THE HEALTHCARE LAW REVIEW

SECOND EDITION

Editor
Sarah Ellson

THE LAWREVIEWS

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EDITOR'S PREFACE

Welcome to the second edition of *The Healthcare Law Review*. The *Review* provides an introduction to healthcare economies and their legal frameworks in 17 jurisdictions, with new contributions from Japan, Korea and Finland. These new chapters, together with updates to the jurisdictions previously covered in the first edition, only serve to emphasise that this is a constantly changing environment. While hugely diverse, it is possible to discern common challenges and similar approaches in very different countries.

Across the globe, leaders recognise the World Health Organization's principle – the health of all peoples is fundamental to the attainment of peace and security and is dependent on the fullest cooperation of individuals and states. Every country wants a health system to care for the sick and promote the well-being of its people. Every nation wants to raise the bar to keep up with improving living standards and expectations. However, every economy requires this to be done at an affordable price. Managing the costs of healthcare and workforce shortages, and ensuring a sustainable model of delivery, seem to be key drivers in each of the countries covered in this publication. One area of focus has been integration between health and wider social care, particularly for the elderly and those with chronic conditions, reducing emergency admissions and improving the chances of care being provided locally, rather than requiring hospital admissions. Another evolving theme has been the ever-increasing role of digital technologies providing options for care at a physical distance from hospitals, clinics and healthcare professionals.

The ways different countries are meeting these demands vary enormously, and for the healthcare lawyer, or the healthcare provider, alternative destinations provide unique challenges, risks and opportunities. This publication identifies the broad characteristics of healthcare to be found in each jurisdiction. It considers: the role of insurance or public payers; models of commissioning; the interplay (or lack of it) between primary, secondary and social care; and the regulatory and licensing arrangements for healthcare providers and professionals.

These continue to be exciting times for the delivery of healthcare, with digital technologies, genomic personalised medicine and the eradication of certain diseases through vaccination. Patients, data and providers are moving globally and the pace of development is relentless. This year has seen a recognition of the real value of data in the provision of care and the development of healthcare technology; this has been coupled with new legislation including the European General Data Protection Regulation, which has impacted not just on data controllers in Europe but on many of the international providers caring for EU citizens. Younger healthcare economies are offering exciting new opportunities in a market where healthcare professionals can be a scarce resource; more mature markets are having to address ageing infrastructure and a pressing need to reform to meet today's challenges.

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Each chapter has been written by leading experts who describe succinctly their own country's healthcare ecosystems. I would like to thank them for the time and attention they have given to this project and also the wider team at Law Business Research for their support and organisation.

Sarah Ellson
Fieldfisher
Manchester
July 2018

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Chapter 8

IRELAND

Tom Hayes, Rebecca Ryan and Michael Finn[1]

I OVERVIEW

There is a two-tier health service in Ireland, comprising (1) the public healthcare system, and (2) the private healthcare system. The public healthcare system is funded by the state. The private healthcare system is funded by private funds and private insurance.

Healthcare policy and expenditure in Ireland is determined by the Department of Health. Public healthcare services are provided by the Health Service Executive (HSE). The HSE owns and runs public hospitals. Other hospitals, known as voluntary public hospitals, receive state funding but are not HSE-owned. Private hospitals are owned by private entities.

II THE HEALTHCARE ECONOMY

i General

Most medical treatment is available free of charge or subject to a subsidised charge under the public health system. There are two types of patient in the public healthcare system: (1) individuals with full eligibility ('medical card holders' or 'public patients'), who are entitled to receive all health services free of charge; and (2) individuals with limited eligibility ('non-medical cardholders' or 'private patients'), who are entitled to some free or subsidised services. Eligibility for a medical card is dependent upon income and is decided on the basis of a means test.

Access to public and private healthcare within this jurisdiction varies for people based on their citizen or non-citizen status. If a person is a national of the European Economic Area (EEA) or Switzerland, or he or she is ordinarily resident in Ireland (i.e., living in Ireland for at least one year), he or she is entitled to receive the same level of healthcare as Irish citizens. If a person is not from an EEA Member State or Switzerland, he or she will only be entitled to certain services free of charge and will have to pay for the remainder. If a person opts for private healthcare services, he or she must pay the full costs of treatment, unless those costs are covered by that person's private health insurance policy.

1 Tom Hayes is a partner and head, and Rebecca Ryan and Michael Finn are partners, of the healthcare group of Matheson.

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ii The role of health insurance

There are a number of private health insurance companies in Ireland. Key providers include VHI Healthcare, Laya Healthcare and Irish Life. As long as an individual is from the EEA or Switzerland, or ordinarily resident in Ireland, he or she is entitled to the same benefits from private health insurance with any of these companies as any other Irish citizen.

Health insurance is not mandatory. However, the most recent statistics indicate that approximately 46 per cent of the Irish population holds private health insurance, a key benefit of which is avoiding public waiting lists for elective procedures.

Private health insurers are regulated by a statutory regulator, the Health Insurance Authority, and under the Health Insurance Acts 1994–2017. The principal objective of the Health Insurance Authority is to ensure that access to health insurance cover is available to consumers of health services with no differentiation made between them.

iii Funding and payment for specific services

The Irish healthcare system is primarily funded by taxation, with contributions from out-of-pocket payments and voluntary private health insurance. As in other countries, revenue from general taxation in Ireland is, of course, not designated specifically for the healthcare economy. Therefore, this sector must compete with other areas of public expenditure for attention as far as funding through taxation is concerned.

Holders of a state medical card (i.e., public patients) are entitled to receive all health services free of charge, including GP services, prescribed medicines, all dental, ophthalmic and aural services, maternity services, inpatient services in public hospitals and specialist treatment in outpatient clinics of public hospitals.

The majority of the population does not hold medical cards (i.e., private patients) but they are still entitled to free maternity services, inpatient services in public hospitals (subject to a daily charge), specialist services in outpatient clinics (subject to a daily charge), assistance towards the cost of prescribed medicines over a monthly limit (€134) (under the Drugs Payment Scheme) and assistance towards the cost of prescribed medicines for certain chronic conditions (under the Long-Term Illness Scheme) or high-cost treatments (under the High-Tech Drug Scheme). They must, however, pay for all GP consultations and all dental, ophthalmic and aural treatments.

Children in Ireland have the same entitlement to health services as their parents. This means that if a child's parents have a medical card, they too are included as a dependant on that card and are entitled to the same range of services as their parents.

Additionally, there is a range of healthcare services available specifically for children. A number of these services are provided free of charge for children even if their parents do not have a medical card. These services are generally provided as part of maternity and infant welfare services, health services for preschool children and school health services. Children are also entitled to vaccination and immunisation services free of charge.

A GP visit card is available to all children under the age of six. This allows free GP care for all children under the age of six. For other children, the GP visit card is means-tested. The HSE is obliged to provide dental services free of charge to preschool children and school children attending state primary schools referred from child health service and school health service examinations. Dental services for children under 16 years of age who attend state primary schools, and are referred from child and school health services, are provided in HSE clinics and primary schools.

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III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

i The scope and role of practice of corporate and professional health and social care providers

Healthcare is mainly delivered by way of primary or secondary care. Primary healthcare services are provided outside of hospitals to people living in the community; for example, by general practitioners, nurses and health clinics. Secondary healthcare is delivered in hospitals to patients normally living at home; for example, outpatient clinics, and accident and emergency clinics.

Doctors

The Medical Practitioners Act 2007 (as amended) regulates the medical profession in Ireland. It provides for the registration and control of medical practitioners, outlines the membership and functions of the Irish Medical Council (IMC) and obligates the IMC to establish various committees to consider complaints made against practitioners.[2] Under the Medical Practitioners Act 2007, an unregistered medical practitioner is not permitted to practise medicine in the state.[3] Registration is on an annual basis.[4]

The main functions of the IMC are to:

a maintain a register of doctors;

b ensure high standards of medical education and training;

c specify standards of practice for doctors, including the areas of professional competence and ethics;

d provide guidance to doctors on compliance with standards of practice;

e promote good medical practice;

f investigate complaints made about doctors and, where necessary, conduct disciplinary procedures. The IMC has the power to suspend, attach conditions to registration or erase a doctor's name from the register; and

g advise the Minister for Health on matters relating to doctors and patient safety.[5]

Nurses and midwives

The Nurses and Midwives Act 2011 regulates nurses and midwives in Ireland and requires all nurses and midwives working in Ireland to register with the Nursing and Midwifery Board of Ireland (NMBI). The NMBI's main functions are to:

a establish procedures and criteria for the assessment and registration of nurses and midwives;

b act as the competent authority for the mutual recognition of professional qualifications of nurses and midwives awarded in or recognised by EU Member States;

c specify standards of practice for registered nurses and midwives;

d specify criteria for specialist nursing and midwifery posts;

e establish committees to inquire into complaints; and

2 www.imt.ie/opinion/guest-posts/medical-practitioners-act-update-14-05-2009/.

3 Section 37 of the Medical Practitioners Act 2007.

4 www.medicalcouncil.ie/Existing-Registrants-/.

5 www.medicalcouncil.ie/News-and-Publications/Publications/Annual-Reports-Statistics-/A-Statistical-Report,-June-2011.pdf.

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f make decisions and give directions relating to the imposition of sanctions on registered nurses and registered midwives.

Dentists

The dental profession in Ireland is regulated by the Dental Council of Ireland (DCI) and only dentists registered with the DCI can practise dentistry in Ireland. The DCI was established under the provisions of the Dentists Act 1985 and its main functions are to:

a establish, maintain and publish a Register of Dentists, Dental Specialists, Dental Hygienists and Dental Nurses;

b regulate the dental education and training provided in Irish dental schools and to set standards required for primary qualifications;

c inquire into the fitness of a dentist to practise dentistry and investigate any alleged professional misconduct. The Council has the power to suspend, attach conditions to registration or erase a dentist's name from the Register;

d make, with approval of the Minister for Health, schemes for the establishment of classes of auxiliary dental workers; and

e advise the dental profession and the public on all matters relating to dental ethics and professional behaviour.

Health and social care professionals

The Health and Social Care Professionals Council (CORU) is an independent regulator established to promote high standards of professional conduct and professional education, training and competence among registrants of health and social care professions.

CORU currently maintains registers for dieticians, occupational therapists, radiographers and radiation therapists, social workers, speech and language therapists, optometrists and dispensing opticians, and physiotherapists. In the future, CORU will also regulate clinical biochemists, medical scientists, orthoptists, podiatrists, psychologists and social care workers.

Each member of these professions will be required to register with CORU when its respective register is established and, from then, only members registered with CORU can legally use the title of those professions.

CORU also handles complaints about the fitness to practise of registered health and social care professionals. This may include, for example, complaints of professional misconduct or poor professional performance.

ii Direct access to medical consultants

GPs supervise and guide the overall health management of their patients in Ireland and facilitate referrals for secondary care in accordance with IMC guidelines. Hospital consultants will see patients following referral from their GP or other treating doctor.

When a patient is admitted to hospital, either in an emergency or on a planned or elective basis, they will be under the care of the admitting consultant.[6]

6 www.ihca.ie/information/information.386.html.

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iii Universal electronic medical records

Universal medical records do not currently exist in Ireland. The current state of health records in Ireland is one of largely paper-based patient notes, held within individual organisations.

Over the next 10 to 15 years the HSE plans to roll out a national Electronic Health Record (EHR) that will enable patient information to be instantly accessed by approved medical personnel. The establishment of a national EHR has been identified as a key capability requirement for the future delivery of healthcare. The project is being overseen by eHealth Ireland, a dedicated entity tasked with using information and communication.

iv Data protection laws

The sharing of patient data is governed by Data Protection Acts 1988 and 2003 (DPA), under which personal data must be obtained for a specified purpose, and must not be disclosed to any third party except in a manner compatible with that purpose. Under the DPA, there are a number of limited bases on which health data may be disclosed, including where the patient has explicitly consented.

If patient data is urgently needed to prevent injury or other damage to the health of a person, then a medical professional may disclose the data. However, if the reason for the disclosure is not urgent, then consent of the patient should be obtained in advance.

Patient data can be disclosed for research or other statistical purposes without the patient's consent in limited circumstances. However, anonymisation or pseudonymisation should first be considered where patient data is disclosed for research purposes.

The General Data Protection Regulation (GDPR) came into effect on 25 May 2018. The GDPR has 'direct effect' and therefore it does not require transposition into Irish law in order for organisations to become amenable to its provisions. The GDPR enhances transparency, security and accountability by data controllers and processors. It requires that personal data shall be obtained only for specified, explicit and lawful purposes and shall not be further processed in any manner incompatible with those purposes. Personal data shall be relevant and limited to what is necessary in relation to the purposes for which they are processed. Personal data shall not be kept for longer than is necessary for the purposes for which the personal data are processed. Personal data can be lawfully processed for the purpose of preventative or occupational medicine, assessing a person's working capacity, for medical diagnosis, for the provision of medical care, treatment and social care, for the management of health or social care systems and services, or pursuant to a contact with a health professional. The HSE's current policy is to delete a patient's medical records after seven years, however data may be held for a longer period if this is in the patient's best interests. The HSE is in the process of developing a national data protection office and is to appoint an Independent Data Protection Officer to advise the HSE on its data protection processes.[7]

v The IMC Ethical Guidelines[8]

In accordance with the IMC Ethical Guidelines, a doctor can share information with other doctors in appropriate circumstances without the patient's consent (e.g., the patient cannot give consent because of his or her medical condition). If disclosure of a patient's information

7 https://www.hse.ie/eng/gdpr/gdpr-faq/.

8 www.medicalcouncil.ie/News-and-Publications/Reports/Guide-to-Professional-Conduct-and-Ethics-8th-Edition-2016-.pdf.

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is necessary as part of the care and treatment of the patient, the Ethical Guidelines permit disclosure to the appropriate person on the basis that they understand that the information is confidential.

The Ethical Guidelines state that where a patient is capable of making his or her own decisions about his or her healthcare, a doctor must first obtain patient consent before disclosing information that identifies him or her. If a patient lacks capacity to consent and is unlikely to regain capacity, the Ethical Guidelines state that a disclosure may be made if it is in the patient's best interests.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Doctors

The IMC is the regulatory body for doctors and it maintains the register of medical practitioners licensed to practise. The IMC also has the power to place restrictions on or revoke such licences, where there is a finding of misconduct or poor professional performance.

The IMC also sets the standards for medical education and training in Ireland. There is a legal requirement for all registered doctors to maintain their professional competence and a legal duty to engage in formal arrangements for lifelong learning and skills development. The IMC oversees doctors to ensure that they fulfil this duty. The IMC receives no state funding and is primarily funded by doctors' registration fees.

Complaints

The IMC is also the regulatory body that receives and investigates complaints against doctors. Under the legislation, on receipt of a complaint, the IMC must commence the formal complaint procedure. The Preliminary Proceedings Committee (PPC) considers all complaints made, and, after gathering and considering sufficient information about the complaint, assesses whether there is a *prima facie* case to warrant further action being taken. If there is a *prima facie* case, the PPC is obliged to refer the complaint to the Fitness to Practise Committee (FTPC) for a fitness to practise inquiry. If the PPC decides that the complaint does not warrant further action being taken, the complaint is not referred to the FTPC. However, the PPC may refer the complaint to another body or authority, or for mediation, or may refer the doctor for a performance assessment.

FTPC inquiries are usually held in public, meaning anyone can attend the inquiry hearing. In certain circumstances, the FTPC can decide that it is not appropriate for the inquiry to be held in public and direct that the hearing should be held in private or part private. This decision can be made on foot of an application by a complainant, a witness or the doctor.

At the conclusion of the FTPC inquiry process, if a doctor is found to have breached his or her professional duties, the FTPC may recommend the imposition of one or more of the following sanctions:

a an advice, admonishment or censure in writing;
b a censure in writing and a fine not exceeding €5,000;
c the attachment of conditions to the doctor's registration, including restrictions on the practice of medicine that may be engaged in by the doctor;
d the transfer of the doctor's registration to another division of the register;
e the suspension of the doctor's registration for a specified period;
f the cancellation of the doctor's registration; and

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g the prohibition from applying for a specified period for the restoration of the doctor's registration.[9]

The finding of the FTPC is then put before the Medical Council for the ratification of the finding and any sanctions. If the IMC imposes any of the above sanctions (except for advice, admonishment and censure) there is a right of appeal against the IMC decision to the High Court. If no appeal is made against the IMC's decision, the IMC must apply to the High Court for confirmation of its decision. The IMC does not need confirmation from the High Court if the sanction is to advise, admonish or censure.

Medical indemnity insurance

The Medical Practitioners (Amendment) Act 2017 (the 2017 Act) requires registered medical practitioners to obtain medical indemnity insurance, except in certain circumstances. The 2017 Act affects doctors that are engaged in private practice. Those who work in the public health service (including private consultants who practise in public hospitals) are covered under the state's clinical indemnity scheme and are not affected by the 2017 Act.[10]

ii Nurses and midwives[11]

The NMBI is the independent, statutory organisation that regulates the nursing and midwifery professions in Ireland. Their role is to protect the health and safety of the public, by setting standards, ensuring that nurses and midwives are competent to practise. Their functions are defined in the Nurses and Midwives Act 2011.

Complaints

The process under the NMBI complaints procedure is very similar to that under the IMC complaints procedure. All complaints received by the NMBI in relation to registered nurses and registered midwives are referred to its PPC. If the PPC is of the view that there is a *prima facie* case to warrant further action, it will refer the matter to its FTPC for a sworn oral inquiry.

The available sanctions and rights of appeal under the Nurses and Midwives Act are largely identical to those outlined above under the Medical Practitioners Act.

Medical indemnity insurance

The Clinical Indemnity Scheme provides indemnity cover for nurses and midwives working in the public health sector and certain voluntary organisations.

Nurses working in the private sector may be covered by their employer's insurance. Under the NMBI Guidelines, nurses must ensure they have professional indemnity insurance.[12] The Irish Nurses and Midwives Organisation Medical Malpractice Scheme provides cover for members who are self-employed or employed outside the state sector.[13]

9 www.medicalcouncil.ie/Public-Information/Making-a-Complaint-/Fitness-to-Practise-Inquiries/Medical-Council-Sanctions.html.

10 www.irishstatutebook.ie/eli/2017/act/10/enacted/en/html.

11 www.nmbi.ie/Registration.

12 www.nmbi.ie/nmbi/media/NMBI/Publications/Code-of-professional-Conduct-and-Ethics.pdf?ext=.pdf.

13 www.inmo.ie/Home/Index/7581/9869.

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iii Dentists

The dental profession in Ireland is regulated by the Dental Council of Ireland, a statutory body created under the Dentists Act 1985. Only dentists listed on the Irish Register of Dentists can legally practise dentistry in Ireland. Dentists must hold appropriate professional indemnity cover.[14]

Complaints

Private patients unhappy with the standard of treatment received can make complaints to Dental Complaints Resolution Service (DCRS). The DCRS is a voluntary service that offers an independent and free mediator service to patients who have complaints about their dentists. To avail of this service, a dentist must be a member of the Irish Dental Association, or have subscribed to the complaints resolution service. The service requires that patients raise their complaints first with their dental practice. Any complaint about private care is eligible for consideration, however, the most serious complaints and issues that relate to a dentist's fitness to practise are referred by the DCRS to the Dental Council. Complaints can be made by public and private patients to the Dental Council.[15]

In addition, public patients unhappy with the service they receive from a dental surgery can make a complaint to the HSE Complaints Officer. If the patient is not satisfied with the recommendations made by the Complaints Officer, they can seek a review from the HSE's Director of Advocacy or complain to the Office of the Ombudsman.[16]

iv Pharmacists

Pharmacists and pharmaceutical assistants must be registered with the Pharmaceutical Society of Ireland (PSI) to practise in Ireland. The PSI's functions are prescribed under the Pharmacy Act 2007. The PSI is responsible for defining and ensuring the standards of education and training for pharmacists qualifying in Ireland.

Pharmacies must apply on an annual basis for continued registration and pay an annual fee. Each pharmacy must have a superintendent pharmacist and a supervising pharmacist, each of whom must have at least three years' appropriate experience. A pharmacy owner cannot lawfully operate a pharmacy without a superintendent and supervising pharmacist. Pharmacists wishing to open a retail pharmacy business must apply to register that pharmacy before it is due to open. The proposed pharmacy will also be subject to an opening inspection prior to registration.

Complaints

A complaint can be made to the PSI about a pharmacist or pharmacy. The process regarding the complaints procedure is similar to the above.

If the PPC decides that there is sufficient cause to warrant further action, then a decision will be made by the PPC to either refer the complaint to mediation or to a committee of inquiry.

14 www.dentalcouncil.ie/files/Professional%20Behaviour%20and%20Ethical%20Conduct%20-%20final%20-%20%2020120116.pdf.

15 www.healthcomplaints.ie/specific-complaints-procedures/dental-council/.

16 www.healthcomplaints.ie/community-based/dental/dental-public-patient/.

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There are two committees of inquiry to which a complaint may be referred: the Professional Conduct Committee and the Health Committee.

The choice of committee will depend on the nature of the complaint.

Complaints that concern matters of professional misconduct or poor professional performance will normally be referred to the Professional Conduct Committee.

Complaints that concern impairment of a pharmacist's ability to practise because of a physical or mental ailment, emotional disturbance or an addiction to alcohol or drugs will normally be referred to the Health Committee.[17]

At the conclusion of the inquiry, the committee will make a decision as to whether the complaint has been substantiated. The committee will then prepare a report setting out the subject matter of the complaint, the evidence presented and the committee's findings. It is the Council that will then decide what, if any, sanctions to impose.

v Institutional healthcare providers

Institutional healthcare providers in Ireland are public and private hospitals, clinics and nursing homes.

There are 48 public hospitals in Ireland. For the purpose of private hospital charges, these are grouped into three categories based on hospital status and level of treatment complexity. Category 1 is comprised of HSE regional hospitals, voluntary and joint board teaching hospitals, Category 2 includes HSE county hospitals and voluntary non-teaching hospitals, and Category 3 is made up of HSE district hospitals.

There are 19 private hospitals affiliated with the Independent Hospital Association of Ireland and involved in the provision of acute care. They collectively provide over one in six acute beds to the Irish healthcare system and employ around 8,000 people. Private hospitals provide a range of diagnostic services, day care, and inpatient and other associated acute hospital services.

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high-quality and safe care for people using health and social care services in Ireland. HIQA is responsible for setting standards for the safety and quality of public or publicly funded hospitals, social care services and residential services. HIQA is responsible for the registration and oversight of these services, which include public and private residential facilities for children and adults with disabilities, and nursing homes. HIQA does not currently regulate private hospitals, though its scope is due to be extended. Designated centres under HIQA's remit can be deregistered for failure to comply with safety and quality standards. HIQA can also bring summary proceedings for offences under the Health Act 2007, which carry penalties of:

a on summary conviction, a fine not exceeding €5,000, or imprisonment for up to one year, or both; or

b on conviction or indictment, a fine up to €70,000, or imprisonment for up to two years, or both.

17 www.thepsi.ie/gns/making-a-complaint/complaints-process.aspx.

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V NEGLIGENCE LIABILITY

i Overview

There is an implied constitutional right of access to the courts in Ireland under Article 40.3.1 of the Irish Constitution. Recipients of healthcare services may seek recourse through the courts by pursuing medical negligence claims against a healthcare provider whom they allege has caused them some form of damage, for example, in the form of personal injuries and pecuniary losses. These claims are usually in the form of medical negligence claims. As a statute of limitation applies in Ireland, claims must be brought within two years of the date of the injury or the date of knowledge that an injury has occurred. This time limit does not apply to cases involving injuries to minors.

For medical negligence claims, liability is usually determined by the court having heard and considered the opinions of independent medical experts. In order for liability to be imposed on healthcare providers, the constituent elements of the tort (see Section V.ii below for an overview of the tort of negligence in Ireland) must be proven 'on the balance of probabilities' – in other words, that there is a greater than 50 per cent chance that the healthcare provider was negligent. Once liability has been determined by the court, the level of damages or quantum is assessed by the court with a view to adequately compensating the patient for the injuries sustained and reimbursing the patient for any financial losses arising from those injuries.

ii Notable cases

Negligence is a tort involving a breach of legal duty by a defendant to take reasonable care that results in damage to the plaintiff. In simple terms, a person is guilty of negligence where they act carelessly or do not take proper care in a situation where they should and in doing so, they cause harm or damage to another party.

To succeed in a claim for negligence against a healthcare provider, a person must establish four key elements:

a Duty of care: that the healthcare provider owed the patient a duty of care. This is usually very easily proven in healthcare-related claims.

b Breach of the duty of care: that the healthcare provider has breached that duty of care by failing to take appropriate care in the circumstances.

c Causation: that the healthcare provider's breach of duty caused the damage that the patient is complaining of, i.e., that the damage would not have been caused to the patient 'but for' the actions of the healthcare provider.

d Damage: that the damage that resulted was reasonably foreseeable and a result of the healthcare provider's breach of duty.

The leading Irish case on breach of duty is *Dunne v. The National Maternity Hospital*.[18] This case established the principal test for establishing liability in medical negligence cases. In general, a medical practitioner will not be found negligent if he or she has followed a general and approved practice in his or her treatment or diagnosis. This practice need not be universally approved but must be approved by a substantial number of reputable practitioners holding

18 [1989] IR 91.

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the relevant specialist or general qualifications. A medical practitioner will not be able to rely on a general and approved practice that has inherent defects that ought to be obvious to any person giving the matter due consideration.[19]

If the allegation of negligence against the medical practitioner is based on proof that he or she has deviated from a general and approved practice, it must be proved that the course taken was one that no medical practitioner of similar specialisation and skill would have followed had he or she been taking the ordinary care required from a person of his or her qualification.[20]

In relation to disclosure and informed consent of medical procedures, it was held in *Dunne* that there is a clear obligation on a medical practitioner to inform the patient of any possible harmful consequence arising from the operation, so as to permit the patient to give an informed consent to the operation concerned. The extent of this obligation to warn varies with what might be described as the elective nature of the surgery concerned.[21]

VI OWNERSHIP OF HEALTHCARE BUSINESSES

Similar to any other business, directors of a healthcare business must be fit and proper in their capacity in accordance with Irish company law (the Companies Act 2014), for instance, they cannot be restricted or disqualified, and must, therefore, meet all their duties as directors as under the 2014 Act.

VII COMMISSIONING AND PROCUREMENT

At present, the HSE both purchases and provides the majority of healthcare services within Ireland.

An *Irish Times* article in 2017 noted that HIQA has said that commissioning would improve the health service in Ireland. It said that Ireland should seek to move to a commissioning model of care similar to that used by the NHS in Britain. Commissioning occurs when healthcare facilities such as hospitals, private clinics and voluntary institutions compete to provide services from the individual up to the national level. In the NHS, it is known as the 'internal market'.[22]

Universal Health Insurance (UHI) is a new system of healthcare, which the government revealed in a 2014 White Paper on UHI that it plans to adopt and introduce by 2019.[23] UHI aims to eliminate Ireland's current two-tier health system and create in its place a single-tier health service that merges the public and private systems, where access to services is based on need and not on ability to pay. This means:

a equal access for all to healthcare, based on need, not income;
b everyone insured for a standard package of curative health services;
c no distinction between 'public' and 'private' patients;
d universal GP care;

19 *O'Donovan v. Cork County Council* [1967] I.R. 173 at 193.
20 *Gottstein v. Maguire & Walsh* [2004] IEHC 416.
21 *Bolton v. Blackrock Clinic Unrep*, SC, 23 January 1997.
22 www.irishtimes.com/news/ireland/irish-news/commissioning-would-improve-health-service-says-hiqa-1.2959831.
23 http://health.gov.ie/wp-content/uploads/2014/04/White-Paper-Final-version-1-April-2014.pdf.

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e universal hospital care to include independent, not-for-profit trusts and private hospitals;

f social care services remaining outside of the UHI system, but integrated with healthcare services around the user; and

g a multi-payer health insurance funding model with competing health insurers.

Following its publication, the Department of Health initiated a major costing project, involving the Economic and Social Research Institute, the Health Insurance Authority and others, to examine the cost implications of a change to the particular UHI model proposed in the White Paper. Having considered the findings of the costing exercise, it was concluded by the then government that the high costs associated with the White Paper model of UHI were not acceptable and that further research and cost modelling in relation to the best means to achieve universal healthcare were needed.

The All-Party Oireachtas Committee on the Future of Healthcare considered this issue and published its findings in its Sláintecare Report.[24] The report encourages a shift away from the current hospital-centric model, which it states will enable the system to better respond to the challenge of chronic disease management and provide care closer to home for patients. The OECD in its Economic Survey of Ireland in March 2018 suggested Ireland 'move towards providing universal access to health and social services and incentivise patients to access care outside of hospitals'.[25] This is discussed further at the end of this chapter.

i Procurement in the Irish healthcare system

The core Irish public procurement rules are contained in a number of statutory instruments, each of which implements EU law Directives into Irish law. Different statutory instruments apply to the public sector, utility companies and the defence sector respectively and there are specific rules on taking court proceedings alleging a breach of Irish public procurement rules. There are also procurement guidelines, codes of practice and circulars issued by the Department of Public Expenditure and Reform (the Guidelines), with which Irish public sector entities are strongly encouraged to comply, although they are not legally binding.

The Irish public procurement law regime, in line with its EU and English law counterparts, is based on the fundamental principles of proportionality, equal treatment and transparency. These principles are intended to ensure that public sector purchasers obtain best value for money and do not favour domestic suppliers. The Regulations explicitly incorporate these principles, stating that: 'in awarding a regulated contract, a contracting entity shall treat all economic operators equally and without discrimination, and act in a transparent way'.

The Regulations apply to 'contracting authorities'. This definition does not generally apply to private entities, although the Regulations can apply to private entities that receive a significant amount of state funding in certain specific and limit circumstances.

Public tenders in the healthcare sector are extremely price-competitive, with suppliers being pressurised to cut prices to meet the competition or by reference to strict benchmarks established by the contracting authority (e.g., international prices, prices paid by other public sector buyers).

24 www.oireachtas.ie/parliament/oireachtasbusiness/committees_list/future-of-healthcare/.

25 https://www.oecd.org/eco/surveys/Ireland-2018-OECD-economic-survey-overview.pdf.

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VIII MARKETING AND PROMOTION OF SERVICES

Advertising of medicinal products is governed by the Medicinal Products (Control of Advertising) Regulations 2007, as well as general consumer legislation such as the Consumer Protection Act 2007. In addition to legislation, there are also codes of practice that apply to advertising, such as the IPHA Code of Practice for Pharmaceutical Healthcare Association edition 8.3, and the Code of Standards of Advertising Practice for the Consumer Healthcare Industry edition 5.2.

The Advertising Standards Authority for Ireland (ASAI) sets out restrictions on the promotion and advertising of healthcare products, services and business in its Code of Standards for Advertising and Marketing Communications in Ireland (7th edition, March 2016) (the Code).[26] The rules under Section 11 of the Code are designed to ensure that marketing communications for medicines, medical devices, treatments, health-related products and beauty products receive the necessary high level of scrutiny. This section stipulates that marketing communications for medical services should not cause unwarranted or disproportionate anxiety or suggest that any product or treatment is necessary for the maintenance of health. It also states that advertisers offering individual treatments, particularly those that are physically invasive, may be asked by the media and the ASAI at any time to provide full details of the treatments, together with information about those who would supervise and administer them. The Code also says that marketing communications for individual treatments should take care not to minimise, trivialise or create unrealistic expectations, in particular in the use of photographs.

Additionally, the Medical Council of Ireland set out restrictions on the promotion of healthcare services for medical practitioners in its Ethical Guidelines. The Ethical Guidelines confirm that information about medical services published in the media, internet or other means is generally in the public interest provided the information is factually accurate, evidence-based and not misleading. The Ethical Guidelines go on to stipulate that a medical practitioner may advertise his or her practice by publicising the name and address of the practice, the practice hours and contact details. The medical practitioner may only include his or her area of specialty if it is one that is recognised by the Medical Council and he or she is entered for that specialty in the Specialist Division of the Register. If a medical practitioner wishes to publish more information about the services he or she provides, he or she must make sure the information is true and verifiable, does not make false claims and does not have the potential to raise unrealistic expectations. The Ethical Guidelines also stipulate that medical practitioners should tell patients before the consultation and treatment what the costs are likely to be.

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

i Organ donation – opt in or opt out

Currently in Ireland, when a potential organ donor is identified, the deceased person's next of kin is asked for his or her consent to allow organ donation to take place. This is known as express consent or an 'opt-in' process to becoming an organ donor. In other words, the

26 www.asai.ie/asaicode/.

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choice and the decision to become an organ donor rests with the next of kin of the deceased, including where the deceased person had an organ donor card or had indicated his or her wish to become an organ donor on his or her driving licence.

The government now intends to change this system to one of 'opt-out' consent. Consent will be deemed unless the person while alive has opted out of becoming an organ donor. However, it is proposed that, even though consent is deemed, the next of kin will, in practice, always be consulted prior to removing any organ. If the next of kin objects to the organ donation, the donation will not proceed.

The Human Tissue Bill will address the giving of consent for the removal, retention, storage, use and disposal of organs and tissues from deceased persons in the context of post-mortems, transplantation, research or anatomical examination.[27] It will also set out the details surrounding a person's right to 'opt-out' of the donation of his or her organs and tissues for transplantation and research. The Government plans to publish the General Scheme of this Bill in the coming months.

This is just one aspect in a package of measures that the Irish government intends to roll out to increase organ donation rates.

ii The future of healthcare in Ireland[28]

In June 2016, a special committee was established with the aim of achieving cross-party consensus on the long-term vision for healthcare and health policy, and to make recommendations to the Dáil (the Irish parliament). The legislative committee published its report on 30 May 2017, outlining its proposals for the future of healthcare in Ireland and a 10-year strategy for healthcare and health policy in Ireland.

The report proposes free GP care for all, free public hospital care, cuts to the prescription charge and the cost of monthly drugs. These benefits would be phased in over a number of years.

One of the key recommendations outlined in the report is for all private work that is currently conducted in public hospitals to be phased out between years two and six of the report's implementation. This aims to free up beds in public hospitals and reduce public patient waiting lists.

The report proposes a universal, single-tiered health system. It also proposes providing everyone resident in Ireland with a 'Sláinte Card' entitling them to free GP care and public hospital care. It is considered that around an extra 900 public health nurses and 600 GPs would be needed in order to implement the proposals outlined in the report. The recruitment process for the new 'Sláintecare' Programme began in January 2018.

X CONCLUSION

In conclusion, healthcare services in Ireland are provided in a two-tier system, both private and public. There are a number of different regulatory bodies governing the provision of

27 http://health.gov.ie/blog/press-release/statement-by-minister-alex-white-on-regulations-on-the-quality-and-safety-human-organs-intended-for-transplantation/.

28 www.oireachtas.ie/parliament/oireachtasbusiness/committees_list/future-of-healthcare/.

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healthcare services in Ireland for both public and private patients alike. Regulatory bodies such as the Medical Council, Dental Council, CORU and the Pharmaceutical Society of Ireland play a pivotal role in ensuring a high standard of care is provided to all patients.

Over the next 10 to 15 years, the HSE has planned to make a number of significant changes to the way healthcare services are provided in Ireland. The HSE plans to roll out a national Electronic Health Record that will enable patient information to be instantly accessed by approved medical personnel. Further, there are proposals to provide free medical care for all, changes to the laws governing organ donation and the phasing out of the provision of private care services in public hospitals.

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Appendix 1

ABOUT THE AUTHORS

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Tom Hayes is a partner and head of the commercial litigation and dispute resolution department at Matheson. He also heads the healthcare group.

During the course of his career he has advised a number of corporates, hospitals, healthcare organisations and professionals concerning malpractice and product liability litigation in high-value and complex cases, as well as offering general advice on healthcare-related issues. He regularly represents professionals in relation to malpractice claims, statutory inquiries, inquests and professional disciplinary proceedings.

He has worked extensively with clients on developing strategies to ensure cases are dealt with efficiently and cost-effectively with an emphasis on minimising legal spend and, in appropriate cases, resolving claims quickly. He has a strong interest in alternative dispute resolution and has successfully mediated a number of claims. In this jurisdiction he regularly advises medical and dental practitioners concerning the defence of disciplinary proceedings before their regulatory bodies and has been involved in some of the most high-profile disciplinary inquiries before the Irish Medical Council, the High Court, Court of Appeal and the Supreme Court in recent years.

He has a strong interest in clinical governance and has lectured extensively on healthcare-related topics concerning risk management and the management of claims, and professional disciplinary litigation generally.

REBECCA RYAN

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Rebecca Ryan is a partner in Matheson's commercial litigation and dispute resolution department specialising in professional indemnity claims (in particular, medical negligence and clinical malpractice), catastrophic personal injuries claims and product liability claims in the healthcare sector.

Rebecca predominantly advises clinical practitioners and their indemnity bodies on the defence of high-value and complex medical malpractice claims in the superior courts. Rebecca also appears before the Medical Council regarding regulatory proceedings, at inquests, and other tribunals of inquiry held by bodies such as the Health Service Executive and the Health Information and Quality Authority. Rebecca provides general healthcare advice to healthcare professionals and the healthcare sector generally. Rebecca is an accomplished advocate with a keen interest in mediation and alternative dispute resolution.

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Michael Finn is a partner in the commercial litigation and dispute resolution department and his practice focuses on complex high-value international and domestic disputes in the life sciences and technology sectors, including contentious intellectual property law matters. Michael advises on the full spectrum of disputes, including commercial litigation, regulatory disputes, investigations and prosecutions, product liability claims and all forms of alternative dispute resolution.

Michael also acts in judicial review proceedings to challenge regulatory and administrative decisions.

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