

**Consultation Paper 8b - Alignment of amount charged for supply of a device with corresponding PL benefit**

Stakeholder feedback analysis report

# Introduction

The purpose of this report is to provide an analysis of stakeholder feedback received in response to the consultation paper on the proposed measure: alignment of amount charged for supply of a device with corresponding PL benefit. Submissions were open to stakeholders between 23 May 2024 and 13 June 2024. A total of 21 submissions were received (Figure 1). The submissions represented the medical technology sector and private hospitals.

**Figure 1 Number and type of respondents.**

Key feedback

Most stakeholders did not support this measure and believed that this will ultimately affect the supply of medical devices to privately insured patients. Some of the key feedback that was received included:

* Most sponsors questioned the need for this measure, as there are very low number of reports of patient out-of-pocket expenses due to gaps for PL items. However, some sponsors did admit that they do charge above the PL benefit for some devices.
* It is difficult for sponsors to determine whether any devices that are sold are destined for privately insured patients or not.
* Sponsors may have very little control over what price is being charged to hospitals and clinicians as some sponsors use distributors to supply products.

Key concerns

Some of the key concerns raised by stakeholders about this proposed measure included:

* Sponsors feel that criminal and legal sanctions for sponsors charging above the PL benefit is disproportionate.
* There are fears that this measure will have long term consequences as many sponsors may choose to opt out of PL, which may potentially lead to increased out-of-pocket expenses or loss of access for patients.
* This measure risks new, innovative products not being listed on the PL as the costs in supplying the device may outweigh any benefit that would be received.

The key issues raised by stakeholders during the consultation are listed in **Table 1** below. In addition, the feedback that was received in response to the seven questions that were asked in the consultation paper can be found in **Table 2** below.

**Table 1: Key feedback and concerns about the proposed measures for the alignment of the amount charged for supply of a device with a corresponding PL benefit.**

This table outlines the key themes that were raised by stakeholders in their feedback on the proposed measures for the Prescribed List gifts, benefits and discounts reporting requirements.

| **Issue** | **Stakeholder feedback** |
| --- | --- |
| ***Need for this measure*** | Sponsors have questioned the need for this measure and have pointed to the Nous Baseline report that indicates that only 0.23% of episodes of care involve a patient payment gap for PL items. Additionally, a small number of sponsors have indicated they do charge above the PL benefit for some devices in the private setting. |
| ***Pricing mechanism for public and private hospital*** | Some sponsors have indicated they supply products to public hospitals at prices higher than the current PL benefits. This is due to the continued benefit decreases on the PL over the past few years, whilst there have been substantial increases in the cost of manufacturing medical devices (due to increases in raw materials, energy and labour costs) as well as increased regulatory costs. |
| ***Long term consequences*** | Many sponsors believe that this measure will have long-term consequences that will see out of pocket expenses for patients increase, as many sponsors will choose to opt out of the PL.  A few sponsors and distributors foresee that new, innovative products developed will not be brought to the Australian market due to significant market access costs and hurdles. Products that are launched globally may not be introduced into the Australian market as the PL benefit for these types of products is inadequate.  Sponsors are disappointed that new and innovative products being assessed by MDHTAC are allocated the same benefit as other less technologically advanced products that already exist on the PL. In such situations, the sponsors may choose to remove the device from PL listing, and new and innovative technologies will be only available to public patients. |
| ***Sponsors and distributors*** | Manufacturers selling devices to third party distributors have no control over the price that they sell their devices for in the market. Additionally, local distributors with manufacturers overseas have no control over prices that manufacturers set and hence sometimes suffer a loss. |
| ***Penalties*** | Sponsors believe that the proposed criminal and legal sanctions for sponsors charging above the PL benefit is a disproportionate response to a practice that is very infrequent and if it does occur, could be for reasonable circumstances. |

**Table 2:** **Key feedback from the questions posed in the consultation paper for the proposed measures for the alignment of the amount charged for supply of a device with a corresponding PL benefit.**

| **Consultation Questions** | **Stakeholder Response** |
| --- | --- |
| 1. Do you charge more than the minimum PL benefit ascribed to any of your PL listed devices/products?    1. If your answer is yes, approximately how many listed products are charged at a higher cost than the minimum PL benefit and why is the cost more? | While most of the respondents stated that they do not charge more than the minimum PL benefit, some stated that their products are sometimes sold to public hospitals at a price that is higher than the minimum PL benefit. This may be due to increasing costs of manufacturing or due to reductions in PL benefits. |
| 1. To what extent do you have control over the price setting for the devices/products you sponsor on the PL?    1. If you do not have full control over the price setting, what other party(s) is involved?    2. Do you have any negotiation power in price setting? | Stakeholders stated that they had a range of control over price setting for their devices – ranging from no control to full control. Generally, hospitals will not buy devices at prices higher than the PL minimum benefit, and when combined with competition for other products and other market forces, made it very difficult to sell above the PL minimum benefit price.  Distributors create a disconnect between sponsors and the sale prices associated with hospitals. Distributors are responsible for their own price setting and contracts and in some instances, they do not have their prices dictated to them by sponsors. And in other cases, sponsors do not have much visibility of how much distributors charge.  Price setting power was more likely to occur in the public system. |
| 1. Are there instances where you charge less than the minimum PL benefit for listed devices/products? | Generally, stakeholders will not charge less than the minimum PL benefit. However, they may if large volumes are purchased. |
| 1. Are there any devices/products you sponsor on the PL where you are absorbing some of the costs because the PL benefit is set too low in relation to the manufacturing costs? If so, can you provide evidence of the manufacturing costs? | Multiple stakeholders stated that if they were looking to bring a new device to market where the manufacturing costs outweighed the PL benefit, then they wouldn’t apply to have that product on the PL. The device may not even be brought to the Australian market. This tended to occur with newly developed devices which were more technologically advanced than existing devices on the PL, but the benefit that was assigned did not recognise the superior factors over the existing listed devices.  Sponsors also stated that manufacturing costs are only one cost in the development and supply of a medical device. There were other costs that needed to be considered that affected the sale price. |
| 1. Do you see any positive implications for this measure? | There may be benefits in that patients may not need to pay gaps, but this may come at the cost of reduced access to devices. |
| 1. Are there any other matters the department should consider when finalising this measure? | Other matters stakeholders suggested that the department should consider included:   * that it would be useful if the department could explain how to request an increase to the PL benefit if they believed it was too low. * It is difficult for sponsors to determine whether any devices that are sold are destined for privately insured patients or not. * the emphasis shouldn’t be on the minimum PL benefit, it should be on clinician choice and the device that will generate the best clinical outcome for the patient. * In circumstances where there is currently a small gap, implementing this measure might result in a much larger out-of-pocket expense for the patient if the measure results in the device being removed from the PL. The patient may now have to cover the entire cost of the device. This, combined with the potential for new and innovative devices not being put on the PL, may lead to consumers questioning the benefit of private health insurance. * Further consideration on the broader implications of the proposed measure on the industry and patient care should be considered. * There is a risk that the measure may end up causing a greater financial burden on hospitals. * The potential sanctions for this may punish a supplier who may be making little or no profit from the sale of these devices. |
| 1. What are your first thoughts on the ability of this measure to shape the integrity of actions, reduce costs and impact the content of applications? | Some of the thoughts from stakeholders on this measure included:   * They believe there has been little consideration made to the costs of innovation, manufacturing, and development, particularly for small innovative companies which are not yet profitable. * While they support the idea of increasing the accountability and integrity of the PL, they have concerns about this proposal. * This measure could lead to products being withdrawn from the PL, particularly those which are sold at a higher price in the public system. This would limit access for privately insured patients and potentially lead to an increase in ex gratia requests made to insurers. * The scale of the problem should be determined first before any criminal/civil sanctions are applied. * Perhaps a mechanism that might be a more effective approach is for the department to investigate developing a reporting process where alleged egregious cases could be investigated and resolved. * The department should explore whether the policy objective could be achieved in other ways e.g. via hospital-insurer contract negotiations. * This measure may result in costs being shifted from private health insurers to patients if it results in devices being removed from the PL. * The overall result of this measure may be reduced patient access and increased patient costs. * Hospitals are aware of gaps existing now, and if they choose to select a product that has a gap over a competitor, perhaps that product has advantages over the others. * There is a potential for applications to become more complex as companies will provide more detailed information while trying to achieve a higher benefit commensurate to the value of their product. If companies cannot achieve that higher benefit, it may not be viable to remain on the PL and they may elect to withdraw from the PL. |