3-D Printing as a small-scale and possibly home-based manufacturing technique has been much in the news over the past year or two; tantalizing stories about prosthetic hands for children with manual deformities “printed” at a purported cost of $50 or so frequently pop up on local news and in online stories and videos. Often, these stories feature the efforts and research conducted by current university students or others who seek to replicate the learning engaged in by prosthetic practitioners, although focused on perhaps only one small segment of limb loss challenges.

It will largely be up to the profession to engage in the public education required to inform consumers and policy makers about the actual costs of providing these services -- costs that are not being quantified in these news pieces. It is apparent at this point, without diving too deep below the surface, that the printers themselves are being distributed often as demonstration models for promotional purposes – promoting the interests of the printer manufacturers perhaps more so than the kids being given a new level of manual dexterity. What would the cost be if it factored in hardware and software acquisition/depreciation costs and schedules, device design and assembly, and the human capital required to tie it all together?

And does the Board as a regulatory entity have a role to play?

If so, it is probably not to determine whether someone offering these devices in a charity context is providing services improperly, without license or credential. However, since we are charged to appropriately implement the Practice Act, we should review our regulatory language to determine if any change is needed to address the manufacturing development and to assure our regulations stay current and meaningful.

**The Power and Responsibility to Refine and Define**

Charged as we are in Ohio with the task of justifying rule language that is promulgated as not in conflict with other federal or state laws, and further to demonstrate its necessity if there is no federal requirement to do so, we have an opportunity to look at what we have done in this regard and to determine if there is more work to do.
In 2008, we adopted the “Device-related and scope of practice definitions” rule as OAC 4779-3-02 to map out where our provisions align with federal DMEPOS sector regulatory language, and to more clearly draw the lines of differentiation where they exist(ed).

In doing so, we drew heavily on the most detailed federal language available that is on point and targeted for regulation of the DMEPOS sector: the CMS DMEPOS Quality Standards. Thus, we modeled the language to define “custom fabricated or fitted medical device” as used in the statute on the Quality Standards Appendix C treatment, as follows:

**4779-3-02 Device-related and scope of practice definitions.**

The following definitions shall apply to the language of Chapter 4779. of the Revised Code:

(E) "Custom fabricated or fitted medical device" as referenced in division (E), (G), or (I) of section 4779.01 of the Revised Code means an orthotic, prosthetic or pedorthic device that is individually made (custom fabricated) or fitted (custom fitted) for a specific patient. Further, it is a device the provision of which requires access to a facility with the equipment necessary to fulfill the ongoing consumer-care responsibility to provide follow-up treatment, including modification, adjustment, maintenance and repair of the item(s).

(1) A custom fabricated item is defined as a device which is individually made for a specific patient. No other patient would be able to use this item. A custom fabricated item is a device which is fabricated based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as x-rays) of the body part. The fabrication may involve using calculations, templates and components. This process requires the use of basic materials including, but not limited to plastic, metal, leather or cloth in the form of uncut or unshaped sheets, bars, or other basic forms and involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling and finishing prior to fitting on the patient.

A **molded-to-patient-model item** is a particular type of custom fabricated device in which either:

(a) An impression (usually by means of a plaster or fiberglass cast) of the specific body part is made directly on the patient, and this impression is then used to make a **positive model of the body part** from which the final product is crafted; or

(b) A digital image of the patient's body part is made using computer-aided design-computer aided manufacture (CAD-CAM) systems software. This technology includes specialized probe/digitizers and scanners that create a **computerized positive model** and then direct milling equipment to **carve a positive model**. The device is then individually **fabricated and molded over the positive model** of the patient.

(2) A custom fitted item is defined as a prefabricated device which is manufactured in quantity without a specific patient in mind. The device may or may not be supplied as a kit that requires some assembly and/or fitting and adjustment, or a device that may be trimmed, bent, molded (with or without heat), or otherwise modified by an individual with expertise in customizing the item to fit and be used by a specific patient.
Questions for Practitioner Board Members and Interested Party Stakeholders:

1. Does 3-D manufacture assisted prosthetic design and manufacturing fall within the allowable scope of practice of a licensed or certified prosthethist?
   
   1.1. Does 3-D manufacture assisted prosthetic design and manufacturing fit within the general description of “custom fabrication and custom fitting”?

2. Does 3-D manufacture assisted prosthetic design and manufacturing entail development of a “computerized positive model” that fits within the current Ohio regulatory language?

3. What changes by amendment, addition or deletion of current language might be indicated to assure that Prosthetic Practitioners can provide services utilizing the most current technologies available?

4. Is there anything about the 3-D printing and manufacture enterprise or protocol itself to indicate it is a technique that cannot or should not be utilized by a professionally-appropriate, standards-based prosthetic practitioner?

5. Are there any other questions to consider in this review?
Toward Collaboration: The 3D-Printing Community and O&P Professionals

By Jon Schull, PhD

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In July 2013, I founded e-NABLE, a global community of volunteers who develop and distribute free, 3D-printed upper-limb prostheses to children who were born missing fingers. Our Google+ community has since grown to more than 4,000 members, we have delivered about 1,000 devices, and we were featured in the February 17 New York Times.

I often remark that e-NABLE makes “children smile, parents weep, and nerds rejoice,” but I should probably add that it also makes some O&P professionals worry about how it will impact their profession. We worry too: We want to make sure we only offer simple and inexpensive solutions when they really are solutions. We must not provide illusory solutions to recipients who have better or more appropriate options. And we want to help, not hinder, O&P professionals and commercial prosthetics manufacturers as they develop and distribute ever-better products and services to ever-wider markets.

So, hat in hand, we approach with open arms, and hope you will reciprocate. The following are ideas for collaboration.

Case review and referral. We are developing a process for “triage” of prosthetic cases: cases in which volunteers can immediately provide a solution, cases that require medical consultation, and cases that e-NABLE cannot serve. We welcome consultation and advice from the O&P community, and want to refer cases that cannot be served by e-NABLE to professionals.

Fact sheets. We would like to collaborate on the development and release of a fact sheet about 3D-printed upper-limb prostheses so we’re on the same page. Professional training. At a recent conference at Johns Hopkins Hospital, Baltimore, we conducted a BOC-certified continuing education credit workshop on e-NABLE’s methods, processes, designs, and technologies. We could develop training with, and for, O&P professionals.

Device certifications. As designs proliferate, we are developing processes for distinguishing “experimental,” “beta,” and “release” e-NABLE devices. A certification
process would allow all of us to be more confident that the right devices are being used in the right cases.

**Medical-grade e-NABLE devices.** We are exploring the use of commercial selective laser sintering services, like Shapeways, for assured quality e-NABLE devices that are less expensive than existing medical devices yet substantially stronger and more reliable than volunteers can reliably produce. These could be made available to O&P professionals.

**A skunkworks for interesting cases and unsolved problems.** We can develop new solutions together. Our community is willing to brainstorm and prototype new solutions for interesting O&P challenges. e-NABLE member Jeff Erenstone, CPO, recently asked our community for ideas to help a patient who had been a professional welder. He and another member—a welder and master machinist— are developing a device together.

**Database development.** A database about the deployment, usage, and feedback of 3D-printed upper-limb prostheses could benefit all parties.

Opportunities abound for collaboration among the e-NABLE community and O&P professionals, and the newly formed Enable Community Foundation is eager to facilitate. To learn more about e-NABLE, visit our website, enablingthefuture.org; participate in a private, moderated discussion forum; and if you agree that we have good work to do together, please join our private Google+ community and introduce yourself.

*Jon Schull, PhD, is the founder of e-NABLE, president of the Enable Community Foundation, and research scientist in MAGIC (the Center for Media Arts Games Interaction and Creativity) at Rochester Institute of Technology. He can be reached at jschull@enablecommunityfoundation.org.*