

## BOARDS AND COMMISSIONS

### Board of Pharmacy

#### (Amended After Comments)

#### 201 KAR 2:450. Unprofessional conduct of a pharmacy permit holder.

RELATES TO: KRS 315.030, 315.025, 315.0351, 315.121, 315.131, 337.355, 337.365

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: This administrative regulation is necessary to ensure that permit holders are provided notice of what may be considered unprofessional conduct. This administrative regulation is required to ensure that the public is protected from pharmacy practices that lead to errors and patient harm, including practices that stem from demands a permit holder places on pharmacists that prevents them from responsibly practicing pharmacy.

#### Section 1. Definitions.

(1) "Provision of pharmacy services" means the services provided to a patient from a licensee, permit holder or registrant.

(2) "Safe practices" mean practices that aim to prevent and reduce risks, errors and harm or threat of harm to the public.

#### Section 2. Unprofessional Conduct. ~~It shall be~~ Unprofessional conduct for a pharmacy permit holder includes, but is not limited to:

(1) Introducing or enforcing ~~Introduce or enforce~~ policies and procedures related to the provision of pharmacy services in a manner that results in deviation from safe practices;

(2) Unreasonably preventing or restricting ~~prevent or restrict~~ a patient's timely access to patient records or ~~essential~~ pharmacy services;

(3) Failing ~~Fail~~ to identify and resolve conditions that interfere with a pharmacist's ability to practice competently ~~with competency~~ and safely ~~safety~~ or creating ~~create~~ an environment that jeopardizes patient care, including by failing to provide appropriate staffing, training and appropriately requested rest and meal periods as permitted by KRS 337.355 and KRS 337.365; ~~and~~

(4) Repeatedly ~~habitually~~, or knowingly failing ~~fail~~ to provide resources appropriate for a pharmacist of reasonable diligence to safely complete professional duties and responsibilities under state and federal laws and regulations; and ~~including, but not limited to:~~

~~{(a)} {Drug utilization review;}~~

~~{(b)} {Immunization;}~~

~~{(c)} {Counseling;}~~

~~{(d)} {Verification of the accuracy of a prescription; and}~~

~~{(e)} {All other duties and responsibilities of a pharmacist under state and federal laws and regulations.}~~

(5) Requiring a pharmacist to operate a pharmacy with policies and procedures that deviate from safe practices; and

(6) Taking disciplinary action or otherwise retaliating against a licensee or registrant that reports or refuses to operate a pharmacy that deviates from safe practices or a pharmacy that deviates from state and federal laws and regulations.

*CHRIS HARLOW, Pharm.D.; Executive Director*

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## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

**Contact Person: Christopher Harlow**

**(1) Provide a brief summary of:**

**(a) What this administrative regulation does:**

This administrative regulation sets forth actions which constitute unprofessional conduct by a pharmacy permit holder.

**(b) The necessity of this administrative regulation:**

This administrative regulation is necessary to place pharmacy permit holders on notice of what constitutes unprofessional conduct.

**(c) How this administrative regulation conforms to the content of the authorizing statutes:**

This administrative regulation, authorized by KRS 315.191(1)(a), establishes actions which constitute unprofessional conduct of a pharmacy permit holder. This conforms to the authorizing statute because the authorizing statute gives the board authority to promulgate regulations to regulate and control pharmacies.

**(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:**

This administrative regulation will ensure that pharmacy permit holders are placed on notice of what constitutes unprofessional conduct. The Board is authorized to promulgate regulations to regulate and control pharmacies.

**(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:**

**(a) How the amendment will change this existing administrative regulation:**

N/A

**(b) The necessity of the amendment to this administrative regulation:**

N/A

**(c) How the amendment conforms to the content of the authorizing statutes:**

N/A

**(d) How the amendment will assist in the effective administration of the statutes:**

N/A

**(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:**

The board anticipates permit holders and licensees will be affected, as permit holders will need to comply with this regulation to ensure safe conditions for the public as well as their employees.

**(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:**

**(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:**

1. Licensees, permit holders and registrants will have to familiarize themselves with this new regulation. 2. This administrative regulation sets forth actions which constitute unprofessional conduct by a pharmacy permit holder. 3. The board will help educate identified entities of this new regulation.

**(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):**

There are no expected costs for the entities identified to comply with this new regulation.

**(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):**

This new regulation will ensure that the public is protected from unsafe practices. Moreover, pharmacists will be provided sufficient conditions to perform their jobs safely.

**(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:**

**(a) Initially:**

No costs will be incurred.

**(b) On a continuing basis:**

No costs will be incurred.

**(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:**

Board revenues from pre-existing fees provide the funding to enforce the regulation.

**(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:**

No increase in fees or funding will be required because of this new regulation.

**(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:**

This administrative regulation does not establish fees or directly or indirectly increase any fees.

**(9) TIERING: Is tiering applied?**

Tiering is not applied because this new regulation is applicable to all permit holders.

## FISCAL NOTE

**(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?**

The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

**(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.**

KRS 315.191(a)

**(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.**

No answer provided.

**(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?**

This administrative regulation will not generate revenue for the board in the first year.

**(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?**

This administrative regulation will not generate revenue for the board in subsequent years.

**(c) How much will it cost to administer this program for the first year?**

No costs are required to administer this program for the first year.

**(d) How much will it cost to administer this program for subsequent years?**

No costs are required to administer this program for subsequent years.

**Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.**

**Revenues (+/-):0**

**Expenditures (+/-):0**

**Other Explanation:**

none

**(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.**

**(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?**

There will be no cost savings from this administrative regulation.

**(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?**

There will be no cost savings for subsequent years.

**(c) How much will it cost the regulated entities for the first year?**

There will be no cost to regulated entities for the first year.

**(d) How much will it cost the regulated entities for subsequent years?**

There will be no cost to regulated entities for subsequent years.

**Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.**

**Cost Savings (+/-):0**

**Expenditures (+/-):0**

**Other Explanation:**

none

**(5) Explain whether this administrative regulation will have a major economic impact, as defined below.**

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This administrative regulation does not have major economic impact.