Australian Government
Department of Health

General use items

Pre-consultation paper – 27 June 2024 workshop with private health insurance stakeholders

Overview

On 1 May 2024, the Minister of Health and Aged Care announced that general use items (GUI) would be retained in Part D of the Prescribed List (PL). This decision follows continuous feedback from multiple stakeholders that removing the GUIs from the PL would have negative clinical implications and potential adverse outcomes for patients.

The announcement comes two years after the initial planned removal of the GUIs from the PL, and a year after insurers and hospitals were requested to negotiate alternative funding arrangements.

We acknowledge the concerns of private health insurers that the announcement about retaining GUI on the PL represent. The department is undertaking further consultation and engagement to identify ways in which these concerns might be addressed – both regulatory and non-regulatory.

What we invite you to do

We ask that you provide us with practical suggestions about ways to increase the integrity of the settings of the PL as well as mechanisms to reduce increased growth in usage of GUIs per episode of care and the resulting increased growth in expenditure (i.e. without any clinical need).

In considering your input to this matter we ask that you provide as much detail and evidence as possible. Please ensure your suggestions remain in the context of the Prescribed List and are reasonable, pragmatic and within the authority of the department.

Questions

At the workshop, we would like to discuss your answers to the following questions.

Integrity

1. What do you see are the key areas of concern for the integrity of the PL settings in the context of the GUIs?
2. If you were to consider prioritisation of these, what would that look like?
3. What are the potential system based-actions (i.e. not fixing of individual errors) that could be taken, by who and when?
4. How would you suggest the success of these actions are measured?
5. What are the likely consequences – positive/negative and who would they effect?

Utilisation and growth in expenditure

6. What sub-categories of GUIs on the PL represent the key areas of growth in utilisation per episode of care and therefore increase in benefit expenditure?
7. Are there specific procedures that represent higher growth in utilisation?
8. If there are concerns that the growth in use is not related to clinical need, how is this determined/measured? Who can validate this?
9. What system-based mechanisms are either in place or need to be put in place to address this problem?
    a. Would these mechanisms be different if there was a demonstrated clinical need?
10. How would you suggest the success of these actions are measured?
11. What are the likely consequences – positive/negative and who would they effect?

Other matters

12. Are there other areas of concern with the retention of GUIs on the PL that need to be considered?

Workshop on general use items integrity, utilisation and growth in expenditure

Meeting Agenda

Date: Thursday, 27 June 2024

Time: 10:00 am to 1:00 pm

Location: Department of Health and Aged Care (Sirius Building 23 Furzer Street, Woden Australian Capital Territory 2606)

Email: prosthesesreform@health.gov.au

#	Agenda Item	Lead
1	• Acknowledgement of Country • Welcome and opening of the meeting • Introductions	Department • Andrew Rintoul
2	• Discussion - Integrity	Department • Andrew Rintoul
3	• Discussion – Utilisation and growth in expenditure	Department • Andrew Rintoul
4	• Questions – Follow up from the department	Department • Andrew Rintoul
6	• Other matters	Private Health Association

From: Ben Harris
To: s22
Subject: GUI letter attachment 9 May 2024
Date: Thursday, 27 June 2024 12:46:26 PM
Attachments: 20240509 PHA Dr Rachel David to Minister Butler re GUI on PL_attachment.pdf

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Ben Harris
DIRECTOR OF POLICY AND RESEARCH
M: s47F | **E:** s47F @pha.org.au
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General Use items controls and tweaks to the list

DRAFT AS AT NOON THU 2 MAY 2024

PHA's major concern is volume and cost being added with no demonstrable clinical benefits. For example, there was a 12.9% volume growth in GUI in 2017/18 on flat surgery volumes.

Recommended overall rules

- Price/volume agreements
    - If the total use of items under each subcategory increases by more than 10% in any year (adjusted for any increases in surgical volume), the price of all items under that code should be reduced by 10% (rounded up to the nearest dollar).
- Ensure no out of pocket costs for consumers as a condition of listing. This is likely to require the price to hospitals not to exceed the PL price.
- Any price increases (i.e. through amendment applications) to demonstrate a public interest case, including the clinical and economic benefits. These public interest cases should be published by the Minister each PL cycle.
- Hospitals provide feedback on the costs of medical devices and standard usage patterns to their medical staff (as previously offered by hospital groups).
- Where hospitals use general use items at a significantly higher rate than their peer group (for example, over 20% to 50% higher than the average depending on distribution), payment will be provided in full only where the treating doctors certify that the unusual use is reasonable and necessary, otherwise a 120% to 150% expenditure cap will apply.
- Remove suffices which do not impact on the patient outcome. These would include price reductions where there is no consumer benefit from device characteristics (we have a list to consider, see below)

Fix mistakes on the list

- Address error in pricing and all adhesion barriers with the same ARTG back to public price (reduce spend by $1.018m)
- Use the Surgiflo price 6ml for Floseal, Purastat 5mls as there's no difference in price at the higher volume between Floseal and Surgiflo (reducing spend by $0.620m)
- Hemoblast VB002 reduced to same price as Floseal, Surgiflo (reducing spend by $0.225m)
- Applicators (03.05.05.05 - Accessory Extender) removed, as they should be incorporated into the device as per public prices (reducing spend by $0.022m)

- Move ET082 PureRegen Gel Sinus from adhesion barriers to nasal code (no price impact)
- Remove internal adhesive applicators (03.08.02.04 - Adhesive Accessory) as they should be included in device cost as per public prices (reduce spend by $1.792m)
- Add conditions of use for Tisseal etc to vascular and dura consistent with IFU
- Remove Evicel as it is a listed medicine, not a device (not eligible)
- Remove ET065 as it is a suture and not eligible
- Remove ET066 as not eligible (reduce spend by $1.081m)
- Tristapler MI287 and GIA stapler AS209 repriced to the sum of the component parts (reduce spend by $2.004m)
- Remove CoreKnot, these are surgical instruments (DE606, DE609)
- Remove anomaly where larger sponges receive much higher remuneration, change to per cm for all sizes (reduce spend by $0.083m)
- Reprice all liquid repair sealants to the highest volume price, rather than paying more for the smaller sizes.
- Place condition on use for all liquid repair sealants to dura, as per IFUs
- ER279 OverStitchTM Endoscopic Suturing System repriced to comparator FQ002

Recommended price reviews

- Remove premium for powered stapler as no HTA assessment was undertaken (reduce spend by $1.129m)
- Remove premium for endoscopic suffice for staplers as no clear difference in performance in most instances (reduce spend by $12.759m).
- Reprice KI010 to $90 as it is readily available at that price (here)
- Reduce price for 03.08.04.04 - Staplers, Non-bone with Disposable Applier to the same as 03.08.04.02 – Staplers. There is no justification for the premium.

Suggested changes to improve integrity

- Remove capital items for infusion pumps and increase cassette cost to compensate (no net financial impact).
    - Remove 03.02.03 - Infusion Pumps, Battery Powered
    - The price of the 03.02.05.02 - Administration Cassettes would need to increase from $26 to $51 to compensate for these items coming off
- Use a single price for pliable patches to remove incentives for larger sizes (no net financial impact)
- Use a per gram price for haemostatic power to remove incentives for larger sizes (no net financial impact)
- Use a single price for absorbable sponges to remove incentives for larger sizes (no net financial impact)

- Consider merging all the items under10.09.01 - Percutaneous Catheters, Single Lumen, removing all suffices and averaging the price (no net financial impact)
- Consider merging all the items under1010.09.02 - Percutaneous Catheters, removing all suffices and averaging the price (no net financial impact)

Suffices to remove

While professional advice is required, these suffices appear to be based on the characteristics of the device rather than an effect on patient care.

For example, stapler reloads are similar regardless of the type of stapler, there is unlikely to be a need for a suffix and additional payment.

03.02.02 - Infusion Pumps, Balloon Based	03.02.02.01 - Fixed Flow Rate	Bolus
03.05.03 - Sponges	03.05.03.01 - Absorbable ≤75cm²	Anatomically Conforming
03.05.03 - Sponges	03.05.03.01 - Absorbable ≤75cm²	Low Antigenicity
03.05.03 - Sponges	03.05.03.02 - Absorbable >75cm²	Low Antigenicity
03.05.04 - Pliable Patches	03.05.04.01 - Absorbable ≤50cm²	Antimicrobial, Low Antigenicity
03.05.05 - Matrix	03.05.05.02 - Liquid >6ml	Complete Biomaterial
03.08.03 - Ligating Devices	03.08.03.01 - Clips	Polymeric Non-resorbable
03.08.02 - Internal Adhesives	03.08.02.02 - Adhesive >2-5ml	Biological
03.08.02 - Internal Adhesives	03.08.02.02 - Adhesive >2-5ml	Synthetic
03.08.03 - Ligating Devices	03.08.03.03 - Clips with Disposable Applier	Laparoscopic

03.08.03 - Ligating Devices	03.08.03.03 - Clips with Disposable Applier	Open
03.08.04 - Staples & Tackers	03.08.04.01 - Staples, Non-bone (Reload)	Curved
03.08.04 - Staples & Tackers	03.08.04.01 - Staples, Non-bone (Reload)	Endoscopic, Articulating/Roticulating

Note on figures used

- Financial outcomes quoted are based on 2021-22 volumes and prices as at 1 March 2023 (not the November list).
    - This list was first done prior to notification of the 1 November 2023 price cuts.

From: Ben Harris
To: s22
Subject: Re: Meeting/workshop request on general use items [SEC=OFFICIAL]
Date: Wednesday, 15 May 2024 12:34:16 PM
Attachments: image001.png
image002.jpg
image003.png

We will come to Woden.

Ben Harris
DIRECTOR OF POLICY AND RESEARCH
T: s47F | M: s47F | E: s47F @pha.org.au
www.privatehealthcareaustralia.org.au

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On 15 May 2024, at 12:30 PM, s22 <s22 @health.gov.au> wrote:

Hi Ben,
Apologies, I just wanted to check if yourself, s47F and s47F would be attending face-to-face or over Webex?
Thank you!
Warm Regards,

s22
Executive Assistant to Andrew Rintoul | Assistant Secretary
Prostheses List Reform Taskforce
<image001.png>

Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
T: 02 6289 s22
E: s22 @health.gov.au
Location: Sirius Building 9.N
PO Box 9848, Canberra ACT 2601, Australia
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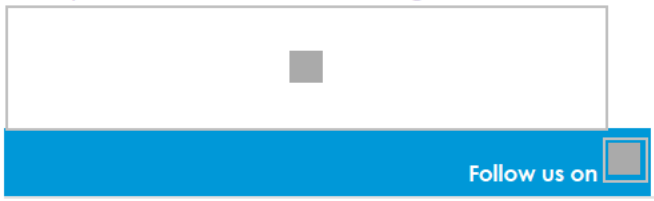
From: Ben Harris <s47F @pha.org.au>
Sent: Monday, May 13, 2024 11:03 AM
To: s22 @Health.gov.au>
Subject: RE: Meeting/workshop request on general use items [SEC=OFFICIAL]

Done. Can you please send the invite as you will need to do a room booking.
For s47F and myself,
Thanks
Ben

Ben Harris
DIRECTOR OF POLICY AND RESEARCH
M: s47F | **E:** s47F @pha.org.au
www.privatehealthcareaustralia.org.au



From: s22 @Health.gov.au>
Sent: Monday, May 13, 2024 10:41 AM
To: Ben Harris <s47F @pha.org.au>
Subject: RE: Meeting/workshop request on general use items [SEC=OFFICIAL]
Good morning Ben,
Can we lock in Thursday 27 June? That would be great!
Just for clarification, are you sending the invite or is this something you would prefer us to do on our end?
Thank you
Warm Regards,

s22
Executive Assistant to Andrew Rintoul | Assistant Secretary
Prostheses List Reform Taskforce
<image001.png>

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Australian Government Department of Health and Aged Care
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E: s22 @health.gov.au
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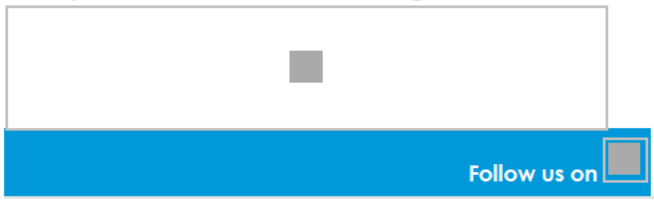
From: Ben Harris <s47F @pha.org.au>
Sent: Friday, May 10, 2024 10:57 AM
To: s22 @Health.gov.au>
Subject: FW: Meeting/workshop request on general use items [SEC=OFFICIAL]
Hi s22 ,
s47F and I would attend, we have the technical expertise.
These dates would suit:
Wed 5 June (pm)
Thu 6
Mon 17
Wed 19
Thu 20
Mon 24

Thu 27
Hope one of these works,
Thanks
Ben

Ben Harris
DIRECTOR OF POLICY AND RESEARCH
M: s47F | **E:** s47F @pha.org.au
www.privatehealthcareaustralia.org.au



From: s22 @Health.gov.au>
Sent: Friday, May 10, 2024 10:07 AM
To: Ben Harris s47F @pha.org.au>; Rachel David <s47F @pha.org.au>; s47F s47F
Subject: RE: Meeting/workshop request on general use items [SEC=OFFICIAL]

Good morning Ben, Rachel, s47F and s47F,
Happy Friday and I hope you have a relaxing weekend ahead of you!
I was wondering if you would be able to give me a list of times that work for you throughout June. Unfortunately, the workshop won't be able to happen before then.
If you can send me a list, that would be great. I will then continue to coordinate internally with the PLRT team to find a time suitable.
Thank you and I look forward to hearing from you all.
Warm Regards,

s22
Executive Assistant to Andrew Rintoul | Assistant Secretary
Prostheses List Reform Taskforce
<image001.png>

Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
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From: Ben Harris <s47F @pha.org.au>
Sent: Thursday, May 9, 2024 4:46 PM
To: RINTOUL, Andrew <s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s47F ; s47F ; Rachel David <s47F @pha.org.au>; s22 @Health.gov.au>

Subject: RE: Meeting/workshop request on general use items [SEC=OFFICIAL]

Thanks Andrew

Ben Harris
DIRECTOR OF POLICY AND RESEARCH
M: s47F | **E:** s47F @pha.org.au
www.privatehealthcareaustralia.org.au
<image002.jpg>

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From: RINTOUL, Andrew <s22 @health.gov.au>
Sent: Thursday, May 9, 2024 4:35 PM
To: Ben Harris <s47F @pha.org.au>
Cc: s22 health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s47F s47F ; Rachel David <s47F @pha.org.au>; s22 @Health.gov.au>
Subject: RE: Meeting/workshop request on general use items [SEC=OFFICIAL]

Hi Ben,

I'll ask s22 to coordinate internally and come back to you with a range of times to hold the meeting.

Kind regards

Andrew

Andrew Rintoul
Assistant Secretary
<image003.png>

Protheses List Reform Taskforce | Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
T: +61 2 6289 s22 | M: s22 E: s22 @health.gov.au
Location: Sirius 9.N.101
PO Box 9848, Canberra ACT 2601, Australia
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From: Ben Harris <s47F @pha.org.au>
Sent: Wednesday, May 8, 2024 5:12 PM
To: RINTOUL, Andrew <s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s47F s47F ; Rachel David <s47F @pha.org.au>
Subject: Meeting/workshop request on general use items

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Andrew,

Rachel and I met with s47F and s47F on Friday on general use items on the PL. They have encouraged us to engage with you on our list of errors, integrity issues and consumer protection measures sent last week.

I ask for an extended meeting/workshop with you and your staff on the 40 issues

we have raised with general use items. I recognise that other than s22 many of your staff have not been around long enough to have had exposure to the general use item history – in particular, the EY report and the department's report on general use items. We have the advantage of the history and the data from funds to add to the repository of knowledge the department has collected over the years, plus the expertise of former device company staff who will be able to help the department come to decisions on how to proceed with protecting consumers' interests.

We propose going through the technical suggestions, where they have come from (eg the EY report), and why we are recommending what we are recommending (eg using the Hereco framework for regrouping). Our line-by-line examination of the general use category as part of the investment we have made while looking for a solution to general use items should be of value to the taskforce.

I think we could get it done in three hours, with me, s47F and s47F going through the list of recommendations to inform your decisions going forward.

Let me know when would suit you and your team,

Thanks

Ben

Ben Harris
DIRECTOR OF POLICY AND RESEARCH
M: s47F | **E:** s47F @pha.org.au
www.privatehealthcareaustralia.org.au

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From: s47F
To: s22
Subject: RE: Meeting/workshop request on general use items [SEC=OFFICIAL]
Date: Friday, 10 May 2024 4:00:58 PM
Attachments: image001.png
image002.png
image003.png
image004.png

Oh, that's great, thanks and sorry for the double-up. You've saved me some time.
s47F

From: s22 @Health.gov.au>
Sent: Friday, May 10, 2024 3:59 PM
To: s47F @pha.org.au>
Subject: RE: Meeting/workshop request on general use items [SEC=OFFICIAL]

Good morning s47F ,

Thank you for you reply, I appreciate it! However, Ben has already provided days that work for the three attendees.

Thank you again!

Warm Regards,

s22
Executive Assistant to Andrew Rintoul | Assistant Secretary
Prostheses List Reform Taskforce
Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
T: 02 6289 s22
E: s22 @health.gov.au
Location: Sirius Building 9.N
PO Box 9848, Canberra ACT 2601, Australia
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From: s47F @pha.org.au>
Sent: Friday, May 10, 2024 3:46 PM
To: s22 @Health.gov.au>
Subject: FW: Meeting/workshop request on general use items [SEC=OFFICIAL]

Hi s22 just touching base to let you know that I'll coordinate some dates at this end and get them to you early next week.

s47F
EXECUTIVE ASSISTANT to CEO
T: s47F | E: s47F @pha.org.au
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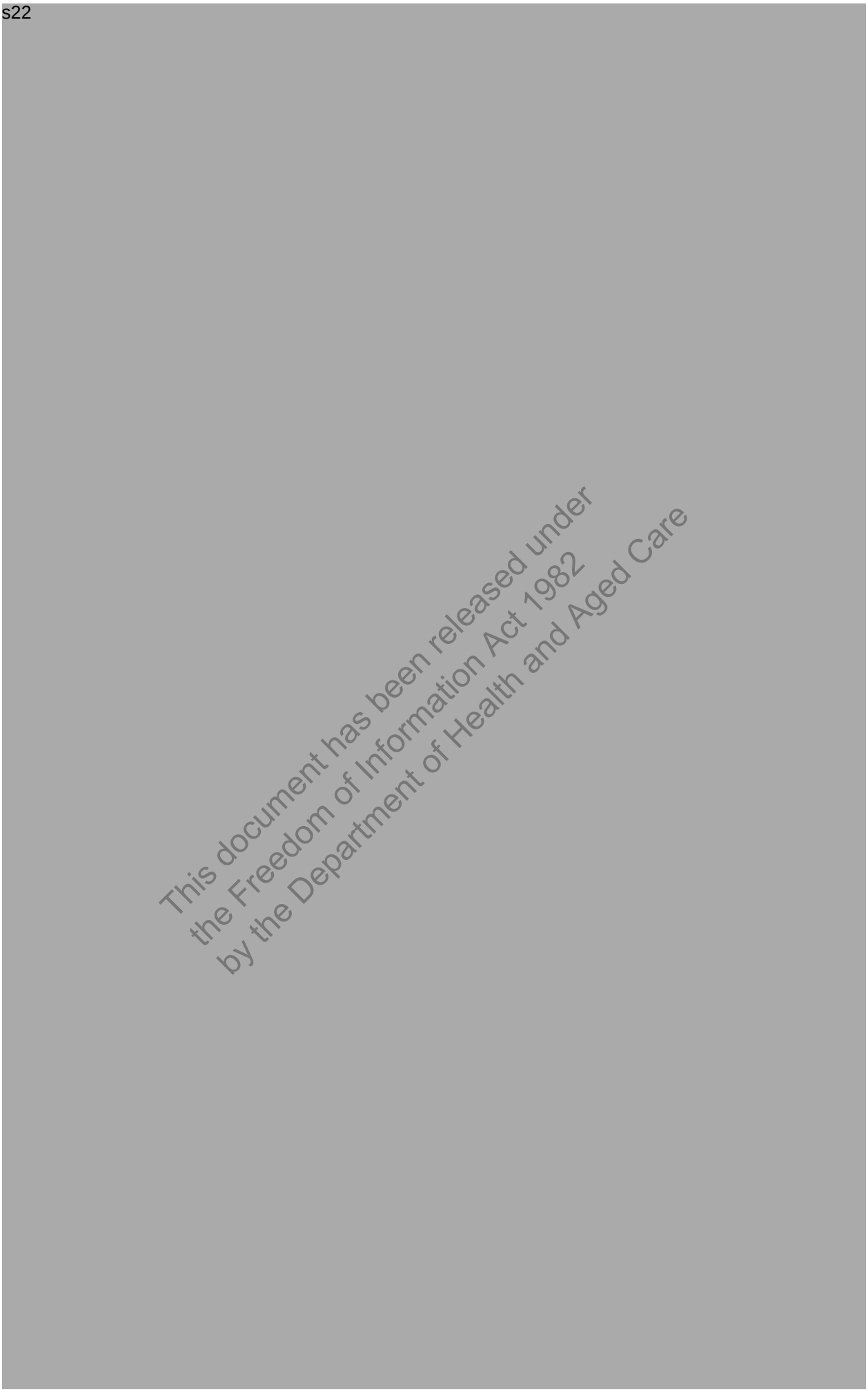
s22

s22

s22

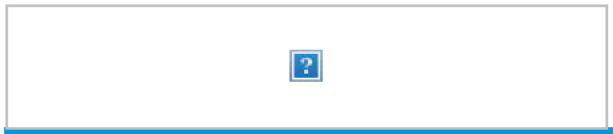


s22

From: Ben Harris
To: RINTOUL, Andrew; Prostheses Reform; s22
Subject: PHA submission on PL gifts and graft (8a)
Date: Friday, 14 June 2024 1:55:36 PM
Attachments: 20240614 PHA submission to Prescribed List Reforms - Consultation Paper 8a_gifts and benefits.pdf

Andrew and team (cc s22
Please find attached PHA's submission on graft, gifts and benefits for the Prescribed List.
Apologies for the delay.
s22 worth having a look at the introduction page,
Thanks
Ben

Ben Harris
DIRECTOR OF POLICY AND RESEARCH
M: s47F | **E:** s47F @pha.org.au
www.privatehealthcareaustralia.org.au



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From: Ben Harris
Sent: Thursday, June 13, 2024 4:53 PM
To: RINTOUL, Andrew s22 @health.gov.au>; prosthesesreform@Health.gov.au
Subject: PHA will be late with our submission on PL gifts and graft (8a), may be tomorrow (eom)
Sorry team, the NSW issue is taking up too much of our time.
We will not be submitting on 8b.

Ben Harris
DIRECTOR OF POLICY AND RESEARCH
M: s47F | **E:** s47F @pha.org.au
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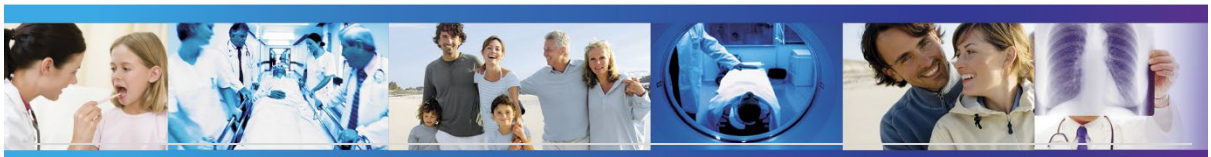

Prescribed List Reforms - Consultation Paper 8a: Gifts, benefits and discounts reporting requirements

June 2024

Contact:

Ben Harris, Director Policy and Research

s47F @pha.org.au

About Private Healthcare Australia (PHA)

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We have 22 registered health funds throughout Australia as members and collectively represent 98% of people covered by private health insurance. PHA member funds provide healthcare benefits for 14.4 million Australians.

Introduction

PHA welcomes the opportunity to contribute to the Department of Health and Aged Care's consideration of improving compliance and transparency for medical devices. However, the proposals outlined in this discussion paper are clearly insufficient. While they may help improve the current situation, these proposals fall well short of current integrity and transparency standards.

PHA recommends medical devices be regulated in the same manner as pharmaceuticals, with mandatory reporting of all gifts, benefits or discounts to a public registry as part of an enforceable code of conduct that aligns with the code of conduct for pharmaceutical companies. This must include penalties for compliance breaches if it is to be effective at any level.

There is no public policy justification for an integrity framework for medical devices which is less rigorous than that for pharmaceuticals.

The current market for medical devices is beset by graft, gifts and various financial incentives with little to no transparency to consumers, payors and the general public. Where money is changing hands without the benefits of transparency, market manipulation and influencing clinical decisions is much more likely to occur, and the spectre of corruption looms over the sector.

The losers are consumers – patients who may be receiving less optimal, or even harmful, medical devices, and those paying for health care (consumers, taxpayers and payors, including health funds).

Tentative steps are not enough – allowing a little bit of corruption is not acceptable to health funds. The Australian Government should do all it can to ensure consumers are receiving the best possible medical devices, which can only occur where there is full transparency over all types of payments and gifts to providers.

Gifts, benefits and discounts reporting requirements

There are multiple ways in which sponsors and hospitals co-operate to provide discounts, gifts, free products, cash rebates and 'transfers of value arrangements' to encourage use of Prescribed List items in the private sector.

These practices:

- Reduce competition in the market because some smaller companies do not have the resources to use them.
- Keep PL rebates high because there is no transparency of true market value.
- Encourage wasteful practices such as unnecessary use of PL items.
- Drive low value care that can harm consumers and the broader health system.
- Drive the provision of poorly performing devices when better options are available.

Rather than the discount being provided to the ultimate payer of the goods, i.e. the holders of private health insurance (PHI) and the taxpayers who subsidise PHI, they are banked by the hospital owners who act as intermediaries without risk in the process.

These practices are not restricted to PL items, but PL items are often involved due to the known high minimum rebate prices. There are several ways in which the set rebate price for PL items is used by sponsors and hospitals for this purpose. This includes:

Cash rebates

This is a very common mechanism used by hospitals to elicit a discount on PL items. A hospital group typically approaches a sponsor to inform them that they will only allow their products to be used in their hospitals if a certain percentage of the PL rebate is paid back to the hospital owner in the form of a cash rebate. This practice has been happening since the rules for the PL changed in the late 1990s/ early 2000s, so that PHI is only obliged to pay the invoiced amount.

The rebates can be extended to include other non-PL items from the supplier utilised in the hospital, e.g. disposable items such as power saw blades and orthopaedic space suits. This provides a competitive advantage to larger multinational companies that can bundle a wide range of PL and non-PL items. Smaller local sponsors who may specialise in a particular surgical specialty or who do not have the capacity to supply such a wide range of items struggle to compete with this.

These opaque rebate arrangements have led to the significant increase in PL items per case over recent years. This can be seen with the significant increase in general use items (GUI) being used in certain surgeries, such as Evicel in hip replacements, often without any evidence or a comparable increase in the same usage in the public system. Evicel sales in hip replacements are almost exclusively limited to where a J&J (Evicel) representative attended the case. This indicates it is not a routine item in use for that surgical intervention unless a sales representative attends for the device company.

Global price fixing

Private hospital providers that have a multinational presence can negotiate with multinational medical device companies to fix a global price for the PL items used in their Australian facilities. This allows the hospital operator to benefit from the fixed rebate price of the PL in two ways. Firstly, they

can take advantage of the revenue generated from the difference in the two prices and secondly, they can offshore that difference to a low tax jurisdiction. This practice sees consumers and taxpayers lose out in two ways from not receiving the discounted price through lower premiums, and from the loss of tax revenue for the federal government which subsidises PHI premiums.

Company dollars schemes

This is a mechanism used by larger multinational companies to ensure their PL items are used within a hospital. This mechanism works on a similar principle to the cash rebates in that a hospital will earn company dollars or credits that can later be redeemed to purchase other non-PL items such as capital equipment or disposables (e.g. Stryker Dollars, Zimmer Dollars or Medtronic Dollars). This effectively provides the hospital with a discount as non-PL goods are provided free of charge through the use of PL items. This again gives an unfair competitive advantage to larger multinational companies.

Free capital

Another common practice is the offer of high-cost capital equipment that is linked directly to the use of PL items, e.g. the placement of an orthopaedic surgical assist device where the contract states a specific number of joint replacement devices must be used from that company per year over a specific number of years within the hospital. These deals can lead to devices being used that do not provide the patient with the best outcome because the surgeon is encouraged to use the device that will pay for the capital equipment.

Straight discounts

Despite the change in rules for the PL mentioned above, PHA has been made aware of surgeon owned day surgery facilities being given a direct discount for PL devices that are then charged to PHI at the full rebate amount. The surgeon owned day surgery then simply banks the difference as profit at the expense of consumers and taxpayers. This sort of behaviour encourages surgeons who own the facility to implant devices that make them the most profit rather than what will provide the best outcome for the patient.

Fellowships

The medical device industry has a history of sponsoring specific surgical fellowships to promote their devices. However, these fellowships are usually tied, not just to a surgical practice, but also to a specific hospital. This is often a public hospital, but private hospitals have also been involved. There is an implied obligation for the surgeons and hospitals involved in these fellowship arrangements to utilise the sponsor company's PL devices. Whilst many of these fellowships offer a valuable expert training experience that improves the skills and knowledge of those who are selected to undertake them, they are yet another way that the high rebates mandated on the PL can be utilised by hospitals to, in effect, receive a free or greatly discounted surgeon funded by consumers and taxpayers.

Free samples

Whilst the offer of free samples for a trial period is common commercial practice across most industries as a competitive tool to generate new business and clients, as the consultation paper states, "the PL is a regulated reimbursement mechanism that does not follow standard commercial arrangements and any incorrect or inappropriate claiming for items against the PL ultimately affects the insured patient." The hospital involved in this activity is in effect receiving 100% of the PL rebate amount as revenue rather than the end consumer and taxpayer. Any PL items offered free of charge, for whatever reason, should not then be billed through to PHI. This would allow sponsors and hospitals to engage in a normal commercial practice whilst still being required to report the transaction on the registry.

Public hospitals

All public hospitals in Australia purchase their surgical devices via a public tender process. The majority of these are done as panel tenders, i.e. all companies are accepted onto the tender. This is done to drive down the prices paid by state governments and to allow surgeons a choice of devices. As this is a competitive process, suppliers routinely offer their devices at a discount to the rebates on the PL. However, despite purchasing the devices at the discounted rate, PHA has evidence that public hospitals still invoice the PHI of any patient that receives treatments as a private patient the full PL rebate amount, thus using the PL system to generate funding. The public hospital and, by default, the state governments are therefore using PHI members and federal taxpayers to enhance their budget positions.

Marketing assistance incentives

Like fellowships, surgeons and hospitals are offered a range of marketing assistance as incentives by the medical device companies to use their devices. This can be as simple as providing generic patient brochures and videos explaining the device and procedure to more bespoke / individualised glossy patient information packs. Whilst this may seem to be standard marketing activity, it is being funded by PHI members and the taxpayer via PL rebates. Any direct to consumer promotion of medical devices should be completely banned.

The majority of these types of discount / incentives and transfer of value arrangements are well known across the healthcare industry but have always been kept opaque by the parties involved, often hidden behind 'commercial in confidence' agreements between device companies and hospitals and medical practitioners. However, as can be seen in the Senate Committee report from 2016, the department has known about them for some time.

Recommendations

Mandatory reporting of gifts, benefits or discounts to a public registry.

There should be mandatory reporting of all discounts / incentives and 'transfer of value arrangements' between sponsors, hospitals and medical practitioners to a registry that is published

quarterly each year. Sponsors and hospitals should be required to report all such transactions, and other people with knowledge of these transactions should be permitted to report them to prevent under reporting. The reporting should detail all individual PL items involved as well as the total value of the incentives provided to hospitals and medical practitioners. There should be penalties for non-compliance.

There should be no threshold – all transfers of value must be reported to ensure integrity.

Medical device companies should be responsible for populating the public registry, but those receiving the benefits should bear responsibility for ensuring it is done correctly. In effect, this would require large penalties for device companies who fail to disclose, and public warnings and smaller penalties for hospitals and medical practitioners to encourage them to ensure the benefits received are properly disclosed by the device companies.

The current opacity of transactions between medical device companies and providers allows for gaming of the PL system, creating unnecessary additional costs that ultimately flow through to consumers during a cost-of-living crisis. A public registry will help reveal the true value of PL items, which should then be reflected in the PL rebate amount, currently set by the Australian Government. Public reporting of these activities will bring transparency for all involved, particularly consumers who pay for private health insurance to contribute to the cost of their own healthcare.

An enforceable code of conduct for medical devices that aligns with the code of conduct for pharmaceutical companies.

Like the pharmaceutical industry, the medical device industry is a multi-billion-dollar sector in Australia. Medical technology companies engage in many activities to build relationships with health professionals and promote sales of their products, including:

- company-sponsored educational events;
- providing cash payments to medical specialists to participate in product development or advisory boards
- engaging key opinion leaders as speakers or consultants;
- paying for travel, meals or professional development; and
- sponsoring post-market trials.

PHA wants an enforceable Code of Conduct for the medical technology industry that aligns with the code of conduct for pharmaceutical companies. Under the code for pharmaceutical company representatives, Medicines Australia must disclose support, incentives and other benefits provided to prescribing doctors by pharmaceutical companies.

This Code of Conduct has been endorsed by the ACCC, who can also enforce the code if required.

The highly competitive business means sales representatives typically work off commissions with incentives to increase the volume of products used and the use of more expensive devices. Research suggests company representatives also spend time in clinical areas, attend surgical procedures, and offer technical support 24 hours a day. Patient consent may not be given for sales representatives to be in clinical settings and company representatives may be involved in hospital purchasing processes as a source of product information, free samples, as well as driving in-house evaluation and training on the product.

This results in a dual role for device company representatives with potentially conflicting interests: working as a commissioned sales representative while also providing advice on medical treatment. We define a sales representative as any person present in a clinical area whose salary is paid by a medical device company, regardless of what their title is or what they claim to be doing. As a team of Australian academics argued in 2018, 'This duality raises the concern that clinical decision-making may be unduly influenced by commercial imperatives', and it creates ethical concerns about the impacts on healthcare costs, the outsourcing of expertise, and issues of accountability and informed consent.

A class action brought against Johnson & Johnson in Australia over its vaginal mesh implants demonstrated how some of these activities can jeopardise clinical care. Internal documents dating from 2009 show Johnson & Johnson representatives used Lamborghinis and ski trips among other incentives to influence doctors as they rushed a class of implants to market and encouraged inexperienced surgeons trained by company representatives to use them. This outsourcing of clinical expertise meant some women later found it hard to find surgeons qualified to remove the defective implants that caused widespread pain and suffering in Australia.

The potential impact on healthcare costs has been documented. In 2013, a 1-year retrospective review of medical records of patients who had percutaneous coronary intervention at a Canadian teaching hospital showed the presence of device representatives was associated with significantly higher costs of balloons and stents per case, driven by the higher costs of the stents selected.

We also need improved controls on medical device company representatives entering clinical areas, including informed patient consent for their presence, and full disclosure of any benefits they provide to doctors or hospitals. An enforceable Code would help ensure decisions about the use of medical devices are fully transparent, and solely based on clinical considerations. The table below outlines differences between the current oversight of pharmaceutical and medical device industries in Australia.

Table 1. The inconsistent approach to regulating pharmaceuticals and medical devices in Australia.

	Pharmaceuticals	Medical devices
The Therapeutic Goods Administration makes sure products are safe for their indicated use	✓	✓
Products are only funded if they are used for the purpose for which they have been assessed	✓	✗
There is a code of conduct enforced by the Australian Competition and Consumer Commission to regulate behaviour of market participants	✓	✗
Prices are compared with international markets to ensure consumers do not pay too much	✓	✗
If competitors enter the market, consumers get a lower price	✓	✗
Sales representatives are prohibited from being in the room when the product is used or prescribed (consulting room, hospital or operating theatre)	✓	✗
Once a product is approved, it can only be used for the clinical indication it was approved for	✓	✗