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Regulating quality and safety of health and social care

International experiences

Daniel Schweppenstedde, Saba Hinrichs, Uzor C. Ogbu, Eric C. Schneider,
Dionne S. Kringos, Niek S. Klazinga, Judith Healy, Lauri Vuorenkoski,
Reinhard Busse, Benoit Guerin, Emma Pitchforth, Ellen Nolte

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The research described in this document was prepared for the UK Department of Health (England) within the PRP project 'An 'On-call' Facility for International Healthcare Comparisons'.

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Preface

This report is concerned with ‘standards of quality and safety’ within health and social care systems. Care standards are intended to support efforts in maintaining and improving the quality of care; they have been developed across countries, although the ways in which they are implemented and applied differs between nations. Taking a range of six countries, we review the regulatory mechanisms that have been implemented to ensure that essential standards of care are applied and are being adhered to, and consider the range of policy instruments used to encourage and ensure continuous quality improvement. We report on Australia, England, Finland, Germany, the Netherlands and the USA, with the information presented reflecting the regulatory systems as of 1 August 2013.

The report is intended to inform policy thinking for the Department of Health and others in developing the regulation of safety and quality of health and social care in England. It was prepared as part of the project ‘An “On-call” Facility for International Healthcare Comparisons’ funded by the Department of Health in England through its Policy Research Programme (grant no. 0510002).

The project comprises a programme of work on international healthcare comparisons that provides intelligence on new developments in other countries, involving a network of experts in a range of countries in the Organisation for Economic Co-operation and Development (OECD) to inform health (care) policy development in England. For more information on the project please see www.international-comparisons.org.uk.

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Contents

Preface.....	iii
List of figures.....	xi
List of tables.....	xiii
Summary.....	xv
Acknowledgements.....	xix
CHAPTER 1 Introduction.....	1
1.1 Background.....	1
1.1.1 Aim of this report.....	1
1.2 Methodology.....	2
1.2.1 Selection of countries.....	2
1.2.2 Data collection.....	2
1.3 About this report.....	3
CHAPTER 2 Overview of findings.....	5
2.1 Context for standards of quality within health and social care systems.....	6
2.2 Standards of quality and safety in health and social care.....	9
2.3 Regulatory strategies and actors for assuring quality of care.....	12
2.3.1 Principal regulatory strategies and mechanisms for health and social care governance.....	14
2.3.2 Main actors responsible for assuring standard adherence in health and social care.....	16
2.4 Effectiveness of regulatory strategies and systems.....	25
2.4.1 Case study: inspections.....	27
2.5 Trends in regulatory approaches.....	29
2.6 Summary.....	31
CHAPTER 3 Australia.....	33
3.1 System overview.....	33
3.1.1 Organisation and financing of the health and social care systems.....	33
3.1.2 Principles of healthcare governance.....	34
3.1.3 Recent reforms of the health and social care systems.....	34
3.2 National framework for care quality.....	36

3.2.1	Sources of minimum standards of quality in the health and social care systems.....	36
3.2.2	Overview of main bodies responsible for standard setting and enforcement.....	39
3.3	National regulatory bodies.....	40
3.3.1	Australian Commission on Safety and Quality in Health Care (ACSQHC)	40
3.3.2	National Health Performance Authority (NHPA).....	42
3.3.3	Medicare and the Professional Services Review Agency.....	43
3.3.4	Australian Children's Education and Care Quality Authority (ACECQA).....	44
3.4	National departments and offices.....	44
3.4.1	Department of Health.....	44
3.5	State/territory-level regulatory bodies in health and social care.....	45
3.6	Quasi-governmental and other actors.....	46
3.6.1	Australian Health Practitioner Regulation Agency (AHPRA)	46
3.6.2	Age Care Standards and Accreditation Agency Ltd. (ACSAA)	47
3.6.3	Australian Council on Healthcare Standards (ACHS)	48
3.7	Case study	49
3.8	Summary and conclusion.....	52
CHAPTER 4 England		55
4.1	System overview	55
4.1.1	Organisation and financing of the health and social care systems.....	55
4.1.2	Principles of healthcare governance	56
4.1.3	Recent reforms of the health and social care systems.....	58
4.2	National regulatory or otherwise framework for care quality	60
4.2.1	Sources of minimum standards of quality in the health and social care systems.....	60
4.2.2	Overview of main bodies responsible for standard setting and enforcement.....	63
4.3	National regulatory bodies.....	64
4.3.1	Care Quality Commission.....	64
4.3.2	Monitor	66
4.3.3	National Institute for Health and Care Excellence (NICE)	68
4.4	Quasi-governmental and other actors.....	70
4.4.1	Regulation of healthcare professionals	70
4.5	Case study	70
4.6	Summary and conclusions	71
CHAPTER 5 Finland.....		73
5.1	System overview	73
5.1.1	Organisation and financing of the health and social care system	73
5.1.2	Principles of health and social care governance	73

5.1.3	Recent reforms of the health and social care systems	74
5.2	National framework regulatory or otherwise for care quality.....	75
5.2.1	Sources of minimum standards of quality in the health and social care systems	75
5.2.2	Overview of main bodies responsible for standard setting and enforcement.....	76
5.3	National regulatory bodies.....	77
5.3.1	National Supervisory Authority for Welfare and Health (Valvira)	77
5.4	Quasi-governmental and other actors	79
5.4.1	National ombudsman	79
5.4.2	The Association of Finnish Local and Regional Authorities.....	79
	Finnish Medical Association	80
5.5	Case studies.....	80
5.6	Summary and conclusion	81
CHAPTER 6 Germany.....		83
6.1	System overview	83
6.1.1	Organisation and financing of the health and social care systems	83
6.1.2	Principles of health and social care governance.....	84
6.1.3	Recent reforms of the health and social care systems	84
6.2	National regulatory or otherwise for care quality	86
6.2.1	Sources of minimum standards of quality in the health and social care systems	86
6.2.2	Overview of main bodies responsible for standard setting and enforcement.....	87
6.3	National regulatory bodies.....	88
6.3.1	Federal Joint Committee (G-BA).....	88
6.4	Quasi-governmental bodies	90
6.4.1	National Association of Statutory Health Insurance Physicians (KBV).....	90
6.4.2	Medical Review Board of the Statutory Health Insurance Funds (MDK) and Medical Review Board of the National Association of Statutory Health Insurance Funds (MDS)	92
6.5	Other actors	93
6.5.1	Institute for Quality and Efficiency in Health Care (IQWiG).....	93
6.5.2	Institute for Applied Quality Improvement and Research in Health Care GmbH (AQUA)	95
6.5.3	German Agency for Quality in Medicine, AQUAMED (ÄZQ).....	96
6.6	Summary and conclusion	97
CHAPTER 7 The Netherlands		99
7.1	System overview	99
7.1.1	Organisation and financing of the health and social care systems	99
7.1.2	Principles of health and social care governance.....	100

7.1.3	Recent reforms of the health and social care system	100
7.2	National regulatory or otherwise framework for care quality	102
7.2.1	Sources of minimum standards of quality in the health and social care systems.....	102
7.2.2	Overview of main bodies responsible for standard setting and enforcement.....	103
7.3	National regulatory bodies.....	103
7.3.1	Health Care Inspectorate (IGZ)	103
7.3.2	Dutch Health Care Authority (NZa).....	107
7.3.3	Health Care Insurance Board (CVZ).....	109
7.3.4	Municipal health services (GGDs).....	110
7.4	Quasi-governmental and other actors.....	112
7.4.1	Central Disciplinary Board, Regional Disciplinary Boards and Medical Supervision Board.....	112
7.4.2	Netherlands Institute for Accreditation in Healthcare (NIAZ)	114
7.4.3	Foundation for Harmonisation of Quality Review in Health Care and Welfare (HKZ)	115
7.4.4	Dutch Institute for Healthcare Improvement (CBO)	115
7.4.5	Royal Dutch Medical Association (KNMG).....	115
7.5	Case study	115
7.6	Summary and conclusions	117
CHAPTER 8 USA.....		121
8.1	System overview	121
8.1.1	Organisation and financing of the health and social care systems.....	121
8.1.2	Principles of healthcare governance	122
8.1.3	Recent reforms of the health and social care systems.....	122
8.2	National regulatory or otherwise framework for care quality	123
8.2.1	Sources of minimum standards of quality in the health and social care systems.....	123
8.2.2	Overview of main bodies responsible for standard setting and enforcement.....	124
8.3	National Regulatory bodies.....	126
8.3.1	The Centers for Medicare and Medicaid Services (CMS)	126
8.3.2	The Department of Veteran Affairs.....	128
8.3.3	Indian Health Service (IHS).....	130
8.3.4	State Departments of Health.....	130
8.3.5	State medical boards.....	131
8.4	Quasi-governmental and other actors.....	131
8.4.1	Quality Improvement Organizations (QIOs)	131
8.4.2	The Joint Commission (JC)	132
8.4.3	National Committee for Quality Assurance (NCQA).....	133
8.4.4	Utilization Review Accreditation Commission (URAC).....	133
8.5	Case studies	134

Case 1: Hospitals (Department of Veteran Affairs)	134
8.6 Summary and conclusion	136
REFERENCES	137
Reference list	138
APPENDICES	159

List of figures

Figure 2.1 Framework for analysis.....	5
Figure 2.2 Regulatory pyramid.....	13
Figure 3.1 Overview of the accreditation cycle performed by ACSAA	48
Figure 4.1 The health and care system in England from 2013.....	60
Figure 5.1. Organisational structure of Valvira.....	77
Figure 6.1 Federal Joint Committee: Legal status.....	89
Figure 6.2 Collaboration between the G-BA and the Institute for Quality and Efficiency in Health Care.....	94

List of tables

Table 2.1 Principles of health and social care in six countries	7
Table 2.2 Sources for and content of standards for health and social care in six countries.....	11
Table 2.3 Regulatory activities and mechanisms for health and social care governance in five countries.....	15
Table 2.4 Principle regulatory mechanisms used by actors involved in governance of quality and safety of health and social care in six countries.....	20
Table 3.1 Summary overview of main government bodies at the national level responsible for standard setting and enforcement in the health and social care sectors in Australia	40
Table 4.1 Summary overview of main bodies responsible for standard setting and enforcement in the health and social care sectors in England.....	64
Table 5.1 Summary overview of main bodies responsible for standard setting and enforcement in the health and social care sectors in Finland.....	76
Table 6.1 Summary overview of main bodies responsible for standard setting and enforcement in the health and social care sectors in Germany	87
Table 7.1 Summary overview of main bodies responsible for standard setting and enforcement in the health and social care sectors in the Netherlands	103
Table 7.2 IGZ activity in 2010	107
Table 7.3 Filed and completed complaints, Regional Disciplinary Boards, 2007-2011	113
Table 8.1 Main organisations in the USA and their role in ensuring patient safety.....	123
Table 8.2 Selected CMS centres and offices	127

Summary

There is a lack of international consensus on what constitutes ‘effective quality regulation’, given the diversity of governance and financing of healthcare systems within which providers in OECD countries operate. Countries vary with regard to the strategies for healthcare quality that have been adopted, and the extent to which legislative measures ensuring quality of care have been implemented.

In this report, we provide an overview of regulatory strategies and actors that different systems employ to govern safety and quality in health and social care. Specifically, we reviewed the range of regulatory strategies and actors in selected high-income countries aimed at ensuring that essential standards of care are implemented and being adhered to, and consider the range of policy instruments used in those countries to encourage and ensure continuous quality improvement. The evidence presented in this report seeks to inform ongoing policy thinking for the Department of Health and others in developing regulation of safety and quality of health and social care in England.

We selected the following countries: Australia, Finland, Germany, the Netherlands, and the United States of America (USA) and included England for comparison. Data collection involved a review of the published and grey literature, using a structured template, complemented by information provided by key informants in the selected countries.

The organisation and governance of health and social care varies across countries

The countries reviewed provide examples of systems that vary in the way that health and social care services are organised and financed. For example, the health systems in Germany and the Netherlands are funded mainly through statutory health insurance (SHI), while Australia, England and Finland principally operate tax-based systems. The USA is a mixed system, with private sources dominating.

Similarly, the six countries represent different approaches to the governance of health and social care. In Finland, administrative and political responsibility is largely devolved to local authorities, while in the Netherlands responsibility for the health and social care systems is shared by central government and corporatist actors. In Germany, regional and local authorities also play a role. In the USA, healthcare regulation is shared between the federal government and the states, as is the governance of social care systems. This is also the case in Australia. In England, health and social care policy is set nationally while the organisation of care is devolved to local organisations, with clinical commissioning groups replacing primary care trusts from 2013, overseen by a newly established national body, NHS England.

The notion of overarching ‘essential standards of quality’ is not commonly used explicitly

While England has implemented overarching ‘essential standards of quality and safety’ for the provision of health and social care services, this approach is not commonly used explicitly in other system contexts. The setting of standards typically applies to particular sectors or settings (eg nursing homes), rather than an overarching ‘essential’ set that is applied across sectors. In Germany and Australia, recent reforms have begun to examine standards that extend across care boundaries, such as primary and secondary care, although cross-sectoral approaches that cover the entire spectrum of health and social care services are not common.

The sources of standards in the health and social care sectors vary by country and may involve overarching, high-level principles that inform quality regulation such as a country’s constitution, national legislation or frameworks. All systems reviewed here have some form of national (legislative) framework or principle in place, which guide the overall development and implementation of standards. The structure and form of these standards vary in terms of their specificity. Standards can thus be generally embedded within constitutional provisions (Finland) or national framework legislation (England, Germany, the Netherlands), or be developed as standards and frameworks for guiding, although not enforcing, service quality (Australia). The USA has a framework for creating national standards, but the considerable power of state governments and the tendency to rely on private markets to purchase and provide care creates challenges to a unified national quality standard.

Countries use a combination of policy instruments to assure quality and safety in the provision of health and social care

We describe four principal regulatory strategies to ensure quality and safety in the health and social care sectors. These are:

- **Command and control:** implies direct enforcement by government (eg licensing professionals and facilities, enforcing performance standards). Mechanisms to secure standard adherence include criminal or civil penalty; licence revocation or suspension; physician revalidation.
- **Meta-regulation:** describes an approach by which the conduct of self-regulation is monitored by an external third party. There may be sanctions and financial incentives that help ensure adherence. Examples include clinical audits conducted externally; mandated incident reporting systems; and consumer complaints ombudsmen.
- **Self-regulation and voluntarism:** *Self-regulation* describes a system in which organised groups regulate the behaviour of their members; this might involve an industry-level organisation or a professional association which sets rules, standards, and codes of practice relating to the conduct of its members. *Voluntarism* is based on an individual firm, organisation, or individual professional, ‘undertaking to do the right thing without any basis in coercion’. These mechanisms include the use of clinical governance, voluntary hospital accreditation, peer review, clinical protocols, performance indicators/targets and benchmarking.
- **Market mechanisms:** refers to a set of rules and institutions of a market economy as applied to the public sector. Mechanisms to encourage adherence to standards include

elements such as incentive payments, governance by contracting, and performance league tables.

All of the countries reviewed, or their systems, employ elements of self-regulation and voluntarism, meta-regulation and command and control, with market mechanisms in the form of selective contracting and public reporting. The use of these strategies is highly dependent on, and integrated with, the health system, policy and institutional context within which regulation takes place, although common themes can be identified. For example, the most common elements are self-regulation and voluntarism, involving the accreditation of providers or facilities, the promulgation of voluntary standards of practice, continuing (medical) education or the use of performance indicators or targets (Australia, Germany, Netherlands, Finland, USA). Similarly, meta-regulation is common, through mechanisms such as external clinical audit, mandated incident reporting and ombudsmen. The explicit use of market mechanisms appears to occur less frequently; examples include selective contracting (Netherlands, USA) and incentive payments (England, USA). All of the reviewed countries employ mechanisms of command and control, mostly in relation to professional licences.

While countries use most of these mechanisms, the relative importance placed on these varies. For example, in Australia voluntary regulation and self-regulation play a core role, using frameworks derived from state-led and intergovernmental committees. In Finland, the standards can be traced back to central government and its constitution, but they operate primarily through self-regulation. In the USA, regulation has traditionally relied heavily on professional self-regulation through board certification and peer review. In the Netherlands, the two dominant mechanisms are self-regulation/voluntarism and meta-regulation.

National-level actors involved in assuring quality and safety in the provision of health and social care vary in the range of enforcement mechanisms they have at their disposal

Based on each country's approaches to quality regulation in health and social care reviewed, we distinguish three categories of regulatory competencies: supervisory and standard enforcement competencies; monitoring and/or standard setting competencies; and quasi-legislator competencies.

Bodies with competencies for supervision and enforcement of standards monitor the activities of health and social care stakeholders, employing formal or informal mechanisms to ensure standard adherence. Relevant bodies are typically situated at arm's length from government. Examples of bodies with such competencies are present in England, Finland, the Netherlands and the USA. Countries such as Australia and England have also set up bodies that have standard setting and/or monitoring competencies, that develop standards in cooperation with key stakeholders, or that monitor the development of key indicators and report to national governments but these bodies typically do not have enforcement competencies. Conversely, Germany and the USA have established quasi-legislator bodies with wide competences in standard setting. Although these bodies are not involved in actual enforcement, the standards they have developed are mandatory: they are enforceable through other (regulatory) bodies and can be evoked before court.

Given the complexity of the health and social care systems, and the diverse political and cultural contexts within which regulatory mechanisms operate, it is difficult to derive

overarching conclusions of whether one system is more effective than another. Each system is characterised by a particular set of relationships between the different professionals and institutions that deliver care, frequently determined by what has happened in the past. However, certain commonalities can be identified in that the countries appear to have been striving towards a greater centralisation of quality regulation. Moreover, there is a collective move towards greater transparency in the sector through making information available on quality and safety as a means of informing service users and funders.

The overall evidence of the effectiveness of regulatory strategies towards ensuring care quality and safety at system level is scarce

Characteristics of effective healthcare regulation and the role of an effective regulator have been defined in the literature. It contends that regulation should, among other things:

- be flexible and adaptive as well as targeted to the content and outcome of each regulatory encounter
- require involvement of stakeholders in both the development and assessment of standards
- employ a range of regulatory strategies and mechanisms, involving both informal and more formal (statutory) approaches to ensure integrity and credibility
- provide for mechanisms ensuring that the regulator is independent and impartial while being accountable for the effects of regulation.

The examples described in this report illustrate that the selected countries principally appear to have implemented regulatory frameworks that exhibit several of these characteristics, although their relative balance varies. However, there is little empirical evidence by which to assess the effectiveness of regulatory strategies for ensuring care quality and safety at system level. The evidence that is available points to the impact of selected mechanisms to enhance standard adherence, such as accreditation, or quality assurance more broadly through, for example, the use of incentive payments or public reporting. However, research has tended to focus on the evidence of impact on provider institutions rather than health systems more generally.

We have identified examples from Australia and the Netherlands that have sought to measure the impact of selected regulatory strategies on standard adherence. These seem to support the notion that regulatory systems need to strike a balance between the use of formal, interventionist instruments and more informal, softer approaches to ensure standard adherence and quality improvement more broadly.

This report has focused primarily on collecting information on existing regulatory mechanisms and actors responsible for ensuring quality of care, rather than comparing levels of patient safety and incidents across the countries examined. In the absence of such information, and of published evidence that examines the effectiveness of existing systems, identifying best practice is not within the remit of this report. What we do provide, however, is a detailed account of the situation in each country, illustrated where available through case studies, about how these regulatory mechanisms are implemented in practice.

Acknowledgements

The project ‘An “On-call” Facility for International Healthcare Comparisons’ is funded by the Department of Health in England through its Policy Research Programme (grant no. 0510002). We are grateful to Professor Martin Roland, Cambridge Centre for Health Services Research, and to Christian van Stolk, RAND Europe, for their very helpful comments and suggestions on earlier drafts of this report.

The views expressed in this report brief are those of the authors alone and do not necessarily represent those of the Department of Health. The authors are fully responsible for any errors.

1.1 **Background**

In February 2012, the English Department of Health set out recommendations to improve its understanding of the regulatory system in its *Performance and Capability Review of the Care Quality Commission*.¹ Among the review's recommendations was the recognition that the Department of Health should develop its capability and capacity on the regulation of safety and quality so as to provide ongoing challenge and support to the Care Quality Commission (CQC) in developing its regulatory model.

In this context, the Department of Health noted a lack of international consensus on what constitutes 'effective quality regulation', given the diversity of governance and financing of healthcare systems within which providers in OECD countries operate. Thus, countries vary with regard to the strategies for healthcare quality that have been adopted, and the extent to which legislative measures ensuring quality of care have been implemented.²

This variation reflects, in part, the prevailing views in individual countries about whether healthcare quality should be subject to legislation, or whether it is more appropriately addressed through voluntary agreements. Furthermore, systems typically employ a range of regulatory mechanisms and strategies targeting different areas that can broadly be subsumed under 'quality of care', including the approval of pharmaceuticals and devices; training of healthcare professionals; registration, licensing and certification of providers; patient safety; and the use of clinical guidelines and of quality indicators.³ Regulatory strategies thus encompass policy instruments such as self-regulation; economic instruments involving the provision of financial incentives or imposing sanctions to encourage provider behaviour change; command and control strategies, involving enforcement by government to ensure adherence to standards; and the use of external regulatory bodies to ensure that healthcare providers implement safety and quality practices.⁴ The applicability of these policy instruments will be influenced by the wider regulatory and cultural context within which a country's health systems sit and their effectiveness on the area to be regulated.

1.1.1 **Aim of this report**

Against this background, this work seeks to inform ongoing policy thinking for the Department of Health and others in developing approaches to the regulation of safety and quality in health and social care in England. We do so through providing an overview of regulatory strategies and actors that different systems employ to govern safety and quality in health and social care. Specifically, we review:

- (i) the range of regulatory strategies and actors in selected high-income countries aimed at assuring that essential standards of care are implemented and being adhered to
- (ii) the range of policy instruments used in those countries to encourage and ensure continuous quality improvement.

1.2 Methodology

1.2.1 Selection of countries

Based on our earlier work on quality assurance in healthcare² we selected five countries for detailed review: Australia, Finland, Germany, the Netherlands, and the United States (USA), and added England for comparison. These countries provide examples of systems that vary in the way in which health and social care services are organised and funded. For example, the health systems in Germany and the Netherlands are funded, mainly, through statutory social insurance, while Australia and Finland principally operate tax-based systems. The USA is a mixed system, with private sources dominating. The selected countries also represent different approaches to the governing of health and social care, which we will describe in further detail in Chapter 2 of this report. As the systems of governance vary, so does the range of policy instruments that are being used to ensure and improve care quality as we shall see in the context of this report.

1.2.2 Data collection

Data collection involved first a review of the published and grey literature as identified from bibliographic databases (PubMed, MEDLINE, AMED, EMBASE, HMIC, CINAHL, HEALTH BUSINESS ELITE, and EBSCOhost, Web of Science, JSTOR); the World Wide Web using common search engines (Google Scholar); and of governmental and non-governmental agencies and organisations with a remit in the area of quality of care and initiatives in the countries under review.

The review sought to identify information on

- (i) the range of agencies or organisations (actors) that are responsible, at national level (governmental, quasi-governmental and non-governmental), for developing, implementing, monitoring, and assuring adherence to standards of care in the health and social care systems
- (ii) the mandate or scope (of action) of the actors identified in (i)
- (iii) the strategies and mechanisms these actors have at their disposal to execute their mandate.

The detailed template for data collection is presented in Appendix A. The data compiled using the template formed the basis for draft country reports developed by the core research team at RAND.

Second, the report was informed by informants participating in the network of the ‘On-call’ facility for international healthcare comparisons (‘IHC network’) and additional experts in the field of healthcare quality and/or regulation to provide information about specific approaches. Experts were asked to review the draft report for their country and to comment on and verify the information presented. The experts were further invited to

provide additional information where appropriate, in particular on areas that are not well documented or which require in-depth understanding of the country context. To meaningfully inform policy development in England we also collected data, using the template described above, for the English health and social care systems and include a separate description of England in this report.

In an attempt to illustrate how a given regulatory framework operates in practice, we furthermore identified recent examples of (gross) violations of standards in health or social care in a selection of countries. Examples include cases of medical misconduct or negligence. We chose hospital and nursing homes as the settings for these examples, mainly because such cases tend to be more widely documented. Cases were identified in collaboration with experts for Australia, Finland, the Netherlands and the USA. For each example, we outline the nature of the case and how it was addressed, the measures taken, as well as the role of further actors involved. Given the highly selective nature of each of the cases considered, we cannot assume these to be representative of a given setting but rather should be seen as a means to highlight the potential advantages and disadvantages of the different regulatory mechanisms in place.

1.3 **About this report**

This report is structured as follows: Chapter 2 reports on the key observations on, approaches to, and mechanisms of regulation to ensure adherence to care standards and quality of care more generally as well as the main actors involved in the selected countries, using a comparative approach. Chapters 3 to 7 are individual reports of each of the six countries reviewed here. These reports follow a common structure: setting the health system context and describing the institutional context in which quality care and essential standard assurance systems are embedded, followed by a detailed account of the actors, mechanisms and approaches to regulating quality of care in each country. Where identified, these chapters further include a brief illustration of exemplar cases of violations of standards of care in the health or social care sectors. Each concludes with a brief summary of main observations and, where available and appropriate, assessments of the (perceived) effectiveness of the regulatory systems in place.

This chapter provides a summary overview of the key observations on, approaches to, and mechanisms of regulation to assure adherence to care standards in five countries, with England included for comparison.

Our analysis drew on the (health) policy analysis framework developed by Walt and Gilson (1994).⁵ This framework provides a structure by which the ‘messy’ elements of policy development can be categorised and better understood. It considers four interlinked components: the context, the content, processes and actors (Figure 2.1).

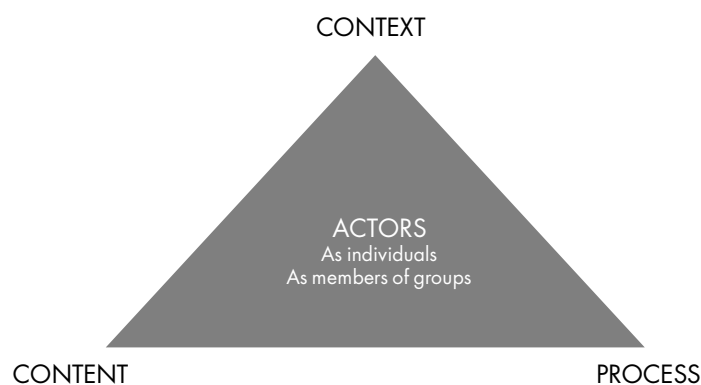


Figure 2.1 Framework for analysis

SOURCE: Adapted from Walt and Gilson (1994).⁵

In an adaptation of this framework, we begin by conceptualising the notion of ‘essential standards of care’ that has been guiding the work presented here (Section 2.1), followed by a brief description of the nature and scope of the health and social care systems in the countries reviewed for this report. These can be seen to provide the *context* within which policy development takes place. Section 2.2 then describes the policy *content* which we here interpreted as the standards of care, and their sources, in each of the countries reviewed. This is followed by Section 2.3, which identifies the *processes*, or principal regulatory strategies seeking to ensure care standard adherence and quality of health and social care, and the characteristics of main *actor(s)* responsible for assuring standard adherence in health and social care. In Section 2.4 we then discuss the evidence of effectiveness of the different regulatory approaches in operation, focusing on inspections as one measure that systems might pursue to monitor and enforce standard adherence. We

close with a brief description of the general trends in quality regulation across the countries reviewed (Section 2.5) and a summary of our observations (Section 2.6).

2.1 **Context for standards of quality within health and social care systems**

This report is concerned with ‘standards of quality and safety’ within health and social care systems. Care standards are intended to support efforts in maintaining and improving the quality of care; they have been developed across countries although the way they are being implemented and applied differs. For example, in England, ‘essential standards of quality and safety’ in service provision have been formulated following 2008 legislation set out in the Health and Social Care Act.⁶ These standards have been defined to apply to both the health and social care systems, but are then contextualised to particular settings (eg nursing homes). Conversely, the notion of overarching ‘essential standards of care’ is not commonly used explicitly in other system contexts.² Therefore, approaches adopted in different settings are not necessarily equivalent and will have to be interpreted within the regulatory and public policy contexts in which they are embedded.

In England, healthcare is commissioned and largely delivered by the National Health Service (NHS), while social care is mainly commissioned by local authorities and individuals, and provided by many different sources.⁷ In England, social care is defined as ‘the care and support provided by local social services authorities pursuant to their responsibilities towards adults who need extra support’, essentially capturing those services that are not provided by other organisations under different legislation.⁸ Other systems conceptualise health and social care differently. For example, in Australia, Finland and the Netherlands, ‘social care’ also includes parts of child and youth care. Long-term care may (implicitly) be captured under social care although it is frequently referred to as a separate entity or sector. For example, in Australia, long-term care (until late 2013) came under the health portfolio. In Germany, the term ‘social care’ as an overarching concept does not exist while long-term care forms an established sector. For ease of comparison, in the following we will use the notion of social care as a generic term while recognising country-specific differences in the nature and scope of this sector.

These differences are further illustrated in Table 2.1, which provides an overview of the principles of health and social care financing and provision in the five countries reviewed here, with England included for comparison. As indicated earlier, with the exception of the USA, in all countries, healthcare services are publicly funded, mainly using national/local taxation or statutory insurance, or a combination of these; the USA is a mixed system, with private sources dominating. All of the countries also fund social care, although the nature and scope of what is funded from public sources varies.

Table 2.1 Principles of health and social care in six countries

	Overall governance of health and social care	Provision and financing of healthcare and social care
Australia	<p>Healthcare funding and governance is shared between the Australian government, the six states and two territories.</p> <p>Medicare Australia is the national authority responsible for processing and dispensing benefits; state health departments administer public hospitals and public health services.</p> <p>Social care is principally under the administrative remit of state/territory governments.</p> <p>National agreements between Commonwealth and states/territories and bilateral intergovernmental programmes are used for the administration of programmes.</p>	<p>Healthcare: Healthcare is provided by public and private providers, with public hospitals funded jointly by the national and state governments, and medical services outside hospitals subsidised through the national level Medicare scheme. Most ambulatory care is delivered by private practitioners. Health system financing is mainly from general taxation, with a small health tax levy and user co-payments.</p> <p>Social care: Social care services (direct welfare services) are typically subsidised by government departments and largely delivered by the private non-profit sector.</p> <p>Long-term care: Long-term care is the responsibility of the Australian government for those aged 65 and older; states and territories plan and oversee service delivery for those with disabilities and those under 65 years. Long-term care is funded by the Australian government and provided mainly by the voluntary sector.</p>
England	<p>The Department of Health is responsible for setting health and social care policy. From April 2013, NHS England has taken on many of the functions of the former primary care trusts (PCTs) with regard to the commissioning of primary care health services, as well as some nationally-based functions previously undertaken by the Department of Health; responsibility for the commissioning of the majority of NHS services has been devolved to local clinical commissioning groups (CCGs). Newly established local health and wellbeing boards oversee the delivery of integrated health and care services.</p>	<p>Healthcare: Healthcare services are organised and delivered through the National Health Service (NHS) and funded through general taxation, with a small national insurance contribution and user co-payments. Most primary care is provided through the NHS public system, as is the delivery of specialist care, although there is a sizable private sector funded through voluntary insurance, direct payments and NHS contracts.</p> <p>Social care: Social care services are provided through a means-tested system delivered at the local level by local authorities. People with assets beyond a set threshold receive no financial state support and need to fund their own care.</p>
Finland	<p>The Ministry of Social Affairs and Health (MSAH) directs health and social services at the national level and defines general social and health policy. The organisation of health and social care is the responsibility of municipalities.</p>	<p>Health and social care: Municipalities provide health and social care services independently or in cooperation with neighbouring municipalities. They can purchase services from other municipalities, non-governmental organisations or for-profit providers. Provision of healthcare is mainly public; municipalities also own and operate most residential care facilities.</p> <p>Financing of healthcare is mainly public, with municipal taxes accounting for almost half of all funding, supplemented by state subsidies, national health insurance (NHI) contributions and some user co-payments; social care is also largely funded through municipal taxes, supplemented by state grants and user fees.</p>
Germany	<p>Governance of the health and social care systems is shared between the federal government and 16 states, and corporate actors, with primary responsibility for the statutory health insurance (SHI) system at federal level within a regulatory framework set out by a series of social code books; federal states are responsible for hospital planning and institutionalised</p>	<p>Healthcare: Healthcare is provided by public and private providers. For the 90% of the population covered by statutory health insurance (SHI), health system financing is mainly from statutory health insurance via the central health fund, complemented by taxation and user co-payments.</p> <p>Social care: Welfare services are provided by mainly private (traditionally non-</p>

	Overall governance of health and social care	Provision and financing of healthcare and social care
	care.	profit) organisations. Federal states are responsible for planning (and guaranteeing the provision) of institutionalised care and schools for children with special needs. Long-term care: Long-term care is financed through statutory long-term care insurance and provided as care allowance, home care and residential care.
Netherlands	Healthcare system governance is shared by the government and the corporatist (self-governance) sector. The role of government is largely restricted to overseeing and defining the rules for the healthcare system, including quality, accessibility and affordability of healthcare. Governance and provision of social care and preventive care are decentralised to local government.	Healthcare: Healthcare services are generally delivered by private providers, with office-based general practitioners acting as gatekeepers to hospital care. Financing of healthcare is through mandatory health insurance and complementary voluntary health insurance. Social care: Institutional care is typically provided by non-profit organisations while formal care at home is provided predominantly by private not-for-profit organisations. Financing of long-term care is through statutory social insurance. Social care is financed through municipal budgets or general taxation.
USA	The federal system of government and the market nature of the US healthcare system mean that governance occurs at multiple levels and involves multiple organisations. Health and long-term care funding is provided by the federal, state and local governments, private health insurers and individuals. Health policy and administration is in the remit of the US Department for Health and Human Services (DHHS), with the Centers for Medicare & Medicaid Services (CMS) responsible for administering the public health insurance programmes. The DHHS also principally oversees long-term care, through the CMS, with Medicaid paying for the largest share of long-term care services.	Healthcare: Most of healthcare in the USA is delivered by privately owned (for profit, not-for-profit) provider organisations. The federal government is also a direct provider of healthcare to the military services, veterans and their relatives, and Native Americans. Approximately half of the payments for healthcare originate from public insurance programmes and the other half originates from privately owned health insurers. Employer-sponsored insurance is the main form of private insurance. Social care: Institutional care is typically provided by private organisations with the majority of funding being derived from the Medicaid and Medicare programmes. Sheltered housing falls under the jurisdiction of local governments.

The countries in this report represent different approaches to the governing of health and social care. In Finland, administrative and political responsibility is largely devolved to local authorities while in the Netherlands, responsibility for the health and social care systems is shared by central government and corporatist actors. In Germany, regional and local authorities also play a role. In the USA, healthcare regulation is shared between the federal government and the states, as is the governance of social care systems. This is also the case in Australia. In England, health and social care policy is set nationally while the organisation of care is devolved to local organisations, with clinical commissioning groups replacing primary care trusts from 2013, overseen by a newly established national NHS Commissioning Board.

Provision of health and social care services typically involves a mix of public and private providers, although the relative balance varies. For example in Finland the provision of healthcare is mainly public and most long-term and residential care is under the ownership and operation of municipalities. In contrast, in the USA healthcare and long-term care provision is mostly private. In Germany and the Netherlands, too, most long-term and social care tends to be provided by private non-profit organisations. In England, all nursing home care and most residential care is provided by private for-profit or not-for-profit (voluntary) organisations, while most of the healthcare provision is through the NHS public system. However there is a sizable private sector both in primary and specialist care.

2.2 **Standards of quality and safety in health and social care**

The sources of standards in the health and social care systems for quality vary among countries, as do the actors involved in standard setting. Sources of standards may involve overarching, high-level principles that inform quality regulation such as a country's constitution, national legislation or frameworks. With the exception of the USA, all systems reviewed here have some form of national framework or principle in place guiding the overall development and implementation of standards. These frameworks are embedded within the overall system of health and social care governance and the wider national legislative framework, which will inform enforceability and level of standard setting. Standards can thus be generally embedded within constitutional provisions (Finland) or national framework legislation (England, Germany, the Netherlands), or be developed as standards and frameworks for guiding, although not enforcing, service quality (Australia). The USA has a national framework for creating national standards, but the considerable power of state governments as the primary regulators of healthcare, and the tendency to rely on private markets to purchase and provide care creates challenges to a unified national quality standard.

We here describe each of these approaches and Table 2.2 provides an overview of the different sources of standards for quality and safety in the five countries reviewed, along with England. At the outset it is important to note that the distinctions used here are not clear cut, and can be interpreted in different ways. Also, while the definition of national quality principles or standards provide for a necessary condition to ensure quality and safety in the delivery of health and social care services, they do not provide for a sufficient condition for standard adherence. To ensure adherence, standards need to be linked to

formal (enforcement) mechanisms which are accepted and implemented by the various stakeholders. We discuss these mechanisms in Section 2.3.

Constitutional provisions and framework legislation governing quality of care

The Finnish constitution sets out the requirement that government must provide adequate care for all citizens. This constitutional requirement provides the legal foundation for national regulation, for example through the 1992 Act on the Status and Rights of Patients, setting out patients' right to information, informed consent to treatment, the right to access relevant medical documents, the right to complain and the right to autonomy.

In the Netherlands, the government has defined quality of care according to three dimensions (effectiveness, conceptualised as clinical effectiveness and patient safety; patient-centeredness; and cost-efficiency) which form the basis of the regulatory system and national regulation as set out in the 1996 Quality of Health Facilities Act ('Quality Act') in particular. Regulation therefore provides for the general requirements for quality of care while professional bodies define how to meet these requirements in a way that safeguards quality and delivers 'responsible care' (*verantwoorde zorg*). For example, the 1996 Quality Act makes a functioning quality system mandatory for all healthcare institutions (except independent professionals such as GPs and dentists), such as the requirements to systematically monitor, control and improve the quality of care and to publish annual reports on quality management and care quality delivered.

Likewise, Germany has embedded standards for the quality of care, or the regulatory framework in which these standards can be developed, using national legislation. Regulation concerning patient care and rights within the statutory health insurance (SHI) system are embedded in the Social Code Book, which sets the regulatory framework for major actors, their roles and obligations in the health and long-term care system and which is complemented by state legislation. Within this regulatory framework the Federal Joint Committee (G-BA) is the highest decisionmaking body in the German SHI system. It brings together providers and funders (SHI funds), with advisory input from patient representatives. It also develops specific regulatory measures on quality standards and assurance mechanisms, involving directives that apply to health and dental care provided under statutory health insurance (SHI) and to approved hospitals.

England would also fall within this category, with Section 20 of the Health and Social Care Act 2008 mandating 'that any service provided in the carrying out of a regulated activity is of appropriate quality' and securing 'health, safety and welfare of persons for whom any such service is provided'.⁹ In line with these stipulations, 'essential standards of quality and safety' in service provision have been formulated, which cover six broad areas.⁶ There are sixteen essential standards of quality and safety that all providers are regulated against. In terms of expectations from the perspective of service users, these can be summarised into five areas (for a detailed overview of the standards please see Chapter 4):¹⁰

1. You should expect to be respected, involved in your care and support, and told what's happening at every stage.
2. You should expect care, treatment and support that meets your needs.
3. You should expect to be safe.

4. You should expect to be cared for by staff with the right skills to do their jobs properly.
5. You should expect your care provider to routinely check the quality of their services.

The standards are embedded within the regulatory framework set by the Department of Health.

Strategies and standards for quality of care

In Australia, health and social care have constitutionally and historically been a state/territory responsibility. However, the Australian government has gradually assumed increasing powers, on the grounds that the centre collects most taxes and distributes funds to the states. As a consequence, an increasing number of frameworks and standards are being negotiated between the Commonwealth and the states and other stakeholders. For example the 2011 National Safety and Quality Health Service (NSQHS) standards provide for a set of measures across services and settings that can be used for internal quality assurance or external accreditation. The standards were developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC) and from June 2013 all clinical health services are expected to adhere to these ‘essential standards of care’. The ACSQHC also developed an Australian Safety and Quality Framework for Health Care in 2010 that sets out three core principles (consumer-centred care, driven by information, and organised for safety) plus 21 areas of action for improvement. The framework is voluntary, seeking to guide health services in the development of quality and safety plans.

Similar to Australia, the USA, has (so far) not introduced national legislation to govern the quality of care. Regulations are traditionally aimed at quality assurance, setting out a minimum standard for infrastructure and organisational features, with sector-specific regulation at state and federal level governing care quality. This includes individual state legislation on licensure of healthcare facilities, with the Centers for Medicare and Medicaid Services (CMS) imposing additional requirements on those healthcare facilities participating in Medicare or Medicaid. The 2010 healthcare reform (Affordable Care Act) established the National Strategy for Quality Improvement in Health Care (National Quality Strategy) to guide local, state, and national efforts to improve the quality of healthcare in the USA. The 1987 Nursing Home Reform Act (OBRA ’87) defines regulatory standards for nursing homes at the federal level supplemented by individual state laws.

Table 2.2 Sources for and content of standards for health and social care in six countries

Country	Source and content of standards
Australia	<p>National Safety and Quality Health Service (NSQHS) Standards developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC) are part of the Australian Health Services Safety and Quality Accreditation Scheme endorsed by the Australian health ministers in 2010.</p> <p>The Standards provide a set of measures that can be applied across services and settings and used as quality assurance mechanism for providers to test whether minimum standards are met or as quality improvement mechanism for goal development. Other national standards include quality of care principles as part of nursing home accreditation, mental health standards, and standards for child day care and also out-of-home care (residential and foster homes).</p>

Country	Source and content of standards
	<p>The ACSQHC also produced an Australian Safety and Quality Framework for Health Care in 2010 that sets out three core principles (consumer-centred care, driven by information, and organised for safety), plus 21 areas of action for improvement. The framework is voluntary to guide health services.</p>
England	<p>National standards for the delivery of care services were first introduced following the 2000 NHS Plan, with the regulatory framework supporting implementation undergoing reform since.</p> <p>The 2008 Health and Social Care Act sets the framework for regulations by securing that any service provided in the carrying out of a regulated activity is of appropriate quality. The stipulations for this are defined further as a set of 16 essential standards of quality and safety' in service provision which are to be implemented by providers in health and social care (and currently regulated by the Care Quality Commission); the 16 standards concern care and welfare of service users; assessing and monitoring the quality of service provision; safeguarding service users from abuse; cleanliness and infection control; management of medicines; meeting nutritional needs; safety and suitability of premises; safety, Availability and suitability of equipment; respecting and involving service users; consent to care and treatment; complaints; records; and requirements relating to workers. The essential standards are due to be updated, alongside the inspection and assessment approach, for April 2014.</p>
Finland	<p>The Finnish Constitution sets out the requirement that government must provide adequate care for all, providing the legal foundation for national regulation such as the 1992 Act on the Status and Rights of Patients, which sets out patients' right to information, informed consent to treatment, the right to see any relevant medical documents, the right to complain and the right to autonomy. Further national legislation defines the quality and standards of healthcare. There are national standards for selected specific service categories, such as elderly care.</p>
Germany	<p>The Social Code Book sets the regulatory framework for major actors, their roles and obligations in the statutory health insurance (SHI) system. Thus, quality and effectiveness measures of services within the SHI system have to comply with the current level of medical knowledge and take account of required technical quality. Service providers must safeguard and develop the quality of services they provide.</p> <p>Stipulations set out in the Social Code Book are further defined by the Federal Joint Committee (G-BA), which issues binding directives on treatments, quality assurance and minimum standards of care, which are implemented by SHI funds, hospitals and associations of physicians. Areas of regulation are: quality management; external quality assurance; cross-sectoral quality assurance; regulation on quality of structures, processes and outcomes; regulation on assessment and monitoring of services by SHI-accredited physicians.</p>
Netherlands	<p>The Dutch government has defined quality of care in terms of effectiveness (clinical effectiveness; patient safety), patient-centeredness and cost-efficiency, which form the basis of the regulatory system and national regulation.</p> <p>National-level regulation provides for the overall requirements for quality of care to be defined further by professional bodies on how to meet these requirements in a way that safeguards quality and delivers 'responsible care' (<i>verantwoorde zorg</i>). For example, the 1996 Quality Act makes quality systems mandatory for all healthcare institutions (excluding GPs and dentists), further stipulating that healthcare institutions have to provide 'responsible care' (defined as care being of a good level, suitable, patient- and needs-oriented); to provide a structure that allows for the delivery of responsible care and communicate how they achieve/maintain it; to systematically monitor, control and improve quality of care; to publish annual reports on quality management and quality delivered.</p>
USA	<p>The 2010 Affordable Care Act required the Department of Health and Human Services (DHHS) to develop a National Strategy for the Improvement of Health Care (National Quality Strategy). The National Quality Strategy is a developing strategy guided by DHHS as an attempt to set national aims and priorities in healthcare quality improvement. The strategy has three aims: better care, healthy people and communities, and affordable care.</p> <p>The Nursing Home Reform act (OBRA'87) deals with nursing home regulation; it defines regulatory standards for nursing homes at the federal level, supplemented by individual state laws.</p>

2.3 Regulatory strategies and actors for assuring quality of care

As the systems of health and social care governance vary between countries, so does the range of policy instruments that are being used and the actors that work towards assuring and improving care quality. We here describe the principal regulatory strategies present in each of the countries reviewed and the main actors involved in quality assurance, including a description of the remit of these actors and strategies extending across health and social care. Before doing so, we briefly discuss regulation as a mechanism in itself to enable placing findings on quality regulation in context.

Regulation has been described in different ways, reflecting different disciplinary perspectives.¹¹ Baldwin et al. (1998) classified definitions of regulation according to the comprehensiveness of the level of control, ranging from mandatory rules enforced by state agencies to total social control.^{12 13} We here view regulation from a ‘management mechanism’ perspective. This allows us to consider a wide range of regulatory strategies that are being used depending on the national context and the particular concept of quality of care. We draw on the conceptualisation of principal regulatory strategies to ensure quality and safety in the healthcare sector as proposed by Braithwaite et al. (2005),⁴ based in part on Ayres and Braithwaite (1992),¹⁴ and also adapted by researchers in other contexts, such as Gunningham and Sinclair (1999) on regulation for environmental protection.¹⁵ This conceptualisation maps the range of regulatory strategies to ensure safety and quality of healthcare while considering the level of state intervention *vis-à-vis* voluntary arrangements with actors involved. This is further illustrated in Figure 2.2.

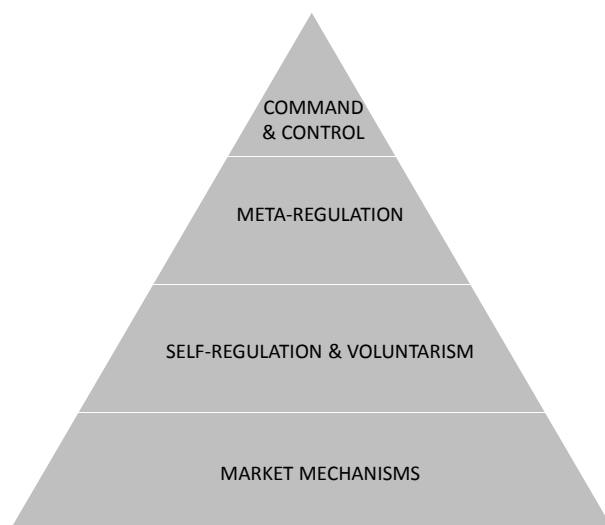


Figure 2.2 Regulatory pyramid

SOURCE: Adapted from Braithwaite (2005).⁴

However, regulatory strategies adopted in a given context have to be interpreted alongside regulatory styles to understand the ways in which strategies are implemented in practice. Two archetypal styles, deterrence and compliance regulation, have been broadly identified in the literature; for example, Lewis et al. (2006) discuss deterrence and compliance played out by healthcare regulatory actors.¹⁶ In this conceptualisation, deterrence regulators

assume that the organisations that they regulate are motivated solely by self-interest and require careful monitoring. Organisations are expected to conform to standards of behaviour imposed by the regulator. Deterrence regulators may make extensive use of quality standards and sanctions for non-compliance. In contrast, compliance regulators assume that the regulated organisations are likely to share their objectives and are worthy of trust and support. This style of regulation will offer advice and guidance and will be slow to use sanctions.

2.3.1 Principal regulatory strategies and mechanisms for health and social care governance

As illustrated in Figure 2.2, Braithwaite et al. (2005) distinguish four principal strategies⁴:

- **Command and control:** implies direct enforcement by government (eg licensing professionals and facilities, enforcing performance standards). Mechanisms to secure standard adherence include criminal or civil penalty; licence revocation or suspension; physician revalidation.
- **Meta-regulation:** describes an approach by which the conduct of self-regulation (see below) is monitored by an external third party. There may be sanctions and financial incentives that help ensure adherence. Examples include clinical audits conducted externally; mandated incident reporting systems; and consumer complaints ombudsmen.
- **Self-regulation and voluntarism:** *Self-regulation* describes a system in which organised groups regulate the behaviour of their members; this might involve an industry-level organisation or a professional association which sets rules, standards, and codes of practice relating to the conduct of its members. *Voluntarism* is based on an individual firm, organisation, or individual professional, ‘undertaking to do the right thing without any basis in coercion’.¹⁵ These mechanisms include the use of clinical governance, voluntary hospital accreditation, peer review, clinical protocols, the use of performance indicators/targets and benchmarking.
- **Market mechanisms:** refers to a set of rules and institutions of a market economy as applied to the public sector. Mechanisms to encourage adherence to standards include elements such as incentive payments, governance by contracting, and performance league tables.

These strategies are not mutually exclusive. Indeed, systems tend to employ a combination of mechanisms, but place different emphases on the various components of each approach. Also, boundaries are not necessarily clear cut.

Table 2.3 shows the main approaches observed in each of the five countries under review, with England added for comparison. We find that all these countries, or systems within, employ elements of self-regulation and voluntarism, meta-regulation and command and control, alongside market mechanisms in the form of governance by contracting. For example, and perhaps not surprisingly in the health and social care sectors, the most common elements are self-regulation and voluntarism, involving accreditation of providers or facilities, promulgation of voluntary standards of practice, continuing (medical) education or the use of performance indicators or targets (Australia, England, Finland, Germany, Netherlands, USA). Similarly, meta-regulation is commonly used, employing mechanisms such as external clinical audit, mandated incident reporting and ombudsmen.

Explicit use of market mechanisms appears to occur less frequently; examples include selective contracting (Netherlands, USA) and incentive payments (England, USA). All of the countries under review employ mechanisms of command and control, mostly in relation to professional licences.

As indicated above, while countries reviewed use most mechanisms, the balance of mechanisms in place varies. Thus, the primary mechanisms employed in Australia are a combination of voluntary regulation and self-regulation, using frameworks derived from state-led and intergovernmental committees (developed through consultative strategies). In Finland, the standards themselves can be traced back to the central government and its constitution, but also operate primarily through self-regulation. In the USA, regulation has traditionally relied heavily on professional self-regulation through board certification and peer review mechanisms. In the Netherlands, the two dominant mechanisms are self-regulation/voluntarism and meta-regulation. As stated earlier, the dominant regulatory mechanism adopted at system level is highly dependent on the cultural and governance context of each country. We therefore discuss regulatory activity in more detail in the next section by describing the role of the regulatory bodies or actors, and their individual dominant regulatory strategy or mechanism.

Table 2.3 Regulatory activities and mechanisms for health and social care governance in five countries

Country	Regulatory activities adopted per principal regulatory mechanisms
Australia	<p>Self-regulation and voluntarism: accreditation, performance indicators / targets, benchmarking, peer review, clinical protocols, continuing education.</p> <p>Meta-regulation: enforced self-regulation; continuous improvement; external clinical audit; mandated incident reporting system; performance indicator reporting; root cause analysis; health complaints ombudsman, standards and guidelines, financial incentives and sanctions.</p> <p>Command and control: professional registration, licence revocation or suspension.</p>
England	<p>Self-regulation and voluntarism: accreditation, performance indicators, benchmarking, clinical protocols, continuing education.</p> <p>Market mechanisms: pay-for-performance, (public reporting).</p> <p>Meta-regulation: enforced self-regulation, annual inspection, external clinical audit, mandated incident reporting system, standards and guidelines, monitoring complaints, mandated public reporting, mandated revalidation.</p> <p>Command and control: fines, public warnings, suspension or cancellation of registration and prosecutions.</p>
Finland	<p>Self-regulation and voluntarism: supervision of health provision, guidance and steering, monitoring, continuing education.</p> <p>Meta-regulation: mandated continuous improvement; external clinical audit; mandated incident reporting system; consumer complaints ombudsman; benchmarking.</p> <p>Command and control: licensing of health professionals; penal sanctions.</p>
Germany	<p>Self-regulation and voluntarism: accreditation, performance indicators / targets, benchmarking, open disclosure, clinical protocols, continuing education.</p> <p>Meta-regulation: enforced self-regulation (ie if self-regulatory mechanism fail, the government may regulate directly), mandated continuous improvement including quality reporting, external clinical audit mandated incident reporting, federal ombudsperson.</p> <p>Command and control: criminal or civil penalty.</p>
Netherlands	<p>Self-regulation and voluntarism: accreditation, performance indicators / targets, benchmarking, peer review, open disclosure, clinical protocols, continuing education.</p> <p>Market mechanisms: governance by contract, (public reporting).</p> <p>Meta-regulation: enforced self-regulation, mandated continuous improvement, external clinical audit, mandated incident reporting system, root cause analysis, consumer</p>

Country	Regulatory activities adopted per principal regulatory mechanisms
	complaints ombudsman. Command and control: criminal or civil penalty, licence revocation or suspension.
USA	Self-regulation and voluntarism: facility accreditation, continuing medical education, licensing and privileging. Market mechanisms: selective contracting, pay-for-performance, public reporting. Meta-regulation: external clinical audits, mandated incident reporting system, consumer complaints ombudsman. Command and control: licence revocation or suspension, medical malpractice legislation.

2.3.2 Main actors responsible for assuring standard adherence in health and social care

Based on each country's strategies towards quality regulation in health and social care reviewed here, we distinguish three main categories of regulatory competencies: (i) supervisory and standard enforcement competencies; (ii) monitoring and/or standard setting competencies; and (iii) quasi-legislator competencies. Below we provide examples for each type of actor in the countries under review and discuss their scope of action. It is important to emphasise that these actors contribute to the (implementation of) regulation for quality and safety in a given system; they do not represent the regulatory system as such. Table 2.4 provides further information, capturing the wider range of actors identified as occupying a key role at national level as it relates to ensuring quality and safety in health and social care; further detail is provided in the specific country section in this report (Chapter 3 to Chapter 8).

Competencies for supervision and enforcement of standards

Bodies with competencies for supervision and enforcement of standards monitor the activities of health and social care stakeholders, employing formal or informal mechanisms to ensure adherence to standards. Relevant bodies are typically situated at arm's length of government. Examples of bodies with such competencies are present in England, Finland, the Netherlands and the USA.

Examples include the **Care Quality Commission (CQC)** in England. Formed in 2009 as a merger of the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission, the CQC is an independent regulator of health and adult social care, and of primary dental care services in England. It also protects vulnerable people, including those whose rights are restricted under the Mental Health Act.¹⁷ All providers of care services, care homes, dentists, home care, hospitals, and, from 2013, GP practices that wish to provide services have to register with the CQC; registration is only possible following legal declaration that providers are meeting essential standards of quality and safety set by the government. The CQC ensures standard adherence through typically annual (unannounced) inspections, and monitoring between inspections, drawing on a range of information sources. Where services do not meet requirements, the CQC has a set of statutory enforcement mechanisms at its disposal such as requesting action plans, issuing warning notices requiring improvements within a given time period, restricting the services that the provider can offer, stopping admissions into the care service, issuing fixed penalty notices, or suspending or cancelling the service's registration.¹⁸ Prosecution is also possible where providers of care services are not registered with the CQC. Results of inspections are made publicly available as a means to inform users of health services about the quality of

care provided. In 2012/13, the CQC has undertaken a strategic review of its purpose and role, with changes to its regulatory approach ongoing. For example, a ‘Chief Inspector of Hospitals’ was appointed in summer 2013, with appointments of chief inspectors of general practice and of adult social care to follow in due course.

The Finnish **National Supervisory Authority for Welfare and Health (Valvira)** is also a standard enforcing body with a range of supervisory powers.¹⁹ Valvira handles social welfare-related supervisory cases where these are of ‘nationwide importance and matters of principle’. Other issues are addressed by the six Regional State Administrative Agencies that collaborate with Valvira on supervising social care and govern social care facilities. Supervision of healthcare facilities and professionals in the public and private sectors seek to ensure adequacy of services, as well safety and appropriate use of medical devices. Competences in licensing include issuance of professional licenses (protected occupational titles; fixed-term licenses) and national licenses for private providers. Several patient complaints are also handled by Valvira, and professional misconduct can result in the revocation of physician’s licenses by Valvira. Given that only a few standards are based on legislation, Valvira will use measures such as conditional fines or license revocation only in very extreme cases.

The **Health Care Inspectorate (Inspectie voor de Gezondheidszorg, IGZ)** in the Netherlands is an independent supervisory body at national level reporting to the Dutch Ministry of Health, Welfare and Sport.²⁰ Established in 1995 as a merger of three areas of state inspection that had existed throughout the 20th century (healthcare, pharmaceutical care, and mental healthcare), it enforces standards but is also partly a standard setting body. Supervision is based on ‘field norms’ set by providers and professional groups, but where such norms are not available, the IGZ develops own supervisory norms. For instance, providers and insurers must produce annual accountability reports (costs, activity and quality) and the IGZ monitors adherence to this mandatory system. The hospital sector is required to report on performance annually. This information is made publicly available through the newly established Institute for Health Care Quality (Kwaliteitsinstituut), and is aimed at informing users of healthcare and purchasers of care (insurers) about the quality of care provided, and at helping providers to improve quality by enhancing transparency. The IGZ has a range of statutory enforcement measures at its disposal: it can for example initiate criminal investigations or report a matter to the Public Prosecution Service, and has the right to lodge a disciplinary complaint and to bring a professional before the Medical Supervision Board. However, in the majority of cases it supervises through the use of non-statutory, informal means such as advice and encouragement, persuasion and incentivising for improvement, or consultation and agreements specifying need for improvement and timeframe.

A possible outlier in this category is the **US Centres for Medicare and Medicaid Services (CMS)**, established in 1977, which administers Medicare, Medicaid and Children’s Health Insurance Program (CHIP).²¹ An agency of the national Department of Health and Human Services, CMS has the role of enforcing and setting standards, it uses financial incentives and payments as the primary means to ensure adherence. CMS acts as a payer in the healthcare system and engages in regulation by setting conditions of participation, which often serve as quality standards for hospitals due to the size of the programme. The primary mode of enforcement is withholding payments to providers and financial

incentives are also used to promote changes in practice by changing payment formulas or through the use of pay-for-performance schemes.

Standard setting and/or monitoring competences

Bodies with standard setting and/or monitoring competences develop standards in a coordinating fashion in cooperation with key stakeholders, or monitor the development of key indicators and report to national governments. They typically do not have competencies for enforcement. Examples of these types of bodies are found in Australia and England.

Thus, the **Australian Commission on Safety and Quality in Health Care (ACSQHC)** is an independent statutory authority and a standard setting body established in 2006 that leads and promotes (in collaboration with providers, professionals, and national as well as state-level health departments) the development of safety and quality standards and indicators.²² These include the National Safety and Quality Health Service (NSQHS) Standards. It also promotes the implementation of 'best practice' safety and quality standards across Australia. The NSQHS standards provide a set of measures across services and settings and can be used for internal quality assurance or external accreditation. The ACSQHC does not have supervisory powers beyond 'reputational' pressures, as responsibility for implementing these standards and initiatives lies with the state/ territory health departments and the private sector. The Australian **National Health Performance Authority (NHPA)**, a statutory authority established in 2010, monitors performance of local hospital networks, public and private hospitals and primary healthcare organisations along 48 indicators (31 indicators for healthy communities and 17 indicators for hospital performance) agreed by the Australian health ministers.²³ The NHPA collects data and relies mainly on public reporting of outcomes but does not have statutory enforcement competencies.

In England, the **National Institute for Health and Care Excellence (NICE)** was originally formed in 1999, and in April 2013 became a non-departmental public body following the 2012 Health and Social Care Act.²⁴ NICE's role is to improve outcomes for people using the NHS and public health and social care services through producing evidence-based guidance and advice for health, public health and social care practitioners; developing quality standards and performance metrics for those providing and commissioning health, public health and social care services; and providing a range of information services for commissioners, providers, users and carers across the spectrum of health and social care. NICE's work on quality standards includes the development of potential indicators for the inclusion in the Quality and Outcomes Framework (QOF), which is part of the general practitioner contract in the UK. More recently, NICE has also begun working with NHS England and other stakeholders in the development of the Clinical Commissioning Group Outcomes Indicator Set (CCGOIS) which seeks to measure the health outcomes and quality of care achieved by newly established clinical commissioning groups.

Quasi-legislator competencies

Quasi-legislator bodies have wide competences in standard setting. While not involved in actual enforcement, standards developed by these bodies are mandatory, enforceable

through other (regulatory) bodies and can be evoked before court. This type of body is present in Germany and the USA.

In Germany, the **Federal Joint Committee** (Gemeinsamer Bundesausschuss, G-BA) is an independent body, which is accountable to the federal Ministry of Health. Newly established in 2004, the G-BA subsumed the tasks of several federal level committees concerned with the promotion and implementation in the German statutory health insurance system.² Among many other tasks, the G-BA sets out regulation on quality standards and assurance mechanisms through directives which are legally binding on providers and statutory health insurance funds. The G-BA does not act as a standard enforcement agency as such; implementation of quality standards is mainly through professional and provider associations with some (legal) oversight by the federal government. An example of a standard enforcing body is the Medical Review Board of the statutory health insurance funds (MDK), established in each state. In the USA, while registration within the CMS requires accreditation, the act of inspection and accreditation is implemented by the **US Joint Commission**.

Table 2.4 Principle regulatory mechanisms used by actors involved in governance of quality and safety of health and social care in six countries

Actors	Legal status and scope	Standards, laws or guidelines	Measures used
Australia			
Australian Commission on Safety and Quality in Health Care (ACSQHC)	Standard setting Independent statutory authority; reports to the Australian Health Ministers (a Standing Council of the Council of Australian Governments) Leads and coordinates, including the development of safety and quality standards and indicators, and promotes implementation	eg <i>Australian Charter of Healthcare Rights; Australian Safety and Quality Framework for Health Care</i> Main example for development of national standards: <i>National Safety and Quality Health Service (NSQHS) Standards</i>	Leads and coordinates the development of good practice in safety and quality, of standards and indicators in collaboration with providers, professionals, and national and state-level health departments and promotes their implementation Relies on persuasion, networked governance through other actors, endorsement by health ministers, and implementation through health departments Uses advice, publications and resources (eg collection, analysis and dissemination of information, formulation and support for the implementation of standards, publication of reports)
National Health Performance Authority (NHPA)	Standard setting Statutory authority from 2010 Monitors hospital performance indicators	Indicators agreed by health ministers	Monitors 48 performance indicators agreed by health ministers which cover all local hospital networks, public and private hospitals and primary healthcare organisations Collected data is reported to governments at national and state level Uses public reporting as a means to exert reputational pressure and facilitating consumer choice
Australian Council on Healthcare Standards (ACHS)	Standard setting Accreditation agency	N/A	Sets standards, the Evaluation and Quality Improvement Program (EQUIP), and inspects and assesses health facilities against these standards Stresses a developmental and educative role in its accreditation procedure and promotes continual quality improvement Provides quality improvement advice
Aged Care Standards & Accreditation Agency Ltd.	Standard setting and inspection Quasi-governmental company established 1998 Accreditation agency	<i>Aged Care Act 1997; Quality of care principles</i>	Inspects against standards Various sanctions Recommends license revocation to Department of Health (national dept).

Actors	Legal status and scope	Standards, laws or guidelines	Measures used
England			
Care Quality Commission (CQC)	<p>Standard setting and standard enforcing body</p> <p>Independent regulator of health and adult social care in England</p> <p>Oversees care homes, dentists, home care, hospitals, GP practices</p>	16 essential standards of quality and safety	<p>Regular (unannounced) inspections and monitoring on standard adherence among care providers</p> <p>Can request action plans, issue warning notices, restrict services, stop admissions into the care service, issue fixed penalty notices, suspend or cancel the service's registration; may prosecute where providers of care services are not registered with the CQC</p> <p>Results of inspections are made publicly available</p>
Monitor	<p>Sector regulator for health services in England</p> <p>Independent regulator, accountable to parliament</p> <p>Responsible for overseeing the performance of NHS foundation trusts in relation to finance and quality of care</p>	Terms for authorisation for each Trust set internally, based on national targets and standards	<p>Each NHS foundation trust is assigned a Monitor relationship manager, who ensures that where the trust fails to comply with its terms of authorisation, the trust's board takes appropriate action.</p> <p>Publishes quarterly and annual reports on foundation trusts' organisational performance, based on mandatory submissions from trusts</p> <p>Assigns each foundation trust an annual and quarterly risk rating that indicate the risk of failure to comply with the terms of authorisation</p>
National Institute for Health and Care Excellence (NICE)	<p>Executive non-departmental public body</p> <p>Produces evidence-based guidance and advice for health, public health and social care providers and commissioners; develops quality standards and performance metrics; provides information services across the spectrum of health and social care</p>	Positive technology appraisals of medicines and devices must be funded by the NHS	<p>Develops quality standards which are defined as "a concise set of prioritised statements designed to drive measurable quality improvements within a particular area of health or care"</p> <p>Develops potential indicators for inclusion in the Quality and Outcomes Framework (QOF), the quality element of the GP contract</p> <p>Supports the development of the Clinical Commissioning Group Outcomes Indicator Set (CCGOIS)</p> <p>Issues recommendations on the use of new and existing medicines and treatments within the NHS through undertaking technology appraisals</p>
Finland			
National Supervisory Authority for Welfare and Health (Valvira)	<p>Standard setting and enforcing</p> <p>Operates under Ministry of Health and Social Affairs</p> <p>Covers health and social care</p>	Standards within health and social care legislation	<p>Healthcare: sets standards and acts as steering body</p> <p>Maintains register of healthcare professionals, supervises healthcare professionals handles patient complaints; ensures safe and appropriate use of medical devices</p> <p>Social care: governs social care facilities; handles social care complaints in</p>

Actors	Legal status and scope	Standards, laws or guidelines	Measures used
collaboration with regional agencies Licenses protected occupational titles Provides national licenses for private providers			
Germany			
Joint Federal Committee (Gemeinsamer Bundesausschuss, G-BA)	Standard setting body; enforcement is mainly in the remit of corporatist actors (eg Medical Review Board of the Statutory Health Insurance Funds (MDK)) Independent legal body accountable to Federal Ministry of Health and subject to its legal supervision Highest decisionmaking body in the statutory health insurance (SHI) system	G-BA's mandate is defined by the Social Code Book	Mandated by law to carry out regulatory tasks defined by the Social Code Book V; decisions of the G-BA have the legal status of directives and are legally binding on providers, SHI funds and patients Responsible for various areas of quality regulation of SHI-covered medical and dental care, as well as for services provided in approved hospitals; this includes for example: national mandatory measures for quality assurance; promotion of quality assurance, hospital quality reporting, and quality management Reporting obligations for providers include quality data for hospitals, collection of national cross-sectoral quality data (commission indicator-based collection of national quality data across all healthcare settings)
The Netherlands			
Health Care Inspectorate (Inspectie voor de Gezondheidszorg, IGZ)	Standard enforcing and partly standard setting body Independent supervisory body at the national level; reports to the Dutch Ministry of Health, Welfare and Sport	Ensures compliance with 25 items of legislation and other legal provisions, including the 1996 Quality Act and the 1993 Individual Health Care Professions Act	Advice and encouragement (persuasion and incentivising for improvement; consultation and agreements specifying need for improvement and timeframe) Annual accountability reports: providers and insurers must produce annual accountability reports (costs, activity and quality); the IGZ monitors the compliance to this mandatory system Statutory reporting duties (eg under the Quality Act requiring institutions to report emergency incidents and cases of sexual abuse) Sets performance indicators for patient safety and effectiveness in collaboration with professional associations and healthcare providers <i>Criminal proceedings</i> (eg right to initiate criminal investigations or report the matter to the Public Prosecution Service) <i>Disciplinary measures</i> (eg right to lodge a disciplinary complaint and to bring a professional before the Medical Supervision Board) <i>Administrative measures</i> (eg right to issue a compliance order and to

Actors	Legal status and scope	Standards, laws or guidelines	Measures used
			initiate instructive measures)
USA			
Centers for Medicare and Medicaid services (CMS)	Standard setting and standard enforcing body Agency of the Department of Health and Human Services (HHS) Administers Medicare, Medicaid, and Children's Health Insurance Program (CHIP). Quality assurance for nursing homes	N/A	CMS enforces standards through 'conditions of participation' Public reporting and payment reforms (value-based purchasing and pay-for-performance) Financial incentives to promote changes in practice either by changing payment formulas or in pay-for-performance programmes Accreditation inspections by the Joint Commission with a CMS review of the Joint Commission accreditation procedures Disqualification from receiving Medicare and Medicaid funds

2.4 Effectiveness of regulatory strategies and systems

There is a lack of international consensus on what constitutes ‘effective regulation in health and social care’, reflecting the diversity of governance and financing of healthcare systems. As we have seen above, the countries reviewed here vary with regard to the strategies for healthcare quality that are being used and the extent to which legislative measures ensuring quality of care have been implemented. While at the broader level, there is general agreement on the part of international organisations and governments as to a list of desirable principles for designing a regulatory regime, such as transparency, accountability and proportionality, it is more difficult to translate general principles into specific strategies for regulating healthcare quality.²⁵

It was beyond the scope of this report to provide a systematic review of the conceptualisation and measurement of ‘effective quality regulation’ although it should be noted that the overall evidence is scarce. At the risk of simplifying what is inherently a complex issue, it is however possible to draw on the wider literature that has discussed effectiveness in the context of healthcare governance. Thus, arguing from a health systems performance perspective, effectiveness can be defined as ‘the degree to which the objectives of a program, care, services, or system are achieved.’²⁶ Such objectives should be set a priori, and be realistic and measurable by means of performance indicators. From this perspective, the ‘effectiveness of quality (of care) regulation’ can be conceptualised as the degree to which (regulatory) objectives for ensuring the quality of care are achieved. Focusing specifically on healthcare regulation, Walshe (2002) identified a set of characteristics for effective regulation and the role of an effective regulator.²⁷ Accordingly, regulation should be ‘responsive’, as proposed by Ayres and Braithwaite 1992.¹⁴ This means that the regulatory regime should be flexible and adaptive as well as targeted to the content and outcome of each regulatory encounter. It should employ a range of regulatory strategies and mechanisms, involving both informal mechanisms as well as more formal (statutory) approaches to ensure integrity and credibility. Effective regulation requires stakeholder involvement as sources of information and agents for change; it would also require a balance between independence and accountability, that is, it should consider mechanisms ensuring that the regulator is independent and impartial while being accountable for the effects of regulation.

The examples described in this report illustrate that the countries involved appear principally to have implemented regulatory frameworks that exhibit several of these characteristics, although the relative balance or weight of these characteristics varies. These frameworks reflect, to a considerable extent, the general governance, political and cultural context within which the systems operate. For example, the German healthcare system is traditionally characterised by a system of self-governance in which key functions are delegated to corporate actors (provider and payer associations); however, recent healthcare reforms have seen a move towards stronger centralisation of some functions, albeit still at corporate actor level.

The available evidence points to the impact of selected mechanisms, such as accreditation,²⁸ to enhance adherence to standards, or quality assurance more broadly through, for example, the use of incentive payments²⁹ or public reporting.^{30 31} Research,

however, has tended to focus on the evidence of impact on provider institutions and consumer choice rather than on health systems more generally. The overall evidence of the effectiveness of regulatory strategies towards ensuring care quality and safety at system level is scarce.

We here summarise some key observations, mainly drawing on published evidence from Australia and the Netherlands. Thus, as we have seen in earlier sections of this report, Australia has few external or arms-length bodies with explicit competences to enforce quality standards in health and social care. Regulatory actors tend to be internal to a service area, while external bodies such as ombudsmen or coroners recommend enforcement action to health or human service departments or other disciplinary bodies. Regulatory bodies appear to prefer strategies of co-regulation, self-regulation by professional associations and industry, financial incentives and the voluntary adoption of ‘codes of practice’ and ‘frameworks’.

This general approach has been shown to be effective in some instances, but not others. Thus, in an early assessment, Braithwaite (2001) argued that, compared to regulatory regimes in place in the USA and the UK, quality of age care in Australia had improved through effective standards monitoring processes in nursing homes. The processes used standards that were patient-centred and focussed on outcomes, and were based on conversational regulation and advice, rather than extensive and ritualised checklists and audits of documents.³² Conversely, the Aged Care Standards and Accreditation Agency (ACSAA), which focuses on continuous quality improvement, has been criticised in the past for failure to impose sanctions in the inspection regime and its focus on outputs rather than outcomes. Thus, analysing the role of sanctions in assuring quality in residential aged care, Ellis and Howe (2010) found that providers addressed identified shortcomings only when faced with enforcement measures preceding sanctions.³³ However, they also highlighted a need for quality assurance systems to be linked to contextual factors driving quality improvement, such as the quality of the workforce, and the availability and effectiveness of a range of sanctions. These, arguably somewhat patchy observations, illustrate the need for regulators to balance regulatory mechanisms using both informal as well as formal strategies as highlighted by Walshe (2002).²⁷

While a low formal intervention rate may be deliberate, evidence from the Netherlands suggests that propensity to intervene may also be determined by more structural reasons. For example, Hout et al. (2010) cite evidence from the mid-1960s and from the late 1980s that found that the Dutch supervisory scheme had historically low intervention rates, at around 10–15 per cent of cases.²⁰ They argue that increasing this rate significantly beyond 10 per cent of cases would not result in better supervision, because of unintended effects such as mistrust among regulated professionals, disruption of the process of self-regulation, reluctance of healthcare providers to interact with regulators as well as gaming. Supervision in the Netherlands, whether in healthcare or other sectors, is mostly based on phased, proportional use of informal and formal intervention. Evidence from the Dutch Health Care Inspectorate (IGZ) suggests that the IGZ chose for many years a ‘soft approach’ that relies mostly on authority and trust and the application of informal measures such as encouragement and advice.²⁰ Friele et al. (2009) also noted that the Dutch Health Care Authority (NZa), which – among other tasks – oversees the implementation of the 2006 healthcare reform, opted for a less interventionist approach based on informal measures

and preventative supervision in order to create confidence among market participants and giving room to act.³⁴ More recently, Tuijn et al. (2011) compared the reliability and validity of judgements generated by a lightly versus a highly structured regulatory instrument used by the IGZ. They found that both types of instruments showed variations in the meaning of judgments, which was taken to indicate validity problems. They also concluded that effective regulatory instruments have to take account of the complexity of care with an accompanying explicit set of standards, alongside appropriate training of those using those instruments.³⁵

These examples seem to support the notion that regulatory systems need to strike a balance between the use of formal, interventionist instruments and more informal, softer approaches to ensure standard adherence and quality improvement more broadly, as highlighted earlier.

2.4.1 **Case study: inspections**

Evidence on the effectiveness of inspections as a means to promote quality improvement in healthcare seems to be very limited. A recent systematic literature review of the effectiveness of external inspection in relation to standard adherence was unable to derive sound conclusions from the evidence reviewed.³⁶

We here briefly reflect on the inspection approaches employed in the countries reviewed in this report. At the outset, it may be helpful to conceptualise inspection. Thus, in line with Gormley (1998) inspection might be conceived of in different ways³⁷, distinguishing for example ‘inspectors styles’, which reflect on training, work experience and demographic characteristics of those carrying out the inspection, and ‘agency styles’, which refer to the statutory mandates, resources and the role of the governance and judicial system. A further distinction can be made between agencies that are ‘task-oriented’, that is, their focus is on technical challenges, and those that are ‘crisis-oriented’, which centre on complex regulatory encounters of interest to the public and politicians.

Within the context of this report we did not attempt to classify countries, or institutions within them, according to inspection ‘styles’ as outlined above. However, it is possible to describe systems according to whether inspections are conceptualised as a regulatory mechanism in itself and to distinguish whether inspection findings are made publicly available to inform service users as well as payers or decisionmakers. It is also possible to detail the extent to which sanctions are linked to the inspection regime and the use of a ‘soft approach’ (eg use of advice and encouragement) versus more formal statutory enforcement measures, or a combination of both.

Information about the skills and capacity, and number of inspectors was not available for most of the countries reviewed here. Data for IGZ in the Netherlands point to a highly specialised skilled inspector workforce (see Chapter 7).

- **Australia:** The **Australian Council on Healthcare Standards (ACHS)** relies heavily on volunteers (constituting half of its surveyors) whose time is underwritten by their employers as ACHS members. It has been criticised as an ‘industry friendly’ accreditor. The ACHS sets standards and assesses against these standards, emphasising the developmental and educative nature of their approach, that is, the use of rewards and achievements rather than sanctions and failures. The ACHS emphasises two

conditions for accreditation: explicit definition of quality (ie standards) and an independent review process aimed at identifying the level of congruence between practices and quality standards.³⁸ The Australian **Aged Care Standards and Accreditation Agency** (ACSAA) enhanced regulatory practice by focusing on continuous improvement. In recent years, and after several scandals, the ACSAA inspection regime was strengthened, although sanctions are still used sparsely and can only be enforced by the Department of Health in cases of sub-standard care.

- **England:** As described earlier, the **Care Quality Commission** (CQC) is responsible for the monitoring, inspection and regulation of care services, to ensure that providers meet the essential standards of quality and safety, and to make findings available to the public. Providers covered by the CQC include hospitals, care homes, domiciliary care services, dental services and general practices.³⁹ About 45 per cent of permanent staff are frontline inspectors, supported by a recently established ‘bank of specialist advisors’, which comprises experienced health and social care professionals. The CQC has aimed to carry out to regular inspections of providers and locations on an annual basis (dentists: every two years). Increasingly, the frequency of CQC inspections is expected to depend on the perceived ‘risk’ involved. For example, services judged to pose a high risk of harm to people who use them, or where people are vulnerable because of their circumstances, would receive more frequent inspection. The five key areas that inspections focus on will be safety, effectiveness, how caring services are, how well they are led and how responsive services are to people’s needs. As noted earlier, the CQC has recently undertaken a strategic review of its purpose and role, with changes affecting the inspection regime ongoing.
- **Finland:** Within the **Association of Finnish Local and Regional Authorities**, municipalities are responsible for monitoring the health and social care services. Some municipalities have developed quality criteria for services and a municipal audit committee assesses whether set operational and financial targets have been met. Traditionally, the inspection or audit system for providers is sanction-led with the Association providing also a simplified self-assessment and quality management system.⁴⁰
- **Germany:** The **Medical Review Board of the Statutory Health Insurance Funds (MDK)** is commissioned to assess whether long-term care services (nursing homes and home care) comply with agreed quality standards. Since 2008 it carries out annual audits of service providers which seek to inform the regional associations of long-term care funds and provide technical advice to nursing homes and other long-term care providers. On-site audits of the MDK are focused on patient-related processes and outcomes, using random samples of patients and residents of nursing homes. Quality inspections are conducted based on guidelines and results of the inspection reports are partly published by the regional associations of statutory long-term care funds. The Medical Review Board of the National Association of Statutory Health Insurance Funds (MDS), established in 2008, provides a report every three years on the quality of outpatient and inpatient long-term care, and aggregates the data from the individual needs assessments of the MDKs. It coordinates the technical work of the MDKs and publishes guidelines for inspections and assessments used across all MDKs.⁴¹⁻⁴³

- **Netherlands:** Within the context of ‘responsive regulation’, the **Health Care Inspectorate (IGZ)** tends to examine cases on an individual basis to determine the most effective enforcement measures. These will usually be ‘soft’ or informal, followed by more formal measures (eg a compliance order or fine), depending on the progress made (for example by a care provider) in a given context.⁴⁴ It seeks to achieve a balance between trust by care providers, and using supervision and inspection to verify adherence to standards as well as disciplinary or criminal proceedings. One example for this approach is *phased supervision* which is aimed at limiting risks in high-risk areas of healthcare.²⁰ The IGZ sets annually performance indicators for patient safety and effectiveness in close cooperation with professional associations and healthcare providers, and collects quality control information from all Dutch healthcare organisations.
- **USA:** Inspections play a role in nursing home regulations enforcement by state **Departments of Health**. The federal government sets national minimum standards of quality according to the 1987 Federal Nursing Home Reform Act (OBRA).⁴⁵ It requires unannounced inspections at least every 15 months, which are to include surveys, interviews with residents and family members and ombudsmen about residents’ daily experiences, and direct observation of residents and their care. Conducted by a multidisciplinary team of trained professionals, inspection results are made available publicly through the Nursing Home Compare website.⁴⁶ State governments have a number of enforcement options at their disposal such as an escalating scale of penalties, which includes directed in-service training of staff, a directed plan of correction, state monitoring, civil monetary penalties, denial of payment for services rendered, temporary management, and closure.⁴⁷ Similarly, within the US **Department of Veteran Affairs (VA)**, the Office of Inspector General (OIG) was created to monitor the healthcare provided to veterans. Among other tasks, OIG is responsible for conducting and supervising audits and investigations,⁴⁸ including of individual healthcare issues and quality programme assistance reviews of medical centre operations. The office makes recommendations to reduce deficiencies observed during their inspections. Physicians practising within the VA system must be accredited and credentialed, and are also subject to external review.⁴⁹

2.5 Trends in regulatory approaches

In this report we have attempted to bring together information on how selected high-income countries approach regulation for quality and safety of their health and social care systems. Given the complexity of these systems, and the diverse political and cultural contexts in which they operate, it is difficult to derive overarching conclusions about relative effectiveness. Each system is characterised by a particular set of relationships between the different professionals and institutions that deliver care, frequently – though not inevitably – determined by what has happened in the past. However, against this background, it is perhaps fair to say that overall, countries appear to have been striving towards greater centralisation of quality regulation, alongside a move towards greater transparency in the sector through making available information on quality and safety as a

means to inform service users and funders, a trend we have discussed in some detail elsewhere.⁵⁰

Greater centralisation of (quality) regulation

Centralisation of quality regulation was observed for all countries reviewed here, with the possible exception of the USA, although the recent Affordable Care Act made provisions for greater steering by the federal government. For example, in Australia, the 2011 National Health Reform Agreement by the Council of Australian Governments has shifted the balance of accountability and control to the national level while increasing local ownership and responsibility. This led to the introduction of new national bodies responsible for standard development and performance monitoring (eg the Australian Commission for Safety and Quality in Health Care and the National Health Performance Authority). Most areas of social care have also seen change, with the Commonwealth taking a leading role in developing standards, national frameworks and legislative arrangements to guide service delivery and improved outcomes. Likewise, in Germany, which is characterised historically by strong reliance on corporate actors in the operation of the health and social care systems, the 2004 healthcare reform introduced a range of measures that sought to enhance the quality of care and efficient coordination. This included the creation of the Federal Joint Committee which brought together, at national level, functions that had previously been dispersed across a range of organisations and groups at the various tiers of the system. More recently, the 2008 reform of long-term care introduced centrally developed quality standards that are binding on long-term care providers, alongside annual (unannounced) inspections, and a requirement to make inspection reports available.

Similar trends can be observed in the Netherlands. The Institute for Health Care Quality (het Kwaliteitsinstituut) was established in January 2013 and is mandated to steer, coordinate and guide all stakeholders involved in improving the quality of care. It has taken on a range of functions which, until recently, were performed by other institutions including indicator development, the publication of performance information, the measurement of patient experience, and the development of multidisciplinary guidelines for chronically ill patients. There is an expectation for the Institute for Health Care Quality to make a major contribution to improving the effectiveness of the current system by taking on a leading position and linking all stakeholders involved in quality of care assurance, control, and improvement. However, its mandate currently only covers the cure and care sector of the Dutch healthcare system; aligning cure, care, preventive care and social care remain a challenge.

In Finland, the organisation and delivery of health and social care is traditionally devolved to municipalities. However, concerns about health inequalities and variation in the availability and quality of services across the country have prompted a recent move to significantly decrease the number of municipalities, involving a restructuring of the present hospital district system into large municipalities and regional municipal federations, and tertiary care organisations with responsibilities in coordination, development and highly specialised care, thus signifying a move to greater centralisation to enhance care quality, among other goals.

Conversely, in the USA, the responsibility for regulating quality and standards of care is divided between the federal and state governments. The traditional focus has been on quality assurance, which aims to ensure facilities meet a minimum standard with regard to structural and organisational characteristics to deliver care. Through a series of state and federal laws, the different levels of government and private organisations combine to ensure the quality of care provided to patients. However, regulators have created a host of new tools centred on the dissemination of performance information (publicly and privately) and payment reforms. These mechanisms serve to regulate quality by directly or indirectly rewarding desired performance behaviour.

Public reporting on quality

As indicated in the preceding section, most countries under review are actively pursuing greater transparency through incentivising or mandating public reporting on provider performance. The only exception among the countries reviewed here is Finland, although the most recent reform of 2010 foresees greater coordination among providers to develop quality management and to ensure patient safety in cooperation with social services.

The (stated) main motivation for establishing quality information systems for patients is to support them in exercising their choice of provider in most systems reviewed here. Thus, it may reasonably be expected that countries where choice and competition of providers form a key element of the healthcare system have the strongest interest in developing such systems for patients. We have previously shown how the USA has a comparatively long tradition of providing this information and of developing quality information systems aimed at supporting user choice.⁵⁰ In the Netherlands, performance information for patients – and commissioners (health insurers) and regulators (government) – is expected to play a key role in further developing recently introduced market-based reforms. Legislation now requires all healthcare providers to report certain information about the quality of their services. For example, all hospitals have to publicly report their performance based on indicators for 43 conditions for hospital care. Similar efforts are made in the NHS in England. Conversely, in countries such as Germany where patient choice of provider forms a core component of the healthcare system, initiation of quality information systems has resulted, mainly, from major quality assurance initiatives at central level, such as the legal requirement, from 2003, for hospitals to publish quality reports every two years.

2.6 Summary

This chapter sought to provide a summary overview of the key observations on, approaches to, and mechanisms of, regulation to ensure adherence to care standards in five countries, with England included for comparison. In this final section we provide a summary of the information presented, followed by a discussion on the key observations made within these countries.

We have highlighted how the notion of overarching ‘essential standards of care’ is not commonly used explicitly in many system contexts.² Standard setting typically applies to particular health and social care settings (eg nursing homes, dentistry). In Germany and Australia, recent reforms have begun to examine standards across care boundaries, such as primary and secondary care, while cross-sectoral approaches that span the health and social

care sectors are not common. Conversely, in England, government standards of quality and safety apply to both health and social care sectors.

We find that all countries reviewed, or systems within these, employ elements of regulatory strategies such as self-regulation and voluntarism, meta-regulation, command and control, and market mechanisms. However, the relative balance between the use of these regulatory strategies and related regulatory mechanisms varies among countries, reflecting the health system, policy and institutional context within which systems sit. Variation is, in part, reflected in the content of standards in each country. Standards can thus be generally embedded within constitutional provisions (Finland) or national framework legislation (England, Germany, the Netherlands), or be developed as standards and frameworks for guiding, although not enforcing, service quality (Australia). In the USA, the traditional focus of regulation has been on quality assurance, which aims to ensure facilities meet a minimum standard with regard to structural and organisational characteristics to deliver care. Through a series of state and federal laws, the different levels of government and private organisations combine to ensure the quality of care provided to patients.

Finally, we note that this report has focused primarily on collecting information on existing regulatory mechanisms and actors responsible for ensuring the quality of care, rather than comparing levels of patient safety and incidents across the countries examined. In the absence of this information, and of published evidence that examines the effectiveness of existing systems, identifying best practice is not within the remit of this report. What we do provide, however, is a detailed account of the situation in each country, illustrated through case studies where available about how these regulatory mechanisms are implemented in practice.

3.1 **System overview**

3.1.1 **Organisation and financing of the health and social care systems**

In Australia's federal system of government, fiscal, functional and regulatory responsibilities are divided between the Australian (or Commonwealth) government, the six states (New South Wales, Victoria, Queensland, Western Australia, South Australia and Tasmania) and two territories (Australian Capital Territory, Northern Territory) that administer regional systems for health and social care. Health system financing mainly comes from general taxation, a small health tax levy and user co-payments. Financial incentives are offered to the public to take out voluntary private insurance (eg for private hospital care, dental care, physiotherapy). In Australia's mixed system, care is delivered by public and private providers. Public hospitals are funded jointly by the Australian Government and states/territories, while medical services (ambulatory care provided by general practitioners and specialists) are subsidised through the national health insurance scheme Medicare. Pharmaceuticals and drug purchase by private community-based pharmacies are subsidised through the Pharmaceutical Benefits Scheme (PBS).^{26 51 52 53}

Social care, that is direct welfare services, comes under the administrative remit of state/territory governments, except for aged residential care, immigration detention of asylum seekers and some indigenous welfare in the Northern Territory. Welfare services are provided by government departments although the majority is delivered by the voluntary sector. The Australian Government has played an increasing role in governing social care, mostly in the form of policy development and as purchaser of social care.

At the national level, the Minister for Health (plus assistant ministers and junior ministers) is responsible, among other matters, for Medicare, hospitals, private insurance, PBS, rural/regional health, mental health, indigenous health and other national health priorities.⁵⁴ Following the national election on 7 September 2013, the incoming coalition government, formed by the Liberal Party and National Party, has rearranged some ministerial portfolios and departmental titles and these new names are used in this report. The Department of Health (previously the Department of Health and Ageing, DoHA) provides policy advice for the government, manages programmes, sets national health policies, subsidises health services and fulfils portfolio outcomes in cooperation with adjunct portfolio agencies.

Regarding social care at the national level, there is a Minister for Social Services (plus assistant ministers and junior ministers). The Department of Social Services (previously the Department of Families, Housing, Community Services and Indigenous Affairs,

FaHCSIA) provides policy advice for the Government, sets national social care policies and manages a range of programmes and services delivered by the non-government sector. The portfolio also includes a number of statutory and non-statutory portfolio bodies (such as the Social Security Appeals Tribunal).

The eight states and territories each have a Minister for Health and a Minister for Family and Community Services/Human Services (or similar title). In some jurisdictions, separate ministers are responsible for disability services, housing and child protection.

3.1.2 Principles of healthcare governance

The 1901 Constitution, under which the states and territories agreed to federate, did not envisage health and welfare roles for the new national government. The only exceptions were pensions for old aged citizens and invalids (the type and scope of pensions and benefits has since greatly expanded). The administration of health and social care services (many of which were delivered by the private and 'church and charitable' sectors) remained the responsibility of the states. The Australian government has gradually extended its policy and funding roles, however, especially since the 1970s, mainly through financing mechanisms and intergovernmental agreements with the states/territories. While political swings determine the style of intergovernmental relations, the Australian government has steadily expanded its policy powers although the administration of health and social care services mainly remains with the states and territories.

The governance and funding of health and social care in Australia's federal system of government is a complex matter, as there are few agreed governance principles, the balance of power for each function involves considerable debate, with national intervention justified usually on grounds of national interest and social equity.⁵⁵ In recent years, however, several governance reforms have sought to clarify respective roles and responsibilities of the Australian government and the states and territories.

In 2011, the highest intergovernmental body in Australia, the Council of Australian Governments (COAG), signed the Intergovernmental Agreement (IGA) on Federal Financial Relations as a means to establish a mechanism for ongoing discussion and agreement on respective government roles and responsibilities and to enhance flexibility in the way services are delivered.⁵⁶ A series of National Partnership Agreements, linked to Specific Purpose Payments, for health, education, housing, disability, Indigenous reform and skills and workforce development were to guide the Commonwealth and states in the delivery of services across the relevant sectors. National Partnership payments fund specific projects and/or reward states that deliver on nationally significant reforms. The financial arrangements include incentive payments to reward performance. The independent COAG Reform Council is to monitor, assess and report publicly the performance of all governments in delivering on outcomes and performance benchmarks specified in each National Agreement.

3.1.3 Recent reforms of the health and social care systems

In previous decades the focus of reforms mainly related to funding and cost containment, levels of efficiency, equity and quality. For example, reforms in 2004/05 introduced changes in tax rebates for people over 65, as well as portability (transfer of cover) and consumer protection (premium stability) as a means to increase affordability of private health insurance. It also addressed Medicare funding provisions and rebates that

incentivised bulk-billing and introduced a Medicare Plus package to absorb increasing the out-of-pocket spending that affected disadvantaged people in particular.⁵²

In August 2011, the Council of Australian Governments (COAG), chaired by the Prime Minister, negotiated the National Health Reform Agreement for the funding and delivery of health, aged and disability care. This included a major reform of public hospital funding with the Commonwealth increasing its funding share to about 60 per cent through to 2019–20.⁵⁶ Activity-based funding using a ‘national efficient price’ (based on diagnosis related groups) forms the foundation for public hospital funding distribution from 1 July 2012. Small rural and regional hospitals will continue to be block funded as will teaching and training functions. The agreement further provided for new governance arrangements by establishing several new statutory national bodies. These included the National Health Funding Pool (NHFP) to ensure a consistent and transparent approach in the funding of public hospitals, statutory recognition for the Australian Commission on Safety and Quality in Health Care (ACSQHC) to lead and coordinate safety and quality improvements, the National Health Performance Authority (NHPA) as an independent Commonwealth statutory authority, and the Independent Hospital Pricing Authority (IHPA), which determines a national efficient price for services used in activity-based funding.

In an effort to enhance the system’s responsiveness to local needs, the reform also established a total of 137 Local Hospital Networks (LHNs), formed by small groups of public hospitals governed by their local management board to increase local accountability for budget management, service delivery and treatment outcomes, as well as Medicare Locals. These are primary healthcare organisations, each bringing together around 40–60 GP practices and other primary care providers as independent legal entities that are funded by the Commonwealth (61 by August 2013), to coordinate care in their region and act as the primary healthcare partners of Local Hospital Networks.

Additional reform efforts include an aged care reform package, commencing on 1 July 2012, which is part of a ten-year reform programme announced by the Australian government to better meet the social and economic challenges of the nation’s ageing population. It prioritises increasing support and care in the home, enhancing access to residential care, increasing support for those with dementia, and strengthening the aged care workforce.⁵⁷ The governance of the health professions was overhauled with new legislation in 2009 and 2010, establishing national boards (replacing the state/territory boards) and setting up an oversight body, the Australian Health Practitioner Regulation Agency. A joint-funded National Disability Insurance Scheme managed by the National Disability Insurance Agency (a statutory body set up under 2013 legislation) commenced in several states from 1 July 2013, designed to provide early intervention and help cover the costs for people with significant and permanent disabilities.

Similar reform efforts were seen in social care, traditionally the remit of state and territory governments, but with the Commonwealth increasingly taking a leading role in developing standards, national frameworks and legislative arrangements to guide service delivery and improved outcomes, and involving mental health, Indigenous welfare, child care and child protection. For example, the National Mental Health Reform established a National Mental Health Commission from 1 January 2012 (from September 2013 reporting to the

Minister for Health) which reports, advises and collaborates across sectors, and also produces an annual Mental Health Report Card to ensure delivery of reforms, as well as greater transparency and accountability in mental health services.⁵⁸ Part of the ten year roadmap for national mental health reforms of the Australian Government, the commission will focus on five priority areas, including, among other things, improving quality, accountability and innovation in mental health services.

3.2 National framework for care quality

Australia does not have standards for health and social care enshrined in its constitution or in a national bill of rights; although general principles are set out in legislation. Australia has been slow to adopt a legislative strategy to regulate essential standards of care or to codify such standards, but instead has relied on intergovernmental and administrative frameworks, funding incentives of joint programmes, and on self-regulation of performance by health professions and the health industry. However, healthcare performance measures have been defined and strengthened from the 2000s onwards with legislation and intergovernmental agreements in various areas that impact on the safety and quality of services.²⁵

3.2.1 Sources of minimum standards of quality in the health and social care systems

National standards for healthcare in Australia, and for aspects of social care, are usually developed through consultative and administrative strategies rather than legislative strategies, with adherence generally sought through financial incentives rather than 'command and control' enforcement sanctions. National standards are more likely to be developed in areas where the funding role of the Australian government enables it to exert various forms of authority.²⁵

The development of national standards is increasingly advocated, accompanied by varying propositions for strategies to promote adherence. In practice, however, many of these standards are aspirational and developmental rather than mandatory. State and territory governments develop standards in their jurisdictions, and industry and professional associations also set standards or 'codes of practice' although implementation is usually voluntary. Numerous frameworks, standards (minimal and optimal), guidelines, codes and protocols have been issued in the health and social care sectors. For example, the National Health and Medical Research Council and the professional associations produce a multitude of public health and clinical guidelines. What remains often unclear, however, are the lines of accountability. Funding bodies can and do de-fund services for inadequate administration and financial management within an organisation, but poor quality outcomes are less likely to attract sanctions than financial misconduct. Funding bodies proceed on the assumption that adherence to good practice principles, and standards where these have been defined, will be voluntarily and progressively adhered to by service providers.

Healthcare

National Safety and Quality Health Service (NSQHS) Standards

The National Safety and Quality Health Service (NSQHS) Standards were proposed by the Australian Commission on Safety and Quality in Health Care (ACSQHC) following

extensive consultation and endorsed by Australian Health Ministers (Commonwealth and states/territories ministers) in September 2011. Forming a mandatory component of the national accreditation scheme endorsed by the Australian Health Ministers in 2010, the national standards represent an important shift towards a national regulatory framework. The national accreditation scheme is based on an intergovernmental agreement and consultations with a range of stakeholders including the private sector. The states/territories can decide how the NSQHS will be implemented in their jurisdiction including selecting an accreditation agency for their services.⁵⁹ In essence, from June 2013, all clinical health services (public and private) are expected to comply with these national standards, which represent 'essential standards of care' that can be used for internal quality assurance or external accreditation:

The Standards provide a nationally consistent and uniform set of measures of safety and quality for application across a wide variety of healthcare services. [...] They provide a quality assurance mechanism that tests whether relevant systems are in place to ensure minimum standards of safety and quality are met, and a quality improvement mechanism that allows health services to realise aspirational or developmental goals. [...] The Standards are integral to the accreditation process as they determine how and against what an organisation's performance will be assessed. The Standards have been designed for use by all health services.⁵⁹

The standards address ten areas, mostly around patient safety, with a view to establishing procedures to reduce the incidence of adverse events:

- Governance for safety and quality in health service organisations
- Partnering with consumers
- Preventing and controlling healthcare associated infections
- Medication safety
- Patient identification and procedure matching
- Clinical handover
- Blood and blood products
- Preventing and managing pressure injuries
- Recognising and responding to clinical deterioration in acute healthcare
- Preventing falls and harm from falls.

Health Performance and Accountability Framework

The 2011 National Health Reform Agreement provides for a Performance and Accountability Framework containing 48 indicators for safety and quality, access and efficiency, and financial performance of health services. The framework forms the basis for the National Health Performance Authority (NPHA), which will report on the performance of health services in line with the framework (see below).⁶⁰ The agreement calls for the states/territories to monitor and report to the NPHA on the performance of their public sector health services. While the states/territories previously reported on financial and activity indicators, these typically did not cover data on hospital quality. The framework thus represents a public reporting regulatory strategy to enhance the overall transparency and accountability of health services through informing purchasers, exerting reputational peer pressure on providers, and enabling informed consumer choice.

Aged care: Quality of care principles

The Australian government has a long history of funding care homes for the aged (government, voluntary and private sector) dating back to the 1950s. As the main funder, it can exert considerable authority in regulating residential and community-based aged care. The Aged Care Act 1997 regulates among others funding and accreditation of residential care, community care and flexible care services, with approved providers under the act eligible to receive subsidy payments. The Quality of Care Principles 1997 are one of the sets of principles established under the act, with the more recent Quality of Care Amendment Principles 2011 (No. 1) seeking to establish coherent standards across community care programmes to support dependent older and disabled people in their own homes.⁶¹ Following the 2011 National Health Reform Agreement, the Australian Government now fully funds a government programme, Home and Community Care, which subsidises services to support people in their own homes (with agreement not so far reached in Victoria and Western Australia).

Social care*National Mental Health Service Standards 2010*

The 2010 National Standards for Mental Health Services, endorsed by the Australian Health Ministers Conference, represent a revision of standards first published in 1996. The Standards are meant to be implemented within a diverse range of mental health services, including public, private and non-governmental organisations, and where mental healthcare is delivered in community-based mental health services and primary care. The standards mark a significant shift in mental health policy and implementation is expected to be incremental, however, with no mandatory requirements for adherence and, so far, no sanctions attached. The 10 standards focus on services delivery, alignment with policy directions, adherence to expected standards of communication and consent, and procedures and practices in place to reduce any risk to service users.⁶²

There also are National Palliative Care Standards, National Disability Standards, Home and Community Care (HACC) National Service Standards, National Community Housing Standards, and standards set by various accreditation bodies.

National Quality Framework for Early Childhood Education and Care

The Child Care Act 1972 established the Australian Government as the funder of day care for pre-school children (crèche or nursery care). These services have greatly expanded since then to long day care, family day care, preschool (or kindergarten) and outside schools hours care. While the Australian Government has regulatory powers as a major funder of childcare, it is not constitutionally responsible for child protection, that is child and family welfare services, which are the responsibility of the states and territories.

It is within this context that the 2009 National Quality Framework for Early Childhood Education and Care has to be seen. The framework, agreed by all governments, established a national authority, the Australian Children's Education and Care Quality Authority (ACECQA), and a regulatory authority in each state/territory for approving, monitoring and quality assessment of early childhood education and care and to oversee the implementation of the framework.⁶³ The framework includes national legislation (Education and Care Services National Law Act 2010 and Education and Care Services National Regulations) and a National Quality Standard with seven quality areas:

educational programme and practice, children's health and safety, physical environment, staffing arrangements, relationships with children, collaborative partnerships with families and communities and leadership and service management.

Furthermore, Standards for the Care of Children and Adolescents in Health Services were developed under the auspices of the Royal Australasian College of Physicians (RACP) and were endorsed by several other professional and industry associations. These standards were developed using the Evaluation and Quality Improvement Program (EQUIP) of the Australian Council on Health Care Standards (ACHS), a non-profit accreditation organisation.⁶⁴

National Framework for Protecting Australia's Children

The National Framework for Protecting Australia's Children (the Framework), adopted by Commonwealth and state/territory governments and non-government organisations in 2009, presented the first long-term national approach to address the safety and well-being of Australian children, with a view to reducing child abuse and neglect. Priority actions include: National Standards for Out-of-Home Care; improved support for young people leaving care; the integration of services in disadvantaged communities; and improved access to early intervention and prevention services, including quality child care for children at risk. Now under the aegis of the Department of Social Services, there will be a report delivered annually to COAG on the progress of the first three-year action plan.⁶⁵

National Standards for Out-of-Home Care for children

The National Standards for Out-of-Home Care (from 1 July 2011) aim to improve the quality of care provided to children and young people in out-of-home care, that is children in residential homes or foster care. The 13 national standards (with 22 to be introduced by 2015) focus on the key factors regarded as directly influencing outcomes for those living in out-of-home care. The Australian government has committed to funding a national annual survey of children and young people in out-of-home care, to capture progress against key areas of the standards.⁶⁶

3.2.2 Overview of main bodies responsible for standard setting and enforcement

Australia operates only a small number of external or arms-length bodies with the capacity to enforce quality standards in health and social care. For example, Australia lacks an external regulatory authority, such as a hospitals inspectorate, with powers of review and enforcement. Regulatory actors often are internal rather than external to a service area, external bodies such as ombudsmen or coroners recommend enforcement action to health or human service departments or other disciplinary bodies. Regulatory mechanisms tend to focus on co-regulation, self-regulation by industry and professional associations, market mechanisms (financial incentives), and voluntary adoption of 'codes of practice' and 'frameworks'. In the healthcare and aged care sectors, the main regulatory bodies are agencies that accredit service providers against a set of criteria, and that can apply regulatory support and sanctions ranging from advice to revocation of accreditation (see later sections). Table 3.1 provides a summary overview of the main bodies responsible, at national level, for standard setting and enforcement in the health and social care sectors in Australia. These are described in further detail below.

Table 3.1 Summary overview of main government bodies at the national level responsible for standard setting and enforcement in the health and social care sectors in Australia

Agency or body	Main roles and functions
Australian Commission on Safety and Quality in Health Care (ACSQHC)	Non-statutory body that leads and coordinates national improvements in safety and quality in healthcare. Provides mainly advice, publications and resources for healthcare professionals, organisations and policymakers. ^{51 52}
National Health Performance Authority (NPHA)	Monitors trends in local health system performance with a focus on longitudinal performance and improvement of local hospital networks and Medicare Locals. Work plan is based on the National Health Reform Agreement (NHRA). ⁶⁷
Professional Services Review Agency (PSR)	Ensures appropriateness and cost-effectiveness of clinical services delivered through Medicare Benefits Schedule (MBS) and the Pharmaceutical Benefits Scheme (PBS) by providing a legislative framework for peer review of practitioners on request of Medicare. ⁶⁸
Age Care Standards and Accreditation Agency Ltd. and Aged Care Complaints Investigation Scheme and Aged Care Commissioner	Independent body responsible for accrediting residential care services, in conjunction with the federal Department of Health and Ageing. Carries out the statutory functions as set out in the Aged Care Act. The Aged Care Commissioner is a statutory appointment independent from both the Department of Health and Ageing and the Aged Care Standards and Accreditation Agency.
Australian Health Practitioner Regulation Agency (AHPRA)	Oversees health practitioner national registration boards.
<i>Priority setting and advisory bodies</i>	<i>Priorities are set in the Australian Health Ministers' Conference deciding on national priorities; a variety of national bodies and forums (such as the Council of Australian Governments, Australian Health Ministers' Conference) were established to inform decisionmaking on priorities.⁵¹</i>

3.3 National regulatory bodies

3.3.1 Australian Commission on Safety and Quality in Health Care (ACSQHC)

Legal status and organisational structure

The Australian Commission on Safety and Quality in Health Care (ACSQHC) is an independent body established in 2006 by the Commonwealth and state/territory governments; it was made a statutory body in 2011 as per National Health Reform Act 2011 (NHR Act). It continues the work of the earlier Australian Council for Safety and Quality in Health Care set up in 2000.

The ACSQHC is governed by a board, is headed by a Chief Executive Officer, and has several committees to ensure a wide range of representation, for example: the Private Hospital Sector Committee (nominees from key private healthcare bodies); Primary Care Committee (primary care advice and liaison with the primary care sector), and the Inter-Jurisdictional Committee (senior managers from the Commonwealth Department of Health and Ageing, and state/territory Departments of Health).²² The Commission reports to the Standing Council on Health under the Council of Australian Governments and the Inter-Jurisdictional Committee forms a key mechanism for implementing programmes agreed by the health ministers.⁶⁹

Scope of action

The ACSQHC leads and coordinates the development of safety and quality good practice and standards in collaboration with providers, professionals and national and state-level health departments. It promotes and supports the implementation of safety and quality

arrangements, programmes and initiatives such as clinical quality registries. The functions of the ACSQHC include the collection, analysis and dissemination of information; formulation and support for the implementation of standards (eg open disclosure, peer review, credentialing for health professionals, health information); the development of guidelines and indicators including practice-level indicators of safety and quality for primary healthcare; and the publication of reports on solutions and progress. Model national schemes developed by the commission include schemes for healthcare provider accreditation.

Examples of programmes for the implementation of standards include the National Open Disclosure Standard, which was trialled in several hospitals.⁷⁰ It calls for staff to disclose to patients when an adverse event or medical injury has occurred, to express regret, give an explanation and discuss how a recurrence will be prevented. Health service organisations now are required to implement open disclosure as part of the 2011 National Safety and Quality Health Service Standards (Standard 1: Governance for Safety and Quality in Healthcare Organisations). While the states/territories have not enacted legislation that mandates open disclosure, civil liability legislation provides some protection against an apology being regarded in court as an admission of liability. The accountability principle is that patients have a right to know when they have been harmed, but providers still worry about being sued, and require better training in how best to disclose a medical injury to patients and their families.⁷¹

Credentialing by health service organisations is used to verify the qualifications or experience of clinicians in their respective healthcare setting and as part of a wider organisational quality and risk-management system. A Standard for Credentialing and Defining the Scope of Clinical Practice in public and private hospitals has been implemented across jurisdictions although implementation varies across states/territories and healthcare settings.⁷²

Regulatory mechanisms to ensure standard adherence

The ACSQHC does not enforce standards and does not have the legal power to directly monitor health providers through inspections or other enforcement mechanisms including sanctions.²⁵ It relies on persuasion, networked governance through other actors, endorsement from the health ministers and implementation through health departments.

The last of these is exemplified by the Australian Health Service Safety and Quality Accreditation Scheme. The scheme supports the implementation of the 2011 National Safety and Quality Health Service (NSQHS) Standards, proposed by the ACSQHC and endorsed by the health ministers, whereby state and territory health departments regulate the service provider agencies and the accreditation scheme in their jurisdictions. Providers may select an approved accrediting agency which will assess adherence to the standards and other accreditation criteria. The ASQHC national coordination programme is responsible for developing and maintaining the standards, for advising health ministers on the scope of accreditation, the approval of accrediting agencies, improving the standards and accreditation system, and the annual reporting on health and safety to health ministers.⁷³ Providers that do not meet mandatory standards will be dealt with by the accreditation agency through for example imposing conditions to be implemented to ensure adherence or revoking accreditation, and the state/territory health departments.

3.3.2 National Health Performance Authority (NHPA)

Legal status and organisational structure

The National Health Performance Authority (NHPA) was established as a statutory authority under the 2011 National Health Reform Amendment (National Health Performance Authority) Act 2011 as part of the 2011 National Health Reform Agreement.²³ The NHPA objective is to improve the performance of health services, and in particular public hospitals, through a monitoring and reporting strategy under the Performance and Accountability Framework.⁶⁷

Members of the NHPA include a chair, a deputy chair and five other members, with each of the seven appointed by the Commonwealth health minister. The deputy chair is appointed with the agreement of the premiers of states/ territories and the other members are appointed with the agreement of the prime minister and premiers of states/territories. The CEO is appointed by the NHPA board in consultation with the health minister.⁷⁴ The Commonwealth health minister may (by legislative instrument) give directions to the NHPA concerning the performance of its functions and the exercise of its powers.

Scope of action

NHPA was established to improve locally relevant and nationally consistent information and thereby promote quality and inform user choice. It assesses equity, effectiveness and efficiency of services and reports on the performance of all local hospital networks, public/private hospitals and primary healthcare organisations.⁷⁵

The 2011 National Health Reform Agreement provides for the creation of the Performance and Accountability Framework encompassing measures of safety and quality, access and efficiency, and financial performance. As noted earlier, the framework includes 48 (interim) indicators: 31 indicators for healthy communities and 17 indicators for hospital performance. The NHPA's strategic work plan is based on the framework.⁶⁰

Regulatory mechanisms to ensure standard adherence

The NHPA does not enforce standards but rather reports to governments who decide on the action to be taken, while public reports are expected to exert reputational pressure and to facilitate consumer choice. The NHPA monitors trends in local health system performance with a focus on longitudinal performance and improvement of local hospital networks (LHNs) and Medicare Locals. This includes comparative analysis of data across sectors and jurisdictions to identify best practices. Reporting obligations include hospital performance reports (public and private hospital, LHNs) based on the Performance and Accountability Framework for which data are already available, and healthy communities reports on Medicare Locals including on healthcare services and health outcomes in local areas and regions, involving data on demography and health status. Standards for the healthy communities report will be drawn, among others, from national service and financial performance standards or targets as agreed by the COAG and the ACSQHC. Furthermore, the NHPA aims to identify high-performing organisations and facilitate best practice dissemination and report poorly performing organisations to the national level, states and territories.⁶⁷ The intention is that some data will be added to the publicly accessible MyHospitals website at <http://www.myhospitals.gov.au/>, which currently publishes some limited information on named hospitals only (eg types of services, waiting times for elective surgery).

3.3.3 Medicare and the Professional Services Review Agency

Legal status and organisational structure

Medicare Australia (formerly the Health Insurance Commission) administers the national health insurance scheme that offers fee rebates to patients for GP and specialist consultations, under the Medicare Benefits Schedule (MBS). It also administers subsidies for purchases of approved pharmaceuticals, under the Pharmaceutical Benefits Scheme (PBS). Medicare monitors service use through statistical interrogation of its database, including indications of over-servicing which could be regarded as a poor quality service, and through a form of peer review. Medicare Australia applies a range of regulatory mechanisms ranging from education of and advice to practitioners to prosecution.

The Professional Services Review Agency (PSR), a small Commonwealth agency under the health portfolio, was set up to investigate 'inappropriate practice', principally allegations of over-servicing under a legislative framework for peer review of practitioners on request of Medicare.⁷⁶ The PSR Scheme is managed by the director, an independent statutory officer appointed by the minister for health under the 1973 Health Insurance Act (appointment is subject to agreement by the Australian Medical Association, AMA). The PSR Panel is comprised of medical and other healthcare practitioners who also form the peer review committees. If a matter requires peer review through a committee, the director will select two panel members and one deputy director to form a committee. The Determining Authority (final decisionmaking body) consists of a permanent chair, a permanent layperson representing the community's interest and a representative of the profession of the practitioner under review. All members of the PSR Panel, the chair and the members of the Determining Authority are appointed by the minister for health after consultation with the AMA and professional bodies. The Executive and Management Committee (director, the executive officer and unit managers) advises the director on planning, budgeting, financial management, performance monitoring and corporate governance. Case officers and support staff coordinate matters and oversee the administration of the process throughout the three stages of the PSR scheme.^{76 77}

Regulatory mechanisms to ensure standard adherence

The PSR process entails three stages. At stage one, the director decides whether inappropriate practice may have occurred in a case referred from Medicare, if the case should be reviewed, if there appears no case to answer, or if the director can enter an agreement with a practitioner acknowledging inappropriate practice. At stage two the Committee of Peers (Committee for the peer review process) reviews the practitioner's Medicare Benefits Schedule and Pharmaceutical Benefits Scheme claims, holds a hearing and decides whether inappropriate practice has occurred. If a conclusion is reached that an inappropriate practice has occurred, findings must be provided to the Determining Authority. At stage three, the Determining Authority will decide on suitable sanctions which may include repayment of monies, a disqualification period, counselling or reprimand, 'naming and shaming' in a public report, or prosecution.⁷⁸ Litigious doctors and lawyers' fees make the PSR an expensive regulatory mechanism though only a small proportion of cases proceed to prosecution.⁷⁹

3.3.4 Australian Children's Education and Care Quality Authority (ACECQA)

Legal status and organisational structure

The Australian Children's Education and Care Quality Authority (ACECQA) is a national body established under the 2010 Education and Care Services National Law with oversight functions on quality early childhood education and care. It monitors and promotes the consistent application of the law and the National Quality Standard (Framework) across states/territories by supporting the work of state and territory regulatory authorities.⁸⁰

Scope of action

As described earlier, the 2009 National Quality Framework for Early Childhood Education and Care (NQF) comprises a national legislative framework, a National Quality Standard, and an assessment and rating system. It applies to long day care, family day care, outside school hours care and preschools.⁸¹ States and territories retain responsibility for licensing and quality assessment of child care services through the establishment of a dedicated regulatory authority, while the ACECQA has system oversight functions on the consistent implementation of the NQF.⁸² The ACECQA thus advises and the states/territories enforce through licensing procedures.

Regulatory mechanisms to ensure standard adherence

The ACECQA is responsible for providing information, standard setting, and training through, for example, promoting quality improvement by approved providers and maintaining national registers of approved providers and certified supervisors; educating and informing about the NQF, publishing guidelines and resources for improved understanding of service quality; determining the qualifications for regulatory authorities' staff and providing training.⁸²

Children's education and care services are to be rated under the Education and Care Services National Law using the National Quality Standard and to be conducted by state and territory regulatory authorities. Outcomes are to be published on the ACECQA website. The rating system is based on five levels of ratings applied across seven quality areas. A service agency can apply to the ACECQA for an external review of ratings in case the respective regulatory authority did not conduct the assessment appropriately or failed to take into account special circumstances or other facts.⁸³

3.4 National departments and offices

3.4.1 Department of Health

The Department of Health (previously the Department of Health and Ageing) has a diverse set of responsibilities with its main purpose to pursue 'better health and active ageing for all Australians'. The department formulates policy and funds the states/territories and the voluntary and private sectors to deliver programmes. As a higher level agency, it plays an important role, usually in partnership with other stakeholders, in developing guidelines and standards for services, promoting quality (good practice), and monitoring whether these guidelines and standards are implemented and achieved. The department exerts influence through its capacity to approve or not approve agencies to deliver programmes and through the use of financial incentives and disincentives.

The policy areas covered by the department include public health and health protection, health promotion and disease prevention, primary healthcare, hospital funding and policy, implementation of the National Health and Hospitals Network, Aboriginal and Torres Strait Islander health programmes and policies, health research, pharmaceutical benefits, health benefits schemes and others specific services including mental health policy and primary mental healthcare.⁸⁴ Following the September 2013 national election, responsibility for ageing is to move to the Department of Social Services. The Therapeutic Goods Administration, within the Department of Health, is responsible for regulating therapeutic goods including medicines, medical devices, blood and blood products.

Other national-level bodies also contribute broadly to the formulation and regulation of quality standards. The Australian Institute of Health and Welfare, an independent statutory authority, provides regular information and statistics on the health and welfare of Australia's population, including data on health expenditure and service provision. The National Health Transition Authority (NEHTA), funded jointly by the Australian Government and the states/territories, leads the uptake of eHealth systems of national significance and delivers urgently needed integration infrastructure and standards.⁸⁵

3.5 **State/territory-level regulatory bodies in health and social care**

Each of the eight states and territories operates a health department and a human services department (or department with a similar label). The departments deliver services directly, but increasingly devolve or purchase services from other agencies. In their capacity as policymakers and purchasers they are engaged in developing, implementing and enforcing guidelines and standards. Health, welfare and education activities account for the great majority of state/territory budgets.

Health complaints commissioners (health ombudsmen) were appointed in each of the states/territories from the 1980s (in addition to the existing parliamentary ombudsmen) to respond to complaints by patients about healthcare services. Their function is to resolve complaints mainly through alternative dispute resolution processes such as conciliation, to ensure accountability to the public from health providers, and to act as 'public watchdogs' in identifying and recommending improvements to health systems. The healthcare complaints commissioners work closely with the professional boards in cross-referring complaints as appropriate. The Queensland commissioner has the additional function of setting and monitoring standards in government health services, while the New South Wales commissioner has the power to directly prosecute where there is a malpractice case to answer.

Auditors in each state/territory are independent statutory officers responsible for auditing the finances of their public sector agencies and their public administration and performance. Auditors therefore play an integrity and accountability role and may table reports in parliament that review the performance of state/territory agencies, such as sub-standard procedures and performance in hospital emergency departments or child protection programmes. Auditors may therefore play an important role in identifying poor quality government services.

Coroners are appointed in each of the states/territories as statutory and independent officers who investigate ‘reportable’ deaths, that is deaths that are suspicious or of unknown cause. They fulfil a regulatory function in healthcare systems in that coronial investigations or inquiries may identify unsafe practices and recommend improvements.

3.6 **Quasi-governmental and other actors**

3.6.1 **Australian Health Practitioner Regulation Agency (AHPRA)**

Legal status and organisational structure

The governance of health professions in Australia was traditionally carried out by state-based boards that differed somewhat in their legislative frameworks, registration requirements, structures and procedures. This arrangement hindered professional mobility but also allowed practitioners who were refused registration in one state to apply for registration in another state instead. Following a critical review by the Productivity Commission in 2005, which drew attention to a lack of transparency and accountability on disciplinary matters, the system of professional registration was modified with the establishment of national boards and independent disciplinary procedures on serious malpractice matters.

Formed under the Health Practitioner Regulation (Administrative Arrangements) National Law 2008, 3.6.1, the Australian Health Practitioner Regulation Agency (AHPRA) is responsible for the implementation of the National Registration and Accreditation Scheme for health professionals (and students).⁸⁶ An Agency Management Committee oversees its affairs, functions and policies. The agency is headed by a CEO who is in charge of three directors and a general counsel. AHPRA operates an office in each state and territory with a national office in Melbourne and around 600 core full-time and part-time staff in total.

Scope of action

The National Registration and Accreditation Scheme (National Scheme) was introduced in 2010 as a single national system to cover (currently) 14 health professions under a single Health Practitioner Regulation National Law (2009), which is in force in each state and territory to protect the public and facilitate access to health services. The National Scheme was established through a national ‘applied laws’ model of concurrent legislation as governance of the professions is not a constitutional responsibility of the Commonwealth.⁸⁷

AHPRA supports 14 National Health Practitioner Boards that are primarily responsible for setting standards and policies that all registered health practitioners must meet. Among other tasks, such as supporting the boards in the development of registration standards, codes and guidelines, AHPRA manages, on behalf of the National Boards, investigations into professional conduct, and the performance or health of registered health practitioners. Patients can complain about registered health practitioners to AHPRA offices or to the Health Complaints Commissions in each state/territory. AHPRA works with the Health Complaints Commissions to ensure the appropriate organisation investigates concerns about registered health practitioners. Another reform under the National Law is to shift serious malpractice allegations away from the boards to panels or tribunals within state-level independent Civil and Administrative Tribunals.

Regulatory mechanisms to ensure standard adherence

National Health Practitioner Board members and the AHPRA's Management Committee are appointed by the Australian Health Workforce Ministerial Council, which comprises of health ministers of the states/territories and Commonwealth. The major regulatory functions of the National Health Practitioner Boards include responsibility for registering health practitioners, investigating and managing notifications about performance, conduct or health of practitioners and for the development of standards, codes and guidelines. The latter may be recommended for approval by Accreditation Authorities; these are appointed by the Ministerial Council for three years to carry out accreditation functions for the health professions under the National Scheme.⁸⁷ AHPRA administers the National Scheme and provides operational/administrative support to the National Health Practitioner Boards and acts on their behalf.

3.6.2 Age Care Standards and Accreditation Agency Ltd. (ACSAA)

Legal status and organisational structure

The Aged Care Standards and Accreditation Agency Ltd (ACSAA), established in 1998 to accredit residential care homes and promote high quality care, carries out statutory functions under the Aged Care Act 1997. A government company, it is subject to the Commonwealth Authorities and Companies Act 1997,⁸⁸ which describes the role of ACSAA as a corporate body. The company is directed by a Board of Directors and a CEO and structured into several departments: corporate affairs and human resources; information services and technology; finance, education, accreditation and operations (including accreditation activity, education delivery, and case management).

Scope of action

The Accreditation Standards are detailed in the Quality of Care Principles 1997 and other aged care legislation related to the accreditation process.⁸⁹ ACSAA's functions include accreditation, re-accreditation visits, review audits (on site assessment, reports, desk audits), and unannounced visits. Where ACSAA finds evidence of serious risk to the health, safety or wellbeing of residents in residential care services it must inform the Department of Health, which can then decide to impose sanctions. ACSAA also monitors the progress of improvements until the risks are removed.⁹⁰ ACSAA thus inspects and recommends while the government department enforces sanctions on sub-standard care.

Regulatory mechanisms to ensure standard adherence

Figure 3.1 provides an overview of the accreditation process performed by the ACSAA. The process commences with a self-assessment by the provider against the Accreditation Standards, followed by an application for (re-)accreditation and an assessment by a team of quality assessors at a site audit. This includes reviews of procedures, records and other documents (such as staff rosters, incident reports, care plans, complaints registers), observing procedures and feedback of residents on satisfaction with services provided. Decisions may include (re-)accreditation or not, or revocation of the home's accreditation. In the case of successful accreditation a certificate will be issued and the decision made public on the ACSAA website. Unannounced visits will follow to monitor 'on-going performance'.⁹¹

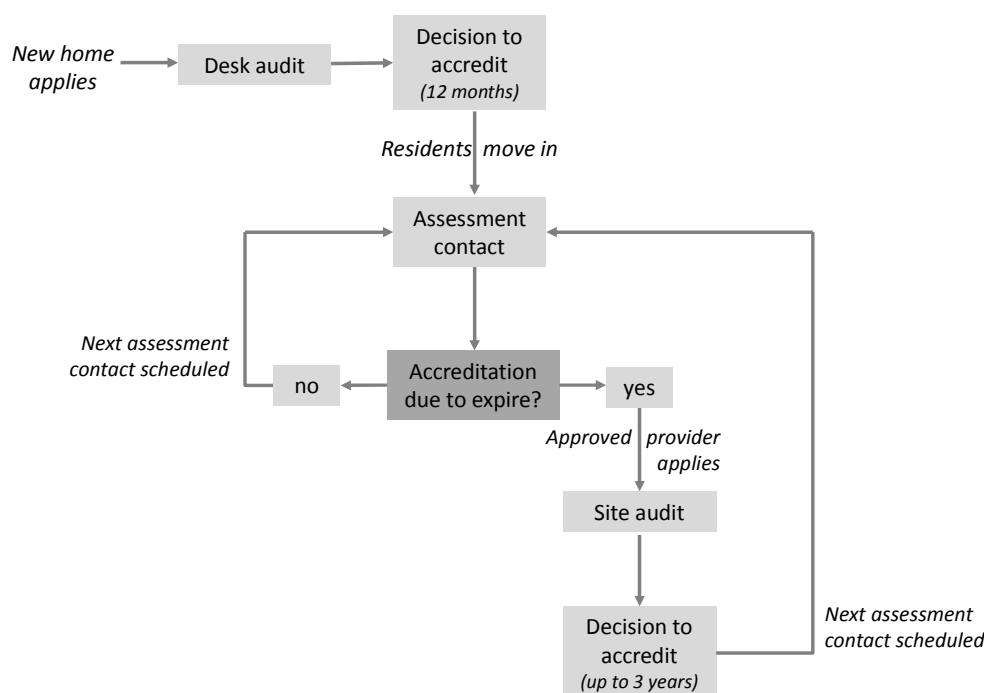


Figure 3.1 Overview of the accreditation cycle performed by ACSAA

SOURCE: Adapted from Aged Care Standards and Accreditation Agency Ltd (2011).⁹²

At any point of the process (assessment contact, site audit or review audit) ACSAA assessors may determine that a residential aged care home fails to meet the standards or establish evidence of serious risk to health, safety and wellbeing of residents. In such cases, a timetable for improvement will be established which sets out the maximum time allowed for the home to meet the expected outcomes and progress towards these outcomes will be monitored. If the provider fails to deliver in the given timeframe, the ACSAA can conduct a review audit and may vary or revoke the home's accreditation. Furthermore the government may decide to impose sanctions.⁹³ Sanctions imposed vary and depend on the circumstances of non-adherence to standards.⁹⁴

3.6.3 Australian Council on Healthcare Standards (ACHS)

The Australian Council on Healthcare Standards (ACHS), established in 1974 as an independent and non-profit organisation, is the largest accreditation provider in Australia for hospitals and also accredits some community health services (over 1,450 organisations by the end of 2012).⁹⁵ The council comprises over 30 representatives from national and state health agencies, professional associations, and industry groups, and the ACHS's revenue stems largely from member fees. Over half its surveyors are volunteers whose time is underwritten by their employers as ACHS members. Because of its membership, the ACHS has been referred to as an 'industry friendly' accreditor.³² The ACHS sets standards, the Evaluation and Quality Improvement Program (EQuIP), and assesses health facilities against these standards. Over the past several years, virtually all hospitals in Australia have sought some form of accreditation. From 1 January 2013, accreditation incorporating the ACSQHC national standards became, in effect, mandatory for all health service

organisations under the Australian Government national accreditation scheme (whether through the ACHS or another accreditation provider).

The ACHS stresses that the two conditions for ‘best practice’ accreditation are an explicit definition of quality (ie standards) and an independent review process aimed at identifying the level of congruence between practices and quality standards.³⁸ It undertakes an accreditation procedure (similar to that conducted by ACSAA for care homes) while placing higher emphasis on the developmental and educative nature performed by its mainly peer surveyors, highlighting the promotion of continuous quality improvement rather than performing an inspection procedure against a checklist of minimum standards. The ACHS includes some mandatory standards and also incorporates the 10 National Safety and Quality Health Service Standards endorsed by the health ministers in 2011. In 2009–10, of 509 organisations surveyed, 19 (4 per cent) were granted conditional accreditation only while the majority (435 organisations or 86 per cent) were granted full or continuing accreditation.³⁸ No information on accreditation results is given in recent annual reports.

The ACHS international arm accredits hospitals in several other countries including Hong Kong, Korea and in the Middle East. The ACHS publishes a list of its members and their accreditation status. As part of its public disclosure initiative, organisations must provide an Agreed Performance Statement (although not the full accreditation report), to be placed on the ACHS website, which includes reference to any outstanding achievement rating/s, or high priority recommendation rating/s, that is, standards have not been met. It does not provide a separate list of sub-standard facilities where high priority improvements (such as the procedure in place for care homes) must be made.

3.7 Case study

Bundaberg Base Hospital, Queensland

The lengthy and complex Bundaberg Base Hospital scandal began with a surgeon, Dr Jayant Patel, whose malpractice was brought to light by a nurse ‘whistleblower’, Toni Hoffman, an experienced intensive care nurse at the Bundaberg Hospital.^{25 96} After her repeated complaints about unsafe practice by Dr Patel were ignored by hospital managers and the health department district manager, she went to see a politician who tabled her letter in the Queensland Parliament in March 2005. A journalist then searched online for Dr Patel’s background in the United States and found that his practice had been restricted in Oregon, and that he had surrendered his licence in New York State in the face of pending disciplinary proceedings. Dr Patel had been located through a private recruiting firm and the Queensland Medical Board approved his application for registration. He was appointed in 2003 as staff surgical officer at a district hospital in Queensland, the Bundaberg Base Hospital, and was quickly promoted to Director of Surgery despite his lack of specialist surgical qualifications.

Reviews and public inquiries

The Queensland health department responded by setting up a clinical review by three surgeons who examined the large number of cases that Dr Patel had operated on in his two years at the hospital. Their damning conclusion, in their later evidence to the Commission

of Inquiry, was that Dr Patel had contributed to the deaths of 13 patients, that his care had been unacceptable in four deaths, and that he had contributed, or probably contributed, to adverse outcomes for 31 surviving patients. The reviewers commented that Dr Patel's skills and standard of care were seriously sub-standard, that he had not been supervised, and that the small size of the hospital meant that he had no peers who could assess his skills and competence.

After a month of adverse media coverage, the Queensland government in April 2005 set up a Commission of Inquiry headed by Anthony Morris QC. However, the Queensland Supreme Court restrained the Commissioner from proceeding with the Inquiry in September 2005 on grounds of 'a reasonable apprehension of bias' given the Commissioner's vigorous questioning of hospital and health department managers. The ex-Commissioner then used parliamentary privilege to deliver a scathing report on Queensland's health sector.

A retired appeals court judge was then appointed to head a new public inquiry with its scope broadened beyond Bundaberg to five other Queensland hospitals where the credentials of doctors were questionable. Dr Patel and Bundaberg, however, were the focus of much of the report and the ensuing publicity. The Davies Report (2005) found that in Dr Patel's two years at the Bundaberg Hospital, staff or patients made 22 complaints about him, which were ignored by hospital and health department managers.⁹⁷ The commissioner identified four factors that had contributed to Dr Patel's 'sustained path of injury and death at the hospital': the hospital budget (hospital managers wanted to meet an elective surgery target and so secure maximum funds and thus Dr Patel was a valuable asset); failure of the medical board and the health department to check his credentials; failure to assess his skills and competence; and lack of an adequate complaints system.

The final report criticised the health minister, the Queensland Medical Board, hospital managers and health department administrators and identified five common causes for problems at Bundaberg and the five other hospitals:

- (i) an inadequate budget that lacked financial incentives for quality and safety
- (ii) a defective administration of 'area of need' registration of doctors
- (iii) absence of any method to assess the competence of doctors
- (iv) no adequate monitoring of performance or investigation of complaints
- (v) a 'culture of concealment' by government, Queensland health administrators and hospital administrators.

The Commissioner referred Dr Patel to the Queensland police under the Criminal Code in relation to fraud, assault, assault occasioning grievous bodily harm, negligent acts causing harm, and manslaughter.

Other regulatory actors were found by the Commissioner to be at fault or ineffective. The Queensland Medical Board was found to be negligent in failing to check Dr Patel's credentials or to assess his competence to practise surgery. Dr Patel's application for registration had been 'fast-tracked' through the Queensland Medical Board as the state health department was desperate to recruit doctors specifically for work in an 'area of need'

in a state public hospital. Dr Patel therefore did not undergo an examination and interview through the Australian Medical Council.

The main accreditation agency, the ACHS, had accredited Bundaberg Hospital in mid-2003 soon after Dr Patel began the work there. And while not criticised in the Davies Report, as an accreditation visit could not be expected to identify Dr Patel's failings at that early stage, the accreditation report did not identify a lack of procedures at the hospital for ensuring a high standard of practice.

Outcomes

The Patel case received enormous publicity and sparked much commentary on the shortcomings of health services in Queensland but also in other states. Hedley Thomas, a journalist for the *Brisbane Courier-Mail* documented the unfolding events in a book, *Sick to Death*.⁹⁸ These events led to the resignation of the minister of health and the director-general of the health department. The Queensland government released an action plan in 2005 that promised a major overhaul of the health department and a multi-billion dollar increase in the health budget. The Beattie Labour government was returned in the September 2006 election, somewhat to the surprise of commentators. The adverse findings from the Davies public inquiry were countered as an electoral issue by additional funds in the health budget, a restructure of Queensland Health, and lobbying the federal government for more doctor training places in Queensland universities. Part of the restructure included the establishment within the department of the Queensland Centre for Healthcare Improvement that embarked upon new programmes of clinical governance, monitoring and public reporting of clinical performance by hospitals, and reporting on adverse events.⁹⁹

The Queensland government also had set up an independent management consultancy review in April into the administration of the Queensland health department. Reporting in September 2005 it called for major administrative reforms to the funding, structure and culture of Queensland's health department.¹⁰⁰ While significant restructuring did occur, Queensland Health remained a huge bureaucracy. In 2009, hospitals still were directly managed by the department under 15 districts, each with a district CEO, with every employee under line management responsibility stretching up to the director-general. This only changed in 2011 throughout Australia with the establishment of Local Hospital Networks and management boards through an intergovernmental agreement on hospital funding as described earlier.

The Queensland Medical Board subsequently deregistered Dr Patel who returned to Australia in March 2009 to face a committal hearing on manslaughter charges. The Queensland Supreme Court in July 2010 sentenced him to seven years in prison on three counts of manslaughter and one of grievance bodily harm to his patients.¹⁰¹ In August 2012, the High Court freed Patel from a Queensland jail and ordered a new trial. The judges ruled that a miscarriage of justice had occurred because the prosecution had radically changed its case towards the end of the 2010 trial from alleging incompetence during surgery to alleging that Patel should not have embarked upon surgery in those cases. The Brisbane District Court discharged the jury in October 2013 after their failure to reach a verdict on one charge of grievous bodily harm by Patel to a patient. Other

charges still pending in late 2013 include manslaughter, grievous bodily harm, fraud and attempted fraud.

The Queensland coroner in 2005 investigated all deaths at the Bundaberg Hospital. Although 13 people had died at the hospital under Dr Patel's care, only two of those deaths had been reported to the coroner. The Coroner's Act was subsequently strengthened.

External accountability of the health system was strengthened with the creation of an independent and statutory Health Quality and Complaints Commission, under the Health Quality and Complaints Commission Act 2006 (Qld). The commission was given powers to investigate complaints and to set and monitor standards for health organisations. The Patel affair also contributed to reforms in the regulation of professionals with the establishment of national boards and the Australian Health Practitioners Regulation Agency. The Australian Medical Council tightened its procedures for assessing international medical graduates. The Queensland Medical Board subsequently embarked on a state-wide audit of over 1,600 international medical graduates.

3.8 Summary and conclusion

In Australia, regulatory activity to improve healthcare safety and quality has increased considerably during the last decade or so, and there has been a proliferation of 'frameworks' and standards in social care. The national and state governments have passed legislation and have established government and quasi-government bodies that use regulatory strategies ranging from persuasion to enforcement. Some essential and mandatory quality standards have been introduced, despite the strong preference in the health and social care sectors towards voluntary guidelines and developmental improvements. Mechanisms for enforcing such standards are not well developed, however, and tend to rely on internal rather than external mechanisms. Health and social care professionals place a high value on the state and the public, trusting them to deliver high quality services although at a price: "the price the state has set is insistence on external accountability and transparency in ... performance".²⁵

The regulatory regime in Australia relies largely on networked governance which is being built via three strategies. First, the division of responsibilities in Australia's federal system of government requires intergovernmental agreements, and such agreements have been brokered through intergovernmental forums, such as the Australian Health Ministers' Council and the Council of Australian Governments (political leverage), through joint funding programmes (financial leverage), and by passing parallel legislation at national and regional levels (legislative leverage). Second, networked governance requires extensive consultation (regulatory conversations) among the many public and private stakeholders in mixed systems of health and social care, and also requires their membership on advisory and decisionmaking committees (representative leverage). Third, governance in complex health and social sectors requires the engagement of professionals (professional leverage). This is particularly so in the case of essential standards the development and implementation of which is highly contested given the sometimes uncertain evidence base, the tradition of professional autonomy, human variability (in patients and clients) and the importance of context (cultural, geographic, administrative).

Quality standards and frameworks, especially in the broad area of social care, generally are aspirational statements that organisations are encouraged to meet in a developmental process over time. There is general agreement on the need for standards, perhaps more appropriately referred to as guidelines, but there is no consensus on enforcement, which is generally very limited. While standards are being routinely defined by government for a variety of social care settings, their implementation is not funded or enforced. These standards are not mandatory since they are not based in legislation and have no financial incentives or sanctions attached. Further, it is difficult for government departments to require the under-funded voluntary sector to raise standards if government does not provide sufficient funds to enable them to do so; also, voluntary sector organisation can always respond by withdrawing their services (or threatening to do so). Services and users in the under-funded community sector mainly self-regulate through 'quality improvement' and 'risk management' strategies, and through external accreditation and audits.

Example: Effectiveness of Quality Regulation in Aged Care

The regulation of aged care is an area in which quality has received considerable attention. A 2011 report by the Productivity Commission, *Caring for Older Australians*, explored options for the redesign of Australia's aged care system to meet future challenges of a growing older population.¹⁰² Among the many issues raised, the report highlighted varying standards of care in relation to residential care payment and access to residential and community services. It argued for an increased focus on enabling consumer choice as a means to drive efficiency and improve quality through, for example, mechanisms such as the publication of quality assurance indicators. It further called for the establishment of an Australian Aged Care Commission to manage all regulatory functions for residential and community aged care.¹⁰³

In an assessment of regulation for quality in nursing homes, Braithwaite (2001) found the standards monitoring process in place in Australia to be effective in improving quality of care, when compared to regimes in place in the USA and the United Kingdom.³² Braithwaite (2001) highlighted the process of conversational regulation and advice rather than reliance on very lengthy checklists and audits of documents, further finding the Australian approach to be consistent in its application of ratings. Sub-standard and very small nursing homes had gradually been closed or taken over. The Aged Care Standards and Accreditation Agency (ACSAA) was found to have enhanced regulatory practice by focusing on continuous improvements, although the absence of imposed sanctions and focus on outputs rather than outcomes were seen as negative features.³²

In recent years, and after several scandals, the ACSAA inspection regime has been strengthened, although sanctions remain rare. One argument is that sanctions should be a last resort only after supportive interventions have failed to achieve standard adherence; the counter argument is that well-publicised sanctions are a necessary deterrent. Ellis and Howe (2010) analysed the role of sanctions in assuring quality in residential aged care, using secondary data on accreditation activities and outcomes (1999/2000 to 2007/08).³³ They found that fewer than 5 per cent of aged care homes (138 out of 2830) had been subject to sanctions over the nine-year period under investigation, while 12 per cent of homes were issued with a Notice of Non-compliance. The authors suggested that providers had addressed identified shortcomings when faced with enforcement measures preceding sanctions. Sanctions were interpreted as having contributed to quality improvement, based

on the observation of an increase in accreditation standard adherence from 76 per cent of homes in 1999 to 90 per cent in 2006. The authors highlighted the need to interpret quality assurance systems in conjunction with contextual factors driving quality improvement, such as the quality of aged care workforce, and the availability and effectiveness of the range of possible sanctions.

It is difficult to link performance indicators and accreditation outcomes in evaluating the quality of care both in hospitals and nursing homes. O'Reilly et al. (2007) examined, based on a literature review, the status of quality monitoring in Australian residential aged care.¹⁰⁴ They argued that accreditation and outcome monitoring were not sufficiently linked and were typically based on administrative outcomes rather than clinical outcomes.

4.1 **System overview**

4.1.1 **Organisation and financing of the health and social care systems**

Healthcare in England is largely organised and delivered through the National Health Service (NHS). Health services provided by the NHS are funded through general taxation, with a small national insurance contribution. The NHS covers all residents; health services are free at the point of use (with some exceptions such as prescription drugs and dental care for certain groups of the population).

Following the 2012 Health and Social Care Act, the NHS in England has undergone considerable change, with reform implementation ongoing at the time of writing. In brief, until March 2013, the NHS was overseen by the Department of Health. Just over 150 primary care trusts (PCTs, established in 2002) were responsible for organising the delivery of care locally for geographically defined populations through a mix of direct service provision and commissioning of primary, secondary and community care within their local communities.¹⁰⁵ PCTs controlled about 80 per cent of the NHS budget. From April 2013, the NHS budget has been entrusted to NHS England, established as an executive non-departmental body formerly known as the NHS Commissioning Board in October 2012.¹⁰⁶ NHS England oversees the delivery of NHS services and has taken on the functions of the former PCTs with regard to contracting and commissioning of primary care health services, as well as some nationally-based functions previously undertaken by the Department of Health.

Most of the NHS commissioning budget is now managed by 211 clinical commissioning groups (CCGs), which are groups of general practices which come together in each area to commission healthcare services for their communities. These include urgent and emergency care, elective hospital care, community health services, mental health services, maternity, newborn, and children's healthcare services, among others.¹⁰⁷ Clinical commissioning groups are supported by 19 commissioning support units. The commissioning of some specialised services, primary care, offender healthcare and some services for the armed forces is responsibility of NHS England. Public health services are commissioned by the newly established Public Health England (PHE) and local authorities, while NHS England commissions, on behalf of PHE, many of the public health services delivered by the NHS.

The provision of publicly financed NHS care is mainly through general practitioners who are the first contact point for primary care and by salaried doctors and nurses in public hospitals (NHS trusts and foundation trusts) providing secondary and tertiary care.¹⁰⁵

General practitioners act as gatekeepers to secondary and specialist care services. Some publicly financed care is also provided by private and voluntary providers. In the hospital sector, the creation of foundation trusts has led to greater financial and managerial autonomy of selected NHS hospitals.

Social care services are provided through a means- and needs-tested system delivered at the local level by local authorities.⁷ Local authorities' adult social care support is determined by eligibility rules defined by central government but applied locally.¹⁰⁸ In 2011/12, state expenditure on personal social services was mainly for residential care (44 per cent in 2012) and day and home care (45 per cent). There has been a steady increase in self-directed support in adult social care, with more than half of people supported by community services receiving such support in 2011/12; about 15 per cent of all direct spend on adult care and support services was on personal budgets.¹⁰⁹ People with assets beyond a set threshold receive no financial state support and have to fund their own care. For example, in 2010, an estimated 45 per cent of care home places (around 35 per cent in residential care homes¹¹⁰) in England were occupied by people who are self-funded.¹¹¹

Almost all nursing care and most residential care is provided by the independent sector (voluntary or private organisations) with the remainder provided in homes run by local authorities. Home care services are also mainly delivered by the independent sector; in 2010, about 12 per cent of home care providers were public bodies, while 74 per cent were private and 11 per cent voluntary organisations.¹¹²

4.1.2 Principles of healthcare governance

The Department of Health (DH) is the central government body principally responsible for setting policy for the health and social care system in England.¹⁰⁵ It is also the principal government department in charge of UK-wide health matters, such as the control of infectious diseases and responses to biological threats. It represents UK health policy in international and European fora.¹¹³

The specific roles and responsibilities of the Department of Health have changed following the 2012 Health and Social Care Act, away from direct responsibility for the delivery of the NHS to one that provides strategic direction and acts as steward for the health and care system, develops national policies and provides leadership.¹¹⁴ Government expectations of the performance of the Department are set out in the form of Government's Business Plans, defining major departmental responsibilities, key policy and implementation actions for the legislative period, as well as indicators to track progress.¹¹⁵ Priorities under the current government are: to enable better health and wellbeing, better care, and better value for the population, to deliver successful change, to work with stakeholders, and to support UK growth.

Responsibility for the delivery of the NHS and care services has shifted to the newly established NHS Commissioning Board (NHS England from April 2013) as set out in the 2012 mandate from the government.¹¹⁶ The mandate established that NHS England shares, with the secretary of state for health, the 'legal duty to promote a comprehensive health service'.¹¹⁶ NHS England is an executive non-departmental public body; it has a wide range of statutory duties and is accountable to the secretary of state and the public. The mandate provides the basis of 'Ministerial instruction to the NHS' and cannot be changed without the agreement of NHS England. At the same time, NHS England is

legally required to pursue the objectives set out in the mandate: (i) preventing ill-health and providing better early diagnosis and treatment; (ii) managing ongoing physical and mental health conditions; (iii) helping people to recover from episodes of ill health or following injury; (iv) ensuring that people have a positive experience of care; and (v) providing safe care and protecting them from avoidable harm. The five objectives correspond to the five domains defined by the NHS Outcomes Framework, which are used to measure progress in the NHS.¹¹⁷

Governance of the health and care system in England is supported by a range of arm's length bodies, in addition to NHS England. These are stand-alone national organisations, financed by and accountable to the Department of Health; they fall into three broad categories: *executive agencies* that are responsible for a particular business area and are directly accountable to the secretary of state for health; *special health authorities*, which provide a service to the entire population; these are distinct organisations that can be under ministerial direction; and *non-departmental public bodies* (such as NHS England), responsible for specific governance functions which provide independent advice to the ministers without taking direction from the department. They are usually accountable to Parliament rather than ministers.

In 2013, the Department of Health worked with a total of 15 arm's-length bodies.¹¹⁸ These include two executive agencies: the Medicines and Healthcare Products Regulatory Agency, which is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe;¹¹⁹ and Public Health England, the national public health agency which fulfils the secretary of state for health's statutory duty to protect health and address inequalities, and to promote the health and wellbeing of the population.¹²⁰

NHS England, the Care Quality Commission (CQC), the National Institute for Health and Care Excellence (NICE) and Monitor are among the seven executive non-departmental public bodies, alongside the Health and Social Care Information Centre, the Human Fertilisation and Embryology Authority and the Human Tissue Authority.¹¹⁸ The CQC is the independent regulator of health and adult social care providers in England;³⁹ NICE produces evidence-based guidance and advice, develops quality standards and performance metrics, and provides information services across the spectrum of health and social care;²⁴ Monitor is the sector regulator for healthcare, overseeing NHS foundation trusts, and, from 2014, independent healthcare providers;¹²¹ the Health and Social Care Information Centre collects, analyses and publishes national data and statistical information and delivers national IT systems and services to support health and care providers.¹²² The two specialist regulators, the Human Tissue Authority (HTA) and the Human Fertilisation and Embryology Authority (HFEA) regulate human tissue, such as donated organs; fertility treatment; and the use of embryos in research.¹¹⁸

In addition there are six special health authorities responsible for various parts of the health and care system. These include the Health Research Authority, responsible for protecting and promoting the interests of patients and the public in health research; the newly established Health Education England which has been tasked with ensuring that the education, training and development of the healthcare workforce is set to improve patient care; the NHS Trust Development Authority, which supports NHS trusts seeking to

obtain foundation trust status; the NHS Business Services Authority, which provides a range of support services to NHS organisations, NHS contractors, patients and the public; the NHS Litigation Authority, which handles negligence claims and improves risk management practices while also having a role in primary care to resolve disputes between commissioners and providers; and NHS Blood and Transplant, responsible for the safe supply of blood, organs, tissues and stem cells.

The Department and arm's length bodies are further supported by a range of advisory non-departmental bodies, for example the NHS Pay Review Body, which advises the NHS on the pay of NHS staff.¹²³

Furthermore, there are eight professional regulatory bodies which regulate health and social care professionals in England and the UK more broadly, and which are overseen by the Professional Standards Authority (which also oversees the Pharmaceutical Society of Northern Ireland as the regulatory and professional body for pharmacists in Northern Ireland).¹²⁴ These include the General Medical Council (GMC), the independent regulator for doctors in the UK responsible for ensuring appropriate standards in the practice of medicine through holding registers of qualified doctors, and promoting good medical practice and standards of medical education and training, among other things.¹²⁵ The Nursing and Midwifery Council is the regulator for nurses and midwives for England, Wales, Scotland, Northern Ireland and the Islands, responsible for their registration and the setting of standards education, training, conduct and performance.¹²⁶

4.1.3 Recent reforms of the health and social care systems

Healthcare reforms in England have, over the past 20 years, focused on the creation of a market within the English NHS, starting with the introduction of an 'internal' market in 1991, which separated the purchasing function from the provision of care.¹²⁷ The reform introduced, among other things, GP fundholding, enabling GP practices to purchase elective care on behalf of their patients. GP fundholding was abolished under the 1999 Health Act,¹²⁸ although the principle of a purchaser-provider split was maintained by introducing primary care trusts (PCTs), which assumed payer responsibilities. This was accompanied by substantial investments into the NHS under the 2000 NHS Plan, with a focus on expanding NHS capacity and increasing staff numbers alongside the introduction of national standards and targets and the strengthening of inspection and regulation, to be supported by newly created national bodies such as NICE and the CQC.¹²⁹

Further reforms saw the introduction of patient choice of hospital, provider incentives through payment reform and the admission of private providers into the NHS.¹³⁰ For example, the 2003 Health and Social Care (Community and Health Standards) Act introduced foundation trusts as a new form of organisation for hospital services, giving NHS trusts greater autonomy, and activity-based funding of hospitals through the 'payment by results' scheme.¹⁰⁵ It also introduced Monitor, the independent regulator of NHS foundation trusts to authorise and regulate new foundation trusts to ensure that they were financially strong and well-managed. The 2004 NHS Improvement Plan introduced GP-practice-based commissioning.¹³¹

Alongside these developments there were efforts to shift care from hospital into the community and more integrated approaches to care provision, with for example the 2006 white paper *Our Health, Our Care, Our Say* presenting a vision for more responsive care,

committing, among other things, PCTs and local authorities to have in place joint teams to care for those with complex needs by 2008, while the 2007 Local Government and Public Involvement in Health Act created a requirement for a joint needs assessment between health and local authorities.¹⁰⁵

Following changes initiated by the 2000 NHS Plan, there was also a continuous drive for quality improvement, with for example the 2008 NHS Next Stage Review emphasising that quality should be the main focus for the NHS, and that clinicians should become the main drivers of change¹³² while the 2009 Health Act introduced the NHS Constitution, which set out rights and responsibilities for NHS patients and providers (eg access, privacy, dignity, choice).⁹

The aforementioned 2012 Health and Social Care Act constitutes the latest set of reforms, which introduced considerable changes to the NHS while expanding further on existing features, such as the further integration between health and social care services and extending patient choice. As described above, changes involved the transfer of responsibility of most healthcare purchasing from PCTs to clinical commissioning groups while public health responsibility was transferred to local authorities, supported by Public Health England. Other changes included the strengthening of patient and public involvement through the creation of Healthwatch England at the national level (set up as a statutory committee of the CQC) alongside local Healthwatch organisations, which are funded by and accountable to the public via local authorities.¹³³ Newly established health and wellbeing boards (n=152) bring together local authorities, clinical commissioning groups, local Healthwatch, public health, social care and children's services leaders to assess the health and care services needs of the local population to ensure collaboration of services and seamless care for the community.¹³⁴ At the national level, the aforementioned Health Education England (HEE) was established as a special health authority to provide leadership for the new education and training system,¹³⁵ and the NHS Trust Development Authority (NHS TDA) to support NHS trusts.¹³⁶

The new vision on the health and care system in England from 2013 is set out in Figure 4.1.

The health and care system from April 2013

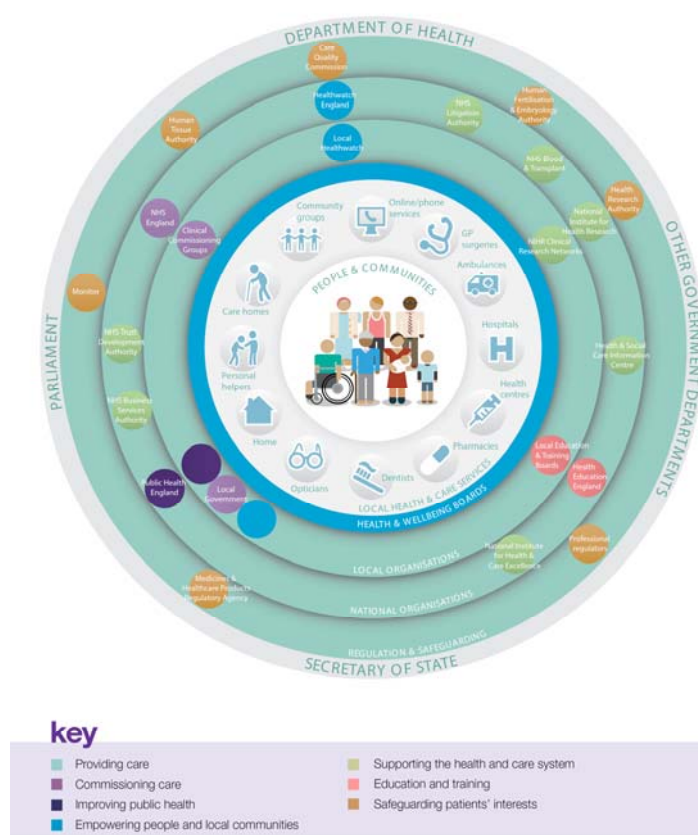


Figure 4.1 The health and care system in England from 2013

SOURCE: Department of Health (2013)¹¹⁴, in accordance with the Open Government Licence v2.0 (URL: <http://www.nationalarchives.gov.uk/doc/open-government-licence/version/2/>)

4.2 National regulatory or otherwise framework for care quality

4.2.1 Sources of minimum standards of quality in the health and social care systems

System-wide approaches towards improving the quality of care in the English NHS can be traced to the 1997 white paper ‘The new NHS’ which sought to make the quality of healthcare central to policy and practice.¹³⁷ It introduced, for the first time, a statutory duty for all health organisations to seek quality improvement through clinical governance.¹³⁸ Considered as ‘the most radical and far reaching effort in the history of the NHS to put systems for healthcare quality assurance and improvement in place’¹³⁹, the ensuing reforms foresaw the creation of new arrangements for settings standards for care, through the establishment in 1999 of NICE, as mentioned earlier, and the development of national service frameworks (NSFs); for the delivery of those standards (through local arrangements for clinical governance¹³⁸); and for monitoring the quality of care and systems for quality improvement, through the introduction of performance measures, and the newly established Commission for Health Improvement (CHI) (see also Box 4.1).¹³⁹

Box 4.1 The National Patient Safety Agency

In a parallel move to safeguard patient safety and following the publication of the report 'An organisation with a memory' by an expert group on learning from adverse events in the NHS chaired by the then chief medical officer in 2000,¹⁴⁰ in 2001, the National Patient Safety Agency was established as a special health authority with the aim of reducing risk and improving the safety of NHS patient care through collecting, reporting, analysing and learning from mistakes and problems that affect patients.¹⁰⁵

A non-regulatory agency, the NPSA was concerned with the monitoring of patient safety incidents, including medication and prescribing error reporting; however, it did not investigate incidents or was involved with disciplinary procedures. In 2004, it set up the National Reporting and Learning Service, a national, non-mandatory patient safety reporting system linked to local trust risk-management systems. The agency was abolished in 2012, following the latest health reforms; its key functions were taken on by NHS England.

The introduction of standards for service delivery sought to reduce variation in the quality of services and ensure uniform quality relative to need across the country.¹⁰⁵ NICE was to be at the core of this effort through the production of evidence-based clinical guidelines, while national service frameworks (NSFs) describe long term strategies for improving specific areas of care. They set national standards and measurable goals within set time frames. Led by a national clinical director, responsibility for implementation remained local in the light of local priorities. By 2010, NSFs had been developed for diabetes (1999), mental health services (1999) and paediatric intensive care (1999) followed by coronary heart disease (2000), cancer care (2000), services for older people (2001), renal services (2004), children's health (2004) and long-term conditions (2005).

NHS providers were initially not legally required to implement NSFs or NICE guidance, but measures to reinforce national standards in healthcare provision were introduced subsequently, with for example the 2003 Health and Social Care (Community Health and Standards) Act permitting the Secretary of State to set standards that are binding on all NHS organisations. These stipulations were further specified in the 2004 NHS Improvement Plan¹³¹ and subsequent 'Standards for Better Health' (2006), which defined standards as 'are a means of describing the level of quality that health care organisations are expected to meet or to aspire to'.¹⁴¹ Standards, in this sense, would also include NSFs and NICE guidance, defined as 'integral to a standards-based system' and stipulations foresaw that NHS organisations would be assessed both on their performance on national targets but also on their delivery of other areas of high quality care including NSFs and NICE guidance.

Overall, standards were seen to form the main driver for continuous improvements in quality, and to reflect this changed emphasis, two types of standards were defined: *core standards* and *developmental standards*. Core standards set out the minimum level of service users have a right to expect whereas developmental standards sought to provide a framework for NHS organisations for the further improvement of service delivery to meet patient expectations.¹⁴¹ Core standards covered seven domains: safety, clinical and cost-effectiveness, governance, patient focus, accessible and responsive care, care environments and amenities and public health.

Monitoring of the extent to which quality of care did improve across the NHS was the initial task of the Commission for Health Improvement, which was also tasked to take a national leadership role on clinical governance, and, where necessary, to investigate specific issues.¹⁰⁵ However, the organisation subsequently became the Commission for Health Care Audit and Inspection (known as the Healthcare Commission) in 2004, and was eventually superseded by the CQC in 2009.¹⁴² Alongside these organisational changes, its remit and influence expanded. For example, the Healthcare Commission acquired a wider remit, including reviewing the standards of care provided by healthcare providers, including in the private and voluntary sector, and commissioners. Reviews were carried out, and published, in the form of 'Annual Health Checks' from 2006; these assessed the performance of each type of NHS organisation (acute and specialist trusts, ambulance trusts, learning disability trusts, mental health trusts and primary care trusts) against core standards, national priorities, and existing commitments identified by the Department of Health.¹⁴³

The system of standards was further revised with the 2008 Health and Social Care Act. Specifically, it specified the framework for quality regulation by securing that any service provided in the carrying out of a regulated activity is of appropriate quality, with Section 20 mandating 'that any service provided in the carrying out of a regulated activity is of appropriate quality' and securing 'health, safety and welfare of persons for whom any such service is provided'.⁹ In line with these stipulations, 'essential standards of quality and safety' in service provision have been formulated. The 2008 Health and Social Care Act also led to the Healthcare Commission being merged with the Commission for Social Care Inspection, to form the CQC as a single integrated regulator for health and adult social care, tasked with enforcing these standards.

There are 16 essential standards, each associated with an outcome that the CQC expects all people who use services to experience as a result of the care they receive.⁶ These standards and related outcomes (Box 4.2) are deemed to apply to all types of providers. They centre on involvement and information (eg respecting and involving service users; consent to care and treatment); personalised care, treatment and support (eg care and welfare of service users, cooperating with other providers); safeguarding and safety (eg cleanliness and infection control, medicines management); suitability of staffing (eg supporting workers); quality and management (eg monitoring, complaints); and suitability of management (eg training, financial position). The CQC will check providers' compliance with essential standards for those of the 16 that most directly relate to quality and safety and providers must have evidence that they meet the outcomes. Twelve further standards and outcomes, relating primarily to routine day-to-day management, are in place, which apply to different types of provider.

Box 4.2 Essential standards of quality and safety and associated outcomes

1. Respecting and involving people who use services

People should be treated with respect, involved in discussions about their care and treatment and able to influence how the service is run.

2. Consent to care and treatment

Before people are given any examination, care, treatment or support, they should be asked if they agree to it.

<p>3. Care and welfare of people who use services People should get safe and appropriate care that meets their needs and supports their rights.</p> <p>4. Meeting nutritional needs Food and drink should meet people's individual dietary needs.</p> <p>5. Cooperating with other providers People should get safe and coordinated care when they move between different services.</p> <p>6. Safeguarding people who use services from abuse People should be protected from abuse and staff should respect their human rights.</p> <p>7. Cleanliness and infection control People should be cared for in a clean environment and protected from the risk of infection.</p> <p>8. Management of medicines People should be given the medicines they need when they need them, and in a safe way.</p> <p>9. Safety and suitability of premises People should be safe from harm from unsafe or unsuitable equipment.</p> <p>10. Safety, availability and suitability of equipment People should be safe from harm from unsafe or unsuitable equipment.</p> <p>11. Requirements relating to workers People should be cared for by staff who are properly qualified and able to do their job.</p> <p>12. Staffing There should be enough members of staff to keep people safe and meet their health and welfare needs.</p> <p>13. Supporting workers Staff should be properly trained and supervised, and have the chance to develop and improve their skills.</p> <p>14. Assessing and monitoring the quality of service provision The service should have quality checking systems to manage risks and assure the health, welfare and safety of people who receive care.</p> <p>15. Complaints People should have their complaints listened to and acted on properly.</p> <p>16. Records People's personal records, including medical records, should be accurate and kept safe and confidential.</p>
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SOURCE: Care Quality Commission (2013).¹⁰

4.2.2 Overview of main bodies responsible for standard setting and enforcement

Table 4.1 provides an overview of the key actors involved in the regulating and assuring quality of care in England that are currently in operation, reflecting the arrangements in place as at 1 August 2013. It should be noted that the actors listed are in a continuing process of redesign following two major reviews and a set of recommendations on quality and safety in the NHS.^{144 145} Where new roles have been decided upon but not yet implemented, these are noted with anticipated implementation date.

Table 4.1 Summary overview of main bodies responsible for standard setting and enforcement in the health and social care sectors in England

Agency or body	Main roles and functions
Care Quality Commission (CQC)	<ul style="list-style-type: none"> • Independent regulator of health and adult social care in England • Setting and enforcing standards for care homes, dentists, home care, ambulances, hospitals, and from 2013 GP practices • Regular (unannounced) inspections and monitoring on standard adherence among care providers • Can request action plans, issue warning notices, restrict services, stop admissions into the care service, issue fixed penalty notices, suspend or cancel the service's registration; may prosecute where providers of care services are not registered with the CQC.
Monitor	<ul style="list-style-type: none"> • Sector regulator for health services in England • Responsible for overseeing the performance of NHS foundation trusts in relation to finance and quality of care • Responsible for ensuring that choice and competition operate in the best interests of patients • Responsible for ensuring continuity of NHS services if a foundation trust gets into difficulty (to be extended to independent healthcare providers from 2014) • Publishes quarterly and annual reports on foundation trusts' organisational performance, based on mandatory submissions from trusts.
National Institute for Health and Care Excellence	<ul style="list-style-type: none"> • Non-departmental public body • Produces evidence-based guidance and advice for health, public health and social care practitioners • Provides information services across the spectrum of health and social care • Develops of potential indicators for inclusion in the Quality and Outcomes Framework (QOF), the quality element of the GP contract • Supports the development of the Clinical Commissioning Group Outcomes Indicator Set (CCGOIS).

4.3 National regulatory bodies

4.3.1 Care Quality Commission

Legal status and organisational structure

The Care Quality Commission (CQC) is the independent regulator of all health and adult social care services provided by the NHS, local authorities, and the independent sector in England. It was formed as a non-departmental public body under the 2008 Health and Social Care Act through the merger of the Healthcare Commission, the Commission for Social Care Inspection, and the Mental Health Act Commission as noted earlier. Any service that provides care that is defined under the 2008 Health and Social Care Act as a 'regulated activity' has to be registered with the CQC to be legally permitted to provide care, and the legislation makes it an offence to provide these activities without being registered with the CQC.¹⁴⁶ In 2013, the CQC regulated over 30,000 care providers, including NHS trusts, independent care providers, independent ambulance services, primary dental care, adult social care and, from April 2013, GP and primary medical services.³⁹

The CQC's responsibilities are to monitor, inspect and regulate services to ensure that providers meet the essential standards of quality and safety, and to make findings available to the public. It carries out this role through setting standards of quality and safety; registering care services that meet the standards; protects the rights of vulnerable people, including those whose rights are restricted under the Mental Health Act; taking action if

care services fail to meet the standards; carrying out in-depth investigations; reporting on the quality of care services; among other things.

Providers have to register with the CQC for the regulated activities they provide as well as each 'location' in which they carry out regulated activities, for example individual care homes where care is provided. Each location receives its own inspection from the CQC.

Regulatory mechanisms to ensure standard adherence

The CQC regulates health and adult social care services through registration, inspection and, where necessary, enforcement action.¹⁴⁷ The CQC has recently undergone an extensive consultation and reorganisation process and it should be noted that change in the detail of the main functions is possible as it implements its strategy for 2013 to 2016.¹⁴⁸

Registration. The CQC registers all providers that are compliant with the essential standards of quality and safety.¹⁴⁹ Once registered, the provider is subject to the CQC's enforcement powers. Recently, GP practices have been brought under the scope of inspection for the first time, significantly increasing the number of organisations for which the CQC is now responsible.

Inspection. The CQC has aimed to carry out regular inspections of providers and locations on an annual basis (dentists: every two years). Increasingly, the frequency of CQC inspections is expected to depend on the perceived 'risk' involved. That is, services judged to pose a high risk of harm to people who use them, or where people are vulnerable because of their circumstances, would receive more frequent inspection. This may include services caring for people with learning difficulties or for people with mental health issues. Inspections may also be unscheduled and as a response to concerns about poor care. In the case of NHS acute trusts, a new surveillance model has been proposed to inform decisions about where, what and when to inspect.¹⁵⁰ Previously, internal auditing at the CQC reported that differences in approaches to inspections were leading to inconsistencies within and between regions.¹⁴⁸ Following the appointment, in July 2013, of the chief inspector of hospitals,¹⁵¹ with appointments of a chief inspector of adult social care and chief inspector of general practice to follow in autumn 2013, it should be noted that the CQC's new inspection model will be tested and further refined to best meet the regulation and inspection needs in each service area. The five key areas that inspections focus on will be safety, effectiveness, how caring services are, how well they are led and how responsive services are to people's needs.¹⁵² The CQC have also committed to publishing better information from inspections and rating exercises available to the public in order to inform choice of provider.

Enforcement. As noted above, the CQC was established as an independent regulator of health and social care as per Health and Social Care Act 2008,⁹ assigning powers to intervene and take action.¹⁸ These include: (i) powers to prosecute unregistered providers of regulated activities; (ii) civil powers to ensure compliance by limiting or changing what a registered person is allowed to do, or by stopping them (temporarily or permanently) from carrying on regulated activities, and; (iii) powers to prosecute, fine and warn registered persons who fail to comply with legal agreements. Before enforcement action, the CQC would take compliance actions which do not take the form of civil or criminal actions but would inform a registered person that they are not compliant with relevant regulation. A judgement framework or 'regulatory response escalator' model is used to help determine

appropriate regulatory action; dependent on whether the impact of non-compliance is considered minor, moderate or major. A detailed overview of CQC's enforcement policies, setting out principles the CQC will follow when using the enforcement powers transferred to the CQC under the 2008 Health and Social Care Act 2008, was published in June 2013.¹⁵³ Given the ongoing changes in the system it is conceivable that these will be further amended in due course.

It should be noted that, at the time of writing, the CQC continued working with the Department of Health, Monitor and the NHS Trust Development Authority to develop effective enforcement powers in the case of an NHS service failing to meet standards, and with the health and safety executive to ensure that appropriate action is taken against healthcare providers who break health and safety law. Part of the role of the chief inspectors mentioned above is that they will make sure that concerns about quality or safety are brought to the attention of all relevant regulators and partners in the health and social care system to promote coordinated action.¹⁴⁸

4.3.2 Monitor

Legal status and organisational structure

Set up in 2004, Monitor is an independent regulator accountable to Parliament and responsible for overseeing the performance of NHS foundation trusts in relation to finance and quality of care.¹²¹ It reports to Parliament on an annual basis and its reports are publicly available. In addition to its regulatory tasks, Monitor provides information about provider performance to serve the information needs of a number of audiences, including the Department of Health, service commissioners at clinical commissioning groups (CCGs), providers and patients.

The Health and Social Care Act 2012 has established Monitor as the sector regulator for all NHS-funded health providers health from 2013.¹³¹ Monitor's core role is 'to protect and promote the interests of patients' through a range of powers that are designed to help commissioners and providers of health services to deliver care for patients that is clinically effective, safe, and results in a positive user experience.¹⁵⁴ The expanded role means working with other bodies, including NHS England, the CQC and NICE, to help ensure that all providers of NHS-funded services, the commissioners of those services and their users ensure the best care is delivered.¹²¹

Scope of action

As noted above, Monitor was set up to oversee the creation of foundation trusts, including governance arrangements, delivery of authorised services, and financial oversight.¹⁰⁵ Monitor could intervene where a foundation trust was in significant breach of the terms of its authorisation, or is at risk of failing to meet national standards and targets, with instruments at its disposal including the removal of any or all directors or members of the board of governors and appointment of interim directors and members of the board.

Following the 2012 Health and Social Care Act, Monitor's scope of action has broadened, with main responsibilities now including:¹⁵⁴

- public sector providers are well led so that they can provide high quality care
- essential NHS services continue when foundation trusts get into difficulty (to be extended to independent healthcare providers from April 2014)

- procurement, choice and competition operate in the best interests of patients, with respect to preventing anti-competitive behaviour between commissioners and providers
- prices for NHS services reward high-quality, efficient providers and incentivise them to deliver care in ways that best meets patients' needs.

Monitor is also responsible for enabling the provision of integrated care that is tailored to the needs of patients. The main tool Monitor has at its disposal to regulate providers of NHS services is the provider licence.¹⁵⁵ Thus, from April 2013, all NHS foundation trusts require a licence from Monitor which stipulates specific conditions that trusts must meet to operate.¹⁵⁶ It is expected that licensing stipulations will expand to cover other NHS providers by April 2014.¹⁵⁵ The licence sets out standard requirements and rules which Monitor expects from all providers of NHS services. These, in addition to general conditions, set out provider obligations in five main areas: pricing; choice and competition; integrated care; continuity of services; and governance conditions.

The licence, introduced in March 2013, also forms the basis for enforcement powers available to Monitor, which it can use to ensure that all licensed providers comply with licence conditions and that all providers and others who may be obliged comply with requests to provide information.¹⁵⁷

Regulatory mechanisms to ensure standard adherence

The regulatory actions available to Monitor include: informal action; enforcement undertakings; discretionary requirements; new licence conditions; removing, suspending or disqualifying directors or governors, and; revoking a provider's licence. These powers are determined as set out in the 2012 Health and Social Care Act. In addition, Monitor may carry out investigations under the 1998 Competition Act which gives it concurrent powers with the Office of Fair Trading (OFT).¹⁵⁷ The way in which they work together is currently decided on a case-by-case basis. From 2013, Monitor also intends to apply a prioritisation framework to decisions about whether to pursue enforcement action. This framework assesses and weighs up the likely benefit to health service users and the likely costs of taking action. Monitor further has to decide whether it should be acting to ensure the best outcomes for health service users, or whether other organisations such as the CQC, the Office of Fair Trading, the Charity Commission or NHS England have more appropriate regulatory tools.

Monitor's core tasks to assess risks to the continued provision of NHS services and to continue overseeing the governance of NHS foundation trusts are further specified in a 'risk assessment framework' which was issued in August 2013 and is set to replace the previous Compliance Framework for financial and governance oversight by Monitor.¹⁵⁶ In brief, under the Compliance Framework, oversight of foundation trusts' organisational performance, included a financial risk rating, which was intended to identify breaches of trusts' terms of authorisation on financial grounds. The new risk assessment framework seeks to preplace this approach by a new continuity of services risk rating to identify the level of risk to the ongoing availability of key services. It will continue using a governance rating, on grounds that NHS foundation trusts should be well-governed. The approach uses three categories, dependent on whether there are no grounds for concern (green

rating); there are grounds for concern at a trust but not yet taken action (amber); or whether Monitor has begun enforcement action (red).

The overall aim of the risk assessment framework is to highlight causes for concern in the areas of the provider licence and findings from (routine) risk ratings will determine the intensity of monitoring undertaken by Monitor. Potential need for regulatory action is identified on a case-by-case basis; risk ratings thus trigger consideration of regulatory action rather than action itself. Further change is envisaged from April 2014 when this will be extended to all providers of NHS services.¹⁵⁶

4.3.3 National Institute for Health and Care Excellence (NICE)

Legal status and organisational structure

NICE has operated within the NHS since 1999. Following the 2012 Health and Social Care Act, NICE became an executive non-departmental public body, with its name changed to the National Institute for Health and Care Excellence, reflecting its additional responsibility for developing guidance and quality standards in social care.¹⁵⁸ NICE is accountable to the Department of Health while operationally independent of government. NICE guidance and other recommendations are made by independent committees.²⁴

Scope of action

The scope of NICE's work includes (i) producing evidence-based guidance and advice for practitioners in the health and social care sector, including clinical guidelines, technology appraisals, reviews of medical technologies and diagnostics, interventional procedures as well as public health and social care guidance; (ii) developing quality standards and performance metrics for providers and commissioners of health, public health and social care services; and (iii) providing access to information services, such as NICE Evidence, an online search engine to identify relevant guidance, the British National Formulary and British National Formulary for Children, and information on new pharmaceutical products to support medicines management and prescribing.²⁴

NICE quality standards are 'a concise set of prioritised statements designed to drive measurable quality improvements within a particular area of health or care'.²⁴ They are developed independently by NICE but in collaboration with a range of stakeholders, including professionals, providers, and service users. The main purpose of NICE quality standards is to enable evidence-based decisionmaking in the provision of health and social care; to provide service users and their families with information about the quality of services they can expect to receive; to help service providers understand the performance of their organisation and assess improvement; and to assure commissioners of the quality and cost-effectiveness of the services they purchase.¹⁵⁹

NICE quality standards consider the complete care pathway, across public health, health and social care, with those for health focusing on the treatment and prevention of diseases and conditions, and which are reflected in the Clinical Commissioning Group Outcome Indicator Set (CCGOIS) (see below).¹⁵⁹ They will also inform payment mechanisms and incentive schemes such as the Quality and Outcomes Framework (see below) and Commissioning for Quality and Innovation (CQUIN) Payment Framework. Quality standards for social care centre on services and interventions to support the social care needs of service users, while those for public health complement NICE's existing work on

public health; these seek to support Public Health England, local authorities and the wider public health community.

By mid-2013, NICE had published around 50 quality standards, with about 120 referred for development another 30 in development.¹⁶⁰ Examples of published quality standards (QA) are:

- Health: Breast cancer (QS12). The quality standard covers the management of early, locally advanced and advanced breast cancer in adults, which includes the management of breast cancers from the point of referral to a specialist team. The QS excludes adults with rare breast tumours or women with an increased risk of breast cancer due to family history (issued September 2011).¹⁶¹
- Public health: Smoking cessation – supporting people to stop smoking (QS43). The quality standard covers smoking cessation and includes support for people to stop smoking and to access smoking cessation services (issued: August 2013).¹⁶²
- Health and social care: Supporting people to live well with dementia (QS30). The quality standard covers the care and support of people with dementia and applies to all social care settings and services working with and caring for people with dementia (issued April 2013).¹⁶³

As part of the quality standards and performance metrics work, NICE undertakes the development for of (potential) indicators for the Quality and Outcomes Framework (QOF), a voluntary incentive scheme for GP practices in the UK and part of the general practitioner contract. More recently, NICE has also begun working with NHS England and other stakeholders in the development of the Clinical Commissioning Group Outcomes Indicator Set (CCGOIS) which seeks to measure the health outcomes and quality of care achieved by newly established clinical commissioning groups.²⁴

In addition to the core roles listed above, NICE also hosts a fellows and scholars programme that aims to foster a network of health and social care professionals ‘committed to improving quality’ in their own communities,²⁴ while NICE International was set up in 2008 to help raising standards of healthcare in other countries through supporting the use of evidence-based decisionmaking in healthcare policy,¹⁶⁴ having delivered technical projects in 35 countries since then.¹⁵⁸

Regulatory mechanisms to ensure standard adherence

NICE has no regulatory standard enforcement powers as such as NICE’s responsibility involves describing the standards in particular areas, rather than implementing them. In this sense NICE is a critical partner and reference point for the CQC and Monitor. For example, NICE standards form the bases of decision making for clinical commissioning groups. Monitor in turn has to ensure the providers are using resources for health care as effectively and efficiently as possible. NICE guidance also helps to give providers and commissioners of care an evidence base for investment and disinvestment.¹⁶⁵ Furthermore, NICE technology appraisals of drugs and devices help to standardise access to healthcare across the country with the NHS legally obliged to fund and resource medicines and treatments recommended by NICE's technology appraisals.²⁴

4.4 Quasi-governmental and other actors

4.4.1 Regulation of healthcare professionals

The majority of healthcare professionals in England are regulated by professionally led statutory bodies. These regulators protect and promote the safety of the public by setting standards for behaviour, education and ethics that health professionals must meet, and by addressing concerns about professionals who are unfit to practise owing to poor health, misconduct or poor performance.¹⁰⁵ The regulators maintain a register of individuals who meet standards of training and who are, therefore, permitted to use a protected professional title; they set standards of training and education, including in many cases requirements for continuing professional development. They also establish standards of practice or codes of conduct and they monitor and enforce standards of practice by taking action against professionals who are not fit to practise.

There are eight health and care professional regulatory bodies covering England:¹²⁴

- The General Chiropractic Council regulates the chiropractic profession.
- The General Dental Council regulates dentists, dental nurses, dental technicians, dental hygienists, dental therapists, clinical dental technicians and orthodontic therapists.
- The General Medical Council, established in 1858, regulates doctors.
- The General Optical Council regulates the optical professions in the UK.
- The General Osteopathic Council regulates osteopaths.
- The General Pharmaceutical Council regulates pharmacists, pharmacy technicians and pharmacy premises in Great Britain.
- The Health and Care Professions Council regulates health, psychological and social work professionals.
- The Nursing and Midwifery Council regulates nurses and midwives in England, Wales, Scotland, Northern Ireland and the Islands.

These bodies maintain lists of professionals who are allowed to practise in the name of their particular professions, and also consider allegations of misconduct or unfitness to practise owing to ill health. In addition, there may be other professional bodies or associations that perform roles complementary to that of the regulating bodies.¹⁰⁵

4.5 Case study

Winterbourne

In May 2011, the BBC's Panorama programme highlighted serious abuse and poor standards of care at Winterbourne View, a hospital for the assessment and treatment of people with learning disabilities who had additional complex needs, operated by an independent sector specialist provider.¹⁶⁶ By the time of the Panorama programme, during 2008 and 2009, the hospital had already undergone a series of (unannounced) inspections by the Healthcare Commission (2008), ongoing regulatory assessment by the Mental Health Act Commission, followed by regulation through the Care Quality Commission.¹⁴⁷

Following the issues raised by the Panorama programme, the Care Quality Commission carried out a compliance review at the hospital, including a site visit, which found that Winterbourne View was non-compliant in 10 of the 16 outcome areas; Winterbourne View subsequently closed in June 2011. Other locations operated by the same provider then also underwent compliance review, with serious concerns about the quality of care identified at a further three, which led to their closure also.¹⁶⁷

The Winterbourne View case highlighted shortcomings in the Care Quality Commission's whistleblowing arrangements. Serious concerns about the quality of care communicated by a member of nursing staff at Winterbourne became first known to the CQC in November 2010 through the South Gloucestershire Safeguarding Adults Team, and subsequently through direct contact by the nurse, seeking to make a 'serious complaint'.¹⁶⁶ Although the issue was followed up by CQC by means of assigning the communication to the Compliance Inspector for Winterbourne View, there were delays because the initial communication was not immediately identified as a whistleblowing incidence. The latter point is important as whistleblowing by someone employed by a provider is viewed as a core source of information for compliance inspectors and should trigger action. However, in this case, action was not taken by the Care Quality Commission, his employers, or the South Gloucestershire Safeguarding Adult Team. An internal management review by the CQC of the regulation of Winterbourne View, noted that this was because "[e]ach assumed the other" would be contacting the nurse about his concerns, when "in fact none of the bodies involved had contacted" him.¹⁶⁶

In response to the Winterbourne View case, the CQC carried out an internal disciplinary procedure and made changes to management of whistleblowing concerns. These included the establishment of a dedicated whistleblowing team which are responsible for tracking and chasing all whistleblowing reports to their respective regions to support regional staff to monitor concerns and ensure they are followed up and issues are resolved.¹⁴⁷ More recently, quality checks of whistleblowing and safeguarding contacts have become one of CQC's key performance indicators of quality.¹⁵²

4.6 **Summary and conclusions**

Healthcare in England is largely organised and delivered through the NHS. Following the 2012 Health and Social Care Act, the NHS in England has undergone considerable change, with reform implementation continuing. The Department of Health is the central government body principally responsible for setting policy for the health and social care system in England. Responsibility for delivery of the NHS and care services has now shifted to the NHS England, an executive non-departmental public body with a wide range of statutory duties and accountable to the Secretary of State and the public. In addition to NHS England, governance of the health and care system in England is supported by a range of arm's length bodies.

The Care Quality Commission (CQC) is the independent regulator of health and adult social care providers in England. The National Institute for Health and Care Excellence (NICE) produces evidence-based guidance and advice, develops quality standards and performance metrics, and provides information services across the spectrum of health and social care. Monitor is the sector regulator for healthcare, overseeing NHS foundation

trusts and, from 2014, other NHS providers. The 2008 Health and Social Care Act gives the CQC the mandate to regulate all providers of health and adult social care against 16 essential standards which are linked to associated outcomes that people who use care can expect as a result of the care they receive. The CQC registers providers that are compliant with the standards of quality and safety and, primarily through inspections, assesses compliance on a regular basis. Specific powers to intervene include powers to prosecute unregistered providers, civil powers to ensure compliance and powers to prosecute, fine and warn registered providers failing to comply with legal requirements.

Monitor is an independent regulator accountable to parliament responsible for overseeing the performance of NHS foundation trusts in relation to finance and quality of care. The main tool Monitor has to regulate is the provider licence, which sets out obligations of providers in five main areas: pricing; choice and competition; integrated care; continuity of services; and governance conditions. Monitor uses a risk rating system to identify risk of failure but regulatory action is considered on a case-by-case basis rather than being automatically triggered. NICE has no regulatory standard enforcement powers per se but is responsible for describing high quality standards and should work closely with the CQC and Monitor.

In addition to these regulators professional statutory bodies also have an important role in England. There are eight health and care professional regulatory bodies covering England. They typically maintain a register of individuals who meet standards of training and who are, therefore, permitted to use a protected professional title; set standards of training and education; and establish standards of practice or codes of conduct against which they monitor and enforce standards.

As noted, regulation has undergone considerable change following the 2012 Health and Social Care Act. At time of writing, the system is also responding to two major reports on quality and safety in the NHS. This includes the independent inquiry into care provided by Mid Staffordshire NHS Foundation Trust,¹⁴⁴ and a subsequent report by the Department of Health setting out a commitment to improving the safety of patients in England.¹⁴⁵ The latter of these recommends a simplification of the regulatory bodies in England but it is not yet clear how this will evolve. However, it is conceivable that the roles and responsibilities of the respective organisations in England will continue to change as new structures and governance arrangements are being implemented.

5.1 **System overview**

5.1.1 **Organisation and financing of the health and social care system**

The public administration system in Finland consists of three levels: state, province and municipality, with six provinces (including the autonomous Åland Islands), 18 regions and 336 municipalities (2011).¹⁶⁸ In line with this overall administrative structure, Finland's health system is highly decentralised. It is mainly funded through local and national taxation and delivery of healthcare is mainly public, with municipal taxes accounting for almost half of all funding, supplemented by state subsidies, national health insurance (NHI) contributions and some co-payments.

Municipalities are responsible for the provision of health and social services, which they deliver independently or in cooperation with neighbouring municipalities. They can purchase services from other municipalities, non-governmental organisations or for-profit providers. Municipalities are responsible for organising primary care: in 2011, local authorities operated 172 health centres of which about 60 per cent are municipal health centres and a further 20 per cent operated by joint municipal authorities.¹⁶⁹ Furthermore, through participation in hospital districts, municipalities oversee secondary and tertiary care. Employers also provide primary care services to their employees as part of occupational health services; these are jointly financed by NHI, employers and employees, and offered by company-owned healthcare units, municipal health centres or, in most cases, private providers.¹⁷⁰ Finland operates a gatekeeping system in which patients are assigned to a GP at their local health centre, with recent moves to broaden choice of primary care provider within geographical limits.

Most residential care facilities, such as nursing homes and health centre hospitals, are operated and owned by municipalities. In 2006, about 90 per cent of nursing home care was provided in municipality-owned institutions; public sector provision of home-based services is under 50 per cent.¹⁷¹ Municipalities may further purchase services both from the voluntary sector (such as sheltered housing, group homes and support for people living in their own home), and private providers (such as private nursing homes and home nursing).¹⁷²

5.1.2 **Principles of health and social care governance**

The foundations of the health and social care within the Finnish system are laid down in the country's constitution, which states that 'the public authorities shall guarantee for everyone, as provided in more detail by an act, adequate social, health and medical services and promote the health of the population'.¹⁷³

In Finland, the role of central government in health and social care is largely that of a steering function, with few levers to directly control health service provision at local level. The Ministry of Social Affairs and Health (MHAS) directs social and health services at the national level. It defines general social and health policy, prepares major reforms and proposals for legislation, monitors their implementation and assists the government in decisionmaking. A main steering tool at national level is the National Development Plan for Social Welfare and Health Care (Kaste Programme)¹⁷⁴ (formerly Social Welfare and Health Care Target and Action Plan). Each incoming government draws up a social welfare and healthcare programme for the forthcoming four years in government that is used to manage and reform social and health policy and is a cooperation plan between municipalities and the state. The programme defines the key social and health policy targets, priority action areas for development activities and monitoring as well as essential legislation projects, guidelines and recommendations, but does not draw up a set of national standards. Municipalities and joint municipal boards for social welfare and healthcare can apply for discretionary government transfers for creating and implementing good practices.

Conversely, municipalities have substantial autonomy in decisionmaking within the legislative framework set by the central government, as guaranteed by the constitution.¹⁷⁵ The municipalities form 20 hospital districts, which cover populations of between 50,000 and 1.2 million residents, and are responsible for organising and providing all inpatient and outpatient specialised healthcare within a region, as well as supplying them with the necessary funding.¹⁷⁶ Each hospital district is governed by a council and an executive board, whose members are appointed by the participating municipal councils, in proportion to the size of each municipality. District councils are thus directly accountable to the municipalities.

During the past ten years, there have been moves to merge primary and secondary care providers into single organisations.¹⁷⁷ These reforms aim at improving the coordination of services, typically organised separately by municipalities and hospital districts, and at reducing inefficiencies of care provision, especially of smaller municipalities.

5.1.3 Recent reforms of the health and social care systems

The 1972 Primary Care Health Act forms the basis for further development of the healthcare and health policy systems. There have been amendments to the system over the years, but it was only more recently that more fundamental changes have been considered.

For example, in 2005, the government launched the Paras-project aimed at restructuring local government and services ('Paras', meaning 'Best') with a view to create a larger population base for service delivery by merging municipalities, and to enhance collaboration between municipalities on service arrangement and provision.¹⁷⁸ During the Paras-project, the number of municipalities decreased by about 100, while municipality cooperation in organising primary care services increased. The current government, in place since June 2011, has replaced the Paras-project with a new project to significantly decrease the number of municipalities to as low as 70–150 municipalities and to restructure the healthcare system. It foresees a restructuring of the present hospital district system into large municipalities and regional municipal federations, and tertiary care organisations with responsibilities in coordination, development and highly specialised

care. These plans are yet to be clarified and revised; they are expected to be confirmed by the end of 2012. The main rationale behind the renewed reform effort is a perception of a weak primary care infrastructure and rising health inequalities, variation in the availability and quality of services across the country, costs pressures *vis-à-vis* an ageing population and workforce shortages at local level.

In parallel, the 2010 Health Care Act, which came into force in May 2011, sought to enhance access to services by introducing patient choice of primary care and secondary care provider outside their area of residence (initially within certain boundaries, from 2014 country-wide) and of a joint register of patient records between primary and secondary care.¹⁷⁹ It also introduced provisions for all local authority healthcare centres to coordinate services, and to develop a plan for quality management and for ensuring patient safety in cooperation with social services. The precise content of such plans is stipulated by governmental decree.¹⁸⁰

In 2001, the government, in cooperation with the Association of Local and Regional Authorities, developed a national framework for the quality of care for the elderly, revised in 2008 in the light of experiences with the earlier framework and research evidence that had emerged since.¹⁸¹ The framework seeks to help municipalities and cooperation districts to develop their services for older people. Municipalities are required to develop local 'old-age strategies' and integrate these into their local budgets. Provisions as set out in the National Framework High-Quality Services for Older People are set to be strengthened within a new law currently in consultation.¹⁸² Specifically, the proposed act seeks to ensure the right of older persons to care according to their needs. Older persons should be entitled to the care and rehabilitation defined in the service plan within the framework of social services. The act stipulates the appointment of a service coordinator responsible for ensuring that the older person will obtain the services set out in an individual service and care plan. It has also been suggested that the care worker will be responsible for ensuring the quality of services and required to report any potential problems in the services provided to the responsible authority. It further sets out stipulations for stronger involvement of older people in decisionmaking about their care. The draft law is currently under consultation.

5.2 National framework regulatory or otherwise for care quality

5.2.1 Sources of minimum standards of quality in the health and social care systems

Legislation in Finland is covered at three levels: the constitution, acts, and decrees, each of which must build on the other. The Primary Health Care Act from 1972 defined the most important specifications for the healthcare system in Finland. In addition to the laws within this act, there is legislation governing for example specialised healthcare, the rights of patients and mental health services. The 2010 Health Care Act has integrated part of the Primary Health Care Act and specialised healthcare act into a single act. In the field of social care, regulation comprises around thirty legislative acts defining and setting requirements for provision of social care.

The Finnish constitution requires the national government to safeguard the implementation of fundamental and human rights, including the right to equal treatment and essential care. This is further specified in the 1992 Act on the Status and Rights of

Patients, which states that ‘[t]he patient has a right to good quality healthcare and medical care. The care of the patient has to be arranged and he/she shall also otherwise be treated so that his/her human dignity is not violated and that his/her conviction and privacy is respected’.¹⁸³ It also states that patients have to be informed, to confidentiality, as well as the right to object and to appeal to the relevant authorities.

In addition to these national frameworks set by government, there is a range of national programmes, information and resources that steer quality of healthcare services. Finland introduced a voluntary healthcare pilot accreditation programme as early as 1993.² The first Finnish National Policy on Quality for Health Care was launched in 1994, followed by a set of recommendations in 1995 and 1999.¹⁸⁴ The Kaste Programme described above also focuses on quality issues, including improved client responsiveness, timeliness and access, a reduction in regional inequalities related to specialist healthcare, and more specifically improved wards for elderly people. Important initiatives involve leadership and management, health of the workforce, monitoring, and benchmarking systems on a national basis. Other than these forms of guidance, there are no obliging standards of care; few exceptions include those for waiting times and maternity and child welfare clinics.

During the last two decades the most important national level tool to steer health and social services has been ‘steering by information’ (in addition to legislation and money). The main actor responsible for this mechanism is the National Institute for Health and Welfare (THL), which has produced benchmarking data for hospital districts. THL is responsible for the majority of quality registers, which in Finland include both health and quality registers; it further provides guidance and information, and conducts research and development-programmes. The quality of services is promoted by a programme enhancing patient safety.

5.2.2 Overview of main bodies responsible for standard setting and enforcement

Given the role of Ministry of Social Affairs and Health as primarily a steering body, there are only few organisations in Finland that have roles comparable to those which set and regulate standards of care in other countries. Table 5.1 provides a summary overview of the main bodies responsible for standard setting and enforcement in the health and social care sectors in Finland.

Table 5.1 Summary overview of main bodies responsible for standard setting and enforcement in the health and social care sectors in Finland

Agency or body	Main roles and functions
National Supervisory Authority for Welfare and Health (Valvira)	Operates under the Ministry of Social Affairs and Health. Its main statutory purpose is to supervise and provide guidance to healthcare and social services providers, alcohol administration authorities and environmental health bodies, and to manage related licensing activities.
Regional State Administrative Agencies	Part of national administration. The agencies strengthen implementation of basic rights and legal protection, access to basic public services, environmental protection, environmental sustainability, public safety and a safe and healthy living and working environment in the regions.
National Institute for Health and Welfare (THL)	Operates under the Ministry of Social Affairs and Health. THL promotes the welfare and health of the population, acts to prevent diseases and social problems and develop social and health services. For social and health care system THL provides guidance and information, conducts research and development programmes and maintains registers and produces statistics.

5.3 National regulatory bodies

5.3.1 National Supervisory Authority for Welfare and Health (Valvira)

Legal status and organisational structure

Valvira is the National Supervisory Authority for Welfare and Health operating under the Ministry of Social Affairs and Health.¹⁹ Its main statutory purpose is to supervise and provide guidance to healthcare and social services providers, alcohol administration authorities and environmental health bodies and to manage related licensing activities. Valvira was created in 2009 as a merger of the National Product Control Agency for Welfare and Health (STTV) and the National Authority for Medicolegal Affairs (TEO/NAMLA). It is a nationwide authority which guides municipalities and Regional State Administrative Agencies on legislation associated with Valvira’s jurisdiction.

The organisation comprises six departments with Information and Customer Services as integrated services across departments (

Figure 5.1).

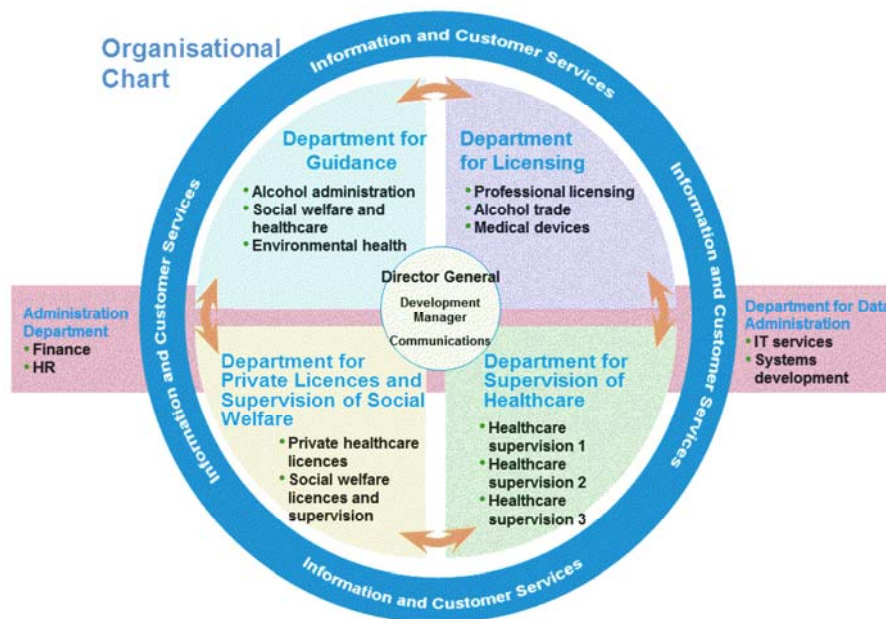


Figure 5.1. Organisational structure of Valvira

SOURCE: Valvira (2013)¹⁹, with permission.

Valvira’s stated purpose is ‘to protect the right of all Finnish residents to a living environment that promotes their health and welfare and to assure their access to social and healthcare services that are both safe and adequate’.¹⁹ From November 2009 on, Valvira

also became responsible for monitoring the manufacture and marketing of medical devices and promoting their safe use; this function was previously held by the Medical Devices Department of the National Agency for Medicines. Its fields of responsibility are in healthcare and social care, alongside medical devices, gene technology, environmental protection and health and the supervision of alcohol and tobacco products. In the following, we only discuss Valvira's competencies as they relate to health and social care specifically.

Concerning healthcare, Valvira's roles include maintaining a register of healthcare professionals, supervision of healthcare providers, handling patient complaints related to severe treatment injuries and granting licences for abortion in special cases. It also monitors the adherence of medical devices to the legislation and regulations and promotes their safe use. However, given that only few standards are based on legislation, Valvira will use measures such as conditional fines or licence revocation only in very severe cases. With regard to social care, Valvira's functions are shared with the Regional State Administrative Agencies which supervises social care facilities. Specifically, Valvira's role is to ensure that guidance given by the agencies is coherent throughout the country. One shared responsibility is social care complaints, which are primarily processed in the appropriate Regional State Administrative Agency but referred to Valvira if the complaint requires an evaluation of a nursing unit.

Valvira's competencies are regulated within the national regulatory framework, including the Health Protection Act, the Primary Healthcare Act, the Act of Specialised Medical Care, the Mental Health Act, the Act on the Status and Rights of Patients, the Act on Healthcare Professionals, the Act on Medical Devices, the Social Care Act and the Act on the Status and Rights of Social Care Customers.

Scope of action

The main areas of scope of action for Valvira are licensing, supervision, and guidance. Licensing in relation to health services and social care includes professional licences, that is, the licensing of protected occupational titles, and fixed-term licences; and private healthcare, namely issuance of national licences for private healthcare providers. Supervision includes healthcare professionals and healthcare units, social care units and the safe and appropriate use of medical devices.

Valvira's guidance role involves the provision of guidance to the six Regional State Administrative Agencies and local authorities in the areas of health services and social care, with the aim to ensure that guidance, licensing and supervision practices are harmonised regionally and locally. Valvira and the Regional State Administrative Agencies carry out their supervisory duties on the basis of jointly agreed supervision programmes.

Regulatory mechanisms to ensure standard adherence

As noted above, Valvira supervises and guides healthcare professionals and medical facilities both in the public and private sector to ensure the adequacy of services different healthcare professionals and medical facilities provide. Supervision of healthcare is divided into four sections:

- (i) ex-post monitoring of individual cases (for example, handling patient complaints after serious treatment injuries)

- (ii) plan-based supervision (supervision following national or municipal healthcare supervision plans or internal supervision of medical facilities)
- (iii) guidance and advice for healthcare professionals and medical facilities
- (iv) issuing of requested statements and official documents to other authorities and courts of justice (including medical statements on causality of injuries for use of insurance officers).

Severe patient complaints (ie related to deaths) are handled by Valvira. Where misconduct by a professional or provider organisation is identified (usually due to patient complaints), Valvira can give orders to correct the situation to prevent their repetition in the future. Valvira may also take measures against professionals for misconduct by taking away physicians' licences.

Valvira also supervises municipal health protection authorities in controlling compliance with the Health Protection Act. This includes environmental health issues, such as food and water safety.

As indicated earlier, in collaboration with the six regional administrative agencies responsible for supervising social care, Valvira handles welfare-related supervisory cases where these are of 'nationwide importance and matters of principle'; other complaints are addressed by the regional agencies. Where Valvira does take responsibility, its handling of the case will be taken as precedent for regional administrative agencies to follow in similar cases. Jointly with the agencies, Valvira develops national supervisory programmes on welfare as they relate, for example, to elderly welfare, child welfare and substance abuse services.

5.4 Quasi-governmental and other actors

5.4.1 National ombudsman

The national ombudsman exercises oversight to ensure that public authorities and officials observe the law and fulfil their duties.¹⁸⁵ The scope of oversight also includes other parties performing public functions. The aim is to ensure good administration and the observance of constitutional and human rights.

5.4.2 The Association of Finnish Local and Regional Authorities

Local authorities are responsible for providing welfare services for their residents, the most important of which relate to social welfare, healthcare, education, culture, environment and technical infrastructure. The membership of the Association of Finnish Local and Regional Authorities consists of the towns and municipalities in Finland. The association also provides services to hospital districts, regional councils and joint authorities. Municipalities are responsible for monitoring the health and social care services they have organised. Some municipalities have their own quality criteria for services. The municipal audit committee assesses whether the set operational and financial targets have been met. In addition, providers, public and private, monitor their own performance. Traditionally the inspection or audit system for providers is sanction led. In addition, the Association of Finnish Local and Regional Authorities provides a simplified self-assessment and quality management system.⁴⁰

Finnish Medical Association

The Finnish Medical Association (FMA) is a professional organisation, with almost all (94 per cent) doctors practising in Finland being members. The association works in numerous ways to develop healthcare and advance medical expertise, on the basis of the professional knowledge of its entire membership. The association is active in relation to ethical issues and safeguarding of the interests of doctors and patients, in Finland and internationally. In the beginning of 2011 the association had 23,130 members, 1,535 of whom were medical students.¹⁸⁶

The Finnish Medical Society (Duodecim)

Duodecim is an independent scientific organisation with almost 90 per cent of Finnish doctors and medical students, altogether over 20,000, as members. The society is responsible for the continuous professional development of doctors, although it is not the sole actor with this responsibility. The main activities include publishing the most important scientific medical journals in Finnish language and extensive educational programmes with yearly medical conventions in all five cities with a medical faculty. The society also produces and updates national evidence-based clinical practice guidelines. The society evaluates continuous medical education and supports research through its own research foundation.¹⁸⁷

5.5 Case studies

Case 1: Use of conditional fines to improve waiting times

Following much public debate about waiting times, legislation came into force in March 2005 that defined maximum waiting times for public sector healthcare. This reform has had a positive impact in reducing waiting times, although several municipalities and hospital districts had considerable difficulties implementing the corresponding legislation. In summer 2007, the National Agency of Medico-legal Affairs (now Valvira) approached municipalities and health centres which did not comply with the maximum waiting time guarantee via a letter, urging them to fully implement the guarantee and asking for written explanation about the situation. In January 2008, hospital districts were approached again and requested to correct the waiting times issues in specialist healthcare so as to demonstrate implementation of the legislation no later than July 2008. In addition, the agency imposed a conditional fine on three hospital districts (Kanta-Häme, Varsinais-Suomi and Kainuu) in March 2008. This was the first time that a national administration had employed conditional fines to steer municipal health service providers. All three hospital districts did respond and managed to rectify the problem, and therefore avoiding the conditional fine.

These measures had some effect in that the number of those waiting more than six months almost halved between December 2007 and April 2008. However, problems remained and Valvira has since imposed further conditional fines on hospital districts; most recently (June 2012) nine (of a total of 20) hospital districts had a fine imposed.

Case 2: Understaffing in a nursing home

Keinukamari is a nursing home in the city of Hämeenlinna. The facility was built in 2008, containing 67 beds. Keinukamari is part of the municipal social services, although the operations of the nursing home are outsourced to the private social- and healthcare

company Attendo, which held a contract with the city of Hämeenlinna until the end of 2012.

In November 2010, staff of Keinukamari raised the issue of understaffing, by lodging a complaint to the Regional State Administration of Southern Finland. In early 2011, the city of Hämeenlinna reported that it had rectified the problem with Attendo. Despite this, by July 2011, the Regional State Administration of Southern Finland stipulated that Keinukamari remained understaffed, requiring a staff to bed ratio of 0.6 compared to the existing 0.5 staff to bed ratio. National guidelines issued by the Ministry of Social Affairs and Health require for this ratio to be 0.7–0.8 (minimum 0.5–0.6). Following this decision, the city of Hämeenlinna and Attendo increased staffing somewhat, noting a ratio of 0.5 as sufficient given that Regional State Administration had approved this ratio when it was permitted to operate as a nursing home in 2008.

However, in May 2012, the Regional State Administration renewed its request for increasing staffing, on grounds that administrative personnel should not be included in the staff to bed figures, giving Keinukamari until July 2012 to rectify the staffing issue. However, the city of Hämeenlinna objected to this request, noting that there was no need to increase staff numbers. The contract with Attendo was terminated by the end of 2012 and from March 2013, the service is operated by the city of Hämeenlinna.¹⁸⁸

5.6 Summary and conclusion

Finland's health system is highly decentralised and is mainly funded through local and national taxation. Health system governance is shared by the centre and the municipalities. Standards of care are practically embedded within the Finnish constitution, which provides the legal foundation for national regulation. Both the Act on the Status and Rights of Patients and the Primary Health Act have served to encompass the main standards of care for all health and social care services. In addition, the National Development Plan for Social Welfare and Health Care (Kaste Programme) defines the key social and health policy targets, priority action areas for development activities and monitoring as well as essential legislation projects, guidelines and recommendations, while not developing national standards as such.

The Finnish regulatory system can be characterised by a system of self-regulation and voluntarism, with some aspects of meta-regulation such as mandated continuous improvement; external clinical audit; mandated incident reporting system; consumer complaints through Valvira as main national regulatory body, the Regional State Administration, and the ombudsman. Other quasi-governmental bodies include the National Ombudsman, the Association of Finnish Local and Regional Authorities, and the Finnish Medical Association. However, most of the regulatory monitoring responsibility is understood to be operated under Valvira.

6.1 **System overview**

6.1.1 **Organisation and financing of the health and social care systems**

In the German federal system, regulation of healthcare is shared between the federal and 16 state governments and corporatist actors. The German health system is financed mainly from statutory health insurance, complemented by out-of-pocket payments, taxation and voluntary health insurance. About 90 per cent of the population are covered by statutory health insurance (SHI), with the remainder covered by substitutive private health insurance.⁵⁰

The Federal Ministry of Health is not directly responsible for ensuring access to healthcare. This function has been delegated to the federal states and corporatist actors at the various levels of administration. For example, responsibility for overseeing ambulatory care in the SHI system is delegated to the federal as well as regional SHI physician associations (Kassenärztliche Vereinigung, KV), while the regulation of hospitals falls under the remit of the states. The main role of the Federal Ministry of Health is to secure and maintain the publicly-financed SHI system.¹⁸⁹

Since 2009, all residents have been required to take out health insurance. SHI contributions are income-dependent (15.5 per cent of gross income since 2011) and shared between employer and employee. Dependants are covered free of charge; those receiving social assistance or long-term unemployment benefits are covered by the state via the municipalities or the labour agency. Under statutory health insurance, patients are entitled to access a comprehensive set of healthcare services, defined by law. Individuals have (almost) free choice of SHI fund, with a risk compensation mechanism (Risikostrukturausgleich, RSA) introduced in 1994 to compensate for differences in populations insured by different funds. Initially adjusted for age, sex and incapacity to work only, since 2009, SHI funds receive centrally allocated risk-adjusted contributions which are additionally based on morbidity.

Healthcare services are provided by a mix of public and private providers. Ambulatory care is mainly provided by office-based primary and specialist care physicians who have been granted a monopoly to provide care outside hospital. Patients generally have free choice of any provider in the ambulatory care sector. Since 2007, SHI funds are legally required to offer GP-centred care plans (GP contracts), in which members agree to always seek care

through their family physician first (although in reality these contracts hardly exist). All patients also have some choice of hospital upon referral. Hospitals are public (eg owned by a state, district or city), private for-profit and private not-for-profit (eg owned by a church-based charitable organisation).

Social care is provided by mainly private (traditionally non-profit) organisations, supporting the elderly, children with special needs, mentally ill and the physically or mentally handicapped. Federal states are responsible for planning (and guaranteeing the provision) of institutionalised care and schools for children with special needs. Long-term care is financed through statutory long-term care insurance and provided as care allowance, home care, or nursing home care.^{190 191}

Statutory long-term care insurance is nearly universal and administration of the scheme is through statutory health insurance funds ('long-term care funds'). Similar to SHI, long-term care insurance contributions are income-dependent (currently 1.95 per cent of gross income; 2.2 per cent for those without children). However, in contrast to healthcare, benefits under long-term insurance are granted upon needs assessment only, according to type, frequency and duration of the need for nursing care and are capped per month according to care needs.

6.1.2 Principles of health and social care governance

Federal legislation relating to social welfare, including health and social care, is set out in a series of social code books (SGB). Social Code Book V defines the roles and responsibilities of all health system actors as they relate to SHI. The social code also defines the entitlements of patients and broadly sets out the principles for the provision, organisation and financing of publicly-financed healthcare. This includes a commitment to solidarity in financing and providing health services; efficiency of service provision and insurance administration; and stability of contribution rates to SHI funds. Social code books are amended each time a new law is passed.¹⁸⁹

In the SHI system, the Joint Federal Committee (Gemeinsamer Bundesausschuss, G-BA) is the highest decisionmaking body. It is composed of the National Association of Statutory Health Insurance Funds and the federal associations of healthcare providers (physicians, dentists and hospitals); patient representatives are involved in an advisory role.^{189 192} The G-BA issues binding directives on treatments, quality assurance and minimum standards of care, which are implemented by the SHI funds, hospitals and associations of physicians (see below).

The principles of governance of long-term care insurance are set out in *Social Code Book XI*. It sets out the tasks of the Federal Association of Long-term Care Funds (Spitzenverband Bund der Pflegekassen).

6.1.3 Recent reforms of the health and social care systems

Over the past 20 years or so, the German healthcare system has seen a succession of reforms that principally aimed at cost containment alongside measures that sought to enhance efficiency, such as through promoting competition among statutory insurance funds; successive efforts to enhance quality of care and overcoming fragmentation between sectors in delivery, administration and financing; and the introduction, in 1995, of statutory insurance for long-term care.¹⁹³

The 2000s saw a series of regulatory changes including, in 2000, the introduction of provisions for the development of integrated care structures between the ambulatory care and hospital sectors through the 2000 SHI Reform Act while the 2001 Risk Structure Compensation Scheme Reform Act introduced, from 2002, structured care programmes for those with chronic disease (disease management programmes, DMPs).¹⁹³

The 2004 SHI Modernisation Act introduced a range of measures seeking to enhance the quality of care, efficient coordination and patient participation. This included the introduction of the G-BA as a means to improve the coordination of decisionmaking across sectors; the G-BA was also delegated tasks for quality assurance to integrate quality measures into administrative decisions and to better link them to incentives and sanctions. The reform further established the Institute for Quality and Efficiency (IQWiG), to support the G-BA in its decisionmaking. It further introduced mandatory annual minimum service volumes as a quality assurance measure in the hospital sector for a range of specific services which have to be met by hospitals if they wish to qualify for reimbursement through SHI. Annual minimum service volumes were introduced nationwide on five surgical procedures: kidney, liver, stem cell transplantation, complex oesophageal, and pancreatic interventions.¹⁹⁴ In addition, the 2004 reform saw a further strengthening of integrated care and of GP-centred care. It introduced medical care centres (MVZ) which provide care across several healthcare specialities within the ambulatory care sector.¹⁸⁹

Provisions introduced with the 2004 reform were enhanced by the 2007 Act to Strengthen Competition in SHI (GKV-WSG).¹⁹⁵ It made health insurance mandatory for all and expanded the existing risk structure compensation scheme to include morbidity-oriented factors in the allocation of payments from the newly established 'Health Fund' as single entity for pooling and allocation of funds within SHI, from 2009. It also introduced a uniform SHI contribution rate set by government (for 2009 and 2010) and stipulated for the federal associations of SHI funds to form a single association from 2008 (National Association of Statutory Health Insurance Funds).

More recent developments include the 2008 reform of long-term care which sought to strengthen the core principle of long-term care delivery which prioritises community care over inpatient care.¹⁹⁶ This was to be achieved through the step-wise increase of care allowance and financial support for short-term care arrangements as well as the introduction of individual advice and support for those eligible for long-term care. It also introduced a range of measures to enhance the quality of long-term care provision, including the introduction of centrally developed quality standards ('expert standards') that are binding on long-term care providers, of annual (unannounced) inspections, and a requirement to make available inspection reports (see below). It further committed the federal government to present to Parliament a report on long-term care, every four years from 2011.

The latest reform efforts include the 2010 SHI Financing Act (GKV-FinG),¹⁹⁷ the 2011 Act for the Improvement of SHI Healthcare Services (GKV-VStG)¹⁹⁸ and the 2013 Patients' Rights Act.¹⁹⁹ GKV-Finanzierungsgesetz, which came into force in 2011, focussed on cost-containment, involving measures to secure financing of the SHI system and reducing expenditure through for example capping spending in ambulatory care and the

pharmaceutical sector in particular. The subsequent SHI Healthcare Services Act introduced a range of measures which is aimed at improving the provision of healthcare services, centring on the ambulatory (outpatient) sector to address under- and oversupply of services.²⁰⁰ The 2013 Patients' Rights Act seeks to strengthen patients' rights, with a key measure involving the incorporation of a so-called 'treatment agreement' between healthcare professionals and patients into the Civil Code (Bürgergesetzbuch, BGB). It introduced a statutory duty for services providers to comprehensively inform about the treatment, including risks, alternatives, and potential implications for costs to treatment; a duty to ensure comprehensive documentation of the treatment process; a right for patients to access their records; and more rights for patients in relation to statutory insurance funds.

6.2 National regulatory or otherwise for care quality

6.2.1 Sources of minimum standards of quality in the health and social care systems

In the German healthcare system, measures to ensure quality of care were traditionally left to professional self-regulation and the monitoring of safety. However, with the 1989 Health Care Reform Act, quality assurance measures became mandatory, with stipulations strengthened in successive reforms; a legal obligation for the hospital and ambulatory care sectors to engage in external quality assurance and internal quality management was introduced in the early 2000s.²⁰¹ The legal requirements are set out in Social Code Book V, constituting a framework within which the various actors have the freedom to make relevant formal arrangements.

Thus, since 2000, hospitals have been required to operate internal management systems as well as to negotiate contracts with SHI funds on external quality assurance measures. This was to enable benchmarking through the use of standardised documentation of quality indicators.⁵⁰ This process was supported by regional offices for quality assurance (LQS). These data were initially compiled and analysed at national level by the Federal Office for Quality Assurance (BQS), established in 2001, with findings fed back to individual hospitals in the form of reports and recommendations. Reporting was on single indications; quality indicators included process measures (eg surgical intervention rates) and outcome measures (eg survival following heart surgery). This system was initially designed for use by providers. Thus, data and indices were published at the aggregate level only; data on individual hospitals were not available in the public domain. However, hospitals were able to view their own performance data and those found to be underperforming on a given indicator ('outliers') were required to explain their results to the BQS.⁵⁰ Data were also published in the form of an annual quality report on hospitals for the years 2001 to 2008. From 2010, these tasks were transferred to the AQUA-Institute (AQUA-Institut für angewandte Qualitätsförderung und Forschung im Gesundheitswesen), a private for-profit research institute (see below), with annual hospital quality reports published since 2010.²⁰² The institute has been commissioned by the Joint Federal Committee to further conceptually develop and implement quality assurance measures that seek to span across hospital and ambulatory care.

Furthermore, since 2003, hospitals have been legally required to produce and publish quality reports every two years (with 2005 being the first reporting year on 2004 data). These were to provide information to and support decisionmaking of all interested parties

in relation to hospital services; guidance for doctors in ambulatory care on referral and follow-up treatment of patients; and hospitals with the opportunity to publish information on quantity and quality of services provided and so help improving transparency.

Format and content of data to be documented by hospitals is determined by the G-BA.⁵⁰ Initially, quality reports only provided information on the scope and volume of services provided. More recently, a limited number of 29 structural, process and outcome measures were added to the reporting portfolio, with national averages provided to allow for comparison. In 2011, the G-BA mandated the public reporting of now 182 quality indicators from 2012.²⁰³ Quality reports have to be submitted to social health insurance and private insurers and their respective associations, which are required to make these available online.

As with hospitals, providers in the ambulatory care sector have been required to implement internal quality management systems according to minimum standards determined by the G-BA in 2006 (see below).

6.2.2 **Overview of main bodies responsible for standard setting and enforcement**

Table 6.1 provides an overview of the key actors involved in the regulating and assuring quality of care in Germany.

Table 6.1 Summary overview of main bodies responsible for standard setting and enforcement in the health and social care sectors in Germany

Agency or body	Main roles and functions
Federal Joint Committee (G-BA)	<p>Highest decisionmaking body in Germany’s self-governing statutory SHI system; independent from government, comprises representatives of the national associations of physicians, dentists, SHI funds and hospitals; patient representatives have an advisory role.</p> <p>Tasks include issuing binding directives, determining coverage and benefits, introducing or prohibiting technologies/ methods of care, or setting quality standards for different types of care.</p> <p>Has the ability to sanction hospitals financially for noncompliance with reporting requirements for quality data.</p>
National Association of Statutory Health Insurance Physicians (KBV)	<p>Represents the interest of the 17 state-level associations of SHI-accredited physicians and psychotherapists.</p> <p>Tasks include negotiating contracts with SHI funds and involvement in determining the benefits package for health services.</p>
Medical Review Board of the Statutory Health Insurance Funds (MDK)	<p>Established by the statutory health insurance (SHI) and long-term care insurance funds in each German state.</p> <p>Independent appraisers of the MDK assess services provided by doctors and other healthcare and long-term care providers for their appropriateness, effectiveness and efficiency.</p>
Institute for Quality and Efficiency in Health Care (IQWiG)	<p>Independent foundation which supports the G-BA; recommendations issued by IQWiG are not legally binding, but have to be considered in the G-BA decisionmaking process.</p> <p>Tasks include review of evidence-based guidelines and, upon request of the G-BA or the Federal Ministry of Health, assessment of benefits and harms of drugs, diagnostic and therapeutic interventions.</p>
AQUA Institute	<p>Independent research institute which supports the G-BA in the development of cross-sectoral quality assurance; also commissioned to oversee external quality assurance of hospital care.</p>

6.3 National regulatory bodies

6.3.1 Federal Joint Committee (G-BA)

Legal status and organisational structure

The G-BA is the highest decisionmaking body in the German statutory health insurance system. It is an independent legal body under public law, accountable to the Federal Ministry of Health and subject to its legal supervision. Its decisions must be submitted to the Federal Ministry of Health for review, which can veto these within a timeframe of two months. Review is limited to verification whether the decision is in line with legislation rather than content.¹⁷⁶ If there are no objections, directives are published in the Federal Gazette and become legally effective upon publication.^{189 204} In case of inactivity by the G-BA, the Federal Ministry of Health may issue a surrogate decision (Ersatzvornahme).

Since its creation in 2004 as a merger of several sector-specific committees at the federal level, the G-BA's structure and scope has undergone successive modification. Following the 2008 reform, the G-BA has only one decisionmaking body, the Plenary Group, which covers all decisions on ambulatory, dental and hospital care provided in the SHI system.^{189 205 206} The Plenary Group comprises of five representatives of the National Association of Statutory Health Insurance Funds, five from the federal associations of provider groups (physicians and psychotherapists, dentists, and hospitals), and three impartial members who also hold the chair. In addition, the group involves five representatives from patient organisations; their role is advisory and they do not have a vote in the decisionmaking process.²⁰⁵ Members are nominated by the respective federal associations and independent members are nominated by the provider or the payer side; decisions are made through majority voting in the plenum with the (independent) chair as the only full-time member.¹⁸⁹

In addition to the Plenary Group, the G-BA comprises a finance committee and, as at July 2012, nine subcommittees on pharmaceuticals, quality assurance, disease management programmes, ambulatory specialist care (regarding highly specialised care), methods evaluation, authorised services (services delivered by non-physicians upon prescription by physicians), health service planning ('needs-based planning'), psychotherapy, and dental treatment.²⁰⁷ A secretariat which includes the impartial members of the G-BA, office management and six units is responsible for managing the G-BA's tasks, such as meeting preparation, providing legal and methodological advice to committees, responding to external and legal inquiries, and public relations.²⁰⁸

Scope of action

The G-BA is mandated to carry out a number of regulatory tasks which are defined in Social Code Book V (§ 91–94).²⁰⁹ The directives of the G-BA are sublegal norms and are binding on all parties in the SHI-system but can be subject to scrutiny in social court (Figure 6.1).²⁰⁴

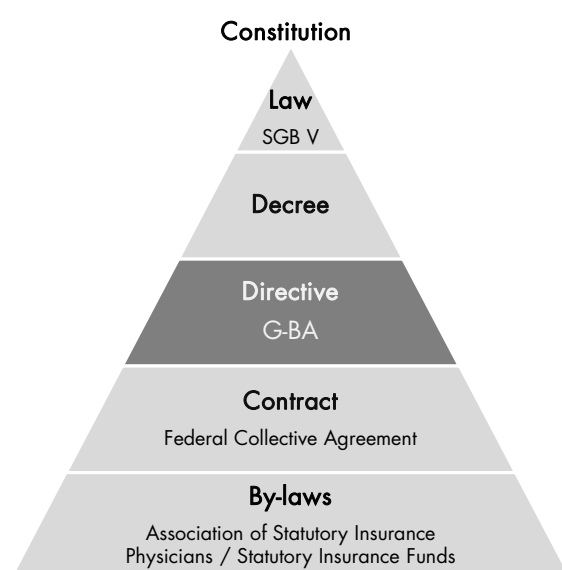


Figure 6.1 Federal Joint Committee: Legal status

SOURCE: Adapted from Gemeinsamer Bundesausschuss (2012).²⁰⁵

The regulatory mandate of the G-BA covers almost all sectors in the SHI system. The G-BA issues coverage decisions based on the general criteria set out in legislation; these stipulate that all SHI members are entitled to services that are adequate, expedient, cost-effective and do not ‘go beyond of what is necessary’. It further stipulates that a therapeutic benefit of services has to be based on the state of current medical knowledge.²¹⁰ Specific areas for decisionmaking include medical treatment; dental care; new technologies (diagnosis, treatment); reproductive, maternal and neonatal health; early detection and vaccination; palliative ambulatory care; medical rehabilitation; prescription of a range of goods and services such as pharmaceuticals, non-medical treatment such as physical therapy, medical aids, home care; and quality assurance. The G-BA is also responsible for negotiating rebates with pharmaceutical suppliers, and has developed a framework contract with the associations of pharmacists for the services provided by pharmacists under SHI.²¹¹

Regulatory mechanisms to ensure standard adherence

The G-BA is responsible for various areas of quality assurance of SHI-covered health and dental care, as well as for services provided in approved hospitals. Areas of regulation are:²⁰⁶

- National mandatory measures for quality assurance
- Promotion of quality assurance
- Continuous (medical) education for specialists, psychological psychotherapists and paediatric and adolescent psychotherapists to receive postgraduate training
- Minimum service volumes
- Quality measurement and control in ambulatory care
- Hospital quality reporting

- Quality management
- Quality assurance of day surgery
- Quality assurance of outpatient treatment in hospital
- Quality indicators for disease management programmes.

We here present two examples of quality assurance measures introduced during the 2000s.

Ambulatory care

Since 2003 providers of ambulatory care have to introduce internal quality management systems with the G-BA being responsible for developing guidelines (but leaving the choice of the respective quality management system to the provider). The regional associations of SHI physicians are required to implement external quality management systems; the development of which is typically based on the work of quality circles (expert groups working on quality of care and safety-related issues) in the realm of a G-BA framework.²¹² Mandatory quality management is further detailed in the Quality Management Directive of the G-BA on care provided in the ambulatory care sector, which has been in force from 1 January 2006.²¹³ Medical practices have been required to implement quality management systems by the end of 2009. While accreditation is still voluntary, it represents a way to demonstrate compliance with federal requirements and various accreditation programmes were developed by institutes or associations of physicians and hospitals such as Quality and Development in Practices (QEP) or Cooperation for Transparency and Quality in Health Care (KTQ).²¹⁴

National mandatory measures for quality assurance

The 2007 health reform set the path for developing multi-sector approaches in quality improvement and the alignment of quality assurance efforts across all healthcare settings in an effort to better address the traditional separation of ambulatory and hospital care in the German health system.²⁰⁶ The aim was to monitor, document and evaluate the quality of healthcare across settings over time, so allowing for comparative longitudinal cross-sectoral analyses. The G-BA, supported by the AQUA Institute (see below), was tasked with the development of a quality assurance directive covering ambulatory care, hospital care, multi-sector procedures, procedures with sector equivalence and cross-sectoral follow-up procedures. In 2010, the G-BA issued a directive on inter-provider and cross-sectoral quality assurance. It set out general requirements, including the collection of national quality indicators by the AQUA Institute, with further evaluation and application of measures for quality assurance to be implemented by the states on the bases of existing systems. The G-BA commissioned AQUA to develop indicators for eight interventions and methodological approaches for cross-sectoral quality assurance.²¹⁵

6.4 Quasi-governmental bodies

6.4.1 National Association of Statutory Health Insurance Physicians (KBV)

Legal status and organisational structure

The National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung, KBV) is comprised of 17 regional associations in the German states. The SHI physician associations are non-governmental public bodies under the legal

supervision of the Ministry of Health at federal or state level. Membership in regional associations is mandatory for physicians and psychotherapists who wish to be reimbursed under the SHI-system. Separate associations were established for dentists. The KBV represents the interests of physicians and psychotherapists at the federal level.^{189 216}

The KBV has two governing bodies: a board of two directors (elected every six years) and a delegates' assembly (60 representatives of regional associations) deciding on policies, guidelines, and regulations on issues in the remit of the KBV and electing the board of directors.^{189 216}

As set out in the Social Code Book V, the KBV and the regional SHI physician associations negotiate collective contracts with the association of SHI funds and other parties, and they determine and review, in cooperation with SHI funds associations, the fee schedule for office-based doctors (Einheitlicher Bewertungsmaßstab, EBM).¹⁸⁹ As noted earlier, the KBV also participates in healthcare decisionmaking at national levels as a formal member of the G-BA.

Scope of action

Physicians in the ambulatory sector reimbursed under the SHI are licensed by their regional association, which acts as a regulatory, administrative, and financing body coordinating between physicians and the SHI funds.²¹⁷

The regional physicians' associations monitor compliance with statutory obligations of doctors and psychotherapists through agreements on federal guidelines for quality assurance.²¹⁸ Relevant regulations in the ambulatory care sector include for example the guidelines of the KBV for quality assurance processes (QA guidelines) and agreements on special examination and treatment methods as part of the federal framework agreements of physicians and SHI funds (Bundesmantelverträge, BMV-Ä/EKV).²¹⁹

Regulatory mechanisms to ensure standard adherence

Central to quality assurance as overseen by the KBV are agreements and guidelines, often implementing decisions made by the G-BA.²²⁰ The 17 regional physicians' associations are responsible for quality assurance, implementation of quality management and approval of services. These responsibilities are based on national agreements and guidelines as well as on regional quality assurance agreements between regional physician's associations and SHI funds. Quality assurance is also informed by the work of 'quality commissions' and 'quality circles' which are adjunct to and/or approved by regional physicians' associations. Enforcement measures can range from requirements for additional training to the withdrawal of licenses for billing.

Within the AQUIK project (Ambulante Qualitätsindikatoren und Kennzahlen), the KBV developed, in 2009, the basis for assessment and steering of quality management in ambulatory care. It identified and tested a wide range of quality indicators used internationally, of which a total of 48 indicators were identified as a reliable set of quality indicators for care provided by SHI-accredited physicians.²¹⁸ Indicators cover a range of condition-specific areas such as hypertension, arthritis, chronic heart failure, urinary incontinence, HIV/AIDS, alongside tobacco use and weight management and organisational issues such as practice management. Indicators were incorporated for example into the Quality and Development in Practices (QEP) quality management

system, a practice certification system established by the KBV and the regional SHI physicians' associations.^{220 221}

6.4.2 **Medical Review Board of the Statutory Health Insurance Funds (MDK) and Medical Review Board of the National Association of Statutory Health Insurance Funds (MDS)**

Legal status and organisational structure

Federal structure of the MDK

The Medical Review Board of the Statutory Health Insurance Funds (MDK) is an umbrella institution established by the SHI funds and statutory long-term care funds, established in the German states. Each state has a regional MDK working group, which operates under the supervision of the Ministry of Social Affairs of the relevant state. The legal form of MDK in the eastern part of Germany is that of a registered association, in the western part it is a statutory body. The regional MDKs the Medical Review Board of the National Association of Statutory Health Insurance Funds (MDS) have established common expert groups and competence centres; together they form the MDK-alliance (MDK-Gemeinschaft).⁴²

Its governing bodies include the administrative board, which decides on the MDK statute, guidelines and budget, and the executive director, who is elected by the board. Members of the administrative board are nominated by the respective administrative boards of the associations of SHI funds. In 2012, the MDK employed around 7,000 staff.²²² The majority of auditors (660 as of September 2011) are nurses (95.8 per cent), and about 60 per cent of auditors have an auditor qualification; while nearly half the staff has a management-related qualification and 28.6 per cent of employees have an academic degree in a care-related subject or another academic degree.²²³

Tasks of the MDS

The MDS was established in 2008 as per Social Code Book V. It advises the National Association of Statutory Health Insurance Funds on issues of service and supply structures and long-term care. Every three years the MDS provides a report on the quality of ambulatory and inpatient long-term care, and aggregates data on individual needs assessments carried out by the MDKs into a national statistic. The MDS also has a statutory obligation to coordinate the technical work of the MDKs and it publishes guidelines for inspections and assessments to be used across all MDKs.²²⁴

Scope of action

The legal basis for the work of the MDK is outlined in Social Code Book V; the MDK is independent in fulfilling its tasks.²²⁵

Assessment of care services

Independent appraisers of the MDK assess the appropriateness, effectiveness and efficiency of services provided by doctors and other healthcare providers on the basis of the current state of scientific knowledge and legal requirements. Appraisers and the MDK do not interfere with medical treatment and services, and final decisionmaking is with the SHI funds.⁴¹ In this context the MDK has for example the statutory task of reviewing the billing of hospitals on behalf of SHI funds.²²⁶

Advice for statutory health insurance (SHI) funds on healthcare issues

The MDK also acts as advisor to SHI funds and their associations in questions of preventive, curative and rehabilitative care, and in designing the service and supply structures. This includes quality assurance in outpatient and inpatient care; hospital planning; development of compensation systems for outpatient and inpatient care; and the effectiveness and efficiency of new diagnostic and therapeutic methods. In addition, the MDK supports SHI funds in contract negotiations with the hospital associations, physicians' associations and other providers. MDK experts take part in deliberations of the G-BA supporting long-term care funds.⁴¹

Assessment of individual needs and levels of healthcare

The MDK carries out assessments of individual levels of care for decisions on reimbursement as per stipulations set out in Social Code Book V. These include reports on matters relating to disabilities; necessity, nature, scope and duration of rehabilitation services and measures; regulation of medicines, bandages, medical aids; assessments of individual needs for and the duration of hospital treatment; and assessment of individual needs for and the duration of home nursing care.⁴¹

Assessment of individual needs and levels of long-term care

Together with the MDK, long-term care funds assign the appropriate individual level of care and negotiate prices with care providers.¹⁹⁰ The MDK assesses individual long-term care needs and the level of individual care required in home care settings or in nursing homes. The MDK does so by assessing eligibility and need for long-term care; recommending the level of care; assessing individual ability to care for self; suggesting preventative and rehabilitative measures; providing recommendations on the type and level of care; and formulating an individual care plan.⁴¹

Quality assessment of long-term care services (home care and nursing homes)

The MDK is commissioned by the statutory long-term care funds to assess whether long-term care services (nursing homes and home care) comply with agreed quality standards.⁴¹ According to Social Code Book XI, the MDK is tasked with providing quality assessments of inpatient and outpatient long-term care services. Following the 2008 of long-term care, the MDK is required to conduct annual audits of service providers as a means to informing regional associations of long-term care funds; they also have to provide technical advice to nursing homes and other long-term care providers. Sections of the inspection reports have to be made publicly available by the regional associations of statutory long-term care funds. On-site audits of the MDK are focussed on process and outcome quality using random samples of patients and residents of nursing homes. Quality inspections are conducted on the basis of guidelines as set out in Social Code Book XI and of MDK guidelines which support the implementation of statutory requirements.²²³

6.5 Other actors

6.5.1 Institute for Quality and Efficiency in Health Care (IQWiG)

Legal status and organisational structure

The Institute for Quality and Efficiency in Health Care (IQWiG), established in 2004, is an independent scientific research institute, which evaluates benefits and harms of drugs,

diagnostic and therapeutic interventions and informs coverage decisions made by the G-BA. IQWiG was awarded a general commission in 2004 (extended in 2008) by the G-BA according to which IQWiG may select evaluation topics independently without prior approval of the G-BA or the federal Ministry of Health. However, priority topics are identified by the G-BA and senior leadership is appointed by the G-BA in consultation with the federal Minister of Health.

IQWiG was set-up as a foundation with a Foundation Council comprising representatives of the National Association of Statutory Health Insurance Funds (six members), the Federal Association for Statutory Health Insurance Physicians (two members), the German Federal Association of Statutory Health Insurance Dentists (two members) and the German Hospital Federation (two members). The board of directors comprises five members, of whom four are appointed by the Foundation Council and one is appointed by the federal Ministry of Health. IQWiG's status and tasks are described by law (ie within the Social Code Book V) and are further specified by a governmental regulation on early assessment of drug benefits and by the G-BA's code of procedure.^{227 228}

Scope of action

IQWiG was established to support the Federal Joint Committee in its decisionmaking process²¹⁰; this relationship is further illustrated in

Figure 6.2.

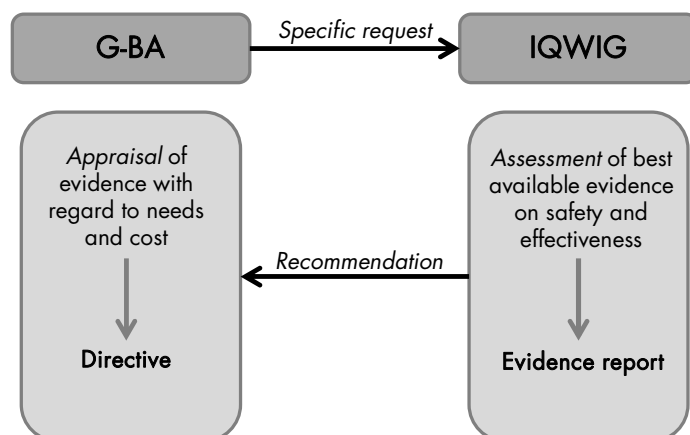


Figure 6.2 Collaboration between the G-BA and the Institute for Quality and Efficiency in Health Care

SOURCE: Adapted from Gemeinsamer Bundesausschuss (2010).²⁰⁵

IQWiG's tasks include reviewing the evidence of diagnosis and therapy for selected conditions, provide evidence-based reports on for example drugs, non-drug interventions, diagnostic and screening tests, and provide recommendations on disease management programmes (DMPs).^{201 229} As noted earlier, IQWiG informs reimbursement and coverage decisions of the G-BA. Two legal duties that are directly related to quality assurance are

reports and statements by IQWiG on the quality of services provided within the realm of the SHI system and the review of evidence-based clinical practice guidelines (CPGs).²⁰¹

Applications for evaluations may originate from various government sources and interested organisations, with the G-BA deciding on priority. IQWiG is then commissioned to undertake the research; it sets up a working group that defines the research question together with the G-BA or relevant stakeholders; develops a research protocol and reporting plan which are made public and can be commented on during hearings and in written form. The actual research usually involves external experts and is completed following additional stakeholder consultations. Final reports and recommendations are not legally binding and cannot be appealed.²²⁸

6.5.2 Institute for Applied Quality Improvement and Research in Health Care GmbH (AQUA)

Legal status

The Institute for Applied Quality Improvement and Research in Health Care (AQUA) is a private, for-profit company. In 2009, it was commissioned by the G-BA to support its statutory obligations for quality assurance, in particular in relation to the development of cross-sectoral healthcare quality assurance.^{230 231}

Scope of action

As set out in Social Code Book V (Section 137a (2)), AQUA's tasks include the measurement and reporting of the quality of care provided in hospitals; the development of cross-sectoral quality assurance; participation in implementation of cross-sectoral quality assurance; and publication of quality assurance measurement.²³⁰

External quality assurance of hospital care

AQUA monitors 30 clinical areas and aggregates annual results on quality indicators for these areas at federal level. Findings are reviewed by a federal Expert Committee of the German Hospitals Association, the National Association of Statutory Health Insurance Funds, the German Nursing Council, the German Medical Association, and patient representatives. Results are published in form of an (annual) hospital quality report, which presents the results of all indicators at patient and hospital level which are part of mandatory documentation. AQUA also prepares feedback reports for participating hospitals, with those hospitals identified as giving cause for concern on quality subject to a 'structured quality dialogue'.²³⁰

The structured quality dialogue seeks to support providers in the continuous improvement of the quality of care provided. Hospitals that were identified as potentially problematic based on quality indicators will be consulted to clarify whether observed outliers may simply be the result of computational or data issues, for example, where numbers are low (eg transplantation), or else, there are underlying quality concerns. Monitoring of clinical areas with low numbers is undertaken by AQUA while state-level regional offices for quality assurance (LQS) monitor clinical areas with a high numbers of cases. Accordingly, either AQUA or the relevant LQS will be involved in the structured dialogue, with supervision of the overall process led by the G-BA sub-committee for quality assurance for former and the steering committees of the federal states for the latter.²³⁰ Where an observed deviation from a reference value for a given indicator cannot be explained by underlying data issues, the hospital in question will be subject to an iterative process which may

involve inspection and discussion, and the development of an improvement plan which the hospital will have to report on.

Cross-sectoral quality assurance

The framework for cross-sectoral quality assurance along the entire care pathway is set out in Social Code Book V. It also stipulates also the rights and obligations of various the stakeholders in the system.²³² Topics for cross-sectoral quality assurance are identified by the G-BA, which commissions AQUA for developing the quality monitoring system. The process involves several stages, including expert consultation and recruitment of expert panel; systematic indicator search and expert review; outline of methodological approach to data collection; preparation of a preliminary report and stakeholder feedback; final report and approval by the G-BA. This will be followed by a directive issued by the G-BA which will make measurement and monitoring of indicators mandatory, with AQUA subsequently collecting and reporting on these indicators.²³²

By 2011, areas already covered or under development included colorectal cancer; arthroscopy of the knee joint; total hip and knee replacement; cataract surgery; cone biopsy; percutaneous coronary intervention (PCI) and coronary angiography. The process of data collection will typically be trialled with a subset of (volunteering) hospitals, and, following relevant regulation issued by the G-BA, data will eventually be collected into a federal data pool for hospitals licensed according to the Social Code Book. Collection of information is based on existing systems used for clinical and administrative purposes, and further supplemented by administrative claims data and patient surveys.²³⁰

6.5.3 German Agency for Quality in Medicine, AQUMED (ÄZQ)

Legal status and core tasks

AQUMED is a non-profit organisation, founded in 1995 by the German Medical Association (BÄK) and the National Association of Statutory Health Insurance Physicians (KBV) to support and advise the founding organisations on quality assurance for medical professionals.²³³ AQUMED's main working areas include appraising or producing guidelines, quality indicators and patient information; disseminating and implementing evidence-based guidelines; coordinating measures to prevent medical errors and enhance patient safety; developing methodologies for guidelines and evidence-based healthcare; and identifying and appraising quality innovations.²³⁴

The bodies of the institute consist of a board, with an annually rotating chair by the president of the BÄK or the chairman of the board of the KBV; a planning group, consisting of four members appointed by the BÄK and four members appointed by the board of the KBV; an advanced planning group, expert groups and the AQUMED's executive team.²³³

AQUMED's 2020 strategy focuses on evidence-based guidelines, improvement of patient safety, knowledge management for physicians in medical settings and across professions, improvement of independent continuous medical education, internationalisation of standards and norms in healthcare.²³³ AQUMED is a relevant actor in the development and implementation of evidence-based guidelines and was the founder of the German Clearinghouse for Patient Information, the co-founder of the German Network for Evidence Based Medicine, and it has set up the national programme for disease management guidelines in 2002.²³⁴

6.6 Summary and conclusion

Regulation of healthcare in Germany's federal system is shared between the federal and state governments and corporatist actors. The federal Ministry of Health is not directly responsible for ensuring access to healthcare as this function has been delegated to the federal states and corporatist actors. Within the SHI system, the Joint Federal Committee (G-BA) is responsible for issuing binding directives on treatments, quality assurance and minimum standards of care, which are then implemented by the SHI funds, hospitals, and physician associations.

Examples of measuring the impact of quality assurance

Evaluations of the impact of quality assurance and monitoring measures are available in the area of hospital care. For example, De Cruppé et al. (2007) examined the effects of annual minimum service volumes for German hospitals in five surgical procedures (kidney, liver, stem cell transplantation, complex oesophageal, and pancreatic) on the compliance rate of hospitals. Using data from a sample of 1,710 hospital quality reports published in 2004 (out of 1810 hospitals), the authors found comparatively high levels non-compliance. For example, of those hospitals performing transplantations, between 9 and 16 per cent did not comply with the standards, which was estimated to affect 1–2 per cent of patients. Also, 29 per cent of hospitals treating complex oesophageal and 18 per cent of those treating pancreatic interventions failed the standards, affecting 2–5 per cent of cases.¹⁹⁴ The authors concluded that excluding hospitals not meeting minimum service volumes from service delivery might raise questions of equality in access to hospital care.¹⁹⁴

The 2010 hospital quality report included quality data from almost 1,800 hospitals and showed that, compared to 2009, 65 quality indicators had improved.²³⁰ However, for the majority of quality indicators (n=236), there was no change, while deterioration was observed for 8 indicators. The federal oversight committees saw particular need for action on 9 quality indicators compared to 21 quality indicators in the preceding year. This observation was interpreted as a trend to overall improvement in the quality of care provided in hospitals in Germany.²³⁰

Evaluations of the activities of regulatory bodies remain limited. Landwehr (2009, 2011) reviewed the procedural and structural set up of the G-BA according to criteria such as inclusiveness, transparency and overall legitimacy.^{235 236} The G-BA, dominated by corporatist actors, was delegated a high degree of decisionmaking power concerning the definition of the health basket. The author noted that the G-BA therefore lacks transparency and inclusiveness due to the limited and restricted number of formal members, and also due to the lack of an appeal procedure, for example in case of ethical misjudgements. However, the involvement of major veto players in the decisionmaking process reduced the potential for opposition and increased effectiveness in terms of being able to make binding allocation decisions and facilitating implementation of decisions.

7.1 **System overview**

7.1.1 **Organisation and financing of the health and social care systems**

In the Netherlands, governance of the healthcare system is shared by the government and the corporatist (self-governance) sector. The role of government is largely restricted to overseeing and defining the rules for the healthcare system, following a move to strengthen market elements in healthcare with the 2006 health reform.^{48,237} From 2006, all Dutch citizens are required to take out (basic) private health insurance. Health insurers are predominantly not-for-profit; they cannot reject applicants and must offer a flat premium as well as basic, pre-defined health service package.⁵⁰ Health insurers, patients and providers interact in three markets (health insurance, healthcare provision, healthcare purchasing) while the government sets the regulatory framework in which competition and interaction takes place.²³⁸ The system has features of a social health insurance system, a national health service system, and a managed care system.²³⁹

The Dutch healthcare system can be distinguished into curative care, long-term care and public health, which is governed by municipal health services (GGDs), and social care. The health insurance system is comprised of four elements. The first element includes a mandatory social health insurance for long-term care (continuous care for chronic conditions) is regulated by the Exceptional Medical Expenses Act (Algemene Wet Bijzondere Ziektekosten, AWBZ) and mainly financed through income-dependent contributions.²³⁸ The second element is basic health insurance covering essential curative care which is regulated by the Health Insurance Act (Zorgverzekeringswet, Zvw). This system is financed by a flat-rate premium and an income-dependent contribution, pooled into the Health Insurance Fund and then allocated among the health insurers using a risk-adjustment mechanism. The third element comprises complementary voluntary health insurance (VHI) for services that are not covered under the AWBZ and Zvw schemes. The fourth element comprises the 2007 Social Support Act (Wet maatschappelijke ondersteuning, Wmo), which made municipalities responsible for the governance and provision of preventive care and social care that had traditionally been financed by the AWBZ. Thus, the Dutch cure and care sectors are governed at central level while social care and preventive care have been delegated to local government.

Healthcare services are generally delivered by private providers in both the ambulatory and hospital sectors, with office-based general practitioners acting as gatekeepers to secondary (hospital) care. They are remunerated through a combination of capitation and fee-for-service.^{240 241} Specialist medical care is provided in hospitals, which have traditionally been

owned and operated by private not-for-profit organisations. Since 2005, hospital services have been reimbursed on the basis of activity.

Long-term care in the Netherlands includes formal institutional care, home care and informal care. The majority of institutional care providers such as nursing homes, semi-residential care for the disabled and sheltered housing are non-profit organisations. Formal care at home is provided predominantly by private not-for-profit organisations and includes a broad range of services such as assistance, personal care, nursing care and treatment, with all services covered under the AWBZ. Domestic help, meals on wheels, home adjustments and transport are under the responsibility of local governments as per the 2007 Social Support Act.

7.1.2 Principles of health and social care governance

The Dutch healthcare system builds on corporatist arrangements with the state delegating regulatory authority to various actors such as associations of providers, insurers, trade unions and employers.²⁴² Governance of the healthcare system is therefore shared by the government and the corporatist (self-governance) sector,⁵⁰ whereby the role of government changed from setting volumes and prices and productive capacity to the setting rules of the game and having an oversight role on the functioning of the markets (principle of ‘managed competition’).²³⁸ In the Dutch healthcare system, the market is the predominant institutional arrangement using contracting as steering mechanism while the state maintains a certain level of intervention (regulation) and enforces (professional) self-regulation within certain limits which are set in collaboration with civil society actors. An example is the principle of ‘responsible care’ (‘verantwoorde zorg’), in which the state provides for a legislative framework for quality standards while the details are worked out by providers and professionals. This approach to health system governance is considered a key feature of the Dutch ‘polder model’, referring to the principle of coordination based on negotiations and consensus seeking between the ‘societal partners’ in healthcare, namely the state, professional bodies, healthcare providers, patients and insurers.²³⁷

The government is advised by a range of organisations to support operational priority setting. These include the Health Council (Gezondheidsraad), which advises the government on the scientific state of the art in medicine, healthcare, public health and environmental protection.²³⁸ The Council for Public Health and Health Care (Raad voor de Volksgezondheid en Zorg, RVZ) is an independent advisory body which supports health policy development by providing strategic advice on all areas of healthcare, social care and public health. The council consists of ten members, who are selected on the basis of their expertise and experience.²⁴³

Providers and insurers must produce an annual accountability reports (costs, activity and quality) and the National Institute for Public Health and Environment (RIVM) as a national research institute produces a biennial national report on health system performance, which is presented to Parliament as a means of holding the health ministry to account to its responsibility for quality, accessibility and affordability of the health system.⁴⁸

7.1.3 Recent reforms of the health and social care system

The most recent comprehensive reform was the 2006 introduction of the Health Insurance Act (Zorgverzekeringswet, Zvw) in 2006 with the abolishment of the distinction between

mandatory health insurance and voluntary private insurance, 'managed competition' in insurance and provider markets, and requiring citizens to take out (basic) private health insurance. Recent developments related to the improvement of care quality standards include the establishment of the Institute for Health Care Quality (het Kwaliteitsinstituut), which, from 2013, has taken on the tasks of the Dutch Council on Quality of Health Care (Regieraad Kwaliteit van Zorg). The Dutch Council on Quality of Health Care was established in 2009 for the coordination of guideline development and implementation.⁴⁸

With the introduction of the three markets into the Dutch healthcare system, transparency on quality of care has become a priority area for the government, based on the notion that for the market to function appropriately requires information to be provided to the key stakeholders in the system. To this end, the government supported the development of a website that provides comparative information on the prices and quality of services provided by healthcare providers, and offered by Dutch health insurers. In addition, the 1996 Quality of Health Facilities Act (Kwaliteitswet zorginstellingen, KZi), the 2006 Health Care Market Regulation Act (Wet marktordening gezondheidszorg, Wmg) and the 2006 Health Care Institutions Admission Act (Wet toelating zorginstellingen, WTZi) all require healthcare providers to report certain information about the quality of their services.

Against this background, the Ministry of Health has stimulated the development of performance indicators to improve transparency of the quality of the Dutch healthcare system. This includes for example the (temporary) Dutch Health Care Transparency Programme (programma Zichtbare Zorg), coordinated by the Health Care Inspectorate (IGZ) to support healthcare providers in the measurement of quality of care.²⁴⁴ All hospitals are required to annually report their performance, currently covering 43 conditions, which are made available to the public. Although the programme was intended to coordinate performance indicator development, other initiatives have started in parallel, including audit activities led by medical specialties (for example the Dutch Surgical Breast Cancer Audit) and health insurers. As a result, the system has become very fragmented, and research is currently underway to analyse the reliability, validity and comparability of the resulting performance information. From 2013, the aforementioned Institute for Health Care Quality has been given the role of steering, coordinating and guiding stakeholders involved in improving quality of care. The Institute for Health Care Quality is part of the Health Care Insurance Board (CVZ) to facilitate the link with health insurers and will take on the Transparency Programme. The vision and work programme of the new organisation are currently being developed, and, at present, it is foreseen that it will cover the cure and care sectors only.²⁴⁵⁻²⁴⁸

The Netherlands Public Health Federation (Nederlandse Public Health Federatie, NPHF) has recently published recommendations for the new Institute for Health Care Quality to also take the lead in developing and implementing a more integrated care approach to measure and assure quality of care.²⁴⁹ They emphasised the need to train all medical professionals (including medical specialists) towards developing a 'public health mindset', which will require integrated policy development, and multidisciplinary approaches.

7.2 National regulatory or otherwise framework for care quality

7.2.1 Sources of minimum standards of quality in the health and social care systems

The Dutch government has defined quality of care according to three dimensions: effectiveness, patient-centeredness and cost-efficiency, following the example of the OECD and WHO. These concepts formed the basis for the regulatory system to safeguard quality of care and so to deliver ('responsible care'). Cost-effectiveness is also considered as a dimension although, in practice, this dimension is often separated from quality of care, given the complexity of measurement.

As noted earlier, in relation to care quality the Dutch healthcare system is governed by the principle of 'responsible care', which is defined as care that is effective, safe, patient-centred and cost-efficient. This means that providers are responsible for the quality of organisational aspects and professionals for the care they provide enforcing professional self-governance. Dutch law provides for the legislative framework for quality and safety standards but does not stipulate a specific model or set of standards, so enabling the development of sector-specific standards, monitoring, control and evaluation mechanisms.²⁵⁰

Two relevant framework laws are the 1993 Individual Health Care Professions Act (Wet op de beroepen in de individuele gezondheidszorg, BIG) and the aforementioned 1996 Quality Act. The BIG Act regulates the provision of care by healthcare professionals for eight professions, including physicians, nurses, and other (non-)medical professions. It regulates quality assurance strategies such as revalidation, disciplinary processes and peer review. The Quality Act makes a functioning quality system mandatory for all healthcare institutions (excluding independent professionals such as GPs and dentists). It stipulates four requirements: healthcare institutions have to provide 'responsible care'; provide a structure that allows for the delivery of 'responsible care' and communicate how they achieve or maintain 'responsible care'; systematically monitor, control and improve the quality of care; and publish annual reports on quality management and quality delivered.²⁵⁰ Both regulations transfer the responsibility for quality to healthcare institutions and professional bodies and gives them the freedom to fulfil requirements by working out sector-specific lower-level regulation in a way that results in 'responsible care'.²³⁸

In addition, service user's rights are relevant with regards to ensuring the quality of (health) care: the 1995 Medical Treatment Contracts Act (Wet op de geneeskundige behandelovereenkomst, WGBO) defines the contractual obligations between patient and provider as they relate to informed consent, privacy protection and liability; the 1994 Health Care Complaints Act (Wet klachtrecht cliënten zorgsector, Wkcz) requires providers to establish accessible complaints procedures and to report annually on the number and type of complaints; and the 1996 Client Representation Act (Wet medezeggenschap cliënten zorgsector, Wmcz) safeguards the representation of clients in healthcare institutions through the creation of client councils.²⁵¹

In addition to the mandatory quality system for all healthcare institutions as enforced by the Quality Act, the Health Care Inspectorate increasingly expects all healthcare institutions to implement a safety management system, which includes, among other things, the annual reporting on activities warranting patient safety. Healthcare organisations are also frequently evaluated on their quality of care by an external

independent organisation (The Netherlands Institute for Accreditation in Healthcare, NIAZ) through accreditation, and by professionals through certification, following the certification scheme of the Foundation for Harmonization of Quality Review in Health Care and Welfare (Stichting Harmonisatie Kwaliteitsbeoordeling in de Zorgsector).

Recent developments further include the measurement and reporting on patient-experience and patient-reported outcomes using the Consumer Quality (CQ)-Index.²³⁹ The CQI is a standardised instrument for measuring patient experience with healthcare providers and insurers. Its development is coordinated by the Centre for Consumer Experience in Health Care (Centrum Klantervaring Zorg, CKZ), the national centre for the systematic measurement of patient experiences in health care.⁵⁰ CQI surveys are developed with public and private funding. Consequently, data are owned by the private organisations although all findings are publicly reported.

7.2.2 Overview of main bodies responsible for standard setting and enforcement

Table 7.1 provides an overview of the main bodies with supervisory functions in the Dutch healthcare system; these are the Dutch Health Care Authority (NZa) and the Health Care Inspectorate (IGZ). The Health Care Insurance Board (CVZ) is responsible for implementation of health insurance legislation and the development of the framework for the insurance system.

Table 7.1 Summary overview of main bodies responsible for standard setting and enforcement in the health and social care sectors in the Netherlands

Agency or body	Main roles and functions
Health Care Inspectorate (IGZ)	Independent supervisory body responsible for the promotion of safe, effective and patient-centred care. Establishes minimum quality standards, enforces statutory regulations on public health, monitors the quality and accessibility of healthcare by investigating incidents and complaints in care facilities and the compliance of providers with statutory safety regulations. ²⁵¹
Dutch Health Care Authority (NZa)	Independent administrative supervisory body overseeing the healthcare sector by monitoring competition and enhancing transparency for purchasers and service users. Can impose obligations on actors with significant market power, impose regulation and set prices when market mechanisms are found to be insufficient to deliver quality care efficiently. ⁵⁰
Health Care Insurance Board (CVZ)	Independent government body under the auspices of the Ministry of Health with quality control and supervisory functions in the area of health insurers/pharmaceuticals. Responsible for the implementation of health insurance legislation; develops the conditions for the insurance system. ²⁵²

7.3 National regulatory bodies

7.3.1 Health Care Inspectorate (IGZ)

Legal status and organisational structure

The Health Care Inspectorate (Inspectie voor de Gezondheidszorg, IGZ or ‘inspectorate’) was established in 1995, bringing together three areas of state inspection that had existed throughout the 20th century (healthcare, pharmaceutical care, and mental healthcare).²³⁸ A national institute, it is part of the Dutch Supervisory Service Public Health as set out in Article 36 of the 2008 Public Health Act (Wet publieke gezondheid, Wpg) and reports to

the Dutch Ministry of Health, Welfare and Sport ('Ministry of Health').²⁰ While the IGZ is independent from the Ministry of Health with an advisory function, it is accountable to the ministry as per agreement of the minister of health. For example, policies, enforcement plans, multi-year activity plans and annual work plans are developed in consultation between IGZ and the ministry and have to be approved by the minister of health.⁶¹

The IGZ is headed by an inspector-general who oversees a deputy inspector-general (head of eight internal services), four chief inspectors, who head the areas of public and mental healthcare, curative healthcare, nursing and long-term care, and pharmaceutical products and medical technology, and one project chief inspector. At the end of 2012, the IGZ had employed 490.5 staff (full-time equivalent).²⁵³ The inspectorate is responsible for 40,000 organisations and companies with a total of approximately 1.3 million employees, including around 800,000 healthcare professionals.²⁵⁴

The IGZ is the main focal point for the supervision of hospitals. It collaborates with four other inspectorates, namely the Inspectorate Infrastructure and the Environment, the Netherlands Food and Consumer Product Safety Authority, Housing, and the Employment inspectorate. All inspectorates undertake a joint risk analysis for hospitals, reported in an annual work plan.²⁵⁵

Scope of action

The IGZ supervises the quality and accessibility of healthcare. As indicated above, responsibilities include a preventive and curative healthcare sub-inspectorate, a mental healthcare sub-inspectorate, and a pharmacy and medical technology sub-inspectorate.²³⁸ The range of tasks include supervisory functions in the aforementioned areas as well as ensuring compliance with 25 items of legislation and other legal provisions, such as European rules and international treaties.²⁰

The supervisory powers of the IGZ are set out in the set of national regulations described earlier, including the Quality Act, which also provides for a patient's right to quality and safety, detailed further in the Dutch government programme 'Seven Rights for the Patient in Healthcare'.²³⁸ The IGZ has also supervisory powers concerning 1994 Health Care Complaints Act (Wkcz).

Supervision by the IGZ is based on the legislative framework although where legislation only provides general standards, IGZ bases its supervision on so-called 'field norms' set by healthcare providers and professional groups where possible. Where no such norms are available, the Inspectorate will develop specific supervisory norms directly.²⁰ While the specific healthcare sectors develop own regulatory instruments, the IGZ seeks to ensure standardised procedures and 'reliable and valid judgments' to encourage quality of care and to justify its regulatory decisions and activities.³⁵

The IGZ supervises adherence to these statutory regulations, investigates complaints and accidents in healthcare and takes appropriate measures; however, IGZ does not comment on the structure of the regulations or assess their impact on the quality of care.²

Regulatory mechanisms to ensure standard adherence

The IGZ performs supervision through theme-based supervision, supervision of incidents and phased supervision. Theme-based supervision is focussed on a single aspect of care provided at national or regional level. It is a form of preventive supervision for situations

which necessitate intervention.²⁰ Incident supervision refers to situations in which the IGZ deploys regulations in response to ‘emergency’ cases that indicate structural shortcomings in care provision.³⁵ Emergencies are defined as “any unintended or unexpected event relating to the quality of care and that has resulted in the death of or serious consequences for a patient or client of the institution”.²⁰ Incident supervision is a form of repressive supervision and regularly results in an intervention. When the inspectorate receives a report which suggests serious shortcomings in the quality of care, or less serious shortcomings which are nevertheless of a structural, ongoing nature, the inspectorate will take enforcement action; measures available range from advice and encouragement to correction or coercion.²⁵⁶ A reporting guideline outlines which reports have to be investigated. Reports are, in principle, submitted on a voluntarily basis although there are also statutory reporting duties, for example under the Care Institutions Quality Act which requires institutions to report emergencies and cases of sexual abuse.²⁰

Phased supervision follows a risk-based approach and can be seen as preventive supervision aimed at limiting risks in areas of the healthcare sectors where risks are greatest.²⁰ Introduced from 2002, the risk-based approach draws on indicators for healthcare quality assessment.³⁵ It sought to address concerns about a lack of systematic insight in the performance of healthcare providers in terms of safety, effectiveness and patient-centeredness.²⁵⁷ In response, and in close cooperation with professional associations and healthcare providers, the IGZ now annually sets performance indicators for patient safety and effectiveness, which are cross-referenced to international developments and collects quality control information from all Dutch healthcare organisations. Exceptions include specialised institutions, independent treatment centres, and private clinics providing a limited healthcare package only.²³⁷

Phased supervision is performed in three stages: First, risks are identified through various information sources including mandatory quality performance indicators submitted by healthcare providers, reports and other indications, patient experiences and others. Based on this quality control information, risks of and shortcomings in quality are assessed and institutions at risk are identified. The IGZ may then opt to conduct a random inspection to investigate the situation on site. It will assess the need for improvement measures to be taken by the healthcare providers under investigation and stipulate a timeframe for implementing these measures according to which providers are obliged to act. If improvement measures are not satisfactory, inspectors can undertake follow-up visits. In the third phase the IGZ can intervene and statutory (enforcement) measures can be applied, such as administrative sanctions and penalty measures.^{20 35}

Enforcement measures

The IGZ has a range of enforcement measures at its disposal, including advice and encouragement, corrective measures, and (coercive) statutory measures (disciplinary and administrative law or criminal proceedings).⁴⁴ The type of enforcement measure pursued by the IGZ is determined by a number of considerations, including the level of dissatisfaction, discomfort, disease, disability and death; the number of people at risk; the way in which care provision is organised and structured; and the attitude of the care provider (eg ignorance, incompetence, non-compliance).

Advice and encouragement are informal remedies thought to improve day-to-day activities of the provider in the form of consultations and agreements between the provider and the IGZ. If these remedies fail, the IGZ may apply corrective measures. It may seek to avoid using formal (statutory) measures by informing providers or individual practitioners that formal measures will be applied when requested changes have not been made within a given timeframe. If a warning issued does not result in desired changes, the IGZ can request an action plan to achieve the required improvements and apply enhanced supervision which offers providers a the final opportunity to address problems.

Where providers fail to meet their duty of care, the IGZ can advise the minister of health to issue written instructions which include measures to be taken by the provider and an implementation period. In urgent matters, the IGZ can also issue a written compliance order for seven days, which can be extended by the minister. In case of non-compliance with the instructions or orders, the minister of health can impose administrative enforcement, which may include closing of (parts of) institutions or imposing an incremental penalty.

In general, cases are examined on an individual basis to determine the most effective enforcement measure. This will usually include soft measures followed by more formal measures (eg a compliance order or fine), depending on the progress made in the specific situation.⁴⁴ The IGZ seeks to achieve a balance between trust in care providers, and using supervision and inspection to ensure adherence to standards as well as disciplinary or criminal proceedings depending on the individual case.

Under the 1993 Individual Health Care Professions Act (BIG), the IGZ is also authorised to bring proceedings to disciplinary courts against individual practitioners. Further, the IGZ may issue a compliance order on any practitioner and those practising a profession for which training is governed under the same act. With respect to the professions regulated under BIG, it has also the exclusive powers to make written referrals to the Medical Supervision Board to assess whether practitioners are fit to practise.

Pro-active publication

The IGZ publishes virtually all reports concerning specific healthcare institutions, especially when there is significant political or public interest.²⁵⁸ The policy of proactive publication has been in place since July 2008 as a means to ensure compliance, to inform patients, health insurers and other stakeholders and to contribute to the transparency of the government. Reports remain on the inspectorate's website for a period of three years. Table 7.2 provides an overview of the activities of the Inspectorate in the year 2010.

Table 7.2 IGZ activity in 2010

Activity	Number
Publications	
Thematic reports	20
Other	6
Phased supervision: completed activities	
<i>Phase 0: Development of performance indicators</i>	11
<i>Phase 1: Data collection</i>	
Instrument development	2
Report of visit (after prioritisation)	1
<i>Phase 2: Judgement</i>	
Instrument development	1
Report of visit	165
Follow-up report of visit	62
Intensified supervision	11
Visit product safety	444
<i>Phase 3: Intervention and enforcement</i>	57
Enforcement of annual accountability reports	
Penalty	9
IGZ (incidents) alerts	
IGZ alerts	80,908
Completed (incidents) alerts by sector	
Health promotion	7
Health protection	14
Primary care	520
Medical specialist and psychiatric care	758
Care for the disabled	818
Elderly care	1,370
Home care	70
Product safety	1,671
Mental healthcare	1,104
Other	6
Issued advice	
Advice to the Minister	503
Other advice	892
Issues statements / declarations	
Issues statements / declarations	17,960

SOURCE: Adapted from Health Care Inspectorate (2011).²⁵⁹

7.3.2 Dutch Health Care Authority (NZa)

Legal status and organisational structure

The Dutch Health Care Authority (Nederlandse Zorgautoriteit, NZa) was established in 2006 as an independent administrative body funded by the Ministry of Health, Welfare and Sport, and whose tasks are defined in the 2006 Health Care Market Regulation Act.²³⁸ The NZa was established with the aim of preventing political bodies to interfere with the actors in the healthcare market.³⁴

The NZa comprises of a Board of Directors, a Directorate Strategy and Legal Affairs, a Directorate Internal Operations and Information, a Directorate Cure Market, a Directorate Supervision and Enforcement, and a Directorate Care Market. In 2010, the NZa was responsible for 1,481 care organisations, 687 cure organisations, 28 health insurers and their care offices across the country.²⁶⁰ In 2011, the NZa employed 207 staff of whom 80 had a medical background (including nursing, medical specialists, allied healthcare), with the remainder having a background in management, policy, economics, or legal affairs.²⁶¹

Scope of action

The NZa is the supervisory body for the implementation of the 2006 Health Care Market Regulation Act (Wmg), the 2006 Health Insurance Act (Zvw) and the 2000 Exceptional Medical Expenses Act (AWBZ).²⁶² It promotes quality by setting those market conditions that encourage quality and innovation in healthcare and can impose tariff and performance regulation.^{2 238}

Its tasks include the monitoring of the transparency and functioning of the healthcare markets, the establishment of tariffs for non-negotiable care and the enforcement of the Health Care Market Regulation Act. It can impose specific obligations on actors that have obtained ‘significant market power’ within a market segment and can set general rules for care providers and health insurers in a market segment in order to increase the transparency of the market for service users and to remove obstacles to effective competition.^{34 238} This reflects the twofold aim of controlling the total cost of paying healthcare providers, ensuring the implementation of insurance legislation and monitoring market developments (supervision), while proactively setting conditions for market forces (regulation) with a preference for the latter to achieve efficient market behaviour.²⁶³ In 2010, 45 general rules were laid down for the care sector and 80 general rules for the cure sector. Four physicians received a financial fine, of whom two were general practitioners receiving a fine for insufficient collaboration following a costs investigation in general practice.²⁶⁴

Regulatory mechanisms to ensure standard adherence

The NZa monitors care contracts and rates according to Article 45 Wmg. Further, under the AWBZ, care providers submit annually performance documents which form the basis for a performance assessment against established indicators. Where providers are found to underperform, additional research will be conducted (‘spearhead research’). Care agencies and the Central Administration Office, which has key financial and administrative tasks in the care and welfare sector, have to submit an annual implementation report about the lawful and effective implementation of the AWBZ.²⁶²

The NZa further prepares a Monitor of Health Insurance Market (Monitor Zorgverzekeringsmarkt), based on surveys and research by the NZa and information provided by third parties, focussing on the quality, accessibility and affordability of insurance.²⁶⁵ Furthermore, health insurers are required to report annually to the NZa on compliance with Health Insurance Act in the form of a performance report; this information is then aggregated in the NZa ‘Implementation Report Health Insurance Act’.

In addition to the functions of the NZa described above, supervision by the NZa uses a Risk Analysis Model (RAM) to provide systematic insight into developments in sectors and

markets. The RAM is a staged approach which couples risk-analysis and enforcement mechanisms (Box 7.1). It involves consumers, providers and insurers with continued risk management and an annual RAM report on risks and risk development. In addition, signals from the market inform supervision.

Box 7.1 The Risk Analysis Model as used by the Dutch Health Care Authority (NZa)

The Risk Analysis Model (RAM) includes ten steps:

Step 1: Collection of information from providers, private sources and relevant research and own studies/experiences.

Step 2: Risks are described and ranked.

Step 3: Analyses of measures for risk reduction available and their effects (control and management mechanisms in the existing legislation).

Step 4: Risk mapping - analysis of the actual affects that might occur.

Step 5: Risk matrix showing the actual impact for each identified risk.

Step 6: Decision on which steps will follow based on classification of risks.

Steps 7–9: Determination of the level of detail to which the NZa will study the risk and application of three types of studies: signal research (NZa waits for signals by providers/insured); confirmative research (did the provider understand the risk and address it?); intensive research (can result in intervention aimed at healthcare provider/insurer).

Step 10: Based on research: intervention (such as discussion with boards of providers) or enforcement action; suggestions to the Ministry of Health for further activity in terms of market barrier removal or risk mitigation; enforcement actions available to the NZa depending on the type of risk: giving instructions, the imposition of a cease and desist order, imposing a fine.²⁶⁵

In 2010, 332 signals were registered (compared to 139 in 2006) of which 103 were related to curative healthcare providers and 69 to health insurers. In addition, in the same year 30 interventions were performed (compared to 49 in 2006) of which 15 were related to health insurers, and 11 to curative healthcare providers.²⁶⁴

Enforcement measures

As outlined above, the NZa has an array of legal instruments at its disposal to enable establishing the general conditions for the healthcare markets.²⁶⁰ These include: giving instructions, imposing a cease and desist order, imposing a fine.²⁶⁵

7.3.3 Health Care Insurance Board (CVZ)

Legal status and organisational structure

The Health Care Insurance Board (CVZ) aims to safeguard the quality, accessibility and affordability of the Dutch healthcare system by promoting the interests of all citizens entitled to care based on the Health Insurance Act (Zvw) and the AWBZ. CVZ is an independent non-departmental government body, acting under the auspices of the Ministry of Health. It comprises an executive board, advisory and supportive departments, a care department (development, research and advice), and an insurance department.²⁶⁶ In 2011, the total number of staff was around 200.

Scope of action

The CVZ provides advice on the composition of the basic healthcare package and clarification regarding its content ('package management'). It explain the rules to insurers,

advice in case of disputes between insured persons and insurers or liaison offices or care providers, design rules to facilitate the implementation of the AWBZ, and perform costs analyses in healthcare.²⁵² The CVZ is advised in its tasks by the Medical Products Reimbursement Committee concerning the assessment of the potential inclusion of new medicines in the basic benefit package, the Package Clarification Committee for the verification of the statutory criteria, and a Package Advice Committee to ensure that the perspective of society is safeguarded.

The CVZ is also responsible for the risk adjustment system in collaboration with the Ministry of Health, the Dutch Health Care Authority (NZa), the Dutch Health Insurers Association (Zorgverzekeraars Nederland, a sector organisation representing Dutch providers of care insurance) and the insurers.

In addition, the Committee on Pharmaceutical Care (CFH) is part of CVZ and is responsible for the assessment of pharmaceuticals regarding their efficacy, efficiency, side-effects, applicability and ease of use before inclusion in the benefits package.²³⁸ Safety, efficacy and quality of pharmaceuticals is generally assessed and monitored by the Medicines Evaluation Board (College ter Beoordeling van Geneesmiddelen, CBG) as an independent organisation, whose members are appointed by the minister of health. Authorisation of a drug and registration for market access by the CBG does not automatically lead to reimbursement by health insurers as the reimbursement decision is taken by CVZ on the basis of advice from the CFH. The medicine reimbursement system only includes prescription pharmaceuticals, which are then covered by basic health insurance and reimbursed by health insurers.

Enforcement measures

All citizens are subject to the Health Insurance Act and the Exceptional Medical Expenses Act, and obliged to take out basic insurance. ‘Special groups’ are those persons who are unable or unwilling to take out insurance or who fail to pay their insurance premiums. Where insured individuals fail to pay their insurance contributions, CVZ collects the taxes that take the place of contributions; those failing to pay their contributions for six months are reported by the insurers as ‘defaulters’ to CVZ. Those refusing to take out insurance will have a fine imposed by CVZ following a reminder. When people remain uninsured after having received a fine (this was the case for 5,129 persons in 2009), CVZ takes out insurance for them and collects the premium. Those not wishing to be insured for religious reasons (‘conscientious objectors’), CVZ manages the tax that takes the place of contributions and assesses and reimburses their claims for care. In 2009, this was the case for 18,335 persons. In addition, care providers can obtain financial reimbursement for services that are part of the basic benefit package provided to a foreigner without a resident permit, who is unable to pay for that care.^{252 267}

7.3.4 **Municipal health services (GGDs)**

Legal status and organisational structure

Regions and local authorities in the Netherlands have become an increasingly important administrative level in public health policymaking.²⁶⁸ Based on the 2008 Public Health Act (Wpg) municipalities have the statutory responsibility to govern public health and social care with public health services being provided by (in 2011) 28 Municipal Health Offices (Gemeentelijke Gezondheidsdiensten, GGDs) carrying out these tasks on behalf of all 443

municipalities.^{238 269} Municipalities are responsible for the integration and coordination of public health services, social care, and curative care. All municipal health offices are part of umbrella organisation 'GGD Nederland' which protects the interests of municipal health offices in discussion with stakeholders and the national health policy level. It also performs projects to improve the performance of all offices. Office directors and municipal policy makers are part of the Board of GGD Nederland.²⁶⁹

Public health services are financed through municipal budgets and the Exceptional Medical Expenses Act (AWBZ) while social care is provided directly by the municipalities and financed through municipal budgets.²⁷⁰ Municipalities also carry out regular public health assessment using epidemiological analysis, as stipulated by the 2008 Public Health Act; assessments are carried out once every four years.²⁶⁸

Scope of action

The Public Health Act requires all municipalities to identify their health targets and work programme for a four year period and report this in a policy document. While GGDs may carry out different tasks, determined by the local municipality as specified in the municipal memoranda about local policy on community health, there are a number of uniform tasks specified in the Public Health Act. These include youth healthcare; environmental health; socio-medical advice; periodic sanitary inspections; public health for asylum seekers; medical screening; epidemiology; health education; community mental health.²⁶⁸ Furthermore municipalities are responsible for the implementation of the 2007 Social Support Act (Wmo), which includes a range of home care services for citizens who have limitations due to (chronic) health problems, ageing or disabilities.

Local authorities were provided with more oversight power through the introduction of a Social Support Act Board (Wmo-raad) to oversee the implementation of the act, which was implemented by almost all local authorities (95 per cent in 2007).²⁷¹ The majority of local authorities exercise this control by granting influence to organisations; many also enter into formal agreements with organisations on the efforts or quality to be delivered. The options are not exclusive but local authorities strike their own balance.

As set out in the Public Health Act, municipalities are responsible for the quality of the organisation of GGDs. For example, they should be staffed by professionals with sufficient expertise in the areas of social medicine, epidemiology, nursing, health promotion, and social sciences. All GGD are required to operate a quality management system. Organisations with a functioning quality management system can apply for a quality certificate at the Foundation for Harmonisation of Quality review in Health Care and Welfare (HKZ). Independent audits are performed to evaluate whether the organisation meets ISO 9001 standards ensuring that the organisation has a systematic quality monitoring system in place that is sufficient to meet the needs of the target population of the services.

For each area in which the GGDs are active, norms have been developed for the delivery of services in collaboration with professional organisations, representatives of stakeholders involved in the provision of care and funding organisations. For each area, a certificate needs to be obtained, and all certified organisations are required to publish an annual quality performance report. Organisations involved in the delivery of services participate in a GGD-Benchmark or Youth Health Care-Benchmark, to compare their own performance

with similar organisations. To participate, organisations complete a standardised online performance questionnaire which is submitted to an independent foundation (Stichting Benchmark GGZ) responsible for the benchmarking information. The performance information includes financial performance, patient experience, employee satisfaction and health outcomes.²⁷²

Regulatory mechanisms to ensure standard adherence

The behavioural norms of all GGD workers are set by the Public Health Act. In case a professional acts against stipulations of the act, depending on the severity, a fine can be issued or the professional can be imprisoned for two to six months or four years.

Supervision

A set of performance indicators have been developed which are used by the IGZ to monitor the quality of care provided by GGDs. In addition, GGD Nederland and ActiZ (national organisation of social care organisations) have developed a set of quality management instruments to enhance the accountability of professionals, organisations and the municipalities. As noted above, municipal health offices are required to report, every four years, according to a nationally set standard, on all activities and health problems, to facilitate comparisons at national level.

National bodies in public health and social care

Where health problems require action across municipalities, the intervention of national level becomes important. The Ministry of Health is responsible for the governance of preventive care while the coordination of preventive care policy has been delegated to the National Institute for Public Health and Environment (RIVM). The RIVM supports the government by performing scientific research to support policy development and supervision of healthcare, the environment and nature. It collects data, and disseminates knowledge on determinants of health problems, and consequences for the organisation of the healthcare system. This is published in the Public Health Status and Forecast Reports, the National Public Health Compass, and the Dutch National Atlas of Public Health.

The execution of public health and social care services is supported by a range of organisation including government funded health promotion organisations (ten in total), research institutes investigating the delivery and performance of preventive medicine; and professional organisations protecting the interests of professionals active in the field of public health and social care services, such as GGD Nederland.²⁷³

7.4 Quasi-governmental and other actors

7.4.1 Central Disciplinary Board, Regional Disciplinary Boards and Medical Supervision Board

Legal status and organisational structure

The system comprising the Central Disciplinary Board (highest body), the Regional Disciplinary Boards and the Medical Supervision Board aims to foster and monitor the quality of professional practice and to protect the general public against incompetence and carelessness.²⁰ There are five regional disciplinary boards with their own regional jurisdiction, each involving two legally qualified members and three health professional members, which address in the first instance disciplinary proceedings that are regulated under the Individual Health Care Professions Act (BIG). One Central Disciplinary Board,

comprising three legally qualified members and two health professional members, forms the level of appeal, as well as the Supreme Court but only in the interest of the law.

Scope of action

Professions that are subject to the disciplinary system are physicians, dentists, pharmacists, midwives, nurses, physiotherapists and healthcare psychologists. Any person may file a complaint (usually a patient or a member of a patient's family), as can the inspector-general for health care at the IGZ. The disciplinary norms that are applied in the proceedings are "inadequate care for the patient or the patient's relatives [and] any other act or omission that is in conflict with good individual healthcare practice".²⁰ These include for example, diagnostic or medical errors, prescription errors, infringement of medical confidentiality, referral errors, sexually inappropriate behaviour, reimbursement errors, inappropriate public behaviour causing unjustified public unrest (for example about an outbreak).²⁷⁴ Individuals can only submit a complaint to the board in the province where the healthcare professional is located.

When a complaint is issued, a preliminary investigation is performed by the board, in which the oral and written statements of all stakeholders are collected and studied. This may result in a resolution if both parties reach consensus and therefore a withdrawal of the complaint. When found to be in the public's interest, a hearing can still be performed. After the preliminary investigation, the 'Raadkamer' (the Council Chamber) will form a judgement. In case the complaint is acknowledged, a public hearing will be planned. Two months after the hearing, the board will reach a decision, which will be sent in writing to the person who issued the complaint, the medical professional under review, the healthcare inspectorate, and the Central Disciplinary Board.²⁷⁴

The Central Disciplinary Board handles appeals against decisions of the Regional Disciplinary Boards and of the Medical Supervision Board. The Medical Supervision Board is also regulated under the Individual Health Care Professions Act (BIG). When professionals are found to be not competent to practice, the Medical Supervision Board can take action on its own initiative (without any immediate complaint first).²⁷⁴

Table 7.3 shows the number of complaints that have been filed (received) and 'completed' (processed) by each of the Regional Disciplinary Boards during 2007–2011.

Table 7.3 Filed and completed complaints, Regional Disciplinary Boards, 2007-2011

	Groningen	Zwolle	Amsterdam	The Hague	Eindhoven	Total	Issued by the IGZ
Number of filed complaints							
2007	99	276	377	388	301	1441	1
2008	98	274	370	323	303	1368	6
2009	97	298	374	366	361	1496	18
2010	152	355	373	345	299	1524	12
2011	165	315	513	392	291	1676	13
Number of completed complaints							
2007	119	203	341	282	350	1295	
2008	155	237	338	332	285	1347	

	Groningen	Zwolle	Amsterdam	The Hague	Eindhoven	Total	Issued by the IGZ
2009	54	288	350	335	282	1309	
2010	131	324	371	348	319	1496	
2011	171	364	368	331	338	1590	

SOURCE: Adapted from Tuchtcolleges voor de Gezondheidszorg (2012).²⁷⁵

Disciplinary proceedings

The sanction regime includes a wide range of options; these include warnings, reprimands, fines of up to €4,500, (conditional) suspension of entry in the BIG registry, striking off the entry in the BIG registry, partial withdrawal of the right of the person entered in the BIG registry to practise the profession, or a combination of these. The Medical Supervision Board assesses the professional's fitness to practise, that is, professionals not competent to practice due to psychological or physical illness, or substance misuse, with the IGZ having the right to and to bring a professional before the Medical Supervision Board.

Publication and dissemination of verdicts

Anonymous verdicts can be published entirely or partially in the Netherlands Government Gazette if disciplinary boards decide to do so given a public interest, and they can furthermore offer verdicts to journals or newspapers.

7.4.2 **Netherlands Institute for Accreditation in Healthcare (NIAZ)**

The Netherlands Institute for Accreditation in Healthcare (Nederlands Instituut voor Accreditatie in de Zorg, NIAZ) was established in 1998 by the major hospital organisations together with the Netherlands Organisation of Hospitals, which support the NIAZ financially and are represented on the board. External parties such as patient organisations, insurance companies, GPs, home care organisations and nursing homes are represented in an Advisory Council and a Panel of Experts representing hospital professionals.²⁵⁰ The aim of NIAZ is to enhance quality improvement and quality assurance; it develops quality standards and accredits externally hospitals at their request using peer review. NIAZ works mainly at hospital and departmental level.²⁷⁶

NIAZ standards are based on the system of the 'Canadian Council of Health Facilities Accreditation' and the ISO 9000 series, but adapted to the Dutch context.²⁵⁰ Standards were developed for accreditation at departmental and hospital level, addressing policy and strategy, process management, means and matter, knowledge and skills, and quality assurance.²⁷⁷ The accreditation process is based on peer review performed by surveyors trained by NIAZ and follows a two-phased process using a 'plan-do-study-act' (PDSA) cycle at the core of the system and with assessment procedures devised for accreditation at departmental and at hospital level.²⁵⁰ The NIAZ accreditation process includes an internal survey system within the healthcare organisation, a self-assessment report, a primary review by the survey team, a survey followed by a report, the development of an improvement action plan by the organisation under review and a follow up check by NIAZ to monitor progress. Organisations participate at their own request in the NIAZ accreditation programme. The resulting accreditation status of the participating healthcare organisations is published on the NIAZ website.

7.4.3 **Foundation for Harmonisation of Quality Review in Health Care and Welfare (HKZ)**

The Foundation for Harmonisation of Quality Review in Health Care and Welfare (Stichting HKZ) was founded in 1994 at the initiative of healthcare providers, insurers and clients. This initiative has its origins at the 'Leidschendam conference' in 1990 which identified a need to create a coherent system of quality assurance and improvement. The Stichting HKZ aims for harmonisation and the accomplishment of quality management systems and external review of such systems. It produces ISO 9001 compatible certification schemes for a variety of healthcare and welfare institutions. Certifications are developed under the authorisation of the Council of Experts in the Health Care Sector. Specific schemes have been developed for example for the elderly, mental healthcare, community care, pharmacies, ambulances and some aspects of hospital care.

7.4.4 **Dutch Institute for Healthcare Improvement (CBO)**

The Dutch Institute for Healthcare Improvement (CBO) is an independent intermediary knowledge institute in the field of quality of care founded on 1979 by the Dutch Association of Chief Medical Officers. In 2010, CBO became part of TNO Consultancy and TNO. Its initial focus on improving the quality of care provided by physicians and other healthcare professionals has expanded since 1999 to also include the organisational aspects of quality of care. It supports organisations to improve quality dimensions and patient safety, patient centeredness, effective and efficient care, and aims to work closely with patients in doing so. CBO develops and provides access to guidelines; however, these are not legally binding, as they are evidence-based statements and recommendations. Overall, CBO functions as a reference institute (benchmark) for quality of care, nationally and internationally, identifying and sharing effective quality strategies.²⁷⁸

7.4.5 **Royal Dutch Medical Association (KNMG)**

The Royal Dutch Medical Association (KNMG) was established in 1849, as the professional organisation for physicians of The Netherlands. Since 1999, the KNMG has become a federation of medical practitioners' professional associations, bringing together the (national) associations of public health physicians (KAMG), salaried doctors (LAD), general practitioners (LHV), elderly care physicians (Verenso), insurance medicine (NVVG), occupational health (NVAB), the Dutch Order of Medical Specialists and a group of individual KNMG members and students.

The KNMG – through legislative boards – is responsible for the regulation of vocational training and registration of specialists. Overall it aims to improve the quality of medical care and healthcare in general, and to improve public health by proactively responding to developments in healthcare and society, by developing guidelines and policies, by lobbying, and by providing services to its members. To promote the medical and associated sciences, and achieve high quality healthcare, it is working closely with government, politics, healthcare insurance companies, patient organisations and other organisations in healthcare.²⁷⁹

7.5 **Case study**

St Radboud University Hospital

In September 2005, a meeting at the Cardio-Pulmonary Centre, St Radboud University Hospital (St Radboud UMC), Nijmegen, discussed outcomes data for cardiac surgery,

collected since 2004, which mortality rates following thoracic and cardiac surgery to be twice the national average (6.7 per cent compared to 2.7 per cent).²⁸⁰ These findings were subsequently reported anonymously to the Health Care Inspectorate (IGZ) and to the press, and made public. The IGZ requested an explanation from St Radboud UMC's Board of Governors for the elevated death rates and whether current circumstances required suspending of surgical activities, and follow-up activities from the initial meeting.²⁸⁰

St Radboud UMC, in a written response to the IGZ, attributed the higher mortality levels, in part, to the case-mix, with patients admitted to St Radboud UMC at higher-than-average risk. Following further analysis, performance was interpreted as qualitatively normal, with the origins of above-average mortality that could not be attributed to the case-mix, seen as multifactorial.²⁸⁰

Subsequently, the IGZ and St Radboud UMC's Board of Governors decided to establish an external investigation committee (EIC). The EIC, chaired by the IGZ, was to examine the quality and safety of the cardio-surgical care pathway and the extent to which observed mortality levels were the consequence of patient related or treatment related factors, and report to the IGZ and the Board of Governors. Using a range of methods, including detailed analyses of mortality rates, a review of case histories, morbidity analysis and a series of confidential interviews with key staff, the EIC identified a serious threat to the quality and safety of patient care that would require immediate corrective action with regard to personnel and organisational structure.²⁸⁰

In response, the IGZ imposed an immediate suspension of adult cardiac surgery, a reorganisation of cardio-surgical chain processes, the development and implementation of written care protocols, the implementation of written agreements on responsibilities, the appointment of specialists for the cardio-surgical chain, and general and medical supervision of perfusionists. It was only in the aftermath of this case that the IGZ has required centres performing heart surgery centres to provide data on mortality and morbidity although such data collection had been under consideration for some time.^{281 282}

Investigation by the Dutch Safety Board

The Dutch Safety Board (Onderzoeksraad voor Veiligheid, OVV), an independent administrative body which performs comprehensive investigations into the (probably) causes of incidents in any conceivable field, performed an independent investigation into the probable causes of the high mortality rates following cardiac surgery at St Radboud UMC. Reporting in 2008, it found that St Radboud UMC was known to have experienced a range of problems since the late 1990s, but that hospital management had mostly focussed on organisational problems, which were not deemed to be a threat to patient care.²⁸³

It highlighted a number of shortcomings, including a lack of appropriate internal monitoring of care processes and outcomes and poor working relationships among medical specialists involved in the cardiac care chain, with the latter raising concerns among referring medical specialists outside St Radboud UMC about the quality of care provided at the cardiac surgery department. Initially related to waiting lists (2002) and poor communication and information sharing, concerns increasingly focused on the outcomes of cardiac surgery. However, these concerns had not led to changes in departmental

policies.²⁸³ Other issues included internal conflicts between the Board of Governors of St Radboud UMC and medical specialists, including cardiac surgeons, staff shortages, and leadership issues. An internal investigation initiated by the Board in 2004 did not lead to a resolution of the problems however.

St Radboud UMC seemed to rely fully on the NIAZ accreditation for its quality of care. However, NIAZ accreditation was limited to the organisation of care, but not, for example, the quality of collaboration between medical specialists, leadership, the functioning of teams or the medical contents, and any risk analysis. The quality system was shaped by paper reporting of the organisation and its organisational conditions.²⁸³

Lessons learned

Systems in place by the IGZ did not detect the failure of the delivery of ‘*verantwoorde zorg*’ by St Radboud UMC.²⁸³ It was only following an anonymous notification about the potential risk to patient care at St Radboud UMC’s cardiac surgery department that the IGZ became into active. The overall approach by the IGZ to the case was reactive and relied on the information provided by St Radboud UMC. Although the IGZ uses performance indicators to evaluate the quality of care, these were unsuitable to detect potential problems at the cardiac surgery department. In case of a complaint regarding the quality of care, the IGZ would take account the explanation of the respective organisation, often deemed sufficient to dismiss the complaint. It was not common practice for the IGZ to evaluate the governance structure, division of responsibilities and improvement actions of the healthcare organisation under review. Until 2005, the IGZ did not use any of its legal pro-active measures with regards to cardiac surgery, to collect information on the quality of care (eg through published mortality rates in the annual reports or consulting external experts).

7.6 **Summary and conclusions**

The Dutch regulatory framework uses a mixture of policy instruments to safeguard the quality and safety of healthcare. The system relies to a great extent on self-regulation and voluntarism, through for example having the medical profession define ‘*verantwoorde zorg*’, develop clinical guidelines and medical training programmes, and having a voluntary system of external accreditation. The role of the Dutch Health Care Authority is a good example of a form of meta-regulation, which it carries out by monitoring competition in the three healthcare markets. In particular, command and control mechanisms regarding the inspection of healthcare quality and safety and licensing of healthcare professionals are in place.⁴

Effectiveness of the system

Hout et al. (2010) analysed the Health Care Inspectorate’s supervisory activities and regulatory instruments based on a literature review and descriptive statistics of the use of regulatory instruments between 2002 and 2007.²⁰ It found that, in 2007, of 4,500 incidence reports, 1,500 resulted in informal measures, while only nine led to rulings by a disciplinary tribunal in the first instance and one compliance order under the Individual Health Care Professions Act. This, as Hout et al. (2010) argued, reflects the wider context of the Dutch supervisory regime, characterised by comparatively low formal intervention rates, of around 10–15 per cent. They further noted however that a greater use of formal

measures that would extent significantly above 10 per cent of cases did not appear to result in better supervision. This may be because of the time required to work through cases and the potential risk of creating mistrust and frustration among actors in the healthcare sector and, possibly, gaming when dealing with a more interventionist supervisory body. At the same time, there was a perception that the IGZ would face greater public and political demand for a more stringent approach to supervision while healthcare professionals criticise the IGZ for being too severe and quick when applying formal measures. In response, the IGZ published an enforcement framework to enhance legal certainty and effectiveness of supervision.

Tuijn et al. (2011) compared the reliability and validity of judgements issued by the IGZ, distinguishing ‘lightly structured regulatory instruments’ (LSI) and ‘highly structured regulatory instruments’ (HSI).³⁵ This was based on analysis of various datasets using descriptive statistics and regression analysis. Regulation with a HSI was analysed using data from 182 reports on inspection visits in risk-based supervision of nursing homes in 2005–6; regulation with a LSI was analysed using 71 reports on regulatory visits in risk-based supervision of hospitals in 2005–7. Analyses found that both types of instruments showed variations in the meaning of judgements, which pointed to validity problems. The authors suggested that a thorough appraisal of regulatory instruments would need to take account of the complexity of care with an accompanying explicit set of standards; commitment of inspectors to the instrument and training of inspectors.

Friele et al. (2009) reviewed the regulatory instruments of the 2006 Health Care Market Regulation Act (Wmg) based on interviews and document review.³⁴ They noted that – like the IGZ – the Dutch Health Care Authority (NZa) appears to opt for acting in a less interventionist way. This is seen to be rooted, in part, by the Wmg aimed towards the NZa creating confidence among market participants and giving room to act. Also, the NZa’s portfolio of regulatory and supervisory instruments requires striking a balance between these two approaches, resulting in the NZa opting for a more cautious approach (informal measures and preventative supervision).³⁴

Overall, and given the corporatist model of the Dutch healthcare sector, the regulatory system of quality and safety of healthcare can be considered as functioning in a reasonable effective manner.²⁸⁴ Nevertheless, the occurrence of several recent quality and safety incidents in healthcare organisations have shown that the division of responsibilities to monitor, assure and improve the safety and quality of care in accordance with the Quality Act remains less than optimal.²⁸⁵ In addition, there remains a continuous challenge to set appropriate quality standards, develop sound quality indicators, particularly with regard to safety and clinical effectiveness, that are comparable, reliable and valid, and to develop evidence-based guidelines.

The fragmented system of healthcare governance at central level for the cure and care sectors, and decentralised governance responsibilities for social care and public health, can be seen to increase the risk for inequity in healthcare provision. A major challenge for the system remains the alignment of these four sectors. In 2009, the Council for Public Health and Health Care identified two key areas for improvement of the Dutch system of governance and quality of care.²⁸⁴ First, it highlighted the need for government to further strengthen its role in overseeing the development of minimum standards of care by health

professionals and experts. It noted that the minimum standards should become legally binding, and that the IGZ should increase transparency and strengthen its enforcement measures regarding the performance of health professionals in terms of these minimum standards of care. At the organisational level, it pointed to the need for the Board of Directors of hospitals to increase their role in steering and monitoring health professionals, processes of care, and creating a culture of internal accountability. Failure to do so would pose a risk towards violating quality standards.

At present, responsibilities for standardising the quality of care are allocated to separate (mostly governmental) bodies, including the Dutch Council on Quality of Health Care (guideline development:); the Dutch Health Care Transparency Programme at the CVZ (Zichtbare Zorg; indicator development²⁴⁴); the KiesBeter website, operated by the National Institute for Public Health and the Environment (RIVM), which provides information on quality performance of healthcare providers and organisations;²⁸⁶ and the Centre for Consumer Experience in Health Care (measuring patient experience). From January 2013, the newly established Institute for Health Care Quality (het Kwaliteitsinstituut) is tasked to provide a steering, coordinating and guiding role for all stakeholders involved in improving quality of care. Part of the Health Care Insurance Board (CVZ), the Institute for Health Care Quality has taken on a range of functions which until recently were performed by a wide range of actors including those mentioned immediately above (guideline development, Zichtbare Zorg, kiesBeter). It also collaborates closely with the Centre for Consumer Experience in Health Care. It has further taken on tasks of CVZ regarding the composition of the basic healthcare package, and of the Netherlands Organisation for Health Research and Development (ZonMw) regarding the development of multidisciplinary guidelines for chronically ill patients.²⁴⁸

Against this background there is considerable potential for the recently established Institute for Health Care Quality to make a major contribution to improving the effectiveness of the current system as it relates to quality assurance, control and improvement. However, its mandate as it is formulated at present only covers the cure and care sectors so missing the opportunity to improve the coherence in quality of care across all sectors, including social care and preventive care. Aligning the cure, care, preventive and social care sectors therefore remain the key challenges of the Dutch healthcare system.

8.1 **System overview**

8.1.1 **Organisation and financing of the health and social care systems**

The healthcare system in the United States (USA) is a market-oriented enterprise. It is supported by a multi-payer model with healthcare spending totalling \$2.7 trillion in 2011, according to National Health Expenditure data,²⁸⁷ and the bulk of this expenditure went towards health insurance, and out-of-pocket expenses. The health insurance system is funded from three main sources; employers, specific taxes, and general tax funds. On average, approximately half of the payments for healthcare originate from public insurance programmes and the other half originates from privately owned health insurers. Employer-sponsored insurance is the main form of private insurance. However, recent reforms expanding public subsidies for low-income individuals to purchase insurance and mandating that all residents obtain insurance coverage are likely to increase the proportion of insurance that is purchased directly by individuals and small employers. The effects on healthcare spending are difficult to predict.

Most of healthcare is delivered by privately owned provider organisations. According to the American Hospital Association, in 2011, there were 1,253 public hospitals and 3,928 private hospitals in the USA.²⁸⁸ These numbers exclude the over 500 nursing homes, mental and prison hospital facilities. Private hospitals are usually non-profit but about a third are for profit. Historically, most professionals are independent contractors, but the proportion employed directly by organisations is increasing.

Federal government spending is organised through insurance programmes targeted to special populations such as the elderly, disabled, and children (Medicare, Medicaid, and Children's Health Insurance Program, CHIP). The federal government is also a direct provider of healthcare to the military services, veterans, and Native Americans. National (or federal) oversight of quality and care standards occurs primarily through 'conditions of participation' requirements defined by the Medicare and Medicaid programs (public payers).²⁸⁹ Since the enactment of Medicare and Medicaid in 1965, these conditions have been revised and expanded.²⁹⁰ Thus, all healthcare facilities receiving funds from Medicare and Medicaid are subject to federal quality oversight by private Quality Improvement Organizations (QIO), and are required to participate in accreditation programmes operated by privately owned, non-profit organisations such as the Joint Commission, and the National Committee for Quality Assurance (NCQA). State governments and private sector payers often adopt quality standards established at the federal level.

In 2012, an estimated 20 per cent (48 million people) were uninsured, either by choice or because it was unaffordable.²⁹¹ Among the insured, the vast majority (55 per cent or 171 million) were eligible for benefits from an employer-sponsored health insurance plan. Almost ten per cent (31 million) of the insured purchased policies directly from an insurance company, while approximately 102 million people received benefits from one of the public payers or health/social welfare insurance programmes (Medicare, Medicaid, Department of Veteran Affairs (VA), Children's Health Insurance Program, TRICARE (military services)).²⁸⁷

8.1.2 Principles of healthcare governance

In the USA, the federal system of government and the market nature of the system mean that governance occurs at multiple levels and involves multiple organisations. Health policy and administration is in the remit of the US Department for Health and Human Services (DHHS), with the Centers for Medicare & Medicaid Services (CMS) responsible for administering the public health insurance programmes.

The responsibility for the regulation of the quality and standards of care in the USA is divided between the federal and state governments. This division is established by the constitution, which gives states primary responsibility for licensure and certification of providers and facilities. The majority of healthcare providers are private, and insurance is provided primarily by private entities. This gives private entities (insurance companies, employers, and related organisations) a role in the regulation of quality based on their exercise of market power, such as in selective contracting and negotiated reimbursement rates. Patient safety issues are the primary driver of regulatory intervention in healthcare.

State regulation of healthcare quality was established in the 1800s through state licensure.²⁹² Traditionally, regulation has relied heavily on professional self-regulation through board certification and peer review mechanisms. The principal organisation responsible for ensuring care standards in the states is the department of health. In addition to federal regulations states pass individual laws that govern the operation of healthcare facilities. These laws supplement and sometimes impose additional standards on providers. Unlike Medicare, Medicaid and CHIP are federal-state partnerships. Both federal and state governments provide funding but the management responsibility resides with state governments. States must meet federal coverage and benefit requirements but have flexibility to add additional services and determine the delivery method and how much to pay providers.

8.1.3 Recent reforms of the health and social care systems

In 2010, the Patient Protection and Affordable Care Act (ACA) was signed into law.²⁹³ The law initiated sweeping changes to the US healthcare system with the aim of expanding coverage to the uninsured, reducing costs and improving quality of care. Among the key changes introduced by the law is the requirement that all residents obtain health insurance or pay a financial penalty, the requirement that insurance companies accept all consumers, limitations to the variation in premiums charged to consumers, and the establishment of state-level health exchanges with four standard benefit packages. In 2012, the US Supreme Court upheld the mandate to purchase insurance as constitutional, describing the penalty as a tax.²⁹⁴ However, by denying the federal government the option to withhold Medicaid funding from states that did not expand Medicaid eligibility they may have hampered

efforts to expand coverage. The ACA is being phased in in stages with the most significant changes taking place in 2014.

Performance reporting and ‘value-based purchasing’ (primarily pay-for-performance), are starting to play an increasingly important role in ensuring quality of care. Regulators have created a host of new tools centred on the dissemination of performance information (publicly and privately) and payment reforms. These mechanisms serve to regulate quality by directly or indirectly rewarding desired performance behaviour.

8.2 National regulatory or otherwise framework for care quality

8.2.1 Sources of minimum standards of quality in the health and social care systems

The USA has a national framework for creating national standards, but does not have a strong central oversight and enforcement mechanism to assure the quality of care. The considerable power of state governments as the primary regulators of healthcare, and the tendency to rely on private markets to purchase and provide care creates challenges to a unified national quality standard. The traditional focus of regulation in the USA has been on quality assurance, which aims to ensure facilities meet a minimum standard with regard to structural and organisational characteristics to deliver care. Through a series of state and federal laws, the different levels of government and private organisations combine to ensure the quality of care provided to patients.

A number of organisations have varying roles in ensuring patient safety in the USA. Mello et al. (2005) described these roles as problem identification, research and innovation, mandate setting, and enforcing compliance.²⁹⁵ Table 8.1 highlights the main organisations and their roles.

Table 8.1 Main organisations in the USA and their role in ensuring patient safety

	Problem Identification	Research and Innovation	Mandate Setting	Enforcing Compliance
Congress			✓	✓
Centers for Medicare and Medicaid Services			✓	✓
State Legislatures			✓	✓
State Licensing Boards			✓	✓
Private Purchasers eg Leapfrog	✓	✓	✓	✓
Joint Commission	✓	✓	✓	✓
Agency for Healthcare Research and Quality (AHRQ)	✓	✓		
National Quality Forum (NQF), Institute of Medicine (IOM)	✓	✓		
Tort liability System			✓	✓

NOTE: Adapted from Mello et al.²⁹⁵

8.2.2 Overview of main bodies responsible for standard setting and enforcement

Hospital regulation

Individual states, through their Departments of Health, are responsible for the licensure of hospitals. However, CMS requires that all hospitals receiving payments from Medicare be accredited by the Joint Commission as an alternative to a review by CMS. Some state governments accept Joint Commission accreditation as sufficient for licensure. The Joint Commission is a private non-profit organisation comprised of professional societies.²⁹⁶ The Joint Commission sets standards that hospitals must adhere to for accreditation, and requires that they participate in quality improvement activities. The majority of individual performance measures are not released to the public but the overall accreditation rating is made public. Some states also have certificate of need laws that govern the establishment and expansion of healthcare facilities.²⁹⁷

Nursing home regulation

Nursing home regulations are enforced by state Departments of Health. However, the majority of funding from nursing homes comes from Medicare and Medicaid. The federal government set national minimum standards of quality with the passage of the Federal Nursing Home Reform Act (OBRA) in the Omnibus Budget Reconciliation Act of 1987.⁴⁵ Laws passed by state legislatures supplement these standards. OBRA requires unannounced inspections at least every 15 months. Inspections are to include surveys, interviews with residents and family members and ombudsmen about residents' daily experiences, and direct observation of residents and their care. These inspections surveys are to be conducted by a multidisciplinary team of trained professionals and the data stored in the Online Survey Certification and Reporting System (OSCAR), maintained by CMS. The results are made available publicly through the Nursing Home Compare website.⁴⁶ State governments have a number of enforcement options available to them which include escalating scale of penalties which include directed in-service training of staff, a directed plan of correction, state monitoring, civil monetary penalties, denial of payment for all new Medicaid or Medicare admissions, denial of payment for all Medicaid or Medicare patients, temporary management, and closure.⁴⁷

An ombudsman system exists to handle complaints from the public and nursing home residents. Ombudsmen are a subdivision of the state department of health. These complaints must be addressed within ten days and complainants have the right to appeal if they feel their issues have not been satisfactorily resolved. All complaints and steps taken to resolve them are publicly available from the office of the ombudsman. The process of resolving complaints and enforcement options available follow a pattern similar to violations discovered during inspections.

Physician regulation

Professional self-regulation is the norm in the regulation of physicians. Professional boards offer certification of physicians who complete an examination and meet other requirements while state medical boards license physicians to practise within each relevant state. State medical boards usually consist of members of the medical community employed by the state government. Some states also include lay members of the public on state medical boards. The requirements for licensure vary between the states. Medical licensing boards have the power to revoke licenses and administer disciplinary actions. Professional boards

have no enforcement power since professional board certification is a voluntary process. Recertification of board-certified physicians is required periodically by the professional boards. The federally administered National Practitioner Database tracks physician licensing and disciplinary actions across all states.²⁹⁸ Individual hospitals are responsible for granting physicians privileges to carry out operations and procedures within the hospital.

Health insurance regulation

States, through their Departments of Insurance, have primary responsibility for the regulation of health insurers within their states. Regulations are primarily aimed at protecting the public from unfair practices and ensuring the financial solvency of insurers.²⁹⁹ All insurers must be licensed by the states in which they practise. Insurers are required to file insurance policies and premium rates with the state. They submit to periodic audits to detect operational problems, non-compliance with state law, and the finances of insurers. Enforcement tools available to states include the revocation of licensure, prohibition of new enrolment, and initiation of receivership or conservatorship.

The passage of Employee Retirement Income Security Act of 1974 (ERISA) placed the regulation of employee benefits (including employee-sponsored health plans) under the jurisdiction of the federal Department of Labor.³⁰⁰ This applies only to the regulation of the employee benefit plan and not the business of insurance described above. ERISA created uniform federal standards for employee benefits.³⁰¹ The primary remedy for violations of ERISA standards is through the legal system and is limited to payment of actual cost incurred. In 1985, the US Congress passed the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA).³⁰² COBRA amends ERISA, and among other provisions provides certain former employees, retirees, spouses, former spouses, and dependent children the right to temporary continuation of health coverage at group rates. In 1996, the US Congress passed Public Law 104-191, the Health Insurance Portability and Accountability Act (HIPAA). HIPAA serves the following functions:

- It limits the ability of a new employer plan to exclude coverage for pre-existing conditions.
- It provides additional opportunities to enrol in a group health plan if you lose other coverage or experience certain life events.
- It prohibits discrimination against employees and their dependent family members based on any health factors they may have, including prior medical conditions, previous claims experience, and genetic information.
- It guarantees that certain individuals will have access to, and can renew, individual health insurance policies.

It also requires the establishment of national standards for electronic healthcare transactions and national identifiers for providers, health insurance plans, and employers. It contains provisions related to patient privacy and dissemination of an individual's medical information.

More recently, the aforementioned Affordable Care Act (ACA) established Health Insurance Exchange (also known as a Health Insurance Marketplace or Marketplace) to be run by either individual states or the Federal government.³⁰³ Exchanges will serve as

marketplaces for individuals and employers to compare and buy health insurance, with the Department of Health and Human Services holding primary responsibility for establishing the standards and guidelines. The law also mandates that all plans sold through the health exchange meet minimum standards described as ‘essential health benefits’ (EHB). The essential health benefits must include items and services within ten categories: (i) ambulatory patient services; (ii) emergency services; (iii) hospitalisation; (iv) maternity and newborn care; (v) mental health and substance use disorder services, including behavioural health treatment; (vi) prescription drugs; (vii) rehabilitative and habilitative services and devices; (viii) laboratory services; (ix) preventive and wellness services and chronic disease management; and (x) paediatric services, including oral and vision care.

To assist individuals in comparing plans and premium prices, the exchange plans are standardised into five categories (Platinum, Gold, Silver, Bronze, and Catastrophic) based on the average percentage of health care services that the plan covers.³⁰⁴ Plans that meet these standards and other requirements on state licensure, pricing restrictions, plan tier offerings, and any other regulations set by the exchanges must be accredited as Qualified Health Plans (QHP) by a government-approved accrediting agency.³⁰³

The ACA also calls for a system that rates the quality of qualified health plans based on relative quality, price, and enrollee satisfaction. This system, known as the Quality Rating System (QRS), was developed with input from multiple sources and currently includes 67 measures (42 that apply to family/self-only plans and 25 that apply to child-only plans). The proposed system is currently open for public comments and will be reviewed in 2014.

8.3 National Regulatory bodies

8.3.1 The Centers for Medicare and Medicaid Services (CMS)

Legal status and organisational structure

CMS is an agency of the US Department of Health and Human services (DHHS). It was established in 1977 as the Health Care Financing Administration (HCFA) to administer Medicare and Medicaid.²¹ In 1995, congress established the Children’s Health Insurance Program (CHIP), which falls under the purview of CMS. The Administrator of CMS is appointed by the president, and confirmed by the US Senate. It has ten regional offices, headed by directors, and a number of field offices. A selected list of centres and offices within CMS are shown in Table 8.2.

Medicare and Medicaid were enacted as part of the Social Security Act in 1965, and extended health coverage to all Americans aged 65 or older, and provided healthcare services to low-income children deprived of parental support, their caretaker relatives, the elderly, the blind and individuals with disabilities. In 1972, eligibility for Medicare was extended to individuals under 65 with long-term disabilities and to individuals with end-stage renal disease. Medicaid eligibility was also linked to the Federal Supplemental Security Income Program. Prior to 1977, the Social Security Administration (SSA) and Social and Rehabilitation Service (SRS) administered Medicare and Medicaid respectively.²¹

Table 8.2 Selected CMS centres and offices

CMS centre	CMS office
Center for Medicare	Office of the Administrator
Center for Medicaid and CHIP services	Office of Clinical Standards and Quality
Center for Clinical Standards and Quality	Federal Coordinated Health Care Office
Center for Medicare and Medicaid Innovation	Office of Public engagement (Medicare Ombudsman Group and Tribal Affairs group)
Center for Consumer Information and Insurance Oversight	Office of Minority Health
Center for Program Integrity	Office of the Actuary

Scope of action

The primary responsibility of CMS is to administer the government welfare programmes, Medicare, Medicaid and CHIP. Medicaid and CHIP are administered in partnership with the state governments. In addition to administering Medicare, Medicaid and CHIP (established 1995). The laws establishing Medicare, Medicaid and CHIP, and subsequent amendments, assign responsibilities to CMS with regard to minimum quality standards. Healthcare facilities receiving funds through these public programmes are required to adhere to these standards as a condition of participation. CMS is responsible for the specification and enforcement of these conditions.

Coverage decisions in Medicare often impact private sector insurers. In Medicare, National coverage determinations (NCDs) are made through an evidence-based process, with opportunities for public participation. In some cases, CMS own research is supplemented by an outside technology assessment and/or consultation with the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on a local coverage determination (LCD). CMS is also tasked with administrative simplification of HIPAA.

Section 402(a)(1)(A) of the Social Security Amendments of 1967 (Public Law 90-248), permits CMS to engage in demonstration projects. These projects are to determine whether changes in methods of payment for healthcare and services under the Medicare programme would increase the efficiency and economy of those services, by incentivising those ends without adversely affecting the quality of the services. Exercising this authority CMS has established programmes such as the star ratings for Medicare advantage plans. More recently, the ACA requires that CMS establish a value-based purchasing programme. It also tasks CMS with assisting in implementation of the Affordable Care Act, such as review of Medical Loss Ratios, the patients' bill of rights and oversight of health insurance Exchanges. The ACA also establishes the CMS Innovation Center, which identifies, tests and spreads new ways to pay for and delivery care, with the aim of reducing costs through improvement.

The Medicare Payment Advisory Commission (MedPAC), an independent congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33), advises the US Congress on payment issues affecting the Medicare programme and analyses access to care, quality of care, and other issues affecting Medicare. CMS also maintains various data systems related to care provided under its programmes.

Regulatory mechanisms to ensure standard adherence

CMS acts as a payer in the healthcare system and engages in regulation by setting conditions of participation. CMS expenditure comprised almost 50 per cent of all health expenditure in 2010. By virtue of the size of the program these conditions and standards often serve as quality standards for hospitals. Some of these conditions of participation include:

- The requirement that all hospitals caring for Medicare patients must be certified and accredited by the Joint Commission.
- The requirement that all hospitals caring for Medicare patients submit themselves to quality review by CMS carried out by private Quality Improvement Organizations (QIO).
- Facilities must participate in the Quality Assessment and Performance Improvement (QAPI) in which they develop, implement, and maintain an effective, ongoing hospital-wide, data-driven quality assessment and improvement programme using measurable quality indicators.
- All hospitals must adhere to the Emergency Medical Treatment & Labor Act (EMTALA), which requires hospitals to provide care to anyone needing emergency healthcare treatment regardless of citizenship, legal status or ability to pay.

The primary mode of enforcement is the withholding of payments to providers. CMS also uses the financial incentives to promote changes in practice either by changing payment formulas or in pay-for-performance programs. The Tax Relief and Health Care Act of 2006 established the Physician Quality Reporting Initiative (PQRI), which authorises a payment incentive for voluntary reporting of the PQRI performance measures.

All nursing homes must comply with the Nursing Home Reform Act, as determined by annual inspections, for them to be reimbursed for treating Medicaid patients. In addition, CMS collaborates with state Departments of Health to withhold Medicaid funding from nursing homes that fail to address safety issues discovered during inspections. The Office of Inspector General (OIG), a division of HHS, is mandated to protect the integrity of HHS programmes, and the health and welfare of programs beneficiaries served by them. Within the OIG, the Office of Evaluations and Inspections (OIE) performs short-term management and program evaluations that focus on issues of concern to the department, Congress and the general public. They recommend legislative, regulatory and operational approaches to correct any deficiencies identified.

8.3.2 The Department of Veteran Affairs

Legal status and organisational structure

The Department of Veteran Affairs (VA), established in 1930 by Executive Order 5398, became a cabinet-level position in 1989 (Public Law No 100-527). The secretary of Veteran Affairs, who is appointed by the president and confirmed by the senate, heads the department. The VA is organised into three main units, Veterans Health Administration (VHA); the Veterans Benefits Administration; and the National Cemetery System. A deputy-secretary is in responsible for the each unit and they report the secretary.³⁰⁵ Seven

assistant secretaries, serve as principal advisors and administer programs in their respective areas of responsibility. There are also fourteen staff offices.

Scope of action

The Veteran Benefits Administration is responsible for the administration of benefits to military personnel including health insurance used to obtain care in VA facilities. VHA manages the VA facilities and is responsible for the

- provision of health services to beneficiaries
- graduate medical training in the VA system
- research activities.

Provision of health services

The VA is the largest integrated health system in the USA. VHA currently runs 152 medical centres, and 1,095 vet centres and community-based outpatient clinics,³⁰⁶ organised into 21 Veteran Integrated Service Networks (VISN), described as ‘integrated networks of healthcare facilities that provide coordinated services to veterans to facilitate continuity through all phases of healthcare.’⁴⁹ In 2010 approximately 8.3 million individuals received care in the VA system.³⁰⁶

Graduate medical training

The VA collaborates with academic medical institutions to provide medical training. In 2011, 36,816 medical residents, 24,520 medical students, 288 Advanced Fellows, and 1,231 dental residents and dental students received some or all of their clinical training in VA. Of its 152 VA medical centres and 6 independent outpatient clinics (IOCs), 124 hospitals and 3 IOCs have affiliation agreements with 114 of 136 allopathic Accredited Medical Schools and 15 of 26 osteopathic medical schools for physician education.³⁰⁷

Research

The VA is a pioneer in healthcare research. Reforms that transformed the VA into a model health system that it is today were supported by VA research.³⁰⁸⁻³¹⁰

Regulatory mechanisms to ensure standard adherence

Regulatory mechanisms within the VA are primarily management practices. The Office of Inspector General (OIG), established by Public Law 95-452, is an independent organisation that includes the Office of Healthcare Inspections (OHI), the Office of Investigations and the Office of Audits and Evaluations, was created to monitor the healthcare provided to the veterans.⁴⁸ OIG is responsible for:

- conducting and supervising audits and investigations
- recommending policies designed to promote economy and efficiency in the administration of, and to prevent and detect criminal activity, waste, abuse, and mismanagement in VA programmes and operations
- keeping the secretary and Congress fully informed about problems and deficiencies in VA programmes and operations and the need for corrective action.

OIG is legally authorised to gain access to all records, reports, audits, reviews, documents, papers, recommendations, or other pertinent materials. In performing its assigned

functions, OHI inspects individual healthcare issues, performs quality programme assistance reviews of medical centre operations, evaluates nationwide healthcare programmes, and provides clinical consultations that are designed to strengthen Veteran's Health Administration's (VHA's) healthcare, and other missions. The office makes recommendations aimed at addressing any deficiencies observed during their inspections. In its most recent six-month reporting period, OIG published 3 national healthcare reviews; 21 Hotline healthcare inspections; 24 Combined Assessment Program (CAP) reviews; and 10 Community Based Outpatient Clinic (CBOC) reviews, covering 49 facilities, to evaluate the quality of care. Physicians practising within the VA system must be accredited and credentialed. They are also subject to external review.⁴⁹

8.3.3 Indian Health Service (IHS)

Legal status and organisational structure

The Indian healthcare system consists of the IHS, tribally operated healthcare services, and Urban Indian healthcare services and resource centres. IHS was established in 1955 and is a federal government programme that provides healthcare services to approximately two million American Indians and Alaska natives. It is an agency in the Department of Health and Human Services (HHS). The Indian Health Care Improvement Act (IHCA), originally passed in 1976 authorises the IHS to provide services.³¹¹ With the passage of the ACA, IHCA was reauthorised indefinitely.³¹² The director of the IHS is appointed by the president and confirmed by the US Senate. Its health services are divided into twelve services areas, each headed by a director who reports to the chief medical officer.

Scope of action

The IHS administer forty-five hospitals, three hundred and twenty-six health centres and over three hundred clinics, health stations and school health centres.³¹³ In addition to providing direct services it contracts or funds Urban Indian Organizations to run Urban Indian Health Projects. Unlike the VHA and Medicare, a portion of the health service budget is used for public health projects such as sewage disposal and waste management. Through its employment practices the IHS also addresses social determinants of health in these populations.

Regulatory mechanisms to ensure standard adherence

All IHS hospitals are accredited by the Joint Commission or certified by CMS.³¹³ Regulation in the IHS is mainly through management practices.

8.3.4 State Departments of Health

States derive their power to regulate the practice of medicine from the Tenth Amendment of the Constitution. Under the police power states have the authority to pass regulations to protect the public health and safety of its citizens. Each state in the USA has a department of health. A commissioner appointed by the state governor runs the department, which is responsible for activities such as:

- Setting and enforcing standards got healthcare organisation
 - Licensure of hospitals, nursing homes and physicians
 - Regulation of health insurers
 - State medical malpractice legislation

- Administration of Medicaid and CHIP
- Direct provision of medical services (eg immunisations)

Healthcare facilities must be licensed by the states in which they operate. The requirements for licensure vary by state but the majority of states rely on the Joint Commission for the accreditation of healthcare facilities. Health insurance is also regulated by the state government, through a variety of departments across the states including Departments of Finance, Departments of Insurance, Departments of Health, Departments of Commerce and Consumer affairs, and Departments of Labor and Economics. The laws governing health insurance usually require certification before a company is allowed to offer insurance to state residents. Insurance companies may also be required to provide a specific minimum set of services. States are responsible for the regulation of nursing homes within their jurisdiction. In addition to the federal law, states have their own laws regulating the functioning of nursing homes. Despite numerous reforms and appreciable gains in quality, studies have criticised the enforcement of the law citing ineffective use of available penalties. State medical boards license medical practitioners.

Malpractice laws vary by state. These laws determine various aspects of the case such as the statute of limitations, whether contributory or comparative negligence is applicable, liability (joint or several), and caps on damages.

8.3.5 State medical boards

State medical boards are responsible for the licensing of physicians in the state. The requirements may include a specific number of years of post-graduate experience, and the permitted number of attempts at the medical licensing exam. The state medical boards are also responsible for the investigation of complaints against physicians, and disciplining of physicians where necessary.³¹⁴ Disciplinary action may range from a reprimand or fines to license revocations, surrenders, suspensions and probation/restrictions.³¹⁵ The size and make up of medical boards vary, as do their financial relationships with state governments.

8.4 Quasi-governmental and other actors

8.4.1 Quality Improvement Organizations (QIOs)

Legal status and organisational structure

QIOs are independent private organisations contracted by CMS to review care by hospitals receiving payments from Medicare or Medicaid.³¹⁶ They are responsible for the external review of Medicare and Medicaid providers and focus on the measurement of care processes and outcomes. CMS contracts with one organisation in each state. These reviews became a condition of participation in 1985. The statutory objectives of QIOs is to improve quality of care for beneficiaries; ensure that Medicare pays only for services and goods that are reasonable and necessary and that are provided in the most appropriate setting; and protecting beneficiaries by expeditiously addressing individual complaints, such as beneficiary complaints, provider-based notice appeals, violations of the Emergency Medical Treatment and Labor Act (EMTALA), and other related responsibilities as articulated in QIO-related law. QIOs have three-year contract cycles with each cycle emphasising different aspects of care. The sixth statement of work focused on improving the quality of care by using a standard set of twenty-two indicators to measure performance

across all states. Currently QIOs are in the tenth cycle or statement of work, which is focused on integrated care for populations and communities.

Scope of action

QIOs work with hospitals on quality improvement in a variety of ways, including providing educational materials, using data collection and feedback to track performance on quality indicators, and assisting hospitals in implementing systems changes (eg standing orders, clinical pathways).

8.4.2 The Joint Commission (JC)

Legal status and organisational structure

The Joint Commission is an independent non-profit organisation engaged in the accreditation and certification of healthcare providers in the USA.²⁹⁶ Founded in 1951, its mission is to continuously improve healthcare for the public, in collaboration with other stakeholders, by evaluating healthcare organisations and inspiring them to excel in providing safe and effective care of the highest quality and value. It was founded by the American College of Surgeon, the American College of Physicians (ACP), the American Hospital Association (AHA), the American Medical Association (AMA) and the Canadian Medical Association (CMA). It derives its regulatory power from the CMS requirement that hospitals, doctor's offices, nursing homes, office-based surgery centres, behavioural health treatment facilities, and providers of home care services receiving payments for Medicare, Medicaid, and CHIP be accredited, with accreditation by the Joint Commission being sufficient to satisfy this requirement. Since 1972, HHS has been required to validate Joint Commission accreditation process. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires that the Joint Commission accreditation process be periodically reviewed and approved by CMS.

Scope of action

The Joint Commission published its first Standards of Hospital Accreditation in 1953. It conducts random surveys of healthcare facilities. To earn and maintain the Joint Commission's Gold Seal of Approval, an organisation must undergo an on-site survey by a Joint Commission survey team at least every three years.

The Joint Commission promotes quality its inspections by establishing new standards. For, example the annual National Patient Safety goals, updated and published annually, focus on problem areas in healthcare and means to address them. These goals have advanced the prevention of hospital-acquired infections and changed the reconciliation process for medicines.

The ORYX initiative was integrated into the Joint Commission accreditation process, and in combination with CMS defined a set of measures of hospital quality, the National Hospital Quality Measures.³¹⁷ The National Quality Forum (NQF) endorses the National Hospital Quality Measures. All hospitals participating in the accreditation process are required to collect and submit the necessary data. Performance is publicly reported through the Quality Check website.

8.4.3 National Committee for Quality Assurance (NCQA)

Legal status and organisational structure

NCQA is a private, not-for-profit organisation responsible for the accreditation of health insurance plans and providers.³¹⁸ It was founded in 1990, with a vision to transform healthcare quality through measurement, transparency and accountability. NCQA grew out of market pressure from insurers interested in the quality of their providers. NCQA is governed by an independent board of directors. The board is comprised of fifteen members plus the president of the organisation. The board chair is an independent director who serves a term of three years as chair. There are no seats on the NCQA board reserved for specific stakeholders. Rather, board composition is structured to include many competencies and a multi-stakeholder model including representatives from employers, physicians, public policy experts, consumer groups and health systems, all of which are instrumental in enabling NCQA to achieve its mission.³¹⁸

Scope of action

In 1991, NCQA, in collaboration with CMS and other stakeholders, introduced the Health Plan Employer Data and Information Set (HEDIS). In combination with the Consumer Assessment of Health Plans Survey (CAHPS), HEDIS is used to assess the quality of healthcare plans and promote continuous quality improvement. NCQA accreditation findings are publicly available. Accredited health plans today face a rigorous set of more than 60 standards and must report on their performance in more than 40 areas. NCQA ratings are used by local and state governments in pay-for-performance programs. As healthcare delivery models have evolved NCQA has added accreditation of Accountable Care Organizations (ACOs) and Patient-Centred Medical Homes (PCMH), and developed disease and case management modules. In 2012, NCQA was recognised as one of two accrediting agencies for Qualified Health Plans in the Health Insurance Exchanges created by the Affordable Care Act.

8.4.4 Utilization Review Accreditation Commission (URAC)

Legal status and organisational structure

URAC is a private not-for-profit organisation with a wide range of accreditation, education, and measurement programmes.³¹⁹ URAC was formally incorporated in 1990, and has more than 30 accreditation and certification programs. URAC is governed by a board of directors comprised of twenty members who represent consumers, providers, employers, regulators, and industry experts

Scope of action

URAC serves as an impartial body reviewing the activities of healthcare organisations and plans and certifying that they meet national standards with regard to quality and accountability. Some states require URAC accreditation for organisations operating within their territory. CMS recognises URAC as a deeming authority for Medicare Advantage Health Maintenance Organizations and Preferred Provider Organizations. In 2012, URAC along with NCQA was selected as an accrediting agency for Qualified Health Plans in the Health Insurance Exchanges mandated by the Affordable Care Act.

8.5 Case studies

Case 1: Hospitals (Department of Veteran Affairs)

National Surgical Quality Improvement Program

The National Surgical Quality Improvement Program (NSQIP) was set in motion by the passage of Public Law 99-166¹⁸ by the US Congress in 1985. The law was passed in response to public concerns about surgical mortality rates in Veterans Affairs (VA) hospitals. It mandated that the Veterans Health Administration compare risk-adjusted surgical outcomes in the VA to the national average for non-VA hospitals. Among the key challenges in making such comparisons are differences in the pre-operative mortality risk for patient populations in VA and non-VA hospitals and VA administrators identified the need for an adequate risk adjustment model as an important precursor to the comparison.³²⁰ From 1991 to 1993 the VA conducted the National VA Surgical Risk Study (NVASRS).³²¹ Building on Iezonni's 'algebra of effectiveness' framework, NVASRS created a database of pre-op risk factors and post-op outcomes and used these data to develop validate a risk-adjustment model.³²⁰

In 1994, the NSQIP, using the NVASRS risk-adjustment model, was implemented across all VA hospitals performing major surgery. NSQIP requires the prospective collection of 77 data elements and data on 30-day mortality, morbidity and hospital length of stay.³²⁰ A dedicated clinical nurse surgical reviewer collects data on-site and transmits data to a centralised facility for analysis. The results are used to promote continuous quality improvement through self-assessment, site visits, and dissemination of best practices. The programme is not intended to be punitive but provides feedback to hospitals in the form of an annual site and specialty-specific review showing anonymous comparative annual risk-adjusted performance data; periodic assessments of high and low outliers; self-assessment tools to help identify strengths and weaknesses; site visits to help identify and address deficiencies in the quality of care; and the identification and dissemination of best practices gleaned from high performers or hospitals demonstrating significant improvement. The programme has been associated with a reduction in mortality and morbidity of 47 per cent and 45 per cent respectively between 1991 and 2007. Among the key strengths of the programme are the perceived validity of the data among surgeons, the use of rigorous statistical analysis, and the collegial relationship between hospital executives and programme administrators. The NSQIP program was validated and adopted by private sector hospitals in 1999.

NSQIP in action

In 2007, NSQIP identified the VA Medical Center at Marion Illinois as having a mortality rate four times the expected.³²² A NSQIP review team conducted a site visit and identified a number of deficiencies in the organisation of surgical services at the facility. As a result in-patient surgery was shut down, and the Office of Inspector General, Department of Veteran Affairs initiated a review. The review involved numerous site visits to the facility and the service network for the hospital, by an expert panel of surgeons and anaesthesiologists. Interviews were conducted with physicians; other clinical and administrative staff; veterans and family members; and VHA leadership at Marion VAMC, VISN 15, and VA Central Office in Washington, DC. Records were subpoenaed from state medical licensing boards and other institutions. The Federation of State Medical

Boards (FSMB) was contacted to determine the extent of information provided VHA, as was the Department of Health and Human Services concerning VHA inquiries regarding the National Practitioner Database (NPDB). Recommendations included addressing deficiencies in the quality management system, credentialing of physicians, privileging of physicians, and facility leadership. The facility has since acted on these recommendations and resumed in-patient surgeries.

Case 2: Nursing homes (Organisation: Centers for Medicaid and Medicare Services)

Partnership to Improve Dementia Care

Antipsychotics are not indicated for the treatment of dementia patients. Studies have shown an increased risk of death for elderly dementia patients taking antipsychotics. Since 2008, the Food and Drug Administration has required 'black box' warnings on both typical and atypical antipsychotics indicating the potential for death when administered to the elderly dementia patients. A section of OBRA (42 C.F.R. §483.25[l]) limits the use of antipsychotic drugs in nursing homes requiring a clinical record of the condition it is being used to treat, attempts to discontinue its use unless contraindicated. CMS encourages the use of alternative forms of non-pharmacological treatment. The law also established a procedure for the investigation of unnecessary or inappropriate drug use in nursing homes. Despite this numerous studies have indicated the widespread use of antipsychotics in nursing homes. A study by Crystal et al. reviewed the use of antipsychotics and explored the safety issues surrounding it.³²³ They noted a 7.4 per cent increase in the use of antipsychotics in nursing homes from 1999 to 2006 and widespread use among patients with dementia. A 2010 CMS report indicated that 39.4 per cent of nursing home residents who had cognitive impairments and behaviour problems but no diagnosis of psychosis or related conditions received antipsychotic drugs.³²⁴ A 2011 report by the DHS Office of Inspector General indicated that 14 per cent of all claims from nursing homes residents with Medicare included antipsychotics and 88 per cent of the atypical antipsychotics prescribed off-label were for dementia.³²⁵ In response to these observations a number of changes have been instituted by Congress and CMS in partnership with other states, facilities, advocacy groups and caregivers.

In 2012, Congress passed the Food and Drug Administration Safety and Innovation Act requiring the Health and Human Services Secretary to issue standardised protocols for obtaining informed consent, or authorisation from patients or their designated healthcare agents or legal representatives, acknowledging possible risks and side effects associated with the antipsychotic, as well as alternative treatment options, before administering the drug for off-label use.³²⁶

CMS has recently launched the Partnership to Improve Dementia Care. This national programme aims to raise public awareness of antipsychotics' misuse, improve regulatory oversight and, reduce antipsychotic use. A short-term target is a 15 per cent reduction in antipsychotic use by nursing homes by the end of 2012. Initiatives contained in the programme include:

- i) Hand in Hand, a training series for nursing homes that emphasises person-centred care, prevention of abuse, and high-quality care for residents
- ii) Training focused on behavioural health to state and federal surveyors

- iii) Public reporting of each nursing home's antipsychotic drug use available on Nursing Home Compare
- iv) Emphasis on non-pharmacological alternatives for nursing home residents, including potential approaches such as consistent staff assignments, increased exercise or time outdoors, monitoring and managing acute and chronic pain, and planning individualised activities.

In addition, CMS is conducting research in a group of nursing homes to better understand the decision to use or not to use antipsychotic drugs in residents with dementia, and improve the overall management of patients with dementia.

8.6 Summary and conclusion

Regulatory activity in the USA is for the most part decentralised with multiple local governmental and private sector agencies involved in assuring quality. The legislation passed by congress and regulations issued by the executive branch focus on quality assurance, which is aimed at ensuring basic minimum structural and operational requirements for healthcare facilities. Each state licenses healthcare facilities within its territory. Most states require Joint Commission accreditation as a condition for licensure. The federal Medicaid and Medicare programmes require healthcare facilities obtain Joint Commission accreditation for to participate in the programme. In the case of nursing homes, federal regulations are supplemented by different laws passed by individual states, each state is responsible for enforcement of these regulations. This illustrates the complex interaction between the federal government, state governments, and private sector quality agencies in the US healthcare system. Malpractice legislation is also used to address the more obvious patient safety issues or medical errors.

Quality of care measurement occurs at multiple levels; organisations such as the National Quality Forum (NQF) and the Agency for Healthcare Research and Quality (AHRQ) have developed a series of quality indicators. AHRQ publishes the annual National Healthcare Quality and Disparities reports. These reports measure trends in effectiveness of care, patient safety, timeliness of care, patient centeredness and efficiency of care.³²⁷ DHHS maintains the Hospital Compare³²⁸ and Nursing Home Compare⁴⁶ websites which show performance metrics for Medicare providers. Comparative performance metrics for health insurance will be available to the public under from the Quality Rating System. The US General Accountability Office (GAO) is an independent, nonpartisan agency that works for Congress, tasked with investigating how the federal government spends taxpayer dollars.³²⁹ As such it often reviews the actions and activities of CMS and other healthcare agencies in government. The GAO has published criticism of the limited use of regulatory powers with regard to nursing homes.^{47 330} They have also recently examined the quality bonus demonstration programme put in place by CMS.³³¹ Among physicians the number and frequency of sanctions levied by the state medical boards varies between states.³¹⁵ The National Quality Strategy is an attempt to unify and streamline the efforts of diverse federal agencies involved in healthcare, with input from private sector stakeholders.

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APPENDICES

Appendix A: Template for data collection

The comparative assessment of regulatory mechanisms in place aimed at assuring that essential standards of care are being implemented and adhered to will be structured along the following key questions, which will be addressed for each of the seven countries under review:

(i) What agency/organisation is responsible for implementing and assuring adherence to essential standards of care in the health and social care systems?

If there are several agencies/organisations that have (part) responsibility in the implementation and monitoring of essential standards in the health and social care systems we would seek to describe each according to:

- a) Administrative tier at which the agency/organisation is located (national, regional, local)
- b) The (legal) status and accountability of the agency/organisation (agency independent of government; regulatory agency reporting to parliament; subordinate to the ministry of health/arm's length body; part of MoH, etc)
- c) Who defines the remit/scope of responsibility of the agency/organisation (law; national/regional government; ministry of health, etc)
- d) What area of the health and social care system/s is the agency/organisation responsible for (eg physicians, nurses, ambulatory care providers, hospitals, long-term care/nursing homes, residential care homes, mental healthcare providers, palliative care providers, public/private sector where applicable, etc) (*see also Section (ii)-(b) below*)
- e) Who makes appointments of senior executives of the agency/organisation?
- f) How is the agency/organisation organised
 - a. Number of departments (organisation chart available?)
 - b. Number and type of staff (professional background; qualification/s)
 - c. Function of staff (operational, strategic; see also question (3) below)

(ii) What is the mandate or scope (of action) of the agency/organisation?

If there are several agencies/organisations that have (part) responsibility in the implementation and monitoring of essential standards in the health and social care systems we would seek to describe each according to:

- a) What are the essential standards of care applied by the agency/organisation? How are these formulated and what is their origin (eg legislator, administrative body issuing decisions, professional association, self-regulatory body)?
- b) Describe the scope of action of the agency/organisation (eg licensing, registration, accreditation, monitoring, inspecting, target setting; peer review, etc).
- c) What (legal) instruments does the agency/organisation have at its disposal to ensure adherence to essential standards (eg criminal/civil penalty, revocation/suspension of licence, incentive payment/withdrawal of funding, peer pressure)
- d) If the agency/organisations is only responsible for part of the system aimed at assuring essential standards of care are being implemented and adhered to, what are the mechanisms for collaboration/working with other agencies/organisations responsible for other parts?
- e) If there are no formal mechanisms for collaboration between agencies/organisations, what is the level of duplication and/or risk of gaps in the system of ensuring minimum standards of care?

(iii) What are the mechanisms for the agency/organisation to execute its mandate?

- a) How does the agency/organisation monitor that essential standards are being adhered to (eg regular inspection, mandatory collection and reporting by the providers being monitored, self-certification of providers of care with ad-hoc inspections)?
- b) How frequently is the monitoring function carried out (eg monthly, quarterly, annually, bi-annually, ad hoc)?
- c) What format is being used for monitoring adherence (eg electronic, paper documentation, on site visits)?
- d) Where (regular) inspection is carried out, who will typically be assigned this task (eg competence/professional background of staff, composition of team where relevant)?
- e) What happens when a provider is found to have violated (some/all) essential standards? Please describe the typical processes in place.
- f) How is information on adherence to essential standards used (eg internal reporting only, reporting to regulator, made public through regulator website)?