

# Notice to the Professions

## Regulation of Personal Sound Amplification Product

February 26, 2020

The College of Speech and Hearing Health Professionals has received questions about the role of regulators and hearing amplifiers, which include a broad range of devices known generally as personal sound amplification products (PSAPs), but also include “over-the-counter” (OTCs) and “direct-to-consumer” (DTC) hearing devices. In BC, some retailers sell various types of hearing amplifiers directly to consumers, which has raised questions from registrants about who can sell hearing devices and how these devices differ from traditional hearing aids.

### Hearing Aids vs. PSAPs

Hearing aids or instruments are regulated in BC under the [Health Professions Act, R.S.B.C. 1996, c. 183](#) (“HPA”), and specifically under the [Speech and Hearing Health Professionals Regulation, BC Reg 413/2008](#) (the “Regulation”). The Regulation defines “hearing instrument” as a device designed or offered to address hearing conditions, which includes traditional hearing aids. Hearing aids are also regulated under Canada’s [Food and Drug Act](#) (the “CFDA”) as a medical device, because they are designed to treat a hearing condition.

Hearing amplifiers and other PSAPs are currently not regulated in BC or Canada. These devices are offered to amplify or improve sound, without treating a hearing condition. PSAPs do not meet the definition of “hearing instrument” under the Regulation or as a “medical device” under the CFDA, as they are not designed or offered for a hearing condition. Therefore, PSAPs do not require a prescription or fitting from a hearing professional registered with the College.

### The College’s jurisdiction

The College has jurisdiction over its registrants to ensure that they meet the minimum standard of practice and legislated requirements. Under the Regulation, while a Registered Audiologist (RAUD) may diagnose and prescribe a hearing instrument, only a Registered Hearing Instrument Practitioner (RHIP) may dispense a hearing instrument. In contrast, anyone may dispense a hearing amplifier or other PSAP – if the device is not a hearing instrument – regardless of whether they are licensed by the College.

The College has jurisdiction over persons who engage in unlawful practice of a speech and hearing profession by practicing restricted activities, which are the activities under the Regulation which only a registrant may practice. These activities include selling or offering to sell hearing instruments, which, as stated above, are devices designed or offered to address hearing conditions.

The College does not have jurisdiction to take regulatory action against persons selling PSAPs. However, if a person is selling these hearing devices and using a reserved title limited to registrants, or performing services restricted to registrants, the College may be required to intervene or take regulatory action.

### **What are other jurisdictions doing about PSAPs?**

Other jurisdictions in Canada are monitoring developments regarding PSAPs and health regulation. In Canada, no jurisdiction currently regulates PSAPs.

In the US, hearing aids are regulated as medical devices, while PSAPs are currently unregulated. However, new regulations will be put in place in August 2020 to outline the regulatory framework specifically for OTCs, which may differentiate between the different types of sound amplifiers and hearing products available directly to the public. The College continues to monitor these developments.

### **What should registrants be doing about PSAPs?**

The College expects that registrants will continue to comply with their professional and ethical responsibilities to ensure client wellbeing is a priority. Registrants must provide clients with accurate information regarding their health condition so that clients can make an informed decision about the most appropriate device for their specific healthcare needs. For some, PSAPs may be an appropriate choice to address their hearing needs. Registrants should ensure clients are informed about the risks from using hearing devices that are improperly fit or that do not effectively address their hearing needs.

### **The College's public protection mandate**

The College has a legislated mandate under the HPA to protect the public. The College continues to monitor the regulatory developments regarding these types of devices to ensure public safety.

If you have questions about whether a device is regulated or have concerns that someone may be engaging in unlawful practice, please contact the College.