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My position, when I appeared before IRRC, and the position of a majority of the State Board of Osteopathic Medicine at its meeting on Wednesday, April 8, 2009, is that the words of § 25.177(a)(3) as presented to IRRC in the Final Rulemaking do not reflect the intent of a majority of the State Board of Osteopathic Medicine, when the Board voted to approve the Final Rulemaking.

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At the April 8, 2009 meeting, by a vote of 6 to 3 (the chair not voting but agreed), a majority of the State Board of Osteopathic Medicine adopted the following amendment to § 25.177(a)(3) in order to clarify the words of the regulation and implement the intent of a majority of the State Board of Osteopathic Medicine when the Board took formal action to approve the Rulemaking. (Additions are underlined; deletions are shown with ~~strikethrough~~.)

3) A physician assistant may prescribe a Schedule II controlled substance for initial therapy, up to a 72-hour dose. The physician assistant shall notify the supervising physician of the prescription as soon as possible, but in no event longer than 24 hours from the issuance of the prescription. ~~A physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply for ongoing therapy if the patient was examined within the first 30 days by the supervising physician. The prescription must clearly state on its face that it is for initial or ongoing therapy.~~ The physician assistant shall have no authority to prescribe a Schedule II controlled substance after the initial therapy of up to a 72-hour dose, until the patient has been examined by the supervising physician and the supervising physician has reviewed and approved the prescription of a Schedule II controlled substance by the physician assistant for up to a 30-day supply. Thereafter, (i) if the supervising physician determines and documents that the patient is chronically ill, the physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply of the Schedule II controlled substance, only if the prescription of a Schedule II controlled substance by the physician assistant is reviewed and approved by the supervising physician at least every 30 days; and (ii) if the supervising physician determines and documents that the patient is terminally ill, the physician assistant may write a prescription for a Schedule II controlled substance for up to a 30-day supply if the prescription of a Schedule II controlled substance by the physician assistant is reviewed and approved by the supervising physician at least every 120 days.

The majority of the Board focused on the clarity and scope of the words “ongoing therapy” in the sentence: “A physician assistant may write a prescription for a Schedule II controlled substance for up to a 30 day supply for ongoing therapy if the patient was examined within the first 30 days by the supervising physician.”

The majority of the Board was concerned that this language is unduly vague, could be subject to multiple interpretations and did not adequately express the intent of the Board that there be ongoing physician involvement in the prescription of Schedule II controlled substances by physician assistants with respect to chronic conditions. The added language was adopted to make crystal clear the intent and requirements of the Rulemaking.

It is important to note that this subsection **only** deals with the prescription of Schedule II controlled substances. These are defined in Pennsylvania law as substances with “. . . a high potential for abuse, currently accepted medical use in the United States, or currently accepted

medical use with severe restrictions, and abuse may lead to severe psychic or physical dependence.” 35 P.S. § 780-104 (2) (emphasis added).

A majority of the State Board of Osteopathic Medicine (including all of the Board’s physician members) strongly believes that, for the protection of the public, ongoing physician supervision and involvement with patient care is essential for the long term prescription of controlled substances on Schedule II.

We believe that the amendment clarifies the words of the Rulemaking. We think that a requirement for ongoing involvement of physicians is particularly important with respect to the prescription of substances where, in the words of the statute, “. . .abuse may lead to severe psychic or physical dependence.” The language adopted by the Board at its April 8 meeting will help to make certain that the public is protected when Physician Assistants prescribe Schedule II controlled substances.

Sincerely,
Joseph C. Gallagher D.O.
Chair, Pennsylvania Board of Osteopathic Medicine