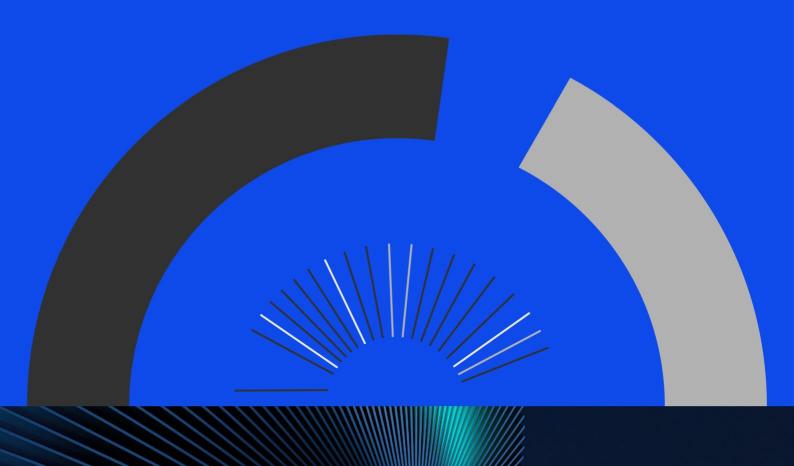
UTS Ageing Research Collaborative (UARC)





A New Model for Regulating Aged Care: A Submission on the Proposed New Regulatory Model Consultation Paper No.2

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1 Background

The 2021 Final Report of the Royal Commission into Quality and Safety in Aged Care (the Royal Commission) found that: "Ineffective regulation has been one of the contributing factors to the high levels of substandard care in Australia's aged care system." (The Royal Commission into Quality and Safety in Aged Care [The Royal Commission], 2021, p.136) In response, the Australian Government is: "developing and consulting on a range of reforms. This includes designing the new model that will be outlined in the new Aged Care Act (the new Act) and its subordinate legislation." (Department of Health and Aged Care [DoHAC], 2023b, p.5).

The University of Technology Sydney Ageing Research Collaborative (UARC) is grateful for the opportunity to make the following submission to the Department of Health and Aged Care (the Department) in response to the matters raised in its Consultation Paper No.2, A new model for regulating Aged Care: Details of the proposed new model.

2 Human rights principles as the foundation of the legal framework

UARC notes that the proposed legislation is to be drafted with human rights principles being the foundation of the legal framework for the subsidised aged care services scheme. The Australian Human Rights Commission notes that 'human rights approaches are about turning human rights from purely legal instruments into effective policies, practices and practical realities.' (Australian Human Rights Commission, 2023).

Aged care legislation must therefore first be clear as to which human rights principles are relevant in this instance, and then promote outcomes that are consistent with a human rights approach. This would include providing protections for older people, developing a practical framework to guide service providers, and establishing an appropriate regulatory scheme.

This poses considerable challenges, and further work needs to be undertaken to determine how such rights are incorporated into legislation, and whose human rights are to be observed, for instance, whether staff are included. The answers to these questions may reveal inconsistencies, competing interests or potential gaps. Finally, the question of regulation, enforcement and consequences for breach or non-compliance with the relevant human rights needs to be addressed.

3 Setting the Objectives for the Subsidised Aged Care Services Scheme

The Department's Consultation Paper No.1 sets out the aim and supporting objectives for the proposed Regulatory Model (DoHAC, 2022a, p.19). They seem unobjectionable, but are more focused on the regulation itself, rather than on the purpose of subsidising care and support services for older people.

Consultation Paper No.2 states (DoHAC, 2023b, p.8): "The proposed new model will introduce changes to the way aged care is currently regulated."

"These changes seek to:

- Increase protections for older people and empower them to exercise their rights
- Drive cultural change in the sector that promotes a new set of values and behaviours across the sector
- Improve provider capability, sector sustainability, and public confidence in the system and providers, and
- Support continuous improvement."

Again, these aims relate to what the regulatory model itself seeks to achieve rather than the objectives of the subsidised aged care services scheme.

UARC considers that the clear articulation of the scheme's objectives is an important overarching issue that the Department and the Government should address. The objectives should encapsulate the intended outcomes from government intervention in the funding, delivery and regulation of essential services which provide care and support for older people in need (the outputs). The 'objectives' enshrined in the current Aged Care Act 1997 (Section 2.1) are a mix of some aims as well as descriptions of the contents of the Act and fall well short of what is required.

There are various statements of aims and objectives that the Department could draw on, including in the Caring for Older Australians Report (Productivity Commission [PC], 2011, p.95) and the Aged Care Roadmap (Aged Care Sector Committee, 2016, p.3). To an extent, the Department's October 2022 Discussion Paper, A New Program for In-Home Aged Care, also provides some guidance (DoHAC, 2022b, p.15), although UARC has identified some shortcomings and suggested enhancements (Woods et al., 2022).

One model which UARC considers to be worth close evaluation is that of the Health Practitioner Regulation National Law 2009 (Cth). Section 3(2) of the Schedule sets

out: 'The objectives of the national registration and accreditation scheme' (Health Practitioner Regulation National Law Act 2009 (Cth), s. 3(2)). These objectives form a sound set of outcome criteria by which the performance of the scheme's outputs can be measured. The subsidised aged care services scheme deserves a similar clarity of objectives.

The scheme's objectives should be sufficiently robust to remain relevant (contemporary) for several decades and be capable of defining the criteria against which the scheme's performance can be evaluated over time. There should be broad support from consumers, providers, the workforce and funders and acceptance across the political spectrum.

UARC considers that the Department should initiate a separate round of consultations on the proposed objectives, either directly by itself or through a third-party process.

4 Undertaking Regulatory Evaluation

UARC supports the Department's commitment to undertake an ex-post evaluation of the new legislation. An evaluation of this nature is consistent with achieving one of the four objectives for the new regulatory regime, being that of creating 'Effective, efficient and contemporary regulation' (DoHAC, 2022a, p.19).

UARC notes, however, that Consultation Paper No.2 offers no further development of the processes proposed for undertaking ex-post evaluation of the new regulatory regime.

By way of background, the Department is subject to the processes required by the Office of Impact Analysis (the former Office of Best Practice Regulation) (The Office of Impact Analysis, 2023). However, these processes have always focused on the examte evaluation of whether the policy proposals have been developed in accordance with the requirement of developing best practice regulation, including appropriate consultation on both the policy and its intended regulatory treatment, rather than an expost assessment of actual outcomes from the government intervention. UARC also notes a history of legislative proposals which have a high priority and/or strong political alignment with the Government of the day being exempted from the full range of best practice requirements.

The Organisation for Economic Co-operation and Development (OECD) has been a leader in promoting ex-ante regulatory evaluation and in developing best practice guidelines (Radaelli et al., 2022). Importantly, the OECD has more recently devoted more resources to developing approaches to ex-post evaluations, noting that governments have "paid remarkably little attention to analysing regulations after adoption" (Coglianese, 2012; Organisation for Economic Co-operation and Development [OECD], 2023).

There is a body of academic literature on legislative effectiveness from a legal perspective (Zamboni, 2018). The literature provides methodological guidance for designing ex-post evaluations of legislation and regulatory instruments. It also critically evaluates factors contributing to legislative failure, including those that can be avoided through appropriate legislative design strategies. This includes attention to the scope of the principal Act, the scope and extent of subordinate legislation, and Parliamentary and sector concerns with over-reliance on secondary legislation (Mousmouti, 2019; Goddard, 2022).

There is a sound body of scholarship in the field of legislative effectiveness and associated frameworks and tools, but in UARC's view, there needs to be much more research into applying the theory and concepts of legislative effectiveness to specific

subjects of law-making. The development of new aged care regulations provides an excellent opportunity to build out that research and develop practical guidance for future legislative development in the broader care economy.

UARC strongly supports an ex-post evaluation of the legislative effectiveness of achieving the objectives of the subsidised aged care services scheme which should be enunciated in the principal Act. Such an evaluation would require both a longitudinal study of the outcomes of the scheme AND an assessment of the contribution to the outcomes from:

- The structure and wording of the principal Act and associated regulatory regime;
- The underlying policy and program designs and implementation.

Benchmarking the current legislative performance would be an essential first step in the evaluation process.

5 Relational Regulation: Facilitating Intrinsic Motivation and Driving Cultural Change

UARC supports the Department's aim of creating a regulatory framework that clarifies and supports relationships between older people receiving subsidised care and support, the providers of those services and the aged care specific regulators. As stated in Consultation Paper No.2: "The new model has a key role to play in helping achieve this shift by placing more emphasis on relational regulation. This approach helps to build relationships, trust and transparency." (DoHAC, 2023b, p.12) Such a regulatory approach can facilitate the desired motivation and drive the desired cultural change.

This submission offers several considerations on how to proceed with this strategy and identifies examples from academic literature to illustrate the points.

Enabling versus Coercive Bureaucracy

The extent to which bureaucracy and associated regulation create a positive and functional or negative and dysfunctional response from individuals will be influenced by whether the bureaucracy is seen as enabling individuals and organisations to deliver tasks and outcomes or is used to coerce their compliance (Adler & Borys, 1996). Enabling regulation will provide guidance to individuals and organisations on how to deliver outcomes more efficiently and enhance their commitment to providing more effective care and support.

UARC argues that the new aged care sector regulatory framework is more likely to deliver intended outcomes for older people and their carers if it is designed in a way that enables individuals and organisations to deliver high quality of care, rather than relying on coercive mechanisms to ensure adherence to rules and procedures.

Motivation

While the objective of the framework might be to drive greater levels of intrinsic motivation on the understanding that this will improve aged care, individual motivation is more nuanced than the stereotypical extrinsic versus intrinsic binary classification (Ryan & Deci, 2000). The focus on motivating individuals can often prefer one or the other of these forms with an external incentive or reward. However, some forms of extrinsic motivation such as integrated or identified extrinsic motivation may be more suitable for motivating behaviours desired in the aged care sector. Understanding this

would be vital in enabling organisations to mobilise the desired range of motivations.

Ecological Systems

Taking an ecological systems approach to the drafting of the new legislative tools would require consideration of macrosystems within which the law sits at a broader societal level (the outcomes that society demands of aged care), mesosystems where regulation has a most direct effect at the organisational level (such as the providers of services), and microsystems which is where the regulation guides and engages the individual (owners, managers, workforce) (Brown & Noone, 2021). Tapping into the desired motivation and driving the desired culture requires a clear understanding of how to design the regulatory framework so that the meso level mediates and translates between the macro and micro. Both motivation and culture (the aggregation of individual behaviours) sit at the individual level, which is controlled and managed within organisations.

This complex area offers significant potential in framing the aged care regulatory regime to be most effective at each of the three levels.

6 Reliance on Consumer Information to Incentivise Quality Improvement

UARC notes that, within the new regulatory model, there is an expectation that providing greater information about the quality of services will provide incentives and motivation for providers to continuously improve quality. Specifically, under the "A new approach to supporting quality care" component of the new model (DoHAC, 2023b, p.17), there are expectations that published information will inform consumer choices, create more transparency and thereby create incentives for providers to ensure high quality and safe care and engage in continuous improvement. Such information may take the form of published Star Ratings, Monthly Care Statements and other forms of published performance reporting of provider outcomes.

However, the assumed causal links between published quality information, consumer behaviour, provider incentives and eventual changes in provider behaviour remain untested and uncertain.

UARC's recent edition of the Australia's Aged Care Sector Mid-Year Report (2022-23) provides a synthesis of academic evidence about consumer and provider responses to Star Ratings in the United States (Sutton et al., 2023). Such evidence shows

- Composite Star Ratings can be a source of confusion for consumers, particularly when there is a lack of transparency about how weightings are applied.
- The causal effects of Star Ratings on consumer demand depend on the baseline quality of a home, its occupancy and the level of local competition.
- Providers are less likely to take action towards quality improvement when located in less competitive markets or when they have high occupancy rates.

The development of quality information which is consistent and relevant to the decision-making of consumers may also be more complex for in-home aged care services relative to residential care. This is due to the comparative heterogeneity of services – reflected in the five home and community care related provider categories within the proposed regulatory model – compared to the more homogeneous circumstances of residential care.

Given the reliance on consumer information as a policy lever to incentivise quality improvement, as well as the high administrative costs of reporting and transparency regimes, UARC would advise that ongoing evaluation work be undertaken to assess:

- Consumer access rates and understanding of quality information about providers.
- The influence of quality information on consumers' choices and demand for services, particularly across different types of markets, service types and consumer cohorts.
- The responsiveness of providers to quality information, including efforts to improve quality as well as communicate to consumers about quality programs.

7 Registration Categories for Providers

Under the section 'Becoming a provider', Consultation Paper No.2 discusses the proposed provider registration model for providers seeking to deliver Commonwealth subsidised aged care services (DoHAC, 2023b, p.21).

The Consultation paper does not address the potential for regulatory ambiguity relating to the scope of regulation of online platforms.

The Productivity Commission 2022 Study Report Aged Care Employment found that (PC, 2022, p.2): "there is little persuasive evidence that a policy to preference direct employment would improve outcomes. It could indeed worsen outcomes." It also found that: "Many older Australians highly value the choice and agency that this model provides, as well as the bespoke nature of the service offerings from platforms that cater for diverse needs." The Report raised a number of relevant issues, as have Support at Home Program design papers (including that older people may inadvertently become employers under such arrangements). Similarly, it is not clear which are the responsibilities and accountabilities of other stakeholders within the new Support of Home Program, such as assessors and care partners.

UARC highlights the issue of whether there is a need to create another registration category specifically for intermediaries that may have the potential for risk-proportionate responsibilities and obligations.

8 Complaint and Feedback Mechanisms to Hold Providers Accountable

UARC supports the continued use of complaints mechanisms to safeguard the safety and rights of older people and to prevent, detect and correct risk, substandard care and poor performing providers. Given the mechanism's involvement of diverse stakeholders in risk identification, it is more likely to detect isolated incidents and initial breaches than traditional regulatory interventions like periodical inspections (Comino, 2011; Scott, 2017, pp. 265-281; Smith, 2010). In light of the deficiencies identified in the current approaches to complaints management, as identified by the Royal Commission, UARC supports the proposed reforms.

Consultation Paper No. 2 outlines several key elements with respect to the reform of complaint management and feedback. UARC wishes to provide commentary on several key aspects of the revised complaint model.

The New Aged Care Complaints Commissioner

The proposed changes in the revised complaints model, as highlighted in Consultation Paper No.2, include the establishment of a new Aged Care Complaints Commissioner within the Aged Care Quality and Safety Commission (DoHAC, 2023b, p.54). However, there is scant detail regarding the responsibilities and authority of the proposed Commissioner, or how this new role might strengthen the safeguard function of complaints management beyond that of the existing Commission as well as that to be undertaken by the Inspector-General of Aged Care.

UARC considers that the new model should clarify the potential roles and responsibilities of the Commission, the Complaints Commissioner (given their responsibility for overseeing the complaints model) and the Inspector-General. In regard to the latter, the Bill to establish the Inspector-General has, as one of the Objects (section 3), that the Inspector-General is to provide oversight of the Commonwealth's administration of complaints management processes across the aged care system.

Empowerment of Advocates and Other Support Networks in Safeguarding Older People

UARC highly values the vital role of advocates and other support networks in providing information, education, assistance and support to older people and their

representatives. UARC, therefore, supports the engagement with advocates and other support networks under the new model.

However, while acknowledging the importance of advocates and support networks for older people and their representatives, the revised complaint model offers limited support or provider access to advocates and support network personnel (DoHAC, 2023b, p.57). This lack of explicit support from the governing authority inhibits their capacity to provide comprehensive support to older people.

Analysis conducted by UARC using evidence from the Royal Commission reveals that advocates and personnel from support networks frequently encounter resistance and denial of entry from service providers. Given the vital role of advocacy groups in empowering older people and assisting aged care providers in identifying risks and non-compliance, UARC recommends that the revised complaint model should grant these advocacy groups and support networks access to older people and their representatives, provided that consent is obtained from them.

Responsive Regulation and Enforcement Actions

UARC notes that the new model intends to adopt a risk-based approach for monitoring care quality and risks and to determine regulatory interventions based on the principle of responsive regulation. Responsive regulation theory posits that compliance-orientated interventions, such as persuasion, education, negotiation and settlement, help improve a regulated entity's understanding of regulatory requirements and motivate them to refocus on problems that they may have overlooked (Ayres & Braithwaite,1992; Gunningham, 2010). While the proposed new model recognises the importance of education in building provider capability and facilitating continuous improvement, educational programs are not formally incorporated into the legislation as a type of enforcement action. The least severe enforcement action under the existing regime, as well as in the proposed model, is the issuance of an action notice. In cases where noncompliance persists, regulators have the option to escalate to enforcement actions.

UARC recommends that the new model considers the incorporation of compliance education as a potential enforcement action for low-risk issues. Research suggests that the certainty of detection and enforcement is more effective than the severity of enforcement actions (Mungan 2019; Ugrin and Odom 2010). Mandatory education could be more effective in fostering compliance and in promoting continuous improvement, compared to Action Notices with a low probability of issuance.

Restorative Justice

The section of Consultation Paper No.2 which addresses "Holding providers accountable" makes an early reference to the role that restorative justice could play in

the new regulatory regime (DoHAC, 2023b, p.50), including in relation to compensation (DoHAC, 2023b, pp.58-59).

UARC notes the views of the Department in relation to restorative justice, including that while it is a useful concept, it can mean different things to different people. There is a substantial body of literature on restorative justice which offers support for the consideration of restorative justice principles in complaints processes as discussed in the Consultation Paper No.2.

References

- Aged Care Sector Committee. (2016, March 25). *The Aged Care Roadmap*.

 Department of Health and Aged Care. Retrieved June 19, 2023, from https://www.health.gov.au/sites/default/files/aged-care-roadmap_0.docx
- Adler, P. S., & Borys, B. (1996). Two Types of Bureaucracy: Enabling and Coercive. *Administrative Science Quarterly*, 61-89. https://doi.org/10.2307/2393986
- Australian Human Rights Commission. (2023). *Human Rights Based Approaches*. Australian Human Rights Commission. Retrieved June 19, 2023, https://humanrights.gov.au/our-work/rights-and-freedoms/human-rights-based-approaches).
- Ayres, I., & Braithwaite, J. (1992). Responsive Regulation: Transcending the Deregulation Debate. Oxford University Press.
- Brown, J. T., & Noone, J. (2021). *Amplify Insights: Financial Wellbeing*. Centre for Social Impact, UNSW Sydney. Retrieved June 16, 2023, from https://apo.org.au/sites/default/files/resource-files/2021-07/apo-nid313197.pdf
- Coglianese, C. (2012). Measuring Regulatory Performance: Evaluating the Impact of Regulation and Regulatory Policy. Organisation for Economic Co-operation and Development. Retrieved June 19, 2023, from https://www.oecd.org/regreform/regulatory-policy/1_coglianese%20web.pdf
- Comino, V. (2011). Towards Better Corporate Regulation in Australia. *Australian Journal of Corporate Law, 26*(1), 1-33. https://doi.org/10.3316/agispt.20114861
- Department of Health and Aged Care. (2022a, September 5). A New Model for Regulating Aged Care Consultation Paper No.1. Department of Health and Aged Care. Retrieved June 16, 2023, from https://consultations.health.gov.au/best-practice-regulation/aged-care-regulatory-framework/user_uploads/final-new-model-for-regulating-aged-care-sep-2022.pdf
- Department of Health and Aged Care. (2022b, October 18). *A New Program for In-Home Aged Care Discussion Paper*. Department of Health and Aged Care. Retrieved June 16, 2023, from https://www.health.gov.au/sites/default/files/documents/2022/10/a-new-program-for-in-home-aged-care-discussion-paper_0.pdf
- Department of Health and Aged Care (2023a, March 3). Inspector-General of Aged Care: Consultation Paper on the Exposure Draft of the Inspector-General of Aged Care Bill. Retrieved June 17, 2023, from https://www.agedcareengagement.health.gov.au/images/inspectorgeneral/consultation-paper.pdf
- Department of Health and Aged Care. (2023b, April 26). A New Model for Regulating Aged Care Consultation Paper No.2. Department of Health and Aged Care. Retrieved June 15, 2023, from

- https://www.health.gov.au/sites/default/files/2023-04/a-new-model-for-regulating-aged-care-consultation-paper-2-details-of-the-proposed-new-model.docx
- Goddard, D. (2022) Making Laws that Work: How Laws Fail and How We Can Do Better. Hart Publishing.
- Gunningham, N. (2010). Enforcement and Compliance Strategies. In R. Baldwin, M. Cave, & M. Lodge (Eds.), *The Oxford Handbook of Regulation* (pp.120-145). Oxford University Press.
- Health Practitioner Regulation National Law Act 2009 (Cth). https://www.ahpra.gov.au/about-ahpra/what-we-do/legislation.aspx
- Inspector-General of Aged Care Bill 2023 (Cth). https://parlinfo.aph.gov.au/parlInfo/download/legislation/bills/r7004_first-reps/
- Mousmouti, M. (2018). Designing Effective Legislation. Edward Elgar.
- Mungan, M. C. (2019). Salience And the Severity Versus the Certainty of Punishment. International Review of Law and Economics, 57(C), 95-100. https://doi.org/10.1016/j.irle.2019.01.002
- Organisation for Economic Co-operation and Development. (2023). *Measuring Regulatory Performance*. OECD Regulatory Policy. Retrieved June 17, 2023, from https://www.oecd.org/gov/regulatory-policy/measuring-regulatory-performance.htm
- Productivity Commission. (2011, June 28). *Caring for Older Australians*. Productivity Commission Inquiry Report Volume 1. Retrieved June 19, 2023, from https://www.pc.gov.au/inquiries/completed/aged-care/report/aged-care-volume1.pdf
- Productivity Commission. (2022, October 21). *Aged Care Employment Study Report*. Retrieved June 19, 2023, from https://www.pc.gov.au/inquiries/completed/aged-care-employment/report/aged-care-employment.docx
- Radaelli, C., Allioii, L., O'Connoriii, K., Alcorniv, R., & Trnkaiv, D. (2022). Regulatory Policy 2.0: Viewpoints and Beliefs about Better Regulation: A Report from the "Q Exercise". OECD Regulatory Policy Working Papers No. 20. OECD Publishing. Retrieved June 19, 2023, from https://doi.org/10.1787/24140996
- Royal Commission into Aged Care Quality and Safety. (2021, March 1). Final Report:

 Care, Dignity and Respect: Volume 1, Summary and Recommendations. Royal
 Commission into Aged Care Quality and Safety. Retrieved June 17, 2023, from
 https://agedcare.royalcommission.gov.au/publications/final-report-volume-1
- Ryan, R. M., & Deci, E. L. (2000). Self-Determination Theory and the Facilitation of Intrinsic Motivation, Social Development, and Well-being. *American Psychologist*, *55*(1), 68–78. https://doi.org/10.1037/0003-066X.55.1.68
- Scott, C. (2017). The Regulatory State and Beyond. In Drahos, P. (Ed.), *Regulatory Theory: Foundations and Applications* (pp. 265-281). ANU Press.

- Smith, G. (2010). Every Complaint Matters: Human Rights Commissioner's Opinion Concerning Independent and Effective Determination of Complaints Against the Police. *International Journal of Law, Crime and Justice, 38*(2), 59-74. https://doi.org/10.1016/j.ijlcj.2010.03.001
- Sutton, N., Ma, N., Yang, J., Lewis, R., Woods, M., Ries, N., & Parker, D. (2023). *Australia's Aged Care Sector: Mid-Year Report (2022-23).* UTS Ageing Research Collaborative. Retrieved June 19, 2023, from https://opus.lib.uts.edu.au/handle/10453/170529
- The Office of Impact Analysis. (2023). Developing the evidence base for decision making. Department of the Prime Minister and Cabinet. Retrieved June 21, 2023, from https://oia.pmc.gov.au/
- Ugrin, J. C., & Odom, M. D. (2010). Exploring Sarbanes—Oxley's Effect on Attitudes, Perceptions of Norms, and Intentions to Commit Financial Statement Fraud from a General Deterrence Perspective. *Journal of Accounting and Public Policy*, 29(5), 439-458. https://doi.org/10.1016/j.jaccpubpol.2010.06.006
- Woods, M., Lewis, R., Brown, D., Parker, D., Sutton, N., Rawlings-Way, O., & Sinclair, D. (2022). Support at Home: Response to the Department of Health and Aged Care Discussion Paper. UTS Ageing Research Collaborative. Retrieved June 21, 2023, from https://opus.lib.uts.edu.au/handle/10453/164333
- Zamboni, M. (2018). Legislative Policy and Effectiveness: A (Small) Contribution from Legal Theory. *European Journal of Risk Regulation*, *9*(3), 416-430. https://doi.org/10.1017/err.2018.32