SAC OAC
Speech-Language & Audiology Canada
Orthophonie et Audiologie Canada
Communicating care | La communication à coeur

December 3, 2018

David Boudreau
Executive Director
Medical Devices Bureau
Health Canada

Dear Mr. Boudreau:

Re: Impact the Medical Device Single Audit Process (MDSAP) on Speech-Language Pathology Services

On behalf of Speech-Language & Audiology Canada (SAC), I am writing to bring your attention to the impact of the Medical Device Single Audit Process (MDSAP) on speech-language pathology services in Canada.

SAC is a member-driven professional organization that supports and represents over 6,600 speech-language pathologists, audiologists and communication health assistants across Canada. Through this support, SAC champions the needs of people with communication and swallowing disorders.

We are extremely concerned that patients with tracheostomies, laryngectomies and dysphagia (swallowing disorder) will not have access to medical devices they need to help them communicate and swallow after MDSAP comes into force on January 1, 2019.

Critically and chronically ill children and adults with tracheostomies, laryngectomies and dysphagia are among the most vulnerable of Canadians. Their health, ability to communicate and quality of life will be harmed without ongoing access to necessary medical devices.

SAC asks that Health Canada consider an exemption to MDSAP for specialized medical devices needed to help people with tracheostomies, laryngectomies and dysphagia to communicate and swallow.

SAC recently consulted our members and associates regarding the impact of MDSAP on their clinical practice and research programs. Speech-language pathology members report that the following medical devices will not be available in Canada after January 1, 2019:

- Passy-Muir Tracheostomy Speaking Valve
- Iowa Oral Performance Instrument

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- Fahl Laryngectomy Tube
- Servox Electrolarynx

More information about these medical devices can be found on the enclosed attachment.

Without ongoing access to these medical devices, the health and well-being of critically and chronically ill children and adults in Canada will be detrimentally affected. SAC wishes to ensure the continued availability of medical devices essential for the appropriate management of tracheostomies, laryngectomies and dysphagia.

I trust you will give due consideration to SAC's concerns, and work to ensure uninterrupted access after January 1, 2019 to these medical devices. We would greatly appreciate the opportunity to meet with you to discuss the concerns raised by our members.

Yours sincerely,

Sincerely,

Joanne Charlebois
Chief Executive Officer
Speech-Language and Audiology Canada

Enclosure
c.c. The Hon. Ginette Petitpas Taylor, P.C., M.P., Minister of Health

Medical devices that will not be available in Canada after January 1, 2019

Passy-Muir Tracheostomy Speaking Valve (PMV): The PMV is a device that is placed on the end of the tracheostomy tube to allow the patient to speak. The use of this device is backed by strong research evidence. Since the PMV allows the patient to breathe through their nose and mouth, it also facilitates improvements in health and quality of life. Although there are alternative speaking valves, they cannot replace the PMV in all clinical situations. For example, the PMV is the only valve that can be used by patients receiving mechanical ventilation. Pediatric patients are of particular concern. Those without PMV may need additional oxygen or a ventilator. Furthermore, some non-ventilated tracheostomy patients report increased need for humidity when wearing a speaking valve other than a PMV. The PMW is also a key component of several Canadian speech-language pathology research labs.

Iowa Oral Performance Instrument (IOPI): The IOPI is a biofeedback device used in the assessment, treatment and study of patients with dysphagia and speech disorders. Speech-language pathologists have no alternative medical device available for tongue pressure resistance training, swallowing therapy and research. The use of this device is backed by strong research evidence.

Fahl Laryngectomy Tube: Laryngectomy tubes are used to keep the tracheostoma open after a laryngectomy and prevent narrowing of the tracheostoma in the months following laryngectomy. Quality of patient care will be affected if speech-language pathologists are unable to recommend the Fahl laryngectomy tube when clinically necessary.

Servox Electrolarynx: An electrolarynx is a medical device that enables a person with a laryngectomy to speak. Although Health Canada reclassified these medical devices before the introduction of MDSAP, the Servox electrolarynx is no longer available in Canada. Servox's decision to leave the Canadian market has been attributed to MDSAP.