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To: Mrs. Pam King, Executive Director
Florida Osteopathic Board of Medicine

07/31/05

Fax: 850 - 412 - 2680 (6 pages total)

Re: Modified Rule Proposal for September 19th Meeting

Dear Mrs. King,

I am faxing you this letter in preparation for the September 19th, 2005, Pain Management Joint Committee meeting of the Osteopathic Board of Medicine, the Board of Medicine, the Board of Nursing and the Board of Pharmacy.

Attached is the rule which I hope the boards will implement at that meeting, or sooner if possible. It is modified from the original rule that I sent to you on 07/06/05. As before, the rule has five components: the rule, full exemptions, partial exemptions, waivers and punishment. Each part is listed and includes an explanation of its purpose, as well as any significant modifications between the 07/06/05 version and this one.

Please distribute this letter and its attachment to the other boards. If you are unable to do so, please let me know so that I may send copies of it to them.

I will contact you later this coming week to discuss details of the upcoming meeting, with regards to my participation by teleconference. If possible, I would like **30 minutes** of presentation time.

Sincerely,

Dr. Robert Ben Mitchell, D.O.

cc: Senty Goudy (F.A.D.A.A.)
Bruce Grant (Florida Office of Drug Control)
Yolly Roberson (Florida Legislature District 104)

Attached: 5 pages

Rule (modified 07/29/05):

No physician shall be, at any one time, prescribing controlled opioid narcotics on an out-patient basis to more than 100 patients. A patient is considered as being prescribed a controlled opioid narcotic by a physician for the entire duration of expected use of the prescribed controlled opioid narcotic, including any outstanding prescribed refills or issued prescription series. These limits are per physician and not per practice site.

Purpose of the Rule:

This rule limits the number of patients that can be treated with controlled opioid narcotics by a physician. The purpose of this limit is to prevent physicians from using the current regulations governing pain management to provide easy opioid access to high volumes of patients. Under these current regulations, established by the Florida Board of Medicine and the Florida Osteopathic Board of Medicine, abusive physicians have created high-volume, high-profit “pill-mills” where a single doctor, charging \$200 per visit, can generate \$1,600,000 annual revenue by working just forty hours per week, fifty weeks per year. Due to these circumstances, prescribed pain medications now kill more Floridians than all illicit drugs like heroin and cocaine combined. These death tolls have been verified by the Florida Department of Law Enforcement in both 2003 and 2004. This rule stops the killing by removing the volume and, therefore, the unwarranted profit from pain management.

The first sentence of the rule, as stated above, has been modified from the original rule proposed July 06, 2005, in a letter from Dr. Robert Ben Mitchell D.O. to Ms. Pam King, the Executive Director of the Florida Osteopathic Board of Medicine. This modification is as follows:

Original (07/06/05): No physician shall be, at any one time, prescribing controlled opioid narcotics on an out-patient basis to more than 100 patients, **or to more than 10% of all the out-patients under their care, whichever is larger.**

Modified (07/29/05): No physician shall be, at any one time, prescribing controlled opioid narcotics on an out-patient basis to more than 100 patients.

The modification removed the bold-typed phrase “**or to more than 10% of all the out-patients under their care, whichever is larger.**” Originally, this phrase was included to allow physicians with practices of more than 1000 patients to treat a proportionately larger number of chronic pain patients. However, this could become a loop-hole whereby abusive physicians could establish fraudulent patient rosters in order to continue prescribing opioids to large volumes of people. It would then fall back on the boards of medicine to determine what constitutes patient status, which in turn would become a quagmire to enforcement of this rule. Therefore, this phrase was removed.

Any physician needing to treat more than 100 patients with controlled opioid narcotics should apply to their state medical board for permission to do so through the waiver system outlined below.

Full Exemption (modified 07/29/05):

This rule does not apply to any physician meeting all three of the following criteria:

- A. The physician has full, unrestricted hospital staff privileges in at least one JCAHO accredited hospital in each county where, or in a county immediately adjacent to where they prescribe controlled opioid narcotics.**
- B. The physician has received and maintains fully active diplomate certification by an A.O.A. or A.M.A. approved medical board in at least one specialty other than Family Practice or General Pediatrics.**
- C. The physician is an approved provider for both Medicare and Medicaid and accepts both Medicare and Medicaid coverage for patients being prescribed or dispensed controlled opioid narcotics.**

Purpose of the Full Exemption:

Currently, most out-patient long-term medication management of people with chronic pain is done by physicians with little oversight. Thus, they purposefully practice at the MINIMUM standards for pain management established by the medical boards. This prevents the boards and, to a degree, the DEA from taking action against them. The outcome of practicing pain management at these minimal standards has been over 2000 pain medication drug deaths confirmed in 2004 (as per the FDLE).

This full exemption, highly modified from the original version of 07/06/05, shifts pain management away from physicians with little if any oversight to those with significant amounts of oversight. PART A ensures that qualifying physicians are full members of the established medical hierarchy in their community, and not just isolated operators practicing by themselves within the community. The phrase **“or in a county immediately adjacent to where”** has been included for physicians whose offices are near to, but separated from their affiliated hospitals by a county line. PART B ensures that qualifying physicians have reached a specialized level of training above that of basic family practice or general pediatrics. PART C ensures that qualifying physicians have met the further demands of oversight provided by both Medicare and Medicaid in caring for patients with chronic pain.

This full exemption no longer includes a provision for physicians practicing in HHS designated medically under-served areas, as to do so would shift the focus of abusive physician behavior from urban settings into these areas. Any physician, including those in HHS designated medically under-served areas, needing to treat more than 100 patients with controlled opioid narcotics should apply to their state medical board for permission to do so through the waiver system outlined below.

Partial Exemption (modified 07/29/05):

Any physician not fully exempt from this rule, may have partial exemption by excluding the following patients from the limits set by this rule:

- A. END-OF-LIFE CARE:** Any patient being treated with controlled opioid narcotics as part of palliation during end-of-life care. Patients meeting this criteria must have their end-of-life status certified by a JCAHO accredited hospice organization.
- B. ACUTE PAIN:** Any patient being treated with controlled opioid narcotics for an acute condition of less than four (4) weeks consecutive duration at any one time, and less than twelve (12) weeks cumulative duration during any one calendar year. Patients meeting this criteria may not be treated with pure schedule II opioids (example: Percocet is okay - oxycodone and acetaminophen; Roxicodone is not okay - oxycodone only).
- C. IN-PATIENT TREATMENT:** Any patient being treated with controlled opioid narcotics as part of their stay in an JCAHO accredited in-patient treatment facility (ex: hospital, nursing home, etc.)
- D. RESEARCH:** Any patient being treated as part of an FDA approved clinical trial regarding controlled opioid narcotics.
- E. MILITARY:** Any patient being treated as part of the physician's service requirements in any branch of the United States Military.
- F. GOVERNMENT:** Any patient being treated as part of the physician's employment requirements with the Federal Government, or the state or its agencies or its subdivisions.
- G. TEACHING:** Any patient being treated as part of the physician's employment requirements in an accredited D.O. or M.D. medical school or post-graduate training program.
- H. GOOD SAMARITAN:** Any patient being treated by a physician acting as a good Samaritan during a medical emergency.
- I. REGIONAL EMERGENCY:** Any patient being treated by a physician during an emergency period designated by local, state or Federal Government (example: immediately after hurricanes, floods, earthquakes, tornados, etc.).

The individual partial exemptions as listed here - A through I - are unchanged from those listed in the original version of 07/06/05. It is hoped that their purposes are self-explanatory.

Waivers (modified 07/29/05):

Any physician with extenuating circumstances not covered by these exemptions listed above may apply to their respective medical board for a waiver of this rule. Each board shall, on a case by case basis, determine the merits of such requests. All approved waivers shall specify information deemed by the medical board to be pertinent for public safety, including but not limited to:

- A. The purpose of the waiver (why does the physician need to treat more than 100 out-patient chronic pain sufferers with long-term controlled opioid narcotics?).
- B. The specific number in excess of 100 out-patients being requested by the waiver. Physicians with approved waivers who exceed their approved excess will still be liable for punishment as outlined below.
- C. The methods of management to be used to ensure patient compliance and safety. As no single method has yet been proven sufficient, multiple methods should be outlined, which may include, but are not limited to:
 - Patient Compliance Coding (*The American Journal of Pain Management*, July 2004, pages 99-107).
 - Mind-Body-Medication Limitations (*The American Journal of Pain Management*, July 2005, pages 98-102).
- D. The requested duration of the waiver (not to exceed 12 months). To allow continuity of care, applicants can re-apply for renewal of existing waivers after 50% of their allotted waiver duration has expired.

Purpose of Waivers:

The rule and its associated exemptions are designed to eliminate the vast majority of deadly physician abuse that is occurring in pain management today. However, neither the rule nor its associated exemptions define what comprises good pain management, as this definition has yet to be written. A lengthy process will be required to create a definition of good pain management, and the rule and its associated exemptions stop bad pain management so that this defining process can begin.

The incorporation of the waiver system into the rule allows physicians, under the auspices of the medical boards, to develop and implement new and innovative principles and practices for good pain management. Over time, the waiver system can be the key to creating a mature and practical approach to long-term medication management of people suffering from chronic pain.

Punishment (modified 07/29/05):

Any physician found by their respective board to be in violation of this rule and/or its exemptions and/or wavier shall immediately have their medical license completely and permanently revoked, without the possibility of future re-licensure. The execution of this punishment in no way prohibits or prevents the medical boards, or any other legal or governing body from further prosecuting the affected physician.

Purpose of the Punishment:

The purpose of this punishment is simple. Physicians are currently killing thousands of Floridians each year by their irresponsible behavior when prescribing pain medications. None of these people they have killed will ever get a second chance. Neither should any of these murderers.

This punishment has been modified from the original version of 07/06/05, including the addition of the second sentence.