

## Summary of comments re: moving all existing and future Special Pricing Arrangement deeds of agreement to monthly invoicing

Consideration for Implementation	Improvement on current delivery	Cash flow issues	Reconciliation and accuracy of data/ invoices	Issues with proposed deed
<ul style="list-style-type: none"> <li>Confirmation that the monthly invoicing arrangement replaces the direct payment to manufacturer arrangement initially contemplated by the Department.</li> <li>Lack of detail in the implementation process and timeframe, in particular the new PBS claims data feed “secure channel”. Changes must be implemented with adequate lead time and appropriate testing and validation of new methods.</li> <li>A pilot period may be necessary and, if not, an implementation period that has a defined time point for reviewing the changes, assessing any unintended consequences and adjusting/improving the processes as needed.</li> <li>The implementation timeline proposed by Department seems ambitious, particularly given the proposed changes haven’t been tested/validated or piloted yet.</li> </ul>	<ul style="list-style-type: none"> <li>Note the movement to monthly invoicing would be an improvement on current delivery. Noting that some invoices are currently sent up 4 quarters at once.</li> <li>Ensuring invoices are sent to at least two responsible persons to ensure no delay at the sponsor’s end.</li> <li>Increased administrative cost with reviewing and paying all SPA rebates on a monthly basis compared with the current staggered quarterly (or longer) processing period.</li> <li>There should be no fee/s associated with the changes to the monthly invoicing.</li> <li>Health to confirm that interest payments will not be applied in future Deeds if monthly invoicing is introduced as there will no longer be a lag in repayment.</li> </ul>	<ul style="list-style-type: none"> <li>Wholesaler credit terms could result in a cash flow issue (e.g. wholesaler terms of 90 days). Sponsors will be out of pocket.</li> <li>Quarterly invoice billing provides reasonable insight into caps and accrual accuracy.</li> <li>Extended payment terms must be applied to invoices for a transitional period of monthly rebate payments to allow for cash-flow alignment.</li> <li>Propose a 6-month transition period once an effective date has been announced for companies to allow for cashflow management.</li> </ul>	<ul style="list-style-type: none"> <li>Aligned with due diligence practices, sponsor companies compare invoiced items to Medicare items (generally 2-3 months) processed. Need commitment to shorten lag times on Medicare data with a move to monthly invoicing.</li> <li>Additional transparency into the tracking of deeds is essential as there is currently no ability to track Deed spend which materially impacts the ability to manage associated rebate payments.</li> <li>Rebate calculations must accurately reflect and align to the supply of a medicine, not a subsidy payment. Processing data is not supply data. This is of particular concern with oncology products under EFC arrangements with known vial sharing.</li> <li>There is some concern on the accuracy of data to be issued by the Department to provide timely, monthly generation of invoices.</li> <li>The basis of rebate calculations must be supported by sufficient data granularity to enable accurate reconciliation of rebate payments and PBS activity.</li> <li>The supporting data be provided in Excel so that it is possible for sponsor companies to easily verify the accuracy and conduct additional analyses as needed.</li> <li>The requirements of pharmacies, particularly those within hospitals, to close and lodge their claims in line with the legislated requirements need to be enforced to ensure the reliability of reconciling rebates to processed prescription data.</li> <li>Seek confirmation that there will be no change to how expenditure cap rebates will be calculated or invoiced.</li> <li>Where there are several PBS restrictions under one PBS item code, that PBS authority code level data be shared with the Sponsor on a routine basis. This data is currently only provided as required for proportional rebate determination but could provide valuable insight into drug utilisation for Sponsor companies.</li> </ul>	<ul style="list-style-type: none"> <li>Concerns with the amendments to the definition of “Processed data” and the deletion of “Usage data”. Need to clarify this to ensure the same type of data are used to reconcile errors or changes from previous months.</li> <li>Intent to issue a single invoice across all of a company’s deeds should be expressly provided for in clause 4.1 to ensure appropriate identification of amount payable under each deed.</li> <li>Clause 7.2 in the proposed deed must reflect that any change to payment arrangements should be considered in negotiation between parties and facilitate collaboration. This clause lacks details.</li> <li>Clause 4.4 - Additional information has been deleted, and it is a concern that there does not seem to be any provision for providing additional data/information, particularly in the context of a disagreement over the invoice amount. This is related to the timeliness, quality, accuracy and accessibility of supporting information.</li> <li>A dispute resolution mechanism will need to be formalised to ensure there is a process to resolve any possible disputes with discrepancy in the data and invoicing.</li> <li>Include a provision for agreement by both parties of any amendments before implementation of New Subsidy Payment Arrangements (rather than simply notice of the amendments).</li> <li>Clarification that any new subsidy payment arrangement would not result in a change to the listed price or effective price of a drug or result in the cost to the company of supplying the drug being higher than if the amendment were not made.</li> </ul>