s22 [redacted]

From: FLYNN, Elizabeth
Sent: Monday, 11 April 2022 1:09 PM
To: PLATONA, Adriana <Adriana.Platona@health.gov.au>; s22 [redacted] @health.gov.au>; s22 [redacted] @health.gov.au>
Subject: FW: URGENT Correspondence from MTAA - Delivering The Government's Prostheses List MoU [SEC=OFFICIAL]

From: Minister Hunt <Minister.Hunt@health.gov.au>
Sent: Saturday, 9 April 2022 10:27 AM
To: MPS <MPS@health.gov.au>; s22 [redacted] @health.gov.au>
Cc: s22 [redacted] @health.gov.au>; FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>
Subject: FW: URGENT Correspondence from MTAA - Delivering The Government's Prostheses List MoU [SEC=OFFICIAL]

For info please – TAAD

s22 [redacted]
Departmental Liaison Officer
Office of the Hon Greg Hunt MP
Minister for Health and Aged Care
T: s22 [redacted] M: s22 [redacted]
E: s22 [redacted] @health.gov.au
Suite M1.41, PO Box 6022, Parliament House, Canberra ACT 2600, Australia

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From: Hunt, Greg (MP) <Greg.Hunt.MP@aph.gov.au>
Sent: Friday, 8 April 2022 9:16 PM
To: Minister Hunt <Minister.Hunt@health.gov.au>
Subject: Fwd: URGENT Correspondence from MTAA - Delivering The Government's Prostheses List MoU

From: Matthew Versi <s47F [redacted]
Sent: Friday, April 8, 2022 8:05:45 PM
To: Hunt, Greg (MP) <Greg.Hunt.MP@aph.gov.au>

Cc: Morrison, Scott (MP) <Scott.Morrison.MP@aph.gov.au>; Sam Develin <Sam.develin@health.gov.au>; wendy.black <wendy.black@health.gov.au>; BEHM, Alex <Alex.Behm@health.gov.au>; Maurice Ben-Mayor <s47F >; Ian Burgess <s47F >
Subject: URGENT Correspondence from MTAA - Delivering The Government's Prostheses List MoU

Dear Minister

Please find attached urgent correspondence from MTAA regarding delivering the Government's Prostheses List MoU.

Sincerely

Matthew

Matthew Versi
Senior Manager, Public Affairs & Advocacy
Medical Technology Association of Australia
M s47F
E s47F
A Level 4/97 Waterloo Road, Macquarie Park NSW 2113
MTAA.org.au | LinkedIn | Twitter

Medical Technology Association of Australia
MTAA Medical Technology ASSOCIATION OF AUSTRALIA
www.mtaa.org.au
Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
Lvl 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600
E: mtaa@mtaa.org.au

8 April 2022

The Hon. Greg Hunt MP
Minister for Health and Aged Care
Federal Member for Flinders
Parliament House
Canberra, ACT 2600

Dear Minister

DELIVERING THE GOVERNMENT'S PROSTHESES LIST MOU

We are writing, ahead of the imminent Federal Election, to raise with you the significant and serious concerns of the Medical Technology Association of Australia (MTAA) regarding the private health insurance lobby's continued campaign to sabotage the future of the Prostheses List MOU, signed last month.

Importantly we would like to, again, acknowledge and thank you for your constructive engagement during the negotiation process, not just over the past 12 months, but in the years leading up to the final signing of the four-year agreement between MTAA and the Commonwealth, supported by our private health sector partners: doctors, private hospitals and consumer groups.

The four-year agreement secured more than $900 million in cuts from the medical technology (MedTech) industry that private health insurance companies will benefit from in the form of savings. These cuts were negotiated with the specific objective of insurance companies passing them on to consumers as savings to private health insurance premiums, while also protecting patient access to, and doctor choice of, life-saving medical technologies. This agreement maintained the guarantee that doctors, not insurance companies, will continue to pick the best medical device based on their patients' needs.

"Yesterday's announcement has seen the Government make some sensible changes to its initial plans that address key concerns raised by the AMA."
– Dr Omar Khorshid, President of the Australian Medical Association

"Health Minister Greg Hunt had achieved a good outcome which preserved clinical choice for doctors, allows patients to access technology with no out-of- pockets costs and delivers additional savings for health insurers."
– Michael Roff, CEO of the Australian Private Hospitals Association

"The Agreement supports the retention of the Prosthesis List while reforming the funding arrangements. These steps should help protect patient access and choice in private health care."
– Leanne Wells, CEO of the Consumers Health Forum

MTAA is concerned the insurance lobby, Private Healthcare Australia (PHA), will use the election period to continue their negative disinformation campaign to pressure the Government on the agreement. We understand that this approach is not universally agreed by groups such as the Members Health Fund Alliance. MTAA believes the Government must stand firm and not give in to some insurers' uncooperative and destructive behaviour through the PHA.

Our MTAA members have asked that we state clearly and unequivocally our vehement rejection of any actions that would publicly undo the years of hard work done to reach this historic four-year agreement. As you know, MTAA has worked tirelessly to ensure our member companies, as well as the wider health sector stakeholders; doctors, private hospitals and consumers, trusted the merits of signing the agreement with the Government.

Were the agreement's guardrails and commitments to be adjusted by the Government, then MTAA's member companies, and our health sector partners, would have justified cause to actively campaign to protect patient choice in Australia.

MTAA's constructive approach with the Government, particularly you and your office, throughout this negotiation process has been critical in bringing along our health sector partners. As indicative in the public statements of stakeholders noted above, the agreement makes sure the reform package benefits patients and not just the insurance companies' bottom line.

The agreement's strength is in its recognition of the key market differentiators present between the public and private systems. Both these systems operate in vastly different environments with diverging market forces driving product prices, access, choice and volume – this is recognised and supported by doctors, hospitals and consumers but it is something insurers have been all too ready to skip over when railing against the Prostheses List.

MTAA stands ready, alongside our health sector partners, to actively and publicly support the Government in delivering the four-year agreement against any potential segment of the insurance industry running a disinformation campaign - as we have done throughout the negotiations.

We strongly urge you not to yield to one, particularly noisy, disgruntled segment of a lobby group who want the Americanisation of our healthcare system, ana who did everything they could to frustrate and derail the negotiations that all other health sector stakeholders engaged with proactively and constructively.

Unlike some insurance companies who raked in multi-billion-dollar profits, increased 'management expenses' and, thanks to the suspension of elective surgery, pocketed a windfall $1.4 billion in deferred claims – of which they're still yet to fully return to consumers – the MedTech industry stepped up to support Australia's vital pandemic response with thousands of ventilators, testing kits and much needed PPE. Despite these challenges and on top of the more than $2 billion in total cuts over eight years, our members have continued to provide life-saving technologies to tens of thousands of quiet Australians.

Our industry might not be the loudest voice in the room, but we're constantly 'having a go' to work with the Government to benefit all Australians. It's important this agreement now 'gets a go' to realise its benefit to the health sector (doctors, hospitals, consumers and MedTech) and to patient access and doctor choice of life-saving medical technologies. We thank you again Minister for your leadership and constructive engagement with the PL reform.

Yours faithfully

s47F

Maurice Ben-Mayor
Chair

s47F

Ian Burgess
CEO

Cc: The Hon. Scott Morrison MP

From: BEHM, Alex
To: FLYNN, Elizabeth
Cc: s22 ; DOWNIE, James; sam.develin@pm.gov.au
Subject: RE: Outcomes of meeting with Minister [SEC=OFFICIAL]
Date: Tuesday, 1 February 2022 7:32:09 PM
Attachments: Agreed negotiated positions - Minister and MTAA v2 31012235.docx
image004.png
image005.jpg
image008.png
image009.jpg
Outcome of meeting Minister and MTAA 280122.docx
image002.png

Hi Elizabeth – pls see amendments plus comment in track (discussed with Sam).

cheers

Alex

From: FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>
Sent: Tuesday, 1 February 2022 4:31 PM
To: sam.develin@pm.gov.au; BEHM, Alex <Alex.Behm@health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; DOWNIE, James <James.Downie@ihpa.gov.au>
Subject: Outcomes of meeting with Minister [SEC=OFFICIAL]

Hi Sam and Alex

Please see attached amended version, entitled "outcome of meeting Minister and MTAA 280122", together with the version Ian sent through.

If this version is acceptable to you, I will send it to Ian asking for their response on the 60/40 and 80% options for general use options with a view to finalizing the savings estimate with a number that can be agreed between IHPA and MTAA.

Elizabeth Flynn
Assistant Secretary, Prostheses List Reform Taskforce

Technology Assessment and Access Division

Australian Government Department of Health
T: 02 6289 s22 | s22
E: elizabeth.flynn@health.gov.au
Location: Sirius Building s22
PO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

100 years signature block

From: FLYNN, Elizabeth
Sent: Monday, 31 January 2022 2:53 PM
To: Ian Burgess <s47F [redacted]>
Cc: DEVELIN, Sam <Sam.Develin@health.gov.au>; DOWNIE, James <James.Downie@ihpa.gov.au>; PLATONA, Adriana <Adriana.Platona@health.gov.au>; 'Paul Dale' <s47F [redacted]>; 'mversi@mtaa.org.au' <s47F [redacted]>
Subject: FW: Outcomes of meeting with Minister [SEC=OFFICIAL]

Thanks Ian

This version now includes items that were not specifically discussed at the meeting with the Minister and I note that some have a long history:

- Request that all Class III and AIMD use the abbreviated listing pathway
  This has been rejected up until now. Clinicians have a strong view that the Class III items need to assessed and therefore would most likely use the focussed HTA pathway.
- Request for comparable products in the 400 general use item group not currently listed are allowed to be listed as an interim measure for procedural fairness.
  This has been rejected by PLAC on the grounds that the items either did not meet the definition or would not in the future and because our intention was to remove the comparable items from 1 July.

I am not able to include these most recent additions from the MTAA in a document you want characterised as "Government proposed negotiating position" because we have not proposed them.

I will need to seek guidance from the MO.

Elizabeth Flynn
Assistant Secretary, Prostheses List Reform Taskforce

Technology Assessment and Access Division

Australian Government Department of Health

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Location: Sirius Building s22
PO Box 9848, Canberra ACT 2601, Australia

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100 years signature block

From: Ian Burgess <s47F >
Sent: Monday, 31 January 2022 12:10 PM
To: FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>
Cc: DEVELIN, Sam <Sam.Develin@health.gov.au>; DOWNIE, James <James.Downie@ihpa.gov.au>; PLATONA, Adriana <Adriana.Platona@health.gov.au>; Paul Dale <s47F >; Matthew Versi <s47F >
Subject: Re: Outcomes of meeting with Minister [SEC=OFFICIAL]

Hi Elizabeth

Thank you for providing the record, the attached incorporates some additions that we have made for clarity and/or to reflect our understanding. I am keen to talk through these changes with you and align on the modelling in order to finalise within the next few days.

I note that rather than the heading in the document "Agreed Negotiated Position", this would be more accurate to be "Government Proposed Negotiated Position". Once confirmed, we will take the Government's offer to MTAA's Board for consideration and decision.

James received further detail on our modelling this morning to enable identification of points of difference in the modelling and we are ready to discuss that after James has reviewed.

Kind regards,

Ian Burgess
Chief Executive Officer
Medical Technology Association of Australia

P s47F | M s47F
E s47F
A Level 4/97 Waterloo Road, Macquarie Park NSW 2113
MTAA.org.au | LinkedIn | Twitter

From: FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>
Date: Saturday, 29 January 2022 at 5:46 pm
To: Ian Burgess s47F
Cc: Sam Develin <Sam.develin@health.gov.au>, DOWNIE, James <James.Downie@ihpa.gov.au>, PLATONA, Adriana <Adriana.Platona@health.gov.au>
Subject: Outcomes of meeting with Minister [SEC=OFFICIAL]

Hi Ian

As just discussed, here is my record of the agreements reached which could form the basis of a letter from the Dept to MTAA or the Minister to the MTAA. Please note that these are in principle agreements as there are some changes in here (compared to existing Govt policy) which the Minister would need to get endorsed – an example would be the 7% "floor" and the year 4 20% PAF.

An outcome of the meeting today is that you will work with IHPA to resolve differences in the modelling assumptions with the objective of achieving $885m (ballpark) in savings.

Elizabeth Flynn
Assistant Secretary, Prostheses List Reform Taskforce

Technology Assessment and Access Division

Australian Government Department of Health
T: 02 6289 s22 | s22
E: elizabeth.flynn@health.gov.au
Location: Sirius Building s22
PO Box 9848, Canberra ACT 2601, Australia

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100 years signature block

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ATTACHMENT A

OUTCOME OF MEETING WITH MTAA FRIDAY 28 JANUARY 2022

The MTAA have raised a number of issues with the PL Reform process. The table below outlines the outcomes following a meeting between the Minister and MTAA on Friday 28 January 2022.

	CURRENT GOVERNMENT POSITION		MTAA POSITION/COMMENT	AGREED NEGOTIATED POSITION
1	**5% price reduction deferral**	Defer price reductions for prostheses where the public/private gap is less than or equal to 5%. This proposal can be administered with the condition that the suppliers of these products are required to submit data each year to ensure that the gap does not exceed the 5% threshold.	• Devices less than 10% above the weighted public price are not reduced. Devices more than 10% above the weighted public price are reduced to the weighted public price plus 10%. No annual review.	Devices less than 7% above the weighted public price are not reduced. Devices more than 7% above the weighted public price are reduced by 40/20/20 % taking account of this 7% "floor" for all products. Shared commitment to agree review process noting Minister has agreed to retain gap between public and private consistent with previous correspondence. No agreement reached on frequency of reviews This element is subject to MTAA agreeing on all the other elements as documented below. Examples, for clarity:

Weighted average public price = 100				
	Current	**FY23**	**FY24**	**FY25**
EG 1:				
PL	105	105	105	105
Differential	5%	5%	5%	5%
EG 2:				
PL	115	109	107	107
Differential	15%	9%	7%	7%
EG 3:				
PL	200	160	140	120
Differential	100%	60%	40%	20%

	CURRENT GOVERNMENT POSITION		MTAA POSITION/COMMENT	AGREED NEGOTIATED POSITION
				In EG 2, the 40/20/20 % reductions in the differential between the PL benefit and the weighted average public price are applied until the 7% floor is reached.
2	**4th year price reductions**	4th year price reduction (likely 20%) will be reviewed in year 3.	• No review in 3rd year but 2 yearly reviews starting end of 4-year period • Following the 4-year reform period (i.e. from FY27), a public price comparison reset (with floor) occurs every two years with reductions phased across the two years 50:50.	No further reductions in year 4 of the reforms Shared commitment to agree review process noting Minister has agreed to retain gap between public and private consistent with previous correspondence. No agreement reached on pricing reviews This element is subject to MTAA agreeing on all the other elements documented below.
3	**General use items**	The group of 400 general use items as endorsed by the CIRG, being reference priced to public hospital prices with the gap fully closed on 1 March 2022 for eight topical adhesives (skin glues) and 1 July 2022 for all remaining items (this is in lieu of delisting), followed by: • close monitoring of these items to manage volume control over 12 months; • IHPA will develop advice on appropriate bundling arrangements for the identified general use items, which will be provided to insurers and private hospitals to facilitate the negotiation of new funding arrangements before the end of 2022; • no new similar items being added to the PL during this time; and • implementation of bundling arrangements and removal of these items from the PL on 1 July 2023. • modifying the schedule of price reductions for cardiac devices to address the claim for ongoing funding for technical support services while achieving the overall PL price reductions anticipated for cardiac devices by delaying the price reductions for CIEDs (three-year schedule for CIED reductions be 20/40/20) while reductions for cardiac stents are brought forward (reduced by full 80% in year one).	Reductions are phased over 2 years - • All items identified for removal (subject to final consultation) are reduced to public without floor phased 60%:40% across 1 July 2022 and 1 July 2023. Note that if removals occur from 1 July 2023 the remaining 40% is assumed for modelling by MTAA. • All applications for these groups that have been delayed or deferred in the last 2 years be included on the list temporarily unless there are additional clinical or administrative reasons not to do so. Products can be included with the condition that they are temporary only until 1 July 2023	MTAA to choose preference of two options: 60% reduction from 1 July 2022 followed by remaining 40% from 1 March 2023;or 80% reduction from 1 July 2022. This element is subject to MTAA agreeing all other elements documented This group of general use items will be bundled and removed from the PL on 1 July 2023. No applications for comparable items will be accepted in the interim, this was not discussed on the call with the Minister.
4	**Cardiac Implantable Electronic Devices (CIEDs) and**	Modifying the schedule of price reductions for cardiac devices to address the claim for ongoing funding for technical support services while industry proceed through the MSAC process by:	• $103m removed from calculation of public price reduction – Applies to FY23. Industry agrees to a properly conducted MSAC review of cardiac services to set payment beyond 1 July 2023 **Note**: MTAA have advised that their modelling assumes continued payment at current rates across the 4 years.	• Delay 4-year reform (40/20/20) of the CIED pricing structure on the PL by one year to 1 July 2023 to allow 18 months for MSAC deliberations on the value of the tech support services • Stents would progress with price reduction (40/20/20) from this year with all other devices.

	CURRENT GOVERNMENT POSITION		MTAA POSITION/COMMENT	AGREED NEGOTIATED POSITION
	Cardiac devices (inc. stents)	• delaying the price reductions for CIEDs (three-year schedule for CIED reductions be 20/40/20 instead of 40/20/20) • reductions for cardiac stents are brought forward (reduced by full 80% in year one).	• The trade-off between coronary stents is a false equivalence, breaks the reform principles and captures products that are sold by companies not providing cardiac services. There is no equivalence between MBS items and cardiac services performed by industry, so the Department's position on the KPMG report is unwarranted. Any reduction in payment will lead to a concomitant loss of services.	• Cardiac companies to give commitment to engage with MSAC.
5	**Regrouping of PL**	1 July 2022 implementation	• Not enough consultation • Re-grouping is savings neutral for every category – Groups that have significantly different public prices are not combined or PL benefit increases are allowed to achieve savings neutrality	• Agree in principle that the new grouping structure is not intended to be an additional source of savings on top of the reference pricing. Letter of comfort to be provided. • Department to ensure adequate consultation with all stakeholders, particularly where anomalies are identified.
6	**Modernised pathways**	The Department is currently consulting on the introduction of a three-tiered approach for assessment of PL applications: • *Abbreviated pathway* – a new pathway for devices that are medium or lower-risk, well-established technologies, and substantially similar in characteristics, intended use and clinical effectiveness to other devices listed on PL in the existing grouping with the benefit set up based on the reference pricing • *Clinical/focused HTA pathway* – the pathway evolving from the existing PL assessments for devices of higher risk and/or that are not well-established technologies (e.g. has a comparator that is a novel device/undergone HTA) and/or has claims for the improved/different characteristics compared with the existing devices listed on PL. Assessments will include comparative clinical effectiveness and/or cost effectiveness assessments with inputs from the relevant experts. • *Full HTA pathway* – there are no MBS items relevant for the use of the device and/or the device is a novel technology and/or there are no comparators on PL. Assessments include the full clinical and cost effectiveness assessments undertaken by MSAC with inputs from relevant experts as required.	• Abbreviated pathway for all applications to join an existing group – this is regardless of regulatory class. Benefits paid would be equivalent to the existing group regardless of the stage of phasing of reductions • Class III and AIMD already receive a much more detailed review by the TGA and this has only increased with EU-MDR. The price of the group is already established by the public referencing process. Clinicians in the private sector can make their own assessment based on evidence before using. Therefore, no relative clinical assessment is required and imposes additional costs on industry via proposed cost recovery. The only issue is identification whether the device belongs in the group, which the Department can undertake if appropriately resourced. Referral to a clinician for identification can be by exception.	• Codesign principles will be used in finalising the listing pathways • MTAA to engage with the consultation process that is open from 11 January to 25 February 2022 and articulate the rationale of including Class III and AIMD devices in the Abbreviated Pathway for discussion with the Department
7	**Pricing of new groups**	The development of new groups under the PL will be dealt with through either the clinical/focused HTA or Full HTA pathways dependent on novelty of the technology and existence of an MBS item – this will be considered at the time	• New device groups that have sufficient public market can take public price – Clinical review to establish that a different group is warranted is still required, but the public price is used to establish the PL benefit. HTA only needed if	• Codesign principles will be used in finalising the listing pathways. • MTAA to engage with the consultation process that is open from 11 January to 25 February 2022 and articulate the

	CURRENT GOVERNMENT POSITION		MTAA POSITION/COMMENT	AGREED NEGOTIATED POSITION
		of application in line with the three-tiered approach outlined above	insufficient public market or if the sponsor elects to not use the public price • Under PL reform the competitive public market establishes the value benchmark unless it is absent. The public market already involves decisions on value that set a cost-effective price through competition. Therefore, an additional layer of cost-effectiveness assessment is unnecessary and imposes additional costs on industry via proposed cost-recovery	rationale for allowing public price referencing for new groups following clinical assessment, for discussion with the Department
8	**Pricing to hospitals**	A key element of the reforms is the introduction, as a part of PL application process, is that companies must declare that there will not be extra charges for the products beyond the PL price, with penalties for false declaration, to ensure no out-of-pocket expenses for consumers.	• No limitations on sale price for any listing – As currently • In the vast majority of situations, the benefit sets the ceiling on the price sold into hospitals and it is frequently less. However, in some situations commercial circumstances require selling at a higher price to maintain supply. The arrangement is a commercial one between supplier and hospital similar to commercial arrangements between hospitals and insurers and should not be interfered with. Hospitals are free to refuse the sale price or limit volume in response.	• This is a key commitment that Government and stakeholders have made as part of the reforms that the value agreed through the PL process is the value charged to hospitals. • This element of the reforms is consistent with PBS policy and protects consumers. Note: MTAA remains concerned that this requirement may result in the supply of some products no longer being commercially viable and will therefore restrict patient access to some technologies. In the vast majority of situations, the benefit sets the ceiling on the price sold into hospitals. However, in some situations commercial circumstances require selling at a higher price to maintain supply. The arrangement is a commercial one between supplier and hospital and should not be interfered with by Government.

Australian Government
Department of Health

Ministerial Submission – Standard
MS22-000121
Version (1)
Date sent to MO:14/02/2022

To: Minister Hunt
Subject: Prostheses List Reforms – further implementation issues – follow up

Critical date: 14 February 2022 – to inform PL reform stakeholders of the way forward

Recommendation/s:	
1. **Indicate your preference** to the implementation approach to the Prostheses List Reforms. Option 1 would be to seek policy authority for the proposal submitted by the Medical Technology Association of Australia (MTAA) (**Attachment A**) and option 2 is to continue to implement existing Government policy.	**1. Agree option 1 (MTAA proposal)** **OR** **Agree Option 2 (Current Government policy)** **OR** **Please discuss**
2. If you agree to option 1, that you **sign** the letter to the Prime Minister seeking policy authority for this new approach, modifying the Australian Government's previously decided and announced approach (**Attachment B**).	**2. Signed/Not signed/Please discuss**
Signature	**Date: / /**
Media Release required? YES/ NO **Comments:**	

Contact Officer:	*Elizabeth Flynn*	*Assistant Secretary, Prostheses List Reform Taskforce, Technology Assessment and Access Division*	Ph: (02) 6289 s22 Mob: s22
Clearance Officer:	*Penny Shakespeare*	*Deputy Secretary, Health Resourcing*	Ph: (02) 6289 s22 Mob: s22

Issues:

1. On 28 January 2022, you met with representatives from the MTAA who presented to you a proposal for an alternative approach to the implementation of reforms to the Prostheses List (refer MB22-000234). This proposal from the MTAA is not consistent with the current Government policy agreed by Cabinet and will produce lower savings to privately insured consumers than current policy, which is scheduled to be implemented from 1 March 2022.

2. The Department subsequently followed up with MTAA to confirm the elements of its proposal discussed at your meeting (details of the current Government position, and the position put forward by MTAA are provided at **Attachment A**).

3. Key changes to the implementation strategy agreed with MTAA are as follows:

   - **Devices less than 7 per cent above the weighted public price are not reduced.** Devices more than 7 per cent above the weighted public price would be reduced by 40/20/20 per cent taking account of this 7 per cent "floor" for all products. For example: if a product has a gap of $100 between the public price and Prostheses List (PL) benefit, the 7 per cent floor would be removed from the gap and the reduction would then be calculated (this would impact the overall reduction):

     Example calculations:
     Without 7 per cent floor = ($100 – 40 per cent = $60 reduction)
     With 7 per cent floor = ($100 – 7 per cent (or $7) = $93 – 40 per cent = $55.80 reduction)

   - **No further reductions in the fourth year of the reforms.**

   - **General use items** will receive a reduction of 60per cent (instead of 100per cent) from 1 July 2022 (this comprises the 8 skin glues which will not take a price reduction on 1 March 2022), followed by the remaining 40per cent from 1 March 2023 before being removed from the PL on 1 July 2023 when bundling arrangements are implemented.
   - **Cardiac Implantable Electronic Devices (CIEDs) and Cardiac devices (including stents).** Delay the four-year reform (40/20/20) of the CIED pricing structure on the PL by one year to 1 July 2023 to allow 18 months for the Medical Services Advisory Committee (MSAC) to deliberate on the value of the technical support services. Stents would progress with a price reduction (40/20/20) from this year with all other devices.

4. Based on the above changes, the Independent Hospital Pricing Authority (IHPA) have indicated the following savings are likely to be achieved over four years (2022–23 to 2025–26) based on annual growth in utilisation:

s45 [redacted]

5. Noting this alternative approach departs from the original Cabinet decision, a letter to the Prime Minister seeking policy authority for this second revision to the implementation approach is at **Attachment B** for your signature.

6. If the Prime Minister provides policy authority got the revised approach, the Department will update all stakeholders.

Background:

Revised approach to implementation

- As approved by you in December 2021 and subsequently approved by the Prime Minister (MS21-001606 refers), the current (first revision) approach and implementation timeline for the staged removal of approximately 400 general use items from the PL involves:
    - the group of 400 general use items as endorsed by the Clinical Implementation Reference Group, being reference priced to public hospital prices with the gap fully closed on 1 March 2022 for eight topical adhesives (skin glues) and 1 July 2022 for all remaining items (this is in lieu of delisting);
    - close monitoring of these items to manage volume control over 12 months;
    - IHPA will develop advice on appropriate bundling arrangements for the identified general use items, which will be provided to insurers and private hospitals to facilitate the negotiation of new funding arrangements before the end of 2022;
    - no new similar items being added to the PL during this time; and
    - implementation of bundling arrangements and removal of these items from the PL on 1 July 2023.
- Subsequent to this, you gave your in-principle approval to propose to stakeholders two further variations to implementation arrangements for the PL reforms (MS22-000002 refers). These were:
    - Defer price reductions for prostheses where the public/private gap is less than or equal to 5 per cent; and
    - modifying the schedule of price reductions for cardiac devices to address the claim for ongoing funding for technical support services while achieving the overall PL price reductions anticipated for cardiac devices by delaying the price reductions for CIEDs (three-year schedule for CIED reductions be 20/40/20) while reductions for cardiac stents are brought forward (reduced by full 80 per cent in year one).
- On 21 January 2022, the Department met with the MTAA to discuss the above changes, noting that you had requested a response by the end of January 2022. MTAA chose not to engage further with the Department, instead requested a meeting with you directly.
- On 28 January 2022, you met with representatives from the MTAA who presented to you a proposal for an alternative approach to the implementation of the reforms (MB22-000234 refers).
- On 11 February 2022, the MTAA advised its preference that the 400 general use items be subject to a 60 per cent reduction from and not before 1 July 2022, followed by the remaining 40per cent gap fully closed from 1 March 2023, with removal of all general use items by 1 July 2023.

Attachments:

A: Alternative approach to reforms as negotiated with MTAA

B: Letter to the Prime Minister re: proposed revised approach to the removal of general use items

Election Commitments / Budget Measures:
The PL Reforms were announced as part of the 2021–22 Budget Measure: Modernising and Improving the Private Health Insurance Prostheses List.

Sensitivities:
The proposed changes to the implementation strategy as detailed by the MTAA have not been discussed with insurer groups or other stakeholders involved in the reform process, including consumer groups and groups representing doctors.

However, advice to the Department through the PHA is that insurer groups are aware of the MTAA proposal and are unlikely to support it. In particular, insurer groups have identified opposition to any delay in reducing the gap for cardiac devices, as cardiac devices represent some of the most inflated (double or more) benefits when compared to prices in the public hospital system.

Consultations:
The Department is continuing to undertake numerous consultations with all key stakeholder groups to implement current Government policy. This includes consumers, private hospital networks, private health insurers, clinicians and medical technology industry.

The Department is currently consulting on the introduction of a three-tiered approach for assessment of PL applications, this consultation closes 25 February 2022. There is also ongoing consultation on structural reforms to the PL.

Communication/Media Activities:
Nil

Cover Page for Ministers' Offices

Minister	**Minister Hunt**
PDR Number	**MS22-000121**
Subject	Prostheses List Reforms – further implementation issues - follow up
Critical Date	**14 February 2022**
Quality Assurance Check (completed by line area)	s22 [redacted]
Contact Officer	Elizabeth Flynn (02) 6289 s22 [redacted] s22 [redacted]
Clearance Officer	Penny Shakespeare (02) 6289 s22 [redacted] s22 [redacted]
Division/Branch	|Health Resourcing| Technology Assessment & Access| Prostheses List Reform Taskforce
Has Budget Branch been consulted if there are financial implications?	Not Applicable

Adviser/DLO Comments:

Return to Dept for:

Redraft ☐

s22 [redacted]

From: BEHM, Alex
Sent: Monday, 14 February 2022 6:44 AM
To: FLYNN, Elizabeth; Minister Hunt DLO
Cc: s22 [redacted]
Subject: Re: Waiver - MS22-000121 [SEC=OFFICIAL]

Ok thanks

On 13 February 2022 at 8:11:54 pm AEDT, FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au> wrote:

Dear s22 [redacted]

As discussed with you on Friday, could you please approve a waiver for MS22-000121 which has a critical date of tomorrow (14 Feb)

Elizabeth

[SEC=OFFICIAL]

ATTACHMENT C

General Use Items proposed for removal from the Prostheses List by Group

Prostheses List Groupings	2018-19			2019-20		
	Number of items	Benefit Paid ($)	Distinct PL Billing Codes[1]	Number of items	Benefit Paid ($)	Distinct PL Billing Codes[1]
03- General Miscellaneous	**989,695**	**220,340,733**	**359**	**999,551**	**210,400,607**	**373**
03.02.02 - Infusion Pumps, Balloon Based	43,346	5,961,639	18	43,544	7,715,781	18
03.02.03 - Infusion Pumps, Battery Powered	9,357	4,462,770	9	9,000	4,205,583	10
03.02.04 - Infusion Pumps, Spring Powered	5,427	764,949	5	5,194	656,957	6
03.02.05 - Infusion Pump Accessories	45,521	978,991	19	46,957	1,012,218	15
03.03.01 - Feeding Tubes	14	2,366	1	******	******	1
03.03.02 - Gastrostomy Tubes	869	144,845	24	875	143,820	25
03.03.03 - Jejunostomy Tubes	208	84,118	9	218	84,708	13
03.03.04 - Caecostomy Tubes	60	19,903	1	******	******	1
03.05.01 - Occluder Pin	******	******	1	..	..	..
03.05.02 - Powder	8,272	747,856	16	9,746	926,002	19
03.05.03 - Sponges	48,745	635,100	11	46,217	562,771	11
03.05.04 - Pliable Patches	58,276	3,112,607	19	57,569	3,063,067	21
03.05.05 - Matrix	38,796	31,328,857	9	41,514	33,208,623	11
03.05.06 - Foam	15,371	2,190,053	4	14,604	2,056,682	4
03.08.01 - Adhesion Barriers	9,175	4,717,235	13	10,282	4,969,493	14
03.08.02 - Internal Adhesives	176,557	44,237,662	62	186,879	43,817,172	68
03.08.03 - Ligating Devices	232,276	22,111,829	67	230,961	20,917,009	61
03.08.04 - Staples & Tackers	297,420	98,831,602	70	295,915	87,036,936	75
03.08.11 - Dynamic Wound Closure Devices	******	******	1	..	..	..
04- Neurosurgical	**2,320**	**1,828,942**	**8**	**3,028**	**2,342,530**	**6**
04.02.05 - Repair, Liquid Sealant (0 to 3ml)	407	309,520	2	332	246,962	2
04.02.06 - Repair, Liquid Sealant (>3 to 6ml)	1,913	1,519,422	6	2,696	2,095,568	4
10- Vascular	**50,268**	**14,657,649**	**51**	**51,365**	**14,541,325**	**57**
10.07.01 - Arterial Closure Devices	30,260	11,207,091	9	31,615	11,211,861	11
10.09.01 - Percutaneous Catheters, Single Lumen	5,048	752,124	19	4,740	676,902	21
10.09.02 - Percutaneous Catheters, Multiple Lumen	14,960	2,698,434	23	15,010	2,652,562	25
Total Proposed for removal	**1,042,283**	**236,827,324**	**418**	**1,053,944**	**227,284,462**	**436**

General Use Items proposed for removal from the Prostheses List by Group – still under consideration by the CIRG

Prostheses List Groupings	2018-19			2019-20		
	Number of items	Benefit Paid ($)	Distinct PL Billing Codes[1]	Number of items	Benefit Paid ($)	Distinct PL Billing Codes[1]
03- General Miscellaneous	**83**	**35,517**	**1**	**66**	**27,891**	**2**
03.08.10 - Anastomosis Clip	83	35,517	1	66	27,891	2
Total under review	**83**	**35,517**	**1**	**66**	**27,891**	**2**

[1]A count of unique Prostheses List Billing Codes for which a Prostheses benefit was paid

. . No data

****** Item counts less than 10 or less than 3 hospitals have been suppressed. Some consequential suppression has been applied.

Australian Government
Department of Health

Ministerial Submission – Standard
MS22-000121
Version (1)
Date sent to MO:14/02/2022

To: Minister Hunt
Subject: Prostheses List Reforms – further implementation issues – follow up

Critical date: 14 February 2022 – to inform PL reform stakeholders of the way forward

Recommendation/s:	
1. **Indicate your preference** to the implementation approach to the Prostheses List Reforms. Option 1 would be to seek policy authority for the proposal submitted by the Medical Technology Association of Australia (MTAA) (**Attachment A**) and option 2 is to continue to implement existing Government policy.	**1. Agree option 1 (MTAA proposal)** **OR** **Agree Option 2 (Current Government policy)** **OR** **Please discuss**
2. If you agree to option 1, that you **sign** the letter to the Prime Minister seeking policy authority for this new approach, modifying the Australian Government's previously decided and announced approach (**Attachment B**).	**2. Signed/Not signed/Please discuss**
Signature: s22 [redacted]	**Date:** 14/2/2022
Media Release required? YES/ NO	
Comments:	

Contact Officer:	*Elizabeth Flynn*	*Assistant Secretary, Prostheses List Reform Taskforce, Technology Assessment and Access Division*	Ph: (02) 6289 s22 [redacted] Mob: s22 [redacted]
Clearance Officer:	*Penny Shakespeare*	*Deputy Secretary, Health Resourcing*	Ph: (02) 6289 s22 [redacted] Mob: s22 [redacted]

Need help with completing this Ministerial Brief?
Please check the Quality Assurance Factsheet attached to this PDR in PDMS

To: Minister Hunt

Adviser: Sam Develin

Subject: MTAA RE: PL REFORMS ON 28 JANUARY 2022

Greg Hunt Signed …….. **Date: / /**			
Comments:			
Contact Officer:	*Elizabeth Flynn*	*Assistant Secretary, Prostheses List Reform Taskforce Branch, Technology Assessment and Access Division*	Ph: (02) 6289 s22 Mobile: s22
Clearance Officer:	*Adriana Platona*	*Assistant Secretary, Prostheses List Reform Taskforce, TAAD*	Ph: (02) 6289 s22 Mobile: s22

Date / Time: Friday 28 January / 2-2:30pm

Meeting Type/Location: Webex

Traditional Custodians: Ngunnawal (Canberra), **Boonwurrung** (Minister's Electorate), **Darug Wallamatta** (MTAA Head Office – Macquarie Park, NSW)

Purpose: to discuss the MTAA's concerns regarding implementation of the PL reforms

Desired Outcomes: to secure MTAA's support of the ongoing implementation of the PL reforms

Key Attendees/Speakers:	Title:	Organisation:	Mobile No:
Maurice Ben-Mayor	Chair	MTAA	s47F
Sue Martin	Deputy Chair	MTAA	-
Ian Burgess	CEO	MTAA	s47F

Stakeholder information:

- MTAA is the national association representing over 75 companies in the medical technology industry. The sector is diverse, comprising small and large entities and domestic and international players. Not all medical devices companies are members of the MTAA.
- The medical technology industry advises that it employs about 19,000 people in Australia.
- MTAA has been a key contributor to the Prostheses List reforms to date and will be a key stakeholder for future reforms, however, there has been some significant resistance to the reforms by MTAA.

Proposed Objective and/or Desired Outcomes:

- For the Minister to negotiate with and secure MTAA's support of the ongoing implementation of the PL reforms.

Stakeholder Objective:

- The MTAA want the Minister to agree to their proposal which outlines "a series of 8 policy measures that for MTAA represent a package not a series of individual negotiation points" (**Attachment C**).

Sensitivities or Contentious Issues:

- MTAA have continued to raise concerns about delays to the Reform process, a main cause of this was the delay in MTAA providing the relevant public sector sales data to inform reference pricing. MTAA were due to provide the data to IHPA by 31 October 2021 however this did not occur until mid-November.
- MTAA do not feel that they have been consulted with thoroughly enough throughout the first six months of the reforms however, MTAA has in fact been consulted with regularly by both your office and the Department (often on a weekly or more frequent basis).

Budget/Financial Implications:

- In the 2021-22 Federal Budget, the Australian Government committed $22 million over four years to support reforms and improvements to the Prostheses List and its arrangements. This funding commences from 1 July 2021.

Attachments

A: Possible negotiation positions that the Minister may wish to propose to MTAA

B: Letter from MTAA 24 January 2022 – meeting request

C: Letter from MTAA 25 January 2022 – proposal for prostheses list reform for discussion

Background:

Revised approach to implementation

- As approved by you in December 2021 and subsequently approved by the Prime Minister (MS21-001606 refers), the revised approach and implementation timeline for the staged removal of approximately 400 general use items from the Prostheses List, will now involve:
    - the group of 400 general use items as endorsed by the CIRG, being reference priced to public hospital prices with the gap fully closed on 1 March 2022 for eight topical adhesives (skin glues) and 1 July 2022 for all remaining items (this is in lieu of delisting);
    - close monitoring of these items to manage volume control over 12 months;
    - IHPA will develop advice on appropriate bundling arrangements for the identified general use items, which will be provided to insurers and private hospitals to facilitate the negotiation of new funding arrangements before the end of 2022;
    - no new similar items being added to the PL during this time; and
    - implementation of bundling arrangements and removal of these items from the PL on 1 July 2023.
- Subsequent to this, you gave your in-principle approval to propose to stakeholders two further variations to implementation arrangements for the Prostheses List (PL) reforms (MS22-000002 refers). These were:
    - Defer price reductions for prostheses where the public/private gap is less than or equal to 5 per cent; and
    - modifying the schedule of price reductions for cardiac devices to address the claim for ongoing funding for technical support services while achieving the overall PL price reductions anticipated for cardiac devices by delaying the price reductions for CIEDs (three-year schedule for CIED reductions be 20/40/20) while reductions for cardiac stents are brought forward (reduced by full 80 per cent in year one).
- On 21 January, the Department met with the MTAA to discuss the above, noting that you had requested a response by the end of January 2022. The Department has yet to hear from the MTAA.
- The Department has also sought a meeting with the MTAA Cardiac Forum and is awaiting their reply.
- On 24 January, the MTAA wrote to the Minister requesting this meeting (**Attachment B**) and subsequently provided a proposal to the Minister on 25 January, outlining their proposal of a "a series of 8 policy measures that for MTAA represent a package not a series of individual negotiation points" (**Attachment C**).

Minister	**Minister Hunt**
PDR Number	**MB22-000234**
Subject	MTAA RE: PL Reforms on 28 January 2022
Due Date	**27 January 2022**
Quality Assurance Check (completed by line area)	s22 [redacted]
Contact Officer	Elizabeth Flynn Ph: (02) 6289 s22 [redacted] Mobile: s22 [redacted]
Clearance Officer	Adriana Platona Ph: (02) 6289 s22 [redacted] Mobile: s22 [redacted]
Division/Branch	|Health Resourcing| Technology Assessment & Access / Prostheses List Reform Branch

Adviser/DLO Comments:

Return to Dept for:

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The *Quality Assurance Check (completed by line area)* section above ensures the line area has considered the Minister's preferences outlined in the Ministerial Briefs Factsheet (attached to this PDR in PDMS). Please contact MPS if you have any questions about this process.

Medical Technology ASSOCIATION OF AUSTRALIA

www.mtaa.org.au

Medical Technology Association of Australia Ltd
ABN: 61 129 334 354
Lvl 4, 97 Waterloo Rd, Macquarie Park NSW 2113
P: (02) 9900 0600
E: mtaa@mtaa.org.au

24 January 2022

Hon Greg Hunt MP
Minister for Health and Aged Care
Member for Flinders
Parliament House
Canberra ACT 2600
Greg.Hunt.MP@aph.gov.au

Dear Minister

RE: URGENT MEETING REQUEST – PROTHESES LIST REFORM

Based on the proposal MTAA received from the Department of Health on Friday, 21 January 2022 on Prostheses List (PL) reform, we seek an immediate meeting with you to achieve a reasonable and pragmatic outcome.

We have two serious concerns to urgently discuss directly with you.

Firstly, we have major concerns with the ongoing delays and lack of true consultation by the Department. The current impasse means we are not able to continue negotiations with the Department and require your urgent intervention.

Secondly, and of greater concern, the Department's current proposals and the recent information about the grouping process put our industry in a worse situation on PL reform than at any time since the Budget announcement last year.

Process Flaws

Our industry is extremely concerned regarding the poor process that the Department has implemented across these discussions. One example is the Department's process to develop the proposed regroupings. Previous regroupings were undertaken via extensive and transparent consultations involving both clinicians and industry over many months and, in some instances, years.

The current process around reviews by the Clinical Implementation Advisory Group (CIRG) has been opaque leading to our great concern that three relatively short meetings of the CIRG are insufficient to ensure full and proper consideration of decisions to regroup masses of items. The Department is currently conducting webinars to advise stakeholders of the regrouping decisions.

Despite this being the first and only engagement with industry, the Department has provided stakeholders only two weeks to respond to the first tranche of changes. We have advised the Department since mid-last year that regroupings could have significant impacts, including directly affecting the public referencing analysis being undertaken by IHPA, requiring longer time periods to be provided to enable proper consultation and implementation.

Furthermore, despite the consultation on the scope of the PL closing 4 months ago, industry still has no knowledge of what products are intended for removal despite multiple assurances of information. We are advised that the Department is consulting with the CIRG, but again, three short meetings of the CIRG at which re-grouping is also being considered is inadequate for making informed assessments about specialised uses of many of these products.

Another example is the Department's failure to commence meaningful engagement with MTAA on cardiac technical support services until mid-November 2021, despite the provision in February 2021 of our detailed submission and report by KPMG and our advice to you, your office and the Department immediately following the May Budget announcement stating PL reforms would remove the existing funding for these services. Despite it being clear there is no 1:1 relationship between MBS items and CIED services by industry, the Department insists that these somehow must match and has rejected the KPMG report.

Unless there is a genuine good faith change in this process, we cannot see that our sector will agree to these reforms before the implementation dates of 1 March and 1 July 2022.

Unacceptable Department Positions

Some of the unacceptable positions MTAA are being asked to now agree to include, but are not limited to, the following:

- No private adjustment, just a threshold test of 5% that is reviewed every year, presumably until it goes away
- A 20% remainder that is subject to 3-year review that could lead to its removal entirely on any basis whatsoever. While industry welcomes your commitment that further reductions after the 40/20/20 might not need to apply, there is significant uncertainty regarding this fourth year with various stakeholders advising MTAA that the Department has stated it does not consider that there should be any gap
- 100% reduction to the public price of around 400 items listed for removal, immediately on 1 July 2022 even though these reductions would far exceed the impact of actually removing the products, while continuing not to list similar products on the PL
- Requirement to trade off faster reductions on cardiac stents in order to get any interim financial payment for the continuation of cardiac technical support services, and
- An obscure regrouping process that is radical and based on the limited information we have to date, is likely to exact much greater reductions than public price referencing alone.

Throughout this discussion we have had delays from the Department's side which has now led to the absurd situation of industry being notified on 21 January 2022 that these items need to be resolved by 27 January 2022 – an interval of a mere three business days. No reasonable stakeholder would think that three business days to resolve these items is acceptable. It leaves industry with the strong view that the Department has not been acting in good faith.

As stated to your office and the Department late last year, the proposal then was intolerable in terms of the size of PL benefit cuts and the aggressive timing, and it is now actually worse. It will dramatically impact our industry beyond anything that is reasonable or necessary. Despite all stakeholders, except insurers, agreeing that costs to supply the private market to maintain choice are higher in the private system than in the public system, there has been every attempt to evade a policy design that recognises this fact.

Currently, our industry is under significant pressure. Elective surgery cutbacks (which are a necessary response to COVID) will again result in financial losses for most of our members, coupled with the other impacts of COVID - including on our workforce; supply chain constraints and pressures; and continued significant escalation in freight and other operational costs. However once again, elective surgery cutbacks will provide a profit windfall for private health insurers, the primary beneficiaries of the current PL reform.

Our industry is the only part of our private health sector that has incurred pricing cuts, specifically to benefit insurers. We are also the only stakeholder to have put forward detailed reform proposals that can actually be implemented, as well as handing over confidential and commercially sensitive industry data to IHPA, to allow for this to progress. Rather than opposing change MTAA, with the support of membership, put a significant savings proposal on the table in February 2021. This was in the expectation that this would be recognised as a reasonable and constructive contribution to helping private health insurance be more valuable to consumers. At present, that is a decision we regret.

Minister, we have lost faith in this process, especially with the Department, and are seriously considering our options available to us. As the responsible Government Minister, we urgently request your intervention and the opportunity to meet to finalise these reforms directly with you to avoid unintended consequences for patients, health care professionals, the private health sector and our industry.

Attending the meeting will be MTAA Chair Maurice Ben-Mayor, Deputy Chair Sue Martin, and CEO Ian Burgess.

Yours faithfully

s47F

Maurice Ben-Mayor
Chairman

s47F

Ian Burgess
Chief Executive Officer

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www.mtaa.org.au

25 January 2022

Hon Greg Hunt MP
Minister for Health and Aged Care
Member for Flinders
Parliament House
Canberra ACT 2600
Greg.Hunt.MP@aph.gov.au

Dear Minister

RE: PROPOSAL FOR PROSTHESES LIST REFORM FOR DISCUSSION

MTAA has demonstrated its good faith in contributing to sustainability of private health insurance by making the only substantive offer of savings on the Prostheses List (PL) by any stakeholder. This was premised on referencing the competitive public market but not treating the private market as the same.

In turn, the Government made a decision in the 2022-23 Federal Budget, that we and other stakeholders strongly endorse, to retain and reform the PL. However, there was significant detail that needed to be resolved. Resolution of that detail would determine whether the reforms would deliver on patient access, value and industry sustainability.

Minister, we advised you in our previous letter that negotiations with the Department have reached an impasse. This is because the resolution of that detail has been heading in the wrong direction in a way that will hurt patients and the private healthcare sector, including our industry. The Department's stated proposals are aggressive and place an intolerable burden on MedTech companies.

In response to your invitation, we attach a proposal for PL reform as an alternative. This will still deliver further substantial savings and involve considerable sacrifice on the part of MedTech. Projected savings across the 4 years would be $885m, higher than any previous offer, factoring in assumptions about removal items and cardiac services. However, it will enable our industry to sustain current levels of device choice in the private sector, with no out-of-pocket costs for patients, and allow our industry to manage the movement of the higher relative prices toward more competitive public levels in line with the reforms.

The proposal is outlined in **Appendix 1** as a series of 8 policy measures that for MTAA represent a package not a series of individual negotiation points.

The acceptance of this proposal by the Government would enable MTAA to lock in major reforms without further disruption. The proposal is reasonable, reflecting further sacrifice and flexibility by our industry on our February 2021 proposal.

We look forward to discussing this proposal with you this Friday, 28 January 2022, and coming to a speedy finalisation on the PL reforms. However, as flagged in our previous letter, we are unable to engage further with the Department on this reform.

Minister, you will depart office this election having achieved a significant legacy in Australian healthcare policy. We hope that substantive PL reform that strikes the balance between patient access, value and industry sustainability will add to this. We strongly believe that this proposal will meet these objectives.

We look forward to hearing from you and finalising this reform.

Yours faithfully

s47F

Maurice Ben-Mayor
Chairman

s47F

Ian Burgess
Chief Executive Officer

APPENDIX 1 - MTAA PROPOSAL TO GOVERNMENT ON PROSTHESES LIST REFORM

MTAA proposal elements in blue are contrasted with known or current indicative positions of the Department in red.

1 - Floor to PL benefit reductions	
Department proposal	5% threshold test reviewed annually - Devices less than 5% above the weighted public price are not reduced. This is reviewed annually to see if the threshold test is no longer met due to public price reductions. Devices more than 5% above the weighted public price are reduced fully to the weighted public price.
MTAA proposal	10% true floor for reductions – Devices less than 10% above the weighted public price are not reduced. Devices more than 10% above the weighted public price are reduced to the weighted public price plus 10%. No annual review.
Rationale	MTAA, as well as peak hospital, clinician and consumer groups, endorsed the fact that the cost to service the private sector is higher than the public due to wider choice and the presence of price/volume arrangements in the public sector that limit choice. The Department proposal provides no recognition of this. It also penalizes companies with devices already close to the public price. It further creates a moving target with annual reviews, rather than a proper re-set against public prices at the end of the 4-year reforms (see Measure 2 below).

2 – 3rd year review of 20% 4th year remainder	
Department proposal	20% 4th year 'remainder' only granted following 3rd year review with open criteria - The Minister's intention to allow the 4th year 20% remainder of the public-private price difference to stay is only granted if a review in the 3rd year of reforms (FY25) shows it is warranted. Terms of the review are unspecified and therefore will be determined by unknown factors at the time. It has been stated that the primary issue is accounting for significant public price reductions but the review is not limited to this.
MTAA proposal	No review in 3rd year but 2 yearly reviews starting end of 4-year period Following the 4-year reform period (i.e. from FY27), a public price comparison reset (with floor) occurs every two years with reductions phased across the two years 50:50.
Rationale	The Minister's offer of a letter of intent to leave the remainder in the 4th year has very limited value if a 3rd year review driven by the Department simply removes the remainder. If the Department is opposed to a difference in PL benefits vs the public price in principle then it is very unlikely this 3rd year review will be positive for industry. The 3rd year review just duplicates a full public pricing review that should occur for implementation after 4-year phasing is completed i.e. 1 year later and periodically thereafter

3 – Reductions to removal items	
Department proposal	Items identified for removal reduced to public price by 1 July 2022 - The 8 topical skin adhesives are reduced on 1 March 2022 and the remaining ~400 items on 1 July 2022 to the public price without a floor or phasing
MTAA proposal	Reductions are phased over 2 years - All items identified for removal (subject to final consultation) are reduced to public without floor phased 60%:40% across 1 July 2022 and 1 July 2023. Note that if removals occur from 1 July 2023 the remaining 40% is assumed for modelling by MTAA. All applications for these groups that have been delayed or deferred in the last 2 years be included on the list temporarily unless there are additional clinical or administrative reasons not to do so. Products can be included with the condition that they are temporary only until 1 July 2023
Rationale	The Department's proposal dramatically penalises industry for the breakdown in insurer-hospital negotiations and results in faster industry impacts than would have occurred with actual removals. This proposal speeds the reductions but not excessively. There are many items scheduled for removal that industry does not agree should be removed and it is already a concession on our part to leave the removals list as it is. The continued rejection or deferral of listing of new applications for these groups is producing serious competitive inequity and is likely in violation of trade obligations. The full competitive set for funding from FY24 also can't be identified unless they are all on the PL. Therefore they need to be added.

4 – Cardiac Services payment	
Department proposal	Lesser reductions for cardiac heart rhythm items in exchange for greater reductions on coronary stents - This applies only to FY23 as MSAC will review the value of cardiac services for payment from FY24. No reductions number has been provided by the Department, but they continue to quote value of $17m based on MBS data vs $103m reported by KPMG for industry
MTAA proposal	$103m removed from calculation of public price reduction - Applies to FY23. Industry agrees to a properly conducted MSAC review of cardiac services to set payment beyond 1 July 2023 Note MTAA modelling assumes continued payment at current rates across the 4 years.
Rationale	The trade-off between coronary stents is a false equivalence, breaks the reform principles and captures products that are sold by companies not providing cardiac services. There is no equivalence between MBS items and cardiac services performed by industry, so the Department's position on the KPMG report is unwarranted. Any reduction in payment will lead to a concomitant loss of services.

5 – PL Group consolidation	
Department proposal	Removal of all sub-groups and suffixes - While we only have information on the proposal for the first tranche, the Department approach so far has eliminated all sub-groups and suffixes including those that represented clinical value and is very likely to result in much greater benefit reductions
MTAA proposal	Re-grouping is savings neutral for every category - Groups that have significantly different public prices are not combined or PL benefit increases are allowed to achieve savings neutrality
Rationale	Group consolidation should be about increasing clarity and efficiency not an additional savings measure on the proposed mechanisms. Groups that have significantly different public prices will do so because the public system has identified meaningful value differences.

6 – Abbreviated pathway	
Department proposal	Abbreviated pathway for Class IIb products and below - The Abbreviated Pathway involving only Department review not clinical review would be limited to products classed by TGA as low and medium risk
MTAA proposal	Abbreviated pathway for all applications to join an existing group - This is regardless of regulatory class. Benefits paid would be equivalent to the existing group regardless of the stage of phasing of reductions
Rationale	Class III and AIMD already receive a much more detailed review by the TGA and this has only increased with EU-MDR. The price of the group is already established by the public referencing process. Clinicians in the private sector can make their own assessment based on evidence before using. Therefore, no relative clinical assessment is required and imposes additional costs on industry via proposed cost recovery. The only issue is identification whether the device belongs in the group, which the Department can undertake if appropriately resourced. Referral to a clinician for identification can be by exception.

7 – Pricing of new groups	
Department proposal	HTA for all new applications for new groups Under all circumstances if there is an application for a new group on the PL, the assessment requires HTA (focused or MSAC)
MTAA proposal	New device groups that have sufficient public market can take public price - Clinical review to establish that a different group is warranted is still required, but the public price is used to establish the PL benefit. HTA only needed if insufficient public market or if the sponsor elects to not use the public price
Rationale	Under PL reform the competitive public market establishes the value benchmark unless it is absent. The public market already involves decisions on value that set a cost-effective price through competition. Therefore, an additional layer of cost-effectiveness assessment is unnecessary and imposes additional costs on industry via proposed cost-recovery

8 – Pricing to hospitals	
Department proposal	Sponsors of new applications agreed not to sell above the PL benefit - In the 'Context' preamble of unrelated consultation papers, the Department has stated an intention that sponsors of new applications would have to give an undertaking not to sell the device to hospitals at a higher price than the PL benefit as a condition of listing
MTAA proposal	No limitations on sale price for any listing – As currently
Rationale	In the vast majority of situations, the benefit sets the ceiling on the price sold into hospitals and it is frequently less. However, in some situations commercial circumstances require selling at a higher price to maintain supply. The arrangement is a commercial one between supplier and hospital similar to commercial arrangements between hospitals and insurers and should not be interfered with. Hospitals are free to refuse the sale price or limit volume in response.

ATTACHMENT A1

REVISED SAVINGS CALCULATIONS FROM IHPA

APPROACH	IHPA ESTIMATES OF PL SAVING OVER 4 YEARS	SAVINGS DIFFERENCE FROM CURRENTLY APPROVED APPROACH
CURRENTLY APPROVED GOVERNMENT POSITION		
1. As outlined in MS21-001606: • Minimum 40/20/20 reductions applied to all devices from 1 July 2022 and • 100% reduction of the gap for the 400 identified general use items on 1 March and 1 July 2022 followed bundling and removal on 1 July 2023[1].	s45	
2. 1 plus foregoing price reductions for prostheses where the public/private gap is less than or equal to 5% (as outlined in MS22-000002) Minimum 40/20/20 reductions applied to all devices excluding those where the public/private gap is less than or equal to 5%		
IMPACT OF POTENTIAL NEGOTIATION POSITION		
s47C		

s22

From: Minister Hunt DLO
Sent: Monday, 24 January 2022 3:17 PM
To: MPS
Cc: Minister Hunt DLO; TAAD Inputs
Subject: MB22-000234 - Meeting Brief due 27 Jan - MTAA RE: PL Reforms [SEC=OFFICIAL]
Attachments: MTAA - Minister Hunt Meeting Request 20220124.pdf

Categories: Andrea

MB22-000234

Hi MPS

Could we please request a meeting brief for the following:

Title: MTAA meeting with Minister Hunt regarding PL Reforms (please see attached for additional info)
Date/Time: 2-2:30pm 28 January 2022
Location: Webex
Assign to: TAAD
Due in MO: 3PM Thursday 27 January

Thank you!

s22
Departmental Liaison Officer
Office of the Hon Greg Hunt MP
Minister for Health and Aged Care
T: s22 M: s22
E: s22 @health.gov.au
Suite M1.41, PO Box 6022, Parliament House, Canberra ACT 2600, Australia

s22 [redacted]

From: s22 [redacted] @health.gov.au>
Sent: Wednesday, 9 March 2022 3:07 PM
To: Ian Burgess s47F [redacted]
Cc: FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>
Subject: MOU schedule 1 [SEC=OFFICIAL]

Hi Ian

Here are our preferred words for your consideration:

Schedule 1 – Methodology for calculation of public price referencing under Prostheses List reform 1 July 2022 to 30 June 2026

The Weighted Average Price is to be calculated by the Independent Hospital Pricing Authority on an annual basis using the most appropriate data, including sponsor-supplied data for financial year ended 30 June 2021 or the most recent available year.

The Weighted Average Price will be calculated based on existing Benefit Groups on the Prostheses List (**PL**) defined as:

- *All billing codes sharing the same category, sub-category, product group, sub-group, suffix and benefit level on the PL*

The Weighted Average Price for a Benefit Group is calculated as follows:

- *Average public price for all devices included under the billing codes in the Benefit Group weighted by private volumes*

New listings of products joining an existing Benefit Group will receive the same benefit level as the other billing codes in that Benefit Group regardless of the stage of reductions phasing, and incorporating the 7% floor.

Examples of application of the 7% floor and the 40:20:20 phasing and no 20% reduction in year 4:

Weighted average public price = 100					
	Current	**1 July 2022**	**1 July 2023**	**1 July 2024**	**1 July 2025**
EG 1:					
PL	105	105	105	105	105
Differential	5%	5%	5%	5%	5%
EG 2:					
PL	115	109	107	107	107
Differential	15%	9%	7%	7%	7%
EG 3:					
PL	200	160	140	120	120
Differential	100%	60%	40%	20%	20%

Alex Behm

Adviser

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