EXAMPLE

PUBLIC HEARING FOR SUBSTANTIVE CHANGES

POTPOURRI

Department of Health and Hospitals Board of Pharmacy

Public Hearing—Substantive Changes to Proposed Rule; Collaborative Drug Therapy Management (LAC 46:LIII.523)

The board published a Notice of Intent to promulgate §523, Collaborative Drug Therapy Management in the November 20, 2006 edition of the *Louisiana Register* (LR 33:2135-2139). The notice solicited comments and testimony. As a result of its analysis of the comments and testimony received, the board proposes to amend certain portions of the proposed Rule. Within Subsection A, the board proposes to amend the definition of the term *Disease Specific Drug Therapy* by modifying the description of the treatment of asthma and deleting the references to hypertension and obesity. Further, we propose to define four additional terms. Within Subsection D, the board proposes to establish minimum educational qualifications for pharmacists collaborating in the management of anti-coagulant drug therapy. Further, we propose to establish certain restrictions for collaborative drug therapy management agreements. Finally, the board proposes to replace the current provision relative to immunization programs at the Office of Public Health in the Department of Health and Hospitals with a different provision recognizing the ability of that office to promulgate their own rules on the subject of immunizations.

Taken together, all of these proposed amendments will closely align the proposed Rule with the proposed Rule on the same topic as published by the Louisiana State Board of Medical Examiners in the November 2006 edition of the *Louisiana Register* (LR 32:2125-2133). The alignment of these Rules will permit the development and implementation of collaborative drug therapy management agreements between physicians and pharmacists. No fiscal or economic impact will result from the amendments proposed in this notice.

Title 46 PROFESSIONAL AND OCCUPATIONAL STANDARDS Part LIII. Pharmacists

Chapter 5. [tab]Pharmacists

§523. [tab]Collaborative Drug Therapy Management

A. [tab]Definitions. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section.

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Disease Specific Drug Therapy—a specific drug or drugs prescribed by a physician for a specific patient of such physician generally accepted within the standard of care for treatment of one of the following diseases or conditions:

a. [tab] treatment and prevention of arterial and venous clot propagation and disease, i.e., anti-coagulant therapy;

b. **[tab]**treatment and prevention of diabetes;

c. [tab]adjustment of medication administered by inhalant for treatment of asthma;

d. [tab]treatment and prevention of dyslipidemia;

e. [tab]smoking cessation therapy;

f. [tab]administration of disease specific vaccines to patients 16 years of age or older; and

g. [tab]such other drugs, diseases or conditions as may be subsequently recommended by the advisory committee and approved by the board.

Drug—

a. **[tab]**a any substance recognized as a drug in the official compendium, or supplement thereto, designated by the board for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in humans or animals;

b. **[tab]** any substance intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals; or

c. [tab]any substance other than food intended to affect the structure or any function of the body of humans or other animals.

Pharmacist—an individual currently licensed by the board to engage in the practice of pharmacy in the state.

Physician—an individual lawfully entitled to engage in the practice of medicine in this state as evidenced by a current, unrestricted license duly issued by the Louisiana State Board of Medical Examiners.

Prescribe—a request or order transmitted in writing, orally, electronically or by other means of telecommunication for a drug that is issued in good faith, in the usual course of professional practice and for a legitimate medical purpose, by a physician for the purpose of correcting a physical, mental, or bodily ailment of his patient.

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B. - C. [tab]...

D. [tab]Standards of Practice

1. [tab]Authority, Responsibility, and Limitations of Collaborative Drug Therapy Management

a. - d. [tab]...

e. **[tab]**Only a pharmacist who holds the academic degree of Doctor of Pharmacy, which degree provided specific training in the area of anti-coagulant drug therapy, shall engage in collaborative drug therapy management in such particular area of practice covered by a collaborative drug therapy management agreement. The board may, in its discretion, grant an exception to this limitation on a case-by-case basis and permit a pharmacist to engage in anti-coagulant drug therapy management with a pharmacist who does not possess the academic degree required by this Section upon the affirmative recommendation and advice of the advisory committee that the pharmacist possesses the equivalent or other acceptable advanced training in the area of practice covered by the agreement.

f. **[tab]**The scope of the collaborative drug therapy management shall not include:

i.[tab]any patient of the physician for whom such physician has not prepared a patient specific, drug specific, disease specific written protocol;

ii. **[tab]**drug therapy management of more than one specific disease or condition. Administration of a vaccine or smoking cessation therapy are excepted from this provision;

iii. [tab]drug therapy management of any patient by more than one registered physician and one pharmacist;

iv. [tab]any patient under the age of 18 years of age. Administration of a vaccine or smoking cessation therapy are excepted from this provision;

v. [tab]pregnant or nursing mothers;

vi. [tab]initiation or discontinuance of drug therapy by a pharmacist, except as specified in the

written protocol;

vii. [tab] the management of controlled substances or drugs of concern; or

viii. [tab]substitution of a drug prescribed by a physician without the explicit written consent of such physician.

2. - 4.c. [tab]...

5. **[tab]**Administration of Vaccines

a. - b. **[tab]**...

c. **[tab]**This Section shall not prevent or restrict the Louisiana Department of Health and Hospitals, Office of Public Health, or any other governmental entity of this state, from administering vaccines under the authority of other laws of this state.

D.6. - E.3. [tab]

AUTHORITY NOTE: [tab]Promulgated in accordance with R.S. 37:1164(37)(b)(i).

HISTORICAL NOTE: [tab] Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 47:

Public Hearing

In accordance with the provisions of the Administrative Procedure Act, specifically at R.S. 49:968(H)(2), the board gives notice of a public hearing to receive additional comments and testimony on these substantive amendments to the proposed Rule. The hearing will be held at 10 a.m. on Friday, April 20, 2007 at the office of the Louisiana State Board of Medical Examiners, which is located at 630 Camp Street in New Orleans, LA. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. Interested persons may submit written comments to Malcolm J. Broussard, Executive Director, Louisiana Board of Pharmacy, 5615 Corporate Blvd., Suite 8-E, Baton Rouge, LA 70808-2537. He is responsible for responding to inquiries regarding these substantive amendments to the proposed Rule. The deadline for receipt of all written comments is 10 a.m. on Friday, April 20, 2007.

Malcolm J. Broussard Executive Director