151.46 PROHIBITED DRUG PURCHASES OR RECEIPT. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

*CANCER DRUG REPOSITORY PROGRAM*

151.55 CANCER DRUG REPOSITORY PROGRAM. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

*RETURN OF UNUSED DRUGS*

151.56 COUNTY RETURN OF UNUSED DRUGS OR MEDICAL DEVICES. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.095 INACTIVE STATUS LICENSE. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION
151.10 QUALIFICATIONS OF APPLICANTS. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.101 INTERNSHIP.

The board may license as an intern any natural persons who have satisfied the board that they are of good moral character, not physically or mentally unfit, and who have successfully completed the educational requirements for intern licensure prescribed by the board. The board shall prescribe standards and requirements for interns, pharmacist-preceptors, and internship training but may not require more than one year of such training.

The board in its discretion may accept internship experience obtained in another state provided the internship requirements in such other state are in the opinion of the board equivalent to those herein provided.

Discussion & Recommendations: This section should default to current ACPE & NABP requirements for experiential training, thereby removing the potential for duplicative or conflicting requirements, which cause an unnecessary challenge for colleges of pharmacy in designing curricula. Definitions 151.01 subd15. Q.v.

151.102 PHARMACY TECHNICIAN.

Subdivision 1. General.

A pharmacy technician may assist a pharmacist in the practice of pharmacy by performing nonjudgmental tasks that do not require judgment of a pharmacist and works under the personal and direct supervision of the pharmacist. A pharmacist may supervise two technicians, as long as the pharmacist assumes responsibility for all the functions performed by the technicians. A pharmacy may exceed the ratio of pharmacy technicians to pharmacists permitted in this subdivision or in rule by a total of one technician at any given time in the pharmacy, provided at least one technician in the pharmacy holds a valid certification from the Pharmacy Technician Certification Board or from another national certification body for pharmacy technicians that requires passage of a nationally recognized, psychometrically valid certification examination for certification as determined by the Board of Pharmacy. The Board of Pharmacy may, by rule, set ratios of technicians to pharmacists greater than two to one for the functions specified in rule. The delegation of any duties, tasks, or functions by a pharmacist to a pharmacy technician is subject to continuing review and becomes the professional and personal responsibility of the pharmacist who directed the pharmacy technician to perform the duty, task, or function.
Subd. 2. Waivers by board permitted.

A pharmacist in charge in a pharmacy may petition the board for authorization to allow a pharmacist to supervise more than two pharmacy technicians. The pharmacist's petition must include provisions addressing the maintenance of patient care and safety. A petition filed with the board under this subdivision shall be deemed approved 90 days after the board receives the petition, unless the board denies the petition within 90 days of receipt and notifies the petitioning pharmacist of the petition's denial and the board's reasons for denial.

Discussion & Recommendations: §151.102 is restrictive in the extreme and does not recognize the value and contribution of a properly trained technician. Neither does it recognize the ability of the pharmacist to manage the staff. As is reflected in §151.01 (subd 16), it is the recommendation of Working Group that incorporate the principles of (1) accountable to the pharmacist, (2) restricted from making decisions that require the professional judgments of a pharmacist, thereby recognizing that a properly trained technician makes professional judgments. Further, the number of trained and credentialed technicians working in a pharmacy should not be subject to arbitrary ratios but rather be left to the professional judgment of the pharmacist. Rule 6800.350 (subd 6) would also need amendment out.

151.12 RECIPROCITY; LICENSURE. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.13 RENEWAL FEE; CONTINUING EDUCATION. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.14 REINSTATEMENTS. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.16 VIOLATION A GROSS MISDEMEANOR. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.17 UNLAWFUL USE OF "PHARMACIST. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.18 UNLAWFUL TO USE MISLEADING NAME. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.19 REGISTRATION; FEES. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION
151.25 REGISTRATION OF MANUFACTURERS; FEE; PROHIBITIONS. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.47 WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENTS. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.48 OUT-OF-STATE WHOLESALE DRUG DISTRIBUTOR LICENSING. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.49 LICENSE RENEWAL APPLICATION PROCEDURES. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.50 RULES. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.51 BOARD ACCESS TO WHOLESALE DRUG DISTRIBUTOR RECORDS. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

MISCELLANEOUS

151.061 UNFAIR PRICE DISCRIMINATION.

Subd. 1. Generally.

Any person doing business in this state and engaged in the (other than at retail) of any prescription drugs, who shall discriminate between purchasers by selling prescription drugs at a lower price or rate to one purchaser or association of purchasers than offered to another purchaser or association of purchasers within this state (other than at retail) after making allowance for the difference, if any, in the grade, quality, or quantity, and after equalizing the distance from the point of distribution and freight costs therefrom, shall be guilty of unfair discrimination. Unfair discrimination occurs when quantity discounts are not reasonably based on actual cost savings to all like purchasers. Unfair discrimination shall embrace any scheme of special rebates, collateral contracts, or any device of any nature which in substance violates the provisions of this subdivision. Nothing in this subdivision shall apply to purchases for their own use by schools, colleges, universities, public libraries, churches, hospitals or charitable institutions not operated for profit.

Subd. 2. Remedy.

Any person injured by unfair discrimination as defined in subdivision 1 may bring a civil action and recover damages, together with costs and disbursements, including reasonable attorney's fees, and receive other equitable relief as determined by the court. The remedies provided by this section are cumulative and shall not be construed as restricting any remedy which is otherwise available.
151.26 EXCEPTIONS.

Subdivision 1. Generally.

Nothing in this chapter shall subject a person duly licensed in this state to practice medicine, dentistry, or veterinary medicine, to inspection by the State Board of Pharmacy, nor prevent the person from administering drugs, medicines, chemicals, or poisons in the person's practice, nor prevent a duly licensed practitioner from furnishing to a patient properly packaged and labeled drugs, medicines, chemicals, or poisons as may be considered appropriate in the treatment of such patient; unless the person is engaged in the dispensing, sale, or distribution of drugs and the board provides reasonable notice of an inspection.

Except for the provisions of section 151.37, nothing in this chapter applies to or interferes with the dispensing, in its original package and at no charge to the patient, of a legend drug, other than a controlled substance, that was packaged by a manufacturer and provided to the dispenser for distribution as a professional sample.

Nothing in this chapter shall prevent the sale of drugs, medicines, chemicals, or poisons at wholesale to licensed physicians, dentists and veterinarians for use in their practice, nor to hospitals for use therein.

Nothing in this chapter shall prevent the sale of drugs, chemicals, or poisons either at wholesale or retail for use for commercial purposes, or in the arts, nor interfere with the sale of insecticides, as defined in Minnesota Statutes 1974, section 24.069, and nothing in this chapter shall prevent the sale of common household preparations and other drugs, chemicals, and poisons sold exclusively for use for non-medicinal purposes.

Nothing in this chapter shall apply to or interfere with the vending or retailing of any nonprescription medicine or drug not otherwise prohibited by statute which is prepackaged, fully prepared by the manufacturer or producer for use by the consumer, and labeled in accordance with the requirements of the state or federal Food and Drug Act; nor to the manufacture, wholesaling, vending, or retailing of flavoring extracts, toilet articles, cosmetics, perfumes, spices, and other commonly used household articles of a chemical nature, for use for nonmedicinal purposes. Nothing in this chapter shall prevent the sale of drugs or medicines by licensed pharmacists at a discount to persons over 65 years of age.

Discussion & Recommendations THIS LANGUAGE SHOULD BE BROADENED TO ALLOW A DISCOUNT TO ANY PERSON, FOR ANY REASON.

151.27 EXPENSES. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION
151.29 VIOLATION A MISDEMEANOR. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.30 COUNTY ATTORNEY TO PROSECUTE. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.301 REPORTS TO COMMISSIONER OF HEALTH. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.302 IMMUNITY. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.32 CITATION. NO RECOMMENDATIONS ARE OFFERED FOR THIS SECTION

151.461 GIFTS TO PRACTITIONERS PROHIBITED.

It is unlawful for any manufacturer or wholesale drug distributor, any agent thereof, to offer or give any gift of value to a practitioner. A medical device manufacturer that distributes drugs as an incidental part of its device business shall not be considered a manufacturer, a wholesale drug distributor, or agent under this section. As used in this section, “gift” does not include:

(1) professional samples of a drug provided to a prescriber for free distribution to patients;

(2) items with a total combined retail value, in any calendar year, of not more than $50;

(3) a payment to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes;

(4) reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting;

(5) compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project;

(6) publications and educational materials; or

(7) salaries or other benefits paid to employees.

Discussion & Recommendations This references “practitioners” and under the current definition pharmacists would be exempted from this section. It should be broadened to include any person who has an impact on medication use. E.g., managed-care, PBM, wholesalers, prescribers, consultants.
Consideration should be given to including device manufacturers as well.