



INSERT DATE

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Dear INSERT NAME,

The Academy of Orthopaedic Physical Therapy, in collaboration with the academy's Imaging Special Interest Group, support the ability of physical therapists to purchase diagnostic ultrasound devices for the continued purpose of research, point-of-care evaluation of patients, physical therapist rehabilitative interventions and procedures, in accordance with their scope of practice. Physical therapists are licensed health care practitioners who are taught at the doctoral level to evaluate, treat, and manage patients with orthopaedic and neuromusculoskeletal conditions. Patients may consult with physical therapists without the requirement of an initial physician consultation. Their graduate curriculum includes background in imaging, radiology, and in differential screening.

Physical therapists are recognized providers of musculoskeletal ultrasonography by the American Institute of Ultrasound in Medicine and the Inteleos Foundation family of certification alliances: the Alliance for Physician Certification and Accreditation, the American Registry of Diagnostic Medical Sonographers, and the Point-of-Care Ultrasound Certification Academy. Pertinently, physical therapists are eligible for the physician's board certification of the APCA-conferred RMSK distinction, which many physical therapists have achieved. Moreover, the AIUM recognizes physical therapists as licensed medical providers of MSK ultrasound. The first published accounts of physical therapist-administered use of diagnostic ultrasound began in the 1980s. Physical therapists have continued to add high-quality peer-reviewed publications to the body of scientific literature, including submissions to the American Journal of Ultrasound in Medicine, Haemophilia, JOSPT, British Journal of Sports Medicine, Research Practice in Thrombosis and Haemostasis, and Blood, to name a few.

There is no federal regulatory basis to preclude physical therapists from purchasing ultrasound imaging devices, which are defined as Class II devices. Other Class II devices traditionally administered by physical therapists include electric stimulation, therapeutic ultrasound, and paraffin baths. Physical therapists have been administering therapeutic ultrasound for its thermal and nonthermal therapeutic effects since the 1950s and have routinely purchased these Class II devices for their practices without restrictions.

Relevantly, under the labelled use delineated in the “Title 21—Food and Drugs Chapter I—Food and Drug Administration Department of Health and Human Services; Subchapter H — Medical Devices; Part 801 — Labeling, Subpart D - Exemptions From Adequate Directions for Use, Sec. 801.109 Prescription devices” is the following:

The labelled use of this Class II device stipulates that the device is:

1. (i) in the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation storage, or wholesale or retail distribution of such device; or
(ii) in the possession of **a practitioner** [emphasis added], such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device
2. Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

The Labelling 1. (ii) simply refers to “a practitioner” and provides examples of practitioners without the exclusion of others. Section 2 follows with specific language concerning sales to “such practitioner for the use in the course of his professional practice.”

It is clear and consistent with FDA stipulations that graduate-trained and licensed physical therapists are eligible for the purchase of diagnostic ultrasound devices, given our long-established precedent of routine purchases of Class II devices and as providers of POC-MSKUS recognized by the AIUM and APCA.

The physical therapy community looks to the continued engagement and collaboration with the vendors and manufacturers of diagnostic ultrasound devices. We anticipate increased demand for ultrasound devices and are excited to continue our integration of this crucial, high-definition, and, above all, safe, non-ionizing evaluative tool into our specialized orthopedic and neuromusculoskeletal practice of physical therapy.

Sincerely,



Dr. Bruno U.K. Steiner PT, DPT LMT, RMSK
President, APTA Imaging Special Interest Group
APTA Academy of Orthopaedic Physical Therapy



Dr. Robert H. Rowe, PT, DPT, DMT, MHS
President, APTA Academy of Orthopaedic Physical Therapy