National approaches to regulating health and social care professions

An evidence brief

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Abbreviations

BIG Act	Individual Healthcare Professions Act (1997)
EU	European Union
GDP	Gross domestic product
OECD	Organisation for Economic Co-operation and Development
UK	United Kingdom

Executive summary

Policy context

Ireland's approach to professional regulation in the health and social care arena has been established over the past 150 years. Sláintecare's call for a health system that ensures patient safe and meets the needs of the population presents an opportunity to consider how professional regulation can be improved, in order to ensure the highest quality of care for the citizens of Ireland. The Department of Health commissioned this evidence brief so that these efforts can be informed by approaches in other countries to regulating health and social care professions. Understanding international approaches to professional regulation can help us move towards a more proportionate system of regulation that ensures public protection, quality service provision, ethical practice, accountability, efficiency, and transparency.

Research question

This evidence brief addressed the following research question:

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The following sub-questions were explored:

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- What specific tools are used to determine whether or not new professions should be regulated?
- What is the justification for determining the appropriate level of regulation for a profession?
- Which professions have been regulated in the past five years?
- Which professions have been deregulated or have had their level of regulation minimised?
- Are there examples of professions challenging decisions regarding their level of regulation at a high level?
- How are European Union countries implementing the Proportionality Directive (Directive (EU) 2018/958)?
- How have countries justified changes to their regulatory systems?
- How have countries justified new approaches to regulation that they have implemented?

Methods

The following countries were included in this evidence brief: the United Kingdom, New Zealand, Australia, the Netherlands, Finland, Sweden, and Denmark. These countries were chosen in close collaboration with the Department of Health. Only countries that are members of the Organisation for Economic Co-operation and Development were considered.

This brief relied primarily on government publications, government websites, and country reports published by international organisations. These documents were identified through online searches and by contacting policy-makers in the included countries requesting relevant documentation. Documents that were not in English were translated using Google Translate. Relevant information from the included sources was extracted and analysed.

Findings

Detailed information addressing the research questions was available for the United Kingdom, New Zealand, Australia, and the Netherlands. Unfortunately, there was minimal information available in the literature regarding Finland, Sweden, and Denmark.

United Kingdom

Through a series of reforms beginning in the early 2000s, a system of independent regulation has been established for health and social care professions in the United Kingdom (UK). In particular, the creation of a powerful meta-regulator – the Professional Standards Authority – was pivotal in the UK's shift away from self-regulation and towards independent regulation. The Professional Standards Authority oversees the work of 10 regulatory bodies and 25 voluntary accredited registers for unregulated professions. In a further move away from self-regulation, and in response to a series of scandals that highlighted challenges with regulators, professional majorities were eliminated from the councils of regulatory bodies. This helped to restore public confidence in professional regulation and removed the perceived lack of independence between regulators and those they regulate.

Regulation is now more transparent in the UK, however the UK Government has stated its ambition to further improve the regulatory system, so that it is more responsive to current and future needs. To this end, a draft bill that would significantly change professional regulation was developed in 2014. It includes an increase in autonomy for regulators from Government, alongside increased power for the Professional Standards Authority to ensure oversight of regulators. Additionally, the UK Government has recently proposed establishing legislative powers to remove individual professions from statutory regulation and to remove individual regulatory bodies. The removal of regulatory bodies would facilitate reducing the number of regulatory bodies by merging regulators.

Moreover, due to the lack of clarity regarding why particular professions have been regulated and others have not, the UK Government has proposed that the Professional Standards Authority take on the statutory role of advising the Government on which health and social care professions should be regulated. This advice would be based on a risk assessment tool developed by the Professional Standards Authority called *Right-touch assurance.* The tool assesses the appropriate level of regulation for professional groups using criteria that establish an occupation risk profile and assess specific extrinsic factors. However, if the Professional Standards Authority were to take on this advisory role, the decision about whether a new group should be regulated would ultimately remain with the Department of Health and Social Care, and the requirement for public consultation would be maintained.

Since the Health and Social Care Act 2012, when the Professional Standards Authority was granted the power to establish its voluntary accreditation scheme for unregulated professions, there have been no major legislative changes to professional regulation in the UK. This is despite continued calls from both regulators and from the Professional Standards Authority for updated legislation. However, with the publication of a white paper in February of 2021 outlining an intention to implement secondary legislation regarding professional regulation, it is anticipated that reforms are forthcoming.

New Zealand

Regulation of health professionals in New Zealand is legislated under the Health Practitioners Competence Assurance Act (2003), which established a single regulatory framework for health professions. Prior to this, the Ministry of Health administered 11 occupational statutes covering 18 health and disability professions. Many of the occupational regulation statutes were deemed old, inflexible, and not appropriate for the needs of health professionals or the public.

The objective of the Health Practitioners Competence Assurance Act is to protect the health and safety of members of the public by providing for mechanisms to ensure that health professionals are competent and fit to practise. Although the Ministry of Health is responsible for the Act's overall administration, the primary responsibility, accountability, and overall functioning of regulation rests with the respective professional authorities. Currently, seventeen regulatory authorities or professional bodies regulate health professionals under the Health Practitioners Competence

Assurance Act. Regulatory authorities are responsible for registration, determining scopes of practice, issuing practising certificates, and handling complaints. Health professions in New Zealand that are not regulated under the Health Practitioners Competence Assurance Act are subject to the Code of Health and Disability Consumers' Rights, as are regulated professions.

The Minister of Health is responsible for extending the Health Practitioners Competence Assurance Act to regulate a new health profession. To do so, the Minister of Health must be satisfied that the health service poses a risk of harm to the public or that it is otherwise in the public interest that the health service is regulated. The Health Workforce Directorate, on behalf of the Minister of Health, assesses applications for regulating new professions under the Health Practitioners Act according to a set of specific primary and secondary criteria. These criteria focus on assessing if the profession poses a risk of harm to the public and if regulation is the best method of diminishing any potential risk of harm. If an application satisfies the primary and secondary criteria, the Health Workforce Directorate undertakes a public consultation process and analyses submissions, subject to the Minister of Health's agreement. A regulatory impact assessment must accompany all applications before a final decision is made to regulate a health profession. The Health Workforce Directorate provides the Minister of Health with a final report based on the advice provided. The Minister may then seek agreement from the Cabinet to regulate a profession.

Australia

Health professions in Australia are regulated under National Registration and Accreditation Scheme. The Health Practitioner Regulation National Law Act of 2009 established a legal basis for the creation of the National Registration and Accreditation Scheme. The National Law consolidated 75 Acts of Parliament and 97 health professional boards into a single meta-regulator with 14 respective National Boards.

The objectives of the National Registration and Accreditation Scheme are to:

- Provide public protection by ensuring that only suitably qualified and registered health professionals may provide their services to the public
- Ensure professional mobility across Australia by reducing the administrative burden for health professionals working in multiple states and/or jurisdictions
- Facilitate high standards of education and training for health professionals
- Ensure rigorous assessment of health professionals trained overseas, and
- Facilitate access to services provided by health professionals following public interest.

Following the establishment of the National Registration and Accreditation Scheme in 2010, 10 health professions were regulated under the National Law, all of which had been previously regulated. Four more health professions were added to the National Registration and Accreditation Scheme in 2012 (Aboriginal health practitioners, Torres Strait Islander health practitioners, Chinese medicine practitioners, and medical radiation practitioners). Paramedics were added to the National Registration and Accreditation Scheme in 2018. Under the National Law, title protection is provided to regulated professions. Both regulated health professionals and unregulated health professionals must adhere to standards of conduct and practice outlined in the National Code of Conduct for Health Care Workers.

To administrate the National Registration and Accreditation Scheme, a new agency, the Australian Health Practitioner Regulation Agency, was established under the National Law. The Australian Health Practitioner Regulation Agency supports the National Boards of regulated professions to ensure public protection through regulation. The Australian Health Practitioner Regulation Agency has five core regulatory functions: professional standards, registration, notifications, compliance, and accreditation.

Each regulated profession has a national board to administer the National Registration and Accreditation Scheme. National boards are responsible for registration, developing standards, codes of conduct, setting registration fees, approving accreditation standards and programs of study, and

protecting the public through the efficient operation of the National Registration and Accreditation Scheme. With support from the Australian Health Practitioner Regulation Agency, the National Boards also oversee the receipt, assessment, and investigation of complaints regarding registered health professionals.

Amending the National Law to regulate a new health profession under the National Registration and Accreditation Scheme is determined by the Ministerial Council. The Ministerial Council considers a submission to regulate a new profession using five steps. A key part of the process involves ascertaining if the profession poses a risk of harm to the public. An Australian Government regulatory impact assessment must accompany every policy proposal, including legislative changes to health professions' regulation. The Office of Best Practice Regulation provides guidance and support for public sector bodies in undertaking a regulatory impact assessment, which is required. The Australian Government has published guidance on performing regulatory impact assessments in the *User Guide to The Australian Government Guide to Regulatory Impact Analysis*.

The Netherlands

The Individual Healthcare Professions Act 1997 determines the regulation of health professionals in the Netherlands. This Act is referred to by its Dutch acronym 'BIG' (*Wet op de beroepen in de individuele gezondheidszorg*). The BIG Act seeks to balance freedom of choice and public protection. Dutch legislation determines that individuals should be free to choose who provides their healthcare, both in complementary and traditional settings. Notwithstanding, to ensure sufficient public safety, various provisions are included in the BIG Act to ensure public protection, including title protection, educational requirements, public registration, and a disciplinary code of conduct for all registered professionals.

The BIG Act has two main categories of regulation – professions regulated under Article 3 and professions regulated under Article 34. Health professionals included in Article 3 are entitled to a protected professional title, have independent autonomy to perform activities relating to their scope of practice, and are subject to disciplinary action. Regulated professions in Article 3 must also be registered and listed on the BIG register. The BIG register is a publicly available online register that lists all regulated health professionals under Article 3. The BIG register also provides details of a health professional's qualifications and competencies to practise. The Central Information Unit manages the BIG register on behalf of the Ministry of Health, Welfare and Sport. Registration on the BIG register is mandatory for professionals in Article 3, with renewal required every five years pending adequate proof of continued professional development and clinical hours. Professions included in Article 34 of the BIG Act have a legally protected academic title. However, they are not registered on the BIG register and are not subject to the same disciplinary rules as those that govern professions under Article 3.

The Minister of Health, Welfare and Sport is responsible for regulating new professions under the BIG Act. The National Healthcare Institute assesses applications on behalf of the Minister using pre-determined criteria. If the application meets the pre-determined criteria, the second step in the regulatory process considers whether to regulate a profession under Article 3 (whereby professionals are registered and have a protected professional title) or Article 34 (professionals are not registered and only have a protected academic title). The decision to regulate a profession under Article 3 is applied if there is a requirement for a professional to perform any restricted activities, or where there is a need to apply disciplinary measures to protect members of the public from potential harm arising from the practice of the profession. The decision to apply Article 34 is made if there is a need for public legal regulation of a degree programme or a need for a title that recognisable to the public. The National Healthcare Institute produces an advisory report regarding the suitable level of regulation, and based on this advice, the Minister decides whether to amend legislation to regulate a profession. For professions regulated under Article 34, a trial period of 5 years is sometimes used (called Article 36a) to determine whether or not to move a profession to Article 3. This provision was created to facilitate task-shifting for restricted activities, in order to increase efficiency in the health system. During this trial period, a profession can temporarily register on the BIG register and is subject to disciplinary rules. At the end of the five-year trial period, the Ministry of Health, Welfare and Sport decides whether to move a profession to Article 3 or return the profession to Article 34.

Finland

Health professions in Finland are regulated under the Health Care Professionals Act 1994. The objective of the Health Care Professionals Act is to promote the safety of patients and to improve the quality of healthcare services by ensuring that a health professional has the necessary education and training, professional qualifications, and other knowledge and skills required to practise their profession. Regulation falls under two categories in Finland: licensed professions and professions with a protected occupational title. Only licensed professionals may practise the profession in the first category. Licensing means that an individual has completed a training programme laid down in legislation, is authorised to work in the profession in question, is entitled to use the occupational title in question, and is registered with the National Supervisory Authority for Welfare and Health. Professions with protected occupational titles may be practised by anyone who possesses appropriate training, experience, and professional skills and knowledge. A health professional with a protected occupational title is not required to register with the National Supervisory Authority for Welfare and Health. Unfortunately, information regarding Finland's approach to regulating new professions was not available in the literature.

Sweden

Health professional regulation in Sweden is legislated under the Patient Safety Act in 2010. The Patient Safety Act ensures title protection for 22 health professionals. Specialist titles are also legislated in the Patient Safety Act for doctors, hospital physicists, dentists, and nurses. The National Board of Health and Welfare is responsible for health professional licensing under the Patient Safety Act. The Patient Safety Act also sets out several obligations for individual health professionals. According to the Act, healthcare workers are personally responsible for their actions. The Patient Safety Act states that the responsibilities of healthcare providers include: the implementation of systematic patient safety work and preventive work; an obligation to analyse adverse events; a requirement to inform patients and relatives as soon as possible when harm occurs; and that patients and relatives should be a part of efforts to improve patient safety. The Health and Social Care Inspectorate is a government agency under the Ministry of Health and Social Affairs and is responsible for supervising healthcare under the Patient Safety Act. Unfortunately, information regarding Sweden's approach to regulating new professions was not available in the literature.

Denmark

Regulation of health professions in Denmark falls under the Danish Health Act (2006). The Danish Health Act's premise is that everyone has easy and equal access to healthcare, that treatment is of high quality, and that patients should have freedom of choice. The Danish Patient Safety Authority is the government state agency responsible for regulating health professionals. The Danish Patient Safety Authority regulates 19 health professional groups, with lists of regulated professionals available to the public via an online register. The Danish Patient Safety Authority also addresses complaints regarding registered health professions and is responsible for the inspection of health institutions and staff. Unfortunately, information regarding Denmark's approach to regulating new professions was not available in the literature.

Synthesis of findings

Professional regulation is essential to ensuring safe, effective, and patient-centred care. However, regulation ought to be proportionate to the level of risk posed by health and social care professions. The countries included in this evidence brief vary in their approaches to addressing this challenge, however there are some common features across the countries. New Zealand, Australia, and the Netherlands have established criteria that are formally required for deciding which new professions to regulate. In all three countries these criteria have been used to regulate new professions. The specific criteria vary; however, in all three cases there is a focus on risk assessment. In the UK, the meta-regulator – the Professional Standards Authority – has designed risk-based criteria for deciding whether or not to regulate new professions. These criteria (which are outlined in *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm*) have been tested, however they are not formally required. The UK Government has, however, proposed that the

Professional Standards Authority be given the legislative power to advise the Government on whether or not to regulate a new profession, using *Right-touch assurance*.

Regarding deregulation of health professions, no professions have been deregulated in the United Kingdom, New Zealand, Australia, or the Netherlands. However, there is interest in potentially establishing a process for doing so in the United Kingdom and New Zealand.

Unfortunately, minimal information was available in the literature regarding the approaches to regulation in Finland, Sweden, and Denmark. Regarding the implementation of EU Directive 2018/958 on a proportionality test before regulating new professions, very little information was available as well.

Our findings from the United Kingdom, New Zealand, Australia, and the Netherlands show that establishing a clear set of criteria for assessing suitability for regulation creates consistency in the decision process. Moreover, establishing specific criteria for assessing risk ensures that patient safety underpins professional regulation. Transparency is also crucial, and public consultations play a key part in this. Once a clear process is established, regular review of the criteria used for assessment and of the process overall is important.

For professions that are regulated, a meta-regulator can play an important role in overseeing regulatory bodies. Additionally, having all regulated professionals listed on the meta-regulator's website, as is the case in Australia, can make this information more easily accessible to the public. For unregulated professions, the UK's accredited registers programme includes professional bodies that adhere to specific standards and provides a voluntary public register of unregulated professionals. In Australia and New Zealand, codes of practice govern unregulated professions. In all countries, responsibility for both regulated and unregulated health professionals meeting the standards of their profession is devolved to the relevant regulatory body or accredited register.

Conclusion

Across the countries for which detailed information was available – the United Kingdom, New Zealand, Australia, and the Netherlands – the decision of whether or not to implement statutory professional regulation is fundamentally based on risk of harm to the public. In assessing risk and other key criteria, these countries all focus on transparency and consistency. For professions that do not meet the required criteria and therefore are not regulated, New Zealand and Australia have national codes of practice that all health and social care professionals – regulated or not – must adhere to. The United Kingdom and the Netherlands provide alternatives to statutory regulation, in the form of voluntary accredited registers in the United Kingdom and legally protected academic titles in the Netherlands. Notably, both national codes of practice and alternatives to statutory regulation could be used in combination to ensure that unregulated health and social care professionals practise safely.

All four countries have invested significant time and resources into developing their processes and criteria for deciding which professions to regulate. The risk-based approaches to proportionality that have been implemented in the United Kingdom, New Zealand, and Australia demonstrate that proportional regulation is not only a European challenge, but a global one. Ultimately, professional regulation aims to protect the public, and countries across the world are striving to ensure that both legislation and practice reflect this. By learning from other countries' approaches, we can move towards a more proportionate system in Ireland, one that both ensures patient safety and allows health and social care professionals to excel in the critical role that they play in society.

1 Introduction

1.1 Policy context

Ireland's approach to professional regulation in the health and social care arena has been established over the past 150 years. Sláintecare's call for a health system that ensures patient safe and meets the needs of the population presents an opportunity to consider how professional regulation can be improved, in order to ensure the highest quality of care for the citizens of Ireland. The Department of Health commissioned this evidence brief so that these efforts can be informed by approaches in other countries to regulating health and social care professions. Understanding international approaches to professional regulation can help us move towards a more proportionate system of regulation that ensures public protection, quality service provision, ethical practice, accountability, efficiency, and transparency.

1.2 Research question

This evidence brief addressed the following research question:

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The following sub-questions were explored:

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2 Methods

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3 UK

The United Kingdom (UK) has a population of 66 million people, 84% of whom live in England, 8% in Scotland, 5% in Wales, and 3% in Northern Ireland.[1] All UK residents are entitled to free public healthcare through the National Health Service (NHS), including hospital, physician, and mental health care.[2] The NHS is primarily funded through general taxation; however, approximately 20% of its budget comes from national insurance, which is a payroll tax paid by employees and employers. Government agencies allocate funds to and oversee local bodies, which govern and pay for care delivery at the local level. In England, these local bodies are referred to as clinical commissioning groups; in Scotland and Wales, regional health boards serve this function; and in Northern Ireland, the Health and Social Care Board is responsible for commissioning services to meet the needs of its population.[2]

There are approximately 1.5 million people in the UK who are registered to practise in a health or social care profession that is regulated by statute.[3] The UK's model of professional regulation is based on a system of self-regulation which, according to the Department of Health and Social Care, has historically "lacked independence and transparency".[3 p6] In an effort to create a more independent system of regulation, there has been a "seismic shift" away from self-regulation.[4 p3] This has been implemented through a series of reforms that began in the early 2000s. The UK Government has announced that further reforms through secondary legislation are forthcoming, in order to ensure that professional regulation "delivers public protection in a modern and effective way".[5 p64]

3.1 Legislation

3.1.1 Current legislation

Responsibility for legislation regarding professional regulation rests with the UK Parliament and the devolved governments of Scotland and Northern Ireland. The UK Parliament is responsible for the regulation of health and social care professions in England and Wales.[3] In Northern Ireland, this responsibility is devolved to the Northern Ireland Assembly. In Scotland, it is devolved to the Scottish Parliament for health and social care professionals who entered regulation after the passing of the Scotland Act 1998.[3] For the purpose of this report, we will focus on legislation and reforms governing professional regulation that have been enacted by the UK Parliament.

Statutory regulation governing protected professional titles in the UK is currently underpinned by the the National Health Service Reform and Health Care Professions Act 2002,[6] the Health and Social Care Act 2008,[7] and the Health and Social Care Act 2012.[8] The National Health Service Reform and Health Care Professions Act 2002 resulted in the creation of the Professional Standards Authority, an independent public body that oversees professional regulatory bodies and is accountable to Parliament.[6] The Health and Social Care Act 2008 created the Care Quality Commission, which has the power to suspend or cancel the registration of health and social care professionals found guilty of relevant offences.[7] In addition, the Health and Social Care Act 2008 eliminated elected professional majorities on the governing councils of regulatory bodies.[7] The Health and Social Care Act 2012 gave the Professional Standards Authority the power to establish a voluntary accreditation scheme for unregulated professions and to advise the UK Government regarding appointments to the councils of regulatory bodies.[8]

In addition to statutory regulation governing protected professional titles, legislation in the UK restricts certain activities to service providers who are fit to carry out the activity.[9] The following activities are regulated in the UK:[9]

- Accommodation for persons who require nursing or personal care
- Accommodation for persons who require treatment for substance misuse
- Assessment of, or medical treatment (other than surgical procedures) for, a mental disorder affecting a person in a hospital where that person is detained under the Mental Health Act 1983

- Diagnostic and screening procedures
- Family planning services
- Management of supply of blood and blood-derived products
- Maternity and midwifery services
- Nursing care
- Personal care
- Services in slimming clinics
- Surgical procedures
- Termination of pregnancies
- Transport services, triage, and medical advice provided remotely, and
- Treatment of disease, disorder, or injury.

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 restricts these activities to service providers who: are of good character; are able, by reason of their health, after reasonable adjustments are made, to properly perform tasks; and have the necessary qualifications, skills, and experience.[9]

3.1.2 Justification for legislative reforms

3.1.2.1 National Health Service Reform and Health Care Professions Act 2002

The formation of the Professional Standards Authority in 2003, following the enactment of the National Health Service Reform and Health Care Professions Act 2002, signalled the UK's first significant shift away from self-regulation. The Professional Standards Authority is accountable to Parliament and oversees regulators. The UK's regulatory structure for health and social care professions was historically firmly grounded in self-regulation, with high levels of autonomy for professions and minimal legislative oversight.[10] Prior to the establishment of the Professional Standards Authority, general oversight of regulators was carried out by the UK's Department of Health and Social Care. However, a need was identified for a body to perform the role of regulating the regulators in "a more systematic manner" than was possible through the Department of Health and Social Care.[4 p192]

Waring *et al.* (2010) have attributed this initial shift towards "state-directed bureaucratic regulation"[11 p551] to three key factors: the pressures of market liberalisation and new public management reforms; changing ideologies and public attitudes towards expertise and risk; and, most significantly according to the authors, high-profile public failures of self-regulation.[11] The Law Commissions – a group of independent statutory bodies that conduct research and consultations regarding legislation and make recommendations for consideration by Parliament[12] – published a joint consultation paper in 2012 which agreed with Waring and colleagues.[4] The Law Commissions' report stated that these "three sources of pressure…undermined the legitimacy of self-regulation and enabled this shift". [4 p3] In particular, the report noted that major scandals in the UK were followed by inquiries whose final reports "criticised self-regulation as self-serving and lacking transparency and accountability, and cast serious doubts on the capacity of a profession to regulate itself satisfactorily".[4 p5]

In order to address the failures of self-regulation, the UK Government's first step was to establish the Professional Standards Authority, thereby creating a meta-regulatory framework. This has allowed a greater level of State control over professional bodies and regulated professions, in order to ensure public safety and minimise risk. The key functions of the Professional Standards Authority, as laid out in the National Health Service Reform and Health Care Professions Act 2002, were to promote the interests of patients and the public in relation to the performance of regulators; promote best

regulatory practice; formulate principles relating to professional self-regulation and encourage regulatory bodies to conform to them; and promote cooperation between regulatory bodies.[6]

3.1.2.2 Health and Social Care Act 2008

The Health and Social Care Act 2008 was implemented following a white paper that was published in 2007: *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century*.[13] This white paper came in the wake of a series of scandals that highlighted failures in the regulatory system and two major reviews published by the Department of Health and Social Care: *Good Doctors, Safer Patients*[14] and *The Regulation of the Non-Medical Healthcare Professions: A Review by the Department of Health*.[15] Notably, the 2007 *Trust, Assurance and Safety* white paper clarified that its purpose was not only to address concerns about the extreme behaviours of a select few health and social care professionals, but primarily to set out a future strategy for sustaining confidence in all health and social care professionals.[13] In particular, the white paper noted the need to ensure that regulation effectively preserves trust in professionalism, protects the public interest, and ensures accountability.[13] It also laid out several fundamental principles for professional regulation, including independence, accountability, proportionality, and flexibility.[13]

Many of the proposed reforms from the 2007 white paper were implemented in the Health and Social Care Act 2008.[7] One of the most influential changes made by the Health and Social Care Act 2008, which fundamentally altered regulation in the UK, was the elimination of elected professional majorities on the governing councils of regulatory bodies.[7] Previously, professionals had formed a majority on all regulatory governing councils. Indeed, in 2007, professional membership on most regulatory councils was approximately 60–70%.[4] The Health and Social Care Act 2008 stipulated that, at a minimum, parity of membership between professional and lay members would be required.[7] The rationale for this was described as follows in the 2007 white paper:

> Patients, the public and health professionals need to be able to take it for granted that the councils act dispassionately and without undue regard to any one particular interest, pressure or influence. This will ensure that the regulators are not only independent in their actions, but, just as critically, that they are seen to be independent in their actions. Doubts based on perceived partiality have threatened to undermine patient, public and professional trust in a number of the regulators over many decades.[13 p23]

Fundamentally, the existence of professional majorities was seen as having undermined the councils' independence.[13] The Health and Social Care Act 2008 also enabled a lay majority to be imposed on councils,[7] but this power has yet to be used.[10]

The 2007 white paper also recommended that the election process for council members, whereby professionals voted on council membership, be eliminated.[13] The white paper noted that because patients and the public could not participate in the election process, "the perception will remain that their own interests are at risk of being given less weight".[13 p26] As a result, the Health and Social Care Act 2008 eliminated elections for council membership, and this was replaced by appointments by the Appointments Commission.[7] When the Appointments Commission was abolished in 2012, the Privy Council began making these appointments.[10] The Privy Council is a body whose function is to advise the Queen.[16] Membership is mostly made up of senior politicians who are current or former members of either the House of Commons or the House of Lords.[16]

The Health and Social Care Act 2008 also sought to increase the independence of the Professional Standards Authority. Regulators would no longer nominate members to the council of the Professional Standards Authority.[7] Instead, the council of the Professional Standards Authority is currently made up of:[17]

- A Chair appointed by the Privy Council
- Three non-executive members: one appointed by the Scottish Ministers, one appointed by the Welsh Ministers, and the third appointed by the Department of Health, Social Services and Public Safety in Northern Ireland
- Three non-executive members appointed by the Privy Council, and

- One executive member appointed by the Professional Standards Authority's council itself.

Additionally, the Health and Social Care Act 2008 required that the Professional Standards Authority report annually on its own performance as well as the performance of each regulatory body.[7]

Finally, the Health and Social Care Act 2008 created the Care Quality Commission, a body responsible for regulating healthcare services, including hospitals and clinics, as well as home care, community, and mental health services.[7] The Care Quality Commission has the power to suspend or cancel the registration of health and social care professionals found guilty of relevant offences.[7]

3.1.2.3 Health and Social Care Act 2012

The Health and Social Care Act 2012 followed a 2011 Department of Health and Social Care report entitled *Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers*.[18] The report advised the UK Parliament that further professions should only be regulated in exceptional circumstances, and that a voluntary register should be established under the Professional Standards Authority for unregulated professions. The Health and Social Care Act 2012 enacted this, and the Professional Standards Authority created a voluntary register programme for unregulated professions – called the accredited register programme – in 2013.[19] The *Enabling Excellence* report also noted that further professions should only be regulated when there is a compelling case that voluntary registers are insufficient to manage the risk.[18]

The *Enabling Excellence* report highlighted that the Health and Social Care Act 2008 was effective in increasing the independence of the regulators to protect the public interest.[18] However, it also noted that the complex web of legislation governing regulatory bodies constrained their ability to adapt and modernise. Additionally, it stated that the regulatory framework was too expensive, and put forward an aim to "simplify the regulatory structure in order to deliver a more flexible system offering better value for money for both registrants and the public".[18 p5] This would be achieved by using the "minimum regulatory force required to achieve the desired result", particularly through the accredited register programme for unregulated professions.[18 p8] This aligned with the Professional Standards Authority's policy of "right-touch regulation".[20] Right-touch regulation emerged from the UK Better Regulation Executive's principles of good regulation, which stated that regulation must be proportionate, consistent, targeted, transparent, and accountable.[21] The Professional Standards Authority added a sixth principle and stated that regulation must also be agile.[20] One suggestion coming out of the *Enabling Excellence* report regarding simplifying the regulatory framework was that the UK Government consider merging regulators as an efficiency and cost-saving mechanism;[18] however, this has yet to be enacted.

The *Enabling Excellence* report also called for an increase in autonomy for regulators, however the report noted that this would require a "commensurate strengthening of [regulators'] public and parliamentary accountability for their performance".[18 p13] The report suggested increasing the role of the Professional Standards Authority in order to ensure accountability among regulators. It suggested that the Professional Standards Authority would be able to provide advice to the UK Government on regulatory matters, including how to ensure that appointments to regulatory councils were effective and transparent.[18] The Health and Social Care Act 2012 enacted these suggestions.

The *Enabling Excellence* report also recommended that the Professional Standards Authority be funded exclusively through a levy on the regulatory bodies (which are in turn funded by professional members). The UK Government's policy intention in no longer directly funding the Professional Standards Authority was to reduce costs to the taxpayer.[10] This was enacted in the Health and Social Care Act 2012, and it had the effect of making the Professional Standards Authority more independent. It would no longer come under the sphere of the Department of Health and Social Care, and appointments to the Professional Standards Authority, which had been made by the Secretary of State for Health, would now be made by the Privy Council. However, the Professional Standards Authority would continue to be accountable to the Parliament through its annual reports.[10]

3.1.2.4 Forthcoming reforms

Alongside the *Enabling Excellence* report, the UK Government asked the Law Commissions to jointly undertake a review of existing legislation and to develop a draft bill for consultation focusing on how to modernise and simplify professional regulation.[4] The Law Commissions are a group of independent statutory bodies that conduct research and consultations regarding legislation and make recommendations for consideration by Parliament.[12] In response to the Government's request, the Law Commissions published a report for public consultation in 2012 regarding professional regulation, and in 2014 they published their final report, including a full draft bill.[22] The Government subsequently ran a public consultation in 2017,[3] in which major changes to professional regulation were proposed based on the Law Commissions' recommendations. These included:[3]

- Reducing the role of the Privy Council role in professional regulation, with the regulatory bodies being given greater powers to set their own rules and operating procedures
- Making regulatory bodies more accountable to the Scottish Parliament, the National Assembly for Wales, and the Northern Irish Assembly, in addition to the UK Parliament
- Requiring that membership of a fitness to practise panel should consist of at least one lay and one registrant member, and prohibiting a registrant majority on fitness to practise panels
- Expanding the list of persons prohibited from sitting on a fitness to practise panel to ensure separation between the investigation and adjudication of fitness to practise cases
- Reducing the number of regulatory bodies
- Establishing barring schemes, whereby prohibition orders could be used as an alternative to statutory regulation for unregulated health and care workers
- Providing the Professional Standards Authority with the statutory role of advising the UK Government on which health and social care professions should be regulated

In response to the public consultation, in 2019 the UK Government stated its intention to take forward legislative changes to the regulators' fitness to practise processes and operating framework.[23] It noted that at present there is little evidence to support the use of prohibition orders as an alternative to statutory regulation for unregulated health and care workers.[23] The Government also stated that it believes that a case can be made for fewer regulatory bodies,[23] and a white paper published in February of 2021 proposed establishing the power to abolish individual regulatory bodies.[5] The 2021 white paper also proposed establishing the statutory power to remove a profession from regulation (see Section 3.2.4.4 for details). In 2019 the UK Government also said that it believes that the Professional Standards Authority is best placed to provide independent advice on which groups of health professionals should be regulated (see Section 3.3.2 for details).[23] While none of these proposals have been enacted in legislation, it is anticipated that reforms are forthcoming following the February 2021 white paper.[5]

3.2 Organisational structure and regulatory status of professions

3.2.1 Healthcare regulators

The Care Quality Commission regulates health and adult social care in England.[24] The equivalent bodies across the UK are Care Inspectorate Wales, the Regulation and Quality Improvement Authority in Northern Ireland, and, in Scotland, Care Inspectorate as well as Healthcare Improvement Scotland. All providers – including institutions, individual partnerships, and sole practitioners – must be registered with the relevant authority. These bodies monitor performance using nationally set quality standards and investigate individual providers when concerns are raised by patients and others.[24]

3.2.2 Professional Standards Authority

The Professional Standards Authority is a meta-regulator that oversees the work of 10 regulatory bodies for regulated professions and 25 voluntary accredited registers for unregulated professions (see Section 3.2.3 for complete lists of regulatory bodies and accredited registers).[25] It is an independent public body and is accountable to Parliament. When it was created in 2003, the Professional Standards Authority was called the Council for the Regulation of Health Care Professions. It was subsequently renamed the Council for Healthcare Regulatory Excellence in 2008, and again renamed the Professional Standards Authority in 2012.[25]

It contains three directorates: Scrutiny and Quality, which oversees regulators; Standards and Policy, which develops standards and regulatory policy; and Operations and Governance, which manages how its services are delivered.[25] It undertakes annual performance reviews of all regulatory bodies and accredited registers that it oversees, and the performance reviews of regulators are used by the UK Government in accountability hearings to assess the performance of regulators. For regulatory bodies, performance reviews are based on the Professional Standards Authority's *Standards of Good Regulation* (see Section 3.2.3.4 for details).[26] Accredited registers are assessed using its *Standards for Accredited Registers* (see Section 3.2.4.1.2 for details).[27] Notably, the Professional Standards Authority consults the public and issues responses when developing standards or making changes to the performance review process.[25]

The Professional Standards Authority also has the power to perform audits of disciplinary decisions made by regulatory bodies in dealing with complaints regarding individual members.[25] Moreover, if a final fitness to practise decision is not deemed to sufficiently protect the public, it can submit referrals or appeals to the High Court in England and Wales, the Court of Session in Scotland, or the High Court in Northern Ireland.[25] This power to submit referrals or appeals is applied to the imposition of sanctions that are unduly lenient – in other words, a decision not to take disciplinary action or to restore a person to the register that the Professional Standards Authority feels should not have been made. "Undue leniency" was defined in 2004 by the English Court of Appeal as a decision that a disciplinary tribunal could not reasonably have reached given the relevant facts and the object of the disciplinary proceedings, or that was otherwise manifestly inappropriate with regard to the safety of the public and the reputation of the profession.[28] In the court case in which this was defined, the High Court held that the Professional Standards Authority was entitled to refer not only cases where a disciplinary tribunal's sanctions may have been too lenient, but also those where the tribunal may have wrongly concluded that there was no professional misconduct.[28] Notably, the English Court of Appeal further highlighted that this was necessary in order to protect the public even though it may allow closed cases to be reopened.

According to the National Health Service Reform and Health Care Professions Act 2002, the powers of the Professional Standards Authority may include investigating complaints regarding how regulators are functioning and giving directions to regulators requiring that they institute certain rules if the Professional Standards Authority deems it desirable for public safety.[6] However, the UK Government has never made regulations to formally provide the Professional Standards Authority with these powers.[10] In the absence of such regulations, the Professional Standards Authority has carried out a more general function of promoting good practice among regulators and working with regulators to resolve complaints that the Professional Standards Authority receives about regulators.[4]

The Professional Standards Authority also performs a number of other roles related to professional regulation. Namely, it undertakes and disseminates research on best practice in professional regulation; performs investigations regarding professional regulation and specific reviews of regulators as requested by Parliament and health ministers; advises the UK Government regarding appointments to the councils of regulatory bodies and regarding professional regulation more broadly; and conducts specific reviews for other countries and provides other countries with advice on request.[25]

The annual budget of the Professional Standards Authority is approximately GB£4 million. [25] Initially, when the Professional Standards Authority was created, it was funded directly by the

Department of Health and Social Care and by the devolved administrations.[10] However, in an effort to make it more independent from the UK Government, a levy on regulatory bodies was introduced in 2015 in order to fund the Professional Standards Authority.[10] As such, it is now funded through fees paid by regulatory bodies and accredited registers, and by commission fees for advice and research on behalf of Parliament, the Department of Health and Social Care, and other bodies in the UK and internationally.[25] The fees owed by each regulator and accredited register to the Professional Standards Authority are calculated based on the number of professional members in each body.[25]

3.2.3 Regulatory bodies and regulated professions

3.2.3.1 Regulatory bodies

Regulatory bodies register health and social care professionals working in occupations that Parliament has said must be regulated.[29] They are the gatekeepers of the professions that they regulate.[3] However, in addition to overseeing the professionalism of every individual practitioner that they register, regulators are also the "guardians of the ethos and culture of each profession as a whole".[3 p4]

There are 13 regulatory bodies for health and social care professions in the UK. Ten of these are overseen by the Professional Standards Authority:

1. General Chiropractic Council
2. General Dental Council
3. General Medical Council
4. General Optical Council
5. General Osteopathic Council
6. General Pharmaceutical Council
7. Health and Care Professions Council
8. Nursing and Midwifery Council
9. Pharmaceutical Society of Northern Ireland, and
10. Social Work England.

The other three regulatory bodies are overseen directly by the relevant parliament:

1. Northern Ireland Social Care Council
2. Scottish Social Services Council, and
3. Social Care Wales.

The number of registrants that each regulator is responsible for varies widely. For example, the Nursing and Midwifery Council has the largest register, with more than 700,000 nurses and midwives, while the Pharmaceutical Society of Northern Ireland registers approximately 2,500 pharmacists.[29] There are also differences in registration fees between regulators. Regulators with larger numbers of registrants are able to charge smaller registration fees, because the cost of running the regulatory body is spread across more registrants (see Figure 1).[29]

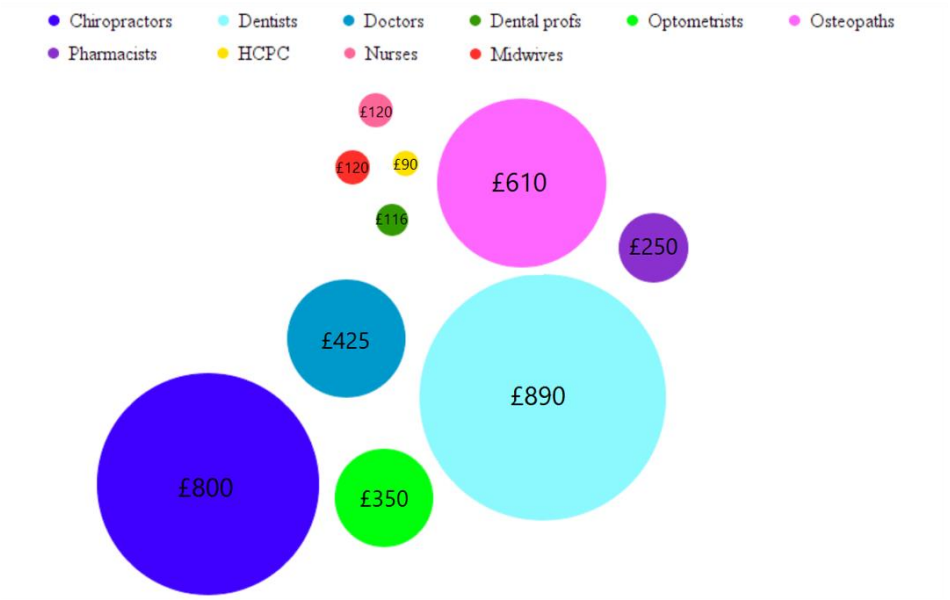

Figure 1 Cost of regulation to registrants (HCPC: Health and Care Professions Council – all HCPC registrants pay same fee, regardless of profession)

Source: Professional Standards Authority, 2018[30]

All regulators have one main objective: to protect the public by ensuring that the professionals whom they register are fit to practise.[29] They are also charged with maintaining public confidence in the profession(s) that they regulate.[29] In order to achieve these overarching objectives, each regulator must:[3]

- Set the outcomes required from undergraduate (and, in some cases, postgraduate) education and training that must be met before registration is granted, as well as inspecting education and training providers
- Set the standards of conduct, performance, and behaviour expected of a registered professional so that professionals deliver care safely and effectively, including updating these standards as required
- Operate a system to ensure that registered professionals continue to meet those standards, that their knowledge and skills are up to date, and that they remain fit to practise
- Keep a public register of qualified professionals who are fit to practise, so that patients and service users know who is and who is not qualified, and
- Investigate complaints and take action in order to restrict the practice of a registered professional where the required standards of conduct, performance, and behaviour are not met.

In addition to these functions, some regulators have other responsibilities. For instance, the General Pharmaceutical Council registers and inspects pharmacies, in addition to registering pharmacists.[29]

The number of professions covered by each regulator varies.[29] The General Chiropractic Council and the General Osteopathic Council each regulate one profession,[29] while the Health and Care Professions Council is the largest regulatory body in the UK, regulating 15 professions.[31]

3.2.3.2 Regulated professions

The health and social care professions that are currently regulated in the UK are shown in Table 1. Regulated professions have protected titles, and it is a criminal offence for a person to:[32]

- Use a protected title to which they are not entitled
- Say falsely that they are on the register of a regulatory body, or

- Say falsely that they have qualifications in a regulated profession.

These are criminal offences whether a person does so clearly or by implication, meaning that an unregistered person may be committing an offence even if they do not use a protected title directly.[32] For instance, if an individual who is not a registered physiotherapist describes the service they provide as physiotherapy, they are committing an offence.[33]

Table 1 Regulated professions in the UK

Profession	Protected title(s)	Regulator
Arts therapists	• Art psychotherapist • Art therapist • Drama therapist • Music therapist	Health and Care Professions Council
Biomedical scientists	• Biomedical scientist	Health and Care Professions Council
Chiropodists/podiatrists	Protected titles: • Chiropodist • Podiatrist Annotations: • Independent prescribing (IP) • Supplementary prescribing (SP) • Prescription-only medicines – administration (POM–A) • Prescription-only medicines – sale/supply (POM–S)	Health and Care Professions Council
Chiropractors	• Chiropractor	General Chiropractic Council
Clinical scientists	• Clinical scientist	Health and Care Professions Council
Dentists, technicians, nurses, hygienists	• Clinical dental technician • Dental hygienist • Dental nurse • Dental practitioner • Dental surgeon • Dental technician • Dental therapist • Dentist • Orthodontic therapist Annotations: • Supplementary prescribing (SP)	General Dental Council

Profession	Protected title(s)	Regulator
Dietitians	• Dietician • Dietitian Annotations: • Supplementary prescribing (SP)	Health and Care Professions Council
Doctors	• Apothecary • Bachelor of medicine • Doctor of medicine • General practitioner • Licentiate in medicine and surgery • Physician • Surgeon	General Medical Council
Hearing aid dispensers	• Hearing aid dispenser	Health and Care Professions Council
Nurses, midwives, and nursing associates	• Midwife • Nurse • Nursing associate	Nursing and Midwifery Council
Occupational therapists	• Occupational therapist	Health and Care Professions Council
Operating department practitioners	• Operating department practitioner	Health and Care Professions Council
Opticians, optometrists, dispensing opticians, and student opticians	• Dispensing optician • Ophthalmic optician • Optician • Optometrist • Student optician	General Optical Council
Orthoptists	• Orthoptist	Health and Care Professions Council
Osteopaths	• Osteopath	General Osteopathic Council
Paramedics	• Paramedic Annotations: • Independent prescribing (IP) • Supplementary prescribing (SP)	Health and Care Professions Council
Pharmacists, pharmacy technicians (England, Wales and Scotland)	• Pharmacist • Pharmacy technician	General Pharmaceutical Council
Pharmacists (Northern Ireland)	• Pharmacist	Pharmaceutical Society of Northern Ireland

Profession	Protected title(s)	Regulator
Physiotherapists	• Physical therapist • Physiotherapist Annotations: • Independent prescribing (IP) • Supplementary prescribing (SP)	Health and Care Professions Council
Practitioner psychologists	• Clinical psychologist • Counselling psychologist • Educational psychologist • Forensic psychologist • Health psychologist • Occupational psychologist • Practitioner psychologist • Registered psychologist • Sport and exercise psychologist	Health and Care Professions Council
Prosthetists/orthotists	• Orthotist • Prosthetist	Health and Care Professions Council
Radiographers	• Diagnostic radiographer • Radiographer • Therapeutic radiographer Annotations: • Independent prescribing (IP) • Supplementary prescribing (SP)	Health and Care Professions Council
Social workers	• Social worker	Social Work England Northern Ireland Social Care Council Scottish Social Services Council Social Care Wales
Speech and language therapists	• Speech and language therapist • Speech therapist	Health and Care Professions Council

Sources: [31][34][35][36][37][38][39][40][41][42][43][44]

3.2.3.3 Professions regulated since 2015

Only one profession has been newly regulated in the UK since 2015 – nursing associates.[45] In 2015, the UK Government announced the creation of the nursing associate role in order to bridge the gap between healthcare assistants and registered nurses.[45] In order to determine the suitability of the nursing associate role for regulation, the Professional Standards Authority assessed the role and the UK Government held a public consultation (see Section 3.3.3 for details).[46] The Government then legislated for nursing associates to be regulated in England, and this came into force in 2020. The Nursing and Midwifery Council is the regulatory body for nursing associates.[45]

3.2.3.4 Standards for regulatory bodies

The Professional Standards Authority assesses the performance of each of the regulators that it oversees on an annual basis using its *Standards of Good Regulation*.[26] The Professional Standards Authority covers 10 of the UK's 13 regulatory bodies, as described in Section 3.2.3.1. The three regulatory bodies that are not overseen by the Professional Standards Authority – the Northern Ireland Social Care Council, the Scottish Social Services Council, and Social Care Wales – are directly overseen by the relevant parliament.

The Professional Standards Authority released an updated version of their *Standards of Good Regulation* in 2019,[26] which came into effect following public consultation and a pilot period. The Standards assess how effectively regulators carry out their core functions: protecting patients and reduce harm; promoting professional standards; and maintaining public confidence in the profession(s) they oversee. Notably, the Standards are informed by the key principles of good regulation – which state that regulation should be:

- Proportionate
- Consistent
- Targeted
- Transparent
- Accountable, and
- Agile.

There are 18 standards that the Professional Standards Authority uses to determine whether or not regulators are effectively carrying out their functions and adhering to the principles of good regulation. These are categorised under five headings: general standards; guidance and standards; education and training; registration; and fitness to practise:[26]

General standards

1. The regulator provides accurate, fully accessible information about its registrants, regulatory requirements, guidance, processes, and decisions.
2. The regulator is clear about its purpose and ensures that its policies are applied appropriately across all its functions and that relevant learning from one area is applied to other areas.
3. The regulator understands the diversity of its registrants and their patients and service users, and of others who interact with the regulator, and ensures that its processes do not impose inappropriate barriers or otherwise disadvantage people with protected characteristics (which are defined in the Equality Act 2010 as age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation).
4. The regulator reports on its performance, addresses concerns identified about it, and considers the implications for it of findings of public inquiries and other relevant reports about healthcare regulatory issues.
5. The regulator consults and works with all relevant stakeholders across all of its functions to identify and manage risks to the public in respect of its registrants.

Guidance and standards

6. The regulator maintains up-to-date standards for registrants, which are kept under review and which prioritise patient- and service-user-centred care and safety.
7. The regulator provides guidance to help registrants apply its standards and ensures that this guidance is up to date, addresses emerging areas of risk, and prioritises patient- and service-user-centred care and safety.

Education and training

8. The regulator maintains up-to-date standards for education and training, which are kept under review and which prioritise patient and service user care and safety.
9. The regulator has a proportionate and transparent mechanism for assuring itself that the educational providers and programmes it oversees are delivering students and trainees that meet the regulator's requirements for registration, and takes action where its assurance activities identify either concerns about training or wider patient safety concerns.

Registration

10. The regulator maintains and publishes an accurate register of those who meet its requirements, including any restrictions on their practice.
11. The process for registration – including appeals – operates proportionately, fairly, and efficiently, with decisions being clearly explained.
12. Risk of harm to the public and of damage to public confidence in the profession related to non-registrants using a protected title or undertaking a protected act is managed in a proportionate and risk-based manner.
13. The regulator has proportionate requirements to satisfy itself that registrants continue to be fit to practise.

Fitness to practise

14. The regulator enables anyone to raise a concern about a registrant.
15. The regulator's process for examining and investigating cases is fair and proportionate, deals with cases as quickly as is consistent with a fair resolution of the case, and ensures that appropriate evidence is available to support decision-makers to reach a fair decision that protects the public at each stage of the process.
16. The regulator ensures that all decisions are made in accordance with its processes; are proportionate, consistent, and fair; take account of the statutory objectives, the regulator's standards, and the relevant case law; and prioritise patient and service user safety.
17. The regulator identifies and prioritises all cases which suggest a serious risk to the safety of patients or service users and seeks interim orders where appropriate.
18. All parties to a complaint are supported to participate effectively in the process.

The evidence that is used to assess each standard is outlined in detail in the Professional Standards Authority's document *Standards of Good Regulation: Evidence Framework.*[47] The results of annual reviews are publicly available on the Professional Standards Authority's website, and they are used by the Professional Standards Authority and by the UK Government to determine areas in which regulators need to improve.[26]

3.2.4 Unregulated professions

3.2.4.1 Ensuring safe practice

Employer controls, credentialling, and the accredited register programme run by the Professional Standards Authority are all used to ensure safe practice among unregulated professions in the UK.[48] Employer controls refer to any requirements that employers put in place to provide assurance of minimum standards of practice, including training, qualifications, codes of conduct, supervision, and appraisal.[48] Credentialling validates the identity and legitimacy of unregulated professions with access to healthcare settings.[48] Accredited registers are voluntary registers of health and social care professionals who are not regulated by law.[45] Accredited registers are described in detail below, as they are fundamental to the UK's approach to overseeing unregulated health and social care professions.

3.2.4.1.1 Accredited registers

The Health and Social Care Act 2012 established the accredited register programme under the Professional Standards Authority.[8] It is important to note that practitioners working in professions that are covered by an accredited register are free to practise without joining a register, because accredited registers are voluntary.[45]

The Professional Standards Authority awards an accredited register quality mark to professional bodies who apply and meet its required standards; this quality mark is valid for 12 months and is reviewed on an annual basis.[49] The Professional Standards Authority currently oversees 25 accredited registers:[49]

1. Academy for Healthcare Science
2. Alliance of Private Sector Practitioners
3. Association of Child Psychotherapists
4. Association of Christian Counsellors
5. British Acupuncture Council
6. British Association for Counselling and Psychotherapy
7. British Association of Play Therapists
8. British Association of Sport Rehabilitators and Trainers
9. British Psychoanalytic Council
10. Complementary and Natural Healthcare Council
11. Counselling & Psychotherapy in Scotland
12. Federation of Holistic Therapists
13. Human Givens Institute
14. International Federation of Aromatherapists
15. Joint Council for Cosmetic Practitioners
16. National Counselling Society
17. National Hypnotherapy Society
18. Play Therapy UK
19. Register of Clinical Technologists
20. Registration Council for Clinical Physiologists
21. Save Face
22. UK Association for Humanistic Psychology Practitioners
23. UK Board of Healthcare Chaplaincy
24. UK Council for Psychotherapy, and
25. UK Public Health Register.

3.2.4.1.2 Standards for accredited registers

The Professional Standards Authority assesses each accredited register annually using 11 standards. Each accredited register must:[27]

1. Hold a voluntary register
2. Demonstrate commitment to protecting the public

3. Take effective action to mitigate risks to the public
4. Have sufficient finance to fulfil its functions
5. Demonstrate its ability to manage the register effectively
6. Demonstrate that there is a defined knowledge base underpinning the health and social care occupation(s) covered by its register or demonstrate how it is actively developing one
7. Ensure that the governance of its voluntary register is directed towards protecting the public
8. Set and require appropriate standards of personal behaviour, technical competence, and business practice
9. Set appropriate educational standards, require that its registrants meet educational standards, and assures itself that they do
10. Maintain a register that is accurate, easily accessible to the public, and supports all those using it to make informed decisions, and
11. Provide clear information about its arrangements for handling complaints and concerns about its registrants, and about itself as an organisation.

Organisations have been suspended from the accredited register programme if they have not met these standards. For example, the Society of Homeopaths was first added as an accredited register in 2014, but in 2019 it failed to meet the required standards.[50] It was given until the end of 2020 to meet specific conditions set by the Professional Standards Authority in order to adhere to the standards, but it failed to do so and has been suspended from the accredited register programme as of January 2021. The suspension will be reviewed in January 2022.[50]

3.2.4.2 Professions that have sought regulation but have not been regulated

The following professions have sought regulation but have not been regulated in the UK:

- Advanced critical care practitioners
- Clinical perfusionists
- Clinical physiologists
- Clinical technologists
- Dance movement psychotherapists/dance movement therapists
- Genetic counsellors
- Herbal medical practitioners
- Maxillofacial prosthetists and technologists
- Medical illustrators/clinical photographers
- Psychotherapists and counsellors
- Public health specialists
- Sonographers
- Sports therapists, and
- Surgical care practitioners.

For some of these professions, public consultations were held, and regulation was not deemed suitable as a result. Consultations were held for psychotherapists and counsellors,[51] public health specialists,[51] surgical care practitioners,[52] and advanced critical care practitioners.[52] The remaining professions listed above did not reach the public consultation stage, because the Department of Health and Social Care did not consider this necessary as there was not a sufficiently strong case for regulation.

3.2.4.3 Challenges in court

There is no evidence in the literature that there have been challenges in court in the UK by professions that have applied to be regulated but have not been regulated.

3.2.4.4 Professions that have been deregulated or have had their level of regulation minimised

According to the available literature, there are no professions in the UK that have been deregulated nor any professions that have had their level of regulation minimised. However, in a 2021 white paper on health and social care, the UK Government proposed establishing the statutory power to remove a profession from regulation.[5] The white paper noted that the expectation is that the vast majority of professionals will always be subject to statutory regulation. However, the UK Government said that "over time and with changing technology the risk profile of a given profession may change, and while regulation may be necessary now to protect the public, this may not be the case in the future."[5 p63]

3.2.4.5 Professions under consideration for regulation

There are two professions currently under consideration for regulation in the UK: physician associates and anaesthesia associates. Following public consultation, the UK Government announced formal approval for regulating both professions in 2019.[52] The Department of Health and Social Care formally asked the General Medical Council to regulate both physician associates and anaesthesia associates, and the General Medical Council is currently establishing the processes and policies required to do so.[53] Regulation of the two professions is dependent on new legislation, which has yet to be enacted. However, the General Medical Council has said that it expects regulation of physician associates and anaesthesia associates to begin in the second half of 2022.[53]

Additionally, the white paper published in February of 2021 noted the UK Government's intention to clarify the scope of professions that can be regulated according to Section 60 of the Health Act 1999[54] so that senior NHS managers and leaders could be regulated in the future if this were deemed appropriate.[5] The UK Government stated that while there are no formal plans to statutorily regulate senior managers and leaders, a review of the fit-and-proper-person test (the Kark Review),[55] published in 2019, recommended putting in place stronger measures to ensure that senior health managers and leaders have the right skills, behaviours, and competencies.
The Kark Review also recommended implementing a means by which those who are unsuitable to work in such roles are unable to do so, and NHS Improvement is currently considering how best to achieve this through non-statutory means. However, the UK Government intends to establish the statutory means to prevent those who are unsuitable to work in senior NHS managerial and leadership roles from doing so, in case this is necessary in the future to address the concerns raised in the Kark Review. The UK Government noted that it will continue to ensure that regulation is only used where public protection cannot be assured in other ways.[5]

3.3 Process for deciding who to regulate

In the UK, the decision of whether or not to regulate a new health or social care profession ultimately rests with the Department of Health and Social Care. However, there is a statutory requirement for public consultation prior to regulation of a new profession, and a point-by-point response from Government to questions posed in public consultation is also required.[56]

3.3.1 Health and Care Professions Council's power to recommend

The Health and Care Professions Council is the only regulator that has had the legislative power to recommend to the Department of Health and Social Care that a profession should be regulated.[51] It is the largest regulator in the UK (see Section 3.2.3.1). It made recommendations to the Department of Health and Social Care from 2003 to 2011, during which time it proposed that 11 professions be regulated.[51] Two of these professions – operating department practitioners and applied psychologists – were subsequently regulated following public consultation, and they are overseen by the Health and Care Professions Council.[51] The remaining nine professions were not regulated.[51]

In 2011, the Health and Care Professions Council closed the application process for aspirant professional groups.[51] This came in the wake of the Department of Health and Social Care's 2011 report *Enabling Excellence: Autonomy and Accountability for Healthcare Workers, Social Workers and Social Care Workers*.[18] The report stated that further professions would only be regulated in exceptional circumstances, and therefore the Health and Care Professions Council believed that it would not be constructive to continue making recommendations about the regulation of further professions "when it was clear that these were highly unlikely to result in the group's regulation".[51 p7] The Health and Care Professions Council further noted that the completion of an application for regulation was a resource-intensive process for the professional groups involved, and one that raised expectations about likely future regulation.[51]

The Law Commissions, in their 2014 review of professional regulation legislation, proposed that the Health and Care Professions Council's statutory power to make recommendations regarding the regulation of new professions should be removed.[22] The UK Government has supported this proposal, stating that because the Health and Care Professions Council was established as a multi-profession regulator and has often assumed regulatory oversight of new professions, it could be seen to have a vested interest in expanding its registrant base.[23] The Health and Care Professions Council's statutory power to make recommendations has yet to be removed; however, as previously described, is has not made any recommendations since 2011. Forthcoming reforms may formally remove the power.

3.3.2 Current administrative approach to regulating new professions

Currently, beyond regulation being up to the discretion of the Department of Health and Social Care and the requirement for public consultation, a statutory process for regulating new professions in the UK does not yet exist. Indeed, the UK Government has noted the absence to date of a common set of criteria to determine the appropriate level of regulatory oversight required for health and social care professionals.[23] The UK Government has acknowledged that this has resulted in health and social care professionals being "brought into statutory regulation on what can appear to be an ad hoc or inconsistent basis."[23] Yet, the UK Government has also clarified that, moving forward, the decision to regulate a health profession must be based on risk of harm, with statutory regulation only used where patient protection cannot be achieved in other ways.[23]

Recent practice provides insight into the UK Government's current administrative approach to deciding whether or not a regulate a new profession. For instance, the two professions described in Section 3.2.4.5 that have been recommended for regulation by the Department of Health and Social Care and are awaiting regulatory legislation – physician associates and anaesthesia associates – were part of a consultation involving four medical associate professions that were considered (including advanced critical care practitioners and surgical care practitioners).[52] For these four roles, the Secretary of State for Health and Social Care announced the UK Government's intention to consult the public regarding whether the professions should be regulated. The consultation asked respondents for evidence on the most proportionate level of regulation for each profession and on which healthcare regulator would be suitable to take on responsibility for the profession if regulation were deemed appropriate.[52]

Health Education England, a public body under the NHS, then worked with representatives of the professions to collate information on the scopes of practice for each role.[52] The Professional Standards Authority's tool for assessing risk and suitability for regulation – *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm* – was then used to assess each of the four professions.[48] This tool is described in Section 3.3.3.

The Department of Health and Social Care then considered the responses to the public consultation, the risk assessment results, and a number of additional factors, including the current number of professionals in each role and their projected growth, entry routes, and the level of professional assurance currently in place.[52] As a result, the Department of Health and Social Care recommended that physician associates and anaesthesia associates be regulated, but did not recommend that advanced critical care practitioners or surgical care practitioners be regulated.[52]

As described in Section 3.1.2.4, in 2017, the UK Government held a public consultation regarding a number of proposed changes to regulation.[3] One of these was a proposal that the Professional Standards Authority take on the statutory role of advising the UK Government on which health and social care professions should be regulated.[3] There were 819 responses to this proposal, and there was no clear consensus, with similar percentages of respondents agreeing (46%) and disagreeing (43%).[23] In response to the results of the public consultation, the UK Government stated that it believes that the Professional Standards Authority is best placed to provide independent advice on which groups of health professionals should be regulated.[23]

The UK Government acknowledged the link between the Professional Standards Authority assessing new groups for regulation and its power to accredit voluntary registers and charge for this accreditation, which was noted by some respondents to the public consultation. Professions that are not statutorily regulated may seek to be added to the Professional Standards Authority's accredited register, and this could create an incentive for the Professional Standards Authority to recommend that such groups should not be subject to statutory regulation. However, the UK Government does not believe this would amount to a conflict of interest, because it is mitigated by the fact that the process for regulating professions is transparent in that it is subject to the statutory requirement for public consultation.[23]

3.3.3 Right-touch assurance

The Professional Standards Authority uses *Right-touch assurance: A methodology for assessing and assuring occupational risk of harm* to assess the appropriate level of regulation for professional groups.[48] The criteria set out in this publication are used to establish an occupation risk profile and to assess specific extrinsic factors. The occupation risk profile is based on three key factors:[48]

- Intervention/complexity – potential for harm caused by professional practice and interventions
- Context – potential risks in the environments in which the intervention takes place (including patients' and service users' homes, where relevant), and
- Agency/vulnerability – ability of service users to exercise control over their care and circumstances (e.g. children, people with disabilities).

The assessment of extrinsic factors considers the following criteria:[48]

- Scale of risk – size of actual/potential practitioner group and size of actual/potential patient or service user group
- Means of assurance – options available to manage the risk of harm, e.g. supervision by a regulated professional or employment controls
- Sector impact – impact of assurance mechanisms on the cost and supply of the occupation, quality of services, and innovation
- Risk perception – need for assurance from employers and probable effects on public confidence, and
- Unintended consequences – implications of identifiable unintended consequences.

Using the results of the occupation risk profile and the assessment of extrinsic factors, the Professional Standards Authority then makes a recommendation for the appropriate level of regulation for a profession.[48] As described in Section 3.3.2, the Professional Standards Authority has previously been commissioned to use the right-touch assurance tool to assess the appropriate level of regulation for health and social care professions. In addition to the four medical associate professions described in Section 3.3.2 that were assessed using the right-touch assurance tool,[52] sonographers have also been assessed using the tool,[57] as well as nursing associates.[58]

Sonographers were not recommended for regulation because most of those practising as sonographers are already regulated in other professional roles, primarily as radiographers.[57] For nursing associates, the Professional Standards Authority highlighted the lack of evidence for the role, given that it was an entirely new profession.[58] The nursing associate role was created in 2015, and

the Professional Standards Authority's report was published in 2016. The scope of the role of nursing associate had not been defined to the level that was required to adequately assess the risks of harm, and data regarding the spread of the workforce across different settings were not available.[58] Therefore, the Professional Standards Authority's recommendation was to register, but not yet regulate, the role.[58] However, following public consultation, the UK Government moved forward with regulating nursing associates in England, and this came into force in 2020.[45]

If the UK Government moves forward with its proposal that the Professional Standards Authority take on the statutory role of advising the UK Government on which health and social care professions should be regulated, the intention is that the right-touch assurance tool would form the basis of the Professional Standards Authority's recommendations.[23] However, the decision about whether a new group should be regulated would ultimately remain with the Department of Health and Social Care.[23]

4 New Zealand

In 2019, the population of New Zealand was estimated to be approximately 4.9 million. The standard of living in New Zealand is generally high, ranking fifth in the Human Development Index in 2011.[59] New Zealand has a long history of being a progressive country, and it is currently one of the highest-performing countries in the Organisation for Economic Co-operation and Development's Better Life Index, with 88% of New Zealand's residents self-reporting good health.[60]

New Zealand has had universal health coverage since 1938. Healthcare is financed mainly through government sources. The balance comes from direct payments by service users, private health insurance premiums, and a small contribution from non-profit organisations. Twenty district health boards oversee the planning, purchasing, and provision of health services at the local level. Patients pay co-payments on some services and products, and approximately one-third of the population has private insurance to fund the cost of co-payments and services not covered by the public system.

The Health Practitioners Competence Assurance Act 2003 governs the regulation of health professions in New Zealand. In 2015, it was estimated that New Zealand had approximately 97,800 regulated health professionals.[61] Each regulated health profession has a regulatory authority responsible for setting scopes of practice for each profession and reviewing and promoting health professionals' competence.[62] In addition, to protect consumer rights, all health professionals (regulated or not) must adhere to the Code of Health and Disability Services Consumers' Rights.[63]

4.1 Legislation

4.1.1 Current legislation

4.1.1.1 Health Practitioners Competence Assurance Act 2003

The Health Practitioners Competence Assurance Act 2003 (hereafter referred to as the Health Practitioners Act) established a single regulatory framework for health professionals. The primary objective of the Health Practitioners Act is "to protect the health and safety of members of the public by providing for mechanisms to ensure that health professionals are competent and fit to practise their professions".[64 p12]

The Health Practitioners Act ensures that critical public protections are in place through the following mechanisms:[65]

- Only health professionals registered under the Act, or who are practising a profession that is regulated by the Act, are granted the use of professional titles protected by the Act.
- Only registered health professionals may perform activities associated with their scope of practice.
- When issuing annual practising certificates, regulatory authorities are responsible for certifying that a health professional is competent to practise in their scope of practice.
- Restricted activities can only be performed by registered health professionals as specified in the Act.

Sections 115 and 116 of the Health Practitioners Act establish a means to extend the Act to include new health professions. Section 115 states that the Minister of Health can recommend to the Governor-General that the Act be extended to regulate a new health profession. Only one profession, paramedicine, has been added to the list of regulated health professions since the Health Practitioners Act was passed in 2003.[66] Paramedics were regulated in 2020.[66]

Section 9 of the Health Practitioners Act restricts the performance of several activities by registered health professionals to protect the public from harm. These activities include:[64]

- Surgical or operative procedures below the gingival margin or the skin's surface, the mucous membranes, or the teeth

- Clinical procedures involved in the insertion and maintenance of fixed and removable orthodontic or oral and maxillofacial prosthetic appliances
- Prescribing of enteral or parenteral nutrition where the feed is administered through a tube into the gut or through a central venous catheter
- Prescribing of an ophthalmic appliance, optical appliance, or ophthalmic medical device intended for remedial or cosmetic purposes or for correcting a defect of sight, and
- Applying high-velocity, low-amplitude manipulative techniques to cervical spinal joints.

4.1.1.2 Code of Health and Disability Services Consumers' Rights (1996)

All professions, regulated or not, providing health or disability services in New Zealand are subject to the Code of Health and Disability Services Consumers' Rights.[63]

This code outlines 10 consumer rights:[67]

1. The right to be treated with respect
2. The right to freedom from discrimination, coercion, harassment, and exploitation
3. The right to independence and dignity
4. The right to services of an appropriate standard
5. The right to effective communication
6. The right to be fully informed
7. The right to make an informed choice and give informed consent
8. The right to support
9. The right in respect of teaching or research, and
10. The right to complain.

An independent Health and Disability Commissioner was also established following the formation of the Code of Health and Disability Services Consumers' Rights to:

- Promote and protect consumer rights when using disability and health services.
- Enhance the quality of disability and health services, and
- Assist in resolving disputes between health and disability service providers and consumers.

4.1.2 Justification for legislative reforms

Before establishing the Health Practitioners Act in 2003, the Ministry of Health administered 11 occupational statutes covering 18 health and disability professions. Many of the occupational regulation statutes were deemed old, inflexible, and not serving health professionals' or consumers' needs in general. This was evidenced in the fact that many of the statutes specified in legislation the courses individuals needed to complete to qualify for registration. As a result, any alterations made to a course required legislation to be amended.[68]

Occupational statutes before the establishment of the Health Practitioners Act included:

- Chiropractors Act 1982
- Dental Act 1988 (dentists, dental technicians, clinical dental technicians)
- Dietitians Act 1950
- Medical and Auxiliaries Act 1966 (medical laboratory technicians, medical radiation technologists, podiatrists)
- Medical Practitioners Act 1995

- Nurses Act 1977 (includes midwives)
- Optometrists and Dispensing Opticians Act 1976
- Occupational Therapy Act 1949
- Pharmacy Act 1970
- Physiotherapy Act 1949
- Psychologists Act 1981

The adoption of the current regulatory framework in NZ was initiated in 1999 with the publication of a policy framework for occupational regulation by the Ministry of Commerce.[69] The framework highlighted the need for regulation to protect the public from the risks of an occupation being carried out incompetently or recklessly. The policy framework required those proposing regulation to identify the risks posed by a particular occupation and the best means of addressing them. The policy document also specified that all government departments and agencies should follow the principles contained in the policy framework in dealing with matters involving professional regulation.[69]

The framework was followed by the Health Practitioners Competence Assurance Bill in 2000, which proposed repealing the existing health regulation statutes and replacing them with a single overarching system of regulation, the Health Practitioners Competence Assurance Act.

The Health Practitioners Competence Assurance Bill outlined the benefits of creating a single regulatory framework for health professions, namely:[68]

- Consistency by ensuring that all occupations would take a uniform approach.
- Flexibility in allowing a greater ability to respond to changing skill sets, diagnostic regimes, and treatments.
- Transparency in establishing which occupations are regulated and how.
- Efficiency in the use of parliamentary time.
- Simplicity in the regulatory process through amendments to a single Act, rather than amending a separate Act for each regulated profession, and
- Economies of scale through combining the disciplinary functions of multiple professions.

The Health Practitioners Act utilised many of the key concepts from the Medical Practitioners Act 1995 in its development, namely:

- Lay participation in registration and disciplinary functions.
- Responsibility for ensuring practising professionals' competence resting with registering authorities.
- Requirement for competence throughout a health professional's career.
- Responsibility for determining requirements for registration resting with registering authorities.
- Separation of the registration and disciplinary functions, and
- Inclusion of quality assurance activities to improve health professionals' practice or competence.

Following the Health Practitioners Act in 2003, several further legislative developments strengthened the regulatory framework in New Zealand. In 2011, the Minister for Regulatory Reform introduced the Regulatory Standards Bill to Parliament.[70] The Bill was produced by the Regulatory Responsibility Taskforce, which the Government had established in 2009 following a recommendation from the Commerce Committee. The Commerce Committee made this recommendation in the context of the Regulatory Responsibility Bill, an earlier version of the Regulatory Standards Bill, introduced in the House as a private member's bill in 2006. The requirements focused on the Government expectation that agencies provide robust analysis and advice to Ministers before the Minister of Health decides on a proposed regulatory change. Consequently, at present, any

applications for regulation of a new profession under the Health Practitioners Act must be accompanied by a regulatory impact assessment.[70]

Further developments in the Health Practitioners Act followed in 2007 with the commencement of the *Review of the Health Practitioners Competence Assurance Act 2003: Report to the Minister of Health by the Director-General of Health*.[71] The review consulted a wide range of responsible authorities, health service providers, professional bodies, unions, educators, and consumer groups. Although the review indicated that the Act was functioning as intended, it proposed several minor legislative amendments, specifically concerning the regulatory process and establishing new professions under the Act. One of the main proposals in the review was the proposed development of primary and secondary criteria for the assessment of new applications.[71] Previously, the Health Practitioners Act did not specify criteria for determining whether or not certain professions ought to be regulated. Instead, professions were considered on a case-by-case basis according to the risks posed to public safety.[68]

4.1.2.1 Director-General of Health's review of the Health Practitioners Competence Assurance Act (2009)

Section 171 of the Health Practitioners Act required that the Director-General of Health review the Act 3 years after it came into force. The review commenced in 2007 and was completed in 2009. The review's objective was to determine whether any amendments to the Act were necessary or desirable. The review concluded that the Act had been received positively and was operating as Parliament intended. However, the report raised concerns that New Zealand already had a proliferation of registered authorities. It reiterated that statutory regulation should only be considered when the benefits outweigh the costs. Consequently, the Director-General's report noted that the Ministry of Health needed to be explicit about the criteria used to advise the Minister of Health on whether or not regulation is justified for a new profession.[71]

The review made several recommendations for legislative and operational changes to improve the efficiency of the Health Practitioners Act:[71]

- The Ministry of Health should move promptly to make recommendations to the Minister of Health regarding those groups that applied for statutory regulation under the Health Practitioners Act.
- The Ministry of Health should examine whether Australia's criteria for unregulated health professionals should be used as a template when drafting health professions legislation in New Zealand.
- The Ministry of Health should review the evaluation process for groups or existing regulatory authorities seeking to have a new health service regulated as a profession. The review would inform the Minister of Health whether statutory occupational regulation is recommended and, if so, what arrangements would be best for appointing a regulatory authority in respect of that profession.
- The Act should give the Minister of Health the power, by Order in Council, to join and restructure two or more existing regulatory authorities or add other professional groups to an existing regulatory authority in situations where, following consultation, the Minister is satisfied that it is in the public's interest to do so.

4.1.2.2 Ministry of Health's strategic review of the Health Practitioners Competence Assurance Act 2012

In 2012, a strategic review of the Health Practitioners Act was undertaken to examine whether the underlying policy and objectives of the Act remained appropriate. The review, titled *2012 Review of the Health Practitioners Competence Assurance Act 2003: A Discussion Document,* produced a series of recommendations that aimed to improve the overall functioning of the Act.[72] The review also included a period of public consultation to consider the recommendations outlined in the review.[72]

The general conclusion arising from the public consultation was that the Act was operating effectively, but it outlined five key areas where the Act could be improved:[72]

- Provide public assurance that the responsible authorities carry out their functions as intended.
- Increase transparency of disciplinary proceedings relating to health professionals.
- Provide greater recognition of the importance of teamwork and team communications across health professions.
- Enshrine the principles of transparency, integrated care, workforce flexibility, and workforce planning, and
- Enhance workforce data collection to assist with health workforce planning.

4.1.2.3 Health Practitioners Competence Assurance Amendment Act 2019

Building on the review carried out by the Director-General of Health in 2009 and the strategic review carried out in 2012, the New Zealand Government published the Health Practitioners Competence Assurance Amendment Bill in 2018. The Bill implemented recommendations arising from the 2009 and 2012 reviews. A regulatory impact assessment was also provided for the proposals resulting from the 2012 review. The Bill was introduced in 2018 and received royal assent in 2019 as the Health Practitioners Competence Assurance Amendment Act 2019.[73]

4.2 Organisational structure and regulatory status of professions

4.2.1 Ministry of Health

The Ministry of Health is responsible for administering the Health Practitioners Act. Section 115 of the Act provides the Minister of Health with authority to extend the Act to include a new profession once the Minister is satisfied that the profession meets the criteria outlined in Section 116 of the Act. Although the Ministry of Health is responsible for the overall administration of the Act, the primary responsibility, accountability, and overall functioning of regulations is that of the respective professional regulatory authorities. In return for increased autonomy for regulated professions, checks and balances exist to ensure that regulatory authorities comply with the Act. Provisions include ministerial powers to appoint regulatory authority board members, determine mechanisms to facilitate dispute resolution over scopes of practice, and determine restricted activities that only regulated health professionals can perform.[65] The Minister of Health is also responsible for a single shared disciplinary body for all regulated health professions governed under the Health Practitioners Act. This independent shared disciplinary body, the Health Practitioners Disciplinary Tribunal, determines disciplinary proceedings against health professionals. Further details on the disciplinary process and the Tribunal is provided in *New Zealand Health Practitioners Disciplinary Tribunal: What Happens Following Notice of Disciplinary Proceedings Against a Health Practitioner – A Guide to Disciplinary Proceedings*.[74]

4.2.2 Health Workforce Directorate

Although overall responsibility for the Health Practitioners Act rests with the Minister of Health, the Health Workforce Directorate in the *Ministry of Health* works on behalf of the Minister of Health to coordinate applications for regulation. The Health Workforce Directorate administering and reviewing the Health Practitioners Act and assesses applications for the regulation of new professions. The Health Workforce Directorate also provides advice on workforce development, gathers workforce data and intelligence, and invests in health workforce training.[75]

4.2.3 Regulatory bodies and regulated professions

In New Zealand, 17 regulatory authorities or professional bodies regulate health professionals under the Health Practitioners Act.[62] Regulatory authorities determine scopes of practice, along with

associated qualifications. Each regulatory authority is responsible for registration, issuing practising certificates, handling health professionals' complaints, and completing competence reviews and recertification processes.[72] Regulatory authorities also have a governance board or council, with some members appointed by the Minister of Health and approximately one-third being laypeople.[72]

Following the enactment of the Health Practitioners Competence Assurance Amendment Act 2019, regulated professional bodies are reviewed every five years to ensure effective performance.[62]

Table 2 Professions and responsible authorities under the Health Practitioners Competence Assurance Amendment Act 2019

Profession	Responsible authority
Chiropractic	New Zealand Chiropractic Board
Dentistry, dental hygiene, clinical dental technology, dental technology, and dental therapy	Dental Council of New Zealand
Dietetics	Dietitians Board
Medical laboratory science and anaesthetic technology	Medical Sciences Council of New Zealand
Medical radiation technology	New Zealand Medical Radiation Technologists Board
Medicine	Medical Council of New Zealand
Midwifery	Midwifery Council of New Zealand
Nursing	Nursing Council of New Zealand
Occupational therapy	Occupational Therapy Board of New Zealand
Optometry and optical dispensing	Optometrists and Dispensing Opticians Board
Osteopathy	Osteopathic Council of New Zealand
Paramedicine	Paramedic Council of New Zealand
Pharmacology	Pharmacy Council
Physiotherapy	Physiotherapy Board of New Zealand
Podiatry	Podiatrists Board of New Zealand
Psychology	New Zealand Psychologists Board
Psychotherapy	Psychotherapists Board of Aotearoa New Zealand

4.2.4 Professions regulated since 2015

As of 1 January 2020, paramedics are regulated under the Health Practitioners Act. The regulation ensures that paramedics are appropriately qualified and competent to practise.[76]

4.2.5 Unregulated professions

The Health Practitioners Act does not regulate all health professions in New Zealand. Statutory regulation is not necessary in occupations where there is a low risk of harm to the public. Furthermore, regulation may not be warranted when professionals work with or under another regulated profession or where employment arrangements provide adequate regulation outside of the Act's framework, thus minimising risk to the public.[63] Statutory regulation of a profession also involves considerable cost. The profession applying for regulation is responsible for the costs associated with regulation. If a profession does indeed become regulated, the regulatory authority or professional body will then charge its members annual fees – such as registration fees, disciplinary levies, and practising certificates –to cover its operating costs. Other forms of regulation outside the Health Practitioners Act can also adequately assess an individuals' competence and fitness to practise. For example, an employer (such as a district health board) may have education and training qualification requirements for employees in non-regulated health professions.

4.2.5.1 Ensuring safe practice

Lack of statutory regulation does not necessarily indicate that a profession lacks professional standards. Regardless of whether a profession is regulated or not, all professionals providing health or disability services in New Zealand are subject to the Code of Health and Disability Consumers' Rights.[72][63]

4.2.5.2 Professions that have sought regulation but have not been regulated

Unfortunately, information regarding professions that have sought regulation in New Zealand but have not been regulated was not available in the literature.

4.2.5.3 Challenges in court

There is no evidence in the literature that there have been challenges in court in New Zealand by professions that have applied to be regulated but have not been regulated.

4.2.5.4 Professions that have been deregulated or have had their level of regulation minimised

Since the Health Practitioners Act was established, no regulated health profession has been deregulated, nor has any profession had its level of regulation minimised.

4.2.5.5 Professions under consideration for regulation

Five professions have submitted applications for regulation under the Health Practitioners Act, as follows:[77]

- Chinese medicine practitioners: In 2011, the Ministry of Health consulted on regulating the Chinese medicine profession. The application is now at step 7 of the 11 step application process outlined in Section 4.3.
- Clinical physiologists: This application is currently on hold at the applicant's request.
- Cardiac perfusionists: A preliminary assessment (step 3) of the application is underway.
- Physician associates: A preliminary assessment (step 3) of the application is underway.
- Western medical herbalists: A preliminary assessment (step 3) of the application is underway.

4.3 Process for deciding who to regulate

Sections 115 and 116 of the Health Practitioners Act outline the process of extending the Act to include new health professions. Section 115 provides the Minister of Health with authority to recommend extending the Act to include new health professions. Section 116 of the Act indicates that the Minister must be satisfied that "the health service poses a risk of harm to the public or that it is otherwise in the public interest that the health service is regulated".[64 p12] The Health Workforce

Directorate assists the Minister of Health by assessing applications for regulation according to predefined criteria.[77]

The 11 steps required for a profession to become regulated are as follows:[78]

1. The prospective applicants meet with the Health Workforce Directorate to outline the extent of the information required and the costs of applying for regulation.
2. The professional body submits an application to the Health Workforce Directorate.
3. The Health Workforce Directorate undertakes a preliminary assessment of the application in order to ascertain whether it satisfies the necessary primary and secondary criteria and seeks further information if needed.
4. If the Health Workforce Directorate determines that the application has a robust case under the primary and secondary criteria, it gathers an expert panel to consider the application. The panel conducts an independent assessment of whether the public is at risk of harm and whether it would be in the public interest to regulate the profession.
5. If necessary, discussions may be held between the applicants and existing responsible authorities to determine if the profession can be regulated under the authority of an already regulated professional body.
6. Subject to the Minister of Health's agreement, the Health Workforce Directorate undertakes a public consultation process and analyses submissions.
7. The Health Workforce Directorate then advises the Minister of Health regarding whether the profession should be regulated and what appropriate responsible authority should regulate it.
8. If in agreement with the proposal, the Minister of Health seeks agreement from the Cabinet.
9. If the proposal is agreed to by the Cabinet, an Order in Council is prepared by the Parliamentary Counsel Office. The Cabinet will then consider the Order in Council and, if agreed, the Minister of Health will recommend to the Governor-General that the profession be designated under the Act.
10. The profession either joins an existing responsible authority or establishes a new responsible authority.
11. The Minister of Health then appoints board members of the responsible authority.

Steps 6 and 7 focus on the Health Workforce Directorate's assessment of the application for regulation by:

a) Reviewing evidence provided in the application, which may include undertaking a separate investigation using overseas experience and evidence
b) Consulting internally for advice on the application, including a regulatory impact assessment with support and advice from the Regulatory Quality Team, an independent unit located within the New Zealand Treasury, and
c) Consulting externally, for example, with district health boards and responsible authorities.

A decision will then be made on whether to regulate the profession in question and, if so, on which authority should regulate it (whether that is an existing authority or a newly established authority).

This decision involves:

a) Considering the information in the application to determine whether to establish a new authority or combine it with existing authority, and
b) In the case of adding a profession to an existing regulated authority, arranging a conversation between the Health Workforce Directorate, the existing authority, and the new profession.[77][78]

Table 3 illustrates the primary criteria used to assess whether or not a profession is suitable for regulation, Table 4 illustrates the secondary criteria, and an overview of the regulation process is outlined in Figure 2.[78]

Table 3 Primary criteria for determining whether to regulate a new profession:

Criterion		Explanation
A	The profession delivers a health service as defined by the Act.	The Health Practitioners Competence Assurance Act 2003 defines 'health service' as "a service provided to assess, improve, protect or manage the physical or mental health of individuals or groups of individuals".[78]
B	(i) The health services concerned pose a risk of harm to the health and safety of the public.	Criterion B(i) seeks to quantify and determine the risk of harm to the public, either direct or indirect. In order to establish whether there is a risk of harm, the profession must engage in at least two of the following activities: • Invasive procedures • Clinical interventions with potential for mental or physical harm, or • Decision-making or exercising judgement which can impact on patient welfare. In order to establish a risk of harm, the applicant is required to detail any information that demonstrates the nature and severity of the risk to service users, as well as the potential risk to the broader public. In order to establish the risk of harm to service users and the broader public, evidence is required on the following: • The nature, frequency, and severity of the harm to, or the consequences for, the consumer • The likelihood of the risk of harm occurring • The nature, frequency, and severity of the potential risk to the public from the practice of the applicant's profession • Any public safety concerns by other stakeholders or the public, and • The extent to which the profession is regulated in similar overseas jurisdictions.
	(ii) It is otherwise in the public interest that the health services be regulated as a health profession under the Act.	In some instances, criterion B(i) will not apply to the applicant, but statutory regulation may still be in the public interest in order to include health professions that: • Engage in professional practice without the supervision or support of peers • Are highly mobile, locum, or work on short tenure • Do not have appropriate guidance from a strong professional (or employer) code of conduct • Provide services to vulnerable or isolated individuals

Criterion		Explanation
		• Receive large numbers of complaints, or • Carry out roles where the training and educational requirements are minimal.
C	Providers of the health services concerned are generally agreed on: (i) The qualifications for any class or classes of providers of those health services (ii) The standards that any class or classes of providers of those health services are expected to meet, and (iii) The competencies for scopes of practice for those health services.	The regulating guidelines under the Health Practitioners Act recognise that criteria A and B may not apply, but criterion C referring to the public interest may apply.

Table 4 Secondary criteria for determining whether to regulate a new profession:

Criterion		Explanation
1	Existing regulatory or other mechanisms fail to address health and safety issues.	Criterion 1 seeks to determine whether potential health and safety issues arising from the profession's practice, which may cause harm, can be addressed in another manner. The means through which health and safety issues may be handled without necessitating statutory regulation include existing statutes that may restrict the profession's activities; the use of other regulatory options, such as product regulation; self-regulation; or supervision by other registered professions.
2	Regulation under the Act is possible to implement for the profession in question.	This criterion is intended to identify any barriers that may impact on the ability to regulate the profession. Matters that may impede regulation may include, but are not limited to, any of the following: • Does the profession have a defined body of knowledge that informs practice standards for that profession? • Does the profession cover a distinct and specific activity displaying some homogeneity? • Is this body of knowledge and clinical expertise teachable and testable? • Where applicable, have functional competencies been defined? • Do the members of the profession require accredited qualifications? • Is the practice of the profession based on evidence of efficacy? • Does the profession have defined routes of entry?
3	Regulation under the Act is practical to implement for the profession in question.	Criterion 3 seeks to determine whether regulation is practical for the profession. This criterion is not intended to provide a loophole for professions to avoid regulation. Instead, it focuses on practicalities regarding voluntary membership registries, whether the professional leadership favours the public's best interests over occupational self-interest, and whether there would be a

Criterion		Explanation
		sufficient number of members to make regulation cost-effective.
4	The benefits to the public of regulation under the Act outweigh the potential negative impacts of such regulation.	Below are the types of things that may be considered when assessing the costs and benefits of regulation under the Act. Benefits of regulation: The benefits of statutory regulation may include, but are not limited to, the following: • Setting requirements for entry into the regulated profession • Setting standards of practice • Ensuring initial and ongoing competence • Ensuring high-quality education to assure those standards • The potential to remove from practice those who fall significantly short of those standards, and • Promoting and enforcing clinical and cultural competencies and standards of ethical conduct. Costs and risks of regulation: The costs of regulation may include, but are not limited to, the following: • The cost of the professionals' time taken to comply with the regulator's requirements • The costs to employers of ensuring that they have additional systems in place necessary for regulated professionals' employment • The costs of registration fees from registrants to their regulator, as ultimately these costs are indirectly paid by the taxpayer (in publicly funded services) or the individual patient (in privately funded services), and • The costs of establishing and maintaining new regulatory regimes for newly regulated bodies.[78]

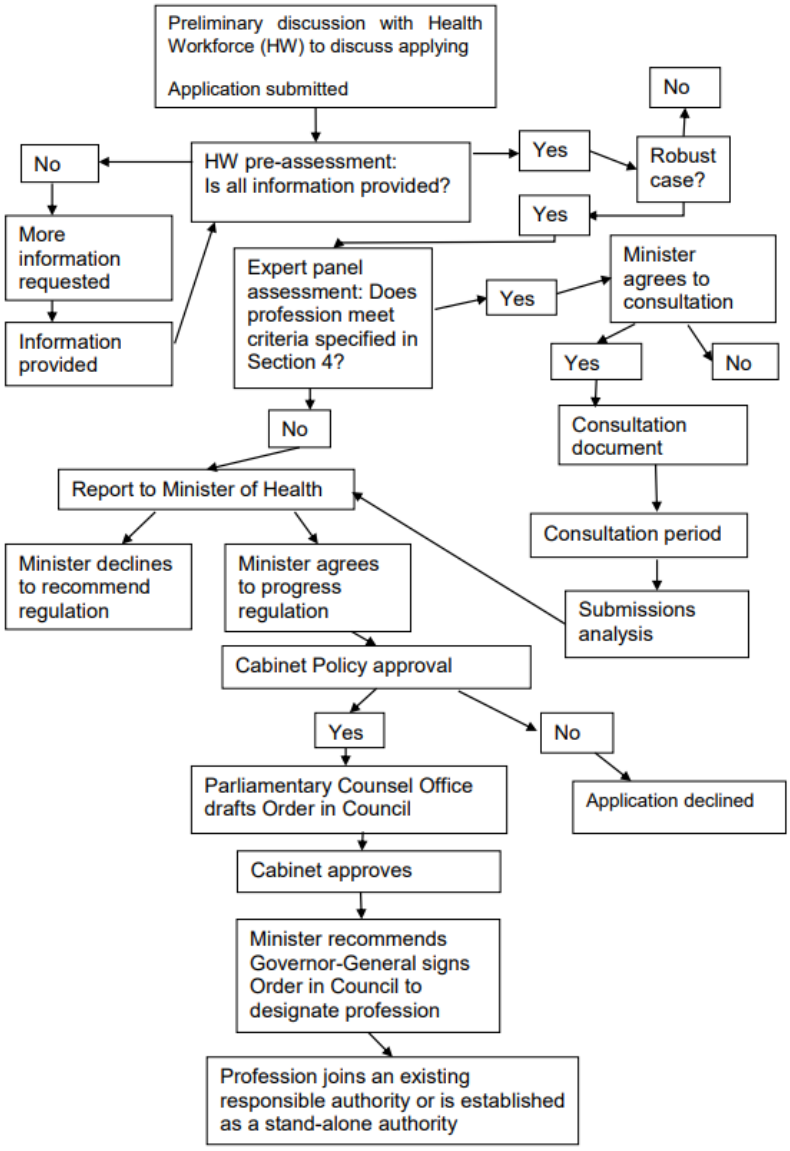

Figure 2 Applying for regulation under the Health Practitioners Competence Assurance Act 2003

Source: Health Workforce, New Zealand Ministry of Health, 2020.[78]

4.3.1 Risk assessment

The primary objective of the Health Practitioners Act is to protect the public from risk of harm. Before recommending that a profession be added to the list of regulated professions, the Minister of Health must be satisfied, under Section 116 of the Act, that the services pose a risk of harm to the public, or that it is in the public interest to regulate them. A review of the Health Practitioners Act by the Governor-General in 2009 recommended adopting additional criteria to assist in advising the Minister of Health whether a profession poses a risk of harm. A central tenant of the assessment is that the health service concerned poses a risk of harm to the health and safety of the public. To establish risk of harm to service users and the broader public, evidence is required on the nature, frequency, and severity of the harm to, or the consequences for, the consumer. Unfortunately, the Health Practitioners Act does not clarify what constitutes 'harm' in the context of public risk.[66][72] As a result, the regulatory authorities must use their own working definitions of risk when applying the Health Practitioners Act. A review of the Health Practitioners Act, titled *2012 Review of the Health Practitioners Competence Assurance Act 2003: A Discussion Document,* provided a working definition of risk of harm or serious harm from the New Zealand Medical Council:[72]

Risk of harm may be indicated by:[79]

- A pattern or practice over a period that suggests the doctor's practice of medicine may not meet the required standard of competence
- A single incident that demonstrates a significant departure from accepted standards of medical practice
- Recognised poor performance where local interventions have failed (this does not exclude notification of serious concerns where internal review or audit is inaccessible or unavailable to the person with the concern), or criminal offending, or
- Professional isolation with declining standards that become apparent.

A risk of serious harm may be indicated when:[79]

- The doctor may seriously harm an individual consumer
- The doctor may pose a continued threat to more than one consumer, and, as such, the harm is collectively considered 'serious', or
- There is sufficient evidence to suggest that the alleged criminal offending is of such a nature that the doctor poses a risk of serious harm to one or more members of the public.

The *2012 Review of the Health Practitioners Competence Assurance Act 2003: A Discussion Document* highlighted the difficulty in establishing a threshold to determine the risk of harm, given the broad spectrum of risk across each profession's scope of practice.[72] The document also highlighted the lack of available tools to help determine whether or how to trade off the risk of harm – whether unlikely or not, or temporary or not – with the benefit of better access to services. The document concluded that the Ministry of Health work with the healthcare sector to develop further the risk framework underpinning the Health Practitioners Act. The risk framework would build on the primary and secondary criteria outlined in Table 3 and Table 4 in order to determine whether statutory regulation is the most appropriate way to regulate health professions.[72]

4.3.2 Regulatory impact assessment

Following the publication of the *2012 Review of the Health Practitioners Competence Assurance Act 2003: A Discussion Document*, broader legislative developments in New Zealand sought to support the use of appropriate risk assessment frameworks in all aspects of legislation, including the regulation of health professions.[72] In 2013, the New Zealand Productivity Commission investigated how to improve the design and operation of new and existing regulatory regimes. In 2017, the Government released a set of updated expectations for government agencies regarding regulatory stewardship.[80] Under the amendments, government agencies must provide robust analysis and advice to ministers before making decisions about regulation. A key aspect of this requirement is a regulatory impact assessment. A regulatory impact assessment must be completed and summarised in a regulatory impact statement before Cabinet propose a regulatory or legislative change. Step 6 of the regulation application process requires the Health Workforce Directorate to undertake a regulatory impact assessment. The assessment is performed with the assistance of the New Zealand Treasury's Regulatory Quality Team. Guidance and templates on producing a regulatory impact statement are available in the *Guide to Cabinet's Impact Analysis Requirements*.[81] The Treasury's Regulatory Quality Team helps government agencies produce regulatory impact statements.[82]

5 Australia

Australia, with a population of 25,693,059, ranks high across many indicators of well-being relative to most other countries featured in the OECD's Better Life Index.[83] Life expectancy at birth in Australia is around 83 years – three years higher than the OECD average of 80 years.[83] The Australian healthcare system is recognised as one of the best in the group of 37 OECD member countries.[84] Australia has a regionally administered universal public health insurance programme, Medicare.[85] The Medicare scheme, which delivers public access to healthcare, is funded by the federal government and provides free or subsidised access to care for Australian citizens and for those who have a permanent resident visa. Medicare is funded primarily by a government levy collected through the tax system.[85] The Australian healthcare system is a hybrid model under which citizens, permanent residents, and refugees can buy private insurance coverage in addition to public insurance.[84] Three levels of government – federal, state and territory, and local – are collectively responsible for providing universal healthcare. States and territories have the majority of responsibility for public hospitals, ambulance services, public dental care, community health services, and mental health care.[85] The regulation of health professions is determined by the National Registration and Accreditation Scheme. Before establishing the National Registration and Accreditation Scheme in 2010, each state and territory had its system for registering and regulating health professionals. The National Registration and Accreditation Scheme consolidated 75 Acts of Parliament and 97 separate health profession boards into a single registration scheme for health professions.[86]

5.1 Legislation

5.1.1 Current legislation

5.1.1.1 Health Practitioner Regulation National Law Act 2009

In 2005, in response to shortages in health professionals and complex health workforce arrangements, Australia's Productivity Commission recommended the creation of a new national scheme.[87] The Australian Government's Health Council signed an intergovernmental agreement for the establishment of a National Registration and Accreditation Scheme in 2008. It was established in conjunction with all the state and territory Ministers of Health.[87] The establishment of the National Registration and Accreditation Scheme was legislated under the Health Practitioner Regulation National Law Act 2009 (hereafter referred to as the National Law), which came into force in 2010.[88] The National Law consolidated 75 Acts of Parliament and 97 health profession boards into one 'super regulator' involving 14 National Boards for registered professions.[89] The agreement and the establishment of the National Registration and Accreditation Scheme ensured that health professionals are registered on a nationwide register to enforce consistent, high-quality, national professional standards.[90] The National Law also established the roles of an ombudsman and commissioner, the Australian Health Practitioner Regulation Agency, and the National Boards. Additionally, the National Law sets out the objectives of the National Registration and Accreditation Scheme and how it should operate.[91] The objectives include:[87]

- Provide public protection by ensuring that only suitably qualified and registered health professionals may provide their services to the public
- Ensure professional mobility across Australia by reducing the administrative burden for health professionals working in multiple states and/or jurisdictions
- Facilitate high standards of education and training for health professionals
- Ensure rigorous assessment of health professionals trained overseas
- Facilitate access to services provided by health professionals, following public interest in such services, and

- Enable the development of health professionals by providing high-quality education and training to ensure an innovative and flexible workforce.

The National Law regulated 10 health professions under the National Registration and Accreditation Scheme following its establishment in 2010. Each regulated profession has a National Board responsible for regulation, registration, and the development of standards, codes, and guidelines. The Australian Health Practitioner Regulation Agency administers the National Registration and Accreditation Scheme and provides administrative support to each National Board.

Sections 121 to 123 of the National Law outlines several restricted practices. Most other statutory restrictions to activities such as prescribing medicines are typically covered within the regulatory frameworks of Australia's states and territories.

Table 5 List of restricted activities under the National Law Act 2009

Restricted activity	Definition of activity	Criteria for performing a restricted activity	Penalty
Dental activity Section 121	Dental activity refers to: 1. Performing any irreversible procedure on the human teeth or jaw or associated structures. 2. Correcting malpositions of the human teeth or jaw or associated structures. 3. Fitting or intra-orally adjusting artificial teeth or corrective or restorative dental appliances for a person. 4. Performing any irreversible procedure on or giving any treatment or advice to a person that is preparatory to or for fitting, inserting, adjusting, fixing, constructing, repairing, or renewing artificial dentures or a restorative dental appliance.	(1) A person must not carry out a restricted dental act unless the person: (a) Is registered in the dental profession or medical profession and carries out the restricted dental act following any requirements specified in an approved registration standard. (b) Is a student who carries out the restricted dental act in the course of activities undertaken as part of: (i) An approved programme of study for the dental profession or medical profession. (ii) Clinical training in the dental profession or medical profession. (c) Carries out the restricted dental act in the course of carrying out technical work on the written order of a person registered in the dentists or dental prosthetists division of the dental profession. (d) Is a person, or a member of a class of persons, prescribed under a regulation as being authorised to carry out the restricted dental act or restricted dental acts generally.	Maximum penalty: AU$60,000 or 3 years imprisonment or both
Optical appliances Section 122	Optical appliance refers to: (a) Any appliance designed to correct, remedy or relieve any refractive abnormality or defect of	(1) A person must not prescribe an optical appliance unless: (a) The person is an optometrist or medical practitioner.	Maximum penalty: AU$60,000 or 3 years

Restricted activity	Definition of activity	Criteria for performing a restricted activity	Penalty
	sight, including, for example, spectacle lenses. (b) Contact lenses, whether or not designed to correct, remedy or relieve any refractive abnormality or defect of sight. (c) Optometrist means a person registered in the optometry profession. (d) Orthoptist means a person whose name is recorded in the Register of Orthoptists kept by the Australian Orthoptists Registration Body Pty Ltd.	(b) The appliance is spectacles and the person is an orthoptist who: (i) Prescribes the spectacles in the course of carrying out duties at a public health facility. (ii) Prescribes the spectacles under the supervision of an optometrist or medical practitioner. (iii) Prescribes the spectacles, on the written referral of an optometrist or medical practitioner, to a person who has had, within the 12 months before the referral, an ocular health examination conducted by an optometrist or medical practitioner. (c) The person is a person, or a member of a class of persons, prescribed under a regulation as authorised to prescribe an optical appliance of that type or generally prescribe optical appliances.	imprisonment or both
Spinal manipulation Section 123	Spinal manipulation refers to: Moving the cervical spine joints beyond a person's usual physiological range of motion using a high-velocity, low-amplitude thrust. Appropriate health profession refers to any of the following health professions: (a) Chiropractic (b) Osteopathy (c) Medical practitioner (d) Physiotherapy.	(1) A person must not perform manipulation of the cervical spine unless the person: (a) Is registered in an appropriate health professional. (b) Is a student who performs manipulation of the cervical spine in the course of activities undertaken as part of: (i) An approved programme of study in an appropriate health profession. (ii) Clinical training in an appropriate health professional. (c) Is a person, or a member of a class of persons, prescribed under a regulation as being authorised to perform	Maximum penalty: AU$60,000 or 3 years imprisonment or both

Restricted activity	Definition of activity	Criteria for performing a restricted activity	Penalty
		manipulation of the cervical spine.	
Birthing practices Section 123A	Midwife means a person registered under this Law in the midwifery profession. Birthing practice refers to an act that involves undertaking the care of a woman by managing the three stages (or any part of these stages) of labour or childbirth and, for this definition, the Minister may from time to time, on the joint advice of the Medical Board of Australia and the National Board established for the midwifery profession, by notice in the Gazette, specify activities that will be conclusively taken to constitute the management of any part of one or more of these stages of labour or childbirth.	(a) Is a medical practitioner. (b) Is a midwife. (c) Is a student who carries out the restricted birthing practice in the course of activities undertaken as part of: (i) An approved programme of study for the medical profession or the midwifery profession. (ii) Clinical training in the medical profession or the midwifery profession. (d) Is acting under the supervision of a medical practitioner or midwife and acting according to any standards, codes, or guidelines issued by the National Board established for the relevant profession. (e) Is acting under a form of delegated authority transferred or conferred by a midwife that the National Board recognises as established for the midwifery profession and is made in accordance with any standards, codes or guidelines issued by that National Board. (f) Is rendering assistance to a woman who is in labour or giving birth to a child, or who has given birth to a child, where the assistance is provided in an emergency.	Maximum penalty: AU$60,000 or 3 years imprisonment or both

Source: Health Practitioner Regulation National Law Act 2009 - P154-156 [91]

5.1.2 Justification for legislative reforms

Prior to establishing the National Law, individual state and territory governments were responsible for regulating health professions. This arrangement resulted in considerable variability across jurisdictions about what professions were regulated and the respective regulatory requirements. The need for regulatory reform was established in 2006 with the publication of the Australian Government's Productivity Commission research report, titled *Australia's Health Workforce.*[92] The report examined the healthcare workforce's issues with supply of, and demand for, health professionals. One issue identified was the increasing reliance on doctors trained overseas, who made up 25% of that workforce at the time of the report. In contrast, the comparable figure for the previous decade was 19%. Workforce distribution issues were another factor identified in the report, with significant healthcare workforce shortages in outer metropolitan, rural, and indigenous communities. In addition, areas of special needs – such as mental health, aged care, and disability services – were also suffering significant shortages in the face of growing demand and changing population demographics. One of the main recommendations in the report proposed the establishment of a single national registration board for health professionals, as well as a single

national accreditation board for the education and training of health professionals, to deal with workforce shortages and pressures faced by the Australian health workforce and also to increase their flexibility, responsiveness, sustainability, and mobility. In response to national registration and accreditation recommendations, the Health Council agreed to establish a single national registration board to facilitate workforce mobility, improve safety and quality, and reduce red tape.

The Health Council advised that its preferred model for a national registration scheme would:[93]

- Involve a single cross-profession national registration board
- Ensure that a presence is maintained in each state and territory
- Facilitate expert input on professional matters for professions covered by the scheme
- Include a primary policy-setting, governance, and implementation role for health ministers
- Be self-funding
- Ensure that the new registration and accreditation activities retain and draw on essential health profession-specific expertise, and
- Include a commitment to involving consultation with stakeholders on these preferred models.

On 26 March 2008, the Health Council entered into an intergovernmental agreement to formulate the National Registration and Accreditation Scheme. Subsequently, a public consultation process was initiated, exploring how it would be structured and implemented. A regulatory impact assessment was also commissioned to assess the regulatory impact of its implementation.

The regulatory impact assessment examined the available options, costs, and benefits for:[93]

- The assignment of accreditation functions and approval of accreditation standards
- The design of the complaints-handling arrangements
- The inclusion of partially regulated professions
- The addition of public protection measures concerning information availability, student registration, and criminal history and identification checks, and
- The addition of a nationally consistent practice restriction concerning aspects of the practice of spinal manipulation.

The regulatory impact statement, titled *Regulatory Impact Statement for the Decision to Implement the Health Practitioner Regulation National Law*, was published in 2009.[93] The regulatory impact statement concluded that the Health Council should implement the National Registration and Accreditation Scheme, as indicated in the intergovernmental agreement.[93]

5.1.2.1 First review of the Health Practitioner Regulation National Law Act 2009

A review of the National Registration and Accreditation Scheme was undertaken three years after its introduction. The *Independent Review of the National Registration and Accreditation Scheme for health professions* was a wide-ranging review that considered the Scheme's efficiency and effectiveness.[86] The review concluded that although the National Registration and Accreditation Scheme had encountered significant challenges in its implementation and more work was required, creating the scheme was considered a success. The review made numerous recommendations for improvements, both in terms of administrative changes and legislative amendments. The Health Council accepted many of the review's recommendations, as detailed in a published communiqué.[86] Of the 33 recommendations proposed in the independent review, the Health Council accepted 9 recommendations, accepted in principle 11 recommendations, rejected 6 recommendations, and deferred decisions on 7 recommendations pending further advice.[86]

5.1.2.2 Second review of the Health Practitioner Regulation National Law Act 2009

The *Independent Review of the National Registration and Accreditation Scheme for health professions*, published in 2014, led to a further review of the efficiency and effectiveness of the Scheme in 2017.[86] The Health Council believed that substantive reform was required due to concerns about the high cost, lack of scrutiny, duplication of, and prescriptive approach to accreditation functions. In response a review, titled *Independent Review of Accreditation Systems within the National Registration and Accreditation Scheme for health professions*, was completed in 2017.[86] The review identified a broad range of opportunities to improve the efficiency and effectiveness of accreditation functions undertaken by accreditation authorities, National Boards, and the Australian Health Practitioner Regulation Agency.[89] It also identified opportunities to facilitate greater responsiveness of health profession education.[89]

5.1.2.3 Health Practitioner Regulation Amendment Act 2017

The first amendment to the National Law was the Health Practitioner Regulation Amendment Act 2017. In summary, the amendment contained the provision for the admission of paramedics to the National Registration and Accreditation Scheme and a range of provisions that enabled improvements to the notifications (complaints) process concerning registered professionals.[94]

5.1.2.4 Health Practitioner Regulation National Law and Other Legislation Amendment Act 2019

A second amendment to the National Law, the Health Practitioner Regulation National Law and Other Legislation Amendment Act was published in 2019. The amendment contained changes to the requirements of treating professionals to notify the Australian Health Practitioner Regulation Agency of concerns regarding other health professionals in their care and increases in penalties for offences contained in the National Law.[95]

The Australian Government is currently drafting a third amendment bill, which is expected to be considered by the Queensland Parliament in late 2021. The amendment bill contains a broader range of proposed amendments that, in summary, include changes to the guiding objectives, principles, and amendments aimed at improving the protection of the public.

5.2 Organisational structure and regulatory status of professions

There are a number of organisations that play a key role in professional regulation in Australia. Figure 3 depicts the relationships between them, and each organisation is described below.

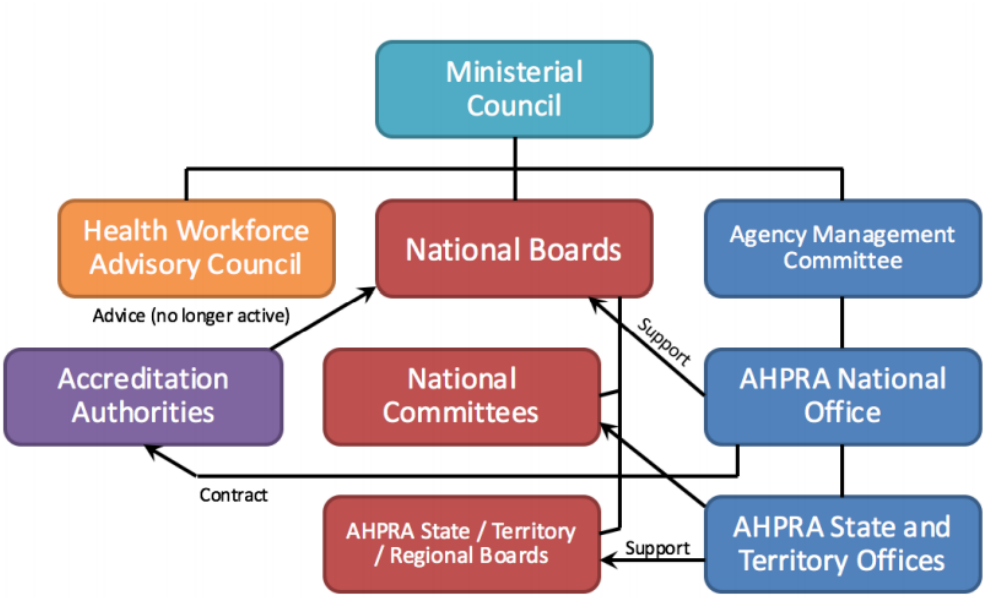

Figure 3 Organisational structure of Australia's National Registration and Accreditation Scheme

Source: Leslie, 2017[10]

5.2.1 Health Council

The Health Council, which comprises health ministers of the participating jurisdictions and the Commonwealth, is responsible for overseeing the National Registration and Accreditation Scheme.

Under the National Law, the Health Council is responsible for approving:[96]

- Registration standards put forward by the National Boards
- Specialties and specialist titles for specialist registration in a profession, and
- Areas of practice for endorsement.

5.2.2 Health Chief Executives Forum

The Health Chief Executives Forum, previously known as the Australian Health Ministers' Advisory Council, is the advisory and support body to the Health Council.

The Health Chief Executives Forum is responsible for providing effective and efficient support to the Health Council by:[97]

- Advising on strategic issues relating to the coordination of health services nationally, and
- Providing a national forum for planning, information sharing, and innovation.

5.2.3 Australian Health Practitioner Regulation Agency

To administer the National Registration and Accreditation Scheme, a new agency, the Australian Health Practitioner Regulation Agency, was established under the National Law. The Australian Health Practitioner Regulation Agency supports the National Boards to ensure public protection through regulation. It has five core regulatory functions:[90]

1. Professional standards: Providing policy advice to the respective National Boards about registration standards, codes, and guidelines for health professionals.

2. Registration: In partnership with the National Boards, ensuring that only qualified health professionals are registered to practice.
3. Notifications: Dealing with any complaints and concerns about health professionals on behalf of the National Boards.
4. Compliance: Auditing and monitoring registered health practitioners to ensure compliance with National Board requirements, and
5. Accreditation: Working with accreditation authorities to ensure that graduating students meet registration requirements. It is also responsible for publishing a publicly available national register of professionals online.

The Agency Management Committee oversees the work of the Australian Health Practitioner Regulation Agency.[90] The Agency Management Committee consists of individuals appointed by the Health Council, where at least three of the five members are not health professionals. The National Boards provide funding to the Australian Health Practitioner Regulation Agency through registration fees paid by health professionals.[10]

The Australian Health Practitioner Regulation Agency also addresses complaints made about health professionals. Under the National Law, complaints are referred to as notifications, and the Australian Health Practitioner Regulation Agency receives these notifications on behalf of the relevant National Board. Following receipt of notification against a health professional, the Australian Health Practitioner Regulation Agency must refer the notification to the applicable National Board(s). If a National Board believes that it is appropriate to proceed with a health professional's notification, it may initiate one of several disciplinary measures. Full details of each disciplinary measures are provided in the Australian Health Practitioner Regulation Agency's *Regulatory Guide*.[98]

5.2.4 National Boards

Each regulated profession has a National Board to administer the National Registration and Accreditation Scheme. National Boards are responsible for registration, developing standards and codes of conduct, setting registration fees, and approving accreditation standards and programmes of study. With support from the Australian Health Practitioner Regulation Agency, the National Boards also oversee the receipt, assessment, and investigation of registered health professionals' complaints. Under Section 178 of the National Law, National Boards can take a range of regulatory actions on grounds related to a registered health professional's conduct, health, or performance.

The National Law sets out the membership requirements of respective National Boards'. All National Boards must comprise of at least:[96]

- One professional member from each of the large jurisdictions and at least one professional member from a small jurisdiction
- Fifty per cent of members from the relevant profession, with no more than two-thirds of the Board being members of the relevant profession
- Two lay members of the community who are not and have never been registered in the profession, and
- One member (either a health professional or a member of the community) from a regional or rural area.

5.2.5 Regulatory bodies and regulated professions

Following the establishment of the National Registration and Accreditation Scheme in 2010, 10 health professions were regulated, all of which had been previously regulated. Four more health professions were subsequently added to the National Registration and Accreditation Scheme in 2012 (Aboriginal health practitioners, Torres Strait Islander health practitioners, Chinese medicine practitioners, and medical radiation practitioners). Paramedics were added in 2018. The National Law provides title

protection to regulated professions making it unlawful for someone to knowingly or recklessly take or use a title to make someone believe they are a regulated health professional.[96]

Table 6 List of health professionals, their national bodies, and associated protected titles

Regulated profession	Professional body	Protected title(s)
Aboriginal and Torres Strait Islander health practice	Aboriginal and Torres Strait Islander Health Practice Board of Australia	• Aboriginal and Torres Strait Islander health practitioner • Aboriginal health practitioner • Torres Strait Islander health practitioner
Chinese medicine	Chinese Medicine Board of Australia	• Chinese medicine practitioner • Chinese herbal dispenser • Chinese herbal medicine practitioner • Oriental medicine practitioner • Acupuncturist
Chiropractic	Chiropractic Board of Australia	• Chiropractor
Dentistry	Dental Board of Australia	• Dentist • Dental therapist • Dental hygienist • Dental prosthetist • Oral health therapist
Medicine	Medical Board of Australia	• Medical practitioner
Medical radiation practice	Medical Radiation Practice Board of Australia	• Medical radiation practitioner • Diagnostic radiographer • Medical imaging technologist • Radiographer • Nuclear medicine scientist • Nuclear medicine technologist • Radiation therapist
Nursing and midwifery	Nursing and Midwifery Board of Australia	• Nurse • Registered nurse • Nurse practitioner • Enrolled nurse • Midwife • Midwife practitioner
Occupational therapy	Occupational Therapy Board of Australia	• Occupational therapist
Optometry	Optometry Board of Australia	• Optometrist • Optician
Osteopathy	Osteopathy Board of Australia	• Osteopath

Regulated profession	Professional body	Protected title(s)
Paramedicine	Paramedicine Board of Australia	• Paramedic
Pharmacy	Pharmacy Board of Australia	• Pharmacist • Pharmaceutical chemist
Physiotherapy	Physiotherapy Board of Australia	• Physiotherapist • Physical therapist
Podiatry	Podiatry Board of Australia	• Podiatrist • Chiropodist
Psychology	Psychology Board of Australia	• Psychologist

Source: [99]

5.2.6 Professions regulated since 2015

In 2015, the Health Council agreed to regulate paramedics under the National Registration and Accreditation Scheme.[87]

5.2.7 Unregulated professions

5.2.7.1 Ensuring safe practice

In response to concerns raised about the risks associated with unregistered or unqualified professionals providing healthcare services, health ministers agreed to the first National Code of Conduct for Health Care Workers, which sets minimum standards of conduct and practice for unregistered health care workers who provide a health service.[100] The National Code, once enacted in a state or territory, applies to any person who provides a health service and is not subject to regulation under the National Registration and Accreditation Scheme. In certain circumstances, it also applies to health practitioners registered under the National Registration and Accreditation Scheme, to the extent that they provide services that are unrelated to or outside the typical scope of practice of their registration.[101] [100]

The National Code includes the following 14 clauses:[100]

- Healthcare workers provide services in a safe and ethical manner
- Healthcare workers obtain consent
- Appropriate conduct about treatment advice
- Healthcare workers should report concerns about treatment or care provided by other health care workers
- Healthcare workers should take appropriate action in response to adverse events
- Healthcare workers should adopt standard precautions for infection control
- Healthcare workers diagnosed with infectious medical conditions
- Healthcare workers should not make claims to cure certain serious illnesses
- Healthcare workers should not misinform their clients
- Healthcare workers are not permitted to practice under the influence of alcohol or drugs
- Healthcare workers with certain mental or physical impairment
- Healthcare workers should not financially exploit clients
- Healthcare workers must not engage in sexual misconduct

- Healthcare workers should comply with relevant privacy laws
- Healthcare workers should keep appropriate records
- Healthcare workers must be covered by appropriate insurance, and
- Healthcare workers to display code and other information.

5.2.7.2 Professions that have sought regulation but have not been regulated

Unfortunately, information regarding professions that have sought regulation in Australia but have not been regulated was not available in the literature.

5.2.7.3 Challenges in court

There is no evidence in the literature that there have been challenges in court in Australia by professions that have applied to be regulated but have not been regulated.

5.2.7.4 Professions that have been deregulated or have had their level of regulation minimised

No regulated health profession has been deregulated in Australia, nor has any profession had its level of regulation minimised.

5.2.7.5 Professions under consideration for regulation

According to literature, no professions are currently formally under consideration for regulation in Australia.

5.3 Process for deciding who to regulate

Under the National Law, the Health Council has the authority to recommend extending the National Registration and Accreditation Scheme to include new health professions. There are five steps in the process that the Health Council uses to make its recommendation (see Table 7).[88]

Table 7 Regulatory assessment criteria and process for adding new professions to the National Registration and Accreditation Scheme for the health professions under the National Law Act 2009

Step		Explanation
1	Submission	A member (a state, territory, or Commonwealth Health Minister) of the Health Council proposes a submission for inclusion. Interested professional associations are encouraged to engage with a Council member and/or the relevant jurisdiction's health department to seek support for their proposal.
2	Preliminary assessment	Following an application for regulation, a preliminary assessment is performed to assess available information and determine whether there is sufficient evidence to justify proceeding with a regulatory impact assessment. The initial evaluation will consider how the submission addresses the following six assessment criteria: 1. Is it appropriate for health ministers to exercise responsibility for regulating the occupation in question, or does the occupation more appropriately fall within another ministry domain? The Health Council is responsible for approving registration standards under the National Law. Some professions provide services across various portfolios, such as education, justice, and community services. Where services cross a range of portfolios, the need for registration standards regarding services other than health services should be considered. If the profession mainly provides services outside of the health portfolio, health ministers may not be the most appropriate body to approve registration standards. Other than health professions' regulation under the National Registration and Accreditation Scheme, another form of regulation may be more appropriate.

Step		Explanation
		2. Does the profession pose a risk of harm to the public's health and safety? Health professions must outline: c) The risks posed by the profession's practice, and d) The severity of the risk. The severity of risk should be substantiated, for example, with data on actual injuries/harm/adverse outcomes and the prevalence of that outcome in the client group and/or population. An explanation should be provided of how regulation under the National Registration and Accreditation Scheme would limit/mitigate each risk enumerated. 3. Do current regulatory or other mechanisms fail to address any health and safety issues? Health professions must address how relevant jurisdictional codes of conduct for unregistered health professions apply to their profession's practice and provide compelling reasons why regulation under such codes of conduct is insufficient to protect the public or client group. 4. Is it possible to implement the necessary regulation for the profession in question? 5. Is regulation practical to implement? Professions must provide evidence of how their profession is defined and how the limits to that profession would be gauged. For example, are there accepted definitions in the literature of what constitutes the profession? What are the particular titles used within the profession, and which titles should be protected? Is there a danger of over-regulation because a wide variety of professionals are accustomed to using the proposed protected title? Evidence should be provided of the number of professionals in the profession and how they have organised themselves. 6. Do the benefits to the public of regulation outweigh the potential negative impact of such regulation? Professions must address the possible negative impacts of regulation under the National Registration and Accreditation Scheme in terms of the cost of registration to professionals (fees, etc.) and possible restriction of services. For example, will registration have unintended consequences in diminishing the number of practitioners willing to provide services in that profession?
3	Health Council decision on a preliminary assessment	Following the completion of a preliminary assessment, the Health Council will either: • Decide no further action – that a regulatory impact assessment is not warranted at this time, or • Decide formal regulatory assessment – that a regulatory impact assessment is warranted.
4	Regulatory impact assessment	If the Health Council approves the preliminary assessment, a formal regulatory impact assessment is undertaken (see Section 5.3.1 for details).
5	Health Council final decision	The Health Council considers the final regulatory impact assessment and advice from the Health Chief Executives Forum and decides whether to amend the National Law to regulate the new profession under the National Registration and Accreditation Scheme.

Source: [88]

If an applicant satisfies the required criteria, the Health Council will recommend amending the National Law to include the profession under the National Registration and Accreditation Scheme.[88] An overview of the process for considering the inclusion of additional professions is outlined in Figure 4.

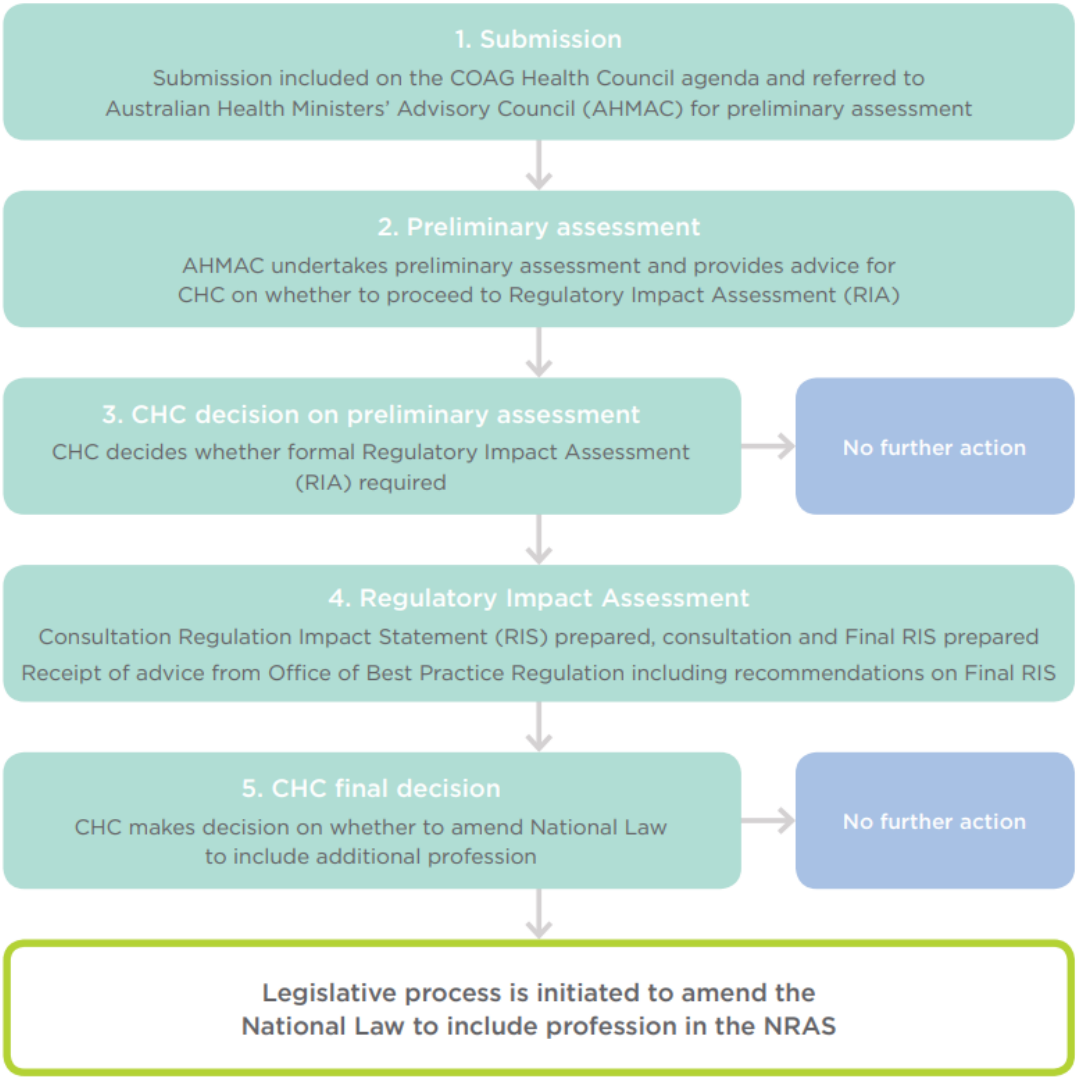

Figure 4 Process for considering the inclusion of additional professions in the National Registration and Accreditation Scheme

Source: Australian Health Ministers' Advisory Council information on regulatory assessment criteria and process for adding new professions to the National Registration and Accreditation Scheme for the health professions [88 p10]

5.3.1 Regulatory impact assessment

All policy proposals in Australia, including legislative changes to the regulation of health professions, must be accompanied by a regulatory impact assessment. The Australian Government has published guidance on performing regulatory impact assessments in the *User Guide to the Australian Government Guide to Regulatory Impact Analysis*.[102]

The Office of Best Practice Regulation provides guidance and support for public sector bodies performing regulatory impact assessments. The Office of Best Practice Regulation assist with:[102]

- Scoping the problem
- Assessing the adequacy of analysis
- Estimating impacts and undertaking a cost-benefit analysis
- Providing technical advice on regulatory cost measurement, and

- Providing training and guidance on the regulatory impact assessment process.

The Office of Best Practice Regulation maintains a public website to report regulatory impact assessment compliance, regulatory impact assessment activity, and post-implementation reviews.

Undertaking a regulatory impact assessment involves a three-step process.[102]

Table 8 Steps for undertaking a regulatory impact assessment

Step		Explanation
1	Preliminary assessment	A preliminary assessment is used to determine whether a regulatory impact assessment is required. The preliminary assessment needs to answer seven key questions: 1. Who will be the decision-maker? 2. What is the policy problem? 3. What are the objectives of government action? 4. What policy options are available? 5. Are there regulatory impacts of the proposal (including any market or competition impacts)? 6. Are there potential regulatory costs of the proposal, including administrative costs, substantive compliance costs, and delay costs, as per the Regulatory Burden Measurement framework? 7. What are the key dates and timelines associated with the project? Following the submission of the preliminary assessment, the Office of Best Practice Regulation will determine whether a formal regulatory impact assessment is required.
2	Preparation of a regulatory impact assessment	The proportionality principle applies to any regulatory impact assessment performed on behalf of the Australian Government. Consequently, the depth of analysis for the seven regulatory impact assessment questions is proportionate to the proposed legislative change's magnitude and the policy development process stage. Therefore, the key determinants of proportionality for producing a regulatory impact assessment are the: • Scale, scope, and gravity of the problem to be addressed • Nature of the proposed intervention and alternative options, and their potential impacts, and • Policy development process stage and the type of decision being taken. The Office of Best Practice Regulation also provides both an early and final assessment in step two of the regulatory impact assessment process. These assessments are undertaken only after the regulatory impact assessment has received certification from the regulatory impact statement secretary, deputy secretary, chief executive, or other delegates responsible for the regulatory proposal. The early assessment focuses on the first four regulatory impact assessment questions and whether the regulatory impact assessment proposal contains an appropriate plan for consultation, including explaining the purpose and objectives of consultation. Once these criteria have been satisfied, the Office of Best Practice Regulation will inform the responsible authority undertaking the regulatory impact assessment whether it has met the requirements and whether the assessment is suitable as a basis for consultation or a decision. In order to introduce regulatory changes, final policy decisions must be accompanied by a regulatory impact assessment through a final assessment. The final assessment is a two-step process:

Step		Explanation
		1. The Office of Best Practice Regulation comments on whether the regulatory impact assessment is consistent with the Government's requirements, sufficiently addresses all seven regulatory impact assessment questions, and provides an accurate description of the status of the regulatory impact assessment at each previous central decision point in the proposal's development. 2. The Office of Best Practice Regulation relies on the certification by the respective secretary, deputy secretary, chief executive, or other delegates to determine the regulatory impact assessment's adequacy. After the second step, the regulatory impact assessment, a one-page executive summary, and the Office of Best Practice Regulation assessment are submitted to the decision-maker if the proposal proceeds.
3	Ensuring transparency	Transparency is one of the main purposes of a regulatory impact assessment. Upon announcement of a final decision, details of the regulatory impact assessment provided to the decision-maker for the final decision is published on the regulatory impact assessment updates website.

5.3.2 Cost-benefit analysis

As part of the Australian Government's regulatory impact assessment, a formal cost-benefit analysis is also required for regulatory proposals that will have a substantial or widespread impact on the economy. The cost-benefit analysis involves a systematic evaluation of a proposal's impact, accounting for all the effects on the community and the economy. It calculates the monetary value of the gains and losses for all people affected. If the sum is positive, the benefits exceed the costs, and the proposed regulation would increase efficiency. Cost-benefit analysis is beneficial as it provides decision-makers with quantitative and qualitative information about the likely effects of a regulation. The cost-benefit analysis also ensures that decision-makers consider all the positive and negative effects of the proposed regulation, and it discourages decisions based only on the impacts on a single group within the community.[103]

The Office of Best Practice Regulation also assists government agencies in performing cost-benefit analyses for regulatory reform.

The Australian Government specifies nine steps in undertaking a cost-benefit analysis:[103]

1. Specify the set of options.
2. Decide whose costs and benefits count.
3. Identify the impacts and select measurement indicators.
4. Predict the impacts throughout the life cycle of the proposed regulation.
5. Monetise (place monetary values on) these impacts.
6. Discount future costs and benefits to obtain present values.
7. Compute the net present value of each option.
8. Perform sensitivity analysis.
9. Reach a conclusion.

Full details and guidance on performing cost-benefit analysis in the context of regulating health professionals can be found in the *Cost-benefit analysis guidance note*.[103]

6 The Netherlands

The Netherlands, with a population of just over 17 million, is one of the most densely populated countries in the European Union (EU).[104] The Netherlands ranks highly across many OECD Better Life Index criteria, such as work-life balance, employment, education and skills, social connections, health status, and environmental quality.[104] Traditionally, the Dutch healthcare system was based primarily on social insurance, with high-income earners relying on private insurance. Four different health insurers provide 90% of the health cover in the Netherlands, with a government-run information website to help the public choose healthcare providers.[105] Although the healthcare system in the Netherlands is one of the most expensive in Europe, it is also one of the top performing in terms of value for money. The primary funding source for healthcare in the Netherlands is compulsory health insurance contributions from all citizens, with the remainder obtained from general taxation.[105] In general, the Dutch approach to the regulation of health professions is liberal, with legislative authorities seeking to impose as few regulatory barriers as possible to avoid unnecessary entry barriers. However, due to public health considerations, the healthcare sector is traditionally more regulated than other professional sectors. As a result, the Netherlands has a hybrid system for regulating health professionals.[106] The Individual Healthcare Professions Act provides a general legislative framework for regulating health professions. The Act, introduced in the Netherlands in 1997, resulted in a single framework for health professionals.[107] The Individual Healthcare Professions Act aims to enhance healthcare quality and ensure adequate public protection from health professionals' misconduct.[107]

6.1 Legislation

6.1.1 Current legislation

6.1.1.1 Individual Healthcare Professions Act (1997)

The regulation of health professionals in the Netherlands is established under the Individual Healthcare Professions Act (1997).[107] This Act, commonly referred to by its Dutch acronym BIG (*Wet op de beroepen in de individuele gezondheidszorg*), seeks to balance freedom of choice and public protection. Dutch legislation determines that individuals should be free to choose who provides their healthcare, both in complementary and traditional healthcare settings. Various provisions are included in the BIG Act to ensure public protection, including professional title protection, educational requirements, public registration, and a disciplinary code of conduct for all registered health professionals.[106]

The BIG Act has two main categories of regulation. The first category, referred to as the 'heavy regime', is based on Article 3 of the BIG Act. The second category, known as the 'light regime', is based on Article 34 of the BIG Act. Health professionals included in Article 3 are entitled to a protected professional title and autonomy to perform activities relating to their scope of practice. Regulated professions must also be registered and listed on the BIG register. The BIG register is a publicly available online register that lists all regulated health professionals under Article 3. The BIG register provides details of a health professional's qualifications and competencies to practise.[108] Registration on the BIG register is mandatory for professionals in Article 3, with renewal required every 5 years. Regulated professionals in Article 3 are also liable to disciplinary measures as determined by regional disciplinary committees and the Health and Youth Care Inspectorate. Disciplinary measures include fines, reprimands, suspensions, and removal from the register in instances where public health is compromised.[109] Professionals in Article 34 have a legally protected academic title. However, they are not required to register on the BIG register nor are they subject to disciplinary measures.

The BIG Act's default is that health professions are not registered in the BIG Act unless regulation is necessary to protect the public from malpractice. The legislation clarifies that recognition, status, or financial and economic motives are not valid reasons for inclusion in the BIG Act.[107]

The BIG Act seeks to balance between freedom of choice and public protection against malpractice. Dutch legislation determines that patients should be free to choose their healthcare provider, both in complementary and traditional healthcare settings. Certain high-risk medical activities or interventions are restricted to specific health professionals to ensure patient safety. These procedures may only be indicated, performed, or delegated by professionals with an independent authority or performed by professionals with a functional independent authority. For professionals with independent authority, the health professional undertaking the procedure must be certified and be proficient in the procedure. For professionals with functional independent authority, the health professional undertaking the procedure must be certified, be proficient in the procedure, and perform the procedures themselves after delegation from a professional with independent authority.[110] [111]

Reserved procedures include:[110]

- Anaesthesia
- Cardioversion
- Catheterisation
- Defibrillation
- Electroconvulsive therapy
- Endoscopy
- Injections
- In vitro fertilisation procedures
- Lithotripsy
- Obstetric procedures
- Prescription of medicine
- Procedures involving the use of radiation and/or ionising radiation
- Punctures, and

Surgical procedures.

6.1.2 Justification for legislative reforms

The BIG Act replaced previous legislation, primarily the Medical Practice Act (*Wet op de Uitoefening van de Geneeskunst;* WUG Act). The WUG Act, introduced in 1865, provided uniform university education and legal protection for the medical profession.[105] In practice, this led to a monopoly of medical practice by physicians'. Although opposition to such a system grew over the intervening years, it was not until 1965 that the first significant steps were taken to consider major reform of the WUG Act. Following several parliamentary committee meetings, investigations, and advisory groups, a consensus was reached that the Government should replace the monopolistic and restrictive WUG Act with new legislation. Several factors were cited to justify replacing the WUG Act with the BIG Act. First, the ban on unauthorised professionals performing medical procedures was frequently violated and therefore was not practical in a modern healthcare environment. Second, since the implementation of the WUG Act, many other laws governing medical professionals had been created, thereby resulting in a convoluted regulatory system. Finally, there was a growing concern for patient safety and a desire for a more transparent disciplinary system for medical professionals. Consequently, the Dutch Parliament passed the BIG Act in 1993 and the Act was implemented in phases between 1994 and 1997.[112] With this transformation, the performance of medical procedures was open to all professional groups, except for a list of 'reserved procedures' deemed too dangerous to be performed independently by unqualified health professionals.[113] [106]

Further legislative amendments to the BIG Act resulted in the addition of a criteria-based approach to risk assessment for the addition of new health professions.[107] Details on the risk criteria are provided in Section 6.3.1.

6.1.2.1 First review of the BIG Act (2002)

In 2002, the Ministry of Health, Welfare and Sport commissioned a review of the BIG Act. The review evaluated whether the BIG Act fulfilled its objective of balance between freedom of choice and public protection. Specifically, the review focused on several key areas: constitutive registration and professional title protection, the jurisdiction of reserved procedures, quality assessment, and disciplinary law and measures. Based on these five key areas, the reviewers used several sub-questions for the evaluation:[114]

- How does the scheme work?
- How functional is the scheme in practice?
- Does the scheme achieve its goal effectively and have side effects occurred?

The review concluded that although the Act had been well adopted and had provided public protection, it was not optimal. The review offered several recommendations to improve the overall functioning of the Act in order to ensure that it achieved its primary objective of balancing freedom of choice with public protection.

Some of the recommendations from the first review of the BIG Act included:[114]

- Enhancing government investment to educate members of the public on the intention, purpose, and importance of the BIG Act in protecting the public from risk.
- Further elaborating on reserved procedures under the BIG Act.
- Improving resources and defining responsibility for the Health and Youth Care Inspectorate concerning the enforcement of disciplinary law associated with the BIG Act, and
- Improving the BIG register's functioning by ensuring that the necessary information is made available to the public.

6.1.2.2 Second review of the BIG Act (2013)

A second review of the BIG Act was undertaken in 2013. Two central questions formed the basis of the review. The first question sought to determine whether the Act achieved its current objective of monitoring professional practice quality and protecting the public against malpractice. The second question sought to explore whether the Act in its current format was future-proof in light of developments in healthcare and society. The review concluded that the BIG Act performs a vital role in protecting public health and, consequently, it did not recommend a fundamental overhaul of the system at that time.

However, the review did make several recommendations to improve legislation further, particularly concerning professional regulation and disciplinary issues.

Recommendations for improving professional regulation included:[107]

- The use of specific assessment criteria for the addition of any new health professions applying for regulation under the BIG Act.
- A legal obligation for registered health professionals to provide details of their BIG registration.
- Additional requirements for re-registration, such as compulsory continuing education, proof of clinical competence, and relevant work experience, and
- Reserved procedures to be designated by Order in Council instead of by law.

Recommendations for improving disciplinary measures identified in the review included:[107]

- The creation of healthcare quality, complaints, and disputes legislation, and the establishment of a National Care Hotline to provide a platform for complaints against healthcare providers.
- Reimbursement of costs for complainants.
- Potential for complainants to change a complaint during the preliminary investigation, and
- A review of disciplinary standards to clarify instances where disciplinary law or case law applies.

6.1.2.3 Third review of the BIG Act (2019)

A third review in 2019 was commissioned by the Minister for Health, Welfare and Sport to determine a long-term vision for the BIG Act. In response the Minister established a steering committee and task force composed of health professionals, health professionals' organisations, patients, and members of the public. The work of the task force is currently ongoing. The Minister has also provisionally suspended new requests for regulation applications under the BIG Act. Requests already submitted to the National Health Care Institute will be processed accordingly.[115]

6.2 Organisational structure and regulatory status of professions

6.2.1 Ministry of Health, Welfare and Sport

At a national level, the Ministry of Health, Welfare and Sport have overall responsibility for health policy relating to the regulation of health professions. It oversees several government agencies involved in the administration of the BIG Act.[116]

6.2.2 Central Information Unit on Healthcare Professions

The Central Information Unit on Healthcare Professions is an executive organisation within the Ministry of Health, Welfare and Sport. Based on legislation or established policy, it makes decisions, registers data, issues permits, and provides support to committees and boards with an oversight function in healthcare. The Central Information Unit on Healthcare Professions manages the BIG register on behalf of the Ministry of Health, Welfare and Sport.[116]

6.2.3 Health and Youth Care Inspectorate

The Health and Youth Care Inspectorate oversees public health service delivery and quality to ensure compliance with legal and regulatory standards. The Inspectorate also reports to and advises the Government and healthcare institutions in the Netherlands. The Health and Youth Care Inspectorate enforces and supervises compliance with the BIG Act and investigates any misuse of professional titles or instances of professional title abuse.[117]

6.2.4 National Health Care Institute

The National Health Care Institute is an independent body that assesses applications for regulation under the BIG Act on behalf of the Ministry of Health, Welfare and Sport. Following the assessment of an application for inclusion on the BIG register, the National Health Care Institute provides an advisory report to the Ministry of Health, Welfare and Sport on the merit of the profession's application for regulation.[118]

6.2.5 Regulatory bodies and regulated professions

Four categories of regulation are legislated under the BIG Act: Article 3 professions, Article 34 professions, Article 36a professions, and Article 14 professions.

6.2.5.1 Article 3 professions

Professions included in Article 3 of the BIG Act:[108]

- Have a legally protected professional title.

- Are listed on the BIG register, and
- Are subject to disciplinary rules.

Regulated professions under Article 3 of the BIG Act also must re-register on the BIG register every five years. To do so, regulated professionals must provide evidence of sufficient clinical hours in the preceding five years. Article 3 professionals must also provide evidence of continued professional development relevant to their profession.[109] Regulated professionals who do not meet the specified criteria or do not renew their registration on time are deregistered and are no longer allowed to carry out their professional role.[119]

The professionals legislated under Article 3 of the BIG Act include:[108]

- Clinical technologist
- Dentist
- Doctor
- Health psychologist
- Midwife
- Nurse
- Pharmacist
- Physiotherapist
- Psychotherapist
- Physician assistant, and
- Remedial educationalist.

6.2.5.2 Article 34 professions

Professions included in Article 34 of the BIG Act:[108]

- Have a legally protected academic title.
- Cannot register on the BIG register, and
- Are not subject to disciplinary rules.

The professionals legislated under Article 34 of the BIG Act include:[108]

- Dental hygienist
- Dental technician
- Diagnostic radiographer
- Dietician
- Medical physicist
- Nurse practitioner in individual healthcare (private nurse)
- Occupational therapist
- Optometrist
- Orthoptist
- Pharmacist's assistant
- Podiatrist
- Remedial therapist

- Skin therapist
- Speech therapist, and
- Therapeutic radiographer.

6.2.5.3 Article 36a professions

Dutch policy-makers have used Article 36a to expand the scope of practice of several professional groups to facilitate task shifting and increase efficiency in delivering care.[111] Under Article 36a, by way of experimentation, specific categories of professionals may be declared independently competent for a certain period to carry out interventions.[107] Nurse practitioners, physician assistants, certain categories of allied medical health professionals, and clinical technologists have all received temporary independent authority to perform reserved procedures, essentially providing them with an expanded scope of practice. Health professionals are regulated under Article 36a of the BIG Act for a maximum of 5 years. At the end of the trial period, the Ministry of Health, Welfare and Sport decides whether to move a profession to Article 3 or return the profession to Article 34.[111]

Professions included in Article 36a of the BIG Act:[108]

- Have a legally protected academic title
- Can temporarily register on the BIG register
- Are subject to disciplinary rules
- May perform reserved procedures, and
- Have temporary functional autonomy.

6.2.5.4 Article 14 professions

The BIG Act also includes the provision for specialist registration under Article 14.[120] Article 14 can only be applied to Article 3 professions, who are registered and have a protected professional title. Specialisations are sub-areas within a profession that require a specific type of expertise. Specialist registers under the BIG Act are available to the public for inspection. Unlike the registers for other professions under the BIG Act, specialist registers are the responsibility of the individual profession. Five professions regulated under Article 3 have provisions for specialist titles under the BIG Act: medicine, dentistry, pharmacy, health psychology, and nursing.

Applications for specialist registration under Article 14 of the BIG Act must satisfy the following criteria:[107] [120] [107]

- In the Minister of Health’s opinion, the profession is sufficiently representative of the profession's practitioners in question.
- The organisation is an association with full legal capacity;
- The organisation lays down rules outlining the procedure for decision-making within the organisation concerning the establishment of a register of specialists, tasks and composition of the various bodies and the amount due, to cover the costs, to examine an application for registration and recognition of a training establishment.
- The organisation has a body that is responsible for the decision to set up a register of specialists and lay down rules on the requirements for registration as specialists and on the recognition of training institutions, respectively trainers, for a speciality, and
- The organisation also has a body responsible for registering specialists, recognising training institutions, respectively trainers and monitoring the implementation of the rules by the approved training institutions, respectively trainers.

Table 9 Summary of regulatory regimes

	Article 3	Article 34	Article 36a (Experimental)
Legally protected professional title	Yes	No	No
Mandatory registration	Yes	No	Yes
Disciplinary rules	Yes	No	Yes
Possibility of granting power to perform reserved procedures	Yes	Yes	Yes

The Disciplinary College for Healthcare deals with complaints about individual health professionals. The Disciplinary College for Healthcare is made up of four regional disciplinary tribunals. Complaints may be submitted against any health professional listed on the BIG register. If a regional disciplinary tribunal determines that a healthcare provider has not complied with its professional standards, it can impose a suitable disciplinary measure.[121]

6.2.5.5 Professions regulated since 2015

According to the available literature, no new professions have been regulated in the Netherlands since 2015.

6.2.6 Unregulated professionals

6.2.6.1 Professions that have sought regulation but have not been regulated

The Dutch Association of Anaesthesia Assistants sought to regulate nurse anaesthetist profession under Article 3 of the BIG Act. In 2020, after assessing the application, the National Health Care Institute (Zorginstituut) advised the Minister for Health, Welfare and Sport not to include the profession under Article 3 of the BIG Act.[122]

Additionally, the Dutch Association for Clinical Chemistry and Laboratory Medicine applied to regulate clinical chemist profession under Article 3 of the BIG Act. In 2020, after assessing the application, the National Health Care Institute advised the Minister for Health, Welfare and Sport not to include the profession under Article 3 of the BIG Act.[123]

6.2.6.2 Challenges in court

There is no evidence in the literature that there have been challenges in court in the Netherlands by professions that have applied to be regulated but have not been regulated.

6.2.6.3 Professions that have been deregulated or have had their level of regulation minimised

No regulated health profession has been deregulated in the Netherlands, nor has any profession had its level of regulation minimised.

6.2.6.4 Professions under consideration for regulation

The National Health Care Institute is currently considering applications for the regulation of three health professions on behalf of the Minister for Health, Welfare and Sport, as follows:[124]

- The Dutch Association for Clinical Physics has applied for regulating the profession of clinical physicist under Article 3 of the BIG Act.
- The National Association of Surgical Assistants has applied for the inclusion of the surgical assistant profession under Article 3 of the BIG Act.

- The Netherlands Institute of Psychologists has applied for the inclusion of the profession of child and adolescent psychologist under Article 3 of the BIG Act.

Following the publication of the 2019 review of the BIG Act and the subsequent establishment of a steering committee, the Minister for Health, Welfare and Sport has decided to provisionally suspend new requests for regulation under the BIG Act until a full review of the Act has been completed.[124]

6.3 Process for deciding who to regulate

The Minister of Health, Welfare and Sport has the authority to recommend extending the BIG Act to include new health professions. Before submitting a formal application, applicants must obtain information from the National Health Care Institute. Following submission of a formal application, the National Health Care Institute assesses the application on behalf of the Minister for Health, Welfare and Sport. The first step in the regulatory process requires the National Health Care Institute to assess an application using a set of criteria established following the 2013 review of the BIG Act (see Table 10).[107]

Table 10 Criteria for determining whether to regulate a new profession

Criterion		Explanation
1	Is the profession aimed at individual healthcare?	• Does the profession mainly occur in the context of individual healthcare, as referred to in Article 1 of the BIG Act? • Does the core of the profession involve direct patient contact? • Is regular care provided?
2	Is the profession a basic profession, and is it sufficiently distinctive?	• Is it a broad basic profession? Is there a clear link between a national vocational training and the profession? • Is the area of expertise sufficiently developed and distinctive from other professions? • Is there a Dutch education program for the profession of sufficient quality and independently assessed. • Is the profession of sufficient size to justify regulation?
3	Is legal regulation of the profession necessary to adequately protect patients?	• Can the quality of the professional practice be guaranteed in other ways (quality assurance within an institution or private regulation)? • If there is no substantial risk to patient safety then regulation is not necessary. • Is the profession freely accessible?

If the profession meets these criteria, a trade-off will then occur as to whether the profession is eligible for inclusion in Article 3 or Article 34 of the BIG Act. In Article 3, professions have a legally protected title, are listed on the BIG register, are subject to disciplinary rules, and must re-register every five years. Professions in Article 34 have a legally protected academic title, but they cannot register on the BIG register nor are they subject to disciplinary rules. A decision to apply Article 34 occurs if there is a need for public law regulation of the degree program or a requirement for a title recognisable to the public, but the need to protect the public is not sufficient to warrant Article 3. Article 3 is applied where there is a need to protect the public through the use of the public register and the ability to implement disciplinary action. For example, the need to protect the public may arise when individuals are dependent or placed in vulnerable positions through their interactions with the health professional.[107]

The National Health Care Institute visits the working environment of the applying profession and undertakes consultations with individual professionals. Interested organisations (e.g. professional

associations with adjacent knowledge areas; educational organisations; or public or semi-public authorities) are encouraged to provide feedback and opinions in response to the application for regulation. After completing these processes, a draft advisory report is produced. Based on the advice provided, the Minister for Health, Welfare and Sport decides whether to regulate the profession in question. If deemed necessary, the Minister will inform the national parliament of their intention to regulate a profession.[125]

6.3.1 Risk assessment

The Integrated Policy and Regulatory Framework impact assessment tool assists civil servants in formulating policy and legislative decisions.[126] The Integrated Policy and Regulatory Framework impact assessment tool was introduced by the Dutch Cabinet in 2011. It brought together 110 different and overlapping quality requirements into one integrated administrative framework, structured around seven central questions.[127] The Integrated Policy and Regulatory Framework impact assessment tool is publicly available online. It provides ministries with the necessary information for developing new policies and regulations and includes links to all existing instruments used in legislative preparation.[127] It is the responsibility of each ministry to provide an adequate response to these seven questions when submitting new legislative proposals. Individual ministries are responsible for guaranteeing the quality of their regulations and therefore for producing an adequate response to the seven IAK questions.[127] It is recommended but not mandatory that government agencies use the tool when formulating or proposing legislative changes. It is unclear from the literature if the tool is used to regulate health professionals.[126] An overview of the Integrated Policy and Regulatory Framework impact assessment tool is provided in Table 11.

Table 11 Overview of the Integrated Policy and Regulatory Framework impact assessment tool

Phase		Goal	Questions
1	Problem analysis	Map the problem.	• Which parties should be involved? • What is the problem? • What is the goal? • What justifies government intervention?
2	Choice of intervention	Determine which intervention(s) should be used.	• Which intervention is the best? Consider: - Interventions - Legality, effectiveness, and feasibility - Introduction of policy
3	Impact assessment	Determine the proposed solution's impact and indicate how this will be evaluated.	• What are the consequences for citizens, companies, the government and the environment?

Source: [126]

6.4 EU Proportionality Directive 2018/958

Unfortunately, information from the Netherlands regarding the implementation of EU Directive 2018/958 on a proportionality test before regulating new professions was not available in the literature.

7 Finland

Finland's population is estimated to be 5.5 million.[128] Life expectancy at birth in Finland is 82 years, which is 2 years higher than the OECD average of 80.[128] Finland ranks highly in the Better Life Index. Specifically, it ranks first among OECD member countries for education and subjective well-being and above average for the following domains: income and wealth; jobs and earnings; health status; environmental quality; personal security; social connections; housing; and work-life balance.[128]

The Finnish health and social care system is the most decentralised in Europe, if not globally. Unlike many European countries, healthcare delivery in Finland is relatively integrated via local governments, known as municipalities. These municipalities, of which there are approximately 300, are responsible for organising most primary care and social services.[129] The Social Insurance Institution of Finland funds public health services through compulsory employer contributions. On the other hand, primary and hospital care are financed from taxes collected by the municipalities and from government subsidies.[130] All Finnish residents can avail of publicly funded health services. Although Finland spends slightly more on healthcare per capita (€3,036) than the EU average (€2,884), it spends substantially less than the other Nordic countries (Denmark, Sweden, and Norway). In Finland, healthcare spending equates to 9.2% of GDP, a lower proportion than the EU average (9.8%), and Denmark, Sweden, and Norway spend (all above 10%).[130]

Please note that for the following sections, no information was available in the literature for Finland:

- Justification for legislative reforms
- Restricted activities, and
- Process for deciding who to regulate.

7.1 Legislation

7.1.1 Current legislation

7.1.1.1 Health Care Professionals Act 1994

Health professions in Finland are regulated under the Health Care Professionals Act 1994. The objective of this Act is to promote the safety of patients and to improve the quality of healthcare services by:[131]

- Ensuring that a health professional has the necessary education and training, professional qualifications, and other knowledge and skills necessary for their practice.
- Organising the supervision of health professionals, and
- Facilitating professionally appropriate cooperation between, and appropriate employment of, health professionals.

7.2 Organisational structure and regulatory status of professions

7.2.1 Ministry of Social Affairs and Health

The Ministry of Social Affairs and Health is responsible for implementing Finland's social welfare and healthcare policy, gender equality policy, and occupational safety and health policy. The Ministry of Social Affairs and Health has a broad mandate. It supervises several independent agencies and institutions, including the National Supervisory Authority for Welfare and Health, responsible for regulating health professions.[132]

7.2.2 National Supervisory Authority for Welfare and Health

The National Supervisory Authority for Welfare and Health, commonly referred to as Valvira, is a centralised body operating under the Ministry of Social Affairs and Health. Valvira is responsible for national guidance and the supervision of health professionals.[133] Supervision of regulated professionals is the responsibility of Regional State Administrative Agencies at a local level, and Valvira supervises these agencies. Valvira also maintains a central register of health professionals. The register contains details of each registered health professional, including their identity code, registration number, and detailed information such as their authorisation to practise and any reprimands, fines, or sentences of imprisonment related to the professional's practice. Part of the register is publicly accessible, and any citizen can check a professional's licence to practise or if they have any pending disciplinary matters. Valvira and the Regional State Administrative Agencies can intervene if health professionals act improperly, and Valvira deals with the more serious cases. The Health care Professionals Supervisory Board, which functions alongside Valvira, can prohibit a professional from practising either temporarily or indefinitely. Additionally, in circumstances where a health professional is no longer capable of practising their profession, the National Authority for Medicolegal Affairs may order the health professional to undergo a medical examination.[133]

7.2.3 Regulatory bodies and regulated professions

Regulation falls under two categories in Finland: licensed professionals and professions with a protected occupational title. Only licensed professionals may practise the profession in the first category. Licensing means that an individual has completed a training programme laid down in legislation, is authorised to work in the profession in question, is entitled to use the occupational title in question, and is registered with the National Supervisory Authority for Welfare and Health. Professions with protected occupational titles may be practised by anyone who possesses appropriate training, experience, and professional skills and knowledge.[131] A health professional with a protected occupational title is not required to register with the National Supervisory Authority for Welfare and Health.[131]

7.2.3.1 Licensed professionals

The following professions are licensed in Finland:[131]

- Pharmacists
- Physiotherapists
- Dentists
- Dental technicians
- Midwives
- Laboratory nurses
- Physicians
- Opticians
- Psychologists
- Speech therapists
- Dieticians
- Radiographers
- Nurses
- Dental hygienists, and
- Occupational therapists.

7.2.3.2 Protected occupational titles

The following professions have protected occupational titles in Finland:[134]

- Assistive technology technician
- Podiatrist
- Chiropractor
- Trained masseur
- Local nurse for social and healthcare
- Naprapath
- Osteopath
- Psychotherapist
- Hospital physicist
- Hospital chemist
- Hospital microbiologist, and
- Hospital cell biologist.

Unfortunately, no further information was available in the literature regarding regulatory bodies and the regulatory status of professions in Finland.

7.3 EU proportionality directive 2018/958

EU Directive 2018/958 on a proportionality test before regulating new professions was implemented nationally by a Government decree (376/2020). Section 8(4) of the Health Care Professionals Act 1994 (559/1994), as set out in Law 262/2015, has been amended to reflect the proportionality directive's implementation.[135] Unfortunately, no further information was available in the literature regarding how exactly the Proportionality Directive will be implemented in Finland.

8 Sweden

The population of Sweden is approximately 10 million. Life expectancy in Sweden is among the highest in the EU; in 2017, the life expectancy at birth in Sweden was 82.5 years, more than 1.5 years above the EU average (80.9 years).[136] Self-reported health among the general population is also high, with almost 78% of people in Sweden reporting being in good health, which is nine percentage points higher than the OECD average of 69%.[137]

Overall, the health system in Sweden performs well in providing reasonable access to high-quality care, but at a relatively high cost. Sweden has the third-highest health spending in the EU both as a share of GDP (11.0% in 2017, compared with the EU average of 9.8%) and per capita (€3,872 EU average €2,884). Most health spending is publicly funded (84%), which is also higher than the EU average (79%).[136]

The Swedish healthcare system is a socially responsible system with an explicit public commitment to ensure citizens' health. The Swedish system provides coverage for all residents, regardless of nationality, while emergency coverage is provided to all patients from the European Economic Area through bilateral agreements.[136] Healthcare in Sweden is decentralised, with regional councils – and, in some cases, local councils or municipal governments – taking responsibility for care delivery. The Health and Medical Service Act (1982) regulates healthcare delivery;[138] it is designed to give councils and municipalities considerable freedom concerning the organisation of their healthcare services. The State is responsible for overall healthcare policy through the Ministry of Health and Social Affairs. All health professionals must obtain a licence to practise in Sweden, with healthcare regulation legislated under the Patient Safety Act 2010.[139]

Please note that for the following sections, no information was available in the literature for Sweden:

- Justification for legislative reforms
- Restricted activities, and
- Process for deciding who to regulate.

8.1 Legislation

8.1.1 Current legislation

8.1.1.1 Patient Safety Act 2010

The regulation of health professions in Sweden is legislated under the Patient Safety Act 2010, which protects 22 health professional titles. Specialist titles are also legislated in the Patient Safety Act for doctors, hospital physicists, dentists, and nurses. The National Board of Health and Welfare is responsible for licensing health professionals under the Patient Safety Act 2010.[139] The Act also sets out several obligations for individual health professionals. According to the Act, healthcare workers are personally responsible for their actions. The Patient Safety Act states that the responsibilities of healthcare providers include:[139]

- The implementation of systematic patient safety work and preventive work.
- An obligation to analyse adverse events, and
- A requirement to inform patients and relatives as soon as possible when harm occurs.

8.2 Organisational structure and regulatory status of professions

8.2.1 National Board of Health and Welfare

The National Board of Health and Welfare is a Swedish Government agency under the Ministry of Health and Social Affairs. The National Board of Health and Welfare is the Government's central

advisory and supervisory agency for health services, health protection, and social services.[140] The National Board of Health and Welfare assesses applications and issues licences to practise for health professionals in Sweden and issues certificates of specialisation for doctors of medicine and dentists.[141] The National Board of Health and Welfare is also responsible for keeping a register of health professionals who have been granted a licence to practise. The register, known as the Register of Licensed Health Professionals, provides information on health professionals' clinical and professional competence to employers, authorities, and the general public. The register also provides data for statistics and forecasts of health professionals' availability.[142] There is no time limit on the validity of National Board of Health and Welfare licences under the Patient Safety Act 2010.[140]

8.2.2 Health and Social Care Inspectorate

The Health and Social Care Inspectorate is a Government agency under the Ministry of Health and Social Affairs responsible for supervising healthcare under the Patient Safety Act 2010.

The Health and Social Care Inspectorate involves several regional divisions, with divisional responsibility for:[143]

- Supervising services in healthcare and social services.
- Supervising regulated professionals, including providing reports to the Medical Responsibility Board regarding the withdrawal of licences and other authorisations, and
- Investigating complaints about healthcare and social services professionals.

8.2.3 Regulatory bodies and regulated professions

The National Board of Health and Welfare regulates 22 professional titles. These professional titles are protected under Section 5 of the Patient Safety Act 2010:[144]

- Audiologist
- Biomedical scientist
- Chiropractor
- Dental hygienist
- Dental practitioner
- Dietitian
- Doctor of medicine
- Healthcare counsellor
- Medical physicist
- Midwife
- Naprapath
- Nurse responsible for general care
- Occupational therapist
- Optician
- Orthopaedic engineer
- Pharmacist
- Physiotherapist
- Prescriptionist
- Psychologist

- Psychotherapist
- Radiographer, and
- Speech therapist.

Unfortunately, no further information was available in the literature regarding regulatory bodies and the regulatory status of professions in Sweden.

8.3 EU proportionality directive 2018/958

EU Directive 2018/958 on a proportionality test before regulating new professions was adopted into law in Sweden in 2020.[145] The regulation applies to Government agencies and replaces previous legislation on the recognition of professional qualifications. Unfortunately, no further information was available in the literature regarding how exactly the Proportionality Directive will be implemented in Sweden.

9 Denmark

Denmark has a population of approximately 5.8 million.[146] Living standards are high, with Denmark performing very well across a host of well-being indices such as housing, work–life balance, civic engagement, health status, and education, among others.[147] Denmark's Scandinavian welfare model has an excellent tradition of reform and strong institutions that underpin the system's basic principle. Life expectancy in Denmark is 81 years, which is 1 year greater than the OECD average of 80 years. Denmark provides a universal healthcare system to all citizens, which is funded largely through taxation. The principle of equity is enshrined in the Danish Health Act (2005), which states that citizens should have equal access to healthcare irrespective of their economic means. All residents of Denmark have access to the public healthcare system, and most services are provided free of charge. National legislation ensures that diagnosis and treatment are provided within certain time limits and establishes a free choice of hospital for patients.[148] Denmark is one of the OECD's biggest spenders on healthcare, spending 10.6% of its GDP, compared with the OECD average of 9.0%.The healthcare system is currently organised into three administrative levels: the national level (State), the regional level (5 regions), and the local level (98 municipalities).[149]

The Danish Ministry of Health defines the framework of the Danish healthcare system. At the national level, the Danish Ministry of Health is responsible for passing health legislation; issuing national guidelines; protecting patient rights; conducting audits; and monitoring health professionals, hospitals, and pharmacies. The Danish Ministry of Health acts through various State agencies, including the Danish Patient Safety Authority.[149] In general, all health and social services are financed by general taxation and are supported by a system of central government block grants, reimbursements, and equalisation schemes.[148]

Please note that for the following sections, no information was available in the literature for Denmark:

- Justification for legislative reforms
- Restricted activities
- Process for deciding who to regulate, and
- Implementation of the EU Proportionality Directive.

9.1 Legislation

9.1.1 Current legislation

9.1.1.1 Danish Health Act (2005)

Regulation of health professions in Denmark is determined by the Danish Health Act (2005). The Act aims to provide easy and equal access to healthcare and ensure that medical treatment is of high quality and that patients have freedom of choice in their healthcare.[150]

9.2 Organisational structure and regulatory status of professions

9.2.1 Danish Ministry of Health

The Danish Health Authority is managed by the Danish Ministry of Health and is responsible for defining the national healthcare system's overall framework.[148] The Danish Patient Safety Authority was created following a merger between the National Agency for Patients' Rights and Complaints and the Danish Health Authority's supervisory functions.[151]

9.2.2 Danish Patient Safety Authority

The Danish Patient Safety Authority is a Government agency with responsibilities across a wide range of healthcare domains, including regulating health professions in Denmark.[152] It regulates 19 health professional groups, with information about regulated professionals made available to the public via an online register.[153] The Danish Parliament has laid down the legal basis for the Danish Patient Safety Authority's work in several pieces of legislation, including the Danish Health Act (2005) and the Danish Authorisation Act.[149] The Danish Patient Safety Authority also handles any complaints against health professionals and is responsible for reporting adverse events. It is also responsible for the inspection of health institutions and staff.[149]

9.2.3 Regulatory bodies and regulated professions

The Danish Patient Safety Authority regulates 19 professional titles:[154]

- Chiropodist
- Chiropractor
- Clinical dental technician
- Clinical dietician
- Dental hygienist
- Dentist
- Medical laboratory technologist
- Midwife
- Nurse
- Occupational therapist
- Optometrist
- Osteopath
- Paramedic
- Physician (medical doctor)
- Physiotherapist
- Prescribing pharmacist
- Prosthetist and orthotist
- Radiographer, and
- Social and healthcare assistant.

Details of registered health professions are available via an online public register, which provides a list of registered health professionals. The register holds information about the registered health professionals, including personal details, profession, registration status, identification number, and specialist title. The register also contains information about whether a health professional is subject to any ongoing disciplinary proceedings.[153]

Unfortunately, no further information was available in the literature regarding regulatory bodies and the regulatory status of professions in Denmark.

9.3 EU Proportionality Directive 2018/958

Unfortunately, information from Denmark regarding the implementation of EU Directive 2018/958 on a proportionality test before regulating new professions was not available in the literature.

10 Synthesis of findings

Professional regulation is essential to ensuring safe, effective, and patient-centred care. However, regulation ought to be proportionate to the level of risk posed by health and social care professions. The countries included in this evidence brief vary in their approaches to addressing this challenge, however there are some common features across the countries. New Zealand, Australia, and the Netherlands have established criteria that are formally required for deciding which new professions to regulate. In all three countries these criteria have been used to regulate new professions. The specific criteria vary; however, in all three cases there is a focus on risk assessment. In the UK, the meta-regulator – the Professional Standards Authority – has designed risk-based criteria for deciding whether or not to regulate new professions. These criteria (which are outlined in *Right-touch assurance: a methodology for assessing and assuring occupational risk of harm*) have been tested, however they are not formally required. The UK Government has, however, proposed that the Professional Standards Authority be given the legislative power to advise the Government on whether or not to regulate a new profession, using *Right-touch assurance*.

Regarding deregulation of health professions, no professions have been deregulated in the United Kingdom, New Zealand, Australia, or the Netherlands. However, there is interest in potentially establishing a process for doing so in the United Kingdom and New Zealand.

Unfortunately, minimal information was available in the literature regarding the approaches to regulation in Finland, Sweden, and Denmark. Regarding the implementation of EU Directive 2018/958 on a proportionality test before regulating new professions, very little information was available as well.

Our findings from the United Kingdom, New Zealand, Australia, and the Netherlands show that establishing a clear set of criteria for assessing suitability for regulation creates consistency in the decision process. Moreover, establishing specific criteria for assessing risk ensures that patient safety underpins professional regulation. Transparency is also crucial, and public consultations play a key part in this. Once a clear process is established, regular review of the criteria used for assessment and of the process overall is important.

For professions that are regulated, a meta-regulator can play an important role in overseeing regulatory bodies. Additionally, having all regulated professionals listed on the meta-regulator's website, as is the case in Australia, can make this information more easily accessible to the public. For unregulated professions, the UK's accredited registers programme includes professional bodies that adhere to specific standards and provides a voluntary public register of unregulated professionals. In Australia and New Zealand, codes of practice govern unregulated professions. In all countries, responsibility for both regulated and unregulated health professionals meeting the standards of their profession is devolved to the relevant regulatory body or accredited register.

11 Conclusion

Across the countries for which detailed information was available – the United Kingdom, New Zealand, Australia, and the Netherlands – the decision of whether or not to implement statutory professional regulation is fundamentally based on risk of harm to the public. In assessing risk and other key criteria, these countries all focus on transparency and consistency. For professions that do not meet the required criteria and therefore are not regulated, New Zealand and Australia have national codes of practice that all health and social care professionals – regulated or not – must adhere to. The United Kingdom and the Netherlands provide alternatives to statutory regulation, in the form of voluntary accredited registers in the United Kingdom and legally protected academic titles in the Netherlands. Notably, both national codes of practice and alternatives to statutory regulation could be used in combination to ensure that unregulated health and social care professionals practise safely.

All four countries have invested significant time and resources into developing their processes and criteria for deciding which professions to regulate. The risk-based approaches to proportionality that have been implemented in the United Kingdom, New Zealand, and Australia demonstrate that proportional regulation is not only a European challenge, but a global one. Ultimately, professional regulation aims to protect the public, and countries across the world are striving to ensure that both legislation and practice reflect this. By learning from other countries' approaches, we can move towards a more proportionate system in Ireland, one that both ensures patient safety and allows health and social care professionals to excel in the critical role that they play in society.

References

1 Central Intelligence Agency. United Kingdom. https://www.cia.gov/the-world-factbook/countries/united-kingdom/#people-and-society (accessed 15 Jan 2021).

2 The Commonwealth Fund. International health care system profiles: England. https://www.commonwealthfund.org/international-health-policy-center/countries/england#:~:text=All%20English%20residents%20are%20automatically,funded%20primarily%20through%20general%20taxation. (accessed 20 Jan 2021).

3 UK Department of Health and Social Care. Promoting professionalism, reforming regulation: consultation document. 2017. https://www.health-ni.gov.uk/consultations/promoting-professionalism-reforming-regulation

4 Law Commission, Scottish Law Commission, & Northern Ireland Law Commission. Joint consultation paper: Regulation of health care professionals; regulation of social care professionals in England. 2012. http://www.lawcom.gov.uk/app/uploads/2015/03/cp202_regulation_of_healthcare_professionals_consultation.pdf

5 UK Department of Health and Social Care. Integration and innovation: working together to improve health and social care for all. 2021. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/960548/integration-and-innovation-working-together-to-improve-health-and-social-care-for-all-web-version.pdf

6 UK Government. National Health Service Reform and Health Care Professions Act 2002. https://www.legislation.gov.uk/ukpga/2002/17/contents

7 UK Government. Health and Social Care Act 2008. https://www.legislation.gov.uk/ukpga/2008/14/contents

8 UK Government. Health and Social Care Act 2012. https://www.legislation.gov.uk/ukpga/2012/7/contents/enacted

9 UK Government. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. https://www.legislation.gov.uk/uksi/2014/2936/contents/made

10 Leslie KM. Balancing Tensions in Regulatory Reform: Changes to Regulation of Health Professions in Australia, the United Kingdom, and Ontario, Canada. 2017.https://tspace.library.utoronto.ca/bitstream/1807/91139/3/Leslie_Kathleen_201706_PhD_thesis.pdf

11 Waring J, Dixon-Woods M, Yeung K. Modernising medical regulation: Where are we now? Journal of Health Organization and Management. *Journal of Health Organization and Management* 2010;**24**:540–55.

12 Law Commission. About us. https://www.lawcom.gov.uk/about/ (accessed 1 Mar 2021).

13 UK Department of Health and Social Care. Trust, assurance and safety: the regulation of health professionals in the 21st century. 2007. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/228847/7013.pdf

14 UK Department of Health and Social Care. Good doctors, safer patients: proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients. 2006. https://webarchive.nationalarchives.gov.uk/20130124073453/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4137276.pdf

15 UK Department of Health and Social Care. The regulation of the non-medical healthcare professions. 2006. https://www.pmguk.co.uk/data/page_files/publications%20and%20reports/2006/R.RegulationNon-medicalHealthProf.pdf

16 House of Commons Library. What is the Privy Council? https://commonslibrary.parliament.uk/research-briefings/cbp-7460/ (accessed 15 Nov 2020).

17 Professional Standards Authority. Meet our Board. https://www.professionalstandards.org.uk/about-us/meet-our-board (accessed 24 Feb 2021).

18 UK Department of Health and Social Care. Enabling excellence: autonomy and accountability for health and social care staff. 2011. https://www.gov.uk/government/publications/enabling-excellence-autonomy-and-accountability-for-health-and-social-care-staff

19 Professional Standards Authority. Accredited registers: ensuring that health and care practitioners are competent and safe 2015. https://www.professionalstandards.org.uk/publications/detail/accredited-registers---ensuring-that-health-and-care-practitioners-are-competent-and-safe (accessed 3 Nov 2020).

20 Council for Healthcare Regulatory Excellence. Right-touch regulation. 2010.

21 Better Regulation Executive. Five principles of good regulation. 2000.

22 Law Commission, Scottish Law Commission, Northern Ireland Law Commission. Regulation of Health Care Professionals. 2014. https://s3-eu-west-2.amazonaws.com/lawcom-prod-storage-11jsxou24uy7q/uploads/2015/03/lc345_regulation_of_healthcare_professionals.pdf

23 Department of Health and Social Care. Promoting professionalism, reforming regulation: Government response to the consultation. 2019. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/820566/Promoting_professionalism_reforming_regulation_consultation_reponse.pdf

24 Care Quality Commission. Who we are. https://www.cqc.org.uk/about-us/our-purpose-role/who-we-are (accessed 30 Jan 2021).

25 Professional Standards Authority. Professional Standards Authority. https://www.professionalstandards.org.uk/ (accessed 15 Nov 2020).

26 Professional Standards Authority. Standards of Good Regulation. 2018. https://www.professionalstandards.org.uk/docs/default-source/publications/standards/standards-of-good-regulation-2018-revised.pdf?sfvrsn=ce597520_11

27 Professional Standards Authority. Standards for Accredited Registers. 2016. https://www.professionalstandards.org.uk/docs/default-source/accredited-registers/standards-for-accredited-registers/standards-for-accredited-registers.pdf?sfvrsn=cc2c7f20_4

28 Casemine. Council for the Regulation of Health Care Professionals v General Medical Council and Ruscillo. https://www.casemine.com/judgement/uk/5a8ff71260d03e7f57ea7210 (accessed 20 Mar 2021).

29 Professional Standards Authority. Professional healthcare regulation in the UK explained. https://www.professionalstandards.org.uk/news-and-blog/blog/detail/blog/2018/04/10/professional-healthcare-regulation-explained (accessed 15 Dec 2020).

30 Professional Standards Authority. Health professional regulation: annual report and accounts 2017/2018. 2018. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/724650/professional-standards-authority-annual-report-and-accounts-2017-2018-print-ready.pdf

31 Health and Care Professions Council. Health and Care Professions Council. https://www.hcpc-uk.org/ (accessed 1 Dec 2020).

32 UK Government. Health Professions Order 2001. https://www.legislation.gov.uk/uksi/2002/254/contents/made

33 Health and Care Professions Council. Misuse of title. https://www.hcpc-uk.org/concerns/what-we-investigate/misuse-of-title/ (accessed 4 Mar 2021).

34 General Chiropractic Council. General Chiropractic Council. https://www.gcc-uk.org/ (accessed 2 Dec 2020).

35 General Dental Council. General Dental Council. https://www.gdc-uk.org/ (accessed 3 Dec 2020).

36 General Optical Council. General Optical Council. https://www.optical.org/ (accessed 4 Dec 2020).

37 General Osteopathic Council. General Osteopathic Council. https://www.osteopathy.org.uk/home/ (accessed 4 Dec 2020).

38 Nursing and Midwifery Council. Nursing and Midwifery Council. https://www.nmc.org.uk/ (accessed 7 Dec 2020).

39 Pharmaceutical Society of Northern Ireland. Pharmaceutical Society of Northern Ireland. https://www.psni.org.uk/ (accessed 6 Dec 2020).

40 General Pharmaceutical Council. General Pharmaceutical Council. https://www.pharmacyregulation.org/ (accessed 10 Dec 2020).

41 Social Work England. Social Work England. https://www.socialworkengland.org.uk/ (accessed 10 Dec 2020).

42 Northern Ireland Social Care Council. Northern Ireland Social Care Council. https://niscc.info/ (accessed 7 Dec 2020).

43 Scottish Social Services Council. Scottish Social Services Council. https://www.sssc.uk.com/ (accessed 10 Dec 2020).

44 Social Care Wales. Social Care Wales. https://socialcare.wales/ (accessed 5 Dec 2020).

45 House of Commons Library. Professional regulation in health and social care. 2017. https://researchbriefings.files.parliament.uk/documents/CBP-8094/CBP-8094.pdf

46 Department of Health and Social Care. Regulation of nursing associates in England. 2017. https://www.gov.uk/government/consultations/regulation-of-nursing-associates-in-england

47 Professional Standards Authority. Standards of Good Regulation: Evidence Framework. 2019. https://www.professionalstandards.org.uk/docs/default-source/publications/standards/proposed-new-standards-of-good-regulation---evidence-framework-(june-2018).pdf?sfvrsn=270c7220_6

48 Professional Standards Authority. Right-touch assurance: a methodology for assessing and assuring occupational risk of harm continue reading from continuum. 2016. https://www.professionalstandards.org.uk/publications/detail/right-touch-assurance-a-methodology-for-assessing-and-assuring-occupational-risk-of-harm

49 Professional Standards Authority. Our work with accredited registers. https://www.professionalstandards.org.uk/what-we-do/accredited-registers (accessed 29 Jan 2021).

50 Professional Standards Authority. Society of Homeopaths - accreditation suspended. https://www.professionalstandards.org.uk/what-we-do/accredited-registers/find-a-register/detail/society-of-homeopaths (accessed 20 Mar 2021).

51 Health and Care Professions Council. Regulation of further professions/occupations. 2016. http://www.hcpc-uk.co.uk/globalassets/meetings-attachments3/council-meeting/2016/february/enc-08---regulation-of-further-professions/

52 Department of Health and Social Care. The Regulation of Medical Associate Professionals in the UK: Consultation Response. 2019. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/777130/maps-consultation-report.pdf

53 General Medical Council. PA and AA regulation. https://www.gmc-uk.org/pa-and-aa-regulation-hub (accessed 12 Feb 2021).

54 UK Government. Health Act 1999. https://www.legislation.gov.uk/ukpga/1999/8/contents

55 Kark T, Russell J. A review of the Fit and Proper Person Test. 2019. https://www.gov.uk/government/publications/kark-review-of-the-fit-and-proper-persons-test

56 UK Government. Code of Practice on Consultation. 2008. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/100807/file47158.pdf

57 Professional Standards Authority. Right-touch assurance for sonographers based on risk of harm arising from practice. 2019. https://www.professionalstandards.org.uk/docs/default-source/publications/policy-advice/right-touch-assurance-for-sonographers-a-report-for-hee.pdf?sfvrsn=9cfd7420_13

58 Professional Standards Authority. Interim report on oversight of Nursing Associates. 2016. https://www.professionalstandards.org.uk/docs/default-source/publications/interim-report-on-oversight-of-nursing-associates---november-2016.pdf?sfvrsn=bf767120_0

59 OECD. How's Life?: Measuring Well-being. OECD 2011. doi:10.1787/9789264121164-en

60 OECD. OECD Economic Survey 2019: New-Zealand. https://issuu.com/oecd.publishing/docs/oecd_economic_survey_new_zealand_ex

61 Kirkman A. Health practitioners New Zealand. https://teara.govt.nz/en/health-practitioners/print

62 New Zealand Government. Responsible authorities under the Health Practitioners Competence Assurance Act. https://www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/responsible-authorities-under-act

63 New Zealand Government. Non-regulated health professions under the Health Practitioners Competence Assurance Act. https://www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/non-regulated-health-professions

64 New Zealand Government. Health Practitioners Competence Assurance Act 2003. https://legislation.govt.nz/act/public/2003/0048/latest/DLM203312.html?search=qs_act%40bill%40regulation%40deemedreg_Health+Practitioners+Competence+Assurance+_resel_25_h&p=1&sr=1

65 New Zealand Government. About the Health Practitioners Competence Assurance Act. https://www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/about-health-practitioners-competence-assurance-act

66 New Zealand Government. How do we determine if statutory regulation is the most appropriate way to regulate health professions? Discussion document. https://www.health.govt.nz/system/files/documents/publications/statutory-regulation-health-professions-discussion-document-jan10.pdf

67 New Zealand Government. Code of Health and Disability Services Consumers' Rights. https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/

68 New Zealand Government. Health Professionals' Competency Assurance Bill Discussion Paper. https://www.moh.govt.nz/notebook/nbbooks.nsf/0/959631f01aa834d84c25696e00833e11/$FILE/HthProfCAB.pdf

69 New Zealand Government. Policy Framework for Occupational Regulation. 1999.

70 The Treasury. Regulatory standards bill. https://www.treasury.govt.nz/information-and-services/regulation/impact-analysis/regulatory-standards-bill (accessed 20 Jan 2021).

71 New Zealand Ministry of Health. Review of the Health Practitioners Competence Assurance Act 2003: Report to the Minister of Health by the Director-General of Health. 2009. https://www.health.govt.nz/system/files/documents/publications/report-minister-hpca-jun09.pdf

72 New Zealand Government. 2012 Review of the Health Practitioners Competence Assurance Act 2003. https://www.health.govt.nz/publication/2012-review-health-practitioners-competence-assurance-act-2003-discussion-document

73 New Zealand Government. Health Practitioners Competence Assurance Amendment Act 2019. https://legislation.govt.nz/act/public/2019/0011/latest/LMS11957.html

74 New Zealand Health Practitioners Disciplinary Tribunal. Health Practitioners Disciplinary Tribunal. https://www.hpdt.org.nz/

75 New Zealand Government. Health Workforce Directorate. https://www.health.govt.nz/our-work/health-workforce/about-health-workforce

76 New Zealand Government. Regulation of Paramedics under the Health Practitioners Competence Assurance Act 2003. https://www.health.govt.nz/news-media/news-items/paramedics-be-formally-regulated

77 New Zealand Government. Regulating a new profession under the Health Practitioners Competence Assurance Act 2003. https://www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/regulating-new-profession

78 New Zealand Government. Applying for regulation under the Health Practitioners Competence Assurance Act 2003. https://www.health.govt.nz/system/files/documents/pages/applying-for-regulation-under-the-hpca-2003-031220.pdf

79 Medical Council of New Zealand. Working definition of risk of harm from the Medical Council of New Zealand. https://www.otago.ac.nz/oms/otago684095.pdf

80 The Treasury. Regulatory stewardship. https://www.treasury.govt.nz/information-and-services/regulation/regulatory-stewardship (accessed 30 Jan 2021).

81 New Zealand Government. Guide to Cabinet's Impact Analysis Requirements. https://www.treasury.govt.nz/sites/default/files/2020-06/guide-cabinet-ia-requirements-june2020.pdf

82 The Treasury. Impact Analysis Requirements for Regulatory Proposals. https://www.treasury.govt.nz/information-and-services/regulation/impact-analysis-requirements-regulatory-proposals (accessed 1 Nov 2020).

83 OECD. OECD Better life index: Australia. http://www.oecdbetterlifeindex.org/countries/australia/

84 Dixit S. A review of the Australian healthcare system: A policy perspective. https://journals.sagepub.com/doi/10.1177/2050312118769211 (accessed 20 Apr 2021).

85 The Commonwealth Fund. International health care system profiles: Australia. https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_fund_report_2017_may_mossialos_intl_profiles_v5.pdf

86 Australian Health Council. Independent Review of the National Registration and Accreditation Scheme for health professions. COAG Health Council. https://www.coaghealthcouncil.gov.au/Projects/Independent-Review-of-NRAS-finalised/ArtMID/524/ArticleID/68/The-Independent-Review-of-the-National-Registration-and-Accreditation-Scheme-for-health-professionals (accessed 20 Apr 2021).

87 Bennett A. Regulation of Health Practitioners in Australia: A National Approach to Polycentric Regulation? *The Sydney Law Review*;**40**:159–81.

88 Australian Health Ministers' Advisory Council. Regulatory assessment criteria and process for adding new professions to the National Registration and Accreditation Scheme for the health professions. https://agedcare.royalcommission.gov.au/system/files/2020-10/AHP.0002.0001.0001.pdf

89 Health Council. Australia's Health Workforce: strengthening the education foundation. https://www.coaghealthcouncil.gov.au/Portals/0/ASReview%20FINAL%20Report.pdf

90 Australian Health Practitioner Regulation Agency. About us. https://www.ahpra.gov.au/About-Ahpra.aspx (accessed 20 Apr 2021).

91 Australian Government. Health Practitioner Regulation National Law Act 2009. https://www.legislation.qld.gov.au/view/pdf/inforce/current/act-2009-045

92 Australian Government. Australia's Health Workforce: Productivity Commission research report. https://www.pc.gov.au/inquiries/completed/health-workforce/report/healthworkforce.pdf

93 Australian Health Ministers' Advisory Council. Regulatory impact statement for the decision to implement the Health Practitioner Regulation National Law. http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=8C09FBB89740842E7EF6ECB53E1885FB?doi=10.1.1.259.9929&rep=rep1&type=pdf

94 Australian Government. Health Practitioner Regulation Amendment Act 2017. https://legislation.nsw.gov.au/view/pdf/asmade/act-2017-50

95 Australian Government. Health Practitioner Regulation National Law and Other Legislation Amendment Act 2019. https://www.legislation.qld.gov.au/view/pdf/asmade/act-2019-003

96 Australian Health Ministers' Advisory Council. Guide to the National Registration and Accreditation Scheme for health professions. https://www.coaghealthcouncil.gov.au/Portals/0/Publication%20-%20Guide%20to%20NRAS%20for%20health%20professions%20-%20as%20published%20on%20COAG%20Health%20Council%20website%20July%202018.PDF

97 Australian Health Council. Australian Health Chief Executives Forum. https://www.coaghealthcouncil.gov.au/Health-Chief-Executives-Forum/Introduction

98 Australian Health Practitioner Regulation Agency. Australian Health Practitioner Regulation Agency Guide 2020. https://www.ahpra.gov.au/News/2020-07-02--Regulatory-guide.aspx

99 Health Council. National Registration and Accreditation Scheme for health professionals. https://www.coaghealthcouncil.gov.au/NRAS (accessed 27 Apr 2021).

100 Health Council. National Code of Conduct for Health Care Workers. https://www.health.qld.gov.au/__data/assets/pdf_file/0014/444101/national-code-conduct-health-workers.pdf

101 Australian Government. Regulation of unregistered health professions in Australia. https://www2.health.vic.gov.au/health-workforce/health-workforce-regulation/regulation-of-unregistered-health-professions

102 Australian Office of Best Practice Regulation. Australian Government Guide to Regulatory Impact Analysis. https://www.pmc.gov.au/sites/default/files/publications/user-guide-ria.pdf

103 Australian Office of Best Practice Regulation. Australian Government guide to cost–benefit analysis. https://www.pmc.gov.au/sites/default/files/publications/cost-benefit-analysis_0.pdf

104 OECD. OECD: Netherlands. OECD. http://data.oecd.org/netherlands.htm (accessed 20 Apr 2021).

105 The European Observatory on Health Systems and Policies. Netherlands: Health system review. file:///C:/Users/SMcAuliffe/Zotero/storage/Q8B7C7G2/Netherlands%20Health%20system%20review.pdf

106 de Bie 2006. Reserved procedures in Dutch health care: policies and perspectives of physicians, nurses and management. https://research.vu.nl/en/publications/reserved-procedures-in-dutch-health-care-practice-policies-and-pe

107 Netherlands Government. The Individual Healthcare Professions Act (BIG Act). https://wetten.overheid.nl/BWBR0006251/2019-01-01 (accessed 20 Apr 2021).

108 Netherlands Government. Regualted professions: BIG Act. 2020. https://english.bigregister.nl/registration/procedures/legislation (accessed 20 Apr 2021).

109 European Parliament. Labour mobility and recognition in the regulated professions. https://www.europarl.europa.eu/RegData/etudes/STUD/2019/631056/IPOL_STU(2019)631056(ANN04)_EN.pdf

110 Netherlands Government. BIG Act restricted activities. https://www.rijksoverheid.nl/onderwerpen/voorbehouden-handelingen/vraag-en-antwoord/voorbehouden-medische-handelingen

111 de Haan M, van Eijk-Hustings Y, Bessems-Beks M, *et al.* Facilitators and barriers to implementing task shifting: Expanding the scope of practice of clinical technologists in the Netherlands. *Health Policy* 2019;**123**:1076–82. doi:10.1016/j.healthpol.2019.07.003

112 Allsop M & Jones D. Quality Assurance in Medical Regulation in an International Context. 2005. https://dora.dmu.ac.uk/handle/2086/11359

113 Netherlands Government. Second evaluation of the Individual Health Care Professions Act (BIG Act) 2014. https://www.google.nl/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwij1aWAuqLtAhV58eAKHRbhAB8QFjAAegQIBBAC&url=https%3A%2F%2Fwww.zorginstituutnederland.nl%2Fbinaries%2Fzinl%2Fdocumenten%2Fkamerstukken%2F2014%2F12%2F2%2Fbeleidslijn-voor-het-wettelijk-reguleren-van-beroepen%2FBeleidslijn%2Bvoor%2Bhet%2Bwettelijk%2Breguleren%2Bvan%2Bberoepen.pdf&usg=AOvVaw1ZakHIHAQqVpYuAU-93gye

114 Roscam Abbing H, Derckx V, e.a X. Review of the BIG Act. 2002.

115 Netherlands Government. BIG Act review. 2019. https://www.raadrvs.nl/binaries/raadrvs/documenten/kabinetsreacties/2019/10/10/reactie-minister-bruins-op-advies-de-b-van-bekwaam/kamerbrief-over-rvs-advies-de-b-van-bekwaam.pdf

116 Netherlands Government. Services and institutions. https://www.government.nl/ministries/ministry-of-health-welfare-and-sport/services-and-institutions (accessed 20 Nov 2020).

117 Netherlands Government. Health and Youth Care Inspectorate. https://english.igj.nl/about-us (accessed 20 Nov 2020).

118 Netherlands Government. Healthcare Institute Netherlands (Zoorginstituut). https://english.zorginstituutnederland.nl/ (accessed 15 Nov 2020).

119 Netherlands Government. BIG Act re-registration. https://english.bigregister.nl/registration/re-registration (accessed 5 Nov 2020).

120 Netherlands Government. BIG Act specialist register. https://english.bigregister.nl/registration/procedures/specialization (accessed 1 Nov 2020).

121 Health Care Disciplinary Tribunals. About the disciplinary boards. https://www.tuchtcollege-gezondheidszorg.nl/over-de-tuchtcolleges (accessed 5 Mar 2021).

122 Healthcare Institute Netherlands. Advice 'The nurse anesthetist in Article 3 of the BIG Act'. https://www.zorginstituutnederland.nl/publicaties/adviezen/2020/03/10/advies-wet-big---anesthesiemedewerker (accessed 10 Dec 2020).

123 Netherlands Health Institute. Advice on clinical chemists. https://www.zorginstituutnederland.nl/publicaties/adviezen/2020/09/11/advies-de-klinisch-chemicus-in-artikel-3-van-de-wet-big

124 Netherlands Government. Healthcare Institute Netherlands - new requests for professional regulation in the BIG Act. https://www.zorginstituutnederland.nl/werkagenda/wet-big-advisering

125 Netherlands Government. Healthcare Institute Netherlands - regulatory process. https://www.zorginstituutnederland.nl/over-ons/werkwijzen-en-procedures/adviseren-over-opname-beroepen-en-erkenning-specialistentitels-in-de-wet-big

126 Netherlands Government. The integrated impact assessment framework for policy and legislation. https://www.cilc.nl/cms/wp-content/uploads/2018/02/IAK-English-02-11-2017.pdf

127 OECD. Regulatory Impact Assessment in the Netherlands - OECD. https://www.oecd.org/regreform/regulatory-policy/regulatory-impact-assessment-in-the-netherlands.htm (accessed 29 Apr 2021).

128 OECD. OECD Better life index: Finland. http://www.oecdbetterlifeindex.org/countries/finland/

129 Keskimäki P. Integrating health and social services in Finland: regional and local initiatives to coordinate care. 2018. https://www.euro.who.int/__data/assets/pdf_file/0011/389666/php-4-4-pp1-eng.pdf

130 The European Observatory on Health Systems and Policies. State of Health in the EU Finland: Country Health Profile. 2019. https://www.euro.who.int/__data/assets/pdf_file/0004/419458/Country-Health-Profile-2019-Finland.pdf

131 Finnish Government. Health Care Professionals Act 1994. https://finlex.fi/en/laki/kaannokset/1994/en19940559

132 Finnish Government. Ministry of Social Affairs and Health. https://stm.fi/en/ministry

133 Finnish Government. The National Supervisory Authority for Welfare and Health -Valvira. https://www.valvira.fi/web/en/valvira

134 Health and Care Professions Council. Health Regulation Worldwide Finland. https://www.healthregulation.org/europe3/finland/

135 Finnish National Agency for Education. Proportionality test for a new or amended regulation of professions and related notification obligation. https://www.oph.fi/en/services/proportionality-test-new-or-amended-regulation-professions-and-related-notification

136 The European Observatory on Health Systems and Policies. State of health in the EU: Sweden: Country Health Profile 2019. https://www.oecd-ilibrary.org/social-issues-migration-health/sweden-country-health-profile-2019_2dcb7ca6-en;jsessionid=P_jNlTqRsqmnwDQdb1VMU58r.ip-10-240-5-45

137 OECD. OECD better life index: Sweden. http://www.oecdbetterlifeindex.org/countries/sweden/

138 Swedish Institute. Healthcare in Sweden. https://sweden.se/society/health-care-in-sweden/ (accessed 10 Mar 2021).

139 Swedish Government. Patient Safety Act 2010. https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/patientsakerhetslag-2010659_sfs-2010-659

140 The European Observatory on Health Systems and Policies. The health system and policy monitor: regulation. Sweden. https://www.who.int/health-laws/countries/swe-en.pdf?ua=1

141 Swedish Government. National Board of Health and Welfare. https://www.government.se/government-agencies/national-board-of-health-and-welfare--socialstyrelsen/

142 Swedish Government. Register of Licensed Healthcare Professionals: Sweden. https://www.socialstyrelsen.se/statistik-och-data/register/alla-register/halso--och-sjukvardspersonal/

143 Swedish Government. Health and Social Care Inspectorate. https://www.ivo.se/om-ivo/other-languages/english/about-ivo/

144 Swedish Council for Higher Education. Regulated professions: Sweden. https://www.uhr.se/en/start/recognition-of-foreign-qualifications/before-you-apply/i-want-to-work-in-sweden/regulated-professions/

145 Swedish Parliament. Ordinance (2020: 757) on proportionality testing in the event of new or changed requirements for professional qualifications. https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/forordning-2020757-om_sfs-2020-757 (accessed 26 Feb 2021).

146 Statistics Denmark. Population in Denmark. https://www.dst.dk/en/Statistik/emner/befolkning-og-valg/befolkning-og-befolkningsfremskrivning/folketal (accessed 27 Apr 2021).

147 OECD. OECD Better life index: Denmark. http://www.oecdbetterlifeindex.org/countries/denmark/

148 Danish Government. Healthcare in Denmark: An overview. https://sum.dk/Media/C/A/Healthcare-in%20denmark%20an%20overview%20english-V16-dec.pdf

149 Schmidt M, Schmidt SAJ, Adelborg K, *et al.* The Danish health care system and epidemiological research: from health care contacts to database records. *Clin Epidemiol* 2019;**11**:563–91. doi:10.2147/CLEP.S179083

150 Danish Government. Danish Health Act 2010. https://www.fysio.dk/radgivning-regler/shttps://www.mindbank.info/item/1194ndhedsjura/sundhedsloven

151 Danish Government. Danish Medicines Agency. https://laegemiddelstyrelsen.dk/en/news/2015/the-danish-ministry-of-health-has-appointed-three-new-directors-general/#:~:text=In%20August%2C%20Minister%20for%20Health,Authority%2C%20the%20Danish%20Health%20Data

152 Danish Government. Danish Patient Authority. https://en.stps.dk/en/

153 Danish Government. Online register: registered health professionals Denmark. https://en.stps.dk/en/health-professionals-and-authorities/online-register-registered-health-professionals/

154 Danish Government. List of regulated professions: Denmark. https://ufm.dk/en/education/recognition-and-transparency/regulated-professions/list-of-regulated-professions (accessed 28 Apr 2021).