



## CARVE-OUTS

February 2016

### Introduction

The Government has introduced the *Australian Government Guide to Regulation*, which outlines the process for developing a regulatory proposal, including a Regulation Impact Statement (RIS).

The *Guide to Regulation* describes some special cases in the RIS process, one of which relates to carve-outs. A carve-out is a standing agreement between the Office of Best Practice Regulation (OBPR) and a department, removing the need for a preliminary assessment to be sent to OBPR for certain types of regulatory change.

A carve-out can be used when anticipated regulatory changes are minor or machinery in nature or likely to occur on a regular basis. A change is minor if it does not substantially alter the existing regulatory arrangements for businesses, community organisations or individuals. Machinery changes are changes that are consequential to, and required as a result of, a substantive regulatory decision, and for which there is limited discretion available to the decision maker.

Carve-outs cannot be applied to proposals where Cabinet is the decision maker.

This guidance note gives further information about carve-outs, explains how to obtain one, and lists the carve-outs currently in place.

If a carve-out is granted, you are still required to quantify the regulatory costs imposed on businesses, community organisations and individuals, along with associated cost offsets, using the Regulatory Burden Measurement (RBM) framework. The regulatory costs and offsets must be reported to portfolio Regulatory Reform Units.

### Objectives

Carve-outs aim to improve the efficiency of the Preliminary Assessment process by reducing the workload for both parties (the department and OBPR) while ensuring consistent advice from OBPR.

### Risks

Key risks include inappropriate carving out of regulatory proposals and misinterpretation of the standing agreement (for example, using the carve-out to cover regulatory proposals that have a greater impact than the proposal was originally intended for). To manage this risk, the agreement must:

- be phrased succinctly and avoid ambiguity in the proposals to be carved out
- state that carve-outs are not an opportunity for broader departmental self-assessment
- be clear that you need to continue to consult OBPR on matters not covered by the carve-out, or where there is uncertainty about where the carve-out applies
- be subject to a periodic review.

Completed carve-outs are listed in Table 1 at the end of this guidance note.

## Criteria

A carve-out can be used for regulatory changes that occur on a regular basis and are minor or machinery in nature, but not for proposals where Cabinet is the decision maker. Potential carve-outs should take into account future expectations about relevant Preliminary Assessments sent to OBPR. If there is a low likelihood of receiving further Preliminary Assessments on a given topic, it may not be worth issuing a carve-out.

Possible categories of carve-outs include indexation, regular, routine administrative and machinery changes. The following examples are from Table 1 at the end of this guidance note.

### Indexation changes

Routine indexation changes use a well-established formula, such as:

- routine indexation of aged care subsidies in line with increases in the Consumer Price Index.

### Regular changes

Regular changes are those about which OBPR is consulted regularly and which are consistently assessed as minor or machinery in nature. OBPR is often consulted on instruments that regularly update information that is considered machinery. For example:

- the Australian Communications and Media Authority regularly contacts OBPR about variations in established licence area plans, factsheets for consumers and other issues.

### Routine administrative changes

Routine administrative changes follow a regular process that has been identified as minor or machinery. They are generally done in accordance with existing legislation and can often be approved by a departmental delegate. They do not require a RIS for further changes. These changes tend to involve legislative instruments, but where an Act is amended it would tend to affect only a schedule or a clause of the legislation. For example:

- the Department of Health regularly updates the listing and price of medicines available under the Pharmaceutical Benefits Scheme.

### Machinery changes

Machinery changes to legislation that do not constitute a new regulatory burden are appropriate for carving out. For example:

- The Attorney-General's Department is required to alter Substituted References Orders because they need to reflect changes contained in Administrative Arrangements Orders or changes in the titles of ministers or departments.

## Carve-out process

OBPR officers assess newly received Preliminary Assessments in order to identify suitable proposals to be carved out. They will inform you when they consider that a series of proposals should be carved out. However, it can be useful for you to recommend potential carve-outs.

The steps in the carve-out process are as follows:

1. You should review Preliminary Assessments previously sent to OBPR. Identify policy areas that meet the criteria for minor or machinery changes made by non-Cabinet decision makers. Consider the likelihood of future Preliminary Assessments arising in those areas.
2. Obtain Executive Level 2 (EL2) clearance for the proposal to carve-out. Email OBPR with a suggestion to consider the carving-out proposal.
3. OBPR will check the appropriateness of the proposed carve-outs.
4. If OBPR concurs, the office will send you a letter confirming that a carve-out has been granted and the proposals that it applies to.

## Approval

The carve-out can be approved between OBPR and the department at the EL2 level and will be periodically published in updates of this note.

## Further information

For further information on carve-outs, OBPR can be contacted on:

Email: [helpdesk-OBPR@pmc.gov.au](mailto:helpdesk-OBPR@pmc.gov.au)

Phone: 02 6271 6270

Table 1: Approved carve-outs at 5 February 2018

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Attorney-General's Department</b>	Amendments to Federal Court Rules of Court	Minor or machinery: Changes to Rules of Court are unlikely to have significant impacts on businesses, community organisations or individuals.	11644	
<b>Attorney-General's Department</b>	Substituted References Orders made under sections 19B and 19BA of the <i>Acts Interpretation Act 1901</i>	Machinery: The orders are altered to reflect changes in Administrative Arrangements Orders or changes in the titles of ministers or departments.	13423	
<b>Australian Communications and Media Authority</b>	Variations to established licence area plans, field trials of mobile jammers, factsheets for consumers and enforceable undertakings	Minor: Variations to individual licence area plans are unlikely to have a more than minor regulatory impact.	13301	While variations to individual licence area plans are minor changes, variations to the way licence area plans work and the creation of new licence area plans could have a significant regulatory impact, and OBPR should be contacted about the need for further regulatory analysis.

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Australian Fisheries Management Authority (AFMA)</b>	Setting total allowable catch (TAC), or total allowable effort (TAE) for a fishery; setting opening and closing dates for fishing season; setting fishing boundaries; directing that fishing not be engaged in sub-areas of a fishery; starting arrangements for a fishing season, such as Vessel Monitoring System start times and assembly areas; prescribing designated areas where operators can undertake gear trials in a fishery prior to the start of the fishing season; annually setting cost recovery levies; the continuation of a requirement to use a turtle or seal excluder device in a fishery; and setting undercatch and overcatch provisions in a fishery	Machinery: AFMA is required to make decisions under current regulatory settings and follow certain procedures when making those decisions.	14421	
<b>Australian Pesticides and Veterinary Medicines Authority</b>	The making of an existing maximum residue limit standard as a legislative instrument	Machinery.	14469	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Australian Public Service Commission</b>	Instruments that deal primarily with intra-governmental public sector employment matters	Minor or machinery.	13837	<p>The standing exemption applies to the following instruments: regulations made under the <i>Public Service Act 1999</i> (PS Act), directions issued by the Public Service Commissioner under the PS Act, directions issued by the Prime Minister under section 21 of the PS Act, rules about the classification of APS employees made under section 23 of the PS Act, determinations about remuneration and terms and conditions of employment issued under subsection 24(1) of the PS Act, determinations about remuneration and terms and conditions of employment issued under subsection 24 (3) of the PS Act, regulations made under the <i>Maternity Leave (Commonwealth Employees) Act 1973</i>, determinations made by the Remuneration Tribunal under the <i>Remuneration Tribunal Act 1973</i>, regulations made under the <i>Remuneration Tribunal Act 1973</i>, regulations made under the <i>Long Service Leave (Commonwealth Employees) Act 1976</i>, regulations made under the <i>Judicial and Statutory Officers (Remuneration and Allowance) Act 1984</i>, and regulations made under the <i>Remuneration and Allowance Act 1990</i>.</p>

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Civil Aviation Safety Authority (CASA)</b>	Foreign and Australian Airworthiness Directives	Machinery: CASA issues airworthiness directives to address unsafe conditions on aircraft and aeronautical equipment. The review of these directives does not require a RIS because it is an obligation of Australia under the Chicago Convention.	14507	
<b>CASA</b>	Amendments to CASR Part 61 to add additional aircraft for the purpose of pilot type ratings	Minor: These amendments do not substantially alter existing arrangements.	14507	
<b>CASA</b>	Amendments to Manuals of Standards (MOSs)	Minor or machinery: MOSs are referenced standards that are not regulatory in nature.	14507	
<b>CASA</b>	Advisory publications (e.g. CAAPs, ACs, information brochures) with no mandatory legislative effect	Minor: These documents are advisory and have no direct or significant indirect impact on businesses, community organisations or individuals.	14507	
<b>CASA</b>	Directions, approvals, permissions and exemptions	Minor or machinery: These instruments do not substantially alter existing arrangements, and their issue is required by the Act and regulations in the course of their administration by CASA.	14507	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Clean Energy Regulator (CER)</b>	Setting the Renewable Power Percentage and the Small-scale Technology Percentage under the <i>Renewable Energy (Electricity) Act 2000</i> in circumstances where the CER uses data derived from modelling of the electricity market by independent third parties.	The making of regulations to set the RPP and STP under the Act is a regular occurrence that takes into account the same considerations each time.	20056	When the default calculation or any other method of calculating the percentages is used, the CER should confirm with the OBPR that a RIS is not required to be prepared.
<b>Comcare</b>	Legislative Instrument to specify the rate of weekly interest deemed to accrue on the superannuation lump sum pursuant to section 21(5) of the <i>Safety, Rehabilitation and Compensation Act 1988</i> (SRC Act).	Machinery. Section 21(5) of the SRC Act requires the instrument to be issued annually. The instrument prescribes a routine update to an annually indexed statutory rate and is machinery in nature.	20920	
<b>Department of Agriculture and Water Resources</b>	Amendments to the <i>Fisheries Research and Development Corporation Regulations 1991</i> to enable the annual transfer of research and development funds to the Fisheries Research and Development Corporation (FRDC).	Minor or machinery: These amendments are made annually to specify the proportion of the annual fishing levy that is equivalent to the research and development component to enable it to be paid to the FRDC each financial year.	20522	
<b>Department of Agriculture and Water Resources</b>	Increases or decreases in agricultural levies where they relate to a levy's existing purpose.	Minor or machinery. Increases or decreases in agricultural levies within the scope of their existing purposes are a regular occurrence in response to changes in the level of industry needs.	22416	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<p><b>Department of Agriculture and Water Resources</b></p>	<p>Routine minor amendments to biosecurity goods determinations.</p>	<p>Minor or machinery: The determinations are typically amended two to three times a year.</p> <p>Changes generally amend existing alternative conditions, add new alternative conditions for certain goods requiring an import permit, and make minor technical amendments.</p>	<p>23368</p>	<p>Carve out applies to amendments to:</p> <p><i>Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016</i></p> <p><i>Biosecurity (Prohibited and Conditionally Non-prohibited Goods—Christmas Island) Determination 2016</i></p> <p><i>Biosecurity (Prohibited and Conditionally Non-prohibited Goods—Cocos (Keeling) Islands) Determination 2016</i></p> <p><i>Biosecurity (Prohibited and Conditionally Non-prohibited Goods—Norfolk Island) Determination 2016</i></p> <p><i>Biosecurity (Prohibited and Conditionally Non-prohibited Goods—Torres Strait) Determination 2016.</i></p> <p>Amendments must:</p> <ul style="list-style-type: none"> <li>be minor or technical amendments of the kind that have been previously made;</li> <li>not have more than a minor regulatory impact on industry; and</li> <li>be in line with the current biosecurity policy settings.</li> </ul>

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Department of Jobs and Small Business</b>	Self-insuring licence eligibility declarations made under section 100 of the <i>Safety, Rehabilitation and Compensation Act 1988</i> (SRC Act) for workers' compensation purposes.	Minor or machinery: These instruments allow eligible entities to join the Comcare scheme where they have applied to do so. The decision to issue the instrument is the routine application of Ministerial discretion as enabled by the Act.	23425	
<b>Department of Communications</b>	Exemptions under clause 9A and clause 21A of Schedule 4 to the <i>Broadcasting Services Act 1992</i>	Machinery.	15001	
<b>Department of Defence</b>	Determine which allowances paid under the <i>Defence Act 1903</i> are pay-related allowances for the purposes of subsection 11(1) of the <i>Military Rehabilitation and Compensation Act 2004</i> .	Minor or machinery: These instruments ensure continuity in compensation payments by ensuring that references to amounts that can be included in compensation payments remain current. They do not alter the existing formulae used for calculating the compensation payments. The determinations simply ensure that there is a current list of allowances that those formulae can draw from.	17489	The allowances that are mentioned in the determinations are part of the ordinary Australian Defence Force benefits. They are either tabled and subject to Parliamentary scrutiny (if made under section 58B <i>Defence Act 1903</i> ) or tabled after determination by the Defence Force Remuneration Tribunal (if made under section 58H <i>Defence Act 1903</i> ).

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Department of the Environment and Energy</b>	Minor changes or bug fixes to software tools accredited under the Nationwide House Energy Rating Scheme (NatHERS)	Minor: Minor changes or bug fixes to NatHERS-accredited software programs are unlikely to have significant impacts on businesses, community organisations or individuals.	21938	Carve-out applies to:  Software bug fixes: defined as a coding error fix to existing software to generate an energy rating that does not affect ratings.  Minor changes to software: defined as a coding error fix that may have a minor impact on NatHERS rating outcomes; or an enhancement/improvement to the existing software to generate or accurately calculate a NatHERS energy rating that may have a minor impact on rating outcomes.
<b>Department of Finance</b>	Certification of Parliamentary Precincts under the <i>Parliamentary Precincts Act 1988</i>	Minor: Regulations provide for the making of a certification by the minister that Commonwealth leased or owned land is a parliamentary precinct under the Act, and therefore the Speaker has certain powers and the Australian Federal Police has jurisdiction. This is intended to cover emergency situations in which Parliament House is unavailable for use.	13038	Minor impacts; land will be subject to Commonwealth lease arrangements.

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Department of Foreign Affairs and Trade</b>	Update the Diplomatic Privileges and Immunities (Indirect Tax Concession Scheme) Determination 2000, and the Consular Privileges and Immunities (Indirect Tax Concessions Scheme) Determination 2000 to reflect the countries currently registered to have access to immunities.	Non-regulatory: Updates to the determination occur 5-6 times annually and do not have regulatory impacts.	22459	Carve-out applies to countries that currently have access to diplomatic and or consular indirect tax concessions.
<b>Department of Health</b>	Dental Benefits Rules 2009	Indexation: Indexing the dental benefit in line with Medicare indexation (which is calculated using the WCI5). Indexation will occur annually.	11949	
<b>Department of Health</b>	Amendments to the Private Health Insurance (Complying Product) Rules. The purpose of this regulatory proposal is to reflect increases in the Nursing Home Type Patient contribution at public hospitals for privately insured patients in all states and territories and privately insured patients in private hospitals.	Indexation: The change is in line with the biannual indexation of Adult Age Pension Rates and Rent Assistance that occurs on 20 March and 20 September each year.	12116	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Department of Health</b>	Amendments to the Private Health Insurance (Complaints Levy) Rules 2007. The Complaints Levy is collected each year from private health insurers to support the work of the Private Health Insurance Ombudsman (PHIO). The amount to be levied from each insurer is calculated by applying insurers' annual membership data to a formula in the Private Health Insurance (Complaints Levy) Rules 2007. Collectively, these amounts must meet the PHIO Complaints Levy budget.	Minor: Minor amendments to the formula are sometimes necessary to address changes to the complaints levy budget to enable the budget to be met. The levy is spread across more than 30 insurers, so the impact on each insurer is minor.	12116	
<b>Department of Health</b>	Amendments to the Private Health Insurance (National Joint Replacement Register Levy) Rules. The National Joint Replacement Register (NJRR) Levy is imposed on each sponsor for joint replacement prostheses; the Levy funds the NJRR. The Private Health Insurance (NJRR) Rules contain the formula for calculating the levy, which sets the rate of the levy imposed on a sponsor on the prescribed levy census days.	Minor: To achieve cost recovery of administered funds for the budgeted costs, minor changes to the formula are occasionally necessary.	12116	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Department of Health</b>	Amendments to the Private Health Insurance (Prostheses) Rules	Routine administrative change: The Prostheses List contains prostheses and human tissue items and the benefit to be paid by private health insurers. Under the <i>Private Health Insurance Act 2007</i> , private health insurers are required to pay benefits for a range of prostheses that are provided as part of an episode of hospital treatment or hospital substitute treatment for which a patient has cover and for which a Medicare benefit is payable for the associated professional service. The Private Health Insurance (Prostheses) Rules are amended twice a year.	12116	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Department of Health</b>	The declaration of a quality assurance activity under Part VC of the <i>Health Insurance Act 1973</i> provides specific protection from civil proceedings (apart from those relating to the breach of the rules of procedural fairness) to health care professionals participating in the activity. The aim of providing this protection is to encourage health care professionals to fully participate in quality assurance activities. The department annually receives up to 20 applications for a declaration of a quality assurance activity each year, including new applications and renewals. Declarations expire after five years, and a new application must be submitted and assessed if cover is to continue.	Minor and machinery: The only requirement placed on organisations under the scheme that may incur a minor cost is the public interest requirement that de-identified research data is to be made publicly available. It is acceptable for such results to be published in a report or on a website. The costs involved in meeting this requirement are likely to be low. Previous advice from OBPR has considered qualified privilege applications to be machinery in nature.	12116	
<b>Department of Health</b>	Declaration under subsections 85(2) and 85(2AA) and 85(2A) of the <i>National Health Act 1953</i> to declare drugs listed on (including any applicable restrictions) or deleted from the Pharmaceutical Benefits Scheme (PBS)	Minor: The Schedule of Pharmaceutical Benefits and related information are available freely on the internet and are available to purchase in other formats (for example, CD-ROM or book). Businesses will only incur costs if they choose not to use the website and purchase the schedule in an alternative format. The cost to purchase the schedule is minimal. Changes are not expected to have a more than minor regulatory impact on individuals.	12116	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
Department of Health	Determination made pursuant to subsections 99ADB (4) and 99ADB (5) of the <i>National Health Act 1953</i>	Minor and machinery: These legislative instruments are produced three times per year to determine price disclosure related reductions of pharmaceutical items as a result of the Price Disclosure Policy.	12116	
Department of Health	Determination under paragraph 98C (1) (b) of the <i>National Health Act 1953</i> to determine conditions of payment for benefits supplied by approved pharmacists and medical practitioners	Minor: The Schedule of Pharmaceutical Benefits and related information are available freely on the internet and are available to purchase in other formats (for example, CD-ROM or book). Businesses will only incur costs if they choose not to use the website and purchase the schedule in an alternative format. The cost to purchase the schedule is minimal. Changes are not expected to have a more than minor regulatory impact on individuals.	12116	
Department of Health	Determination under section 84AF of the <i>National Health Act 1953</i> to list the responsible person and ABN for all brands of listed drugs on the PBS	Minor: The Schedule of Pharmaceutical Benefits and related information are available freely on the internet and are available to purchase in other formats (for example, CD-ROM or book). Businesses will only incur costs if they choose not to use the website and purchase the schedule in an alternative format. The cost to purchase the schedule is minimal. Changes are not expected to have a more than minor regulatory impact on individuals.	12116	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Department of Health</b>	Determination under section 85B of the <i>National Health Act 1953</i> to determine prices of PBS items or brands subject to a special patient contribution, therapeutic group premium or brand premium	Minor: The Schedule of Pharmaceutical Benefits and related information are available freely on the internet and are available to purchase in other formats (for example, CD-ROM or book). Businesses will only incur costs if they choose not to use the website and purchase the schedule in an alternative format. The cost to purchase the schedule is minimal. Changes are not expected to have a more than minor regulatory impact on individuals.	12116	
<b>Department of Health</b>	Determination under sections 93 and 93AA of the <i>National Health Act 1953</i> to determine PBS items available and maximum quantities thereof as emergency supply items for medical practitioners and nurse practitioners	Minor and machinery: The Schedule of Pharmaceutical Benefits and related information are available freely on the internet and are available to purchase in other formats (for example, CD-ROM or book). Businesses will only incur costs if they choose not to use the website and purchase the schedule in an alternative format. The cost to purchase the schedule is minimal. The determination amended as required, and the changes are machinery in nature. Changes are not expected to have a more than minor regulatory impact on individuals.	12116	
<b>Department of Health</b>	Determination under subsection 84BA(2) of the <i>National Health Act 1953</i> to provide for revised public hospital patient PBS co-payment amounts	Machinery: This update occurs annually.	12116	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
Department of Health	Determination under subsection 85A(1) and (2) and 88(1C) of the <i>National Health Act 1953</i> to determine the form, manner of administration, maximum quality and maximum number of repeats of those drugs and medicinal preparations which may be prescribed by authorised optometrists	Minor: The Schedule of Pharmaceutical Benefits and related information are available freely on the internet and are available to purchase in other formats (for example, CD-ROM or book). Businesses will only incur costs if they choose not to use the website and purchase the schedule in an alternative format. The cost to purchase the schedule is minimal. Changes are not expected to have a more than minor regulatory impact on individuals.	12116	
Department of Health	Determinations under section 85, 85A and 88 of the <i>National Health Act 1953</i> to determine form and strength, manner of administration, maximum quality, maximum number of repeats and brands of listed drugs on the PBS	Minor: The Schedule of Pharmaceutical Benefits and related information are available freely on the internet and are available to purchase in other formats (for example, CD-ROM or book). Businesses will only incur costs if they choose not to use the website and purchase the schedule in an alternative format. The cost to purchase the schedule is minimal. Changes are not expected to have a more than minor regulatory impact on individuals.	12116	
Department of Health	ETP National Health (Emergency Treatment Program) Special Arrangements Instrument 2010 (Special arrangement under Section 100 of the <i>National Health Act 1953</i> for the supply of methoxyflurane)	Machinery: Changes are unlikely to occur on a regular basis.	12116	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Department of Health</b>	Private Health Insurance (Benefit Requirements) Rules under item 3A of the table in section 333-20 of the <i>Private Health Insurance Act 2007</i>	Machinery: The purpose of the regulatory proposal is to reflect increases to the Nursing Home Type Patient minimum benefit and reflect changes to the table of facilities for the purpose of determining second tier default benefits.	12116	
<b>Department of Health</b>	Private Health Insurance (Health Insurance Business) Rules and Private Health Insurance (Data Provision) Rules	Minor: Amendments reflect minor changes to insurer and hospital data reporting specifications, which commence at the beginning of each reporting year from 1 July, or on the day they are registered if registered after that date. Development of changes to the data reporting specifications occurs through consultation with industry through the Hospital Casemix Protocol Working Group and advice from insurers, service providers and software vendors.	12116	
<b>Department of Health</b>	Regulatory amendments to update listing and price of medicines available under the PBS and National Immunisation Program (NIP)	Machinery.	12116	Only those elements relating to listing and pricing for the PBS and NIP are covered by this exemption.

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Department of Health</b>	Special arrangements under section 100(1) of the <i>National Health Act 1953</i> to make arrangements for the supply of pharmaceuticals in the highly specialised drugs program at public hospitals to non-admitted patients, day admitted patients or patients on discharge	Minor: The Schedule of Pharmaceutical Benefits and related information are available freely on the internet and are available for purchase in other formats (for example, CD-ROM or book). Businesses will only incur costs if they choose not to use the website and purchase the schedule in an alternative format. The cost to purchase the schedule is minimal. Changes are not expected to have a more than minor regulatory impact on individuals.	12116	
<b>Department of Health</b>	Special arrangements under section 100(1) of the <i>National Health Act 1953</i> to make arrangements to supply chemotherapy pharmaceuticals at public hospitals to non-admitted day patients, day patients or patients on discharge	Minor: The Schedule of Pharmaceutical Benefits and related information are available freely on the internet and are available to purchase in other formats (for example, CD-ROM or book). Businesses will only incur costs if they choose not to use the website and purchase the schedule in an alternative format. The cost to purchase the schedule is minimal. Changes are not expected to have a more than minor regulatory impact on individuals.	12116	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
Department of Health	Special arrangements under section 100(1) of the <i>National Health Act 1953</i> to provide an adequate supply of special pharmaceutical products to persons receiving treatment with highly specialised drugs as non-admitted patients, day patients or patients on discharge at private hospitals	Minor: The Schedule of Pharmaceutical Benefits and related information are available freely on the internet and are available to purchase in other formats (for example, CD-ROM or book). Businesses will only incur costs if they choose not to use the website and purchase the schedule in an alternative format. The cost to purchase the schedule is minimal. Changes are not expected to have a more than minor regulatory impact on individuals.	12116	
Department of Health	Changes to forms issued by the Office of the Gene Technology Regulator intended to cover the inclusion of certain information, such as additional contact details, or technical or procedural information relating to the genetic modification work being undertaken	Minor or machinery.	12796	Minor technical and administrative changes only; does not extend to changes to guidelines or legislation.
Department of Health	Therapeutic Goods Administration—amendments to increase fees and charges for therapeutic goods and manufacturing licences	Minor or machinery: These amendments are calculated using a well-established formula.	14416	If the way the fees and charges are amended changes, that may require a RIS.
Department of Health	Therapeutic Goods Administration—discretionary standards in relation to medical devices	Minor: These amendments are not regulatory in nature, since they are made to voluntary standards that can be used by stakeholders if they choose. There is no expectation of compliance.	14416	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
Department of Health	Therapeutic Goods Administration—administrative amendments to forms which are referred to in the legislation	Minor or machinery: Amendments simply reflect existing underlying requirements.	14416	If the underlying requirements on business to provide information are amended, a RIS may be required for that amendment.
Department of Health	Therapeutic Goods Administration—adding new ingredients to the Australian Register of Therapeutic Goods	Minor: Does not appear to have a regulatory impact on businesses, community organisations or individuals.	14416	If ingredients are removed from the Australian Register of Therapeutic Goods, a RIS may be required.
Department of Health)	Therapeutic Goods Administration—updates to Therapeutic Goods Order 70B	Machinery: Decision maker has no discretion when making the updates.	14416	
Department of Health	Therapeutic Goods Administration—adding new substances to the Poisons Standard	Machinery: Decision maker has no discretion in terms of which schedule a new substance is added to.	14416	Does not cover amendments to the listing of an existing substance on the Poisons Standard or the removal of an existing substance from the Poisons Standard, which may require a RIS.
Department of Health	Therapeutic Goods Administration—down-scheduling of substances on the Poisons Standard	Machinery.	14416	
Department of Health	Therapeutic Goods Administration—correction of minor errors on the Poisons Standard	Machinery.	14416	
Department of Health	Therapeutic Goods Administration—correction of inadvertent scheduling errors on the Poisons Standard	Machinery.	14416	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
Department of Health	Therapeutic Goods Administration—urgent scheduling where it relates to new substances or derivatives of existing Schedule 9 substances on the Poisons Standard	Machinery.	14416	Does not cover instances where urgent scheduling relates to up-scheduling of existing substances.
Department of Health	Therapeutic Goods Administration—annual consolidation of Standard for the Uniform Scheduling of Medicines and Poisons	Machinery.	14416	
Department of Health	Therapeutic Goods Administration—release of information under s. 61 of the <i>Therapeutic Goods Act 1989</i>	Minor: The release of such information does not change the regulatory requirements for industry or require industry to provide additional or different information to the TGA.	15070	
Department of Health	Therapeutic Goods Administration—changes to the <i>Therapeutic Goods (Permissible Ingredients) Determination</i> made under s 26BB of the <i>Therapeutic Goods Act 1989</i>	Machinery.	21645	
Department of Immigration and Border Protection	Regular updates to educational business partners of universities participating in streamlined visa processing arrangements	Minor	14615	
Department of Immigration and Border Protection	Student visa assessment level settings	Minor: Does not have a regulatory impact on businesses or community organisations. Does not appear to have a more than minor regulatory impact on individuals.	14622	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
Department of Immigration and Border Protection	Legislative amendments which give effect to the United Nations Security Council Consolidated Travel Ban List	Minor: Does not have a regulatory impact on businesses, community organisations or individuals.	14721	
Department of Immigration and Border Protection	Tariff Concession Orders	Machinery: Tariff concession orders help industry become more internationally competitive and reduce costs to the general community by reducing duties where there is no local industry to protect.	14509	
Department of Immigration and Border Protection	Amendments to the <i>Migration Regulations 1994 – Specification of Arrangements for Child Visa Applications</i> to exclude specified countries	Minor.	21693	
Department of Infrastructure and Regional Development	Annual determination of electricity fees applicable to the Indian Ocean Territories (IOTs) of Christmas Island and the Cocos (Keeling) Islands	Minor: The determinations set electricity fees in the Indian Ocean territories.	21021	
Department of Infrastructure and Regional Development	Aviation bilateral agreements	Minor and/or machinery.	14326	
Department of Social Services	Scheduled increases to aged residential care subsidies and charges based on the Government's pension indexation arrangements	Machinery: Relates purely to changing the amount of funds available to program recipients.	11719	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Department of Social Services</b>	Aged Care (Flexible Care Subsidy Amount—Innovative Care) Determination: Provision to allow for the payment of flexible care subsidy to an approved provider in respect of innovative care provided to a care recipient and routine indexation in line with increases in CPI as a measure of movements in the non-labour costs of providers	Indexation	12116	
<b>Department of Social Services</b>	Aged Care (Amount of Flexible Care Subsidy—Multi-Purpose Services) Determination	Indexation: Routine indexation of subsidy in line with increases in the CPI as a measure of movements in the non-labour costs of providers.	12116	
<b>Department of Social Services</b>	Aged Care (Amount of Flexible Care Subsidy—Transition Care) Determination	Indexation: Indexation of subsidy in line with increases in the CPI as a measure of movements in the non-labour costs of providers.	12116	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Department of Social Services</b>	Aged Care (Residential Care Subsidy—Adjusted Subsidy Reduction) Determination	Indexation: Indexation of subsidy in line with increases in the CPI as a measure of movements in the non-labour costs of providers and decisions of Fair Work Australia as a measure of non-productivity based movements of the wage costs of providers. This is in accordance with policy upon which extensive consultation was undertaken. Adjustments are likely to have low or no impact on aged care sector and consumers.	12116	
<b>Department of Social Services</b>	Aged Care (Residential Care Subsidy—Amount of Oxygen Supplement) Determination	Indexation: Routine indexation of subsidy in line with increases in the CPI as a measure of movements in the non-labour costs of providers.	12116	
<b>Department of Social Services</b>	Aged Care (Residential Care Subsidy—Amount of Viability Supplement) Determination	Indexation: Routine indexation of subsidy in line with increases in the CPI as a measure of movements in the non-labour costs of providers.	12116	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Department of Social Services</b>	Aged Care (Residential Care Subsidy—Amount of Basic Subsidy) Determination	Indexation: Indexation of subsidy in line with increases in the CPI as a measure of movements in the non-labour costs of providers and decisions of Fair Work Australia as a measure of non-productivity based movements of the wage costs of providers. This is in accordance with policy upon which extensive consultation was undertaken. Adjustments are likely to have low or no impact on aged care sector and consumers.	12116	
<b>Department of Social Services</b>	Aged Care (Residential Care Subsidy—Amount of Enteral Feeding Supplement) Determination	Indexation: Indexation of subsidy in line with increases in the CPI as a measure of movements in the non-labour costs of providers and decisions of Fair Work Australia as a measure of non-productivity based movements of the wage costs of providers. This is in accordance with policy upon which extensive consultation was undertaken. Adjustments are likely to have low or no impact on aged care sector and consumers.	12116	
<b>Department of Social Services</b>	Aged Care (Home Care Subsidy Amount) Determination	Indexation: Routine indexation of subsidy in line with increase in the CPI as a measure of movements in the non-labour costs of providers.	15163	

Department	Proposal	Why is the proposed change an indexation, routine administrative or minor or machinery change?	OBPR reference number	Comments / limits on carve-out
<b>Food Standards Australia New Zealand (FSANZ)</b>	Applications that: <ul style="list-style-type: none"> <li>• permit voluntary addition of nutritive substances to foods</li> <li>• use optional methods of analysis</li> </ul>	Minor: These applications do not have a significant impact on businesses or individuals.	14943	
<b>FSANZ</b>	Applications relating to: <ul style="list-style-type: none"> <li>• maximum residue limits</li> <li>• food additives</li> <li>• processing aids</li> <li>• genetically modified foods</li> </ul>	Machinery: The applications are part of implementing a regulatory framework where the use of the new processing aids, additives or genetically modified food is voluntary once the application has been approved.	12065	
<b>FSANZ</b>	Applications that request permission to irradiate a range of fruits and vegetables as a phytosanitary treatment, primarily against fruit fly	Machinery: The applications are part of implementing a regulatory framework where the use of irradiation as a treatment is voluntary once the application has been approved.	13845	
<b>Treasury</b>	Specific Listing of Deductible Gift Recipients	Minor: Few recipients are listed in a given year. These listings have no material impact on community organisations.	14181	