



MISSISSIPPI STATE BOARD OF MEDICAL LICENSURE

John K. Hall, M.D., J.D., Executive Director

August 31, 2016

Mark Garriga
Butler Snow
P.O. Box 6010
Ridgeland, MS 39158-6010

Re: Request for Declaratory Opinion - Rule 1.9 Labeling Requirements for
Dispensing Physicians

Dear Mr. Garriga:

The Mississippi State Board of Medical Licensure has received your request on behalf of Southern Bone & Joint Specialists, P.A. (ASBJ@) for a declaratory opinion pursuant to Mississippi Code Section 25-43-2.103, and provides this response.

INQUIRIES

You have asked the following, under the facts outlined in your letter:

1. Under the facts provided, would an SBJ physician providing non-prescription, over-the-counter drugs as described above be a "dispensing physician" as described in Rule 1.9?
2. If the Board's answer to Question 1 is in the affirmative, would the SBJ physician be required to ensure that the drugs dispensed be labeled with:
"(A) The name of the patient to whom the medication was dispensed"?
"(B) The date that the medication was dispensed"?
"(E) The name and address of the physician dispensing the medication"?

(Note: The name, strength and quantity of the medication, and directions for taking or administering the medication, will be on the label, as required by the U.S. Food and Drug Administration.)

3. If the Board's response is in the affirmative to Question 1 and in the affirmative to any of the inquiries in Question 2, may the physician delegate any of those duties?

BACKGROUND

You explain that part of SBJ's patient population are workers' compensation patients who often require certain non-prescription, over-the-counter (AOTC@) medications to treat their healthcare needs. SBJ proposes to make certain routinely needed OTC medications available for sale exclusively to SBJ's workers' compensation patients in its offices. These OTC medications would be limited to those described in Attachment 1 to your request letter, i.e., the ALidoPro patch@ and ALidPro@ pain relief ointment.

Your letter also states the following regarding how these OTC medications would be given to the patients:

If the patient, in [the physician=s] sole discretion, opts to obtain the non-prescription, over-the-counter drugs at SBJ's offices, the SBJ physician will personally hand the medication to the patient. The medication, obtained from a third party manufacturer regulated by the U.S. Food & Drug Administration, will be pre-packaged, and will be pre-labeled by the manufacturer or distributor with the name, strength and quantity of the medication, and directions for taking or administering the medication. The labeling will meet all U.S. Food and Drug Administration requirements for over-the-counter drugs. The label will also include the name and telephone number for SBJ. The workers' compensation carrier for the patient will be billed for the drugs provided, and the patient will be billed for his or her co-payment or deductible, if any. If a refill is needed, it will be supplied in the same manner. The drugs will be maintained as required by Administrative Code Rule 1.8 Drug Maintenance Requirements. Additionally, SBJ's physicians will abide by all record keeping and documentation requirements with respect to medications provided to their patients in the office setting.

ANALYSIS

The answers to your inquiry are found in a review of the relevant portions of the Board=s Rules 1.2 *Definitions* and 1.9 *Labeling Requirements for Dispensing Physicians*.

Rule 1.2 defines "Dispense" means "

to deliver a controlled substance or legend drug other than by administering or prescribing to an ultimate user or research subject including the packaging, labeling, or compounding necessary to prepare the substance for that delivery.

Rule 1.9 provides:

For the purposes of this rule, a "dispensing physician" shall mean any physician who shall dispense to a patient for the patient's use any controlled substance, legend drug or other medication where such medication is purchased by the physician for resale to a patient whether or not a separate charge is made. Every dispensing physician, as defined above, who shall dispense a controlled substance, legend drug or any other medication shall insure that all such substances dispensed be labeled containing the following information:

- A. The name of the patient to whom the medication was dispensed.
- B. The date that the medication was dispensed.
- C. The name, strength and quantity of the medication.
- D. Direction for taking or administering the medication.
- E. The name and address of the physician dispensing the medication.

The label required by this rule shall be written in legible handwriting or typed and shall be permanently affixed to the package or container in which the medication is dispensed. This labeling requirement shall not apply to prepackaged samples or starter packs in their original packages or containers.

The two (2) pain relief OTC medications at issue are neither "controlled substances" nor "legend drugs" as defined in the applicable Mississippi statutes and regulations, but rather are OTC drugs that could be obtained independently by the patient without a prescription.

RESPONSES

1. Under the facts provided, would an SBJ physician providing non-prescription, over-the-counter drugs as described above be a "dispensing physician" as described in Rule 1.9?

Yes. Under the Rule as cited any SBJ physician providing medication as described is a "dispensing physician."

2. If the Board's answer to Question 1 is in the affirmative, would the SBJ physician be required to ensure that the drugs dispensed be labeled with:

- "(A) The name of the patient to whom the medication was dispensed"?
- "(B) The date that the medication was dispensed"?
- "(E) The name and address of the physician dispensing the medication"?

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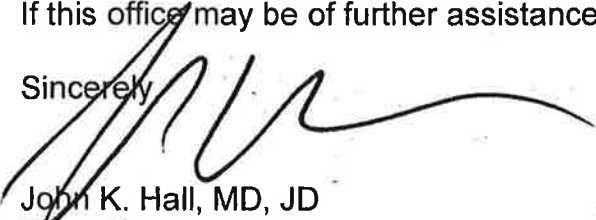
Any physician meeting the definition of dispensing physician as described above is subject to *all* of the conditions of Rule 1.9 Labeling Requirements for Dispensing Physicians.

3. If the Board's response is in the affirmative to Question 1 and in the affirmative to any of the inquiries in Question 2, may the physician delegate any of those duties?

The Rule does not permit delegation of any of the duties of the dispensing physician.

If this office may be of further assistance to you, please let me know.

Sincerely,

A handwritten signature in black ink, appearing to read 'John K. Hall', written over the word 'Sincerely'.

John K. Hall, MD, JD
Executive Director

JKHshp