This document contains links to websites where you can find national legislation and health laws. We link to official government legal sources wherever possible. Where we link to unofficial sources this is noted and users should take this into account before relying on these materials. We recommend checking with the relevant national government if you have questions about the currency or validity of any unofficial source of law.

**Legal system**

| Legal system | Common law |

**National law database**

| Language: | English |
| Link: | [http://www.irishstatutebook.ie](http://www.irishstatutebook.ie) |
| Nature: | The Irish statute book |
| Organisation responsible for the website: | The office of the attorney general |

**Health law database**

| Language: | English |
| Nature: | Official website of the ministry of health of Ireland |
| Organisation responsible for the website: | Irish ministry of health |

**Legal UHC start date**

| Legal UHC start date | 1970 |

**Source:**

[http://www.euro.who.int/__data/assets/pdf_file/0004/85306/E92928.pdf](http://www.euro.who.int/__data/assets/pdf_file/0004/85306/E92928.pdf)

**The health system and policy monitor: regulation (PDF)**

As part of its Health Systems in Transition (HiT) series the European Observatory on Health Systems and Policies systematically describes the functioning of health systems in countries as well as reform and policy initiatives in progress or under development. The HiT health system reviews cover the countries of the WHO European Region as well as some additional OECD countries. This PDF includes information about the country’s regulation. To see the complete HiT report of this country go to: [http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits](http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits)
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HSPM Contributors: Burke S, Barry S, Keegan C, Thomas S, Cylus J
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4. Regulation and planning

4.1 Regulation

Overall responsibility for the health care system lies with the Government, under the direction of the MoHC in accordance with legislation enacted in the Oireachtas (legislature). The Minister is responsible for the strategic development and overall organization of the health service, including the setting of statutory regulations and orders. The DoHC provides support to the Minister and the Government by advising on the strategic development of the health system, evaluating the performance of the health system and working across sectors to promote health and well-being. Ultimately, the DoHC is charged with the responsibility of holding the health care delivery system accountable for its performance.

Since 2005 the HSE has had full operational and financial responsibility for managing the public health system. Each year an annual national health service plan is prepared by the HSE. This must be approved by the MoHC within 21 days and is guided by the 2001 Health Strategy, legislative acts and government priorities. This detailed plan, running to almost 200 pages for 2008, sets out how the health budget will be allocated to hospitals, primary care and other services, and also indicates measures put in place to monitor and control implementation (HSE, 2007f). This includes a ceiling on employment levels within the health system.

Historically, issues of service quality and quality initiatives have been ad hoc and fragmented. Health had been a relatively low priority on the political agenda during the 1980s and early 1990s, where economic recovery was the key issue. It was only with the issue of the contamination of blood products that such concerns came to prominence both on the political agenda and in the public consciousness. More recent high-profile inquiries, such as that at Our Lady of Lourdes Hospital in Drogheda, highlight the need for effective surveillance and monitoring systems.

For the public sector, the independent HIQA, which came into being in 2007, is responsible for setting and monitoring compliance with standards, monitoring health care quality, providing programmes of accreditation for independent health care providers, and conducting investigations where there may have been serious risks to the safety of patients or staff within the health (and social) care system.

4.1.2 Regulation of the private insurance market

As indicated in Chapter 2 Organizational structure and Chapter 3 Financing, VHI plays an important role in health care and over half of the Irish population are covered by some form of private insurance scheme. The three open enrolment insurers, together with the closed enrolment schemes, are all monitored by the HIA. This was established in February 2001 under the Health Insurance Act of 1994 to regulate the private insurance market following the enactment of the European Third Non-Life Insurance Directive.

With an income of €2.01 million in 2007, raised through a levy of 0.14% of all basic health insurance premiums paid to either commercial or restricted undertakings in Ireland (HIA, 2008), the HIA has a number of functions. These include evaluation and analysis of returns made under risk-equalization regulations, as well as more general developments in the private health insurance market. The HIA makes recommendations on risk equalization between insurers, maintains a register of insurers, and monitors all schemes to ensure that they comply with Minimum Benefit Regulations. The HIA also assists consumers of health insurance with complaints and puts information on different insurance products into the public domain.

4.1.3 Quality assurance and accreditation

Awareness of quality concerns in the health system
The 2001 Health Strategy recognized that there was a need for a more comprehensive and coordinated national and local programmes. The strategy identified a number of weaknesses in the system including:

- inadequate and poorly integrated information systems to support the measurement of inputs and outcomes on a quantitative or qualitative basis within the health system;
- insufficient investment in the development of intellectual and organizational capacity to carry out comprehensive research and analysis of policy options;
- lack of an overriding national structure responsible for the development, dissemination and evaluation of the impact of agreed national quality protocols and standards;
- a lack of mechanisms between employers and professional regulatory bodies for identifying the scope of – and boundaries between – the role of the regulators to assure individual competence, as well as that of the employers to manage performance at work; and
- concerns about a “blame culture” in which quality audits and evaluations make individual practitioners feel isolated and vulnerable.

At the same time, public and political awareness of quality issues in health care had been heightened as a result of tragic blood transfusion scandals, when it transpired that more than a thousand haemophiliacs, pregnant women and others had been infected with HIV and with hepatitis C. This led to the establishment of the high-profile Finlay and Lindsay tribunals, which reported their findings in 1997 and 2002, respectively (Finlay, 1997; Lindsay, 2002).

**Quality assurance mechanisms**

HIQA was established in part as a response to the weakness in the system. It is responsible for setting national standards for the provision of health and social care services, except Mental Health Services. These standards incorporate minimum standards for quality and safety for a given service, as well as developmental standards to support moving towards excellence. They are being developed by expert working groups based on evidence and best practice within Ireland and internationally. Detailed standards being implemented at the time of writing include those for: independent assessment of needs for people with physical and intellectual disabilities, symptomatic breast disease, residential care settings for older people, infection prevention and control and hygiene.

Multidisciplinary teams of professional and lay reviewers monitor whether standards are being met by undertaking site visits. They also work with health care organizations to identify areas for improvement and recognize good practice. Reports of Quality Assurance Reviews are published on HIQA’s web site, together with an action plan from the service provider outlining a programme to address the recommendations of the report.

HIQA recently organized the Hygiene Services Quality Review, the most comprehensive review of its kind ever undertaken in Ireland (HIQA, 2007c). A series of unannounced visits, which were conducted by HIQA’s assessors, focused on corporate management, service delivery and included interviews with staff, managers, patients and visitors. The Review set new benchmarks for hospitals to aim for, on behalf of their patients. Individual detailed reports have been provided to each hospital to inform them of areas of strength and areas for further improvement. Hospitals were rated as being “very good”, “good”, “fair” or “poor”. No hospital was rated as “very good” and seven (14%) were rated as “good”. A total of 35 hospitals (68%) achieved a “fair” rating, while nine (18%) hospitals were rated as “poor”. The Review concluded that hospitals can and should do better in terms of improving hygiene.

HIQA also has responsibility for most accreditation mechanisms for publicly funded health care services in Ireland. The former Irish Health Services Accreditation Board has been subsumed into HIQA. Under this board two accreditation scheme frameworks have been developed in consultation with international experts, for acute and palliative care, respectively – each with three different grades of accreditation. While participation in the accreditation scheme is voluntary, over 95% of all acute care and 33% of all palliative care organizations have applied for accreditation at the time of writing (HIQA, 2007a). Organizations which receive accreditation status must demonstrate that they have an extensive organization-wide risk-management approach in order to maximize patient safety; make use of a quality system which actively seeks to identify problems within the provision of care and rectify them; and be predominantly compliant with all key aspects of health service provision identified in the two scheme frameworks (Irish Health
Services Accreditation Board, 2004). Each completed accreditation sets out strengths and areas for improvement. It also specifies priority actions to be taken; these can be the subject of follow-up inspections. The Social Services Inspectorate, operating since 1999, has also been subsumed within HIQA. It is responsible for registering and inspecting all residential services for older people, people with disabilities and children in need of care and protection.

Until 2005 the Comhairle na nOspidéal (The Hospital Council) was a statutory body set up under the Health Act of 1970. Its main functions were to regulate the number and type of appointments for consultant medical staff in hospitals, and to specify qualifications for such appointments. It also advised the MoHC on matters relating to the organization and operation of hospital services and published reports relating to such services. The Comhairle and its functions were subsumed into the HSE.

4.1.4 Regulation of health care professionals

In terms of regulating health care professionals, a number of professional associations and statutory bodies play a role in Ireland, largely maintaining registers, as well as running and/or accrediting training and education.

Since 1979, the Medical Council (Comhairle na nDochtuirí Leighis) has been responsible for the standards of education and training for undergraduate and postgraduate medical students. It also maintains the register of doctors, sets professional standards and implements disciplinary procedures. It is funded through annual registration fees. Since 1995 the Medical Council has undertaken annual inspections of medical schools. All doctors on the specialist registers of the Medical Council must participate in 50 hours of continuing medical education/continuing professional development every year, or 250 hours over a 5-year period. The scheme is to be extended to include all doctors on the general register and they will be asked to demonstrate that at least 25 hours of continuing medical education/continuing professional development have been participated in, for the purposes of clinical audit or peer review processes. The Irish College of General Practitioners (ICGP), founded in 1984, is the recognized body for the accreditation of specialist training in general practice in Ireland and is recognized by the Medical Council and the Postgraduate Medical and Dental Board as the representative academic body for the specialty of general practice.

An Bord Altranais (Nursing Board), with a budget of more than €5.8 million in 2005 raised largely through retention and registration, education and examination fees, has legislative responsibility under the 1985 Nurses Act for the registration of nurses in Ireland (An Bord Altranais, 2006a). This includes a number of different disciplines: general, midwives, psychiatric, sick children, public health, intellectual disability and tutors. It also provides verification of qualifications to allow Irish nurses to work outside the country. The Board is required to assess, every five years, the adequacy and suitability, effectiveness and efficiency of hospitals and institutions for nurse training, and to ensure that all Board regulations and European Directives are complied with. The Board also approves a number of post-registration education courses for continuing medical education. The Government gave its approval for the publication of the draft heads of a new Nurses and Midwives Bill in November 2007 to facilitate a public consultation process. The purpose of the Bill will be to modernize the regulatory framework for nurses and midwives and to enhance patient safety and the protection of the public. The Bill will be consistent with the Government’s commitment to strengthen and expand the provisions for the statutory regulation of health professionals.

Under the Pharmacy Act of 2007, a new Pharmaceutical Society of Ireland was established, replacing the old society that dated back to 1875 (see Chapter 5 Physical and human resources). The new society maintains the register of pharmacists and pharmacies in Ireland, is responsible for the assessing and accrediting degree courses, inspecting pharmacies, drawing up codes of conduct and quality assurance, processing complaints and acting as the competent authority for the recognition of qualifications outside of Ireland.

Under the Dentists Act of 1985 the Dental Council (An Comhairle Fiaclóireachta) is responsible for the registration of dentists and accreditation of courses. The Opticians Board (Bord na Radharcmhastoirí) fulfils a similar role for ophthalmic and dispensing opticians. Under the 1956 Act it also regulates the prescribing, dispensing of prescriptions and sales of spectacles. Set up in 2000, following the 1993 review of the Ambulance Service, the Pre-Hospital Emergency Care Council is responsible for the accrediting institutions training emergency medical technicians, while the National Council for the Professional
Development of Nursing and Midwifery, set up in 1999, has the same role for specialist postgraduate nursing/midwifery courses. Since 1995 the National Social Work Qualifications Board accredits training courses and validates international qualifications in social work.

The Health and Social Care Professionals Act 2005 provides for the establishment of a system of statutory registration for the following 12 health and social care professionals: clinical biochemists, dieticians, medical scientists, occupational therapists, orthoptists, physiotherapists, podiatrists, psychologists, radiographers, social care workers, social workers, and speech and language therapists. This new system of statutory registration will apply to the 12 professions regardless of whether they work in the public or private sectors or are self-employed, and is the first time that fitness-to-practise procedures will be put in place for these professionals on a statutory basis.

The Health and Social Care Professionals Council now has overall responsibility for the regulatory system and a committee structure to deal with disciplinary matters. There is to be a registration board for each of the professions to be registered, with administrative support to be provided by the Council. The Council was launched by the MoHC in March 2007 and has 25 members, including the Chairperson. A suitable organizational structure is being put in place and it is hoped to have some of the registration boards in place by the end of 2008.

**Recent reform: the Medical Practitioners Act of 2007**

The new Medical Practitioners Act of 2007 will make continuing professional development and education compulsory under the auspices of the Medical Council. It will also ensure that competence assurance will be given a statutory basis. This new legislation is intended to reduce the risk of events, such as that which took place at Our Lady of Lourdes Hospital in Drogheda, from being repeated. Serious gaps in monitoring and surveillance structures were highlighted in an inquiry into peripartum hysterectomies at Our Lady of Lourdes Hospital. This inquiry had been established by the Government in 2004 following the decision of the Medical Council to remove Dr Michael Neary from the Register of Medical Practitioners after finding him guilty of professional misconduct. The Inquiry examined how the rate of peripartum hysterectomies performed at the Lourdes Hospital in Drogheda from 1974 to 1998 compared with that in other hospitals. It also looked at how existing monitoring and reporting systems functioned and what had been done in recent years to improve quality control procedures.

The report concluded that the rate of 188 peripartum hysterectomies during the 25-year period was “truly shocking”. The rate of caesarian hysterectomies at the hospital was 1 per 37 caesarian sections compared with between 1 per 300 and 1 per 254 elsewhere. No concerns were raised with the Health Board about this until 1998; moreover, an unidentified person or persons had undertaken a deliberate, careful and systematic removal of certain historical records, together with master (key) cards and patient charts. The report concluded that the isolation of the unit played a role in the lack of awareness about what constituted good practice and went on to say that any isolated institution which fails to have in place a process of outcome review by peers and benchmark comparators could produce a similar outcome to that which occurred in the Lourdes Hospital.

**4.1.5 Mental health**

Mental health is the only area of the health care system that does not fall under the auspices of HIQA. Instead, responsibility rests with the Mental Health Commission (MHC), a statutory body set up under the Mental Health Act of 2001 and launched in April 2002. Its primary functions are to “promote, encourage and foster the establishment of high standards and good practices in the delivery of mental health services and to take all reasonable steps to protect the interests of persons detained in approved centres under the Act’ (MHC, 2003). It includes an Inspectorate of Mental Health Services (replacing the former Inspectorate of Mental Hospitals) which legally must visit and approve annually all mental health service facilities. This can include unannounced visits to facilities where the Inspectorate previously has had concerns. The MHC also runs mental health tribunals which review all decisions on the involuntary detention of individuals. The MHC has 13 members; as well as health service professionals it must also include a social worker, a lawyer, three individuals from voluntary bodies – of which two must have or have had a mental illness – and a member of the general public.

In assessing mental health services, the MHC makes use of a quality framework that it has developed in
consultation with stakeholders (MHC, 2006). This is applicable to all mental health services, including services for children and adolescents, adults, older people, people with learning disabilities and mental health problems and the forensic mental health services. It applies in all settings, whether at home, in the community or in institutional settings. There are eight themes within the framework:

1. provision of a holistic, seamless service and full continuum of care provided by a multidisciplinary team;
2. respectful, empathetic relationships between people using the mental health service and those providing them;
3. an empowering approach to service delivery;
4. a high-quality physical environment that promotes good health and upholds the security and safety of service users;
5. access to services;
6. family/chosen advocate involvement and support;
7. staff skills, expertise and morale; and
8. systematic evaluation and review of mental health services underpinned by best practice.

In total, 24 standards have been developed for these themes, with 14 initially implemented in 2007.

4.1.6 Complementary and alternative medicine practitioners

Following on from a commitment in the Health Strategy 2001, a report was prepared by the Institute of Public Administration which set out a number of the issues involved in the regulation of complementary practitioners (O’Sullivan, 2002). As a result, a National Working Group was established in 2003 to advise the Minister of Health on the regulation of complementary and alternative medicine (CAM) practitioners. The Report of the National Working Group on the Regulation of Complementary Therapists made a number of recommendations to strengthen the regulatory environment for complementary therapists, including improved voluntary self-regulation for the majority of therapies and statutory regulation for Acupuncturists, Traditional Chinese Medicine practitioners and Herbal practitioners (Garvey, 2006).

However, the group also found that the sector was fragmented and did not have governance structures. In response to the Report, it was decided that the DoHC would support greater voluntary self-regulation for all therapies in the first instance (DoHC, 2006i). Alongside the publication of the Report, an Information guide for the public was also launched. It offers guidance for members of the public when choosing to visit a complementary therapist. In line with the Report’s recommendations, facilitated work days have been provided for a number of complementary therapy professional associations to develop and harmonize common basic standards of practice, education and training. In addition, the Higher Education and Training Awards Council is developing standards for complementary therapy education courses.

4.1.7 Regulation of medicines and medical products

Under the Irish Medicines Board Act of 1995 and in line with European Directives, the Board is responsible for the licensing of the manufacture, preparation, importation, distribution and sale of medicinal (and veterinary) products. Total income in 2006 was €20.12 million, of which €15.97 million was generated through fees (IMB, 2007a). Since 2001 the IMB has also been responsible for the surveillance of active implantable, in vitro diagnostic and general medical devices, coupled with self-regulation by manufacturers.

The IMB conducts inspections at sites of manufacture and distribution of medicines and by means of random sampling of products both pre and post authorization. It is also responsible for assessing the quality, safety and efficacy of products (and blood donation/testing), as well as investigating any adverse effects and reactions. The IMB is also the competent authority for the regulation of traditional herbal medicines. This is in line with EC Directive 2001/83/EC, transposed into Irish law in 2007. This legislation is designed to provide an appropriate legal framework for placing traditional herbal medicinal products on the market within the EC. It introduced a simplified registration scheme that gives traditional herbal medicinal products recognition and enhanced status, while aiming to protect public health (IMB, 2007b).

Advertising of medicinal products is governed by statutory regulations. The 2007 Medicinal Products (Control of Advertising) Regulations ban the advertising of products that do not have either market
authorization or (in the case of herbal medicines) a certificate of traditional use. The regulations also ban the direct-to-consumer advertising of prescription-only medicines. There are also restrictions on the advertising and marketing of prescription pharmaceuticals to people qualified to prescribe or supply. These include a prohibition on the “supply, offer or promise to such persons of any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy.” However, a reasonable level of hospitality may be offered at sales promotion events (Houses of the Oireachtas, 2007).

The HSE has established a National Corporate Pharmaceutical Unit to negotiate with industry regarding pharmaceutical prices. Prices for pharmaceuticals are governed by agreements between the HSE and Irish Association of Pharmaceutical Manufacturers of Ireland (APMI) and IPHA with the latest agreement coming into effect in September 2006 (see Section 6.6 Pharmaceutical care).