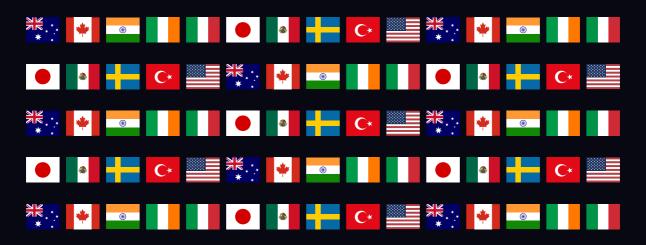
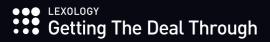
HEALTHCARE REGULATION

Ireland





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Healthcare Regulation

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Quick reference guide enabling side-by-side comparison of local insights, including into organisation, financing and structure of the healthcare system; pricing and reimbursement; healthcare organisations and business structures; competition, anti-corruption and transparency; regulation of healthcare services and professionals; data protection, privacy and digital health; and key developments.

Generated 21 September 2023

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ORGANISATION, FINANCING AND STRUCTURE OF THE HEALTHCARE SYSTEM

Organisation

How is healthcare in your jurisdiction organised? What is the role of government?

Healthcare in Ireland is delivered through both a public and private healthcare system. The public system is funded by the state whereas the private system is funded by private funds including private insurance.

Healthcare policy and expenditure in Ireland is determined by the Department of Health and the Health Service Executive (HSE). The HSE owns and funds public hospitals, which include hospitals owned by the HSE and hospitals owned by religious orders or similar institutions that are publicly funded.

Law stated - 11 August 2023

Key legislation

What key legislation governs the provision of healthcare services in your jurisdiction?

The key legislation governing the standard at which such service must be provided is the legislation which regulates medical professionals and in particular the following:

- · The Medical Practitioners Act 2007 (as amended), which regulates the medical profession in Ireland; and
- · The Nurses and Midwives Act 2011 (as amended), which regulates nurses and midwives in Ireland.

Law stated - 11 August 2023

Financing

How is the healthcare system financed in the various patient care sectors?

The Irish healthcare system is primarily funded by taxation, with contributions from out-of- pocket payments and private health insurance.

Up to 2016, public hospitals were funded by a block grant based on the previous year's activity. Since then, the HSE has introduced Activity Based Funding (ABF) for inpatient and day-case services. Prices paid to each hospital are now specified for each weighted unit of inpatient work and each weighted unit of day-case work. Emergency care, outpatient care and other services continue to receive traditional block grant allocations for the time being. ABF is being developed on a phased basis starting with inpatient and day-cases in hospitals before widening to other areas such as outpatients. The Healthcare Pricing Office plays a central role in the implementation of ABF with its key functions being to (1) set the national Diagnostics Related Group prices on which the ABF system is based; and (2) manage the Hospital In-Patient Enquiry dataset.

Out-patient charges: if you are referred by your General Practitioner (GP) to a public hospital for diagnostic assessments such as X-rays or laboratory tests, there is no charge if you attend as a public patient. If you attend for these tests in a private hospital, there is a cost and these charges finance private hospitals. This will vary depending on the type of test, service or procedure.

Delivery structures

What are the basic structures for the delivery of care to patients in your jurisdiction?

In general, healthcare is 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 GPs, 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.

There are limited differences between public and private care; the main differences are the cost (and method of paying) and the waiting list times for access to consultants and care.

Holders of a state medical card (ie, 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 do not hold medical cards (ie, 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 (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. A GP visit card that allows for free GP care is available to all children under the age of six.

Law stated - 11 August 2023

Access and coverage

What rules govern access to treatment and emergency services? Which items and services are covered and which are not covered?

All residents in Ireland, and citizens from EEA countries and Switzerland are entitled to Irish public hospital services. However, certain charges apply. Lower-income citizens are eligible for a medical card that entitles them to certain free services. People who show up at accident and emergency departments without being referred to by a general practitioner are subject to a charge of €100 although some categories of patients are exempt from this charge.

Law stated - 11 August 2023

Exclusions from statutory coverage

Are any groups excluded from statutory coverage? Are any groups covered under alternative schemes?

Long Term Illness Scheme (LTIS) and High Tech Drug Scheme (HTDS).

LTIS provides that people suffering from certain conditions can get access to free medicines and medical appliances for treatment of the condition.

HTDS is a patient-specific pharmaceutical care and treatment programme that covers high-cost medicines.



Gaps in cost coverage

Are there any gaps in cost coverage?

Yes.

Law stated - 11 August 2023

HEALTHCARE PRICING AND REIMBURSEMENT

Pricing

How are prices for healthcare services set and paid for in your jurisdiction? To what extent is the cost of healthcare services governed by law or regulation?

There are no hospital charges for public inpatient care or day service care. The removal of these charges was announced as part of Budget 2023 and came into effect on 17 April 2023. Inpatient and day service charges still apply for inpatient and day service care up until and including 16 April 2023.

Law stated - 11 August 2023

Reimbursement

How is reimbursement for healthcare services structured?

Any person who is ordinarily resident in Ireland is legally entitled to either free or subsidised approved prescribed medicines and certain medical and surgical aids and appliances. For products dispensed under the state-sponsored community drug schemes, the reimbursement price of items is set by the HSE by reference to the criteria set out in the 2013 Act. Pharmacy contractors provide community pharmacy services to the eligible population across the various community drug schemes operated in Ireland. In return, pharmacy contractors are paid a dispensing fee and are reimbursed for the price of the product.

Patients are required to make co-payments under certain government schemes. Whether or not a co-payment is required, and the level of the co-payment, depends on the scheme under which the medicinal product is dispensed.

Under the General Medical Services (GMS) scheme, a patient receives their medicine after paying a nominal fee per item prescription charge. The GMS scheme is a means-tested scheme that applies to those who do not have sufficient means to pay for their medicine. There is an exception to these charges under the related Hi-Tech Scheme, which covers expensive medicines required for long-term care, the Health Amendment Act 1996 scheme, which covers hepatitis C treatment as a result of contaminated blood and the Misuse of Drugs Regulations 1998, which covers methadone. Under these schemes, no co-payment is required. Under the Drug Payment Scheme, the patient pays a maximum co-payment for all medicines supplied to them and their family. Under the Long-Term Illness Scheme, the patient receives medicines for specific long-term medical conditions, such as diabetes and epilepsy, free of charge and no co-payment is required.

Law stated - 11 August 2023

Adjudication



If applicable, what is the competent body for decisions regarding the pricing and reimbursement of healthcare services?

The HSE is the competent body for determining the price and reimbursability of medicines. HSE policy is determined by the Department of Health. In addition, the HSE uses Health Technology Assessments and other mechanisms to generate information about the clinical and cost-effectiveness of health technologies to determine the reimbursement status (or continued reimbursement status) of medicines. These are carried out by the Health Information and Quality Authority or groups within the HSE.

Law stated - 11 August 2023

HEALTHCARE ORGANISATIONS AND BUSINESS STRUCTURES

Legal authorisation

What steps are necessary to authorise the provision of healthcare services, and what laws govern this?

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 Medical Council and obliges the Medical Council to establish various committees to consider complaints made against practitioners. Under the Medical Practitioners Act 2007, an unregistered medical practitioner is not permitted to practise medicine in the state. Registration is on an annual basis.

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.

Dentists

The dental profession in Ireland is regulated by the Dental Council (established by the Dentists Act 1985) and only dentists registered with the Dental Council can practise dentistry in Ireland.

Health and social care professionals

The Health and Social Care Professionals Council (CORU) is an independent regulator established by the Health and Social Care Professionals Act 2005 (as amended) 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 dietitians, occupational therapists, radiographers and radiation therapists, social workers, speech and language therapists, optometrists and dispensing opticians, medical scientists and physiotherapists. In the future, CORU will also regulate clinical biochemists, 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.

Pharmacists

Pharmacists and pharmaceutical assistants must be registered with the Pharmaceutical Society of Ireland (PSI) to practise in Ireland. 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.

Institutional healthcare providers

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

The Health Act 2007 established the Health Information and Quality Authority (HIQA), which 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 is an independent authority established to drive high-quality and safe care for people using health and social care services in Ireland. 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. Public healthcare providers are not authorised or registered with HIQA under current legislation, but they do fall under its remit.

The Department of Health has prepared legislative proposals for a mandatory licensing system for public and private hospitals and other providers of high-risk healthcare activities. It aims to improve patient safety by ensuring that providers do not operate below core standards, which are applied in a consistent and systematic way. Under separate draft legislation, HIQA's remit will be extended to the private health service and HIQA will be given the function of setting standards for private hospitals and private acute services and monitoring compliance with standards in the same way as it does for the public health service.

Law stated - 11 August 2023

Legal structures

What types of legal entities can offer healthcare services?

There are no specific rules in Ireland around the types of legal entities that can offer healthcare services.

Law stated - 11 August 2023

Foreign companies

What further steps are necessary for foreign companies to offer healthcare services?

Foreign companies must comply with the same requirements as companies incorporated in Ireland.

Law stated - 11 August 2023

Healthcare arrangements

What regulatory and legal issues commonly arise in relation to healthcare arrangements? What are the main rules and principles that apply to extraterritorial participation in these arrangements?



Issues that commonly arise in relation to partnerships between providers (including non-Irish providers) to deliver healthcare services in Ireland include the following:

- · legal issues regarding who is liable for delivery of the services and whether insurance cover is held;
- legal issues regarding whether delivery of the services is compliant with professional regulation;
- legal issues regarding whether delivery of the services or the partnership is compliant with any licensing of the relevant healthcare facilities or hospitals; and
- legal issues regarding whether the partnership triggers any Irish regulatory filing requirements, for example, under competition or foreign investment screening rules.

Law stated - 11 August 2023

COMPETITION, ANTI-CORRUPTION AND TRANSPARENCY RULES

Authority enforcement

Are infringements of competition law by healthcare providers pursued by national authorities?

The Irish regulator is competent in this sector, to the extent competition law is applicable.

Law stated - 11 August 2023

Private enforcement

Is follow-on private antitrust litigation against healthcare providers possible?

Yes, follow-on private antitrust litigation against healthcare providers is possible, but no such action has proceeded to judgment before the Irish courts to date.

Law stated - 11 August 2023

Anti-corruption and transparency

What are the main anti-corruption and transparency rules applicable to healthcare providers?

Under the Criminal Justice (Corruption Offences) Act 2018 (the Corruption Offences Act), it is an offence for any person to corruptly:

- · give or receive a bribe (the offences of 'active' and 'passive' corruption);
- give, offer, request or accept a bribe to exert influence over the act of an official (ie, a politician or any person working for the state or a public body) in relation to the official's office or employment (the offences of active and passive trading in influence); or
- create or use a false document with the intention of inducing another person to do an act in relation to their employment or position to the prejudice of that or another person.

The Corruption Offences Act provides that if a company is found to be guilty of a corruption offence and the offence was committed with the 'consent or connivance, or was attributable to any wilful neglect' of a director, manager, secretary or other officer of the company then that individual can also be found guilty of the offence.

The Corruption Offences Act also provides for the 'corporate offence' that enables a body corporate to be held liable for



the corrupt actions committed for its benefit by any director, manager, secretary, employee, subsidiary or agent of the body corporate with the intention of obtaining an advantage for the body corporate. The single defence available to corporates for this offence is demonstrating that the company took 'all reasonable steps and exercised all due diligence' to avoid the offence being committed. While there is no Irish guidance on the legislation yet, such 'reasonable steps' will include ensuring adequate policies and procedures are in place and that steps are taken to promote and ensure a corporate culture of reporting suspicions or concerns in relation to corruption.

'Corruptly' is defined in the Corruption Offences Act as including:

acting with an improper purpose personally or by influencing another person, whether by means of making a false or misleading statement, by means of withholding, concealing, altering or destroying a document or other information, or by any other means.

Consequences for breach of anti-corruption laws include imprisonment, fines or both.

There is no requirement under Irish legislation to publicly report information about Transfers of Value, which is provided to healthcare professionals, healthcare organisations or patient organisations. However, the Irish Pharmaceutical Healthcare Association (IPHA) Code of Practice for the Pharmaceutical Industry (Edition 8.5 – effective 1 March 2021) (IPHA Code), a self-regulatory or voluntary code, sets out the requirements on companies to make information regarding Transfers of Value publicly available. These requirements only apply to members of the IPHA and reflect the EFPIA standards (IPHA is a member of the EFPIA). The Code provides that each member must document and publicly disclose (subject to internal corporate compliance and feasibility), the Transfers of Value that it makes, either directly or indirectly, on the IPHA Central Report, to allow a comprehensive report to be made available from IPHA on Transfers of Value in Ireland. These disclosures may also be made on each company's relevant website; however, this is provided the disclosures are unrestricted and publicly available.

Law stated - 11 August 2023

REGULATION OF HEALTHCARE SERVICES

Licensing authority and process

Which authorities are charged with licensing and regulating patient care facilities and healthcare professionals? What licensing processes apply?

The following authorities are charged with regulating healthcare services and professionals in Ireland.

Services

- The Health Information and Quality Authority regulate the following patient care facilities; acute and community healthcare services, children's services, disability services and older people's services; and
- the Mental Health Commission regulates mental health services in Ireland.

Professionals

- · The Nursing and Midwifery Board of Ireland regulates nurses and midwives in Ireland;
- · the Dental Council regulates dentists, oral surgeons and orthodontists in Ireland;
- CORU regulates counsellors, psychotherapists, dieticians, occupational therapists, physiotherapists, podiatrists,

radiographers, social care workers and speech and language therapists in Ireland;

- · the Medical Council regulates medical doctors in Ireland;
- the Pharmaceutical Society of Ireland regulates pharmacists in Ireland; and
- the Pre-Hospital Emergency Care Council regulates pre-hospital emergency care providers in Ireland.

Law stated - 11 August 2023

Cross-border regulation

What requirements and restrictions govern the mobility of licensed health professionals across borders?

The EU Directive on Professional Qualifications allows EU citizens to have professional qualifications mutually recognised.

Applications for UK health and social care professional qualifications to be recognised in Ireland are processed as 'third country' applications. Notably, the third country process will not apply if you had:

- · a UK professional qualification recognised in Ireland before 31 December 2020; or
- an Irish professional qualification recognised in the UK before 31 December 2020.

Under the European Union (Recognition of Professional Qualifications) Regulations 2017 (S.I. No. 8 of 2017) the Medical Council has an obligation to inform the relevant competent authorities in other member states when a doctor's registration is restricted or prohibited. This obligation equally applies across the Irish regulated professions. Regulation 87(3) of S.I. No. 8 of 2017 states:

The competent authority in the State shall inform the competent authorities of all other Member States about a professional whose pursuit in the State of the activities, in their entirety or in parts thereof, has been restricted or prohibited, even temporarily, by authorities or courts in the State.

Law stated - 11 August 2023

Collaboration between healthcare professionals

What authorisations are required for collaboration between healthcare professionals? How is this regulated?

No specific authorisation regime for such collaboration.

Law stated - 11 August 2023

Collaboration between patient care facilities and healthcare professionals

What authorisations are required for collaboration between patient care facilities and healthcare professionals? How is this regulated?

No specific authorisation regime for such collaboration.



Training of healthcare professionals

What educational and training requirements must physicians and healthcare professionals satisfy to obtain the right to practise in your jurisdiction?

All medical practitioners, seeking to practise medicine in Ireland must be registered with the Medical Council. The registration process differs between practitioners who qualified in Ireland, in an EU member state or outside of Ireland. To ascertain which Division of the Register a practitioner can apply to the Medical Council has developed this online eligibility resource for practitioners.

Registration with the Medical Council will see a practitioner added to one of the relevant Divisions of the Register of Medical Practitioners.

From 6 November 2017, all medical practitioners applying to register with the Medical Council must provide evidence of professional medical indemnity.

Law stated - 11 August 2023

Discipline and enforcement

What civil, administrative or criminal sanctions, penalties, corrective measures and related tools may be imposed on patient care facilities and healthcare professionals for regulatory non-compliance?

This varies by professional body.

Law stated - 11 August 2023

Patient complaints

How are patient complaints processed and adjudicated?

In Ireland, a patient can make a complaint regarding healthcare treatment received in the following ways:

- Pursuing a legal claim via the civil courts. Generally, a successful claim will result in the award of damages.
- Direct complaint to the service provider. It will be a matter for the service provider as to how they will address a patient's complaint.
- Make a complaint to the Office of the Ombudsman regarding the Health Service Executive. The Ombudsman will
 conduct an investigation and prepare a report on its findings.
- Make a complaint to a regulatory (eg the Medical Council, the Nursing and Midwifery Board of Ireland). In this regard, each regulatory authority has a statutory process directing how complaints are investigated. This includes and initial screening stage, followed by a public Fitness to Practise Inquiry (if necessary) to ascertain whether the has been a failure on the practitioner's behalf. The outcome of any such investigation is the imposition of a sanction on the practitioner's registration.
- Make a complaint to An Garda Síochána, if the alleged action was criminal in nature. An Garda Síochána will
 conduct an investigation before deciding whether a criminal prosecution is merited.



DATA PROTECTION, PRIVACY AND DIGITAL HEALTH

Responsible authorities and applicable legislation

Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation?

The Data Protection Commission (DPC) is the national independent authority responsible for compliance with data protection and privacy in Ireland.

Regulation (EU) 2016/679 (General Data Protection Regulation (GDPR)) is directly effective in Ireland. It is supplemented by the Irish Data Protection Act 2018 (the 2018 Act), which provides for certain national derogations permitted under the GDPR, and sets out the regulatory and enforcement powers of the DPC. The 2018 Act also repeals the Data Protection Acts 1988 and 2003, except those provisions relating to the processing of personal data for the purposes of national security, defence and international relations of the state.

Law stated - 11 August 2023

Requirements

What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

The basic requirements placed on healthcare providers (HCPs) are the same as on any organisation acting as a controller or processor of personal data.

An HCP, as a controller, must adhere to the seven principles of the GDPR, namely:

- · lawfulness, fairness and transparency;
- purpose limitation;
- · data minimisation;
- · accuracy;
- · storage limitation;
- · integrity and confidentiality; and
- · accountability.

In addition, under article 6 of the GDPR, the processing of personal data by a HCP, as a controller, shall only be lawful where one of the following applies:

- · the consent of the data subject has been obtained;
- the processing is necessary for the performance of a contract;
- the processing is necessary for compliance with a legal obligation;
- · the processing is necessary to protect the vital interests of the data subject or third party;
- the processing is necessary for the performance of a task carried out in the public interest; or
- the processing is necessary for the purposes of the legitimate interests of the HCP or a third party.

HCPs will often be dealing with 'special categories of personal data', as defined by article 9(1) of the GDPR, in particular health data. The processing of this data is prohibited unless one of the exceptions listed in article 9(2) applies.

There is a regular need for qualified personnel, including the appointment of a data protection officer (DPO). Article 37(1) of the GDPR requires a controller or a processor to designate a data protection officer in certain circumstances, including where their core activities consist of large-scale processing of special categories of personal data pursuant to article 9. As the core activities of HCPs involve the processing data concerning health data, they should appoint a qualified and competent DPO. The DPO will be required to act in accordance with the duties and tasks set out in articles 38 and 39 of the GDPR.

Law stated - 11 August 2023

Regulatory guidance

Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The DPC has not issued any specific guidance under the GDPR for the healthcare sector.

The Health Research Regulations 2018 (S.I. No.314 of 2018) (the 2018 Regulations) set out mandatory safeguards to be taken by a controller, when processing personal data for 'health research' purposes (as defined in those Regulations). These safeguards apply in addition to the requirement to have a lawful basis for processing such data under articles 6 and 9 of the GDPR. In particular, the 2018 Regulations require a controller to obtain the explicit consent of the data subject for such processing.

The 2018 Regulations have been amended by way of the Data Protection Act 2018 (Section 36(2)) (Health Research) (Amendment) Regulations 2021 (the 2021 Regulations). The 2021 Regulations were developed in consultation with the DPC, in order to clarify the safeguards required to be implemented by a HCP, in relation to retrospective chart reviews, and pre-screening for the purpose of assessing eligibility or suitability for inclusion in health research.

The Data Protection Act 2018 (Access Modification) (Health) Regulations 2022 (S.I. No. 121/2022) (the 2022 Regulations) regulate data subject access to health data. Under article 15 of the GDPR, a data subject has a right of access to a copy of their personal data, which can only be restricted in limited circumstances. The 2022 Regulations allow a controller to restrict a data subject's access to their health data where the controller has 'reasonable grounds' to believe that granting access would be likely to cause 'serious harm' to the data subject's physical or mental health. Where the controller is not an HSP, it is entitled (but not legally required) to consult with a health practitioner before making a decision on whether or not to provide a data subject with the health data concerned. The 2022 Regulations specifically prescribe how such consultation is now to take place.

Law stated - 11 August 2023

Common infringements

What are the most common data protection and privacy infringements committed by healthcare providers?

Common data protection and privacy infringements committed by HCPs include a failure to obtain adequate consent from patients or failing to establish a lawful basis for processing under article 6 and article 9 of the GDPR. Case studies of the DPC highlight the increased protection afforded to health data under data protection legislation, and the importance of having an appropriate lawful basis to process such data.

In addition, the DPC's Annual Report for 2022, shows the importance of controllers implementing security measures appropriate to the risk profile of the personal data processed, in line with article 32 of the GDPR. The DPC imposed a number of fines following receipt of data breach notifications last year, in particular where such breaches involved

special categories of personal data, such as health data. Accordingly, it is vital that HCPs ensure that appropriate security measures are in place to protect personal data from unauthorised access or disclosure. and take proactive steps to test the effectiveness of such measures and implement repeated staff training.

Law stated - 11 August 2023

Digital health services

Which authorities regulate the provision of digital health services and what is the applicable legislation? What basic requirements are placed on healthcare providers when it comes to digital health services?

There is currently no specific legislation governing the provision of digital health services (aside from temporary measures around e-prescriptions) but legislation is due to be introduced to align with the future eHealth strategy.

Telemedicine is available in Ireland. Telemedicine describes the delivery of healthcare services through information and communication technologies to promote the health of individuals and their communities. It involves the exchange of information between doctors and patients, or between doctors and professional colleagues, for the diagnosis, treatment and prevention of disease and injuries, and for research, evaluation and continuing education.

The Medical Council has developed a guide entitled 'Telemedicine Phone and Video Consultations, A guide for doctors'. This guide provides information for practitioners in relation to a variety of matters, including obtaining patient consent, continuing professional development and maintaining patient privacy and confidentiality.

Law stated - 11 August 2023

UPDATE AND TRENDS

Key developments

Are there any current or foreseeable legislative initiatives, court cases, laws or other rules that affect the regulation of healthcare? What has recently changed (or will likely change), and what steps need to be taken in preparation?

The Regulated Professions (Health and Social Care) (Amendment) Act 2022 was enacted in October 2020. This Act introduces a number of amendments to existing legislation governing the regulation of professionals practising in the Irish healthcare arena (including doctors, nurses, pharmacists, dentists and other health and social care professionals). The purpose of these amendments is to modernise the investigation of complaints functionality for the aforementioned regulators. The majority of the main provisions are yet to be enacted.

Jurisdictions

Australia	Clayton Utz
* Canada	Stikeman Elliott LLP
• India	LexOrbis
Ireland	Matheson LLP
Italy	CMS Italy
Japan	Anderson Mōri & Tomotsune
Mexico	OLIVARES
Sweden	Cirio Advokatbyrå AB
C* Turkey	Gün + Partners
USA	Norton Rose Fulbright