Private Healthcare Australia
Better Cover. Better Access. Better Care.

Unit 32, Level 1, 2 King St, Deakin ACT 2600
T (+61) 2 6202 1000
F (+61) 2 6202 1001
www.privatehealthcareaustralia.org.au
ABN: 35 008 621 994

29 March 2019

Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Consultation: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices

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 are safe and effective and implicitly place expectations on PHI funds to be a representative for them within health sector delivery. We thank the TGA for recognising this critical issue but also delivering proposed measures that are not onerous on manufacturers, sponsors and clinicians. The commitment to educating patients on their personalised device to facilitate informed consent is a positive step.

PHA expect 3D printed devices to continue to expand both in volume, complexity and indications; it will be critical that the TGA remain abreast of evolving new technologies adopting 3D/personalised design and novel supply channel changes that we expect will also result. Device production in non-manufacturing settings such as doctors' consulting rooms or hospitals is concerning for reasons of safety and appropriate record keeping. We support restriction of MDPS to class IIa and below. It may be prudent for sponsors and manufacturers to perform regular checks to ensure use is consistent to the conformity assessment.

While not a feature of this review, PHA and PHI funds are equally concerned that an appropriate framework is established to determine benefits for these devices. We note that a number of personalised and 3D printed devices are already being funded including oral and maxilla facial implants on the Prostheses List. With orthopaedics also likely to offer personalised designed and 3D printed implants in the near future we feel it critical that the TGA/Department of Health undertake a consultation on benefit setting for personalised/3D devices. PHA's research would indicate that a move to personalised implants should reduce the cost to serve the market (i.e. reduced instrumentation and removal of standardised implant inventory).

On this basis we believe it is critical that this consultation and potential roundtables are held sooner rather than later, given the devices that have been listed to date have been done so at a higher benefit level (in some cases significantly) than other devices. We do not believe an HTA or MSAC review was involved in generating that higher benefit.

Under the proposal, devices that are patient-matched (but currently classified as custom-made) would no longer be exempt from the third party regulatory oversight mechanism. A potential unintended consequence

of the proposed changes is that manufacturers may seek to modify (or amend their description of their approach to manufacturing) personalised medical devices so that the manufactured devices are classified as custom-made rather than patient-matched. This would have the effect of diluting the intended expansion of third party assessment to include additional devices.

Under the proposal, newly classified custom-made devices will have new obligations including allowing the TGA to inspect manufacturing sites. However, the frequency of inspections and, especially, the consequences arising from such inspections to manufacturers is not specified.

Though it is acknowledged that current legislative boundaries applying to the TGA will continue to limit regulatory application to (the newly defined) custom-made devices, perhaps consideration should be given to regulating the manufacturing process (and inputs) of custom-made devices. Though custom-made devices are manufactured to meet specific requirements set by the responsible clinician, not all aspects of manufacturing are entirely bespoke and some assurances (and assumptions held by the referring clinician) would have been provided and met by the manufacturer. At the very least, the manufacturer could warrant to the clinician that the manufacturing process delivers output which meets specifications (implicit and explicit) set by the clinician.

While we recognise that further detail will be developed under each reform proposal, the consultation paper is not clear as to when the manufacturer's written statement on a custom-made device is to be provided to a patient, nor the key subject matter to be included in the written statement (other than whether or not the custom-made device complies with the essential principles). If not otherwise specified, an unintended consequence of this may be that the patient is not provided with timely and relevant (and accessible) information from the manufacturer regarding the custom-made device. We recommend the TGA consider principles of timeliness (eg before the device is implanted and not after), relevance (eg warrants from the manufacturer as to the performance limits of the custom-made device) and accessibility (eg use of language that can be understood by the patient and/or the patient's proxy) in relation to this written statement from the manufacturer.

It is unclear whether the UDI as presently contemplated will apply to patient-matched and adaptable medical devices.

In addition to the proposed requirement for manufacturers to retain data on custom-made devices for 15 years, we suggest a requirement be placed on manufacturers to retain data which would emulate the requirements under the UDI construct. This would mean post-market surveillance activities would be enhanced if custom-made devices also carried the equivalent of a UDI.

In addressing the specific questions provided:

1) *Do you support the proposal to change the way personalised medical devices are 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?*

Yes, PHA supports the proposed changes, and we believe they recognise the true nature of the design intent as well as increase the scrutiny over the manufacturing process. True custom devices are separated from patient matched devices which employ a consistent process or protocol and are personalised only to the extent of patient anatomy. For patients, it is important they receive appropriate information on the device to provide informed consent. We believe the extension of data maintenance from 5 to 15 years is appropriate for high risk devices.

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

Benefits include:

- Alignment to global best practice
- Standardised conformity assessment (levelling playing field for manufacturers / sponsors)
- Authority in third party oversight to TGA including reviews of manufacturing sites
- Reduced risk and greater information for patients referred to a patient specific device
- Potential for clearer pathways around benefit inclusion

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

When tighter guidelines are applied it usually impacts those that are under-reporting or chasing short cuts. These manufacturers or sponsors may have the greatest requirement for step-up; however this is to the benefit of the TGA and patients.

There are already examples in the market place of 3D printing of patient-specific medical devices at level IIb (see http://www.anatomics.com/company/news/ "3D Printing Lab at Wollongong Private Hospital"). These products are not listed and yet are permanently implanted. The proposed scheme is clear in that MDPS are to be "classified as Class IIa or below" (p15), however the example "Mandibular implants produced by a 3D printing manufacturer" (p20) would be akin to an implant, non-bio absorbable, and therefore a class IIb level medical device. Is the proposal to move non-bio absorbable implants to level IIa?

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

If personal devices are listed on the Prostheses List, this will mean that PHI funds will need to change their payment systems for these devices. Currently personal devices not on the Prostheses List are only funded by PHI funds on an ex gratia basis. IIa devices, if temporary and disposable, are currently often bundled in DRG or Theatre payments.

We do recognise that greater regulatory control would facilitate easier recalls and identification of impacted patients. We would see this framework working in partnership with the introduction of UDIs.

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.*

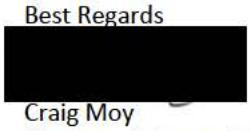
In the longer term we would expect reduced cost resulting from extended recording of devices (15 years). Linking the devices to a UDI would also be likely to reduce the cost of identifying members impacted by a recall. Compliance with the new regulatory requirements should be prerequisite for personal devices to be listed on the Prostheses List. To ensure that Prostheses List benefits are set at an appropriate level for these novel devices, we recommend the TGA/Department of Health consult on the benefit-setting methodology to be applied to such devices.

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

Funds will need a sufficient lead time to implement changes to payment models if devices are listed on the Prostheses List.

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

Best Regards



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