



Australian Organ and Tissue Donation and Transplantation Authority Bill 2008

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Australian Organ and Tissue Donation and Transplantation Authority Bill 2008

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House: House of Representatives

Portfolio: Health and Ageing

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Links: The [relevant links](#) to the Bill, Explanatory Memorandum and second reading speech can be accessed via BillsNet, which is at <http://www.aph.gov.au/bills/>. When Bills have been passed they can be found at ComLaw, which is at <http://www.comlaw.gov.au/>.

Purpose

The primary purpose of this Bill is to establish the Australian Organ and Tissue Donation and Transplantation Authority (the Authority). This Authority is to implement the Government's proposed package of reforms to institute a nationally consistent and coordinated system of organ and tissue donation for transplantation. The Bill also establishes the Australian Organ and Tissue Donation and Transplantation Advisory Council, which is to advise the Chief Executive Officer (CEO) of the Authority on relevant matters.

Basis of policy commitment

The creation of a national organ donation scheme as a means to improve rates of donation in Australia was one of the key ideas discussed at the 2020 Summit in May this year. Following the 2020 Summit, on 2 July 2008 the Rudd Labor Government announced a proposed national reform package intended to 'establish Australia as a world leader in organ donation for transplantation'.¹ One of the key features of this reform package was the establishment of a new independent national organ donation and transplantation authority to coordinate national organ donation reform initiatives and programs. This Authority, to be set up by 1 January 2009, was to drive and oversee the set of reforms that was endorsed by the Council of Australian Governments on 3 July 2008.² Key features of

1. N. Roxon and K. Rudd, [\\$136.4 million national plan to boost organ donation and save lives](#), media release, 2 July 2008.

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the reform package are outlined in a series of fact sheets available at the Department of Health and Ageing website.³

Committee consideration

The Senate Standing Committee for the Scrutiny of Bills raised concerns about the powers of delegation given to the CEO of the Authority. These concerns were addressed to the satisfaction of the Committee by an advice from the Minister for Health and Ageing, Nicola Roxon.⁴

Background

The following background and analysis is effectively a summary of the material provided in the Parliamentary Library research paper, ‘The future of organ donation in Australia: moving beyond the “gift of life”’. For a more detailed account of the organ donation sector in Australia, please consult the paper at: <http://www.aph.gov.au/Library/pubs/rp/2008-09/09rp11.pdf>.

While a majority of Australians support organ donation, comparatively few actually donate their organs. At 10 donors per million members of population, Australia performs poorly relative to comparable industrialised nations.

At present, around 1,800 Australians are on waiting lists for an organ donation.⁵ Without an increase in the rate of organ donation, waiting lists are expected to grow in the future, as the demand for organ transplantation is anticipated to rise with an ageing population and the increased incidence of lifestyle diseases such as obesity and Type 2 diabetes. Not only are waiting lists for organ donation expected to increase in the future but so, too, are the numbers of Australians dying whilst waiting for an organ transplant.

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2. Council of Australian Governments’, Communique, 3 July 2008 at http://www.coag.gov.au/coag_meeting_outcomes/2008-07-03/docs/communique20080703.pdf, accessed 7 October 2008.
 3. A World’s Best Practice Approach to Organ and Tissue Donation for Australia at [http://www.health.gov.au/internet/main/publishing.nsf/content/B5AC5303C8932F30CA25747A000BF6A4/\\$File/ORGAN%20FACT%20SHEET.pdf](http://www.health.gov.au/internet/main/publishing.nsf/content/B5AC5303C8932F30CA25747A000BF6A4/$File/ORGAN%20FACT%20SHEET.pdf), accessed on 28 October 2008.
 4. Senate Standing Committee for the Scrutiny of Bills, Eleventh Report of 2008, 15 October 2008 at <http://www.aph.gov.au/senate/committee/scrutiny/alerts/2008/index.htm>, accessed on 16 October 2008.
 5. Australia and New Zealand Organ Donor Registry (ANZOD), *Registry Report 2008*, ANZOD, <http://www.anzdata.org.au/anzod/Updates/anzodsummary.htm#Donors>, accessed on 14 October 2008.

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In this context, there is substantial interest in finding ways of translating Australians' stated commitment to organ donation into improved actual organ donation rates.

In response to the need to improve rates of organ donation and transplantation, all Australian governments signed up to a 10-point National Reform Agenda in July 2006. This Agenda has as its primary goal an increase in safe, effective and ethical organ and tissue donation for transplantation. The Howard Government committed \$28 million for national initiatives towards achieving this goal and, in October 2006, commissioned the National Clinical Taskforce on Organ and Tissue Donation (the Taskforce) to provide it with evidence-based advice on ways to improve the rate of organ, eye and tissue donation for transplantation in Australia.⁶

In its final report, submitted in January 2008, the Taskforce noted that, despite a long list of reports, reviews and organisations that have been created in an attempt to increase the nation's organ donation rate over time, no significant inroads have yet been made. The Taskforce attributed Australia's inability to increase organ donation rates to a number of factors, chief of which was the fragmented nature of the organ donation and transplantation sector. Unlike other comparable nations, Australia does not have a national organ donor coordination network or single coordinating agency. Instead, the system is state- and territory-based, with each jurisdiction operating under its own organ and tissue donation-related legislation, procedures and practices. Indeed, not only is there variation between jurisdictions, but also within them, with individual hospitals and clinics operating according to their own different practices.⁷

Essentially, the Taskforce highlighted the need for national coordination of all major aspects of Australia's organ donation and transplantation system. These include: communications with the public about donation; clinical triggers and notification protocols to identify potential donors; waiting list criteria and organ allocation protocols; and, data collection and dissemination on Australia's organ donation and transplantation performance. The Taskforce recommended the establishment of a national donation and transplantation authority, comprising clinicians and governments, to coordinate the above activities and any future organ donation-related reforms on a national basis.⁸

A number of the Taskforce's recommendations—including the establishment of a National Authority—are reflected in the Government's national reform package.

6. National Clinical Taskforce on Organ and Tissue Donation, *Final Report – 2008: Think nationally, act locally*, Department of Health and Ageing, Canberra, 2008.

7. *ibid.*, p. 148. Many barriers to increased organ donation have been identified as lying within Australia's hospital system. See *Medical Journal of Australia*, vol. 182, no. 5, 7 March 2005.

8. National Clinical Taskforce on Organ and Tissue Donation, *op. cit.*, p. 20.

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Commentary and analysis

Should the Bill be passed, and the Government's reforms implemented, this would represent a significant departure from, and improvement over, existing arrangements. While specific aspects of Australia's system have in the past been conducted on a national basis, these have not, on the whole, been successful. This is undoubtedly because they were not part of a broader and more consistent program of national coordination.

The establishment of a National Authority could be the first step on the road to bringing Australia's system into closer alignment with world's best practice nationally coordinated organ donation and transplantation systems, such as Spain's. Spain currently has the highest rate of organ donation in the world (34.3 donors per million population in 2007)—largely due to its commitment to improving organ donation rates throughout the country's entire health care system. Organ transplantation has a specific budget allocation in Spain, and all aspects of organ donation and transplantation activities are nationally coordinated and consistent. Perhaps most importantly, a standardised donation process and proactive donor detection program is run by designated organ transplant coordinators in the nation's hospitals.⁹

Each of these features is more-or-less mirrored in the Government's proposed national reform package.

Opt-in vs opt-out (or presumed consent)

One feature of Spain's system, however, that is not to be introduced to Australia as a part of the proposed reforms is that nation's presumed consent, or opt-out, system of legal consent for donation. Under an opt-out system of consent, people are assumed to wish to donate their organs after death, unless they officially register their objections beforehand. This system differs from Australia's opt-in arrangements, wherein a person must explicitly give their consent to become an organ donor after death.

The question of whether or not Australia should introduce an opt-out system of consent has provided the main point of discussion in recent debates over reform of the nation's organ donation sector.

Several commentators have expressed their support for the introduction of an opt-out system to Australia, on the basis that this could lead to an increase in the number of organs available for transplantation.¹⁰ However, the Government chose not to change Australia's

9. B. Miranda et al, 'Optimising Cadaveric Organ Procurement; the Catalan and Spanish Experience', *American Journal of Transplantation*, vol. 3, pp. 1191-1192; R. Matesanz, 'Factors influencing the adaptation of the Spanish Model of organ donation', *Transplantation International*, vol. 16, 2003, p. 737.

10. Both ACT Senator, Gary Humphries and Western Australian Health Minister, Jim McGinty, are reported to have advocated the introduction of an opt-out system and Queensland

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framework of legal consent for donation as a part of its reform measures, in keeping with the recommendation of the Taskforce.¹¹

In considering changes to the legislative basis of consent for organ donation in Australia, the Taskforce recommended against the introduction of an opt-out system by any Australian state or territory.¹² It did so primarily on the grounds that ‘when international comparisons in donor rates according to consent laws (and actual practice) are considered, there is no clear correlation between opt-out systems and better performance in organ donation’.¹³ However, there is some evidence to suggest that opt-out systems do indeed help to increase the number of donated organs available for transplantation. For example, a recent study of opt-in and opt-out systems, conducted over a ten-year period for 22 countries, concluded that, when other determinant factors affecting donor numbers were accounted for, those countries with opt-out legislation in place had deceased organ donor rates that were 25 to 30 per cent higher than those with opt-in legislation.¹⁴

Under current Constitutional arrangements, legislative responsibility for organ donation lies with the states and territories. Until Parliament does legislate for an opt-out (or opt-in) system, organ donation and transplantation activities will continue to be undertaken largely through regulation and administration. While the Authority could require

Premier, Anna Bligh has told that state’s Parliament that she sees ‘merit in Australia adopting an opt-out system’. See, respectively, ‘Roxon blocking organ reform’, Media release, 21 April 2008; Editorial, ‘Rudd’s organ opt-out plan goes missing’, *West Australian*, 3 July 2008 at <http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22media%2Fpressclp%2FPFWQ6%22>; and ‘Opt out system puts organ donation back on agenda’, 1 May 2008 at http://www.medicalsearch.com.au/News/Opt_out_system_puts_organ_donation_back_on_a_genda-31939. See also A. Howe, ‘Have they the ticker?’, *Herald Sun*, 7 February 2008; T. Richards, ‘Government considers organ donation, 11 people die’, *Crikey*, 14 March 2008.

11. Earlier this year, in the lead-up to the 2020 Summit, Prime Minister Kevin Rudd was reported to have expressed support for the introduction of an opt-out system. D. Giles, ‘Organ donors at record low call for opt-out law to save lives’, *Sunday Mail Brisbane*, 27 April 2008. At the 2020 Summit itself, one of the ideas agreed on was ‘the establishment of an opt-out system for organ donation, as in Spain’. Commonwealth of Australia, Australia 2020 Summit Final Report at http://www.australia2020.gov.au/docs/final_report/2020_summit_report_5_health.pdf. Nevertheless, it has been reported that following the 2020 Summit, Mr Rudd made no further mention of an opt-out scheme. See Editorial, ‘Rudd’s organ opt-out plan goes missing’, *West Australian*, 3 July 2008.
12. *ibid.*, p. 157.
13. *ibid.*, p. 15.
14. A. Abadie and S. Gay, ‘The impact of presumed consent legislation on cadaveric organ donation: A cross-country study’, *Journal of Health Economics*, vol. 25, 2006, pp. 599-620.

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compliance with a policy or protocol, standard or code of practice (as determined by the Authority) as a term or condition of financial assistance, under clause 57 of the Bill, it could not compel the states and territories to comply. As a result, were any of the states or territories to choose to introduce an opt-out system of consent—as some have indicated they are considering—they would be free to do so.

For example, a Queensland Parliamentary Committee is currently exploring the option of introducing an opt-out system to that state. Among other things, the Committee is seeking crown law advice on whether or not the state could adopt an opt-out system independent of the other states and territories. The Committee tabled its report on 28 October 2008.¹⁵

Various other possible options for boosting organ donation rates in Australia were not considered by the Taskforce, and do not form a part of the Government's proposed package of reforms. These options are discussed in the Parliamentary Library paper, 'The future of organ donation in Australia: moving beyond "the gift of life"', along with a proposed alternative basis and approach to organ donation in Australia.

Position of significant interest groups/press commentary

To date, there has been no significant public comment on the Bill, and what little comment there has been has been strongly supportive. For example, Dr Tim Mathew, Medical Director of Kidney Health Australia, has welcomed the Bill on the grounds that it should enable reforms that would significantly improve Australia's organ donation rate.¹⁶ Earlier, Chris Thomas, CEO of Transplant Australia, provided his support for the Government's proposed package of reforms. Mr Thomas thought it likely that the reforms would increase the number of organs available for transplantation.¹⁷ In speaking on the Bill, Leader of the

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15. The report can be accessed at:
<http://www.parliament.qld.gov.au/view/committees/documents/ORGAN/Organ%20and%20Tissue%20Donation%20Report%20of%20Select%20Committee%2024%20October%202008.pdf>. For other background on opt-out issues see R. Desmond, 'Opt out system puts organ donation back on agenda', Australian Associated Press, 2 May 2008. A recent summit convened by the Western Australian Government also examined the option of an opt-out system for that state and a large number of MPs in WA have indicated their support for the consideration of such a policy in the state. See D. Guest and Y. Phillips, 'Opt-out scheme "would see organ donations double"', *West Australian*, 20 May 2008 and D. Guest, 'Let's debate organ plan: Hames', *West Australian*, 24 March 2008.
 16. Kidney Health Australia, 'World's best practice national reform plan for organ and tissue donation for transplantation',
<http://www.kidney.org.au/Transplantation/tabid/583/Default.aspx>, accessed on 24 September 2008.
 17. Teamlife Transplant Australia, 'Reform package should double our rate of donation', 2 July 2008, <http://www.transplant.org.au/content.aspx?PageID=27&ItemID=97>, accessed on 8 October 2008.

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Opposition, Malcolm Turnbull indicated that the Coalition strongly supports the objectives of the Bill and expressed his support for the legislation and for other future measures calculated to promote organ donation. Mr Turnbull stated, ‘if this legislation proves to be inadequate, we will continue to work in a genuine bipartisan fashion to promote organ donation’.¹⁸

Financial implications

The reform package enabled by the Bill provides for total Australian Government funding of \$151.1 million over four years. This figure consists of \$136.4 million in new funding and \$14.7 million in transfers and offsets from existing organ and tissue program funding.

Main provisions

Clause 4 of the Bill provides definitions for expressions used throughout the Bill. These include:

- ‘organ’ means an organ of a human body (within the ordinary meaning of that expression). According to the [Wikipedia](#) entry on organ transplantation ‘organs that can be transplanted are the heart, kidneys, liver, lungs, pancreas, penis and intestine’. The Explanatory Memorandum also details the intentions of the Bill and provides a list which is not intended to be exclusive.¹⁹ The point is made in the Explanatory Memorandum that the definition is based on existing state and territory legislation and is intended to be broad and general.
- ‘tissue’ means a part of a human body (other than an organ), or a part of an organ, or a substance extracted from an organ or part of a body. Once again, according to the Wikipedia entry on organ transplantation, ‘tissues include bones, tendons, cornea, heart valves, veins, arms and skin’.
- ‘partner’ is defined as a spouse or de facto partner and ‘de facto partner’ will have the meaning that is in the *Acts Interpretation Act 1901* (the AIA). Currently the AIA does not have a definition of ‘de facto partner’ but the Same- Sex Relationships (Equal Treatment in Commonwealth Laws – General law Reform) Bill 2008 before the Parliament will provide, if passed, that a person will be a de facto partner of another person (whether of the same sex or a different sex) if the relationship is registered under a state or territory, or they have a relationship as a couple living together on a genuine domestic basis. If passed, this new definition will commence on the day of

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18. Malcolm Turnbull, Shadow Prime Minister, ‘Second reading debate: Australian Organ and Tissue Donation and Transplantation Authority Bill 2008’, House of Representatives, *Debates*, 18 September 2008.
 19. Explanatory Memorandum, Australian Organ and Tissue Donation and Transplantation Authority Bill 2008, p. 4.

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Royal Assent of that Bill, which is likely to be before the commencement date of this Bill.

Clause 8 establishes the Australian Organ and Tissue Donation and Transplantation Authority (the Authority) which will consist of the Chief Executive Officer (the CEO) and staff. The function of the Authority is to assist the CEO in the exercise of his or her functions (**clause 9**).

The Note to the clause makes clear that the Authority will not have a legal identity separate from the Commonwealth and the Explanatory Memorandum states:

It is intended that the Authority will be a prescribed agency for the purposes of the *Financial Management and Accountability Act 1997*. This means that the Authority will be subject to that Act.

The Review of the Corporate Governance of Statutory Authorities and Office Holders (the Uhrig review) was released on 12 August 2004.²⁰ One of the recommendations of the Uhrig review was that the legislative basis for statutory agencies should be simplified—the *Financial Management and Accountability Act 1997* should be applied to budget funded statutory authorities; the *Commonwealth Authorities and Companies Act 1997* should be applied to authorities that are legally and financially separate from the Commonwealth.

The CEO's functions are set out in **clause 11** of the Bill and include, in part, such functions as:

- Formulating, in writing, policies and protocols relating to organ or tissue donation and transplantation matters (hereafter referred to as 'organ donations') (**paragraph 11(1)(a)**)
- Declaring, in writing, standards and codes of practice relation to organ donations (**paragraph 11(1)(b)**)
- Carrying out educational, promotional and community awareness programs relevant to organ donations (**paragraph 11(1)(f)**)
- Making financial grants on behalf of the Commonwealth in relation to organ donations (**paragraph 11(1)(g)**), and
- Advising the Minister about organ donations (**paragraph 11(1)(j)**)
- Performing such other functions as specified in a written instrument by the Minister.

In performing the functions, the CEO must have regard to the objectives and other matters outlined in **clause 12**, and must also comply with any written policy principles that the

20. Uhrig, *Review of the Corporate Governance of Statutory Authorities and Office Holders*, Commonwealth of Australia, June 2003.

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Minister gives under **clause 13**. The Minister's instructions and policy principles are not legislative instruments (**subclause 11(6)** and **subclause 13(4)**) which has the effect that they will not be disallowable by Parliament.

The CEO is appointed by the Minister, and for a term not to exceed 5 years (**clauses 14** and **15**). The CEO may not engage in any other employment without the Minister's approval (**clause 20**) and must make full disclosure to the Minister to avoid any conflicts of interest. The Minister may terminate the appointment for the standard reasons such as misbehaviour, incapacity, bankruptcy and so on (**clause 22**).

The Minister may also give written directions of a 'general nature' to the CEO by way of legislative instrument (which are also not disallowable and not subject to the 'sunset arrangements' in the *Legislative Instruments Act 2003*, see notes one and two to **clause 30**).

Part 4 of the Bill establishes the Australian Organ and Tissue Donation and Transplantation Advisory Council (the Council) which will consist of a Chair and at least 9, and no more than 15, members (**clauses 31** and **33**).²¹ The Council's function is to advise the CEO 'about organ or tissue donation and transplantation matters' (**clause 34**).

Members are appointed by the Minister, who must consult State and Territory counterparts and any other persons the Minister considers appropriate (**paragraphs 34(2)(a)-(d)**). Appointments are for a period not exceeding 3 years and (**subclause 34(4)**).

To be eligible for appointment to the Council, members must have expertise in certain areas of endeavour, such as public administration, organ or tissue donation and transplantation matters, business, management, finance, health consumer issues or other appropriate fields of expertise (**subclause 34(6)**).

In terms of accountability and transparency, Council members must make disclosures to the Minister and to each other (**clauses 42** and **43**) and hold office subject to any terms and conditions determined by the Minister (**clause 43**).

There will also be Expert Advisory Committees (the Committee/s) which will be appointed by the CEO to advise the CEO 'about organ or tissue donation and transplantation matters' referred to it by the CEO (**clauses 44** and **45**). Members will be part-time and for a period not exceeding 3 years, and appointments can be terminated by the CEO (**clause 46**).

The Bill provides similar regulation regarding the establishment of committees, while not specifying details such as how many members comprise a committee or how many committees may be established by the CEO.

21. See also **clause 5** which makes clear that there are 'taken to be 15 members in addition to the Chair' for the purposes of determining whether there is a vacancy.

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The Explanatory Memorandum²² explains the rationale for the two tier structure:

This two tier advisory structure will allow the CEO to receive advice from a range of appropriate expert sources to assist him or her in the effective performance of his or her functions.

All of the persons appointed under the Bill will have their remuneration determined by the Remuneration Tribunal (**clauses 17, 38 and 48**) apart from the staff of the Authority who will be engaged under the *Public Service Act 1999* (**clause 25**). It should be noted that the CEO can also engage suitably qualified persons as consultants on terms and conditions determined by the CEO (**clause 26**).

On behalf of the Commonwealth, the CEO can enter into agreements with the states, territories or a person to make a grant of financial assistance which relates to one or more organ or tissue donation and transplantation matters (**clauses 54-56**).

Clause 57 deals with compliance with policies, protocols, standards and codes formulated or declared by the CEO under paragraphs 11(a) and (b). Under **subclause 57(1)**, compliance with these is voluntary – presumably on the basis that the Commonwealth does not currently have the constitutional power to require compliance on organ donation matters by non-Commonwealth bodies or persons.²³ However, as previously noted in this Digest, the Commonwealth can make compliance a condition of any grant of financial assistance, contract etc: **subclause 57(2)**.

The *Privacy Act 1988* does not apply to deceased people. However, the Privacy Act does have some relevance to the matters dealt with in the Bill. **Clause 58** specifies that the deceased person's partner, or other authorised person yet to be established by regulation, must give consent for the release of information that might identify a donor or recipient.

Clause 58 seeks to preserve patient confidentiality by preventing the CEO from publishing or disseminating information that might identify a donor or recipient without consent from the person or a person who is authorised to consent on the person's behalf.

Clause 59 preserves the operation of state and territory laws that can operate concurrently (that is, laws that are not inconsistent with the Bill), and **subclause 59(2)** specifically provides that the provisions of the Bill do not affect any laws (statutory or common law) relating to the giving of consent to the removal of an organ or tissue (from a living or a dead person). It is worth noting in this context, that the Bill goes to issues of governance and establishing the Authority, the Council and the Committees, but does not deal with

22. *ibid*, p. 17.

23. The States could of course refer constitutional power to the Commonwealth under section 51(xxxvii) of the Constitution. Note also the Commonwealth does have constitutional power with respect to the Northern Territory and the ACT under section 122 of the Constitution.

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issues or details such as consent and administration of organ transfer procedures in general, areas that are a state or territory responsibility.

Concluding comments

It is likely that the establishment of an Australian Organ and Tissue Donation and Transplantation Authority would, along with other elements of the Government's national reform package, help to improve the rate of organ donation and transplantation in Australia—at least in the short- to medium-term. While the reform package has been welcomed by a range of commentators, it is debatable whether or not the proposed changes will meet Australia's existing demand for organs, or provide for a sustainable supply of organs into the future.

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