



Australian Government
Department of Health

PBS PRICING FORUM

DECEMBER 2018



Statutory Price Reductions and Ministerial Discretion

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OVERVIEW

- Changes to the National Health Act that have occurred in 2018 and what they mean for the prices of medicines on the Pharmaceutical Benefits Scheme (PBS).
- Starting with: a pricing refresher discussing F1, F2 and the Combination Drugs List.
- Moving to: (1) anniversary reductions; (2) new presentation exemptions; (3) sliding scale first new brand reductions.
- Finishing with: questions.



F1/F2, FIRST NEW BRAND AND 25%

Formulary or New Brand	Brand/ Drug	MOA (Manner of Administration)	What happens?	Then?
F1	ABCOriginal	Oral	25% SPR	F2 – subject to price disclosure
New	ABCGeneric	Oral	Must list at 25% lower price	F2 – subject to price disclosure
F1	ABCOriginal	Injection	No SPR until new brand with same MOA and bioequivalent /biosimilar	F2 – must report for price disclosure but no reduction until bioequivalent brand lists or >10% discounting



FIRST NEW BRAND, 25% AND CDL

Formulary or New Brand	Brand/ Drug	MOA (Manner of Administration)	What happens?
F1	ABCOriginal (\$10)	Oral	25% = \$7.50. Drug moves to F2 and PD applies.
New	ABCGeneric	Oral	List price = \$7.50. F2 and PD applies to single ingredient drug.
CDL	ABCOriginal (\$10) & XYZOriginal (\$5)	Oral	Drug combination remains in CDL. ABC - 25% = \$7.50. XYZ = \$5. Total price = \$12.50



F1/F2/FIRST NEW CDL BRAND AND 25%

Formulary or New Brand	Brand/ Drug	MOA (Manner of Administration)	What happens?
CDL	ABCOriginal (\$7.50) & XYZOriginal (\$5.00)	Oral	XYZOriginal - 25% = \$3.75. No further reduction to ABCOriginal. Entire CD moves to F2 and PD applies. New price = \$11.25.
New CD	ABCGeneric & XYZGeneric	Oral	List price = \$11.25. In F2 and PD applies.



F1 ANNIVERSARY REDUCTIONS - 2018

How many years has the <i>drug</i> been on F1?	Reduction that applied in 2018
5 years but less than 10 years	5% Applied on 1 April 2018
10 years but less than 15 years	10% ("catch-up") Applied on 1 June 2018
15 years or more	14.5% ("catch-up" of 10%+5%) Applied on 1 June 2018



MINISTERIAL DISCRETION - TWO STEP PROCESS

Step 1: Decision by Minister or delegate to exercise discretion

- If Yes – Go to Step 2.
- If No – reduction occurs by operation of the Act.
- Before the final decision is made, an indicative decision will be communicated and you have the opportunity to respond.

Step 2: Decision by Minister or delegate on the reduction that applies

- A further exercise of discretion will be made as to whether a full or partial waiver is applied.
- Before the final decision is made, an indicative decision will be communicated and you have the opportunity to respond.



NEW PRESENTATIONS

Threshold questions:

1. Is the Sponsor bringing forward the new pharmaceutical item (PI) the same Sponsor that has the existing PI on the PBS?
 - Yes (go to 2)/ No (first new brand reduction applies).

2. Is the new PI a new presentation?
 - Yes (go to 3)/ No (first new brand reduction applies).



NEW PRESENTATIONS

Threshold questions:

3. How long has the existing PI been on the PBS?
 - 5 years or less = exemption from the first new brand reduction. Will remain exempt as there is no exercise of discretion that expires.
 - Between 5 and 10 years = Ministerial discretion can be requested. Will remain exempt until the 10 year anniversary, when in effect the discretion “expires”.
 - 10 years or more = first new brand reduction applies.



NEW PRESENTATION EXEMPTION

New brand is (a) brought to the PBS by the same Sponsor and is (b) a new presentation	What happens?
Within 5 years of the original PI listing on the PBS	No reduction. Will remain in F1 until there is a first new brand that is not a new presentation.
Between 5 years and 10 years of the original PI listing on the PBS	Discretion to exempt from first new brand reduction. Lapses at 10 years. Once the discretion has lapsed it will trigger an SPR and move to F2.
10 years plus of the original PI listing on the PBS	Automatically takes the reduction for a first new brand.



NEW PRESENTATIONS

- Encouraging innovation that contributes to better outcomes for patients.
- Does not intend to incentivise new formulations of existing drugs which will simply delay or reduce brand competition.
- Examples of ‘new presentations’ include:
 - Auto injector (new) vs vial and a syringe (old)
 - Effervescent tablet (new) vs capsule (old)



25% FIRST NEW BRAND 'SLIDING SCALE'

Reduction off AEMP since 1 January 2016	Reduction that applies to both the existing and new brand	Examples
40% or more	0%	Drug has been subject to reference pricing which has reduced the price by 60%, therefore it will have no further reductions. No exercise of discretion is required.
>15% and <40%	Up to 24.99%	<p>Price on 1/1/2016 = \$100</p> <p>Drug has been reduced by 14.5% in anniversary price reductions and a subsequent 15% reference pricing reduction resulting in a current price of \$72.68</p> <p>The drug will be reduced to 60% of the 1 January 2016 price, which is \$60 (17% reduction from current price) unless Ministerial discretion is exercised.</p>
<15%	Up to 25%	Drug has taken 10% due to an anniversary price reduction. It will take 25% unless the Minister exercises discretion to apply a lower percentage.



25% FIRST NEW BRAND REDUCTION

- Even if your drug has been reduced by 40% or more the Minister may still accept an administrative lower price offer.



OTHER QUESTIONS

- What happens when a first new brand reduction would coincides with an anniversary reduction?
- Can statutory price reductions be altered retrospectively?
- What is the impact of caretaker conventions?



PBS PRICE CHANGES SECTION

- Any other questions
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New PBS payment arrangements for medicines with special pricing arrangements

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Overview - the Budget measure

- 2018-19 Budget measure - Improving Access to Medicines – additional funding for new medicines and improved payment administration
- Government to pay a 'net' price for medicines (F1 formulary) with special pricing arrangements, rather than paying the higher published price and receiving rebates from manufacturers
- Will reduce PBS revenue and expenditure (\$5.4 billion estimated)
- First 12 months from 1 July 2019 will involve a smaller sub-set of the medicines with special pricing arrangements being included in new payment arrangements



Purpose

The measure seeks to address issues raised by the Independent Review of Pharmacy Remuneration and Regulation by:

- Increasing consumer access to high cost medicines
- Addressing cash flow concerns from pharmacists and wholesalers
- Addressing the financial risks associated with the payment of large rebates to the Australian Government for some high cost medicines



Activity to date

- Late 2017 – discussions commence on potential new arrangements
- Early 2018 – discussions expand to include specific companies and other parts of the supply chain (wholesalers, compounders, pharmacy etc)
- March 2018 – large-scale stakeholder forum, focusing on reconciliation and payment
- May 2018 – Budget measure announced
- May – November 2018:
 - Technical working groups held, providing advice to Project Advisory Board – multiple meetings with a range of stakeholders
 - Several Project Advisory Board meetings
 - Significant work to develop systems specifications, legislation, administrator role and other architecture and processes



New payment arrangements – describing the activities

- As the medicine passes through the supply chain, existing arrangements for invoicing (at the public price) and payment are expected to continue
- Terms of trade are matters for the parties concerned, but may be subject to re-negotiation
- DHS will make two payments – one to the pharmacy comprising the sum of fees and mark-ups, and one to a manufacturer at the effective price of a medicine
- As Government will have paid for the medicine cost in full, any outstanding invoice will need to be dealt with – through a rebate, payment, credit (etc). The arrangements for this will be matters for parties to negotiate



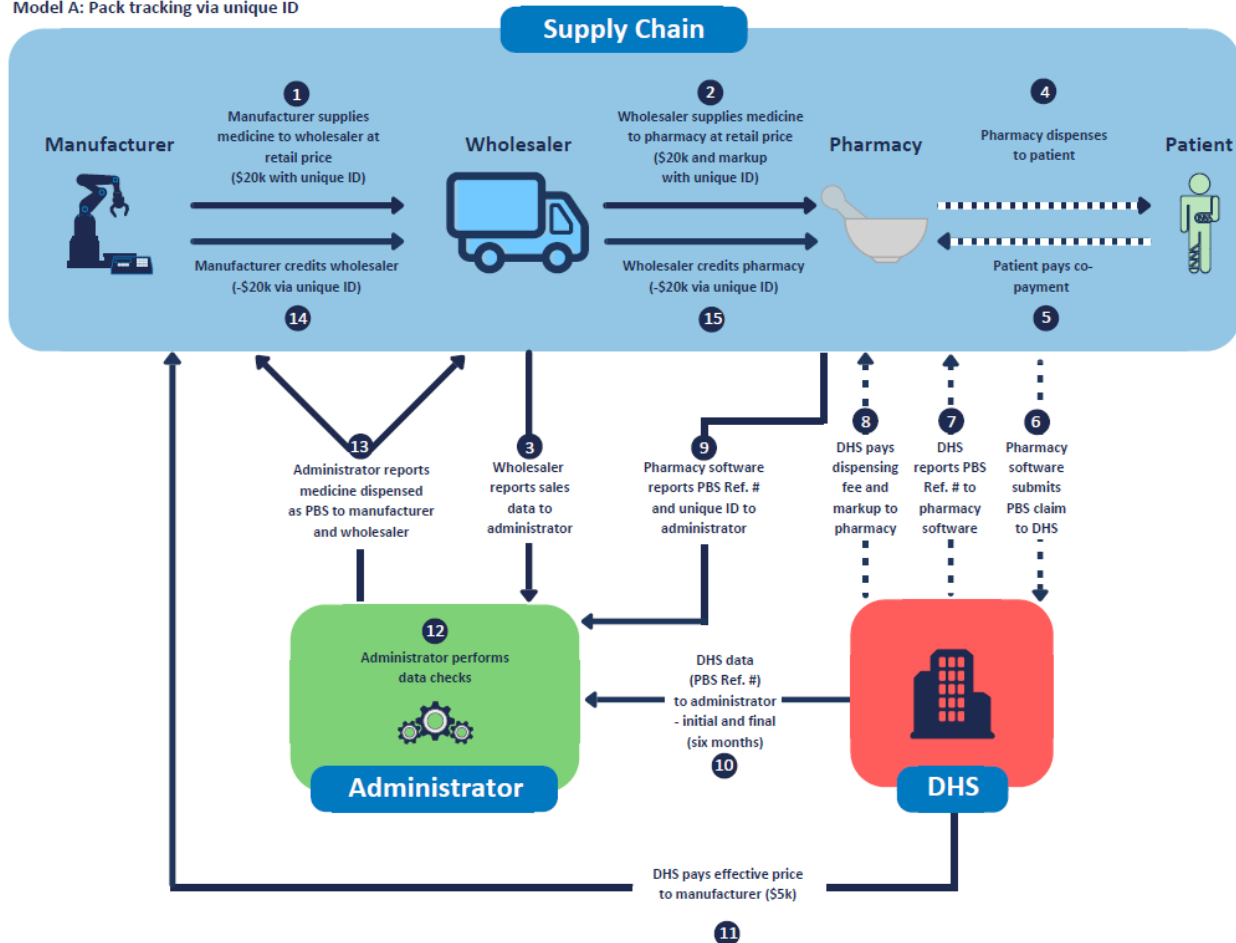
New payment arrangements – describing the activities

- Dispense and Department of Human Services systems will pass information to an administrator, ensuring data is available for reconciliation *if needed*
- Importantly, systems changes are being developed and deployed to enable *automatic* transmission of payment requests. This is expected to extend to all systems, including your own, enabling payment to be automated
- The systems changes are being designed to enable any approach to reconciliation or payment to operate



Models for reconciliation and payment

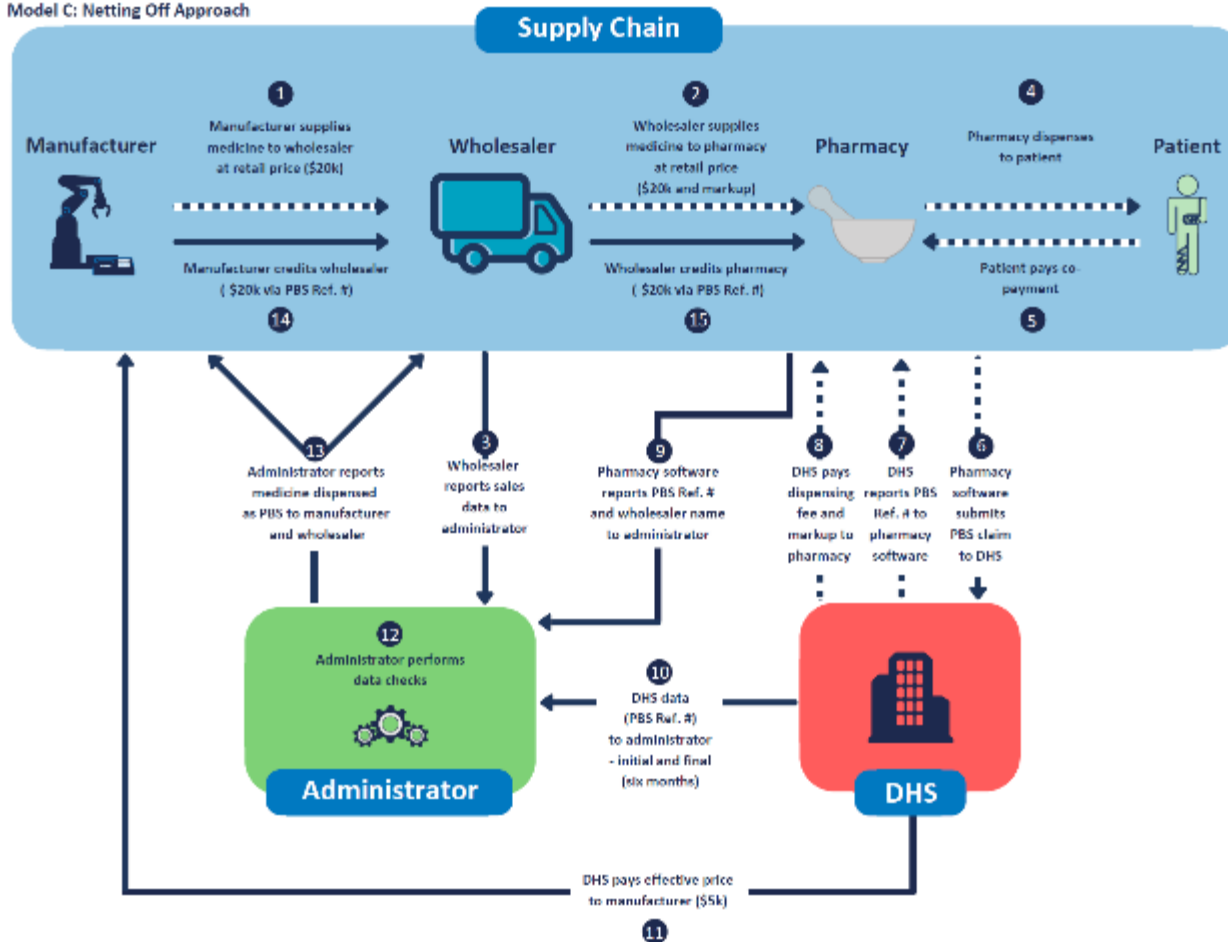
Model A: Pack tracking via unique ID





Models for reconciliation and payment

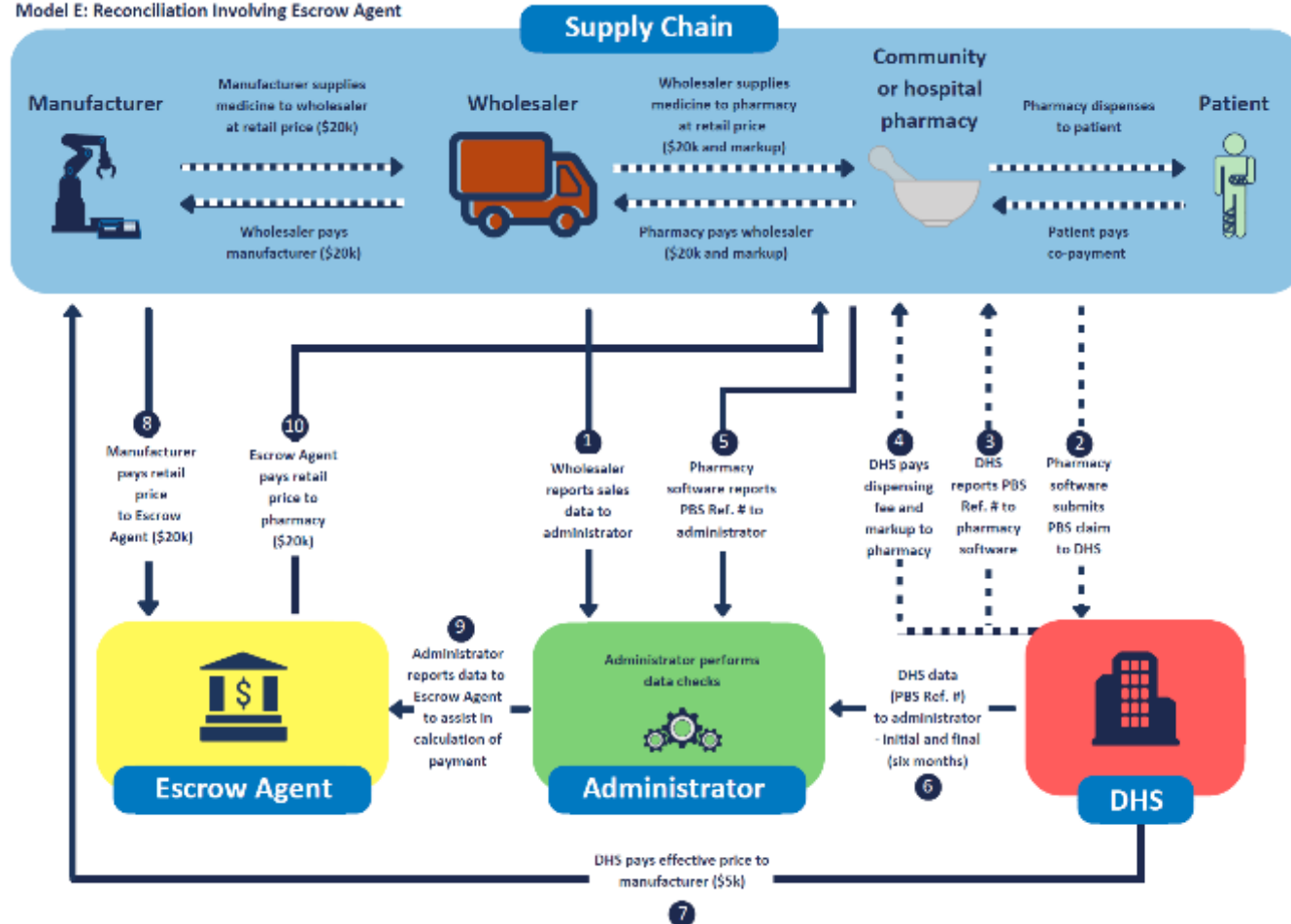
Model C: Netting Off Approach





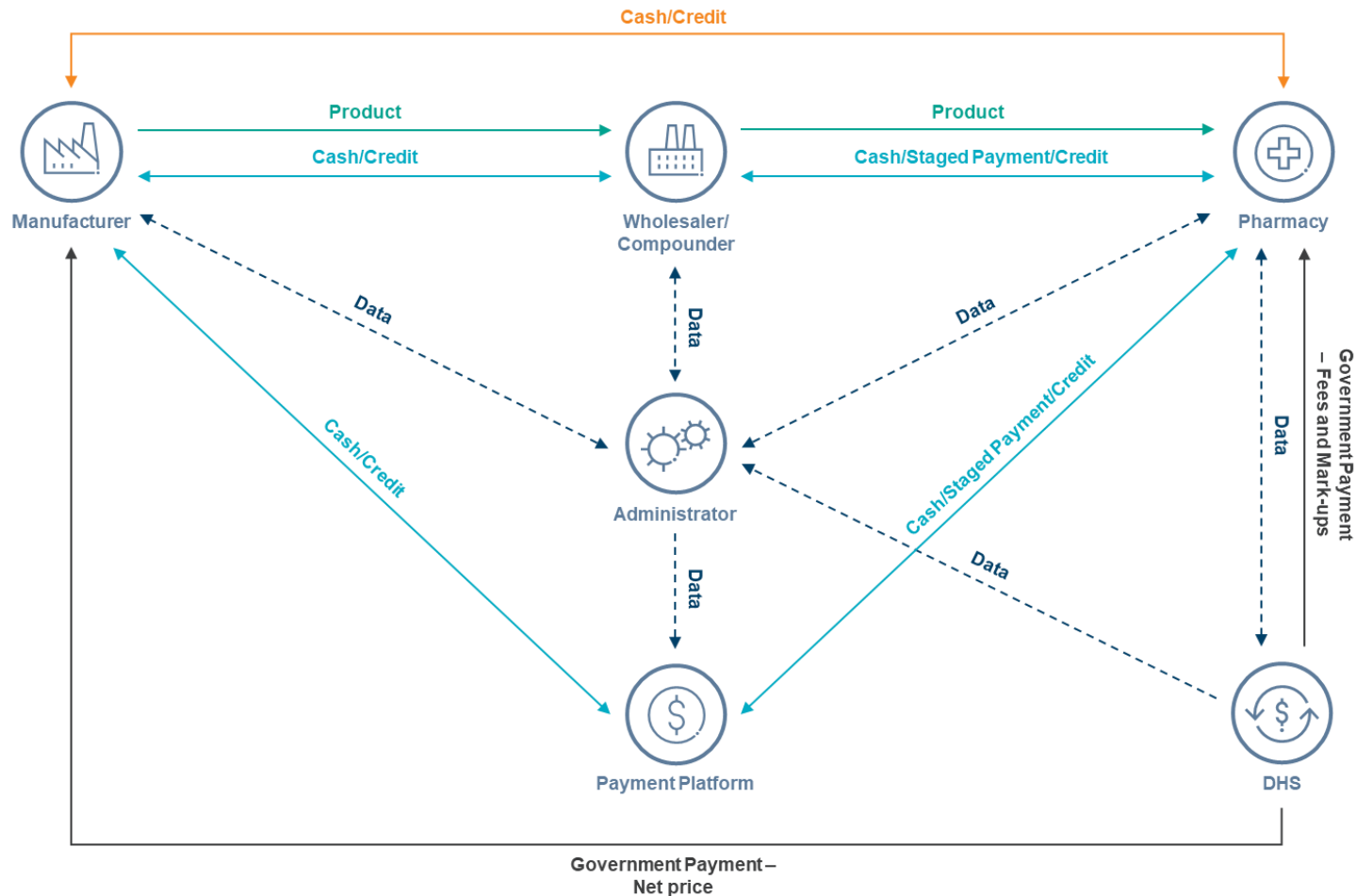
Models for reconciliation and payment

Model E: Reconciliation Involving Escrow Agent





Models for reconciliation and payment – a combined view





Models for reconciliation and payment – a combined view

What is used to reconcile	Method(s) of payment	How participants may choose to pay or seek payment
PBS Reference Number + UID	Full cash payment under the terms of trade	Through the supply chain (e.g. Manufacturers → Wholesaler, Wholesaler → Pharmacy)
PBS Reference Number (no UID)	Staged cash payment under terms of trade	Direct between two parties (e.g. Manufacturer → Pharmacy)
	Credit payment under the terms of trade	Through a Third-Party (e.g. Payment Platform)



Role of administrator

- Centralise data, enabling common view across parties
- Expected to give net view of credits/payments, with functionality to give different breakdowns, such as:
 - Amount payable by medicine by day, week, month, year
 - Amount payable by pharmacy (private sales)
 - Total payable vs paid (if functionality/connectivity allows)
- Provide a back-up to automated processes; i.e. it is not expected administrator data will necessarily be accessed by each business daily
- Will not be funded to take over business functions i.e. will not send credit or cash payment requests on your behalf
- Note: for your IT systems people, we have an expected language to use when talking to administrator systems (JSON)



What does this mean for a manufacturer with a F1 medicine that has a SPA or a medicine that may have a SPA?

- A range of implications have been discussed with some sponsors and with peak bodies – for example:
 - Timing of inclusion of medicines – some are slated for 2020 (including EFC medicines), and some are not aimed for inclusion due to the smaller scale of initial roll-out
 - GST
 - Revenue recognition
 - Systems changes to accommodate reporting and payment changes
 - Training in administrator system/s (once an administrator is brought in)
 - Reconciliation and payment approaches and any resulting negotiation
- We cannot formally advise on some of these matters, but we recommend you seek information from your peak body as appropriate



What does this mean for a manufacturer with a F1 medicine that has a SPA or a medicine that may have a SPA?

- Department will initiate contact with companies (January onwards) about involving your medicine in new arrangements from 1 July 2019 – this would require a change to an existing Deed
- For those companies not requested to be involved in the first phase, we are happy to discuss the measure and its implications
- We are updating our website with information as we progress in implementation
- We also continue to have regular discussions with peak bodies
- Take-home message: keep in touch with your peak body, and with the Department via the website or directly (pbs.subsidy@health.gov.au)



Questions

Contacts

Contacting the PBS Subsidy Taskforce

- Email: pbs.subsidy@health.gov.au
- Telephone (David Nott): (02) 6289 7903

Contacting the Pricing team

- General pricing: pbspricing@health.gov.au
- Price Disclosure: pricedisclosure@health.gov.au / (02) 6289 2303
- PBS Statutory Price Reductions: PBSSPR@health.gov.au
- Price Increases: PBSPriceIncreases@health.gov.au