Ohio Association of Rheumatology (OAR) Position Paper on the Role of the Rheumatologist in the Treatment of Pain as a Component of Rheumatic Diseases

By

The Board of the OAR

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I. Definitions

A. Rheumatology

1. Rheumatology is the evaluation, diagnosis, and treatment of rheumatic diseases. Rheumatic diseases are broadly defined as any disease affecting the musculoskeletal system, and whose etiology reflects degenerative, inflammatory, immune and biochemical mechanisms. Rheumatic diseases are often systemic diseases affecting multiple body systems. Examples of rheumatic diseases include osteoarthritis (degenerative); gout and pseudogout (inflammatory); rheumatoid arthritis and systemic lupus erythematosus (autoimmune, inflammatory); osteoporosis (biochemical/endocrinologic).

B. Rheumatologist

1. A rheumatologist is a physician trained in internal medicine and the subspecialty of rheumatology. Such physicians are generally certified in both internal medicine and rheumatology by the American Board of Internal Medicine.
2. The subspecialty of rheumatology is generally a two-year clinical training program. Although such training does include the management of pain by non-pharmacologic and pharmacologic methods, the primary objective of rheumatology training is not the treatment of acute or chronic pain. The instruction in pain management by didactic lectures, review of the medical literature, and mentoring in the clinic is variable from program to program, depending on the curriculum of the particular program. Expertise in the treatment of pain is often the result of self-instruction and continuing medical education occasioned by the necessity to treat pain as a component of rheumatic diseases.

C. Treatment of acute and chronic pain by rheumatologists

1. Rheumatologists treat *acute* pain of the musculoskeletal and other body systems. Gout and pseudogout, two related disorders mentioned above, are examples of rheumatic diseases that can present with acute, mild to severe pain due to an inflammatory arthritis of one or more joints. Pain is the response to an acute inflammatory process causing the arthritis. Because pain reflects an intense inflammatory response, the rheumatologist treats the inflammatory response with an anti-inflammatory agent(s). Successful treatment of inflammation results in rapid control of pain. However, depending on the clinical circumstances, the rheumatologist may elect to treat the patient concomitantly with an analgesic agent. This is compassionate care to relieve pain and suffering; however, treatment with an analgesic agent does not treat the cause of the inflammatory process. Therefore, the primary objective of treatment is not pain management.
2. Rheumatologists also treat *chronic* pain of the musculoskeletal system and other body systems. An example is a widespread pain disorder, the most common in practice being fibromyalgia syndrome (FMS). Because FMS affects the musculoskeletal system, patients with such symptoms are often referred to rheumatologists by other physicians for evaluation, diagnosis and management. Because FMS is characterized by allodynia and hypersensitivity to pain, treatment, in part, may necessitate prescription of non-scheduled or scheduled analgesic agents for more than 30 days. However, pain treatment is only a single component of a multi-faceted approach to chronic, widespread pain that generally includes non-pharmacologic and pharmacologic modes. Thus, although treatment of pain is an objective of FMS management, treatment also includes physical therapy and massage; short- or long-term psychotherapy of depression and anxiety, especially

utilizing behavior modification therapy; and, treatment of specific non-pain related components, including fatigue and insomnia. In order to treat pain unresponsive to non-narcotic and narcotic analgesics, patients may be referred to a specialist in pain medicine for additional evaluation and treatment modalities. Thus, in this example, the objective of the rheumatologist is management of the non-pain and pain-associated symptoms often in association with other specialists, such as pain medicine.

II. Primary Objective of Rheumatologic Care

A. Holistic medicine

1. The term holistic medicine has several connotations. In this Paper, holistic medicine refers to treatment of the whole patient. As noted in I-A(1) above, rheumatic diseases are often systemic disorders. Therefore, it is necessary to treat, to the extent possible, the aberrant immune, biochemical and genetic mechanisms that result in rheumatic diseases.

B. Pain

1. It is generally accepted that pain is a nociceptive process involving a stimulus, induction of nerve impulses that utilize pain fibers, and transmission of such impulses to the spinal cord and cephalad to the brain. Specific regions of the brain possess pain receptors that result in the experience of pain. Local regions of inflammation, such as joints, create nociceptive stimuli via products produced by injured cells; one such factor is Substance P. This and other nociceptive products can also be produced by other events, including local pressure, heat, or chemicals. In inflammation, other proteins are released by injured cells or by cells attracted to the area of inflammation that significantly contribute to rheumatic diseases. Thus, pain is only a single outcome of tissue injury in rheumatic diseases.

C. Primary objective of rheumatologic care: Treatment of etiology, symptoms and signs of rheumatic disease

1. As discussed above, rheumatic diseases are systemic processes having multiple etiologies, often unknown. Symptoms and signs of these heterogeneous disorders are disparate, variable and inconstant. The primary objective of rheumatologic care is the evaluation, assessment of etiopathogenesis, and treatment of the symptoms and signs to the full extent of medical science.
2. To accomplish this primary goal, rheumatologists perform detailed and methodical histories and physical examinations of patients. Rheumatologists also utilize the panoply of ancillary laboratory and imaging techniques currently available for diagnosis and treatment. Such assessments require honed clinical judgment and discretion to identify etiopathogenesis and diagnoses. Rheumatologists often have long-term patient-physician relationships because most rheumatic diseases are chronic, recurring, often progressive and require interval follow-up assessments.
3. A secondary objective of rheumatologists is restoration of an active and meaningful lifestyle that permits independent living, enjoyment of family and friends as well as gainful employment. To achieve this worthy goal, rheumatologists treat symptoms and signs of disease. As detailed above, one outcome of disease pathogenesis may be acute or chronic pain. Therefore, as a component of holistic medicine, rheumatologists seek to treat pain effectively to the extent possible to relieve suffering and achieve the above goals [II-C(3)].

III. Rheumatologic Care Does Not Necessitate a Pain Management Clinic

A. Definition of a pain management clinic

1. Emergency rule 4731-29-01 Standards and Procedures for the Operation of Pain Management Clinic states in A-5: ""Pain management clinic" means a facility to which all the following apply: (a) The *primary* (our emphasis) component of the practice is treatment of pain or chronic pain; (b) The majority of patients of the prescribers at the facility are provided treatment for pain or chronic pain that includes the use of controlled substances, tramadol, carisoprodol, or other drugs specified in rules by the board…."

B. Grandfathering clause

1. In a June 10, 2011 communication to Ohio physicians, The Ohio State Medical Association (OSMA) provided interpretation and clarification of the above emergency rule. Qualifications include "providing pain medicine that meets the definition of a pain management clinic (a majority of your patients are prescribed controlled substances for the treatment of pain that is expected to last more than 30 days)."
2. A "majority" means more than 50% of patients.
3. The "Grandfathering Clause" is meaningless for several reasons. First, there was insufficient time from the passage of Emergency rule 4731-29-01 Standards and Procedures for the Operation of Pain Management Clinic to June 20, 2011 to allow rheumatologists to accurately assess their prescription of scheduled and non-scheduled agents (cf. above) in their practice, especially determining whether or not they met the 50% standard. Second, the Clause does not clarify the differences between rheumatology practices versus pain management practices. Third, by limiting the requirement to rheumatologists in practice three years or more, this Clause does not address new graduates in the field of rheumatology. Fourth, this Clause does not address the situation of a rheumatologist two years in practice that is prescribing pain medications to the majority of patients. Lastly, this Clause does not address rheumatology practices that may exceed the 50% threshold of prescribing at some time in the future.

C. Inconsistent standards for private practice rheumatologists versus hospital system-employed rheumatologists

1. Emergency rule 4731-29-01 Standards and Procedures for the Operation of Pain Management Clinic states in A-5: " 'Pain Management Clinic' does not include the following: (a) A hospital…or a facility owned in whole or in part by a hospital;…." Many practicing rheumatologists have joined as employees of private hospital systems. These hospital-based rheumatologists provide the exact same care, using the same modalities, and prescribing the same medications, including scheduled and non-scheduled agents indicated above, as rheumatologists in private practice. They are not required to participate in the training or teaching of medical students, interns, residents or fellows. Under Emergency rule 4731-29-01 Standards and Procedures for the Operation of Pain Management Clinic, hospital-employed rheumatologists are exempted from this law, creating an inconsistent and unfair standard of care as well as precedent.

IV. Positions of the OAR

A. The Board of the OAR has determined the following positions:

1. The OAR unanimously opposes the requirement and imposition of Emergency rule 4731 29-01 Standards and Procedures for the Operation of Pain Management Clinic on rheumatology practices. As stated in several sections above, the primary objective of

rheumatologic treatment is <u>not</u> pain control and management; therefore, rheumatology practices should not be forced to redefine their primary objective.

2. The OAR proposes that rheumatologists be exempted from Emergency rule 4731-29-01 <u>Standards and Procedures for the Operation of Pain Management Clinic</u>. Specifically, the OAR proposes that rheumatology practices be exempted from the 50% rule and the requirement to form or practice within the structure of a Pain Management Clinic. This should pertain whether or not rheumatologists' practices involve the treatment of pain in a minority or majority of rheumatic disease patients. Such a requirement is in direct violation of the mission of the OAR (see Appendix A, <u>OAR Mission Statement)</u>.

B. Unintended consequences and concerns of Emergency rule 4731-29-01 <u>Standards and Procedures for the Operation of Pain Management Clinic</u>

1. The Board of the OAR is concerned about potential unintended consequences of this law. In its deliberations, Board members raised many questions, concerns and potential consequences. Several such issues will be briefly iterated below.
2. As stated above, rheumatologists treat *acute* and *chronic* pain based on evidence, guidelines from pain societies, and experience as do primary care physicians. What is different about rheumatologic practices is that a higher proportion of patients with chronic rheumatic disorders have a pain component that requires treatment. Therefore, rheumatologists' practices may, at some time, exceed the arbitrary 50% limit in the law. If the law remains unchanged and continues to impact rheumatologists' practices, it should also be applied to primary care practices and <u>all</u> other physicians' practices who treat pain.
3. It is recognized that most specialists in pain management are trained in anesthesia and interventional anesthesia; they are usually not internists who are diagnosticians trained to manage and treat medical disorders. As such, most pain management specialists cannot diagnose, evaluate, and treat rheumatic diseases, even those that include a pain component. Interventional anesthesiologists' primary practice objective is to treat and relieve pain, which is a symptom of an underlying disorder of any cause. By contrast, rheumatologists' primary practice objective is to diagnose and treat the disease process, of which pain is only one component. Recognizing this fundamental difference in practice objectives is crucial to understanding OAR's position that rheumatologists should be exempted from Emergency rule 4731-29-01 <u>Standards and Procedures for the Operation of Pain Management Clinic</u>.
4. An unintended consequence of Emergency rule 4731-29-01 <u>Standards and Procedures for the Operation of Pain Management Clinic</u> may be that rheumatologists could markedly limit their treatment of the pain component of rheumatic diseases to avoid triggering the 50% threshold. This would directly affect the quality and access of care of patients whose rheumatic disorder has a pain component that significantly affects and restricts their lifestyle, including family interpersonal relations, social activities, and employment function. In response, such patients could seek management of their pain and suffering from other physicians, including pain management specialists. This could have the unintended effect of further fragmenting and hindering quality of care, the ability of subspecialists and generalists to collaborate on care decisions due to the number of physicians involved in a single patient's care, and potentially lead to adverse and unanticipated drug-drug interactions.

5. Emergency rule 4731-29-01 Standards and Procedures for the Operation of Pain Management Clinic regulates the non-scheduled agents, tramadol and carisoprodol, similar to scheduled agents. Moreover, the reach of the law also includes pregabalin (Lyrica), a schedule V agent as well as schedule II and III agents. The Board is not aware that there is significant misuse or illegal abuse of agents such as tramadol and pregabalin. Because these agents are frequently used along with other pharmacologic agents and non-pharmacologic modalities, we are concerned that appropriate prescription of these agents could also be affected, again hindering compassionate treatment of pain. The Board recommends that these agents be dropped from the list of agents proven to have a high abuse history.