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Medical Devices Branch
Therapeutic Goods Administration
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Consultation: Regulation of software, including Software as a Medical Device (SaMD)

TGA team,

Thank you for the opportunity to provide input to the above consultation on behalf of the Private Health Insurance Industry (PHI) and their peak body Private Healthcare Australia (PHA).

Private health funds are the custodians of members' contributions and these are limited by affordability. As with all health system funding, these funds are a public good and are constrained. Our members expect that medical devices including software are safe and effective and implicitly place expectations on PHI funds to be a representative for them within health sector delivery. PHA recognise the global nature of downloading software/apps in a virtual environment make it challenging to regulate these categories in the same way as medical devices supported through traditional supply chains. We support the TGA's position that the growth of software and the level of intervention it now offers places many of these products/programs in high risk TGA classifications.

We support this proposed consultation and the changes proposed. PHA is supportive of the concept of a level playing field and remains concerned that these changes can be successfully implemented. The ability for global multinationals to act outside of the jurisdiction of the TGA in software will represent a challenge, particularly where not having an Australian sponsor provides for lower cost and the ability to offer products/programs that would otherwise be regulated in Australia.

In addressing the specific questions provided:

1) *Do you support the proposal to change the way medical device software is regulated? Why or why not? If you do not support the proposal, do you have any suggestions for an alternative that would be acceptable to you?*

PHA supports the regulation of software for the reasons outlined by the TGA in the consulting document, particularly for the damage this software could represent and similarly the ability to hold the sponsor / manufacturer to account. This should be viewed in parallel with ensuring sanctions related to inappropriate advertising are also achieved. We remain concerned about the ability to achieve this while maintaining an appropriate and level playing field between suppliers.

2) *What do you consider to be the benefits and disadvantages of the particular proposals for change?*

The benefits clearly relate to greater scrutiny on this emerging field of devices and accountability of suppliers/sponsors to meeting Australian standards. For the TGA and greater government it will give capacity to address the public, who may have perceptions that certain APPS or software have been appropriately reviewed by the TGA when this may not be the case. Though not related to this consultation this situation is similar to many technologies employed in the facial aesthetics and cosmetic surgery area, where the general public believes these items have been reviewed by the TGA.

3) *Do you believe there will be any unintended consequences arising from the proposed changes?*

We do not foresee any unintended consequences, but the TGA will need to link software suppliers with a local sponsor, or the threat will remain that software suppliers will increasingly move their business models offshore to avoid cost and scrutiny associated with TGA listing. It can be assumed that few consumers will seek to identify for themselves whether a software medical device carries appropriate regulatory clearance from the TGA to operate in Australia if accessed through the internet.

4) *What changes would you need to make (if any) to meet the new arrangements? If not, what are the impediments?*

We do not anticipate any changes to PHA and PHI funds. It may be advantageous for the TGA to do an initial screen of the market to identify which software as a medical device is being offered in Australia and identify the local sponsor (prior to making the change, to avoid offshoring of the operation). Similarly those identified as operating in the market without a local sponsor should be approached to comply with local TGA requirements (assuming no capacity exists for the TGA to block overseas sites, or referencing them in some way as not regulated by the TGA).

5) *What financial impact (both costs and savings) would implementing the proposed amendments have for you? If possible please provide a breakdown of the impacts. This information will be used to quantify the financial impact to all affected stakeholders.*

No cost imposition to PHA or PHI entities. There is a potential long-term cost saving by avoiding harm which may arise from from health fund members using non validated software devices, resulting in hospitalisation or other specialised treatment funded by PHI.

6) *What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional arrangements.*

N/A

Thank you again for the opportunity to contribute to this consultation.

Best Regards

[redacted]

Craig Moy
Director of Access & Reimbursement
On behalf of Private Healthcare Australia and the Private Health Insurance Industry member funds