



Common Sense Initiative

Mike DeWine, Governor
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Business Impact Analysis

Agency, Board, or Commission Name: Occupational Therapy, Physical Therapy, and Athletic Trainers (OTPTAT) Board

Rule Contact Name and Contact Information:

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Regulation/Package Title (a general description of the rules' substantive content):

Authority to engage in 3-D printing of open-source prosthetic kits

Rule Number(s): 4755-70-01

Date of Submission for CSI Review: 11/27/2019

Public Comment Period End Date: 12/20/2019

Rule Type/Number of Rules:

New/ 1 rules

No Change/ rules (FYR?)

Amended/ rules (FYR?)

Rescinded/ rules (FYR?)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**
- d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**

Please include the key provisions of the regulation as well as any proposed amendments.

Ohio Revised Code Section 4779.08 (A)(16), as amended by House Bill 166 (133rd General Assembly) permits the OTPTAT Board to “establish requirements for an individual who is not licensed under this chapter to practice prosthetics or orthotics and prosthetics to engage in the 3-D printing of open-source prosthetic kits.” This rule sets the requirements to obtain the authority to engage in 3-D printing of open-source prosthetic kits.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

Ohio Revised Code Section 4779.08 (A)(16),

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

If yes, please briefly explain the source and substance of the federal requirement.

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No. The regulation does not implement a federal requirement or program.

5. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

There is no federal requirement. This is pursuant to Ohio law.

6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

As technology of 3-D printing evolves, there is a national movement to provide an alternative product in the prosthetics space that is 3-D printed. This technology is typically developed by individuals with knowledge, interest, or experience in engineering, but not necessarily with a medical background, such as training in prosthetics. As more individuals get involved in filling a demand for 3-D printed prosthetics, it is important to have some oversight of this niche as it evolves with the ultimate goal of protecting the patient/limb recipient. The legislature gave the Board oversight in this area and the Board hopes to learn more about the training and activities of 3-D printing with the goal of evolving regulation as the technology changes.

7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

Number of authorities granted by the Board, time it takes to receive permission from the Board, complaints received by the Board, discipline issued by the Board

8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

The OTPTAT Board established a workgroup to help develop this rule. The workgroup met on September 10, 2019 and September 27, 2019 both in -person and via phone. The group continued to discuss drafts via email ultimately producing the draft submitted to CSI. This draft was sent out for comment to all licensed orthotists, prosthetists, and pedorthists. The members of the OTPTAT Board also all reviewed the draft. Members of the working group included:

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Brian Weaver, licensed prosthetist-orthotist and member of the OPP Advisory Council

Lynn Busdeker, PT and member of the OTPTAT Board

Beth Ann Ball, OT and member of the OTPTAT Board,

Trevor Vessels, public member of the OTPTAT Board,

Aaron Westbrook, founder of Form5 Prosthetics

Dianne Farabi, Executive Director Ohio O & P Association

Carrie Kuruc, Common Sense Initiative

Michael Sotak

Mac McClellan, POA Texas

Connor Hart, Hands of Hope Foundation

Enable UC

Additionally, OTPTAT Board staff consulted with the following individuals who have various experience in 3-D printing:

Ivan Owen, eNable

Jamie Basch, OT

Alexis Wagner

Tracy Slemker, LPO

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

The workgroup discussed several approaches to regulation. The iterations of this rule draft incorporated feedback from the workgroup, such as asking individuals to identify if they do not have liability insurance and to limit the production of 3-D prosthetics by unlicensed people to upper limb. Other ideas were difficult to implement, such as limitations on the materials that may be used since this is a constantly evolving space.

In addition to the workgroup, the following feedback was received as a part of early stakeholder release efforts:

Jay Estoquia	The rules and guidelines for 3-D printing licensure seem fair to me and I hope can be a benefit for the people that need it.
Owen Yager	I was the previous president of Enable UC and currently their Graduate Advisor for 2020. Here are my questions regarding the 3-D Printing Rules

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Enable UC Graduate Advisor	<ol style="list-style-type: none"> 1. What exactly will I have to do on my end to be a person who creates "3-D printed open-source kits" if this was passed tomorrow? 2. Why can't we create lower limb prostheses? (Section B) I am currently doing projects with lower limbs and I see no problem using this technology to do so. 3. Why is there a fee? Where does this money go, and do licensed prosthetists have to pay a yearly fee? I see no reason for a fee when we are not making money off of this technology. (section G) 4. How can you prevent us from creating prosthetics for customers? (Section H)
Tamara Singer, L.Ped	Only those who hold Ohio Board licensure as a Prosthetist, Orthotist, or Pedorthist shall be able to perform their duties within their scope of practice. If you don't hold a license, you don't practice. OT, PT, and ATC shall practice within their scope of practice ONLY!
Nick Denroche CP	<p>In regards to your request for comments on the proposal to grant authority to unlicensed individuals regarding open source 3D printed upper extremity prostheses, please take into consideration the following thoughts / comments:</p> <p>As a CP who is licensed to practice prosthetics in the States of OH and NJ and who has been 3D printing for 5 years for both prosthetic and non prosthetic applications I have concerns regarding a non-certified individual fitting a prosthesis. My understanding is that this applies exclusively to upper limb prostheses and not lower limb. There are currently very few individuals with access to the type of equipment that would be required to fabricate a structurally sound and safe 3D printed lower limb prosthesis. I don't believe the board should grant any type of provision for the fitting of a lower limb prosthesis by someone who doesn't hold an ABC prosthetics certification.</p> <p>In regards to open source upper limb 3D printed prosthetics, I would urge caution with allowing non-certified individuals to perform this function. Traditional prosthetic material science and fabrication techniques are vastly different from 3D printed technologies. They have been tested and validated whereas the majority of open source 3D printable prosthetics have not. The fitting and fabrication of upper limbs prosthetics is also a highly specialized area of application in the field, even among certified individuals. The likeliness of someone having the knowledge of upper</p>

	<p>extremity anatomy, prosthetic fitting techniques, functional knowledge of how an upper extremity prosthesis is intended to function, being able to thoroughly educate the person being fit on proper usage, wear and care instructions, etc. in addition to material science regarding 3D printed components without having completed a formal prosthetics education program seems to me as though it would be highly unlikely.</p> <p>No matter what type of 3D printing is being used to create the components of the prosthesis, most likely filament feed machines (FFF / FDM) or SLA resin printers, there are many different types of materials that can be utilized. Many are hybrid materials like PETG combined with Carbon Fiber or different Nylon composites. The strength of these materials is not known and is dependent not only on the make up of the filaments or resins but also in the fabrication process it's self. Many prints using FFF or FDM machines have very long print times, some with over 24 hours of continuous printing. From my experience this increases the chances that you may not get a "perfect" print. Some of the layers may not bond together as intended which leads not only to warpage and distortion of the end product but compromises strength and integrity as well. As there are literally hundreds of different machines now available for retail purchase ensuring quality control and production of these devices would be nearly impossible without having someone who is both qualified to fit and fabricate upper extremity prostheses and also possess a knowledge of 3D printing technologies assess the machines, materials and techniques being used to fabricate these devices. Whether or not some of these materials may cause skin irritation is also not known and should be taken into consideration.</p> <p>That being said, I would hate to see measurements enacted that would stifle or prevent the exploration and adoption of new technologies into the field of prosthetics. If there is a way to properly vet applicants prior to granting them special provision than I think it would acceptable to allow them to operate under strict guidelines limiting them only to the fabrication and fitting of open source 3D printed upper extremity prostheses. I would be happy to share my additional thoughts on this proposal if requested.</p>
Ivan – eNable	<p>Glad that this is starting to happen. Put it out there in open source. Because it was there for a year, now nobody can patent it. Began to grow very rapidly. It is important, particularly at the organization level. Lower limb needs particular knowledge – a “nightmare” without it. Likes the language that is there. Would be interested in building in exemptions and protections. Such as for oneself or family. This is supported by current</p>

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	federal law (depending on the origin of the file they are using – intellectual property-wise). If they download a device that has certain intellectual property and they print it and assemble it for self or loved one, it constitutes pre-market prosthetic components. Those licenses are for people not profiting off of it. Essentially public domain.
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11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

None. This is a new field. Ohio is the first to attempt to regulate.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

The authority to 3-D print was contrasted with licensure, which is what the law requires for the rest of the professions overseen by the OTPTAT Board. License is not the standard mentioned in the law pertaining to the authority to engage in 3-D printing of open-source prosthetic kits.

13. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

With regard to the required education to receive authority to 3-D print open source prosthetics kits, the Board does not prescribe a specific coursework path, but instead requires the applicant to describe to the Board how he/she has the knowledge to 3-D print open source prosthetics kits.

14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

Review of current Ohio law.

15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The agency plans to upgrade the eLicense system to intake applications for permission to do 3-D printing of open source prosthetic kits. The cost of doing so is estimated to be over \$20,000. But this is consistent with all other business practices of the agency. The Board hopes to begin accepting applications in the spring. All applications will be considered by a Board members and recommendations made for approval. Over time, the Board will be able

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to gather more information on what to expect in an application and standard guidelines to issue authority for 3-D printing of open source prosthetic kits.

Adverse Impact to Business

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community; and

The scope includes individuals who wish to have permission to 3-D print open-source prosthetic kits, the individuals with limb loss seeking such a product, employers of individuals who wish to 3-D print open-source prosthetic kits

b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and

Fees, time, educational costs

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

There will be an application fee of no more than \$25 every two years. There will be time spent learning the skills to 3-D print open-source prosthetic kits, which is an advanced skill with a 3-D printer. There may be a cost to such education, but since there is no particular path to gaining education, it is difficult to estimate. One can glean knowledge through school or even online through youtube.

17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

This rule attempts to balance basic public protection with the flexibility to allow technology to develop.

Regulatory Flexibility

18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

No. The creation of this authority is to allow this technology to evolve without a prosthetist license required.

19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

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The Board will take into account first time offenses for any violations, especially since this is an emerging area of work.

20. What resources are available to assist small businesses with compliance of the regulation?

The Board staff may be contacted at any time to provide assistance with an application, via phone, email, web, facebook, twitter, or mail.