EXHIBIT L

STATE BOARD OF PHARMACY

SUBJECT: Regulation 7; Drug Products/Prescriptions

DESCRIPTION: The proposed changes define how pharmacists may therapeutically substitute a therapeutically equivalent product if allowed by a prescriber in accordance with Act 274 of 2013.

PUBLIC COMMENT: A public hearing was held on October 8, 2014, and the public comment period expired on that date.

The following groups and individuals contributed comments to the Board of Pharmacy during the public comment period and public hearing on proposed changes to Regulation 7.

Against the Proposed Changes

Pharmaceutical Research and Manufacturers of America, PhRMA
Letter from John A. Murphy III, Assistant General Counsel
Appearance by Leo Hauser and Marvin Parks with comments

Written comments by PhRMA took specific issue with the statutory definition of Therapeutic Substitution by comparing it to the FDA definition of therapeutic substitution from the Orange Book which evaluates the equivalency of generic drugs that contain the same active ingredients. They further state that this should not apply to biosimilar products since the FDA does not show them to be therapeutically equivalent. Verbal comments from Leo Hauser and supported by Marvin Parks supported the same points as the letter they delivered to the Board.

RESPONSE: The board and staff asked clarifying questions of Mr. Hauser and Mr. Parks and inquired as to why PhRMA specifically testified that they were not against the original house bill HB 1185 with changes that were made in the language of the bill during the public comment process in the Arkansas legislature. The board members also questioned what problems PhRMA had identified in other states with similar processes approved that would show validity to their concerns expressed with their language. In response, the representatives states that they did not know why there had been a change in this opinion so that PhRMA was now against this regulation change nor were they aware of any other places this was allowed. Board staff pointed out that a similar practice has been in place in Kentucky for over a decade and that the definition of Therapeutic Equivalence is the same language that was incorporated into statute with HB1185.

National Alliance on Mental Illness
Letter from Andrew Sperling, Director of Legislative Advocacy
Appearance by Kim Arnold, Executive Director, NAMI Arkansas

NAMI pointed out a 3 part plan of Time, Safety and Trust as their message to take care of patients in their letter which would include their assertion that time is more important to

psychiatric patients and that if a therapeutic substitution cannot occur that the pharmacist must fill their original prescription giving it the highest priority order status overriding other prescriptions in process or waiting customers to avoid wait times for the mental health prescription. They suggested that therapeutically substituted prescriptions should have emergency listings for the local area attached for patients and suggested a requirement to send multiple verifications to the prescriber until receipt is acknowledged from the prescriber. NAMI also suggested that this process involves a different level of trust between a pharmacist and patient and suggested the printed definition of "therapeutically equivalent" be attached to the prescription as well as a written signed certification that the prescription has been therapeutically substituted. They also suggested that the pharmacy should have "appropriate, scientific documentation" that demonstrates the substituted prescription provides the defined effects.

NAMI also requested that psychotropic medications be excluded completely from this process in part due to concerns that this process will cost the state of Arkansas more money in the long run.

RESPONSE: The board thanked Ms. Arnold for her comments.

Bill Phillips and Bradley Phillips
Appearance on behalf of DaySprings Treatment

Mr. Phillips appeared on behalf of DaySprings Treatment asking that this regulation not apply to psychotropic medications due to concerns regarding effects on patients.

RESPONSE: The board thanked the commenters for their comments.

Concerned Citizen, Family Support Partner with AO/DaySpring Behavioral Health
Email sent

This concerned citizen outlined her concerns that, "Therapeutic substitution allows third parties to overrule this decision-making process, without prior approval of the patient, and only requires physician notification AFTER the substitution has been dispensed."

RESPONSE: The regulation defines this as a process where these decisions cannot be made or even considered without the approval of the treating prescriber as well as the agreement of the patient.

Biotechnology Industry Organization
Letter from Patrick Plues, Senior Director, State Government Affairs

Concerns were expressed that this regulation could be interpreted to extend to biological products or biosimilars and that the regulation does not establish the therapeutic equivalence in accordance with accepted scientific and regulatory standards.

RESPONSE: The board accepted these comments into the record.

Arkansas Psychiatric Society

Letter from Bonnie L. Cook, Executive Director, Arkansas Psychiatric Society

The Arkansas Psychiatric Society was concerned that the regulation changes would grant pharmacists, albeit with "physician consent," prescribing authority without a full patient medical history let alone medical training. They also expressed concern that individual drugs within the therapeutic classes used to treat psychiatrically ill patients have very different clinical indications, mechanisms of action, and side effect profiles as well as expressing concerns that this regulation establishes a new definition of therapeutic equivalence which has no precedence or context for practicing physicians. They expressed concern that physicians are not informed as to what they are authorizing and that they were concerned if patients utilizing psychotropic drugs are at all times cognitively capable of understanding the pharmaceutical transaction.

RESPONSE: The board accepted these comments into the record.

Depression and Bipolar Support Alliance

Letter from Allen Doederlein, President, Depression and Bipolar Support Alliance

DBSA shared concerns that this regulation undermines a person's ability to choose the right treatment that a clinician identifies as the best fit for a serious, life-threatening condition. They were concerned that this eliminates the sanctity of the patient/doctor relationship by allowing pharmacists to substitute medications without prior physician approval, therefore jeopardizing the health of individuals living with mood disorders and expressed their thoughts that antidepressants and anti-psychotic medications should be exempt from pharmacist substitution.

RESPONSE: The board accepted these comments into the record.

Mental Health America

Letter from Nathaniel Counts, J.D., Policy Associate, Mental Health America

Mental Health America made 3 points, that this regulation has no applicability to psychotropic medications, that therapeutic substitution for these medications would be harmful for individuals and that therapeutic substitution would be expensive for the State of Arkansas due to potential emergency department visits, hospitalizations, loss of productivity and potential incarceration.

RESPONSE: The board accepted these comments into the record.

For the Proposed Changes

Express Scripts

Appearance by Dennis McAllister, R.Ph., D.Ph., FASHP
Senior Director, Pharmacy Regulatory Affairs Express Scripts, Inc.
Member Arizona State Board of Pharmacy

Dr. McAllister spoke in favor of these changes pointing out that this puts specific language in place to reflect the practice that many pharmacists and prescribers have had for decades albeit unofficial. He went on to compliment the Board and our legislature for taking a proactive role in pursuing this method to help pharmacists and prescribers to serve their patients with speed in giving appropriate service of their needed medications while protecting the prescriber's intent of therapy with these regulations. He spoke of his role not only with Express Scripts but also as a member of the Arizona Board of Pharmacy where they are pursuing similar language to allow 'Preferred Drug List Compliance' as they have named this process. He pointed out that in his experience in these roles as well as many others including Past President of the National Association of Boards of Pharmacy, Fellow of the American Society on Health Systems Pharmacists and a former pharmacy owner, that pharmacists will always try to do the right thing to help their patients and that this rule lets the prescriber retain control of the process to actively approve it when they feel it is appropriate for their patients.

RESPONSE: The board thanked Dr. McAllister for his comments.

Arkansas Pharmacists Association

Scott Pace, Pharm.D., J.D.
Chief Operating Officer, Arkansas Pharmacists Association

Dr. Pace spoke in favor of this regulation change as well. Dr. Pace pointed out that this regulation change puts into regulation what pharmacists are already doing in order to deal with formulary management for insurance companies and pharmacy benefit management companies. He went on to comment that the specific issues of concern for specific patient populations were the very reason this regulation and the establishing statute were worded in this manner so that nay prescriber with concerns for their patients regarding therapeutic interchange of medications such as psychoactive medications would not allow therapeutic substitution for those patients. Dr. Pace pointed out three specific issues in favor of this regulation change that were backed by the Arkansas Pharmacists Association and Arkansas Medical Society during the public hearing process on the original house bill: (1) the prescriber retains the control over approving this process; (2) the patient has to agree for the substitution to take place; and (3) the pharmacist must provide a cost savings to the patient to complete the substitution.

RESPONSE: The board thanked Dr. Pace for his comments.

After all of these comments were accepted, the Board also discussed issues regarding how a prescriber could issue the notification that therapeutic substitution could be done. The Board pointed out that prescribers have long had the ability to express their orders verbally including instructions such as "do not substitute, brand name medically necessary" or similar instructions to relay that a pharmacist could not generically substitute a prescription. Physicians have the ability to transmit orders verbally for virtually any medication or order including controlled substances. This discussion led to the determination that restricting the prescriber's ability to choose therapeutic substitution as a viable alternative for a patient's care when giving a prescription verbally would cause unavoidable delays between the pharmacist and prescriber until the pharmacist could

speak with the prescriber again and could also cause adverse issues for the patients. One of the speakers for this regulation change even spoke of a specific instance with his family where a loved one needed a prescription for an albuterol inhaler and since the one available was not a generic equivalent, the pharmacist could not substitute it until they were able to contact the prescriber even though the medications in that instance were not only therapeutic equivalents but also held the same amounts of the same active ingredients yet caused an undue delay for a patient needing albuterol for their trouble breathing.

The Board went on to discuss the fact that these points were all discussed at length during the public hearing process with the legislature at the time that HB1185 was being considered in committees and were largely comments against language that already exists in statute that can be used by pharmacists.

The Board also requested a show of hands for those present in the audience to reflect how many people in the audience were there in favor of the proposed regulation change and then those in attendance against the proposed regulation change. There were approximately 35 individuals present in favor of these proposed changes and 5 present who were against the proposed regulation changes.

At the end of the discussion, the Board voted unanimously to adopt this regulation as proposed without any substantive changes made to the proposed regulation change.

The proposed effective date is November 30, 2014.

CONTROVERSY: The board expects there will be testimony against this regulation change to match testimony against the bill which was passed by the General Assembly. While this could be seen as controversial, this practice is already part of the Arkansas code and more specifically, the Arkansas Pharmacy Practice Act.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: These rules implement Act 274 of 2013, which allows a prescription to authorize the pharmacist to substitute a therapeutically equivalent drug that is at a lower cost to the patient and communicate that authorization by any generally accepted means of communication of a prescription from a prescriber to a pharmacist. Ark. Code Ann. § 17-92-101(17). The Arkansas State Board of Pharmacy is authorized to make reasonable rules and regulations, not inconsistent with law, to carry out the purposes and intentions of § 17-92-101 *et seq.*, and the pharmacy laws of this state that the board deems necessary to preserve and protect the public health. Ark. Code Ann. § 17-92-205(a).

Rec. 10-8-14

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

DEPARTMENT/AGENCY____Arkansas State Board of Pharmacy_____
DIVISION_____
DIVISION DIRECTOR____John Clay Kirtley, Pharm.D., Exec. Director_____
CONTACT PERSON_____ John Clay Kirtley, Pharm.D., Exec. Director _____
ADDRESS__322 South Main Street, Suite 600, Little Rock, AR 72201_____
PHONE NO._501-682-0190_____**FAX NO.**_501-682-0195___
E-MAIL_john.kirtley@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING _John Clay Kirtley, Pharm.D., Exec.Dir
PRESENTER E-MAIL __john.kirtley@arkansas.gov_____

INSTRUCTIONS

A. Please make copies of this form for future use.
B. Please answer each question completely using layman terms. You may use additional sheets, if necessary.
C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

RECEIVED
OCT 13 2014
BUREAU OF LEGISLATIVE RESEARCH

Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
Room 315, State Capitol
Little Rock, AR 72201

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1. What is the short title of this rule?

   Regulation 7- Drug Products/Prescriptions

2. What is the subject of the proposed rule?

   Therapeutic Substitution of Prescriptions

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes __ No_X__

If yes, please provide the federal rule, regulation, and/or statute citation.

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes_____ No__X____

If yes, what is the effective date of the emergency rule? _____

When does the emergency rule expire? _____

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes_____ No_____

5. Is this a new rule? Yes___ No__X___ If yes, please provide a brief summary explaining the regulation.

Does this repeal an existing rule? Yes_____ No__X___ If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does.

Is this an amendment to an existing rule? Yes_X__No___If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give Arkansas Code citation.

Ark. Code Ann. §§ 17-92-205 and 17-92-316

7. What is the purpose of this proposed rule? Why is it necessary?

The proposed changes will amend Regulation 7 to allow pharmacists to therapeutically substitute prescription drugs when allowed by a prescriber as described in Arkansas Code § 17-92-101 and Act 274 of 2013.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).
www.arkansas.gov/asbp/lawbook.html

9. Will a public hearing be held on this proposed rule? Yes__X___ No_____
If yes, please complete the following:
Date:__10/8/2014 _____ _____

Time:___9:00 AM_____
Place:_ Arkansas State Board of Pharmacy, 101 E. Capitol Suite 218, Little Rock, AR 72201

10. When does the public comment period expire for permanent promulgation? (Must provide a date.) _____10/8/2014_____

11. What is the proposed effective date of this proposed rule? (Must provide a date.) _____11/30/2014 __Pending Legislative Review _____

12. Do you expect this rule to be controversial? Yes_X___ No _____ If yes, please explain.
We expect that there will be testimony against this regulation change to match testimony against the bill which was passed by the general assembly. While this could be seen as a controversial bill, this practice is already part of the Arkansas code and more specifically the Arkansas Pharmacy Practice Act.

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

Arkansas Pharmacists Association	For
Arkansas Medical Society	For
Pharmaceutical Research and Manufacturers of America, PhRMA Leo Hauser and Marvin Parks	Against
National Alliance on Mental Illness	Against
Bill Phillips and Bradley Phillips, DaySprings Treatment	Against
Concerned Citizen, Family Support Partner with AO/DaySpring Behavioral Health Services	Against
Biotechnology Industry Organization	Against
Arkansas Psychiatric Society	Against
Depression and Bipolar Support Alliance	Against
Mental Health America	Against
Audience members	Approximately 35 For
	5 Against

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas State Board of Pharmacy
DIVISION

PERSON COMPLETING THIS STATEMENT
John Clay Kirtley, PharmD, Executive Director
TELEPHONE NO. 501-682-0190 **FAX NO.** 501-682-0195
EMAIL: john.kirtley@arkansas.gov

To comply with Act 1104 of 1995, please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE
Regulation 7 -- Drug Products/Prescritpions

1. Does this proposed, amended, or repealed rule have a financial impact?
   Yes ____, ____ No ___x_____

2. Does this proposed, amended, or repealed rule affect small businesses?
   Yes ___ No __x___

   If yes, please attach a copy of the economic impact statement required to be filed with the Arkansas Economic Development Commission under Arkansas Code § 25-15-301 et seq.

3. If you believe that the development of a financial impact statement is so speculative as to be cost prohibited, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please give the incremental cost for implementing the rule. Please indicate if the cost provided is the cost of the program.

Current Fiscal Year		**Next Fiscal Year**	
General Revenue	0	General Revenue	0
Federal Funds	0	Federal Funds	0
Cash Funds	0	Cash Funds	0
Special Revenue	0	Special Revenue	0
Other (Identify)	0	Other (Identify)	0
Total	0	Total	0

5. What is the total estimated cost by fiscal year to any party subject to the proposed, amended, or repealed rule? Identify the party subject to the proposed rule and explain how they are affected.

Current Fiscal Year	**Next Fiscal Year**
$____0____	$____0____

6. What is the total estimated cost by fiscal year to the agency to implement this rule? Is this the cost of the program or grant? Please explain.

Current Fiscal Year	**Next Fiscal Year**
$____0____	$____0____

ARKANSAS STATE BOARD OF PHARMACY

Board of Pharmacy Regulation 07 –Drug Products/Prescriptions

Summary of the Substantive Changes

Proposed changes will adopt language defining how pharmacists may therapeutically substitute a therapeutically equivalent product if allowed by a prescriber in accordance with Arkansas Act 274 of 2013.