

State Board of Orthotics, Prosthetics, and Pedorthics



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REGULATION OF ORTHOTIC, PROSTHETIC, AND PEDORTHIC SERVICES/DEVICES IN OHIO SUMMARY REVIEW OF LICENSES REQUIRED, DEVICE CLASSIFICATION, AND DEFINITIONS “HOW DO OHIO STANDARDS COMPARE TO THE FEDERAL REGULATORY PROTOCOL?”

The State Board of Orthotics, Prosthetics, and Pedorthics was asked by the National Supplier Clearinghouse to supply Ohio-specific data for its [state licensure directory](#). Below is the basic response that was provided on March 15, 2012.

1. Ohio requires appropriate licensure to engage in the practice of orthotics, prosthetics and pedorthics. The regulated practices of those professions include Custom Fabricated Orthotics (OR01), and Custom Fitted Orthotics (OR02), requiring licensure in Orthotics. The practice includes evaluation, measure, initial fit, modification, adjustment, final fit and dispensation of a device. The fitting/dispensation of diabetic therapeutic shoes (S02, S03) is considered the practice of Pedorthics in Ohio (Pedorthist, Orthotist, Prosthetist, or Prosthetist-Orthotist license required). A Prosthetist or Prosthetist-Orthotist license is required for Limb Prosthetics (PR01).

2. The following professions are exempt from O&P licensure in Ohio and may engage in the practice of O&P and Pedorthics to the extent competence is recognized under their own licensure provisions:

MD, DO, DPM, PA (Physician Assistant), Chiropractor, Nurse, Occupational Therapist, Physical Therapist, Athletic Trainer
[ref [ORC Sec. 4779.02\(B\)\(1\)](#)].

> Pharmacies/pharmacists are not exempt <

3. Ohio law does not use the specific term “off the shelf.” “Unmodified, over the counter” is used to specify an exception to footwear considered to be within the scope of regulation. [[ORC Section 4779.01\(G\)](#)]

4. The Ohio statute exempts certain prefabricated devices from the scope of regulation, and the Board clarified those exemptions in the administrative rule series; see [Ohio Admin Code Rule 4779-3-02](#), which incorporates CMS Quality Standards language for the definition of custom fitted, and lists the exemptions (most or all of which are considered generally to be OTS/OTC (OR03) in character) at OAC Rule 4779-3-02 (E)(2). In addition, we have provided a definition of “minimal fitting”, which is the Ohio statutory language corresponding most closely to the CMS description “minimal self adjustment.” The Ohio language focuses more on device characteristic-specific details, see sub part (G) of the same rule:

“Minimal fitting” as used in section 4779.01 of the Revised Code and [rule 4779-3-02](#) of the Administrative Code means a prefabricated device which is fit for size by use of not more than two simple body size measurements; which is sized as small, medium, large, extra large, 2xl, 3xl; which is fastened or fit to the body or body part by use of elastic or self-fastening straps, buttons or strips; which is not molded by the consumer-care provider to fit the consumer; and which is not provided by the manufacturer with items or component parts which are intended or designed to be custom molded, heat moldable or custom fitted.”

5. Breast prostheses/mastectomy fitting (PD01) and other “cosmetic” work (PD03) are specifically exempted from OP&P licensure requirements at [ORC Section 4779.01\(I\)](#).

6. We have developed a guidance document demonstrating how the Ohio regulatory rubric is applied to determine if a prefabricated device is considered custom fitted (reserved for licensed dispensation) or not custom fitted, and thus not reserved for licensed dispensation:

<http://opp.ohio.gov/rp/DMEPOS%20Codes%20combo%20with%20references%2006.2011.pdf>

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