



Australian Government

Department of Health and Aged Care

Consultation Paper 8a - Gifts, benefits and discounts reporting requirement

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: Prescribed List (PL) gifts, benefits and discounts reporting requirements. 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, private hospitals and private health insurers.

Respondents by type

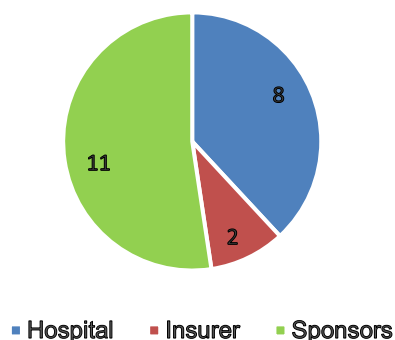


Figure 1: Number and type of respondents.

Key feedback

There was a mixed reaction to this measure. Some stakeholders supported the measure, while others opposed it. The key feedback that was received included:

- If this measure was currently in place, most respondents stated they would have little to no gifts, benefits and discounts to report having received during the last financial year.
- One suggestion was that instead of implementing this as a legislative requirement, the department could conduct a targeted, time limited audit to determine the size and shape of the problem to be solved. Additionally, the penalties associated with this measure should only be determined once the problem has been identified.
- Some sponsors supported this measure, and confirmed that they don't provide any gifts, benefits and discounts claiming that providing discounted products erodes the market.
- The reporting process might become more challenging where sponsors engage distributors to facilitate the supply of devices.

Key concerns

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

- The main concern from stakeholders was the extra regulatory burden and administrative costs that would be a result of maintaining the proposed register.
- A majority of stakeholders raised concerns that the proposal did not have a strong evidence base to outline the policy problem that was to be solved.
- Stakeholders were concerned with the inclusion of 'discounts' in the register and whether this would include 'rebates'.
- Confidentiality was a major concern, as details of contracts and arrangements between hospitals and sponsors for the provision of devices was commercially sensitive. In addition, there were concerns about the publication of details in the reports.

The details of the key issues raised by stakeholders during the consultation are listed in **Table 1**. The feedback received in response to the 12 questions in the consultation paper can be found in **Table 2**.

Table 1: Key feedback and concerns about the proposed measures for the Prescribed List gifts, benefits and discounts reporting requirements.

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

Issue	Stakeholder feedback
<p>Excessive Regulatory burden and administrative cost</p>	<p>Most stakeholders are concerned about the excessive regulatory burden and administrative costs for maintaining the register.</p> <p>Stakeholders feel the current proposal will require considerable resources (time and personnel) and hence could further increase the cost of delivering medical technology to Australian patients. They also have questions about the funding mechanism required to undertake this reporting.</p> <p>Many feel that the reporting will be very difficult and, in some cases, impossible due to the variety of supply arrangements and uses in hospitals that may breach patient privacy. Collating such data will be difficult, especially across large organisations where there are multiple departments offering different services.</p> <p>Insurers believe it is appropriate for all value transfers to be recorded and reported by both hospitals and device sponsors to the department to facilitate cross referencing and validation.</p>
<p>Use of the product</p>	<p>Sponsors are unlikely to know whether the gift, benefit, or discount was applicable to a privately insured patient, a self-funded patient, or a patient funded by third-party payers such as workers' compensation or compulsory third-party motor vehicle insurance providers.</p> <p>Self-funded patients, Veterans Affairs and Workers compensation are also treated in private facilities and may be subject to different commercial arrangements at the request of state government or individual facilities. This would create anomalies which would need to be accounted for in the reporting data.</p> <p>There will be further issues if this is applied to private cases in public hospitals, as suppliers will often not know whether the product is supplied for a public or private patient.</p>
<p>Confidentiality issues</p>	<p>Stakeholders had concerns over the publication of these registers/reports as they may contain information that is commercially sensitive (procurement contracts). Commercial arrangements between sponsors and hospitals include highly sensitive information, with stakeholders stating that the proposed reporting requirements conflict with the confidential nature of the relationships between sponsors and hospitals as private entities.</p> <p>The consultation notes that for transparency purposes, and when appropriate, the department may publish a summary of</p>

Issue	Stakeholder feedback
	<p>annual reports. Stakeholders express concern over the publication of reports that may contain information that is commercial in confidence.</p> <p>Stakeholders also requested that there be reasonable protection against Freedom of Information requests for this information.</p>
Clarity around the scope	<p>Stakeholders requested more clarity about the scope of what this is trying to achieve, and particularly the new inclusion of 'discounts' in the register which has not previously been mentioned. A few stakeholders wanted to know if 'rebates' were to be included in the reporting.</p> <p>Stakeholders were also interested in knowing how the department intends on using this information once it is received and would not like it to be shared outside of the department to any other entity.</p> <p>Most of the respondents stated that if this proposal was already in place, for the last financial year, they would have very few gifts, benefits or discounts to report.</p> <p>Insurers did mention that there are several ways in which sponsors and hospitals co-operate to provide financial incentives etc, such as cash rebates and global price fixing.</p>
Questions around rebates and other forms of discounts	<p>A few stakeholders were interested to know if rebates are also included in the definition of discounts, as discounts are a deduction in the purchasing price of the product, while rebates are a portion of the total purchase amount that is returned or refunded after the purchase has been made.</p> <p>Also, sometimes items are offered to hospitals when the product is nearing an expiry date with a goal of minimising wastage in the health system, so the question is will that also be considered in the register.</p>
Sponsors and distributors	<p>Sponsors often engage distributors to facilitate the supply of products. This proposed measure would result in a duplicative reporting process, with both sponsors and distributors potentially being required to report on the same transactions, leading to inefficiency and redundancy.</p> <p>The consultation proposes that the sponsor would have a legal reporting obligation. Where the sponsor has a third-party distributor for the supply of the medical device, they may not have the oversight of the data to report. The sponsor also does not have visibility of which items on the PL are ultimately claimed by hospitals.</p>
Penalties	<p>Stakeholders feel that penalties for such a measure are unwarranted as there could be many reasons for inadvertently providing inaccurate information. Additionally, the department should first determine the scope and scale of the issue before trying to implement penalties.</p>

Table 2: Key feedback from the questions proposed in the consultation paper for the proposed measure for the Prescribed List gifts, benefits and discounts reporting requirements.

Consultation Question	Stakeholder Response
1. Do you have any current reporting mechanism for receipt of gifts, benefits or discounts?	Most stakeholders stated that they do not currently have any system in place that would record gifts, benefits and discounts. Any mechanism to record these would need to be created. Some organisations did record rebates or samples that were provided to hospitals as part of education or training.
2. Are there any specific implications for your organisation if this measure includes reporting of discounted items?	<p>Most respondents stated that they did not give or receive gifts, benefits, or discounted PL devices, while others said it would increase the administrative burden and costs. Some stakeholders were concerned at how any crude data received may be misinterpreted, with some data being recorded that looks like it was free or discounted, but it was just recorded in a way that negated any system limitations or was due to wastage.</p> <p>Identifying which discounts or PL items should be reported may also be difficult due to dealings with self-funded patients, Veterans Affairs and Workers Compensation patients being treated in private hospitals.</p>
3. If this proposal was currently in place, approximately how many PL listed items would your organisation need to report on for the last financial year for: <ul style="list-style-type: none"> a. Gifts b. Benefits c. Discounts 	Most respondents reported that if they were required to report any gifts, benefits and discounts for the last financial year, they would not have any to report. Other stakeholders suggested that with the total number of transactions their organisation is involved in, combined with the large number of items on the PL, it would take some significant resources to extract this data, and would result in a large amount of work for the department to analyse.
4. What safeguards or assurances would you like to see addressed when this measure is implemented?	<p>The main concern stakeholders had was regarding the confidentiality of any data that was provided. At a minimum, the data should not be shared outside of the department and should be protected from Freedom of Information requests.</p> <p>Some stakeholders would like to see a system where data on gifts, benefits and discounts that was reported could be collated with data from the receiving party to check for the accuracy of reporting.</p>

Consultation Question	Stakeholder Response
	Any regulatory changes made because of the data, should be subject to extensive consultation with industry to ensure that it doesn't risk the sustainability of private hospitals, medical device companies or create out of pocket costs for consumers.
5. Are there any confidentiality limitations on the use of information proposed to be reported on?	<p>Stakeholders were mixed on their responses for this question. Some would like to know immediately if any PL item was provided as a gift, benefit or discount and they would encourage this information to be made publicly available, while other stakeholders believed that any information provided should not be shared or used for other purposes.</p> <p>Purchasing contracts made between sponsors and health care providers can be quite sensitive in nature and there is the potential for the identification of patients through data matching when small numbers are involved.</p>
6. Do you see any positive implications for this measure?	<p>Some stakeholders stated that this measure will help maintain the integrity of the PL pricing by providing a fairer and more competitive private healthcare system, while providing a benefit for smaller businesses and help reduce unethical behaviour. While transparency in dealings may provide useful and informative data to stakeholders, if this information was taken out of context, this may result in incorrect conclusions about commercial arrangements.</p> <p>Other stakeholders disagreed and couldn't see how this measure would provide any positive implications.</p>
7. What are the advantages and/or disadvantages for your stakeholder group maintaining this register?	<p>Some disadvantages include that this adds an additional layer of administrative burden and reporting. The disadvantage of sponsors maintaining this register is that in many cases the sponsor is not the actual supplier of the device – as this is often undertaken by the distributor. It can also be difficult for the sponsor to know how the device is being used and if it is being supplied for a privately insured patient.</p> <p>With hospitals facing increasing operating costs pressure, it would be unreasonable to add this extra regulatory burden onto hospitals. Any gifts, benefits or discounts provided to hospitals are not of the magnitude that greatly affects their profitability. Any reduction of such benefits would only further affect their sustainability and may cause greater volatility in the private sector.</p>

Consultation Question	Stakeholder Response
<p>8. Could this measure negatively impact negotiations between your stakeholder group and another? Please explain.</p>	<p>Some stakeholders believe that this measure may negatively impact negotiations. If confidentiality was not maintained or if the data was analysed out of context and the reason for the discount was not fully known, this could lead to incorrect conclusions which may impact negotiations.</p> <p>Other stakeholders stated that they believe that this measure would benefit smaller enterprises and the private healthcare system.</p>
<p>9. Are there any other matters the department should consider when finalising this measure?</p>	<p>Stakeholders suggested that:</p> <ul style="list-style-type: none"> • Where products are sold via a distributor, sponsors may require more time to access the data. • Not all variables and potential scenarios that need to be considered related to the register may have been appropriately considered. • A more targeted approach should be undertaken so that this measure does not turn into a burden on hospitals and sponsors. • There is very little benefit for patients, and this measure does not contribute to the sustainability of the private health care sector.
<p>10. Would it be easier to report all items that were gifts, free or discounted, or should there be a threshold, such as the item or discount being below certain amount or discounted by a certain percentage?</p> <p>a. If you believe a discount threshold is the better option, what amount or percentage do you think the threshold should be?</p>	<p>There was a mixed response to this question. Some stakeholders believed that some sort of threshold would be a sensible idea, while others believed that creating a threshold may potentially make the burden higher by having to identify what devices were relevant to be reported whilst excluding others. Other stakeholders stated that companies shouldn't be giving away PL items for free, and therefore all gifted items should be reported.</p>
<p>11. Can you please give us your opinion on which stakeholder group should be responsible for the register and reporting, and the advantages and disadvantages for each group. Should both sponsors and hospital report?</p>	<p>Most of the responses indicated that sponsors would be the best stakeholder group to report and maintain a gift and discount register, while others stated that hospitals should keep the register. Two stated that both sponsors and hospitals should be required to maintain a register so that it could be compared.</p> <p>While it was suggested that sponsors were the best stakeholder group to maintain the gifts, benefits and discounts register, it was pointed out that sponsors alone may</p>

Consultation Question	Stakeholder Response
	not have the necessary information to be able to report these details, particularly if a distributor was involved. Sponsors were not aware of what distributors did in relation to gifts, benefits and discounts for hospitals and clinicians, nor would they be able to confirm that a particular device was used for a private patient.
12. What other items do you consider could be included in the register?	While some stakeholders stated that no other items should be included in the register, others stated that all incentives should be included, such as packaging and bundling arrangements, rebates, tech credits and company dollars and preferred supplier agreements.