2019 HOUSE OF DELEGATES

Proposal for New Business
MPhA House of Delegates
Resolution 19-004
Category: Pharmacy Practice

Topic:

Encouraging Change within Minnesota's Pharmacist "Scope of Practice"

Proposal (Proposed Policy Statement)*:

Resolved, MPhA endorses: 1. Pharmacy professionals exploring innovation and practice change that improves the patient care experience, public health, and public safety, utilizing skills at the highest level of their clinical ability. 2. The concept of "permissionless innovation" for changes in legislation and regulation related to pharmacy practice, reasonably believed to improve the patient care experience, quality, and service value with minimal additional risk to patient safety. 3. The use of robust accountability mechanisms, with policy makers efforts to broaden pharmacists scope of practice.
See attached.

_Brent Thompson_____ _____6/5/19_____
New Business Submitted By Date Submitted

___Past President_____
District/Academy

OFFICE USE ONLY
_____June 7, 2019_____
Date Received
_____1:04pm_____
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Deadline for submission: June 10, 2019 - 5:00 p.m.

Recognizing there are significant valuable modifications warranted in the current Minnesota Pharmacy Practice Act, MN Chapt. 151, MPhA has been actively advocating and searching for strategies to help improve our "scope of practice" A great deal of strong work at the legislature has occurred, in collaboration with the Minnesota Pharmacy Alliance, since the release of the white paper "Enabling Pharmacists to Respond to the Health Needs of Minnesota Communities", from the Center for Leading Healthcare Change. An overwhelming majority of the recommendations in this document, suggested a need for significant deregulation to remove barriers, and the desire for language which broadens our "scope of practice." However, a thorough revision of the entire practice act, as envisioned in the white paper hasn't come to fruition. Equally important in this effort will require the complete repeal and replacement of our current pharmacy rules chapters. Just as seen in other states recently, MPhA should continue working towards a broader scope of pharmacy practice, allowing for improved patient care and safety.

A health professional's scope of practice consists of the activities that he or she is authorized to provide in his or her state.

- Physicians scope is generally broad, anything not specifically prohibited is considered permitted. "born free"
- Non-physicians scope is restricted, anything not specifically permitted is generally considered prohibited. "born in captivity"
- This forces non-physicians to chip out little crumbs of practice to add to their scope, that have been tirelessly vetted, rather than allowing them to practice to the level of their clinical ability or seek innovations to improve public health and safety. The pharmacy profession is constantly itemizing the services it can provide and this process is continuously making the gap between ability and authority larger.

Piecemeal changes to "scope of practice" laws can't keep up. From 1/11 to 12/12, over 2 years, 1795 scope of practice bills were introduced in US state bodies, with only 19% success. The process and timelines to make significant and meaningful practice change is long and difficult. A commonly sighted, recent example of this was the addition vaccinations to pharmacists scope. It took from 1994 to 2009 for it to become widely recognized in all 50 states, and even with this, states including Minnesota still have arbitrary restrictions on which immunizations pharmacists can provide. Another more current example of the painful legal process of change, would be our national push for provider status.

It is argued and reasonable to believe external market forces/extralegal means would be a greater authority in determining a non-physicians clinical ability. These might include: (1) consumer acceptance and demand; (2) payer policies; (3) private accreditation or credentialing; (4) facility policies; (5) liability insurance; and (5) professional ethics and self-restraint, among other factors. Adams AJ. Toward permissionless innovation in health care. J Am Pharm Assoc. 2015; 55:359–62.

Permissionless innovation is a concept advanced by economists at George Mason University. It refers to the notion that "experimentation with new technologies and business models should generally be permitted by default." To date permissionless innovation has been embraced mostly by the digital technology world, however has recently been considered by the Idaho Board of Pharmacy as a vision of understanding in their complete overhaul to Idaho's practice act and rules book. The board along with policy makers were able to decrease regulatory language and burden by nearly 50% over a two year period, using the vision of permissionless innovation.

Some concepts to consider:

Precautionary Principle	Permissionless Innovation
• The belief that new practices or innovations should be curtailed or disallowed until their proponents can prove that they will not cause harm. • Fear of worst-case scenarios and "what ifs" • Prescriptive regulation to prevent potential harms	• The belief that experimentation with new technologies and practice models should generally be permitted by default; burden of proof on proving harm • Allows bottom-up solutions and breathing room for innovation • Back-end accountability

When scope of practice regulations are prescriptive and restrictive, efforts to innovate takes an act of legislature, subjecting it to political considerations, rather than evidence based care.

Regulations should keenly focus on standards that "must" occur, as opposed to "how" it occurs, or "where" it occurs.

The Practice Act should focus on the "practice" of pharmacy, not the "business" of pharmacy.

Barriers to reform might include:

- a fear of every "what if"
- business or professional concerns masquerading as "safety concerns"
- judging policy by ones own interests
    - "I don't want to"
    - "I wouldn't let my tech's do"

Adam Thierer author of Permissionless Innovation: The Continuing Case for Comprehensive Technological Freedom, suggests 3 reforms which should resonate with MPhA's strategies to broaden practice:

1) **The Innovator's Presumption**: Any person or party (including a regulatory authority) who opposes a new technology or service shall have the burden to demonstrate that such proposal is inconsistent with the public interest.

2) **The Sunsetting Imperative**: Any existing or newly imposed technology regulation should include a provision sunsetting the law or regulation within two years.

3) **The Parity Provision**: Any operator offering a similarly situated product or service should be regulated no more stringently than its least regulated competitor.

Understandingly, with the freedom to grow outside of regulatory burden, strong accountability to a standard of care is necessary. The Minnesota Board of Pharmacy exists to promote, preserve, and protect the public health, safety, and welfare by fostering the safe distribution of pharmaceuticals and the provision of quality pharmaceutical care to the citizens of Minnesota. MPhA should support and encourage a strong regulatory authority to ensure the public of safety entrusted to the profession within a common standard of care.