

4755-70-01

**3-D Printing of Open-Source Prosthetic Kits.**

- (A) Pursuant to section 4779.02 (C) of the Ohio Revised Code, the Ohio Occupational Therapy, Physical Therapy, and Athletic Trainers Board must grant to a person who meets the requirements listed in paragraph (C) of this rule the authority to engage in 3-D printing of open-source prosthetic kits. Such a person must not represent that the person is authorized to practice prosthetics or orthotics and prosthetics under chapter 4779 of the Revised Code and may not use the title “licensed prosthetist” or “licensed prosthetist-orthotist.”
- (B) “3-D printing of open-source prosthetic kits” includes the fabrication of upper limb prostheses using a 3-D printer with designs originating from open-sources. The Board will not grant authority to 3-D print open-source lower limb prostheses.
- (C) A person seeking authority to engage in 3-D printing of open-source prosthetic kits must submit an application that demonstrates the person meets the following requirements:
- (1) The applicant demonstrates proficiency in the use of 3-D printing applications. Examples of ways an applicant can demonstrate proficiency include:
    - (a) 3-D printing coursework;
    - (b) Relevant training or credentials that include knowledge of appropriate material use and an understanding of how a person with limb difference uses the printed device; and
    - (c) Examples of experience printing 3-D products for individuals in the limb-different community.
  - (2) The applicant must keep on file the contact information of a medical professional for each person to whom a 3-D printed prosthetic is designed or provided. The applicant must agree to cooperate with the designated medical professional upon request to provide continuity of care. The medical professional must be an individual who holds a current, valid licensed, certificate, or registration issued under Chapter 4723, 4729, 4730, 4731, 4755, or 4779 of the Revised Code and in whose scope prosthetics is included.
  - (3) The applicant must disclose in written form to each recipient of a 3-D printed prosthetic the following:
    - (a) That the applicant does not hold a license to practice prosthetics or prosthetics-orthotics under Chapter 4779 of the Ohio Revised Code; and
    - (b) If applicable, that the applicant does not carry liability insurance.

(D) All applications for authority to engage in 3-D printing of open-source prosthetic kits must be submitted to the Occupational Therapy, Physical Therapy, and Athletic Trainers Board on forms provided by the board. The Board will retain all applications, statements, and other documents so submitted according to public records guidelines.

(E) Applications must be:

(1) Submitted electronically;

(2) Signed electronically;

(3) Accompanied by a fee of up to \$25;

(4) Accompanied by such evidence, statements, or documents as specified on the application.

(F) Any application received in accordance with this rule that remains incomplete one year after the initial application filing must be abandoned and no further processing must be undertaken with respect to that application.

(1) If the application process extends for a period longer than one year, the board may require updated information as it deems necessary.

(2) No application for authority to engage in 3-D printing of open-source prosthetic kits may be withdrawn without approval of the board.

(3) Submitted fees are neither refundable nor transferable.

(G) All persons with authority to engage in 3-D printing of open-source prosthetic kits must renew their authority by the thirty-first day of January in each even-numbered year. When authority to engage in 3-D printing of open-source prosthetic kits is issued by the board on or after October first of an odd-numbered year, that authority is valid through the thirty-first day of January of the second even-numbered year.

(1) There will be a renewal fee of \$25.

(2) Persons who fail to submit the renewal fee, completed application, and any other required information by the deadline will have their authority to engage in 3-D printing of open-source prosthetic kits automatically expire.

(3) The licensure renewal notice shall be sent to the e-mail address on file with the board.

(H) The Occupational Therapy, Physical Therapy, and Athletic Trainers Board, upon review of the application materials, may grant, deny, or revoke authority to engage in 3-D printing of open-source prosthetics kits.

(I) In accordance with Chapter 119. of the Revised Code, the Ohio occupational therapy, physical therapy, and athletic trainers board may suspend, revoke, or refuse to issue or renew the authority to engage in 3-D printing of open-source prosthetic kits, or reprimand, fine, place an authority holder on probation, or require the authority holder to take corrective action courses.

Effective: 6/29/2020

Five Year Review (FYR) Dates: 06/01/2025

CERTIFIED ELECTRONICALLY

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Certification

05/28/2020

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Date

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Rule Amplifies: 4779.08, 4779.40