Thursday, July 2, 2020

Florida Board of Pharmacy
4052 Bald Cypress Way Bin C-04
Tallahassee, FL 32399-3258

RE: Rule Making Authority 465.1865, 64B16-31.007 Collaborative Practice Certification – Chronic Health Conditions

Dear Board of Pharmacy Committee Members,

The Florida Society of Rheumatology (FSR) represents the physicians and other medical professionals practicing rheumatology in the state of Florida and facilitates the recognition of the role of the rheumatologist as the provider of choice for patients with arthritis, chronic pain, osteoporosis, and musculoskeletal disease.

We manage a select, specific group of highly complex autoimmune diseases that require specialized medications that modulate the immune system - much like oncologists who use chemotherapy, immunomodulatory and at times immunosuppressive medications to treat cancer. These medications have specific indications, target the immune system, and have to prescribe with great care and consideration to the appropriate patient, in order to maximize effectiveness and minimize side effects.

In response to the Collaborative Practice Certification – Chronic Health Conditions, the FSR respectively requests that section (8) eight, “any disease state that is expected to last greater than (1) year or more and will require ongoing medical treatment and drug therapy services” be deleted from the proposed rule. The FSR agrees that the Board of Pharmacy has the authority to approve certain chronic health conditions, but to unilaterally allow all chronic health conditions to be subjected to this agreement raises serious concerns for the care and safety of our patient community.

FSR believes the Board of Pharmacy shares our concern to protect the health, safety and welfare of our unique patient population, and each condition should be considered prior to inclusion. Just because a health condition is expected to last greater than (1) year, does nothing in the consideration as to if the disease state lends itself well to a written constraints of collaborative practice and if comorbidities outside the chronic condition also need to be part of the management of the drug therapies in question.
After all, the pharmacist is not managing the disease, but the drug therapies to be used in treating that disease, and the pharmacist does not go to school or have the required training to be a specialist in any one disease type, so we believe training must be added to the CME requirements for each disease state added.

Furthermore, the FSR opposes the BOP from including “osteoporosis” in section (5) five of the Collaborative Practice Certification – Chronic Health Conditions. There are many choices in the treatment of osteoporosis. The choice of the right treatment depends on the severity of the disease as well as comorbidities. It is not a simple decision in many cases whether the patient should or should not receive treatment. There are many drug choices for therapy in osteoporosis. The choice of which drug should be used not only depends on the severity of disease but also other additional diseases the patient may have, or comorbidities. So, the choice of which drug to use in a specific patient is a complex decision, within a mostly elder and fragile patient population.

The diagnosis must be verified by thorough review of the patient’s history, bone mineral density scan results and often, imaging study. Cognitive evaluation is also done by the physician to verify the diagnosis and severity of disease to select the right drug. After verifying that the diagnosis is, in fact, osteoporosis, the patient’s history of related comorbidities is determined and the severity of each of those must be ascertained to select the medication which will not only be the most effective, but importantly, the safest for that unique patient.

Osteoporosis is complex to manage and could result in permanent negative patient outcomes if treated improperly. There are a number of underlying causes/contributing factors for osteoporosis which must be evaluated and treated differently for optimal treatment results. We oppose the management of this condition by consulting pharmacists, and this disease does not fit into a simple algorithm of care such as the other conditions contemplated under a collaborative agreement.

We do not object to “osteoarthritis” being included in section (5) five. When treating osteoarthritis, care pathways are more straightforward algorithms of care, conducive to a collaborative agreement.

However, many of our patients have arthritis that represents an inflammatory and/or autoimmune disease. These are complex diseases that even physicians outside of our specialty do not manage. These diseases require complex assessments to ascertain whether the current treatment is effective and safe. Conducting these assessments is not simple and straightforward. It is often not obvious whether a treatment regimen should be changed. It takes specialized training and experience to be skilled enough to conduct these assessments competently.

In the case of the best known of these diseases, rheumatoid arthritis, such assessment includes obtaining validated patient reported outcomes, conducting a physical exam including a swollen and tender joint count, as well as review of radiology and laboratory findings. Synthesizing this information and then making the decision whether treatment should be changed is something that is beyond the scope of a consulting pharmacist. After the decision is made to change therapy, the decision of what the next best treatment regimen is also complex. This capacity takes experience and specialized training, beyond the scope of a consulting pharmacist.

Other examples of complex inflammatory and autoimmune diseases that FSR believes should not be managed by a consulting pharmacist include systemic lupus erythematosus and psoriatic arthritis. This is not an inclusive list as there are many more diseases in this category of inflammatory and autoimmune
arthritis. It is the firm opinion of FSR that Consulting Pharmacists should not be allowed to manage these forms of inflammatory and autoimmune diseases.

FSR stands committed in working with the Florida Board of Pharmacy in helping provide the best treatment options for Floridians with chronic conditions. Toward that end, please include us as an interested party in any future communications regarding the proposed rule. Thank you for your consideration.

Respectfully,

Guillermo J. Valenzuela, MD
President
Florida Society of Rheumatology