From: FLYNN, Elizabeth
To: Paul Dale
Cc: s22 Ian Burgess
Subject: RE: PL Reform issues for discussion with MTAA 16 August [SEC=OFFICIAL]
Date: Tuesday, 23 August 2022 1:56:51 PM
Attachments: Prostheses List Reforms - Answers to MTAA questions 23 Aug.docx
image001.png
image002.jpg

Dear Paul and Ian

Please find attached a consolidated response to your two emails on various reform matters.

In relation to the topics for the MTAA conference, if you think the nominated topics are the key areas your members would like an update on then let's confirm:

1. Evaluation framework – what does success look like, approaches to measure it?

2 – Listing process – changes and further issues for resolution

3 – Post listing reviews – how these are to be conducted, possible outcomes

Can you advise if the intention is to address them all in a single session? I would like to involve a number of staff if possible.

Elizabeth Flynn
Assistant Secretary, Prostheses List Reform Taskforce
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
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Location: Sirius Building s22
GPO Box 9848, Canberra ACT 2601, Australia
The Department of Health and Aged Care acknowledges First Nations peoples as 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 all Elders both past and present.

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From: Paul Dale s47F >
Sent: Monday, 22 August 2022 1:50 PM
To: FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; Ian Burgess s47F >
Subject: FW: PL Reform issues for discussion with MTAA 16 August

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi Elizabeth

Thanks again to you and the team for the discussion today. The topics we did not get to discuss I originally flagged were:

- Listing inequities for General Use items

- Maximum price
- PLAC successor

Your response on these as soon a possible would be welcome, ideally before MTAA's Board meeting on Wednesday.

We also agreed that in August we would discuss the best topics for the MTAA conference 6-7 October. We have three sessions set aside and would like the Department involved in each.

My proposition is that the topics floated at the time we asked for your involvement are still very relevant

1 – Evaluation framework – what does success look like, approaches to measure it?

2 – Listing process – changes and further issues for resolution

3 – Post listing reviews – how these are to be conducted, possible outcomes

Let me know whether you think these make sense at this stage and we can progress detail and other speakers etc.

Kind regards,
Paul

Paul Dale
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From: Paul Dale
Sent: Thursday, 11 August 2022 2:32 PM
To: FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; Prostheses Reform <s22 @health.gov.au>; Ian Burgess s47F ; Matthew Versi s47F
Subject: PL Reform issues for discussion with MTAA 16 August

Dear Elizabeth

Thank you for the opportunity to meet with you this Tuesday 16 August. The purpose of this email is to outline some of our ongoing concerns and questions to enable a better discussion on the day. Apologies in advance on its length. Our goal is to collaborate with you to achieve the best outcomes arising from the Memorandum of Understanding, but also clearly communicating MTAA's positions and understanding whether they will be/have been accepted, modified or rejected and for what reasons in the latter case. We also want to understand the progress of reforms and highlight the challenges we see.

s22

PROSTHESES LIST REFORMS – RESPONSE TO MTAA QUESTIONS RECEIVED VIA EMAIL 11 AUGUST AND DISCUSSED IN PERSON WITH IAN BURGESS AND PAUL DALE ON 16 AND 22 AUGUST

International Price Referencing in the Evaluation Framework

Last we met on 24 June we raised again our strong concern that the use of international price referencing in relation to the Prostheses List is inappropriate even for the Evaluation Framework. This seems to have been included purely at the behest of the insurers.

We understood from the conversation with you that it would only apply to the devices that don't have a public reference. We are not sure how this lines up with our understanding of comments by Adriana Platona at the 26 May Stakeholder Meeting that any international price referencing for the Evaluation process would be high level not product by product, which seems to suggest a much broader application.

While we continue to not accept international price referencing in relation to the Evaluation process, we would like clarification on exactly how you see it being applied. Our recollection is you also undertook to provide a list of products it would apply to, if applicable. We would also like an exact understanding as to how and when the decision will be taken to include international price referencing or not, if the decision has not been taken already. This is a matter of highest priority for MTAA.

Response:

We intend to use international pricing as an option where there is no domestic information. This information will likely be sought from the sponsor as part of the application and will be captured in the HPP database.

The monitoring and evaluation framework will consider relevant country level international comparisons as one of several indicators to help us determine if the reforms have been successful, acknowledging that health systems are different and the range of devices may be more limited in other markets. This is standard practice in any health policy evaluation. The stakeholder advisory group will have the opportunity to review and provide input to development of the plan.

Bundling of removals

We remain committed to working through the process of determining the bundles. We have advised IHPA that we are concerned the Terms of Reference for the Reform Working Group seem to pre-empt the decision about whether bundled payments would be negotiated or mandatory and also seem to suggest that IHPA does not necessarily need to provide a bundled price out of this project. If these are in the terms of reference given to IHPA by Department, we request that this be corrected so it is neutral about the nature of the payments and that a bundled price is an essential outcome.

Response:

The Independent Health and Aged Care Pricing Authority (IHACPA) (formally IHPA) is an independent agency (independent from the Department) with its own Board. IHACPA have developed the ToR for the Working Group and while the Department was asked for feedback prior to the first meeting of the Working Group, we provided no significant comments other than to provide advice on the inclusion of some additional members. The Dept understands that IHACPA is very willing to consider and has in fact made changes to the ToR subsequent to the first meeting. You should raise any further concerns regarding this process with IHACPA directly.

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Furthermore, as highlighted by MTAA at the Stakeholder Meeting 20 July, the Department has left open the possibility that, arising out of the post-listing reviews (see further comments below) and also the current approach to regrouping (see also further comments below), further billing codes will be removed from the Prostheses List.

While we don't accept that these additional removals should necessarily occur, we request that IHPA's recommendation on bundling should explicitly include any products which the Department *does* decide to remove within the period of IHPA's current workplan or before 1 July 2023 and not only General Use items. Any removal of items beyond that date should be factored into arrangements to change bundles over time.

Response:

IHACPA has proposed to the Bundling WG that while the bundles will be finalised in Dec 2022 there will be another opportunity for additions and changes in March 2023 and that items not identified by Dec could be included at this stage. IHACPA will propose a process to keep the bundles current as part of its advice.

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Listing inequities for General Use items

The Memorandum of Understanding signed by the Government and MTAA requires a 'good faith discussions' on the Department's policy not to list comparable General Use items. MTAA doesn't consider that a clear reason for this has been provided and seeks clarification on the exact rationale, bearing in mind that many of these products do not fall afoul of any current criteria listed in the Prostheses List Guide.

Response:

The rationale for not accepting new applications is that the Department has clearly signalled what is coming off because it does not meet the criteria and it would lead to confusion if comparable items were received as applications, only to be rejected. This does not mean that like products will not be considered in the bundling arrangements being developed by IHACPA.

Non-implantables

In our previous discussion on 24 June we pointed out that 'specific purpose' criteria (even though not termed this way) are now being used to remove 'General Use' items that otherwise qualify for the PL because implantable, but single use devices that are disqualified from the current PL because they aren't implanted continue to be excluded. At present, affected 'General Use' items are taking faster benefit reductions and competitors cannot be listed. We seek a rectification of this unfair situation as soon as possible, allowing single use non-implanted devices that otherwise qualify to seek listing on 1 March 2023.

The Prostheses List Consultation paper of December 2020 pointed out that the proposed change to the criteria if the PL was to be retained had *two sides*:

> 'In addition, it is proposed that benefits be payable for specific purpose medical devices where the intention of the accompanying medical procedure is to remedy disease or dysfunction through use of the specific medical device (e.g. hip replacement, stent, balloon angioplasty). The device should not be one that is used as an adjunct to the procedure (e.g. sutures, haemostatic agents, adhesives).

It should be noted that this definition **no longer requires that the device be implanted** but retains the requirement that the device be therapeutic. The focus is on the device being one that is intended to remedy a medical condition.

A consequence of confining scope as proposed would be that most general use medical devices and consumables would no longer be funded through the PL, but would continue to be funded through other mechanisms, such as contracts between insurers and hospitals.' [emphasis added]

At this point, the application of the change is going only one way and we request your assurance this will be rectified and clarification of the process leading to this.

Response:

We will shortly release a consultation paper on legislation changes that represents the evolution of our thinking in this area. Based on the first consultation paper responses and our own research, we do not intend to proceed with the change around the device no longer needing to be implanted at this time.

However, the proposed changes to the listing criteria include greater transparency about what is considered appropriate for listing on Part C of the PL. This will enable consideration amongst other factors of, devices of high value, novel technology, alternatives to implantable medical devices listed on Part A and unmet patient need. The request to list devices on Part C will undergo HTA by MSAC.

MTAA has been invited to submit the six technologies that MTAA believes would/should qualify for listing based on producing similar outcomes to a currently listed implantable device.

Regrouping

The regrouping activity is enormously time consuming for companies and 27-day deadlines for response have been reimposed by the Department. Unfortunately, sponsors are not getting an equally quick engagement from Hereco or the Department on the feedback it provides. Our responses on the first two tranches of consultation were provided mid-April with no response.

MTAA requested a dialogue on the issues raised in our feedback and although assurances have been provided that this will occur, there is no sign of this, only demands for fast turnarounds in giving feedback. At the moment, we haven't seen any sign that all the feedback that has been provided has been reviewed and considered. Our members are understandably questioning whether it is worth the time to respond.

We request an immediate plan on how dialogue on feedback will occur. These issues are serious and complex, and the regrouping will be significantly jeopardised if second round consultation does not commence. Please understand that sponsors consider this regrouping to be of the utmost importance and MTAA will strongly oppose a rushed process. Already the 3 webinars in August and the follow up required are becoming unworkable for sponsors affected by multiple regroupings, as well as the MTAA secretariat which has to ensure consistency of response across groups.

Furthermore, in order to try to minimise the number of groups, the consultant Hereco are making recommendations that are not viable and likely will result in ordering issues, confusion and increased costs. The relentless pursuit of consolidation of groups for its own sake has never made sense. Devices are complex and some consolidation, particularly of accessories or different sizes, just hides the complexity. The most important objectives should be clarity and transparency about what is in the grouping and functionality in how the list operates. Hereco needs to be advised of this and not make recommendations that notionally decrease the number of groups to hit some assumed

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target but in reality sacrifice transparency and functionality. An example is consolidating devices of different sizes that are designed to match the treatment area in the body. In some cases, if these are consolidated into one at the same benefit, then the supplier will be incentivised to only supply the smaller size, meaning more could be used at greater cost.

Response:

We acknowledge that the regrouping project is a very complex piece of work and that it is a key priority for sponsors. Please be assured the webinars are not the only consultation that will take place. While we accept that your sponsors needed additional time to consider the regrouping, we did take this feedback on board after the first webinar and have extended the time for submissions to a total of 5 weeks (this was agreed to by MTAA and other stakeholders at the time). We have also ensured that supporting documentation is distributed a week before the webinar to ensure stakeholders can review before and ask appropriate questions during the webinar. I would like to reconfirm that hereco are "proposing" a regrouped structure and we recognise that there may still need to be amended before finalisation and implementation. We are working towards July 2023 for implementation of new grouping structure.

As indicated in our meeting, I understand that MTAA's initial questions were responded to by hereco in February which fed into your submissions in April. Given the time constraints under the hereco contract we are unable to ask them to respond to individual submissions but I can assure you that all feedback is being considered and where relevant incorporated into the proposed regrouping that hereco will deliver in mid-November.

Hereco has not been asked to address benefit discrepancies in the new groups. Once the proposed regrouping has been finalised by hereco, the Department will commence consultation on the benefit setting element. At this stage if there is still concern regarding the clinical implications of any element of the regrouping the Department will consider this advice and consult with CIRG and hereco where necessary.

Just so you are aware, we have received a very small number of submissions from stakeholders all of which have been forwarded to hereco for consideration in their review and finalisation of their proposed regrouping.

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Post listing reviews

As pointed out by MTAA at the Stakeholder Engagement meeting, the lack of information about the announced pilot reviews caused significant consternation due to the lack of understanding of their rationale. Subsequently emails were sent directly to sponsors with more information. However, concern remains high including about the scope of these reviews and no further information has been provided on content and timing.

Furthermore, our members have strongly objected to the reviews being undertaken before a proper consultation process on the Post Listing Framework and we request that proper consultation on this be allowed first. The fact that the reviews are labelled 'pilot' provides no comfort that there will be any extra layer of assurance that they will in the end be done with appropriate transparency and consideration of the relevant details.

MTAA's response on the proposed Framework (sent today) emphasises that sponsors must be allowed to comment on whether the review is necessary at all before a final decision is taken to

commence the review. Unfortunately, this did not occur in this case, but the opportunity would still be welcome for sponsors, providing assurance of due process and appropriate use of resources.

We have also pointed out in our feedback on the Framework that PLAC or its successor should be the central recommending body for all review decisions. If sector advisors are not to be included on PLAC's successor (see below) then these reviews should also be subject to recommendations by these advisors.

Response:

The Post-Listing Review Framework is an initiative of the PL Reform program. It aims to formalise a review process and sets out a systematic approach to evaluating devices on the PL, be they surgically implanted medical devices, human tissue items, and other products listed on the PL.

The principles behind the Review Framework align with medicine review initiatives conducted across the Department, such as the Post Market Review and the Drug Utilisation Review frameworks. (Sponsors of medicines are not given the opportunity to influence whether a review should proceed).

The Department retains its legislative obligation to prioritise the interests of patients and the integrity of the private health benefits system – and will consider and seek input from the public, health practitioners, peak bodies, and independent advisors in the nomination for and conduct of reviews of devices listed on the PL.

The Post-Listing Review Framework has been published on the PL reforms web page and open for comment since June 2022 – and will remain open until the current reviews are conducted and finalised (these current reviews will take place during 2022 and 2023 and will "test" the appropriateness of the Post-Listing Review Framework which will be amended accordingly). In keeping with Departmental program improvement processes, the Department aims to refine the review process – if and as required – as informed by the lessons learned through the conduct of the pilot reviews.

Thank you for the comments provided by the MTAA. PL stakeholders are encouraged to provide (further) comment on the Review Framework via email at PLreviews@health.gov.au during the pilot reviews.

The Department may conduct consultation sessions with PL stakeholders should the feedback received warrant such an approach. Otherwise, refinements to the Review Framework will be made and communicated on the PL reforms website and a PHI Circular will be published accordingly to alert stakeholders.

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Maximum price

At our meeting back in April we asked about the meaning of the lines in the context section of Consultation Paper #1 as follows:

> • introducing, as a part of PL application process, a declaration by companies 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

Our understanding of your comments at the time was that there was not an intent to impose maximum prices on the sale of PL items to hospitals, whether new or existing, but that there was an

intent to ensure all items that are needed for the implant and use of a device are listed on the PL and not sold separately.

We request further information on whether this remains the case, clarity on the policy and how and when it will be decided, for instance in legislation or some other way. MTAA remains strongly opposed to price controls on sales to hospitals. We understand that the recent benefit reductions have been passed on to hospitals with few concerns.

Response:

The legislation consultation paper will outline our proposed approach to include an application requirement that ensures sponsors put forward the full system for inclusion on the PL to ensure there are no 'out of pocket' expenses for insured patients for additional items essential to implanting the primary device. The whole system should undergo HTA, not just the primary device.

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PLAC successor

At the Stakeholder Engagement meeting you advised that a decision has been made to replace PLAC with further details forthcoming. EY's review into PLAC recommended that it be split into a decision-making committee of experts only and a purely consultative committee of sector members. If the proposal is to remove sector advisors from the main recommending body we have serious concerns. There is evidence that expert committee members on their own do not correctly assess all issues without input from the sectors. We request further information on the decision taken and specifically industry representation in the proposed governance arrangements.

Response:

The outcome of the PLAC review (EY), Governance options (AHTA) and proposed way forward will be announced shortly, however it is likely that (in line with both the recommendations of EY and AHTA) medical device and private health insurance industry representative stakeholders will be removed as members/observers of the committee due to their direct and indirect pecuniary interests that could be deemed as actual or perceived conflicts of interest which could affect their duties as committee members advising the Minister for Health.

Listing processes

The only positive promise for industry coming out of the PL reforms, which otherwise involved significant benefit reductions and further scrutiny of the PL, is 'streamlining listing of new devices' (Budget announcement) and the commitment in the MOU that MTAA and the Department would co-design the new listing pathways, noting *no other stakeholders are mentioned*. Therefore, there will be significant focus by MTAA and its members whether processes actually are streamlined and MTAA's input is front and centre of the new pathways.

We appreciate the efforts of the workshops run by AHTA to try to land on solutions for reasonable listing pathways for PL items. Nonetheless, MTAA made three significant requests prior to and during the workshop on which have not had a positive response. We would like absolute clarification on whether the Department considers a decision has been taken, for what reasons and if not when and how this will occur.

1. Class III devices included in Tier 1 pathways

We understand from our previous discussion that the Department has ruled this out for at least 2 years. We are seeking confirmation that this decision is final and the reasons for it. The Tier 1 pathway is meant to determine interchangeability in cases where this is straightforward. No rationale has been provided why Class III devices are any more difficult to assess interchangeability for than Class I or II. If anything, they are easier to assess.

We understood also that CAGs are being consulted on the use of Tier 1 for Class I and II devices for all categories of the PL and that as a result some Class I and II devices may also be required to go through Tier 2. We would like a clear understanding of how and when the consultation with CAGs will occur, whether the Department believes CAGs have right of veto and how MTAA will be consulted on any recommendations by the CAGs. Our default position is that, at the least, no Class II product groups seeking the same grouping should be required to go through Tier 2 unless there is a very compelling reason for them doing so, i.e., more than CAGs 'want to have a look' or don't trust the TGA etc.

Response:

There is no involvement of CAGs in the Tier 1 (Departmental) pathway. Any application that requires a clinical assessment will be either Tier 2 or Tier 3. Class III devices are deemed high risk and should be subject to significant scrutiny by a HTA organisation under Tier 2 (and/or MSAC through Tier 3). Therefore, will not be considered in Tier 1.

Although the TGA assesses safety, quality and performance, the Department expects a device that will be privately funded will be assessed by the PLAC (or equivalent) and its relevant subcommittee for their comparative clinical and cost-effectiveness. We propose that the new listing pathways should be implemented for two years, with a review at that time to consider if Tier 1 can be opened further.

Furthermore, we understand there is no intention to change or abolish the '2 year rule' now applied by CAGs to joint replacements. Please confirm that this is a final decision and the reasons for it.

Response:

There is no change to the 2-year rule which was developed on the advice of the relevant CAG.

2. Use of public prices in lieu of HTA for new groups

MTAA has argued that it is entirely consistent with the PL reforms that where an established public price exists for a device that CAGs determine warrants a new group due to superior performance that instead of going through an HTA to determine the premium it could take the public price. This would save resources and speed up the process while delivering a price that has been competitively determined in the public market. This issue was ruled out of AHTA's scope in the third workshop, but not in the first two, which appears to have been a deliberate decision by the Department.

Our understanding of our previous discussion was that the Department is still open to this possibility. We would like clarification as to why the issue was removed from AHTA's scope – and presumably therefore its forthcoming consultation paper - and if so, what the process would be to progress this discussion if it is not actually part of the consultation process.

Response:

As indicated in the meeting, the Department intends to ask for the public price as a part of the application process (as well as international pricing) to enhance our understanding of the device

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more broadly as well as using it to inform pricing under the PL. The Department is further considering the feasibility of using public pricing instead of HTA or, alternatively, as an adjunct to HTA.

3. Use of MSAC when there is no new MBS item number required

The premise of the AHTA discussion paper and workshops was that MSAC would still be a potential pathway if no new or amended MBS item was required to list the device on the PL. MTAA has argued that MSAC should be limited to situations to these situations only, and if a suitable MBS item number is already in existence, then a focused HTA is all that is required. We seek understanding on whether a decision has already been taken on this and if not whether there is a genuine openness to consider MTAA's position in the upcoming consultation process.

Response:

This will be further clarified in the next stage of listing pathway consultation.

Legislation and Compliance

We would appreciate more information about the issues that both the proposed legislation and the compliance framework are trying to solve, as well as directionally some of the solutions being considered for consultation. In particular, in the case of compliance, comments from the Department seem to reflect that it will all focus on sponsor compliance, rather than the compliance of all parties including insurers. Your assurance around this would be useful.

Thanks again for the opportunity to meet and we hope this email is useful in enabling a good discussion of the issues we wish to raise. Let us know if there are any questions or responses in the meantime.

Response:

Consultation paper will be released shortly, further:

LEGISLATION

The Department is finalising the scheduling of the webinars in response to requests from key stakeholders that the proposed Legislation webinars be opened to a broader audience. The details will be released around the end of August along with the Consultation Paper on legislation. Webinars are likely to be conducted in September.

This consultation will provide input to help finalise the drafting of the first amendment Bill.

COMPLIANCE

The Department is responsible for the integrity of and confidence in health programs administered by the department and reported to Government – and thus conducts compliance and assurance activities across major health programs.

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Compliance initiatives have largely been absent across the prostheses list program to date. In response the PL Compliance and Assurance function has been established as part of the PL Reform program.

At the core of the PL program, the Government, the public, and health professionals expect that PL stakeholders – be they medical device companies (sponsors and manufacturers), private hospitals and private health insurers – understand and adhere to legislated rules and policy requirements that govern the benefit price settings of the PL. These intended behaviours set the benchmark for compliance and assurance across all PL stakeholders participating in the PL arrangements.

Forthcoming for review on the Consultation Hub is the Prostheses List Compliance Strategy. The Strategy identifies the principles which govern the Department's compliance, assurance and enforcement functions, and the associated priorities in support of the PL. It also sets out the compliance obligations within the context of the legislative instruments, and the steps the Department may take where there are concerns about non-compliance activities.

The Strategy is applicable to all PL stakeholders. In taking actions to encourage, strengthen and enforce compliance with the PL system, the Department will always prioritise the interests of patients and the integrity of the private health benefits system.

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Minister	**Minister Butler**
PDR Number	**MC22-017150**
Subject	Joint Letter to Minister Butler from APHA, CHF and MTAA
Initiator	**Mr Michael Roff, Dr Elizabeth Deveny, Mr Ian Burgess**
Contact Officer	s22 [redacted]
Clearance Officer	Elizabeth Flynn 02 6289 s22 [redacted] s22
Division/Branch	|Health Resourcing| Technology Assessment & Access

Adviser/DLO comments:	Returned to Dept for: REDRAFT ☐ NFA ☐

Please complete	
Quality Assurance Check (completed by line area)	s22 [redacted]

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Australian Private Hospitals Association | CHF Consumers Health Forum of Australia | MTAA Medical Technology Association of Australia

08 September 2022

Hon Mark Butler MP
Minister for Health and Aged Care
PO Box 6020
Parliament House
Canberra ACT 2600

RE: PROSTHESES LIST REFORM

Dear Minister

We write on behalf of the Australian Private Hospitals Association (APHA), Consumers Health Forum (CHF) and Medical Technology Association of Australia (MTAA).

We wish to reaffirm our support for the Memorandum of Understanding (MoU) between MTAA and the Commonwealth, signed in March 2022. We resoundingly reject calls from Private Healthcare Australia to overturn the agreement. To do so would result in unintended consequences for patients and would remove the patient access and doctor choice guarantee protected under the Prostheses List and this agreement.

The agreement strikes the right balance between delivering more than $900 million in savings to health insurers, preserving clinical choice and protecting patients from out-of-pocket costs, and was the result of exhaustive consultation with all stakeholders. We commend you, and the Government, for signing a commitment to deliver on the MoU, including the outstanding areas of Prostheses List reform still to be finalised.

Since the finalisation of the MoU, we have been working with the Department of Health to solve the outstanding items of reform to ensure funding certainty and patient choice is maintained.

In particular, funding certainty is required before general use devices are removed from the Prostheses List, scheduled to occur on 1 July 2023. Without this, patients will face out-of-pocket costs, there will be increased costs for hospitals and restrictions on clinical decision making potentially limiting the availability of some procedures in the private sector. We contend that no items should be removed from the list until viable alternative funding arrangements are guaranteed.

Given the complexity and enormity of the remaining reforms to the Prostheses List, we have serious concerns regarding the timelines set out by the Department to resolve these matters, and stress stakeholders do not see them as achievable in their current iteration.

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To ensure we, as key private health sector stakeholders, can work constructively with the Department to achieve positive reforms that prioritise quality outcomes for patients and ensure the sustainability of the private health system, we request that you discuss with us the need for appropriate and necessary amended timelines for the specific outstanding items to progress Prostheses List reform.

We look forward to hearing from you regarding this matter.

Signed

s47F

Michael Roff
Chief Executive Officer
Australian Private Hospitals Association

Dr Elizabeth Deveny
Chief Executive Officer
Consumers Health Forum

Ian Burgess
Chief Executive Officer
Medical Technology Association of Australia

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s22 [redacted]

From: Minister Butler
Sent: Thursday, 8 September 2022 4:37 PM
To: MPS
Subject: MC22-017150 - Joint Letter to Minister Butler from APHA, CHF and MTAA
Attachments: Joint Letter to Minister Butler - APHA, CHF, MTAA.pdf

Categories: s22 [redacted]

MC22-017150

M reply – TAAD

Thanks
s22 [redacted]

From: Michael Roff <michael.roff@apha.org.au>
Sent: Thursday, 8 September 2022 4:11 PM
To: Minister Butler <Minister.Butler@Health.gov.au>
Cc: nick.martin@health.gov; HENRY, Pat <Pat.HENRY@Health.gov.au>; Jo Root <J.Root@chf.org.au>; Ian Burgess <s47F [redacted]>; Matthew Versi <s47F [redacted]>; Lucy.Cheetham@apha.org.au
Subject: [ATTACHMENT UNSCANNED]Joint Letter to Minister Butler from APHA, CHF and MTAA

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Minister

Please find attached a joint letter regarding Prostheses List reform, signed by the Australian Private Hospitals Association, Consumers Health Forum and Medical Technology Association of Australia for your attention.

Yours sincerely

Michael Roff
CHIEF EXECUTIVE OFFICER
Australian Private Hospitals Association
Australian Private Hospitals Association
P: 02 6273 9000
W: www.apha.org.au
PO Box 4502, Kingston, ACT 2604

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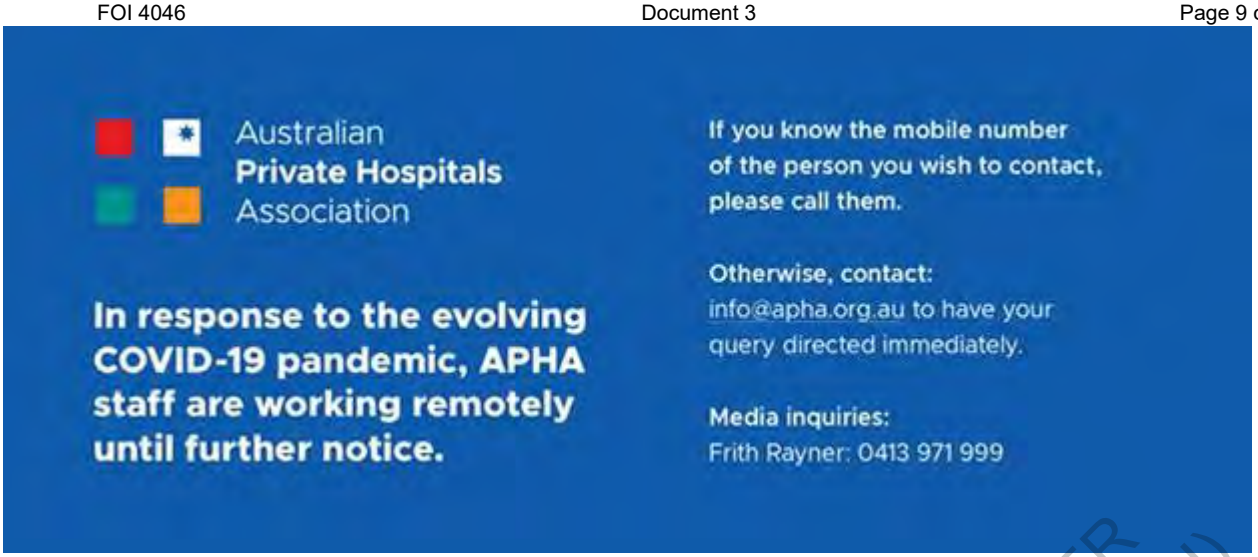

Get involved with the Valuing Private Hospitals Campaign. Fan us on Facebook http://www.facebook.com/valuingprivatehospitals or follow us on twitter http://twitter.com/#!/priv8hospitals

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The Hon Mark Butler MP
Minister for Health and Aged Care

Ref No: MC22-017150

Mr Michael Roff
Chief Executive Officer
Australian Private Hospitals Association
michael.roff@apha.org.au

Dr Elizabeth Deveny
Chief Executive Officer
Consumers Health Forum
ceo@chf.org.au

Mr Ian Burgess
Chief Executive Officer
Medical Technology Association of Australia
s47F [redacted]

Dear Mr Roff

Thank you for your correspondence from yourself and your colleagues of 8 September 2022 regarding Prostheses List (PL) Reform, specifically in relation to the Memorandum of Understanding (MoU) signed by the Medical Technology Association of Australia (MTAA) and the previous Minister for Health.

The MoU promises significant reform and savings under the PL, thus I have instructed the Department of Health and Aged Care to continue to deliver on the activities outlined in the MoU. The MoU also clarifies the process for the implementation of new funding arrangements for General Use consumable items, which will also deliver predictability for patients, hospitals and insurers. These items can be better funded through bundled funding arrangements which continue to be co-designed with the sector.

As you would be aware, the Independent Health and Aged Care Pricing Authority (IHACPA) has formed a PL Reform Working Group, of which the Australian Private Hospitals Association, the MTAA and the Consumers Health Forum of Australia are members. This working group has been established to support the provision of advice on alternative bundling arrangements to insurers and private hospitals and has contributed to the Consultation Paper on Bundling Arrangements for General Use Items on the Prostheses List and can be found at www.ihacpa.gov.au/resources/consultation-paper-bundling-arrangements-general-use-items-prostheses-list, which is currently open for consultation closing on 12 October 2022. The outcome of this work will facilitate the negotiation of new funding arrangements of these products between private hospitals and private health insurers. The IHACPA will provide its advice on alternative bundling arrangements to the department in December 2022. It is expected that ineligible items are continued to be available to Australian patients and there are no unintended out-of-pocket consequences for patients with an adequate level of cover. I encourage you to continue to work with IHACPA in your respective roles as members of the working group and provide feedback to the consultation process.

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In parallel to the IHACPA process, the department is exploring options for the implementation of the bundles from 1 July 2023. I also encourage you to work with the department and where possible have discussions with private health insurers to workshop options for future funding arrangements of bundled general use items. Any subsequent advice on options can be provided to the PL Reform Taskforce within the department.

I appreciate your ongoing support of the reforms and look forward to continuing to work with you to implement these reforms.

Thank you for writing on this matter.

Yours sincerely

Mark Butler

4 /10/2022

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Australian Government
Department of Health and Aged Care

Meeting Brief
MB22-002780
Version (1)
Date sent to MO: 7/09/2022

To: Minister Butler

Adviser: Mr Pat Henry

Subject: MEETING WITH MTAA (DISCUSS PROSTHESES LIST AGREEMENT AND HTA REVIEW)

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

Date / Time: TBC

Meeting Type/Location: TBC

Traditional Custodians: TBC

Purpose: The Medical Technology Association of Australia (MTAA) would like to meet to discuss the Prostheses List Reforms, including the Memorandum of Understanding (MoU) they entered with the previous Minister, and the Health Technology Assessment (HTA) Policy and Methods Review (see: **Attachment A – Letter from MTAA**).

Key Attendees/Speakers:	Title:	Organisation:	Mobile No:
Maurice Ben-Mayor	Chair	MTAA	s47F
Susan Martin	Vice Chair	MTAA	
Ian Burgess	CEO	MTAA	
Paul Dale	Director, Policy	MTAA	

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Key Matters/Issues:

Prostheses List Reforms

Refer to **MB22-002554** for information provided in follow up to a meeting between the Department and the Minister on Prostheses List reforms and potential next steps. (**Attachment C** to this brief – Issues not explicitly covered by the MoU - describes additional issues that the MTAA may seek to raise with you.)

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Discussion Guide:

Proposed Objective and/or Desired Outcomes:

Prostheses List Reforms

- Provide MTAA with an update on the PL Reforms and indicate that there will be no further concessions granted in relation to the MoU, and that the Government expects that all reforms to reduce prices of devices for privately insured Australians will be fully delivered.
- Indicate that you will host a meeting of all stakeholders to affirm your commitment to the PL Reforms in the coming months.

s22

[redacted]

Stakeholder information:

- The Medical Technology Association of Australia (MTAA) is the national association representing the majority of companies in the medical device industry that supply products to the Australian health system. MTAA aims to ensure the benefits of modern, innovative and reliable medical devices and technology are delivered effectively to provide better health outcomes to the Australian community.

Prostheses List Reforms

- On 14 March 2022, the former Minister and the MTAA entered a Memorandum of Understanding (MoU) to finalise policy parameters for the PL Reforms, as a result of ongoing pushback from the medical devices industry. The MoU with MTAA included the following modifications to previously announced PL Reforms:
    - where device prices are less than 7% higher on the PL compared to the weighted average price in public hospitals, no reduction will be made to the PL benefit;
    - no further reduction in year four of the announced reforms (locking in on an ongoing basis that 20% of the current differential between public and private prices would remain); and
    - benefit reduction of general use (consumable) items for two years rather than removal of ineligible consumable products in the first year (60% differential reduction on 1 July 2022 and 40% on 1 March 2023 before removal from the PL on 1 July 2023 when bundling arrangements are implemented).
- The Department has provided the following earlier briefings on the MoU: MB22-002554, MB22-001845 and MB22-001657.

Stakeholder Objective:

Prostheses List Reforms

- MTAA has stated in its letter (**Attachment A**) it is "concern[ed] about PHA's ongoing campaign to reverse the PL Agreement and wind back the doctor choice and patient access guarantees of the PL".

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- MTAA will likely seek your ongoing support of the MoU as well as further commitment to a number of issues not covered by the MoU:
    - general use items;
    - modernised listing pathways;
    - regrouping the PL to negate any further price corrections within PL items; and
    - guaranteed future funding/ongoing access to cardiac services through the PL or another funding stream.

  (**Attachment C** provides further detail on the above).

s22 [redacted]

Sensitivities or Contentious Issues:

Prostheses List Reforms

- The need for reform is not agreed by stakeholders. There have been significant delays to implementing the PL Reforms in the first 12 months, mostly as a result of a lack of consensus from key stakeholders and delays in the provision of information.
- Private health insurers (particularly those represented by Private Healthcare Australia (PHA)) are strongly opposed to the MoU and have asked the Minister to step away from the agreement. They have also repeatedly requested access to the calculations/ assumptions related to the savings that would result from the MoU (see below).
- The Government has received enquiries from the media in regard to the Government's intended approach to the PL Reforms.

s22 [redacted]

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Budget/Financial Implications:

Prostheses List Reforms

Estimated savings

Changes agreed to in the MoU will increase savings from the originally forecast $700-800 million arising from the PL Reforms (that was advised to insurers ahead of the 2022 premium setting process) to a revised estimate of $900 million. These estimates were calculated based on the following assumptions (which have not been shared publicly and some of the assumptions may be disputed by stakeholders such as PHA):

- 7% floor on all PL items;
- 0/40/20/20% reduction of the public/private price differential over four years on Cardiac Implantable Electronic Devices (CIEDs - noting that the reduction on CIEDs has been delayed by 12 months under the MoU and will commence 1 July 2023);
- 60/40% reduction of price differential over two years for general use (consumable) items ahead of removal from the PL;
- 40/20/20% reduction of price differential over three years on all other PL items; and
- 5% annual growth on utilisation of the PL over the next four years.

The table below shows the estimated savings comparison each year, dependent on utilisation growth over the next four years:

s45

Attachments:

A. Letter from MTAA requesting meeting (15 July 2022)
B. Biographical details - Include a biography of key attendees
C. Issues not covered by MoU

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Attachment B

Biographies

	**Maurice Ben-Mayor, Chair, MTAA** Maurice Ben-Mayor has more than 20 years of experience in the Medical Technology sector. He is President for Stryker South Pacific, a position he has held since 2015. Prior to this, Maurice spent seven years serving in a number of director roles within Stryker's sales and marketing divisions. Maurice originally joined Stryker as a marketing manager in 2003. Prior to Stryker, Maurice worked as a sales representative for medical devices company, Synthes. Maurice is passionate about innovative technology, developing people and building high-performing cultures. Maurice holds a Bachelor of Science (Psychology) and an MBA, both from The University of New South Wales. He is also the current Chair of the Medical Technology Association of Australia.
	**Sue Martin, Vice Chair, MTAA** Sue's career with Johnson & Johnson, the largest healthcare company in the world, spans over 20 years and includes experience across multiple countries and functions. Since January 2018, Sue has been Managing Director for Johnson & Johnson MedTech (JJMT) Australia and New Zealand. She is responsible for the company's entire MedTech portfolio in ANZ, including orthopaedics, general and speciality surgery, cardiovascular, and breast reconstructive surgery products. Sue is a member and co-chair of the Johnson & Johnson Family of Companies Board in Australia and New Zealand and represents Australia and New Zealand on the MedTech Asia-Pacific Leadership Board. She is also the executive sponsor for Global Community Impact (GCI) across Johnson & Johnson Australia and New Zealand, which includes overseeing the company's Reconciliation Action Plan (RAP), with a focus on health equity for our First Nations populations. Sue has been a board member for MTAA since 2018 and Vice-Chair since 2019.
	**Ian Burgess, Chief Executive Officer, MTAA** Ian has been the CEO of MTAA since January 2017. He is an experienced CEO and Director, previously working as CEO of the Australian Dental Association (NSW Branch), Ortho Group Pty Limited (OGL), and the Australian Orthopaedic Association Limited (AOA). Ian is also a member of the Australian Institute of Company Directors and a non-executive director of the Red Nose Ltd. He holds an MBA from Macquarie University and a Bachelor of Economics from the Australian National University.
	**Paul Dale, Director, Policy, MTAA** Paul has been the Director of Policy covering reimbursement and industry issues for MTAA since January 2019. Before working in life sciences consulting during 2018, Paul worked for 17 years in the pharmaceutical industry in Australia and the US including 5 years in global strategic pricing and market access roles. Locally, Paul's roles have spanned government affairs, strategic policy, market access, marketing and sales. He played a key role on pharmaceutical industry committees during periods of PBS reform and the US-Australia Free Trade Agreement negotiation and has managed government and stakeholder communication strategies on product access issues. He particularly enjoys the depth of immersion in the healthcare system involved in medical device policy work.

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Attachment C

ISSUES NOT COVERED BY MOU

Further to the changes made to the Reforms as a result of the MoU, the MTAA has continued to seek commitment from the Minister on the following issues that are not covered by the MoU:

s47G(1)(a) [redacted]

General Use items

s47C [redacted] This process is being led by IHACPA, which has formed a Prostheses List Reform Working Group (MTAA is a member) to support the provision of advice on alternative bundling arrangements to insurers and private hospitals to facilitate the negotiation of new funding arrangements of these products.

IHACPA will commence a public consultation process on 14 September 2022 to support the development of its advice on alternative bundling arrangements, and will publish its advice on alternative bundling arrangements in December 2022. It is expected that ineligible items are continued to be available to Australian patients and there are no out-of-pocket unintended consequences for patients with an adequate level of cover.

s47C [redacted]

MTAA continues to dispute the Government's position that PL listing applications for new General Use items will not be accepted as they no longer meet the listing requirements. The MTAA claim that this is anti-competitive behaviour as the MoU allows for competitor products to remain on the PL for a year longer than originally anticipated. It should be noted that even if the Department agreed to receive new applications and these are not rejected for being ineligible, the soonest they could be listed would now be March 2023, with the plan to remove the entire group of items in July 2023.

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The Department remains committed to removing ineligible items on 1 July 2023 and not accepting new applications for items in this category.

Modernised listing pathways

A key element of the MoU was the co-design of the modernised listing pathways. The Department honoured this request by holding co-design workshops with key stakeholders (including the MTAA and medical device companies) to work through stakeholder issues with the Department's proposed approach to the new three-tiered pathway:

- Tier 1: Departmental Assessment Pathway
- Tier 2: Clinical/Focused HTA Pathway
- Tier 3: Full HTA Pathway (Medical Services Advisory Committee (MSAC)

MTAA have raised concern that other stakeholders are involved the co-design process, and believe that MTAA's input should be "front and centre" of the new pathways. Its input includes:

MTAA feedback	Department position/response
Class III devices should be included in Tier 1 – Departmental assessment pathway	Class III devices are deemed high risk and should be subject to expert scrutiny by a HTA organisation under Tier 2 (and/or MSAC through Tier 3), not lower levels of Departmental assessment in Tier 1. Although the TGA assesses **absolute** safety, quality and performance, the Government expects a device that will be funded will be assessed by the PLAC (or equivalent) and its relevant subcommittee for their **comparative** clinical and cost-effectiveness, to ensure consumers are not meeting costs of new devices that do not work as well as something already available. The Department acknowledges some stakeholders (particularly MTAA) may be disappointed with this outcome and will monitor the impacts of this decision before potentially reviewing it.
Public prices should be used in lieu of HTA for new groups so these can be considered under Tier 1	The Department intends to ask for the public price as a part of the application process. However, the Department does not agree that the provision of public pricing will negate the need for HTA (which will assess comparative clinical and cost-effectiveness against comparator products) for all devices.
Tier 3 (Full HTA/MSAC) should be limited to situations where new MBS item number are required	Tier 3 Pathway will be used to establish the effectiveness, safety and cost-effectiveness of the subject device when used for its intended purpose. The pathway is congruent with the existing MSAC assessment process. The outcome of the Tier 3 Pathway is the provision of a new or amended MBS item number (if required), and evidence to inform benefit setting for the subject device.

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The Department remains committed to consulting with all key stakeholder groups, including consumers and clinicians. The Department is currently finalising a report on the proposed pathways which will take into consideration the feedback from MTAA and all other stakeholders before being put out for further public consultation in the coming months.

Regrouping of the PL

A significant element of the PL reforms is the regrouping of the PL to ensure it reflects appropriate clinical practice, groups like items together in terms of clinical outcomes and benefits mandated for those outcomes, and in streamlines the number of items listed on the PL which currently sits at over 11,500 items. MTAA believe that consultation on this process is being rushed by the Department.

The Department understands the complexity of this project and the need for broad and thorough consultation of the regrouping process and as such has made no commitment as yet to an implementation date for the new structure of the PL. Stakeholder consultation is currently taking place regarding the clinical relevance and implications of the proposed regroupings and this will be followed up with further consultation on the benefit setting component of the final proposed regrouping once it is delivered to the Department in late 2022.

It should be noted that a significant negotiation piece in the MoU was that the Government would not make additional saves from the regrouping exercise and the Department is working extremely hard to honour this commitment which has significantly increased the workload of the PL Reform Taskforce. This remains a significant weakness in the architecture of the PL within existing items, over and above the price comparison with an external benchmark of public or international prices.

Guaranteed future funding/ongoing access to cardiac services through the PL or another funding stream

To ensure continued access for patients to Cardiac Implantable Electronic Devices (CIEDs), the MoU provides for a one-year deferral of PL Reform related benefit reductions for the CIED category while the Medical Services Advisory Committee (MSAC) considers the value of the technical support services provided by medical device companies to patients with CIEDs. It is understood that MSAC may also provide suggestions on possible funding arrangements for these services, other than these being added into the costs of the device.

The MSAC deliberations are only in their early stages and there is no indication what the Committee will recommend, however MTAA continue to push that the PL Reforms should provide a guarantee future funding/ongoing access to cardiac services through the PL or another funding stream:

> *"cardiac implantable electronic devices needed to be considered differently as part of PL Reform due to the nature of the ongoing services, provided by industry employed allied professionals, that are provided in support of the cardiologist throughout the life of the patient… Whilst a Medical Services Advisory Committee (MSAC) Review is being undertaken, there is likely to be some policy issues that need to be addressed to ensure these services continue to be provided at no additional cost to patients and are available to patients as required regardless of where they live."*

s47C [redacted]

There is no intention for the Department to expedite the MSAC process, extend the deferral of the PL Reform related benefit reductions for CIEDs nor find alternative funding arrangements for CIEDs while the MSAC process is underway.

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Minister	**Minister Butler**
PDR Number	**MB22-002780**
Subject	**Meeting Brief: Meeting with MTAA (discuss prostheses list agreement and HTA review)**
Contact Officer	Elizabeth Flynn (02) 6289 s22 s22
Clearance Officer	Penny Shakespeare (02) 6289 s22
Division/Branch	|Health Resourcing| Technology Assessment & Access Division| Prostheses List Reforms Taskforce Branch

Adviser/DLO comments:	Returned to Dept for: REDRAFT ☐ NFA ☐

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s22

From: Minister Butler DLO
Sent: Wednesday, 24 August 2022 6:07 PM
To: MPS
Subject: FW: MEETING BRIEF | FW: FW: MEETING REQUEST – TO DISCUSS PROSTHESES LIST AGREEMENT AND HTA REVIEW [SEC=OFFICIAL]

Categories: s22

Hi Team

Understand Minister is meeting with MTAA following a departmental briefing (MB22-001845).

Can I please have a meeting brief in the MO by 6 Sept from TAAD. I don't have a meeting time/date yet but want it in system (understand dept already on it).

If I get details we will send, otherwise leave those bits as TBC by EA.

Kind regards

s22
Departmental Liaison Officer
Office of the Hon Mark Butler MP
Minister for Health and Aged Care
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T: s22
Suite MG.50 | PO Box 6022
Parliament House, Canberra ACT 2600

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www.mtaa.org.au

15 July 2022

The Hon. Mark Butler MP
Minister for Health and Aged Care
Parliament House
Canberra ACT 2600
via: minister.butler@health.gov.au

Dear Minister

RE: MEETING REQUEST – TO DISCUSS PROSTHESES LIST AGREEMENT AND HTA REVIEW

I'm writing to you regarding the most recent negative news story in The Saturday Paper, instigated by Private Healthcare Australia (PHA), attacking the four-year Prostheses List (PL) Agreement MTAA signed with the Commonwealth.

The private health insurance lobby's consistent and unnecessary public attacks against doctors, private hospitals, consumer groups and MedTech are a serious concern to our members who, like you and your team, are focused on helping support the government's efforts to manage the latest COVID-19 outbreaks and ensuring vital life-saving services are still able to be delivered to those in need.

We'd like to discuss with you our concerns about PHA's ongoing campaign to reverse the PL Agreement and wind back the doctor choice and patient access guarantees of the PL. Like the Labor Government, MTAA believes patients, not insurer profits, must be at the heart of our healthcare system.

MTAA would also like to discuss our strong recommendation that the Department of Health's HTA Review process be widened to include MSAC reviews of medical technologies, in-line with recommendation 31 of the House of Representatives Standing Committee on Health, Aged Care and Sport's '*The New Frontier – Delivering better health for all Australian*' report. We believe this requires MTAA membership on the review committee.

We appreciate the many and varied demands of your time and can be amendable to your schedule to find a suitable meeting time. I note for your team that MTAA will be in Canberra during the week of the 25th of July 2022, in case there should be a suitable time during that week to meet with you and your Chief of Staff, Mr Nick Martin.

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Medical echnology Association o Australia Limited ABN 61 129 334 354

Medical Technology Association of Australia
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I've asked Matthew Versi, Director, External Affairs and Communications, to follow-up with your office in the coming days to help with arranging meeting details with your team.

Should you or your team have any questions, please feel free to reach out directly on s47F

Yours faithfully

s47F

Ian Burgess
CEO

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