

American Pharmacists AssociationHouse of Delegates – March 18-21, 2022

To be completed by the Office of the Secretary of the House of Delegates

Item No. 9

Date received: 2/16/2022 Time received: 7:05 PM

NEW BUSINESS (To be submitted and introduced by Delegates only)

Introduced by: <u>Lauren Ostlund (MN), Madeleine Davies (MN), Riley Larson (MN), Lorri Walmsley (AZ), Jennifer Adams (ID)</u>
(Name)

<u>2/16/2022</u>	Arizona, Idaho, Minnesota Delegations
(Date)	(Organization)

Subject: Pharmacists' application of professional judgment

Motion: Adopt the new proposed policy regarding pharmacists' application of professional judgment

Pharmacist's application of professional judgment:

- 1) APhA <u>supports</u> pharmacists, as licensed health care professionals, in their unrestricted use of professional judgment throughout the course of their practice to act in the best interest of patients.
- 2) APhA <u>asserts</u> that a pharmacist's independent medication review and use of professional judgment in the medication distribution process is essential to patient safety.
- 3) APhA <u>opposes</u> the creation of state and federal laws that negate a pharmacist's right to exercise professional judgment in the best interest of patients' clinical outcomes.
- 4) APhA <u>calls for civil</u>, criminal, and legal liability protections for pharmacists and pharmacies if the right to use professional judgment is limited by state and federal laws.

Background:

There has been an emerging trend with recently proposed state legislation across the country that is potentially limiting or prohibiting a pharmacist's use of professional judgment regarding medications they deem clinically inappropriate. While the intent of much of the legislation targets off-label dispensing during the pandemic, several versions are more expansive and would apply to pharmacy practice beyond the pandemic. If passed, these bills create a dangerous precedent undermining a pharmacist's application of professional judgment. The pharmacists' role in medication review and patient safety is imperative within the health care team to protect patients from potential harm. These pieces of legislation are in direct conflict with many state and federal laws^{25, 26} requiring

pharmacists to conduct drug utilization reviews and to assess medication safety in the course of prescription dispensing.

Several versions of state legislation have liability protections for pharmacies and pharmacists, but many do not. Regardless of civil and criminal liability protections, these potential laws may still create internal conflicts for pharmacists from an ethical and moral responsibility. Limiting the professional judgment to refuse to fill a prescription with a clinical conflict that cannot be resolved, and may cause harm to a patient, places the pharmacist in an ethical dilemma to either knowingly break the law or potentially harm a patient. Further, some third party plans have policies limiting the payment for off-label uses, which may result in third party chargebacks causing additional financial liabilities and harm to pharmacies. Most significantly, these pieces of legislation may result in harm to patients by limiting the pharmacists' application of professional judgment.

When reviewing existing APhA policies, we contemplated if the current policy was sufficient, if a modification was needed or if a new policy item would be most appropriate. The following policies were considered for potential modification during our process: Pharmacist Conscience Clause, Code of Ethics for Pharmacists, Mission of Pharmacy, Potential Conflicts of Interest in Pharmacy Practice, Pharmacy Practice: Professional Judgement, Non-FDA-Approved Drugs and Patient Safety, Regulatory Infringements on Professional Practice, and Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents. While there were policies that partially fit the authors' intent, there was not a policy that was all-inclusive and would be suitable to defend pharmacists' judgment against this type of legislative attack. Therefore, a new policy statement from APhA is imperative to support pharmacists' right to use professional judgment when reviewing medications for safety and efficacy. Furthermore, this policy is paramount to protect public safety and to prevent potential reputational harm to the profession.

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Current APhA Policy & Bylaws:

Pharmacist Conscience Clause (1998, 2004)

- 1. APhA recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure patient's access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal.
- 2. APhA shall appoint a council on an as needed basis to serve as a resource for the profession in addressing and understanding ethical issues.

(JAPhA. 38(4):417; July/August 1998) (JAPhA. NS44(5):551; September/October 2004) (Reviewed 2010) (Reviewed 2015)

Code of Ethics for Pharmacists (1994)

Preamble: Pharmacists are health professionals who assist individuals in making the best use of medications. This Code, prepared and supported by pharmacists, is intended to state publicly the principles that form the fundamental basis of the roles and responsibilities of pharmacists. These principles, based on moral obligations and virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

- I.A pharmacist respects the covenant relationship between the patient and pharmacist. Considering the patient-pharmacist relationship as a covenant means that a pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust.
- II.A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner. A pharmacist places concern for the well-being of the patient at the center of professional practice. In doing so, a pharmacist considers needs stated by the patient as well as those defined by health science. A pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.
- III.A pharmacist respects the autonomy and dignity of each patient. A pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health. A pharmacist communicates with patients in terms that are understandable. In all cases, a pharmacist respects personal and cultural differences among patients.
- IV.A pharmacist acts with honesty and integrity in professional relationships. A pharmacist has a duty to tell the truth and to act with conviction of conscience. A pharmacist avoids discriminatory practices, behavior or work conditions that impair professional judgment, and actions that compromise dedication to the best interests of patients.
- V.A pharmacist maintains professional competence. A pharmacist has a duty to maintain knowledge and abilities as new medications, devices, and technologies become available and as health information advances.
- VI.A pharmacist respects the values and abilities of colleagues and other health professionals. When appropriate, a pharmacist asks for the consultation of colleagues or other health professionals or refers the patient. A pharmacist acknowledges that colleagues and other health professionals may differ in the beliefs and values they apply to the care of the patient.
- VII.A pharmacist serves individual, community, and societal needs. The primary obligation of a pharmacist is to individual patients. However, the obligations of a pharmacist may at times extend beyond the individual to the community and society. In these situations, the pharmacist recognizes the responsibilities that accompany

these obligations and acts accordingly.

VIII.A pharmacist seeks justice in the distribution of health resources. When health resources are allocated, a pharmacist is fair and equitable, balancing the needs of patients and society. (Adopted October 27, 1994)

Mission of Pharmacy (1991)

APhA affirms that the mission of pharmacy is to serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes. (Am Pharm. NS31(6):29; June 1991) (Reviewed 2004) (Reviewed 2010) (Reviewed 2015) (Reviewed 2018)

Potential Conflicts of Interest in Pharmacy Practice (2011)

- 1. APhA reaffirms that as health care professionals, pharmacists are expected to act in the best interest of patients when making clinical recommendations.
- 2. APhA supports pharmacists using evidence-based practices to guide decisions that lead to the delivery of optimal patient care.
- 3. APhA supports pharmacist development, adoption, and use of policies and procedures to manage potential conflicts of interest in practice.
- 4. APhA should develop core principles that guide pharmacists in developing and using policies and procedures for identifying and managing potential conflicts of interest. (JAPhA. NS51(4): 482; July/August 2011) (Reviewed 2016)

Non-FDA-Approved Drugs and Patient Safety (2009)

- 1. APhA calls for education and collaboration among health professional organizations, federal agencies, and other stakeholders to ensure that all manufacturer, distributor, and repackaged marketed prescription drugs used in patient care have been FDA-approved as safe and effective.
- 2. APhA supports initiatives aimed at closing regulatory and distribution-system loopholes that facilitate market entry of new prescription drugs products without FDA approval.
- 3. APhA encourages health professionals to consider FDA approval status of prescription drug products when making decisions about prescribing, dispensing, substitution, purchasing, formulary development, and in the development of pharmacy/medical education programs and drug information compendia. (JAPhA. NS49(4):492; July/August 2009) (Reviewed 2014) (Reviewed 2019)

Regulatory Infringements on Professional Practice (2001, 1990)

- 1. APhA, in cooperation with other national pharmacy organizations, shall take a leadership role in the establishment and maintenance of standards of practice for existing and emerging areas in the profession of pharmacy.
- 2. APhA encourages a cooperative process in the development, enforcement, and review of rules and regulations by agencies that affect any aspect of pharmacy practice, and this process must utilize the expertise of affected pharmacist specialists and their organizations.
- 3. APhA supports the right of pharmacists to exercise professional judgment in the implementation of standards of practice in their practice settings. (Am Pharm. NS30(6):45; June 1990) (JAPhA. NS4(5)(suppl 1):S7; September/October, 2001) (Reviewed 2007) (Reviewed 2012) (Reviewed 2017) (Reviewed 2020)

Controlled Substances and Other Medications with the Potential for Abuse and Use of Opioid Reversal Agents (2014)

- 1. APhA supports recognition of pharmacists as the health care providers who must exercise professional judgment in the assessment of a patient's conditions to fulfill corresponding responsibility for the use of controlled substances and other medications with the potential for misuse, abuse, and/or diversion.
- 2. APhA supports recognition of pharmacists as the health care providers who must exercise professional judgment in the assessment of a patient's conditions to fulfill corresponding responsibility for the use of controlled substances and other medications with the potential for misuse, abuse, and/or diversion.
- 3. APhA supports pharmacists' access to and use of prescription monitoring programs to identify and prevent drug misuse, abuse, and/or diversion.

- 4. APhA supports the development and implementation of state and federal laws and regulations that permit pharmacists to furnish opioid reversal agents to prevent opioid-related deaths due to overdose.
- 5. APhA supports the pharmacist's role in selecting appropriate therapy and dosing and initiating and providing education about the proper use of opioid reversal agents to prevent opioid-related deaths due to overdose.

(JAPhA. 54(4):358; July/August 2014) (Reviewed 2015)(Reviewed 2018) (Reviewed 2021)

Accountability of Pharmacists (2020)

- 1. APhA affirms pharmacists' professional accountability within their role in all practice settings.
- 2. APhA advocates that pharmacists be granted and accept authority, autonomy, and accountability for patient-centric actions to improve health and medication outcomes, in coordination with other health professionals, as appropriate.
- 3. APhA reaffirms 2017 Pharmacists' Role Within Value-based Payment Models and supports continued expansion of interprofessional patient care models that leverage pharmacists as accountable members of the health care team.
- 4. APhA advocates for sustainable payment and attribution models to support pharmacists as accountable patient care providers.
- 5. APhA supports continued expansion of resources and health information infrastructures that empower pharmacists as accountable health care providers.
- 6. APhA supports the enhancement of comprehensive and affordable professional liability insurance coverage that aligns with evolving pharmacist accountability and responsibility. JAPhA. 2020; 60(5): e9

Pharmacy Practice: Professional Judgment (2004, 1977)

- 1. APhA supports a pharmacist's right, regardless of place or style of practice, to exercise individual professional judgment and complete authority for those individual professional responsibilities assumed.
- 2. APhA supports decision-making processes that ensure the opportunity for input by all pharmacists affected by the decisions.

(JAPhA. NS17:463; July 1977) (JAPhA NS44(5):551; September/October 2004) (Reviewed 2007) (Reviewed 2012) (Reviewed 2017) (Reviewed 2020)

New Business Items are due to the Speaker of the House by **February 16, 2022** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at <a href="https://example.com/house/ho