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THE CARTELS AND LENIENCY REVIEW
THE TAX DISPUTES AND LITIGATION REVIEW
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Welcome to the first edition of The Healthcare Law Review, the latest addition in The Law Reviews series. The Review provides an introduction to healthcare economies and their legal frameworks in 16 jurisdictions. 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.

The ways different countries have gone about this 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.

We live in uncertain times. From the future of America’s Affordable Care Act (‘Obamacare’) to China’s integration of its urban and rural healthcare insurance systems, dramatic restructuring is under way as countries try to provide comprehensive access for populations. Dynamic jurisdictions such as the UAE are looking to leapfrog countries burdened with historic and long-standing systems, attracting new providers but also recognising for the first time issues around mental health and geriatric care. To manage budgets, governments such as the UK’s are commissioning care that includes social care and a greater focus on public health and wellness. Keeping up to date with new models of care and the legislative frameworks across the world is a challenge.

But these are also 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.

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 new project and also the wider team at Law Business Research for their support and organisation.

Sarah Ellson
Fieldfisher
Manchester
August 2017
Chapter 1

BRAZIL

Renata Fialho de Oliveira, Priscila David Sansone Tutikian, Fábio Luiz Barboza Pereira, Michele Lyra da Cunha Tostes, Andrea Piccolo Brandão and Vanessa Bertonha Felício

I OVERVIEW

Pursuant to the 1988 Brazilian Constitution, health is a fundamental social right of every person (Article 6) and a duty of the state (Article 196). In Brazil, the constituent power has melded health with social security and afforded universal, gratuitous and equal access to the public health system to all, with no distinction whatsoever. It is correct to state, thus, that in Brazil, individuals have the subjective right to demand free access to the public healthcare structure, and it is an obligation of the state to provide it.

The Constitution determines that health actions and services have public character and it is within the public power’s responsibility to regulate, supervise and control them. Their execution, on the other hand, may be carried out by the state (directly or indirectly, through third parties via a public contract) or by private parties on their own (Article 197).

The institutional mechanism whereby the public power materialises (or seeks to materialise) ample access to health is the Unified Health System (SUS). SUS’s legal basis is composed mainly by: (1) the Federal Constitution, (2) Law No. 8,080/1990 (the Organic Health Law) and (3) Law No. 8,142/1990.

Under the Federal Constitution and the Organic Health Law, all entities of the federation (union, state, federal district and municipalities) are bound to SUS and must cooperate with actions and resources to render health services. Also, they are joint and severally liable with respect to healthcare.
Notwithstanding the above, among the three of SUS’s constitutional directives, the first of them is the directive of ‘decentralization in a sole direction in each governmental level’ (Article 198, I). Such directive mandates the municipalisation of treatment, meaning that services to the population shall be taken care by the municipalities. Pursuant to this directive, not only federal and state hospitals shall be managed by municipalities, but also the relationship between SUS and private healthcare providers shall be implemented through the municipalities.

The other two of SUS’s constitutional directives are whole treatment (Article 198, II) and community participation (Article 198, III). The whole treatment directive indicates that the government must use its entire means to fulfil its duties; that is, the state’s obligation may not be limited, mitigated or divided. The community participation directive has been regulated by Law No. 8,142/1990 and requires that each governmental level maintain two collegiate bodies, the Health Conference and the Health Council.

The Brazilian Federal Constitution ensures the private enterprise freedom to participate in healthcare (Article 199). Such participation may take place pursuant to two different regimes: (1) alongside SUS in a complementary manner (i.e., to complement certain treatment needs when SUS’s availabilities are insufficient to ensure adequate coverage in a certain area), and (2) outside SUS, with supplementary character.

Any time the private enterprise participates in healthcare in a complementary manner, i.e., by executing a public contract or partnership, philanthropic entities and non-profit organisations shall be given preference (Article 199, Section 1). The criteria and amount of consideration for services and coverage parameters shall be approved by the National Health Council (Organic Health Law, Article 26).

Whenever properly licensed practitioners and private legal entities, on their own initiative, act with the aim of promoting, protecting and recovering health outside SUS, this is designated supplementary healthcare. Even if independent from any formal agreement with SUS, supplementary healthcare remains, nonetheless, bound to SUS’s legal scheme in that SUS’s ethical principles and rules issued by SUS direction must be observed for its regular operation. Apart from that, the legal regime for provision of healthcare services does not face restrictions as regards scope; that is, private entities may render services in all levels of complexity.

The direction of SUS is incumbent to each level of the government: at a national level, to the Ministry of Health, at the state, federal district and municipality levels to the State Health Secretary, Federal District Health Secretary, and Municipal Health Secretary or equivalent, respectively. In view of the decentralisation directive provided for by the Brazilian Constitution, in each of the union’s, state’s, federal district’s and municipal’s administrative sphere, entities of their direct and indirect administration have authority to deliver, commission, license and regulate healthcare services in consonance with the guidelines of the Organic Health Law, Law No. 8,142/1990 and SUS Basic Operational Norm (NOB 1/96), among others.
At a national level, the Brazilian Ministry of Health is the highest sanitary authority, responsible for ultimately resolving health issues in Brazil. The Ministry of Health counts in its organisational structure authorities, foundations and state-controlled companies responsible, at the federal level, for public health actions and services. The most relevant institutions bound to the Ministry of Health are the National Health Committee (CNS), the National Sanitary Surveillance Agency (ANVISA), and the National Supplementary Health Agency (ANS).

CNS operates as the highest decision-making body of SUS, approving and maintaining the healthcare budget, as well as managing, evaluating and resolving issues concerning public healthcare policies.

ANVISA, created by Law No. 9,782 of 1999, is a federal agency with broad authority relating to the coordination of the National Sanitary Surveillance System, including, among several other competences, powers to issue general rules concerning national sanitary surveillance.

ANS, created by Law 9.961/2000, is the agency competent for regulating, standardising, managing and inspecting activities that guarantee supplementary healthcare. ANS, thus, regulates, controls and supervises private entities that operate health plans or insurance, or render private services that are not legally bound to SUS.

II THE HEALTHCARE ECONOMY

i General

Free access to the public health system is ensured by the 1988 Federal Constitution and the Organic Health Law. Within SUS, public services are rendered directly (i.e., by public hospitals) or indirectly by means of the execution of a public contract between the SUS manager, usually a municipality, and private parties (Article 199 of the Constitution and Articles 24 to 26 of the Organic Health Law), free of charge. The Brazilian government is still not prepared to fulfil its duties as regards healthcare, and does not own the necessary infrastructure to so, lacking hospitals, laboratories and clinics. Thus, the partnership with private parties is a relevant means of pursuit of its constitutional goals.

Private healthcare is available with complementary character (within SUS) and with supplementary character (independently from SUS).

According to CNS’s data, in June 2017, the total number of hospitals in Brazil amounted to 6,778, among which, 70 per cent are private hospitals, 1 per cent belong to the union, 8 per cent to the states and 21 per cent to the municipalities.

As reported by ANS, on March 2017, the rate of the Brazilian population covered by private insurance plans (with and without dentistry coverage) was of 24.5 per cent, meaning that almost one-quarter of the Brazilian population uses private healthcare services relying on private health insurance or a plan.

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8 Law No. 10,683 of 2003, which regulates the organisation of the Presidency of Brazil and Ministries, sets forth in its Article 27 the topics within the Ministry of Health's authority.
10 www.cns.org.br/links/DADOS_DO_SETOR.htm.
ii The role of health insurance

Private health insurance plays an important role in Brazil, representing a relevant alternative to the much-demanded and sometimes inefficient public healthcare system. Recently, owing to the increase of life expectancy, healthcare has become a major concern of Brazilian citizens, and has incremented the search for this type of service, in which the insured has freedom of choice. Despite its importance, in Brazil, the purchase of health insurance is absolutely voluntary. Labour laws in general do not oblige an employer to contract health insurance for its employees, however, this may be obligatory to certain categories of employees depending on the provisions of the applicable collective bargaining agreement executed with the relevant union.

iii Funding and payment for specific services

Every two years, SUS issues a list of medical products available to citizens free of charge, provided that each municipality has its own list prepared according to demand. Each municipality also has a high-cost medicine list that may be supplied free of charge upon receipt of a special clinical report and, in some states, a proper form. Another governmental programme, by means of which one may access basic free of charge or discounted medicine, is the Brazilian Popular Drugstore Programme.

As regards the funding and payment for supplementary services, in Brazil, health insurance carriers are subject to specific legislation and ANS’s regulations. In relation to the coverage of health treatments or medical appointments, ANS issues, from time to time, a list of proceedings, examinations and treatments with mandatory minimum coverage. Carriers are, notwithstanding, free to offer additional coverages or to cover additional proceedings and treatments with extra charges. The list of proceedings, examinations and treatments with mandatory coverage currently in force is an annex to ANS Resolution No. 387/2015. Any product, service or equipment not included in such list may be offered by health insurance carriers as additional coverage.

Prescriptions, wellness services and alternative health therapies are generally paid by citizens personally.

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

Article 198 of the Federal Constitution sets forth that SUS comprehends a regionalised and hierarchical net. By referring to a regionalised system, the Constitution points out to territorial organisation (Decree No. 7,508 of 28 June 2011, which regulates the Organic Health Law, governs the setting up of Health Region and Health Attention Nets). The term ‘hierarchical’ indicates the need to organise treatment according to the different levels of complexity and a net of references and counter-references to optimise the use of the resources in primary, secondary and tertiary treatment units.

The universal and equal access to public healthcare is ordered by the primary care and must be based on the severity of the individual and collective risks, with due regard to
specifics for people with special protection pursuant to the legislation. Hospital and special ambulatory services, as well as others of higher complexity or technological density, shall be referred to the Health Attention Nets, which are primary care, urgent and emergency care, psychosocial care and specific healthcare for those who need special care as a result of labour hardship (open access) (Articles 9 to 11 of Decree No. 7,508 of 28 June 2011).

The Brazilian jurisdiction supports the use of electronic or digital medical records, however, the current challenge is to implement easily accessible universal records. Although there is a set of general rules that sparsely protects privacy rights and personal data, there is still no specific law to protect sensitive data and ‘protected health information’ contained in patient records, nor is there any definition of what can be considered ‘sensitive data’. The Brazilian Federal Medical Council issued Resolution No. 1,821/2007, which regulates the replacement of physical files of patients’ medical charts for a digital medical record, which by analogy, is a reference to regulate other issues related to the storage and sharing of patient information.

Currently, Bills of Law No. 4,060/2012 and No. 5,276/2016 are under discussion in Congress and, if approved, will regulate the processing and sharing of personal data. Bill 5,276 classifies medical information as ‘sensitive data’, a category of personal information that shall receive a higher degree of protection. Meanwhile, this matter shall be analysed taking into account the Federal Constitution, the Consumer Defence Code, Law No. 12,965/2014, known as the Brazilian Internet Act, and Decree No. 8,771/2016, which regulates it, whenever data transits within the digital or virtual environment.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

The Brazilian healthcare system is regulated by several entities of the direct and indirect administration at the federal, state and municipal levels.

Various bodies have concurrent legislative authority to issue sanitary and health rules. To start with, the National Congress, as well as the state’ legislative assemblies and municipal chambers have concurrent and supplementary jurisdiction to legislate about health and sanitary matters. Moreover, the president, governors and mayors are competent to issue decrees and regulations covering health topics. In addition, the Ministry of Health, State Health Secretary, Federal District Health Secretary and Municipal Health Secretary, or equivalent, as well as SUS’s regulatory agencies (ANVISA and ANS), besides the federal and regional professional councils, all have authority to regulate health matters and issue normative rules in this regard.

At a national level, the Brazilian Ministry of Health is the highest sanitary authority. The most relevant institutions bound to the Ministry of Health are CNS, ANVISA and ANS. Both ANVISA and ANS have, among others, licensing authority.

ANVISA is an agency with vast authority relating to the coordination of the National Sanitary Surveillance System, including powers to control production and commercialisation of products and services subject to sanitary control, including the environment, processes,
supplies and technology related thereto, as well as to issue normative regulations connected with its scope of authority.\textsuperscript{15} ANS is the agency competent for regulating, controlling and supervising private entities that operate health plans or insurance.

The Organic Health Law and Law No. 9,782/1999, which instituted the National Sanitary Surveillance System, set forth that regulation, standardisation, control and sanitary surveillance, are incumbent to institutions of direct and indirect public administration of the union, the states, federal district and municipalities. The Ministry of Health’s Resolution No. 1565/1994 organised the distribution of authority among such governmental entities. Sanitary surveillance at all such levels is exercised through the issuance of regulations, execution of actions and services and political and administrative inter-sectorial articulation (Article 10). In general, municipalities have more executory roles.

Both institutional healthcare providers as well as professionals are subject to licensing and rules issued by professional bodies, such as the Medicine Federal and Regional Councils, the Dentistry Federal and Regional Councils and the Pharmacy Federal and Regional Councils.

\textbf{ii Institutional healthcare providers}

Healthcare is a regulated industry, meaning healthcare providers must obtain and maintain several licences, enrolments and authorisations to operate legally. In addition to general registrations (such as registration with federal, state and tax authorities, environmental licences and licences attached to the real estate), the main specific licences required from institutional healthcare providers are indicated below.

All institutional healthcare providers must obtain and maintain a licence granted by the applicable sanitary surveillance authority. This licence may be granted on a municipal or state level, according to the location of the healthcare provider. In several locations in Brazil, each activity or service rendered requires a specific sanitary licence. The specific legislation of each state and municipality where the healthcare facilities are or will be based must be carefully reviewed to ascertain the applicable sanitary licences for each business.

The National Healthcare Facility Enrolment is a general registry to which all healthcare facilities must register.\textsuperscript{16}

Medical and dentistry institutional healthcare providers shall enrol with the Regional Medicine Council and Regional Dentistry Council, respectively, and register before such body the technically responsible doctor or dentist, as the case may be. Similar rules apply to nursing services, pharmaceutical services, radiology services and transplant services, among others.

Brazilian law provides for administrative and criminal sanctions for the unlicensed provision of services. Except for environmental crimes, in Brazil, only individuals are criminally liable for offences. Thus, if an institutional healthcare provider operates without valid licences, then its administrators may be punished with six months to two years’ imprisonment.

Both regional and federal authorities may inspect the institutional healthcare provider’s premises at any time to check compliance with the applicable laws and regulations. In case of violation, the licences and authorisations may be suspended or revoked.

\textsuperscript{15} Article 7 of No. 9,782/1999 sets forth ANVISA’s authority and scope of action.

\textsuperscript{16} Ministry of Health Ruling No. 511 of 2000.
The law ensures a proper administrative proceeding for a refusal to grant or withdrawal of licences and authorisations.

iii Healthcare professionals

The regulation as regards to licensing healthcare professionals is extensive. Doctors, nurses, dentists and pharmacists must comply with a long list of requirements to be eligible to exercise their profession. Brazilian legislation is categorical when it comes to enforcing the mandatory enrolment with the competent authorities for all healthcare professionals.

With regards to medicine, Federal Law No. 3,268 and Decree No. 44,045 set forth that doctors are only allowed to render health services if their titles, certificates or diplomas are duly registered with the Ministry of Education and if they are enrolled with the applicable Regional Medicine Council.

When it comes to nursing, Federal Law No. 2,604 and the Federal Nursing Council’s Resolution No. 311 set the main legal framework with respect to the compulsory registration of nurses.

Dentistry is regulated by Federal Law No. 4,324 and Decree No. 68,704, which establish that dentists may only render dentist services upon the registration of their diplomas with the Ministry of Education and their enrolment with the Regional Odontology Council.

Federal Law No. 3,820 regulates the compulsory licensing of pharmacists. According to referred law, only those registered with the applicable Regional Pharmacy Council are allowed to render pharmaceutical services.

The general rule in Brazil is that unlicensed professionals may not render health services and that licensed professionals must not delegate acts restricted to them to other professionals. Notwithstanding, certain ancillary and technical activities and services associated with the healthcare industry may be rendered by unlicensed professionals, provided that they are supervised by a licensed professional.

Disciplinary sanctions may apply to healthcare professionals who fail to comply with the applicable laws. The sanctions vary from warnings, fines, suspension or withdrawal of the licence to practise, depending on the seriousness of the act. Moreover, healthcare professionals who perform healthcare services without the required licences may face criminal sanctions and be punished with six months to two years’ imprisonment.

Professionals may appeal against a refusal to grant or withdrawal of a licence to practise, as provided for in the legislation that establishes the Federal and Regional Councils and the regulation of such bodies.

There is no legislation in Brazil determining compulsory purchase of malpractice insurance by healthcare professionals.

V NEGLIGENCE LIABILITY

The imposition of liability must be examined from two main standpoints: (1) the liability of healthcare professionals, arising from the provision of services in a direct and personal way; and (2) the liability of institutional healthcare providers.¹⁷

From a physician’s liability standpoint, the obligation is to provide attentive care and employ his or her knowledge in the best possible way to improve a patient’s health condition

– without being bound to any promise of healing or achievement of a certain result (except for physicians who specialise in aesthetic surgery). This general obligation related to the provision of medical services, thus, is an obligation of means, and not an obligation of results. Therefore, for a physician to be held liable for damages to a patient, fault must be proven (negligence, recklessness or malpractice) – that is, the general standard of fault-based liability applies. However, legal doctrine advises for a cautious interpretation of these concepts, since it is also important to assess the conditions in which the physician is providing medical care. For instance, in the public health system, often the professional is confronted with lack of adequate equipment, structure and support staff, among other adverse conditions, which may impair the provision of the service – so the services performed by the physician should be assessed in light of these circumstances.

Hospitals, laboratories, clinics and other healthcare providers (including those operated by the state directly or indirectly) are subject to strict liability standard (Article 14 of the Consumer Defence Code (CDC) and Article 927, sole paragraph, of the Civil Code), which disregards the existence of fault. However, when it comes to liability owing to the actions of members of a hospital’s staff, their fault must be proved, which means that the hospital will be held accountable (strict liability, based on Article 932 of the Civil Code) if its employees or agents acted with fault. In this scenario, since the patient can be qualified as a consumer according with the CDC, healthcare providers (e.g., physicians and the hospital) will be jointly liable for the damages. However, the corresponding healthcare provider have recourse against those responsible for the damage, and may succeed if able to prove that the damage was caused by such professional acting with fault.

From a procedural perspective, there are two important highlights. Firstly, the burden of proof regarding the physician’s fault can be switched by the court – so the consumer (patient), deemed technically vulnerable, does not have to produce this evidence. If that happens, the physician will have to demonstrate his or her regular and legal conduct, and that he or she has acted with all the due care, not constituting a negligent or reckless practice. According to the Superior Court of Justice, the fault-based liability of the physician does not prevent the reversal of the burden of proof. Secondly, if a patient files a lawsuit solely against the hospital because of an alleged fault committed by a member of the staff, it will not be able to call this member to the proceeding, even though the latter could be the one to

20 ‘The State is a legitimate defendant to join the passive action of an indemnity claim based on medical malpractice supposedly occurred in care provided within SUS by a private hospital with whom the State signed a management contract’ (São Paulo Court of Appeals, lawsuit No. 2069342-16.2013.8.26.0000, ruled on February 2014).
21 For instance, a hospital was held liable for damages caused to a patient due to the absence of a specialised physician and lack of a vacancy in the intensive care unit, which aggravated the patient’s health condition (Superior Court of Justice, lawsuit No. 1.145.728/MG, ruled on June 2011).
22 The Superior Court of Justice recognised a hospital’s strict liability due to its physician on duty’s fault (misdiagnosis), who was member of the clinical body (Superior Court of Justice, lawsuit No. 696.284/RJ, ruled on December 2009).
23 As seen in: Superior Court of Justice, lawsuit No. 696.284/RJ, ruled on December 2009.
blame for the occurrence of the damage. This understanding arises from a CDC provision\textsuperscript{24} that prohibits possible co-defendants from being called to the lawsuit, so that the patient can be more easily compensated, avoiding a discussion of fault (as the hospital’s liability is strict).

\section*{VI OWNERSHIP OF HEALTHCARE BUSINESSES}

Article 199 of the Brazilian Constitution sets forth that healthcare is open to private enterprise. The provision of healthcare services by private actors may take place pursuant to two different regimes, alongside SUS (complementary healthcare) and outside SUS (supplementary healthcare). The legal regime for private parties to provide supplementary healthcare services does not face restrictions; that is, private entities may render services in all levels of complexity. It is important, however, to take into account that any health activity holds public status and is subject to governmental control (Brazilian Constitution, Article 197).

Pursuant to the Federal Constitution, foreign and domestic investors enjoy the same level of protection. Restrictions to investment in certain areas, however, remain. Previously included in the list of restricted business activities, the offer of health services by entities with direct or indirect foreign capital has become authorised by Law No. 13,097/2015. Such law modified Article 23 of the Organic Health Law and expressly authorised entities with foreign capital to install, operate and exploit general hospitals, specialised hospitals, policlinics, general clinics and specialised clinics.

Among the players in the healthcare sector, the ones which face most restrictions are health insurance plan operators. Any entity intending to do business in the supplementary health market in Brazil must first obtain a licence to do so. The procedure for obtaining an operating licence from ANS is preceded by the health insurance plan operator’s and product’s registration with the competent ANS Board of Officers. The list of requirements for an entity to obtain an operating licence as a health insurance plan operator is quite extensive and contains several restrictions, such as minimum net worth, collateral assets, minimum requirements for board members and officers, and enrolment before medical or dental regional councils.

\section*{VII COMMISSIONING AND PROCUREMENT}

In view of the decentralisation directive of SUS, the commission of services tend to take place at the municipal level.

As a default rule, the Brazilian Constitution establishes that all purchases and sales made and all services and works hired by the public administration, including health services, shall be subject to a public bid. Law No. 8,666/1993 is the federal public bids and contracts law.

The requirements to participate in a public bid or to execute a public contract are usually set forth in the ‘request for proposal’, however, a few standard pre-qualification requirements include legal, tax and labour regularity, and technical and financial requirements.

Law 8,666/1993 sets forth some exceptional and specific cases in which the public bid may be deemed unnecessary or unfeasible. For example, the competitive procedure may be

\textsuperscript{24} Article 88 of the Consumer Defence Code (Law No. 8.078/1990).
waived in cases of extreme urgency, war or state of emergency, among others; or be deemed unfeasible, when the nature of the product or service is singular and only one supplier has the expertise. Within SUS or in connection with Brazilian Public Health Policy, it is common for public bids to be deemed unnecessary or unfeasible.

VIII  MARKETING AND PROMOTION OF SERVICES

Marketing and promotion of services in the healthcare sector are very strictly regulated and should observe several rules issued by Brazilian Advertisement Self-Regulating Council (CONAR), ANVISA, as well as regulations issued by the relevant professional bodies and those of the Consumer Defence Code.

Exhibit G of CONAR’s Brazilian Advertisement Self-Regulation Code deals with advertisement of healthcare services and businesses. According to the Exhibit, advertisements of healthcare services and business shall not promote:

a  the cure of diseases that have no proper treatment according to proven scientific knowledge;

b  methods of treatment and diagnosis still not scientifically approved;

c  specialisation still not approved by the respective professional career;

d  offer of diagnosis or treatment at distance; or

e  prosthetic products that require tests and diagnoses of specialised doctors.

Also, healthcare professionals shall not promote:

a  the exercise of more than two specialisations; or

b  activities that are prohibited by the respective professional ethics codes.

Whenever hospital and similar services are advertised, the medical management in charge thereof must be mentioned. Moreover, the advertisement of clinical and surgical treatments (such as weight loss or plastic surgery) shall be governed by the following principles:

a  it must be in accordance with the rules of the professional and governmental bodies applicable to the matter;

b  it shall mention the medical management in charge;

c  it shall contain a clear and adequate description of the type of treatment or diet;

d  it shall not contain testimonials given by laymen; and

e  it shall not contain promise of cure or reward to those who have no success after the use of the treatment or diet.

All descriptions, assertions and comparisons relating to facts or objective data shall be capable of being substantiated, and advertisers and agencies shall supply the documentary evidence whenever so requested. Advertising campaigns are also forbidden to attract the lay public by means of ‘before and after’ visual comparisons or ‘results of the advertiser’s product’ versus ‘results of competitor’s product’ visual comparisons.

In addition, healthcare providers must follow specific rules concerning marketing and advertisement provided for by the relevant professional body and their codes of ethics (medical, dentistry, nursing, pharmaceutics, psychology councils, etc.).

From a consumer law perspective, consumers are granted the right to easy access to adequate and clear information with details regarding quantity, characteristics, composition, quality, price and risks involved in any product or service rendered both by physicians and
companies in the healthcare sector. The CDC distinguishes the concepts of misleading and abusive advertising, both equally forbidden: misleading advertising is that which may lead the consumer to error in regards to the aforementioned requisites, while abusive advertising is capable of inducing the consumer to behave in any way that is harmful to his or her health or safety, among others.

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

One pressing issue in Brazil regards the further regulation and permission for private healthcare providers to exploit the various facets of telemedicine. Currently, the Medical Ethics Code forbids the prescription of treatment and other procedures without the direct exam of the patient, except in case of emergency or urgency and proven impossibility of rendering it (Article 37). The rendering of services through telemedicine is regulated by the Federal Medical Council Resolution No. 1,643/2002, which defines telemedicine as the ‘exercise of medicine through interactive methodologies of audio-visual communication and data with the purpose of treatment, education and research in Health’. Both institutions and practitioners that render telemedicine services must register with the Medical Regional Council where they are located. Resolution No. 1,643/2002 is quite laconic and the interpretation adopted so far has been predominantly conservative, in that telemedicine is deemed legal only if provided for second medical opinion and provided that the patient is accompanied by a local doctor when enjoying telemedicine services, among other few exceptions.

Technology and easy access to communication tools have tremendously evolved since the issuance of Resolution No. 1,643/2002 and telemedicine will each day prove to be an irreversible reality. As a matter of public policy, the relevant regulatory bodies should take a careful approach when designing permitted and forbidden telemedicine activities. Also, such concept shall be clearly differentiated from e-health, telecare, e-care and mobile health because, so far, there is no consensus about those terms and the limits of their legality. In a country with dimensions such as those of Brazil, telemedicine may become an extremely relevant tool to increase access to healthcare and education in remote areas. It is yet to be seen, but any upcoming public policy with regards to telemedicine may represent a relevant change to healthcare practice in Brazil.

As regards privacy laws, in a scenario of constant modernisation of the health sector in Brazil – as it can be seen from the implementation of digital systems and massive databases such as the public DATASUS (SUS Informatics Department) – it is important to rethink how to reconcile technological innovation with the rights and guarantees of patients, such as the confidentiality of their information and the privacy of their data. The approval of Bills of Law No. 4,060/2012 and No. 5,276/2016 may bring new developments in this field.

X CONCLUSIONS

As we tried to describe in this article, healthcare regulation in Brazil is extremely sparse and complex, in part due to the myriad of legislative and infra-legal entities competent to govern health matters. Navigate such regulatory landscape may prove to be a challenging exercise, especially when the call is innovation, due to a general bureaucratic propensity.

In view of the advancement of technology and several market players and institutional investors’ interest in novelty, it is reasonable to expect that further regulation for telemedicine, e-health, telecare, e-care and mobile health will be issued, and if not, at least that the
competent authorities will possibly have their views on such matters tested, hopefully aiding in the construction of a coherent case law and the advancement of healthcare in Brazil through technology.\textsuperscript{25}

In addition to a certain level of legal uncertainty, excessive regulation tends to lead to illegal practices. Brazil is going through a particular time in its history, and contemporary developments indicate a trend toward intolerance with regard to harmful acts.\textsuperscript{26} The enactment of Law No. 12,846/2013 (the Brazilian Anticorruption Law) was another signal of the countries’ authorities commitment in this matter. Private practices have also been enhancing their internal policies concerning, among others, compensation models and ethical supply chains.\textsuperscript{27}

The market for mergers and acquisitions has been quite busy since the entry into force of Law No. 13,097/2015, which authorised the participation of foreign capital in healthcare providers. There has been, since then, a significant increase in transactions in this area, both by market-players seeking organic growth and institutional investors. Consolidation in the domestic market and the trend to get organised and reinforce housekeeping and professional management to attract investment have also been noteworthy. This scenario will tend to remain unchanged in the coming months.

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\textsuperscript{25} Technology is a current topic of major concern among hospitals. The topic of the 2017 Congress of the National Association of Private Hospitals (ANAHP) taking place in November 2017 relates to hospitals’ technology transformation ‘The Hospital of the Future: the Future of Hospitals’ (www.conahp.org.br/2017/programacao).

\textsuperscript{26} Partially as an indirect consequence of the car wash massive process to fight corruption.

\textsuperscript{27} The topic of the 2016 3-day Congress of the National Association of Private Hospitals (ANAHP) was ‘Ethics: Sustainability of Healthcare in Brazil’.
Chapter 2

CANADA

Lynne Golding, David Rosenbaum, Daniel Fabiano, Laurie Turner, Rosario Cartagena and Kimberly Potter

I OVERVIEW

Canada is a federated country comprising 10 provinces and three territories, populated by over 36 million people. Under a ‘separation of powers’ concept, Canada’s Constitution allocates responsibility for various matters between the federal government of Canada on the one hand, and the provincial governments on the other. Thus, while the government of Canada is responsible for the delivery of healthcare to a subset of Canada’s population, generally, the regulation and funding of healthcare is within the provincial jurisdiction.

Regulating the delivery of healthcare is a significant function of our provincial governments. This fact is not surprising, given that the delivery of healthcare is, year-in and year-out, among the issues of greatest import to Canada’s populace, and given that it is the subject of 35–45 per cent of almost all the provincial governments’ budgets. Provincial legislatures pass laws relating to, among others: healthcare delivery; health protection and promotion; the governance and operation of facilities in which healthcare is delivered; the delivery of mental healthcare, cancer care and home care; the regulation of healthcare professionals; healthcare privacy, procurement, accountability and transparency; and the means by which physicians may be compensated for the provision of their services.

II THE HEALTHCARE ECONOMY

i General

The Canada Health Act is likely the most recognised statute in Canada. Certainly, it is the single most important statute in defining how healthcare is delivered in Canada – even though, as said above, under the Canadian Constitution, the federal government has no jurisdiction to regulate healthcare. How then did it acquire this influence? Through its purse. The Canada Health Act is a funding statute. In it, the government sets out a number of

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2 As the distinction between a province and a territory is not important for the purposes of this paper, all will be referred to herein as ‘provinces’.

3 Statistic provided by Statistics Canada.

4 The government of Canada provides direct healthcare services to First Nations people living on reserves, Inuit populations, serving members of the Canadian Forces, eligible veterans, inmates in federal penitentiaries and some refugee claimant groups.
conditions. If in a year the healthcare system of a province meets the conditions, the province will be entitled to its full share of the Canada Health Transfer for that year. Aggregating billions of dollars,\(^5\) no province can afford not to be in compliance.

### ii The role of health insurance

To meet the conditions of the Canada Health Act, each province must have a health insurance plan in effect that, among other things, is:

- \(a\) publicly administered;
- \(b\) comprehensive;
- \(c\) universal;
- \(d\) portable; and
- \(e\) accessible.

To be accessible, provincial health insurance plans must prohibit extra billing and user charges for medically necessary healthcare services. In practice, the prohibition on extra billing means that physicians and dentists are unable to charge any amounts in addition to those they are being paid by the provincial healthcare insurance system.

While a detailed description of each of these criteria is outside the bounds of this chapter, the result is that each province has its own government-operated health insurance plan that pays for insured health services, meaning medically necessary healthcare services rendered to insured persons. While the provincial plans vary in a number of ways and provide some limited exceptions, for the most part, Canadians receive all medically necessary healthcare through their provincial health insurance system. Physicians, hospitals and other healthcare providers are prohibited by provincial law from charging Canadians for medically necessary healthcare. Canada is one of only two countries in the world that makes the purchase of supplemental or private healthcare for medically necessary healthcare services illegal.

We note that the term ‘medically necessary’ is not necessarily used in provincial health insurance statutes. The term has come to mean any healthcare service a province has agreed to fund in the fee schedule to its health insurance plan statute. Similarly, although for ease we refer in this chapter to ‘Canadians’ as those who are entitled to the benefits contemplated by the Canada Health Act and the provincial health insurance statutes, technically those entitled to such benefits are ‘insured persons’. An insured person is an ‘eligible resident’ of a province (generally, someone who lives in a province for a specified amount of time per year, whether or not the person is a Canadian citizen, and including landed immigrants).\(^6\)

### iii Funding and payment for specific services

Provincial health insurance statues prohibit private insurance companies from selling insurance for medically necessary healthcare services delivered to Canadians (since these services are paid for by each province's health insurance plan). Nonetheless, a limited private insurance market exists, including for:

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\(^5\) In 2017–2018, the aggregate Canada Health Transfer was approximately C$37 billion dollars.

\(^6\) For example, in order to be an eligible resident in Ontario (i.e., receive health insurance coverage in Ontario), an individual must, among other things, be present in Ontario for 153 days in any 12-month period.
a dental services (since only dental services delivered in hospital, and dental services provided to certain age groups and those living below specified income levels are covered by the provincial health insurance plans);
b prescription drugs (since, with limited exceptions including in the case of drugs prescribed to seniors and those living below specified income levels, only drugs administered in hospital are covered by the provincial health insurance plans);
c out-of-country insurance (since the provincial insurance plans will only cover healthcare delivered outside of Canada in limited circumstances and in limited amounts); and
d non-medically necessary services (e.g., most physiotherapy, chiropractic services and home care).

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

The desired entry point for healthcare in Canada is the general practitioner or family physician. While historically, many family physicians practised medicine independently, the low ratio of family physicians to Canada’s population and the desire of a better work–life balance among physicians has led to a different organisational structure. Over the past decade or more, family physicians have increasingly come to organise themselves in groups where they practise not just with other physicians, but in many cases also with other allied healthcare providers, such as social workers, nutritionists and nurse practitioners.7 In some jurisdictions, patients are expected to ‘roster’ with such a team, and have all of their primary healthcare needs met there.

Nearly all other practising physicians in Canada are specialists (e.g., surgeons, oncologists, obstetricians, anaesthetists). Access to patient-facing specialists is generally obtained via referral from a family physician.

It is expected that most patients will have their primary healthcare needs met through their family physician in the family physician’s office. However, since not all patients have family physicians, and because family physicians are not always accessible in a timely manner (e.g., after hours), a large number of Canadians continue to have their primary healthcare needs met through hospital emergency departments or after-hours clinics. Both modes are considered inefficient and expensive. A growing number of hospital-sponsored urgent care centres are emerging to meet patient demands stemming from, among other things, the inaccessibility of their family physicians.

Healthcare is delivered in a number of settings:
a private clinics: including the offices of physicians and other specialists;
b surgical centres, or in Ontario, independent health facilities: generally for specialty day surgeries or diagnostic procedures;
c community health centres: clinics for marginalised or other specific populations;
d community centres: clinics for specialised procedures provided by allied health professionals, such as infusion clinics or for speech pathology, physiotherapy, etc.;
e hospices: for palliative or end-of-life care;

7 In big cities, these physicians and other allied healthcare providers are sometimes organised into community health centres. These centres are similar in many respects to other physician organisations but they are operated by a charitable corporation with a view to treating particularly impoverished or other marginalised groups in society.
private homes or seniors homes: where patients receive ‘home care’, including clinical (e.g., wound care and physiotherapy) and non-clinical (e.g., light housekeeping) care, and respite care for family caregivers;

hospitals: of which there are many types – acute, chronic, tertiary, community, etc.; and

long-term care (nursing) homes.

It should be noted that since not all healthcare services are medically necessary (and as such, are not insured services under provincial health insurance plans), services in a number of the settings referred to above may be paid for privately (i.e., outside of the provincial health insurance system), including by Canadians and their private insurers.

For a number of years, Canada has been developing a national electronic health record (EHR) system, through a collaboration of the government of Canada, a federal agency (Canada Health Infoway), provincial governments and other health sector organisations. EHRs are intended to ensure that legible and available patient records are readily available whenever they are needed by healthcare providers. This national initiative is also intended to ensure compatibility across different provincial or regional systems, so that a patient can receive healthcare anywhere in Canada, and have his or her EHR accessible to healthcare providers.

The national EHR initiative is supplemented by other provincial electronic health record initiatives. For example, provinces have supported the conversion of paper-based systems to electronic systems at family physicians’ offices and hospital systems, and have developed systems that focus on particular aspects of the health sector, such as chronic disease management.

While the EHR system is developing at local, micro-levels (in a specific hospital; with a pharmacist; with a family physician), secure connectivity between sites and large-scale adoption is still on the horizon.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

Healthcare professions are governed by legislation that sets out, among other things, the scope of the practise of the profession, qualifications for entry into the profession, governance structure and requirements, and other restrictions on the practise of the profession. The primary purpose of such legislation is public protection.

Most healthcare professions are regulated by their own professional ‘college’, which is a corporation. In Ontario, for example, there are currently 26 of these colleges, which regulate various healthcare professions, including medicine, nursing and dentistry. Each college has a council that manages and administers the college’s affairs and functions as the college’s board of directors. Generally, colleges are funded by the healthcare professionals that comprise their membership, but some receive operating funding from the government.

Colleges are required by legislation to ensure that the public has access to qualified, skilled and competent healthcare professionals. Among other things, colleges are tasked with developing, establishing and maintaining the following: standards of qualification, standards of practice, quality assurance programmes and standards of professional ethics. The colleges also investigate complaints regarding their members’ conduct and may impose disciplinary measures on those healthcare professionals within their jurisdiction.
With respect to healthcare professionals, many provinces in Canada have moved away from a licensing model to a registration model with a focus on harm prevention.

ii Institutional healthcare providers

Professionals within institutional healthcare providers

Employers in Canada have vicarious liability for the acts of their employees. Thus, hospitals, long-term care homes, private clinics and other healthcare providers are diligent in ensuring that healthcare providers they employ are qualified to practise. Where healthcare providers provide healthcare services in a hospital, long-term care home or other healthcare institution on a non-employed basis, the institution applies the same rigour but to a higher scale, knowing that in most cases it is these non-employed professionals who will be overseeing and directing the care provided by other professionals. Physicians constitute by far the largest number of professionals providing healthcare services in such institutions on a non-employed basis. Others may include dentists, midwives and nurses of the extended class (nurse practitioners).

Institutional healthcare providers themselves

With a limited number of exceptions, hospitals in Canada are charitable organisations that are not privately owned. They are not licensed per se, but are classified by the government as to type (e.g., acute; chronic, tertiary, community) and receive funding from their provincial government (or a government intermediary). The funding is based on a number of criteria, including population base, patient composition and fixed-service fees. In some provinces, hospitals are overseen by volunteer boards; in other provinces, they are overseen by a regional authority. Hospitals are not legally limited in the services that they offer, but given that nearly all of their operating revenue comes from the provincial government (or a government intermediary), generally they cannot expand into new service offerings without government support.

Long-term care homes and independent health facilities (which provide insured services) are operated under licence. A large percentage of the long-term care homes and independent health facilities are privately owned, and a market exists for the purchase and sale of such licences. It is noted, however, that long-term care home licences and independent health facility licences cannot be transferred without the consents required by the applicable statute.

Subject to the comments above regarding independent health facilities, generally, licences are not required to operate private clinics that are not engaged in surgical procedures. However, in some provinces, such as British Columbia, Alberta, Ontario and Quebec, private clinics providing surgical procedures outside of hospitals are subject to accreditation or licensure by the College of Physicians and Surgeons of that province. For instance, in Ontario, a physician is not permitted to commence using a private clinic premises for the purposes of performing procedures that are performed under general or local anaesthesia, or parenteral sedation (as well as many types of procedures that are performed under local anaesthetic), until those premises have passed an inspection conducted by an inspector from the College of Physicians and Surgeons of Ontario.
iii Healthcare professionals

The requirements for registration as a member of a healthcare profession are set out in the various healthcare profession statutes in each province, which were described in Section IV.i above.

Healthcare professionals are required to have professional liability insurance. In certain cases, it is a requirement of registration with a college that the applicant demonstrates that he or she will have such insurance as of the anticipated date for the issuance of his or her certificate of registration.

The healthcare profession statutes also often provide a means by which certified healthcare professionals in other provinces can have their extra-provincial credentials recognised without having to go through the entire registration process anew.

Some healthcare professions have different classes of certification, each of which may have its own registration requirements. Moreover, different classes of certification may have different terms, conditions and limitations imposed on the certificate of registration, which limit the healthcare professionals’ scope of practice. For example, there may be limitations imposed on the member’s ability to provide care to patients, perform controlled acts and supervise the practice of the profession by another person. Where the registrar of the college has doubts as to whether the applicant fulfils the registration requirements, or is of the opinion that terms, conditions or limitations should be imposed on a certificate of registration, notice is normally provided to the applicant, and the applicant is often given an opportunity to make submissions.

It is an act of professional misconduct to contravene a term, condition or limitation imposed on a member’s certificate of registration. If a member commits an act of professional misconduct, the member may be subject to sanctions, including the following:

- the member’s certificate of registration may be revoked or suspended;
- terms, conditions or limitations may be imposed on the member’s certificate of registration;
- the member may be reprimanded; and
- the member may have to pay a fine.

There are procedural fairness requirements set out in the legislation that give the member an opportunity to be heard and challenge disciplinary decisions.

Where a healthcare professional is found by the court to have contravened a healthcare profession statute, he or she may be subject to fines or imprisonment. For example, aside from certain limited exceptions, it is an offence for a person to perform a controlled act (meaning an act that poses a potential risk of harm to the public if performed by an unqualified person) unless the person is a member authorised by a healthcare profession statute to perform the act, or the performance of the act has been delegated by a person so authorised to another person. On conviction for the offence, a person may be liable to a fine or imprisonment.

V NEGLIGENCE LIABILITY

Negligence claims are pursued through actions in court. To be successful in a claim for negligence, a plaintiff must establish that the defendant owed him or her a duty of care, the
defendant breached that duty by falling below the standard of practice that is applicable in the circumstances, the plaintiff suffered harm and there is a causal connection between the harm and the negligence.

Healthcare providers owe a duty of care to their patients, the scope of which has broadened to include the duty to obtain informed consent, to warn patients of inherent dangers in products, and not to abandon patients. Healthcare professionals are not held to a standard of perfection, but, rather, are held to a standard of a prudent and diligent professional in similar circumstances. Damages may include out-of-pocket expenses incurred as a result of the negligence, as well as general damages for pain and suffering, loss of past and future income, and the cost of future care. Causation is proved by demonstrating that the injury would not have occurred ‘but for’ the defendant’s negligence on the balance of probabilities.

Healthcare facilities, such as hospitals, can be held directly liable for negligent management or administration of the facility where the negligence causes or contributes to the harm of the plaintiff. For example, a healthcare facility may be found liable for failing to properly train or supervise employees, protect patient confidentiality or hire competent staff. Healthcare facilities may also be held vicariously liable for the negligence of their employees (which would not normally include doctors, as doctors are typically not employees of the facility).\(^9\)

i Notable cases

*R v. John Doe, 2016 FCA 191*

Privacy class actions involving healthcare providers is an emerging area in Canada. A class action was recently certified on behalf of participants in the Marijuana Medical Access Program (MMAP) after letters were sent to the participants with the programme’s name on it (thereby revealing the participants’ association with MMAP). The class action followed a finding by the Office of the Privacy Commissioner that Health Canada violated federal privacy laws. The plaintiffs alleged many causes of action. The Federal Court of Appeal confirmed the order for certification, but only with respect to the causes of action of negligence and breach of confidence.

More generally the issue of privacy surrounding personal health information has recently garnered significant attention on account of numerous high-profile cases involving unauthorised collection, use or disclosure of personal health information by healthcare professionals and institutions (each of which have obligations under privacy laws to protect personal health information in their custody or control). For example, in 2016, two individuals became the first health professionals to be convicted of an offence under Ontario’s health privacy legislation for unauthorised ‘snooping’ into the electronic health records of a high-profile patient of the hospital where they were employed. In addition to being terminated from their employment, both individuals were also fined under the province’s health privacy legislation.

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\(^9\) Further details on physicians status within institutions is included above in Section IV under the heading, ‘Professionals within Institutional Healthcare Providers’.
On one hand, the expanding use of technology within healthcare institutions brings with it new challenges in ensuring that personal health information is not collected, used or disclosed in unauthorised manner; on the other hand, such technology makes it easier for such unauthorised collection, use or disclosure to be detected.

**Benhaim v. St-Germain, 2016 SCC 48**

In another recent case from Quebec, the Supreme Court of Canada considered whether, in a medical malpractice case where the defendant’s negligence has undermined the plaintiff’s ability to prove causation, an adverse inference of causation must be drawn against the defendant. The action was brought by the spouse and child of a patient who died of cancer. The defendant physicians failed to investigate a chest x-ray that the plaintiffs alleged would have allowed earlier detection of the cancer. The trial judge found that while the physicians were negligent in their diagnosis, it was not established on a balance of probabilities that their negligence was the cause of the patient’s death because evidence showed the cancer was likely already incurable. However, it was not possible to confirm the exact stage because of the defendant physicians’ fault.

The majority of the Supreme Court held that there is no legal requirement for a trier of fact to draw an adverse inference of causation where the defendant’s negligence has undermined the plaintiff’s ability to prove causation. An adverse inference of causation is not triggered as a matter of law, but rather, is within the discretion of the trial judge. The Supreme Court observed that ordinary rules of causation operate in medical liability cases. In such cases, the defendant is often in a better position to determine causation. The plaintiff is not required to prove causation with medical certainty, but, the Supreme Court held, requiring a trial judge to draw a presumption where the plaintiff has adduced little affirmative evidence is too low of a threshold. The trier of fact may draw an inference of causation, but the nature of the principle is permissive.

**Paur (Committee of) v. Providence Healthcare, 2017 BCCA 161**

The British Columbia Court of Appeal recently upheld a finding that the defendant hospital was liable under the Occupiers Liability Act (OLA) for a patient’s injuries after the patient, who was being held under the Mental Health Act, attempted to commit suicide in a hospital bathroom. Two nurses were also found liable for negligence for delay in attending to the patient. The admitting physician was not held liable, as the Court of Appeal accepted the finding of the trial judge that physicians are not required to take into account the design of hospital bathrooms.

The Court of Appeal discussed the standard of care applicable to hospitals in the design of their premises and observed that the standard of care under the OLA is the same as the common law negligence standard, and that the hospital had a duty to take reasonable steps to keep patients safe while being held in the hospital. The trial and appeal courts consulted Ministry of Health standards for hospitals. The standard is of reasonable rather than complete safety, and there is no single standard among hospitals with respect to admission and design. The Court observed that hospitals must balance complete safety and complete freedom and privacy, but noted that where there is a risk of loss of life the balance must weigh in favour of safety. The decision underscores the need for hospitals to ensure that their facilities and staffing protocols reasonably protect patient safety and limit the risk of suicide.
VI OWNERSHIP OF HEALTHCARE BUSINESSES

While healthcare in Canada is generally paid for publicly (with taxpayers’ dollars), it is provided in large part by those in private business; including physicians and private clinic operators, long-term care home operators and, in Ontario, independent health facility operators.

Though some physicians are hospital employees (e.g., radiologists, those working in labs and research areas and a limited number of hospitalists), most physicians are self-employed or working in partnership with other physicians. Physicians may incorporate medical professional corporations to enter into leases and other non-clinical agreements and their spouses or family members may own a non-controlling percentage of such businesses (provided that the physicians themselves remain liable for the professional services they provide). The same is true for certain other healthcare providers, such as dentists and optometrists. A market exists for the purchase and sale of all such businesses, but control of these professional corporations is limited to other healthcare professionals of the same designation.

Non-professionals may provide services to professional corporations and so may indirectly participate in the business arrangements of such professionals. Private corporations that provide space and other administrative services to healthcare professionals are common. Opportunities exist for purchase and investment in these service corporations. Notwithstanding their private nature, these corporations and the professionals practising within them are required to comply with the provincial laws prohibiting private payment for professional services. Private payment for professional services is at the middle of a high-profile case that originated in British Columbia, Cambie Surgeries Corp v. British Columbia (Medical Services Commission), 2013 BCSC 2066.

Like other provinces, British Columbia prohibits the use of private insurance for insured services and does not allow services provided in a private surgical clinics to be billed outside of the public insurance plan. The constitutionality of these restrictions is being challenged at this time by Cambie Surgeries Corp, an owner and operator of two private healthcare facilities in British Columbia. Cambie alleges that prohibitions on extra billing and private insurance violate Canada’s Charter of Rights and Freedoms by limiting timely access to medical services for residents. While British Columbia’s public insurance legislation does not preclude private clinics or private billing, it prohibits a public/private model like Cambie’s, in which a private clinic engages in extra billing in addition to receiving funding for insured services. While the trial is adjourned until September 2017, it is anticipated that the decision of the court will be appealed to the Supreme Court of Canada, since it could have a significant impact on how healthcare services are delivered and funded in Canada.

VII COMMISSIONING AND PROCUREMENT

Some Canadian healthcare providers (e.g., hospitals and health authorities) are subject to public procurement rules. These rules arise out of national and regional domestic trade agreements; provincial statutes and procurement directives; and the specific policies of each public sector purchaser. Procurement rules are intended to ensure fairness, transparency and accountability in decisions about the use of public funds. They apply to contracts for the purchase of goods or services that meet or exceed certain value thresholds. Generally, these rules require those contracts to be awarded through an open competitive process — that is, a process that is open to any person to submit a bid. They also require public sector purchasers to share material information with prospective bidders at the outset; evaluate bids consistently
and only against stated criteria; and publish information about successful bids. Also, new public procurement requirements require provincial governments to designate an impartial administrative or judicial authority to review challenges from bidders or prospective bidders (either in the first instance, or as an appeal body).

VIII MARKETING AND PROMOTION OF SERVICES

Communication with the public about healthcare services is regulated to ensure accuracy and maintain professionalism. Healthcare professionals may advertise for the purpose of providing information relevant to informed decision making. Only individuals admitted to a college can use professional designations such as ‘doctor’, ‘dentist’ or ‘physiotherapist’. Provincial legislation and colleges’ policies prescribe how professionals can market their services and describe their qualifications and education. For example, legislation and college policies prohibit advertising that is false, misleading or unprofessional, endorsements or testimonials and claims of superiority, comparisons or guarantees. Non-compliance may be considered professional misconduct.

Though it is generally acceptable to advertise fees for services that are not publicly funded, some colleges have policies that place restrictions on fee advertisements for professional services; for example, restrictions on the use of promotional deals in advertisements. Interestingly, however, there are no corresponding restrictions on the ability of institutional healthcare providers to advertise their services.

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

Given Canada’s ageing population, the high percentage of our GDP expended on healthcare, the comparatively poor health outcomes achieved, and the challenges created by the single payer healthcare system, it is likely that there will be both micro and macro changes to the healthcare landscape in the years to come. For example, the use of e-health and telemedicine represent a micro change that may create new opportunities. However, currently, legal and structural barriers to e-health and telemedicine exist; for example, no national framework for telemedicine exists.

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Chapter 3

CHINA

Min Zhu

I OVERVIEW

China’s healthcare system is mainly composed of the healthcare services sector, healthcare insurance sector and drugs and medical equipment sector, which are supervised by three separate government departments. Specifically, the PRC National Health and Family Planning Commission (NHFPC) is responsible for supervising the medical institutions and medical services industry, the Ministry of Human Resources and Social Security is responsible for formulating the basic healthcare insurance system and policy and for managing healthcare insurance funds, and the China Food and Drug Administration is responsible for drug and medical equipment registration and supervision.

II THE HEALTHCARE ECONOMY

i General

Healthcare services can be divided into basic healthcare services and special healthcare services, depending on coverage scope and extent of the specific services.

Basic healthcare services

Basic healthcare services are composed of public healthcare services and basic medical services. The scope of basic public healthcare services in China has been revised and expanded since the launch of China’s healthcare reform in 2009. The National Basic Public Healthcare Service Standards (Third Edition), promulgated in 2017, stipulate that basic public healthcare services consist of 13 types of services, including residents’ health file management, vaccinations, health administration for special groups (children aged under six, pregnant women, the elderly, and patients with hypertension, type 2 diabetes, severe mental disorders and tuberculosis), infectious diseases and public healthcare emergency reporting and treatment, and so on.

1 Min Zhu is a partner at Han Kun Law Offices. The firm also wishes to acknowledge the contributions to this publication by Serina Wei, an associate at the firm.
Special healthcare services

In addition to basic healthcare services, the Chinese healthcare system also includes special healthcare services, which refer to medical services provided by medical institutions to satisfy special medical needs, such as specified surgical operations, full nursing care, special wards, specialist outpatient services and medical cosmetic surgery.

ii The role of health insurance

China’s basic healthcare insurance system currently includes a basic urban employee healthcare insurance system, a healthcare system for urban residents and a new rural cooperative healthcare insurance system. Among these, the basic urban employee healthcare system is compulsory, and requires all urban employers and employees to contribute to the system. Urban residents who are not covered by the basic urban employee healthcare insurance system, including students, children and other non-employed urban residents, may voluntarily choose to purchase the urban resident healthcare insurance. A new rural cooperative healthcare insurance system, the rural medical mutual aid system, has been designated for rural residents and is mainly funded by government financial appropriations and supplemented by individual and collective contributions. Rural residents may choose to participate in the system at their discretion.2

According to the Opinions on the Integration of the Basic Healthcare Insurance System for Urban and Rural Residents promulgated by the State Council in 2016, the above three basic healthcare insurance systems will be integrated into a unified basic healthcare insurance system applicable to both urban and rural residents. At present, the healthcare insurance system for urban residents and the new rural cooperative medical insurance system have been successfully integrated.

iii Funding and payment for specific services

In addition to basic healthcare services, medical institutions also provide special healthcare services to satisfy non-basic medical needs. Special healthcare services may be provided by both public and non-public medical institutions. However, the amount of special medical services provided by public medical institutions is limited, and cannot exceed 10 per cent of all healthcare services that such institutions provide.

According to the relevant provisions of the current basic healthcare insurance system in China, the cost of special healthcare services will not be covered by the national healthcare insurance system. Such costs are to be directly undertaken by the individual incurring such costs or reimbursed by commercial health insurance.3

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

i China’s healthcare services system

China’s healthcare service system is developed under a dual structure for urban and rural areas. The rural healthcare system is composed of three grades of medical institutions, which

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3 Opinions of the CPC Central Committee and the State Council on Deepening Reform of the Medical and Healthcare Systems, Article 10 (CPC Central Comm., St. Council, promulgated 17 March 2009).
are county hospitals, township hospitals and village clinics. The urban healthcare system is also made up of three levels of medical institutions, which are the regional central hospitals, community healthcare service centres, and clinics and infirmaries. Densely populated cities also have tertiary hospitals with advanced technology and equipment. The entire healthcare service system is known as the ‘dual and three grades’ system.

ii Graded treatment system
In China, patients can freely choose the hospitals from which to receive medical treatment. However, for a long period of time, public hospitals have often been overcrowded since they possess better medical resources. By contrast, community hospitals are less frequently visited, although they provide more accessible and convenient healthcare to residents. In response to this issue, the General Office of State Council, in September 2015, promulgated the Guidance on Promoting Graded Medical Treatment System Construction in order to alleviate overcrowding and promote the rational allocation of medical resources. The guidance describes a graded medical treatment system framework and stipulates that, by 2020, China will improve the graded medical treatment system through graded treatment methods for primary initial diagnoses, two-way referrals, divisions for acute and chronic diseases and communication between institutions.

iii Application of electronic medical records
Electronic medical records are an important means to promote healthcare services informatisation and will help to improve the quality and efficiency of medical services. In 2010, the Ministry of Health, a predecessor to the NHFPC, initiated work on its hospital informatisation construction pilot scheme, focusing on the promotion of electronic medical records. Since then, the use of electronic medical records has been gradually phased in across the country. In 2017, the NHFPC promulgated the Regulations on the Management of Electronic Medical Records Applications (for Trial), which stipulate a series of requirements for the content, writing and saving, use and storage of electronic medical records. The Regulations, together with a series of supporting national and industry standards for electronic medical record systems, data management and medical terminology, constitute the management framework for electronic medical records in China.

iv Personal information protection
The Regulations on Management of Medical Records at Medical Institutions stipulate that medical institutions and their medical staff should keep strictly confidential the personal information contained in patients’ medical records and should not disclose personal information for non-medical, teaching or research purposes.

Recently, the government has promulgated a series of laws and regulations and judicial interpretations, with the purpose of more effectively protecting citizens’ personal information. The General Principles of Civil Law, which is to be implemented on 1 October 2017, for the first time defines the right of citizens to their personal information as an independent civil right. The Cybersecurity Law, which came into force on 1 June 2017, and the majority

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4 Bluebook 2017 at page 16.
provisions of Chapter 4, ‘Network Information Security’, are intended to provide more protection for personal information. The Interpretations on Several Issues Concerning the Application of Law in the Handling of Criminal Cases Involving Infringement of Citizens’ Personal Information, which came into force on the same day as the Cybersecurity Law, defines the constitutive elements for several criminal acts involving the infringement of personal information and significantly reduces the threshold for imposing criminal penalties on personal information infringement.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

The NHFPC is the department primarily responsible for approving the establishment of medical institutions in China, and for practice approval and administrative oversight. Specifically, the NHFPC is responsible for:

a developing medical institutions, medical technology applications, medical quality, medical safety and medical service policy and organisational standards;
b developing medical personnel practice and service standards;
c formulating medical institution and healthcare industry administrative measures and exercising supervision;
d participating in drug and medical equipment clinical trial administration; and
e being responsible for leading the oversight of nationwide medical institution assessments, and for developing public hospital operating oversight, performance evaluations and assessments.

ii Institutional healthcare providers

Establishment of medical institutions

Medical service providers that intend to set up medical institutions and practise medicine in China must comply with the Medical Institutions Establishment Plan, and fully consider the location and coverage radius of the medical institutions, the distribution of medical resources and medical service needs.

The approval process before a medical institution may commence operations can be divided into two steps: establishment approval and approval to practise medicine. When preparing to establish a medical institution, the medical institution operator should submit a detailed report to the NHFPC to describe the establishment preparation plans, including site selection, diagnosis and treatment projects, institution size (number of ward beds), funding sources and planning, personnel status, management system and so on. Construction of medical institutions may commence after obtaining the approval of the NHFPC and acquiring the approval for establishment of medical institutions. After completing the necessary preparatory work before the medical institutions commence business, such as site construction, equipment purchase, personnel hiring and system construction, the medical institutions should apply to NHFPC to practise medicine and apply for the issuance of the Permit for Medical Institutions to Practise Medicine.

Penalties for medical institution violations

When practising medicine, medical institutions must strictly comply with the approved business scope and approved medical treatment projects, the relevant laws and regulations
and technical medical standards. Medical institutions that practise business without a permit for medical institutions to practise medicine, or whose medical treatment activities exceed the scope specified therein, may be imposed with fines, have illegal income, drugs and equipment confiscated, and have their practice permits revoked.

**New regulations for doctors establishing personal clinics**

In February 2017, the NHFPC revised the Detailed Rules on the Implementation of Administrative Regulations of Medical Institutions, to delete the stipulation that ‘personnel in services with medical institutions, retired due to illness or suspended from duty without pay shall not apply to establish medical institutions.’ This means that, in the future, doctors who are employed with hospitals, retired or suspended from duty without pay may apply to establish clinics or serve as the legal representative or person in charge for medical institutions, provided other conditions for establishing medical institutions are not violated. This is regarded as a major signal for the beginning of reforms in China that will permit doctors to freely practise medicine.

### iii Healthcare professionals

In China, physicians, nurses and pharmacists need to practise medicine in accordance with the Medical Practitioners Law, Nurses Regulation and the Regulations on the Administration of Medical Institutions and other relevant administrative requirements.

**Medical practice by medical practitioners**

Medical practitioners are subject to a registration system. Candidates who possess the requisite degree, have work experience as an assistant physician or have practised medicine after engaging in clinical practice for a certain period of time under the guidance of a practising physician may sit for the medical practitioner licensing examination. Upon passing the examination, candidates may obtain a medical practitioner’s licence and may register to practise medicine with the healthcare administrative department.

The registration of medical practitioners will remain valid indefinitely. However, registered medical practitioners are subject to an assessment of their professional abilities, work performance and professional ethics by an agency under the purview of the NHFPC on a regular basis. Those practitioners who failed the assessment will be ordered to suspend their practice for three to six months to receive training and continuing medical education.

Anyone who practises medicine without completing registration will be ordered to cease practising, subject to the confiscation of illegal income and medical equipment and imposed with a fine at least 100,000 yuan by the healthcare department. If serious consequences result from unauthorised practice, such as causing injury to visiting patients, spreading or potentially spreading diseases, the violator will be regarded subject to criminal liability in accordance with the Article 236 of the Criminal Law, which stipulates liabilities for the illegal practice of medicine.

**Practice by nurses**

Candidates intending to practise nursing also need to pass a qualification examination and complete registration to commence practice. Prior to practice registration, candidates need to complete the prescribed professional nursing courses and engage in clinical nursing practice for a certain period of time. Registered nurses should practise nursing at their registered
practice location. Nursing practice registrations are valid for five years. Upon expiry of the term, registered nurses may apply to the health administrative department to renew their registrations.

**Multi-site practice**

The previous Interim Measures on Medical Practitioner Practice Registration stipulated that physicians were only permitted to practise medicine at the medical institution registered as their place of practice, which effectively meant that physicians could only practise medicine at one medical institution. In February 2017, the NHFPC promulgated the new Administrative Measures on Medical Practitioners’ Practice Registration. One of the highlights of the measures is to provide for medical practitioners to practise medicine at multiple locations. Thus, in the future, doctors may practise medicine at multiple medical institutions located in multiple locations.

V **NEGLIGENCE LIABILITY**

Medical institutions and physicians that harm patients during the provision of medical services are held liable in accordance with the relevant provisions of Chapter 7 of the Tort Liability Law, ‘Medical Damage Liabilities’. Liability is determined based upon the fault liability principle and, to some extent, in accordance with the presumption of fault principle. In addition, the Medical Malpractice Treatment Regulation also specifies rules related to the prevention, handling, technical evaluation and administrative handling of medical malpractice cases. When physical injury occurs, if the relevant liability is not provided for in the Tort Liability Law or the Medical Malpractice Treatment Regulation, the relevant provisions apply from the Interpretation of the Supreme People’s Court on Several Issues Concerning the Application of Law in Hearing Cases of Compensation for Personal Injury Tort Liability Act and the Medical Malpractice Law.

i **Overview**

When hearing a medical dispute, the courts often assess whether the medical institutions should be subject to liability based on three aspects. First, whether the medical institution is at fault and the role the medical institution played in contributing to the malpractice. Second, the cause and effect between the fault of the medical institution and damage suffered by the patient. Third, the scope of loss suffered by the patient. In general, a medical malpractice determination is regarded as a neutral and credible basis to determine the allocation of fault between medical institutions and patients. Unless the procedure for making the medical

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6 Tort Law of the People's Republic of China (Standing Comm., Nat’l People's Cong., promulgated 26 December 2009, effective 1 July 2010). Article 54 provides that medical institutions bear compensatory liability in cases where both the medical institution and medical practitioners are at fault for harming patients during diagnosis and treatment. Article 55 stipulates that medical practitioners must fully explain the medical risks of treatment and alternatives to treatment and receive consent from the patient or family. Failure by a medical practitioner to do so which results in harm to the patient will subject the medical institution to compensatory liability. Article 58 provides for the presumption of fault by the medical institution in cases where the medical institution conceals, refuses to provide, forges, tampers with or destroys case data in a dispute in violation of laws and regulations or other medical standards.
malpractice determination was not lawful, courts tend to depend upon the determination to allocate fault attributable to the medical institution and to decide the liabilities to be undertaken by the medical institution.

ii  Notable cases

The dispute over medical damages between Shen Bo, Meng Xiaoxia and the Second Affiliated Hospital of Zhengzhou University in 2014\(^7\) is of notable significance with respect to application of the presumptive fault principle in determining the liability of medical institutions. In this case, the plaintiff held that the defendant hospital should bear full responsibility for the death of the patient because the hospital had committed serious malpractice in treating the patient and had tampered with medical records for the purpose of avoiding responsibility. However, the defendant argued that the hospital revised the medical records solely for the purpose of improving the content of the records and that there was no substantial difference between the original records and the modified records. The defendant’s argument was not adopted by the court for lack of reasonableness. In fact, both the first instance and the second instance courts found that the hospital was presumed to be at fault and subject to primary liability for the malpractice claim, since it had tampered with and concealed medical records and failed to give a reasonable explanation of such conduct.

VI  OWNERSHIP OF HEALTHCARE BUSINESSES

China’s medical and healthcare system is established on the basis of the basic healthcare insurance system, by which public medical institutions are obliged to provide the substantial part of basic healthcare services. Public medical institutions include government-funded medical institutions and medical institutions run by state-owned enterprises. For historical reasons, public medical institutions have easier access to high-quality medical resources, including scientific research and teaching, clinical trials, advanced equipment and professionals.

In recent years, the government has encouraged social capital to invest in the establishment of medical institutions and to participate in the provision of medical services. However, while the number of private medical institutions has exceeded public medical institutions,\(^8\) the public health institutions still occupy an unshakably dominant position in the medical services market because of the high-quality medical resources that they possess.\(^9\)

Foreign-invested medical institutions wishing to enter the Chinese market should refer to the Guidance Catalogue of Foreign Investment Industries (revised in 2017), which stipulates that medical institutions belong to the foreign investment restricted industries, and foreign-invested medical institutions may only be established in the form of a joint venture or a cooperative enterprise. The Interim Measures for the Administration of Sino-Foreign Joint Ventures and Cooperative Medical Institutions further stipulate the total amount of investment, the minimum proportion of Chinese capital or equity and the term of operations

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\(^7\) Ref. doc. no.: (2014) Zheng Min Yi Zhong Zi No. 500.

\(^8\) See the latest statistics of April 2017 at www.moh.gov.cn/mohwsbwstjxxx/s7967/201706/41573016be1b41719c8ca68d6fb05e9d.shtml.

\(^9\) Bluebook 2017 at page 16.
of the Sino-foreign joint ventures and cooperative medical institutions. In addition, the local Medical Institution Organisation Plan should also be complied with when establishing foreign-invested medical institutions.

VII  COMMISSIONING AND PROCUREMENT

As mentioned above, China’s healthcare services are divided into basic healthcare services and special healthcare services. Basic healthcare services include public healthcare services and basic medical services. Public healthcare services are regarded as a form of public goods, which are mainly funded by government outlays and provided to urban and rural residents on an equal basis.

Medical services for treating non-basic diseases, or those regarded as discretionary diagnosis and treatment measures are considered special healthcare services. The costs of special healthcare services are to be undertaken by individual patients or reimbursed by the patient’s commercial medical insurance. Patients have the freedom to choose what medical services to receive, and the medical expenses will be directly deducted from the basic medical insurance fund, if covered, or will otherwise be paid for by the individual patients.

VIII  MARKETING AND PROMOTION OF SERVICES

In China, the publication of medical, pharmaceutical, medical equipment and health food advertising is subject to content reviews by the advertising authorities prior to publication. Advertising review organs include the food and drug regulatory authorities, health-planning committee and the industrial and commercial administrative departments.

In accordance with the provisions in the PRC Advertising Law, drug and medical device advertising cannot include:

a  assertions or guarantees as to efficacy and safety;

b  efficacy rates or cure rates;

c  comparisons of the safety or effectiveness of drugs or medical devices with those of other medical institutions;

d  the use of advertising spokespersons to endorse or provide testimonials; and

e  medical advertising disguised as health and well-being advice.

IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

‘Internet plus’ and medical big data are currently two popular concepts in the medical services market in China. Many start-ups and investment institutions are especially focused on emerging businesses in these areas, including telemedicine, internet hospitals, mobile medicine, smart medicine and other medical service sub-sectors.

These emerging forms of healthcare have played a significant role in promoting the diversification of medical services as advocated by the state. While government regulators have maintained an open and welcoming attitude towards these new services, they have also exhibited a certain degree of caution. For example, the current NHFPC regulations

limit telemedicine services to occur only between medical institutions,\textsuperscript{11} which has caused a number of mobile healthcare companies to abandon or amend their business plans in this area.

\textbf{X CONCLUSIONS}

In 2009, the government of China launched a new round of healthcare reforms. To date, this round of reforms is ongoing and continues to face significant difficulties. Integrating urban and rural resident insurance systems, improving the graded healthcare system, implementing electronic medical records, allowing doctors to practise medicine more freely and achieving the optimal allocation of medical resources are all difficulties being faced during the current reform effort. The reforms also present an unprecedented opportunity for social capital to participate in the medical and health industry that cannot be overlooked.

\textsuperscript{11} Opinions of the National Health and Family Planning Commission Concerning the Advancement of Medical Institution Telemedicine Services (Nat'l Health and Family Planning Comm., promulgated and effective 21 August 2014).
I OVERVIEW

Healthcare in the United Kingdom is dominated by the National Health Service (NHS), which was set up in 1946\(^2\) to provide universal healthcare, largely free to citizens at the point of access. The NHS is not a single organisation but a network of national and local organisations all operating under the NHS ‘brand’. In particular, it is important to note that the makeup and organisation of the NHS varies between the four nations of the United Kingdom: this chapter will focus on England. While private healthcare is readily available in the UK, the vast majority of people use the NHS either for the entirety of their healthcare or as a gateway before choosing to access private healthcare at the secondary care stage.

In the UK healthcare is currently provided distinctly from personal, non-medical care (‘social’) care, with different legislative schemes in place; the NHS is governed by, among others, the National Health Service Act 2006, while social care is provided by local authorities, primarily under the Care Act 2014. This divide is increasingly being questioned by both patients and practitioners, with many attempts at improving integration at a local level in particular to keep patients out of hospital and to discharge them appropriately. Integrated care has tended to be successful in spite of the legislation, rather than because of it.

Healthcare services are commissioned either at the local level by clinical commissioning groups (CCGs) made up of local general practitioners\(^3\) or, for more specialised commissioning, on a national level by the National Health Service Commissioning Board\(^4\) (more commonly known as NHS England). Funding pressures on the NHS and the consequential priorities and choices have been political priorities. The biggest impact of Brexit is likely to be on the availability of healthcare professionals.

All healthcare providers are regulated by the Care Quality Commission (CQC).\(^5\) In addition, most individual healthcare professionals must be registered with the regulator for their individual profession.

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1 Holly Bontoft is an associate and Sarah Ellson is a partner at Fieldfisher LLP. Our thanks go to our colleagues Alison Dennis, Sonal Patel, Nicholas Pimlott and Debbie Nicholson.
2 National Health Service Act 1946.
3 Section 1I National Health Service Act 2006.
4 Section 1H National Health Service Act 2006.
5 Section 1, Health and Social Care Act 2008.
There is an increasing role for private healthcare provision, either directly to the NHS (for example, by running specific NHS provided services) or by providing privately available services directly to patients. While this has been politically contentious, this does not seem likely to change in the short term, and private providers are as closely regulated as the NHS.

II THE HEALTHCARE ECONOMY

i General

Approximately 11 per cent of the UK population has some form of private medical cover, although this is rarely comprehensive, and according to the King's Fund, cover is not provided for accidents and emergency or for general practice (although private general practice services, both walk-in services and online, are available). In addition, some people choose to receive private treatment for specific activities, such as elective surgery or physiotherapy, where there may be a wait to receive such services on the NHS.

In England, NHS hospital treatment and primary care is free at the point of use to those ordinarily resident in the United Kingdom. It is funded through general taxation and national insurance deducted from salary. There are fixed, statutory charges for certain items of NHS care, such as prescription medicines and devices, dental treatment and optical treatment. There are then a range of exemptions from these charges available on the basis of age, income or certain medical conditions. These NHS charges and exemptions are set by the Department of Health, but are subject to parliamentary approval.

As a current member of the European Union, UK nationals are entitled to healthcare when visiting any European Union Member State as if they were a national of that state, and this is reciprocated for other EU nationals in the UK. It is uncertain whether such provisions will remain after Brexit.

In February 2017, the government announced its intention to amend UK law from April 2017 to make (non-exempt) overseas visitors chargeable for many NHS secondary and community care services. Visitors and migrants who are entitled to an exemption from charge for NHS services under Immigration Health Surcharge arrangements will no longer be able to receive free NHS-funded assisted reproduction services (such as IVF) as part of their exemption. This legislation has not yet been fully enacted, but is expected to be by the end of 2017.

ii The role of health insurance

Some UK citizens opt to have private health insurance, often as a tax-efficient employment benefit, but it is not compulsory. However, EU nationals living in the UK and not

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7 Regulation 3(1) National Health Service (Charges to Overseas Visitors) Regulations 2015/328.
8 Section 172 National Health Service Act 2006, National Health Service (Dental Charges) Regulations 2005 (as amended) and National Health Service (Charges for Drugs and Appliances) Regulations 2015.
employed are required to have comprehensive sickness insurance.\textsuperscript{11} What is considered to be ‘comprehensive’ has become a matter of debate since the referendum vote in favour of Brexit, with the future status of current EU residents in the UK unclear.

Private health insurance is available in a variety of forms, including access to private specialists and hospitals, or as a rebate for time spent in NHS care. In addition, private healthcare services are also available on a non-insurance, ‘pay-as-you-go’ basis. The private healthcare market has come under close scrutiny in recent years from a competition perspective. In 2014, the Competition and Markets Authority published its final report into the UK private healthcare market.\textsuperscript{12}

iii Funding and payment for specific services

NHS services are commissioned at a local and national level by either the local CCG or NHS England; what services are routinely commissioned is the remit of the National Institute for Health and Care Excellence (NICE). NICE has existed in various forms since 1999, but in its most recent reincarnation was established by Section 232 and Schedule 16 of the Health and Social Care Act 2012.

NICE has various powers to produce guidance and recommendations to NHS bodies on care pathways and technologies they are expected to provide.\textsuperscript{13} NHS bodies are legally obliged to fund medicines and treatments recommended by NICE’s technology appraisal recommendations,\textsuperscript{14} however, other forms of guidance and recommendation do not have the same level of authority.\textsuperscript{15}

For example, NICE guidelines recommended that IVF should be offered to women under 43 years of age who have been trying to get pregnant through regular unprotected sex for two years, or who have had 12 cycles of artificial insemination. However, the final decision about who can have NHS-funded IVF in England is made by local CCGs whose criteria may be stricter than those recommended by NICE; as this is not a technology appraisal recommendation CCGs are not required to follow the guidance. There is very limited acupuncture provision available on the NHS in the absence of NICE recommendations.

NICE’s role, when asked by the Department of Health to produce a technology appraisal recommendation, is to assess the clinical and financial efficacy of the technology. Since July 2016, the Cancer Drugs Fund has been a third option at the end of the NICE technology appraisal process. The current version of the Cancer Drugs Fund acts as a managed access fund for cancer drugs where it is determined that more information is required to determine clinical effectiveness.

In some cases further funding is available through Individual Funding Requests (IFRs). Where NHS England’s duty to provide health services under Section 1H(3) of the

\textsuperscript{11} Immigration (European Economic Area) Regulations 2016.

\textsuperscript{12} www.gov.uk/cma-cases/private-healthcare-market-investigation#final-report.

\textsuperscript{13} See, in particular, Regulations 5 and 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

\textsuperscript{14} Regulation 7(6) National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

\textsuperscript{15} The obligations to comply with different types of NICE guidance, guidelines and recommendations were most recently explored in \textit{R (Rose) v. Thanet CCG [2014]} EWHC 1182 (Admin), which confirmed that, while CCGs and other health bodies are required to comply with technology appraisal recommendations, other forms of NICE guidance should be seen as ‘relevant considerations’ (paragraphs 22 to 27).
2006 Act is not met under NICE technology appraisal recommendations, individuals can request funding for treatments that have not been recommended through an IFR. What is considered to be an exceptional circumstance, and the law surrounding IFRs, is discussed in the recent case of *S v. NHS England* [2016] EWHC 1395 (Admin).

As set out above, standard charges apply to a number of NHS services. In England they are set out in Regulations.16

### III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

England, and the UK more widely, has a healthcare system heavily reliant on primary care practitioners (general practitioners (GPs)) delivering family medicine and acting as gatekeepers to secondary and tertiary care, which in the NHS is rarely directly accessible, except in emergencies.17

GP businesses are normally run as independent businesses, providing services to the NHS under the General Medical Services (GMS), Personal Medical Services (PMS) or Alternative Provider Medical Services (APMS) contracts with NHS England. While these are private law contracts negotiated between NHS England and the British Medical Association (acting as the representatives of all GPs, whether or not they are members of the BMA), many of the provisions are required under the National Health Service (General Medical Services Contracts) Regulations 200418 or the National Health Service (Personal Medical Services Agreements) Regulations 2004 respectively.

NHS hospitals and secondary services are run by local trusts or foundation trusts. While these are still NHS bodies, they are independent of clinical commissioning groups of NHS England. The relationship is contractual; trusts and foundation trusts are providers of services commissioned by CCGs and NHS England. Emergency services are almost exclusively available through the NHS, as a result of the large costs of operating in this area. However, secondary or hospital care may be provided by either the NHS or by private providers. Private secondary care may either take place in physically separate private hospitals, or, alternatively, in private patient units (PPUs) located in NHS hospitals; under Section 44 of the National Health Service Act 2006, NHS Foundation Trusts may provide private healthcare ‘only to the extent that its exercise does not to any significant extent interfere with the performance by the NHS foundation trust of its functions’. While it is not usually possible for patients using the NHS to see a medical consultant without first being referred for secondary care by a GP, there is nothing to prevent this in the private sector.

It should be noted that social care is, at present, provided under an entirely separate legislative scheme by local authorities.19 However, there has been an increasing movement in recent years towards the integration of both different health services and of health and social

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16 National Health Service (Charges for Drugs and Appliances) Regulations 2015 and the National Health Service (Dental Charges) Regulations 2005 (as amended).
17 This position is slowly beginning to change, with the recent introduction in some areas of allowing patients to self-refer to NHS physiotherapy services in certain situations.
19 See generally the Care Act 2014, and specifically Section 18(1) of the Act.
England

Care, albeit while retaining separate legal systems for each. This is being provided through Sustainability and Transformation Partnerships across England, and explicit integration agreements in some areas, most noticeably, Greater Manchester.

Healthcare in the UK now benefits from a near universal Summary Care Record for each patient, which contains basic information and is accessible by a range of NHS bodies. In England (and to some extent in Wales, Scotland and Northern Ireland) healthcare records are held at a local level; i.e., with primary care records held with the GP, and secondary care records with the relevant hospital. Attempts to create a universal digital healthcare record for every NHS user (known as ‘care.data’) ran into significant controversy in 2014 when the process of gaining consent from individuals was hampered by inadequate attempts to inform patients of the use of their data, and concerns that some data could be sold to pharmaceutical or insurance companies.

The UK’s data protection law (which regards information about a person’s physical or mental health or condition to be sensitive personal data) will be significantly strengthened by the introduction of the EU General Data Protection Regulation in 2018, which will come into force in the UK despite the ongoing Brexit negotiations.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

There are a range of healthcare regulators in the UK, some of which operate on a UK-wide basis, while others operate in only one of the four nations. There are separate regulators for healthcare operators and healthcare professionals.

ii Institutional healthcare providers

The key regulator for institutional health providers in England is the Care Quality Commission (CQC), which was established by the Health and Social Care Act 2008. Whether a provider requires regulation by the CQC is dependent on what activities they are providing; carrying out a ‘regulated activity’ without being registered with CQC is a criminal offence subject to a potentially unlimited fine or up to 12 months’ imprisonment, as well as lesser regulatory sanctions. The regulated activities are set out in the Regulated Activities Regulations and include:

- the provision of personal care at home;
- residential accommodation together with nursing or personal care, or with treatment for drug and alcohol misuse;
- treatment for a disease, disorder or injury by or under the supervision of a healthcare professional, or a social worker where the treatment is for a mental disorder;

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20 Both the Secretary of State for Health and local authorities have a duty to promote integration of health and social care services under Section 13N of the National Health Service Act 2006 and Section 3 of the Care Act 2014 respectively.
21 www.england.nhs.uk/stps/.
22 www.gmhsic.org.uk/.
23 Section 2(e) Data Protection Act 1998.
24 Section 1 Health and Social Care Act 2008.
25 Section 10(1) and (4), Health and Social Care Act 2008.
26 Schedule 1, Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
surgical procedures (including all pre-operative and post-operative care) carried out by a healthcare professional; diagnostic and screening procedures; and medical advice in cases where immediate action or attention is needed, or triage provided, over the telephone or by electronic mail.

In order to be registered, a new provider must register with the Care Quality Commission (CQC), which will assess the suitability of the applicant to provide the regulated activities. In addition, all registered providers must have a registered manager responsible for the overall management of the service, who also must be considered fit for the role. Among others, the following documents may be required:

- a. statement of purpose;
- b. management policy/procedures document;
- c. safeguarding policy and procedures document;
- d. planning permission document;
- e. building regulation document;
- f. registered manager supporting evidence; and
- g. governance document.

The CQC anticipates that, once an application is sent to them, a notice of decision will be provided in approximately 10 weeks. Registration (as either a provider or manager) can be granted either unconditionally or with conditions. Appeals against a decision on registration are made to the First Tier Tribunal. When assessing an application, the CQC will focus on:

- a. compliance with the fundamental standards, including person-centred care, dignity and respect, consent, safe care and treatment and staffing;
- b. good management and safeguarding; and
- c. whether the provider's directors are of good character and have the necessary skills, competence, experience and qualifications, including whether they have been responsible for any previous incidents of serious misconduct or mismanagement, have any convictions or have been declared bankrupt.

Once registered, providers are required to share information with the CQC, in particular to notify it of any changes in registered details, or of certain adverse incidents that may take place. In addition, the CQC operates a regime of both announced and unannounced inspections of providers, which will be assessed against key lines of enquiry. The CQC has wide-ranging enforcement powers to place conditions on registration or to suspend or even cancel registration where there have been breaches of its requirements.

As a result of a failure in 2011 of Southern Cross, one of the largest care providers in England, the CQC also has limited market oversight powers in relation to certain care providers deemed 'too big to fail'. Under market oversight powers, the largest care providers

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27 Section 11, Health and Social Care Act 2008.
28 Section 32 Health and Social Care Act 2008.
29 Sections 17 and 18 Health and Social Care Act 2008 and the Care Quality Commission (Registration) Regulations 2009.
30 Sections 54 to 56 Care Act 2014 and the Care and Support (Market Oversight Criteria) Regulations 2015.
and those providing very specialist services are required to provide detailed information to CQC on their financial sustainability and to cooperate with engagement and potentially contingency planning.

iii Healthcare professionals

Healthcare professionals in England are usually required to be registered with one of the eight different regulators: the General Medical Council (GMC), the Nursing and Midwifery Council (NMC), the General Dental Council (which regulates the wider dental team), the General Pharmaceutical Council (which regulates pharmacists and pharmacy technicians), the General Optical Council (GOC) (optometrists and dispensing opticians), the Health and Care Professions Council (HCPC) (a wide range of professions, including speech therapists, physiotherapists, paramedics and bioscientists), the General Osteopathic Council and the General Chiropractic Council. Some of these operate on a UK-wide basis, while others only operate in certain nations. These regulators are overseen by the Professional Standards Authority for Health and Social Care (PSA). In addition, the PSA accredits voluntary registers for health and care professionals (such as psychotherapists or complementary healthcare practitioners) where there is no legal requirement for registration. Not all individuals involved in front-line care are regulated, including ‘healthcare assistants’ who may provide a wide range of services to patients, and operate under the direction of a registered healthcare professional.

Where a profession is regulated by one of the above regulators, registration is compulsory under the provisions of their respective legislation. Each regulator sets out its requirements for initial registration (i.e., qualifications, experience and good character), continued registration (i.e., standards to be complied with and continuing professional development) and disciplinary procedures to address serious concerns about a regulator’s fitness to practise. In recent years some regulators, most notably the GMC and NMC, have introduced requirements for revalidation, whereby registrants must have their continuing professional development and ongoing fitness to practise confirmed by a practitioner responsible for them. There have been proposals to overhaul the regulation of professionals in the UK (including a Law Commission report on the regulation of health and social care professionals). However, at present, no indication has yet been given for when legislation might be submitted to Parliament.

31 Medical Act 1983.
34 Pharmacy Order 2010/231.
35 Opticians Act 1989.
36 Health and Social Work Professions Order 2001 2002/254. The Children and Social Work Act 2017 makes provision for a separate regulator (Social Work England) for social workers, who are currently regulated by the HCPC, however, at the time of writing no date has been appointed for these provisions to be brought into force.
37 Osteopaths Act 1993.
39 National Health Service Reform and Health Care Professions Act 2002.
V NEGLIGENCE LIABILITY

i Overview

As a result of the UK’s implementation of Directive 2011/24/EC on the application of patient’s rights in cross-border healthcare, all of the professional regulators require their registrants to have indemnity arrangements providing appropriate cover for their practice.42 In the vast majority of circumstances, this indemnity or insurance arrangement will be provided by their employer. In most claims for medical negligence, the primary defendant will be the NHS Trust (represented by the NHS Litigation Authority, also known as NHS Resolution) or the private corporate provider, rather than the individual practitioner. The practitioner’s employer (or hospital with whom they have a relationship) would usually be deemed to have vicarious liability for any negligence occurring, subject to the nature of the relationship between the practitioner and the institution and the connection between the wrongdoing and the relationship, both of which must be sufficiently close that it is just and reasonable to impose liability.

The cornerstone of medical negligence case law in the UK is the concept of consent – patients are required to be fully informed of the risks of treatment before continuing. As a result, patients are normally required to sign consent forms (or have them signed on their behalf) setting out the risks of treatment before any but the most common procedures are carried out.

ii Notable cases

The most significant recent case is the Supreme Court decision of Montgomery v. Lanarkshire Health Board43 (while this is a Scottish case, most of its principles will apply throughout the UK), which revisited a patient’s right to information about the risks of a procedure in light of perceived societal changes in the relationship between a patient and their doctor. Lord Kerr’s leading judgment noted that, rather than the previously paternalistic approach towards patients, they are ‘now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession. They are also widely treated as consumers exercising choices: a viewpoint which has underpinned some of the developments in the provision of healthcare services’ (Paragraph 75). This has most recently been formulated as ‘a duty on the part of doctors to take reasonable care to ensure that a patient is aware of material risks of injury that are inherent in treatment . . . a duty of care to avoid exposing a person to a risk of injury which she would otherwise have avoided’.44 The test of materiality is ‘whether, in the circumstances of the particular case, a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it’ (Paragraph 87).

In May 2017, surgeon Ian Paterson was sentenced to 15 years’ imprisonment, having been found guilty of wounding with intent and unlawful wounding, for carrying out unnecessary breast operations after exaggerating the patients’ risks of cancer; the sentence was later increased to 20 years on appeal. While over 250 negligence claims arising from

42 For example, Section 44C Medical Act 1983 and Article 12A Nursing and Midwifery Order 2001.
43 (Scotland) [2015] UKSC 11.
44 Montgomery v. Lanarkshire Health Board (Scotland) [2015] UKSC 11, para 82.
operations performed on the NHS have been settled, litigation is ongoing as to whether indemnity arrangements provided for those operations performed privately will cover the claims.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

As discussed above, the Regulated Activities Regulations require directors of registered providers to comply with a range of requirements. These include that the directors:\(^\text{45}\)

- are of good character;
- have the qualifications, competence, skills and experience necessary;
- are able by reason of their health to perform their roles;
- have not been responsible for or contributed to any serious misconduct or mismanagement in the course of carrying out a regulated activity;
- are not bankrupt;
- are not included in a barred list preventing them from working with children or vulnerable adults; and
- have not been convicted of an offence or erased from a register of health or social care professionals.

There is no prohibition on an internationally owned or non-national business being CQC-registered, however, there must be a registered premises in the UK from which the service is provided and sufficient evidence must be provided to secure registration.

Between April 2012 and April 2014, the Competition and Markets Authority (and its predecessor organisation, the Competition Commission) investigated the supply of privately funded healthcare in the UK, and concluded that features of the market prevented, restricted or distorted competition, having an adverse effect on competition. As a result, the Private Healthcare Markets Investigation Order (2014) was brought into force. Among wider prohibitions, the Order restricts the circumstances where a clinician can refer a patient to a private hospital where that clinician has, directly or indirectly, a share or financial interest in:

- that hospital;
- the hospital operator that owns or operates that hospital or facility; or
- in the diagnostic equipment or equipment used at that hospital.

To avoid sanction, the referring clinician must comply with certain conditions, including a 5 per cent limit on shares in the private hospital and various prohibitions on referral incentives.

VII COMMISSIONING AND PROCUREMENT

Since the reforms of the Health and Social Care Act 2012, provision of services within the NHS has been based on a provider–commissioner basis. Services are commissioned by either NHS England on a national basis, or by CCGs on a local basis, supported by local Commissioning Support Units, depending on the nature of the service and how commonly those services are required (by way of example, routine services, such as physiotherapy, would

be commissioned on a local basis by the CCG, whereas complex, rare procedures, such as proton beam radiotherapy, would be commissioned by NHS England. The commissioned services may be provided by NHS providers, such as hospital trusts, or by private companies. The exact services to be commissioned will be based on recommendations by NICE and the available funding. The commissioning of health services is done by means of the NHS Standard Contract, which sets out the standard terms to be expected for the commissioning of all health services except primary care (the commissioning for family and primary healthcare is discussed in Section III above). The terms of the contract are mandated each year by NHS England.

Since 18 April 2016, NHS procurement of healthcare services is subject to ‘light touch’ regulation and overseen by Monitor (now known as NHS Improvement).

Outside of the NHS, commissioning of private healthcare services must take place in accordance with general UK (and EU) procurement laws, which are outside the scope of this chapter. For the procurement of supplies (as opposed to services), the Public Contracts Regulations 2015 would apply; for routine procurement, many NHS bodies use NHS Shared Business Services (a joint venture between the Department of Health and a private company).

VIII MARKETING AND PROMOTION OF SERVICES

The vast majority of health services being provided by the NHS limits the role of marketing in UK healthcare. The NHS ‘lozenge’ (essentially the letters ‘NHS’ in white on a blue background) is an exceptionally widely recognised symbol, and the NHS provides branding guidelines for this logo. Private healthcare services such as dentistry, fertility, walk-in primary care and sight testing, can be marketed and promoted, provided this is in accordance with the codes provided by the regulator, the Advertising Standards Authority (ASA).

The professional regulators also provide guidance in mandatory codes or standards on the marketing of services. This is considered particularly important for services such as dentistry, which are normally provided by private providers even when being funded by the NHS. The professional regulators place an obligation on professionals to ensure advertising, promotional material or other information is accurate and not misleading and does not exploit patients’ vulnerability or lack of knowledge. Under Regulation 20A of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, all CQC-registered services are required to display on each of their premises and each of their websites the rating given at the last CQC inspection.

The ASA’s advertising codes prohibit misleading, harmful or offensive advertising and require that all advertising must be legal, decent, honest and truthful, deal fairly with consumers and not be misleading or offensive. The ASA provides publicly available codes and may make publicly available rulings and impose sanctions. The advertising of medicinal products is regulated by Part 14 of the Human Medicines Regulations 2012. This strictly controls the circumstances when a product may be advertised and the content of any such advertisement. It is an offence to advertise a medicinal product unless it has a UK or EU

47 Public Contracts Regulations 2015 and National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013.
48 Section 62 Health and Social Care Act 2012.
marketing authorisation or certificate of registration and there are separate requirements for marketing to the public and to those who may prescribe medication. Prescription-only medicines cannot be advertised at all. Therefore, the promotion of health services that specify a treatment with a product that is not authorised in the UK or by the EU, or for a use that is not on label or that is a prescription-only medicine will breach these strictly enforced laws. Commercial practices of traders are also regulated by the Competition and Markets Authority and local trading standards offices, who enforce the Consumer Protection from Unfair Trading Regulations 2008 and the Business Protection from Misleading Advertisements 2008, both of which prohibit misleading, unfair and aggressive commercial practices.

IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

Since 2008, there has been a continuous pressure on NHS budgets, leading to increased innovation in order to drive cost efficiencies. The focus on innovation has also led to a greater role for localism in the NHS, with the introduction of Vanguard sites to pilot new ways of providing services, and Sustainability and Transformation Plans, whereby each local area has created a plan to provide services with more limited resources and a focus on integrating health and social care.

There has also been an increasing turn to the provision of services digitally in recent years, particularly with a rise in remote online services. While this may provide great opportunities in terms of speed of access, increased access for those in remote areas and potentially lower costs services, there are also concerns about patient safety. Regulators including the GMC and GOC have consulted and provided advice on such services. In April 2017, the CQC renewed its focus on the regulation and inspection of online providers to ensure their safety. There continues to be some tension between innovation and safe practice and regulation in this rapidly evolving area.

In July 2017, the government published ‘Your Data: Better Security, Better Choice, Better Care’ setting out its commitment to ensure the English health and social care system realises the full benefits of sharing data in a safe, secure and legal way. To address concerns about inappropriate access and use of data, the government expects that by December 2018 people will be able to access a digital service showing who has accessed their summary care record, and by March 2020, see how data has been used for purposes other than their direct care.

In relation to the Paterson case, the government has committed to a comprehensive inquiry to ensure that any lessons are learnt in the interests of ensuring patients are protected in future. Announcements on this are expected in summer 2017.

The UK continues to lead the world in its genomics work. The Department of Health set up Genomics England in 2013, which by July 2017 had sequenced over 31,730 genomes from NHS patients with rare diseases and common cancers creating a unique platform for research and delivery of personalised care.

The potential impact of Brexit has yet to be fully realised, but issues such as workforce mobility and those healthcare-related issues determined by EU law, such as the requirement of healthcare practitioners to have indemnity cover, marketing authorisations for new drugs and procurement rules are all likely to be under scrutiny in the negotiations.

49 www.genomicsengland.co.uk/the-100000-genomes-project-by-numbers/.
CONCLUSIONS

English healthcare is largely delivered in a unique environment dominated by the NHS. However, the service is undergoing great change with opportunities for new providers to enter the marketplace to deliver services for or alongside the NHS. Innovation and new approaches are being driven by the need for cost efficiencies, a desire for greater integration of care and in an environment that wants to embrace new technology and personalised medicine.
I OVERVIEW

The healthcare system in Germany is based on four principles.\(^2\)

\(a\) Statutory insurance: All citizens and permanent residents of Germany must generally have statutory health insurance, provided that their gross earnings are below a certain threshold. Anyone who earns more than such threshold can voluntarily choose a private insurance instead of the statutory health insurance.

\(b\) Parity financing: Healthcare is financed for the most part by insurance premiums that are based on a percentage of income, shared between the employee and employer. However, these premiums are only based on a percentage scale up to a certain income level. Anyone earning more than this amount pays the same maximum premium.

\(c\) Solidarity: In the German healthcare system, statutory health insurance members mutually carry the individual risks of loss of earnings and the costs of medical care in the event of illness. Everyone covered by statutory insurance has an equal right to have access to care – regardless of their income and premium level.

\(d\) Self-governance: While the state sets the conditions for medical care, the further specific setup, organisation and financing of individual medical services is the responsibility of the legally designated self-governing bodies within the healthcare system. They are made up of members representing doctors and dentists, psychotherapists, hospitals, insurers and the insured people. The Federal Joint Committee is the highest entity of self-governance within the statutory health insurance system.

II THE HEALTHCARE ECONOMY

i General

Germans are offered three mandatory health benefits, which are co-financed by the employer and employee:

\(a\) health insurance;

\(b\) accident insurance; and

\(c\) long-term care insurance.

There are two different types of health insurance: public health insurance and private insurance.

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1 Stefanie Greifeneder is a partner in the Munich office of Fieldfisher (Germany) LLP.
2 Reference is made to www.ncbi.nlm.nih.gov/pubmedhealth/PMH0078019/.
Both systems of health insurance struggle with the increasing cost of medical treatment and the changing demography. About 89.4 per cent of the persons with health insurance are members of the public system, while 10.6 per cent are covered by private insurance (as of 2016).³

Accident insurance for working accidents is paid for by the employer and basically covers all risks for commuting to work and at the workplace.

Long-term care is paid by the employer and the employee fifty-fifty, and covers cases in which a person is not able to manage his or her daily routine (provision of food, cleaning of housing, personal hygiene, etc.). The insurance premium is about 2 per cent of the yearly salaried income or pension of the insured, with employers and employees each paying half of the total premium.

ii The role of health insurance

All citizens and permanent residents of Germany are required by law to have health insurance. Everyone who has statutory health insurance in Germany is entitled to the same healthcare – regardless of how much they pay for their insurance. The premium is determined solely by income level. Statutory health insurance is based on the principle of solidarity, so people who earn more money pay more than those who earn less, and healthy and ill people pay the same amount. In this way, if people get ill, the costs of their medical care and loss of earnings are shared by everyone with that insurance.

The statutory health insurance is a mandatory insurance scheme. Enrolled in this scheme are employees and their dependants. It is financed by members’ contributions, which are paid as payroll taxes by the employer and the employee. For unemployed individuals, the contributions are paid by the employment agency. An exception are the self-employed, who are not covered by the statutory health insurance, but can buy private insurance. People eligible for statutory health insurance with a high income (over €57,600 in 2017) have an opt-out option if they choose private insurance instead.

The statutory health insurance operates under the principle of benefits in kind. This means that the insured receives healthcare services without being issued a bill for the services.

iii Funding and payment for specific services

All employees pay a health insurance contribution based on their salary if they are enrolled in the public health insurance. The actual contribution rate is calculated by a panel of experts at the Federal Ministry of Finance (BMF) and is the same across all statutory insurers. From 2015, the premium is 14.6 per cent of the gross income, but only up to a certain income level. The employer and insured employee share the costs equally, paying 7.3 per cent each. Insurers may charge extra fees if their insurance premiums and other funding sources are not sufficient to cover their costs.

Most of the statutory health insurance benefits are standard services and compulsory for all of the insurance providers. The services covered include practice-based treatment by family doctors, specialists and psychotherapists, hospital-based treatment and – under certain circumstances – treatment in rehabilitation facilities. These services also include screening tests, necessary vaccinations (not travel vaccinations) and medical care related to pregnancy and birth.

³ Data published by vdek under www.vdek.com/presse/daten/b_versicherte.html.
Prescription drugs are nearly always covered. Treatments like physiotherapy or speech therapy and medical aids like prosthetic devices or hearing aids are also covered by statutory health insurance, as long as they are medically necessary and have been prescribed by a doctor. People have to pay a certain amount out of their own pocket for these services, though. This amount is fixed by law. The out-of-pocket costs for prescribed drugs range between €5 and €10, depending on their price. Children and teenagers under 18 do not have to pay these additional costs.

The services covered also include dental check-ups, dental treatment, gum treatment, and orthodontic treatment. When it comes to dental prosthetics, statutory health insurers pay a fixed amount. Before any dental work involving prosthetics is started, the dentist makes a treatment and cost plan that must be submitted to the insurer. The insurer then decides what costs will be covered, giving a better idea of how much the patient will need to pay him or herself.

If a patient has special requests – such as a private room in hospital, treatment by a senior consultant or certain dental treatments – the patient has to pay for those costs by him or herself. Private health insurance companies offer separate policies for some such special requests.

With the exception of out-of-pocket costs, all costs for services that are covered are paid by the insurer directly to the care provider. This means that the patient is not involved in the transaction.

Private insurers charge risk-related contributions. The premium in the private system is based on an individual agreement between the insurance company and the insured person defining the set of covered services. The amount of the premium depends on the level of services chosen and the person’s risk and age of entry into the private system. For privately insured patients there is a refund of costs, meaning they have to pay the amount for healthcare at the time of being sick, and the insurance reimburses them with the costs later.

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

The difference between outpatient and inpatient care needs to be distinguished. Whereas outpatient care does not require a prolonged stay of the patient at a facility, inpatient care generally refers to medical services that require admission into a hospital. Outpatient care also includes care received in a hospital or at a psychiatric institution that does not involve an overnight stay.

In Germany, outpatient care is mainly provided by the individual practices of self-employed doctors, dentists, psychotherapists or other healthcare professionals. The first point of contact is usually the family doctor (i.e., a general practitioner, internist or paediatrician). Where necessary, the family doctor may refer the patient to suitable specialists for specific medical problems. The patient may also go straight to a specialist without any referral of the family doctor.

Besides individual practices, a number of joint practices and medical care centres exist, where two or more doctors or other healthcare professionals provide healthcare services. The advantage of such joint practices is that they may offer services that might otherwise only be available in hospitals. This particularly applies to special examinations or day surgery.
In the case of inpatient treatment, patients are charged with additional fees for accommodation and meals that are not covered by the statutory health insurance. These fees are agreed upon between the patient and the hospital in a separate contract before the treatment starts.

Inpatient medical care also includes rehabilitation. Rehabilitation facilities provide treatments that help people to regain independence and improve their performance after getting over serious illness or recovering from intensive therapy. These treatments include physiotherapy, psychological care and help learning how to use medical aids and appliances. This is often done immediately after a hospital stay (for instance, following surgery). There are also rehabilitation facilities for people with mental illnesses and addictions.

As of 2015, electronic medical chip cards are used nationwide by all patients who are insured with a statutory health insurance. The electronic medical chip card encodes information on the patient’s name, address and date of birth, along with details of insurance coverage and the patient’s status regarding supplementary charges.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

To a large degree, regulation is delegated to self-governing associations within sickness funds and provider associations, which are together represented by the most important body, the Federal Joint Committee. This committee is the highest decision-making body within the self-governing healthcare system. It includes members representing doctors, dentists, psychotherapists, statutory insurers, hospitals and patients. As the central entity of federal-level self-governance, the Federal Joint Committee makes decisions concerning which medical services will be covered by the statutory insurers and what form that coverage will take.

Besides the Federal Joint Committee, the key regulators in Germany are as follows:

a The Federal Ministry of Health (BMG): The BMG has a supervisory role for the governmental institutions, statutory health insurance, social insurance, prevention and the effectiveness of the healthcare system. It is responsible for policy-making at the federal level. Furthermore, the task of the BMG is to draft administrative guidelines that establish the framework of the self-governing activities within the healthcare system.

b State Ministries of Health: The Ministries of Health in the 16 federal states of Germany are primarily responsible for the provision of healthcare, in particular, hospital planning. The Ministries of Health manage disease registers and management of infection outbreaks.

ii Institutional healthcare providers

Quality of care is addressed through a range of measures broadly defined by law, and in more detail by the Federal Joint Committee. As of 2016, the Institute for Quality and Transparency (IQTiG) is responsible for developing instruments for interfaculty and intersectional quality assurance on behalf of the Federal Joint Committee. In addition, the institute develops criteria for evaluating certificates and quality targets and ensures that the published results are comprehensible to the public.

All hospitals are required to publish findings on selected indicators, as defined by the IQTiG, to enable hospital comparisons. Volume thresholds have been introduced for
a number of complex procedures (e.g., transplants), requiring that hospitals perform a minimum number of such procedures to be reimbursed for those procedures. Process and, in part, outcome quality is addressed through the mandatory quality reporting system for the roughly 2,000 acute-care hospitals. The Hospital Care Structure Reform Act, which came into effect on 1 January 2016, introduced a focus on quality-related hospital accreditation and payment.

Structural quality is further assured by the requirement that providers have a quality management system, by the stipulation that all physicians continue their medical education, and by health technology assessments for drugs and procedures. For instance, all new diagnostic and therapeutic procedures applied in ambulatory care must receive a positive evaluation for benefit and efficiency before they can be reimbursed by sickness funds.

Although there is no revalidation requirement for physicians, many institutions and health service providers include complaint management systems as part of their quality management programmes. In 2013, such systems were made obligatory for hospitals.4

iii Healthcare professionals

German medical students have to pass primarily scientific basic study before they are admitted to the clinical part of their university courses. After the medical approbation examination (usually after five years), a phase of five to seven years as assistant or resident physician follows before the physician can pass the specialisation examination for one of the clinical fields. During this time of specialisation, a clearly defined catalogue of diagnostic or operative procedures must be fulfilled (such as a certain number of the most important operations in the field where the physician is specialising). After passing this additional examination, the specialised physician can either pursue his or her profession in a hospital or as self-employed physician in private practice.

Training for the nursing profession is fixed at three years. It has to follow a government-prescribed curriculum, be offered by schools that stand under state supervision and provide theoretical education as well as on-the-job training. The examination is also state-controlled. After a number of years in the job, nurses can acquire additional special certificates, for example, as an operation nurse or anaesthetics nurse. These additional training courses usually take another two years of on-the-job training.

To practise medicine or carry out specialty training in Germany, all physicians must be in possession of a valid full or temporary licence to practise. The full licence to practise is valid across the country for an unlimited period of time. The temporary licence to practise is limited to a certain time period and is valid only within the federal state in which it was issued.

In this context, the federal government’s Recognition Act came into effect on 1 April 2012. It has improved the procedure for assessing and recognising professional and vocational qualifications obtained outside Germany. It allows individuals to have the equivalence of their professional qualifications assessed in Germany, regardless of nationality.

The state health authorities of the respective federal state are responsible for issuing full and temporary licences to practise. Physicians wishing to practise in Germany must also become a member of one of the 17 State Chambers of Physicians. Each of the 16 federal states of Germany (and two in North Rhine-Westphalia) has a State Chamber of Physicians.

4 Reference is made to http://international.commonwealthfund.org/countries/germany/.
As corporations under public law, these bodies are responsible for the administration of all matters related to specialty training in Germany. The state laws governing the healthcare profession and the activities of the Chambers set out the responsibilities of the State Chambers of Physicians with respect to physicians professionally active, or residing, within their area of jurisdiction.\(^5\)

**V NEGLIGENCE LIABILITY**

**i Overview**

German medical liability law is based on the German Civil Code and its provisions on liability arising from contracts and torts. These principles have been substantiated by German case law. The individual who treats a patient is liable for an error in treatment if the treatment causes injury to life, the body or the patient’s health. Independently of error in treatment, the individual providing medical care is liable for mistakes made in the context of obtaining informed consent. The prerequisite is that the doctor makes a mistake when obtaining informed consent, e.g., that the doctor does not fully inform the patient of all possible risks. Such mistake needs to be causal for the patient’s consent for the treatment. In the absence of effective consent, the treatment is considered illegal, irrespective of the fact of whether it was free of treatment error or not. The most common causes of liability are treatment errors, wrong diagnosis, wrong medication, lack of information and lack of documentation.

Damages in medical malpractice cases are awarded on the basis of the Civil Code provision on indemnity for losses suffered. Damages are entirely compensatory. Punitive damages are not awarded in Germany. The cost of treatment, rehabilitation, mitigation of the consequences of permanent damage and long-term care can be generally awarded in medical malpractice cases and in personal injury cases. In addition, earnings losses are compensated and damages for pain and suffering are awarded. However, the amounts of such compensation claims are much lower than in US cases, for example.

Doctors who are in private practice in Germany must have occupational liability insurance in place that meets the costs arising from medical malpractice cases. The doctors and dentists who are employed in a hospital can, as a rule, join the hospital’s institutional occupational liability insurance. The occupational liability insurance covers personal injury, and material and property damage, as well as lawyers’ fees and procedural costs.

**ii Notable cases**

One of the most recent decisions of the German Federal Court of Justice was handed down on 14 March 2017. The German Federal Court of Justice decided in this case that a doctor might also be held liable for medical malpractice if he or she has not pointed out the necessity and urgency of further medical inventions with regard to the patient. This decision underlines that medical malpractice has a large scope and does not only apply in cases of error in treatment.

Case law in previous years often referred to the question on the burden of proof. Under German Civil Law, it is generally the claimant who has the burden of proof. In medical malpractice cases, this is often difficult as the patient does not have insight into the medical

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5 Reference is made to www.bundesaerztekammer.de/weitere-sprachen/english/work-training/ work-and-training-in-germany/.
work of the doctor. Therefore, many decisions of the German courts have looked at the questions in which cases it is justified to reverse the burden of proof by various presumptions. For example, a treatment error was held to be presumed when an injury occurs that corresponds to a known risk inherent in the treatment that the physician should have been able to control. Also, a physician was held to be presumed to be at fault for an error if he or she has not recorded the course of the treatment or not kept records. Causation was held to be presumed if the physician carried out a procedure for which he or she had not been certified and also if the physician committed a serious treatment error that is capable of causing the injury at issue. These cases are now implemented directly into the German Civil Code (Paragraph 630h).

VI OWNERSHIP OF HEALTHCARE BUSINESSES

Ownership of a hospital can be with:

a the government, on the local level (i.e., towns and counties) or on the state level, where the federal states are responsible for university hospitals as part of their responsibility for education;

b free non-profit institutions, such as the big churches with their federations, the Red Cross with its nurse societies and other non-profit organisations; or

c private for-profit companies and hospital chains.

Most hospitals in Germany treat all patients, regardless of whether they have statutory or private health insurance. Large hospitals usually have public backing; in other words, they are financed by the state or municipality. Charity-run or church-run hospitals are operated by organisations such as the Red Cross. There are also many privately run hospitals, some of which will only see patients who are privately insured. These hospitals are typically smaller and more likely to be specialised.

Physicians either work in their individual, solely owned practice or in partnership with other doctors. In addition, a new legal form, the Medizinisches Versorgungszentrum (MVZ), was introduced in Germany in 2004. MVZs are licensed medical service providers that may be owned by any person or entity entitled to render any services or sell products within the statutory health insurance. This means that medical appliance shops or physiotherapist service providers can be owners of an MVZ.

VII COMMISSIONING AND PROCUREMENT

Most healthcare services of hospitals are provided by employees of the hospitals. Besides this, some services, such as laboratory services, are purchased by the hospitals from third parties. The commissioning of such services for government-sponsored hospitals has to be made by public tenders. Those tenders are national tenders if the value of the services procured does not exceed €209,000 net. If this threshold is exceeded, the tender has to be made Europe-wide. Outside of government-sponsored hospitals, commissioning of private healthcare services must take place in accordance with general German and EU procurement laws, which are outside the scope of this chapter.
VIII MARKETING AND PROMOTION OF SERVICES

Advertising for the services of doctors is limited in Germany by the German Act on Healthcare Advertising, the Act against Unfair Competition and the German professional codes of doctors and dentists.

The rules for advertising the services of doctors have changed considerably in recent years. Up until a few years ago, doctors were banned from almost any advertising. In the course of the liberalising of the jurisdiction of the German Federal Constitutional Court on the professional rights of freelancers (including doctors), the provisions have become less restrictive. Since 2002, factual job-related advertising is permitted. Only ‘unlawful’ advertising that improperly affects the patient, and thus could lead to a medical health hazard, is forbidden. This includes, in particular, misleading and comparative advertising.

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

In December 2015, Germany passed a bill for secure digital communication and healthcare applications (the E-Health Act), which provides for concrete deadlines for implementing infrastructure and electronic applications and introduces incentives and sanctions if schedules are not adhered to. Statutory health insurance physicians receive additional fees for transmitting electronic medical reports (2016–2017), and will receive additional fees for collecting and documenting emergency records (from 2018) and managing and reviewing basic insurance claims data online. From July 2018, statutory health insurance physicians who do not participate in online review of the basic insurance claims data will receive reduced remuneration. Furthermore, to ensure greater safety in drug therapy, patients who use at least three prescribed drugs simultaneously can receive an individualised medication plan, starting in October 2016. In the medium term, this medication plan will be included in the electronic medical record.⁶

X CONCLUSIONS

Germany’s healthcare system is largely characterised by the public health insurances that provide access to care for nearly everyone. However, the German healthcare market, which is one of Germany’s largest-growing markets, is expected to be subject to profound changes over the course of the next years, as digital healthcare becomes more and more important in ensuring a sufficient healthcare supply to patients. In this context, regulators and the legislator still have a long way to go to pave the way to a digitally driven healthcare system. This is all the more important in light of the demographic change in Germany, with its drastic increase of elderly people.

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⁶ Reference is made to http://international.commonwealthfund.org/countries/germany/.
Chapter 6

IRELAND

Tom Hayes, Rebecca Ryan and Michael Finn

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 (with the exception of accident and emergency 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.

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1 Tom Hayes is a partner and head of the healthcare group, and Rebecca Ryan and Michael Finn are partners in the healthcare group of Matheson.
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 44 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 1994–2015. 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 (with the exception of accident and emergency 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 (€144) (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 Drugs 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.
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. 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.

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.

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

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3 Section 37 of the Medical Practitioners Act 2007.
4 www.medicalcouncil.ie/Existing-Registrants/.
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 you are admitted to hospital, either in an emergency or on a planned or elective basis, you will be under the care of your admitting consultant.6

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

v The IMC Ethical Guidelines

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 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:

- an advice, admonishment or censure in writing;
- a censure in writing and a fine not exceeding €5,000;
- the attachment of conditions to the doctor’s registration, including restrictions on the practice of medicine that may be engaged in by the doctor;
- the transfer of the doctor’s registration to another division of the register;
- the suspension of the doctor’s registration for a specified period;
- the cancellation of the doctor’s registration; and
- the prohibition from applying for a specified period for the restoration of the doctor’s registration.  

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.9

ii Nurses and midwives10

The NMBI is the independent, statutory organisation which 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.11 The Irish Nurses and Midwives Organisation Medical Malpractice Scheme provides cover for members who are self-employed or employed outside the state sector.12

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.13

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

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10 www.nmbi.ie/Registration.
12 www.inmo.ie/Home/Index/7581/9869.
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.\textsuperscript{14}

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.\textsuperscript{15}

\textbf{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.

\textit{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.

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.\textsuperscript{16}

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.

\textsuperscript{14} www.healthcomplaints.ie/specific-complaints-procedures/dental-council/.
\textsuperscript{15} www.healthcomplaints.ie/community-based/dental/dental-public-patient/.
\textsuperscript{16} www.thepsi.ie/gns/making-a-complaint/complaints-process.aspx.
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 21 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.

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:

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

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 qualification.

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.

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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.

A recent Irish Times article 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’.21

Universal Health Insurance (UHI) is a new system of healthcare, which the government revealed in a 2014 White Paper on Universal Health Insurance that it plans to adopt and introduce by 2019.22 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;
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.23 The report encourages a shift away from

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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. This is discussed further at the end of this article.

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), which Irish public sector entities are strongly encouraged to comply with, 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).

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 8.2, 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). 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

24 www.asai.ie/asaicode/.
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 stipulates 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 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. 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.

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

The future of healthcare in Ireland

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.

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 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.

I OVERVIEW

The Italian National Health Service (NHS) was established in 1978 by Law 833/1978 and provides universal coverage to the Italian population (citizens and foreign residents). The NHS is funded by the central and local government through the use of general taxation and, in small part, by the fees charged to the citizen as co-participation to the cost of the services provided. Healthcare services are provided in the Italian territory by the 19 regions and the two autonomous provinces through the local health structures. As a result of such decentralisation, significant differences of the level of care are experienced among the different regions, despite the fact that, in principle, all the services included in the essential healthcare basket (LEA) should be equally collectable in all Italian regions. The central government retains supervisory control and overall responsibility for the NHS in order to ensure essential levels of health services homogeneously across the country. By Decree of the Prime Minister dated 12 January 2017, a new LEA has been established to replace what had been in place since November 2001. The new LEA, *inter alia*, includes new rare diseases, new vaccines, updated procreation and neonatal screening assistance, and updated specialist and diagnostic assistance.

The 2017 Budget Law fixed the financing of the NHS by the central government at €113 billion for 2017, €114 billion for 2018 and €115 billion for 2019. Health budget funds are allocated to the regions on the basis of criteria set forth in the three-year National Health Plan generally based on population structure, type of health structures located in the relevant territory. Each region shall set its own regional health plan based on the National Health Plan, and in case of excess cost that cannot be covered by the region’s own resources, restrictions are imposed until recovery of the deficit. Regarding the cost of medicinal products, a complex and controversial mechanism for refunding excess cost was established by Article 15 of Law No. 135/2012, which imposed that the region cover the 50 per cent of the extra cost and the pharmaceutical companies to cover the remaining 50 per cent based on the ‘company budget’ system. The implementation of the coverage of the excess budget by pharmaceutical companies was subject to judicial review by the administrative courts and, as a result of several decisions of the administrative courts, was amended by Decree Law No. 113/2016 in an attempt to settle the pending issues and recover a significant part of the deficit. The issue regarding recovery of excess costs is still pending, but the 2017 budget law introduced certain significant changes to the part of health budget allocated for medicinal products.
The share for the cost of medicinal products of the health budget funded by the central government is 14.85 per cent, of which, 7.96 per cent is for the medicinal products supplied in the territory (mainly through the pharmacies) and 6.89 per cent for medicinal products purchased by the public health structures (hospitals). The allocation between territorial expenses and hospital expenses changed significantly because products that were formerly part of the territorial expenses are now in the hospital expenditure with a significant reduction of cost resulting from cancellation of the pharmacist margin.

Another significant innovation introduced by the 2017 Budget Law is the creation of two €500,000 funds for innovative drugs: one for innovative drugs and one for innovative oncological drugs. The institution of these new funds shall give more resources to the supply of innovative products.

II THE HEALTHCARE ECONOMY

i General

The peculiarity of the Italian NHS is that it guarantees the right to extensive healthcare assistance to all Italians and foreign residents, without discrimination based on income, social status or gender. The Italian NHS is based on the principles of universality, equity and solidarity and constitutes an implementation of one of the fundamental principles set forth in Article 32 of the Italian Constitution: ‘The Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent.’

According to the Report on the sustainability of the NHS issued by GIMBE Foundation in 2017, the most critical factors undermining the sustainability of the NHS in recent years have been the progressive aging of the population, the increased cost of innovative products (in particular, medicinal products) and the increasing demand of health services by the population.

Health services include hospital admissions, emergency care, the services of general practitioners and paediatricians, supply of a significant number of medicinal products (included in the reimbursable class), diagnostics services essential to health and hospice assistance.

The supply of healthcare services to all citizens takes place through public and private health structures, which must be accredited by the competent regions. Each region should define its own model of accreditation that should comply with safety and quality requirements defined at national level. The principle is that accreditation is the necessary requirement for a healthcare structure to be an accountable provider of the NHS.

ii The role of health insurance

Because of the presence of the NHS, private care insurance in Italy is not mandatory and is not an important market in Italy. Private health insurance available in Italy may be complementary or supplementary, covering healthcare services excluded from the LEA, offering the possibility of choosing a private hospital, reducing the waiting time for the supply of assistance services or paying for additional comfort services not offered by the

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NHS. Private insurance is available to individuals and their families. Several collective labour agreements (industry and services) provide in favour of personnel supplementary insurance paid by the employer offered by mutual insurances under the supervision of the unions. During the past few years there has been an increase of private insurance as a result of cost containment measures that have restricted access to certain health services, reduced comfort of patients hospitalised in public structures and caused long waiting lists for free healthcare and diagnostic and prevention services. While the contribution to complementary insurance provided by collective labour agreements is tax deductible, the cost of individual supplementary health insurance is not tax deductible, but the medical expenses covered by insurance companies do qualify for the 19 per cent tax allowance even if they are paid or refunded by the insurer.

According to a Report on the Coordination of Public Finance of the Court of Accounts in the year 2015, the total public expenditure for health services was €112.408 billion and €34.887 billion of private cost. The private cost was paid by integrative insurance funds for only €4.476 billion and by private health insurance policies for €0.902 billion. The majority of private expenditure (87 per cent) was paid out of pocket by the population.

iii Funding and payment for specific services

Funding of the NHS is provided by general taxation. The services included in the LEA are provided by public or private health structures, and include NHS healthcare professionals being available free of charge to the whole population. For some services, such as drug prescriptions and diagnostic services, a small co-payment (called a ‘ticket’) is required of the taxpayer, but several categories are exempt from any co-payment. The exemption is granted to people on low incomes, people affected by serious diseases, unemployed people and minors. Decisions on the co-payment (i.e., its amount and the services on which it is due) pertain to each region and, indeed, the system is different in each region. According to the Court of Accounts in 2016, the payment of tickets cashed by all the regions amounted to €2.885 billion.

Wellness and dentistry services are not included in the LEA, except for in very serious cases. Health costs of any type (doctor’s fees, general costs, specialist’s fees, surgery costs, pharmaceutical costs, medical devices cost, tickets for co-payment, etc.) paid directly by the individual taxpayer qualify for a 19 per cent tax allowance once the threshold of €129.11 has been taken out.

Spending on medicinal products has been subject to a number of measures in order to reduce costs, including the implementation of pharmaceutical budgets for regions, company’s budget for pharmaceutical companies, reductions in wholesale and pharmacy margins, and price cuts on generics based on reference pricing. The necessity of a new model of government of pharmaceutical expenses has often been discussed, but the implementation appears too complex.

According to ISTAT in 2015, the services paid by citizens personally (in total, approximately €35 billion) are allocated as follows: 39.1 per cent for medicinal products, 25.3 per cent for dentistry services, 13.3 per cent for medical profession services, and less than 10 per cent for equipment and medical devices.
In Italy, primary care is provided by the NHS through self-employed practitioners and paediatricians who are paid a yearly capitation fee by the NHS, based on the number of people on their list and on the number of additional services provided to their patients (such as home visits, vaccinations and small surgeries). One of the basic principles of the NHS is the freedom of the individuals to choose their family doctor, through whom they shall be receiving free of charge (or with limited co-payment) various kinds of assistance, such as visits at the doctor’s office, visits at home, drug prescriptions, diagnostic prescriptions and certificates. The citizen is free to select a professional of his or her choice from those who are part of the NHS. The same applies to paediatricians, who can be chosen with no charge to families for all children up to the age of 14.

The payment levels, duties and responsibilities of the general practitioners belonging to the NHS are determined in a collective bargaining agreement signed by central government and the GPs’ trade unions. Incentives in the form of increase of fees are provided for GPs who do not work in a solo practice, but join a base group or network group with other practitioners and paediatricians in order to provide continued assistance and reduce recourse to emergency care at the public hospitals.

The development of digital health is encouraged with the aim of rationalising resources of the NHS and achieving reduction of public expenditure.

The Regulation regarding Electronic Health Records (FSE) was issued by decree of the Prime Minister (DPCM No. 179 of 15 September 2015) at the end of quite a long process started in 2009 with the issuance of the Guidelines for the use of Electronic Health Records and Health Files by the Ministry of Health and by the Data Protection Authority. The Data Protection Authority clarified, inter alia, that patients should give their specific consent regarding health data separately from that requested for the purposes of medical treatment; additionally, they should be empowered to have certain clinical events and data ‘blanked’ from the electronic record.

Law No. 98/2013 imposed on all regions the implementation of the FSE in their territory, within a deadline that has been postponed several times. The delay was a result of technical difficulties and absence of clear directives on the implementation of the new electronic system.

In the 2017 Budget Law, new financial resources have been allocated for the creation of the national network for connection and interoperation of the FSE regionally. The first regions to implement the FSE were those with the more efficient health structures and organisation (Emilia Romagna, Lombardy, Tuscany and Sardinia). More recently, Lazio implemented the FSE from 1 March 2017. The minimum contents of the FSE, as provided in Decree 179/2015, are, in addition to the identification details of the patient and the consent or denial to organ donation: medical reports, emergency care reports, dismissal letters, a patient’s summary drafted and updated by the family doctor selected by the patient and a pharmaceutical dossier. Each region can add ‘integrative’ information on the FSE, such as prescriptions, reservations, medical records, vaccinations, diagnostic plan, participation to clinical trials, etc. A part of the FSE ‘personal note’ can be loaded directly by the patients with information regarding therapies and health services also provided in private structures. The FSE contains strict rules for the protection of data privacy regarding consent of the patients, information regarding data protection and the right to access the electronic records.
IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

Licensing of healthcare providers and professionals is the responsibility of both the central government (Ministry of Health) and the local government (regions).

The competent directorate of the Ministry of Health is the Healthcare Professions and Human Resources of the NHS General Directorate, which is responsible, *inter alia*, for disciplining healthcare professionals, supervising professional rolls and orders, regulating the relationship between the NHS and universities in respect of personnel of the university hospitals.

On the other hand, the organisation of the healthcare services pertains to the regions, which are responsible for authorising private health structures to provide healthcare services in the relevant territory and to set the safety and technical requirements for the issuance of the authorisation.

Institutional healthcare providers are licensed through a complex system, which includes authorisation, accreditation and agreements pursuant to Article 8 *bis* of the Legislative Decree No. 502/1992.

The system can be summarised as follows:

a. the authorisation is the first step, required to start any new healthcare facility or to exercise medical practices;

b. the accreditation is the licence for structures providing healthcare services on behalf of the NHS; and

c. the agreements are the contractual tools by virtue of which structures or professionals can provide healthcare services paid by the NHS.

While authorisation is mandatory in order to carry out any activity, accreditation and agreements are on a voluntary basis.

i Healthcare professionals

The regulation of healthcare professionals has been revised by the introduction of new categories of professionals and the reorganisation of healthcare-related university degrees.

Healthcare professionals were originally regulated by Royal Decree No. 1265/1934 (the Healthcare Act). The professionals were divided in three categories:

a. the main healthcare professionals (physicians, veterinary, pharmacists and from 1985, dentists, as separate from physicians3);

b. the ancillary healthcare professionals (nurses, obstetricians, health assistants); and

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3 The dental profession was reformed in 1985 (Law 409/1985). In Italy, dentists must have a degree in medicine and surgery or in dentistry. They are the only professionals authorised to supply services for the prevention, diagnosis and treatment of diseases of the teeth, mouth, jaws and associated tissues. Law 409/1985 regulates the health profession of “dentist” and sets forth specific requirements for professional training. Currently the lawful exercise of dentist profession in Italy is permitted only to:
- graduates in dentistry and dental prosthesis;
- graduates in medicine and surgery enrolled in the graduate programme prior to 28 January 1980, with or without specialisation in dentistry;
- graduates in medicine and surgery enrolled in the graduate programme after 28 January 1980, in possession of the diploma of specialisation in dentistry or admitted to dentistry in accordance with Legislative Decree No. 386/98.
The three categories were radically amended in order to give birth to a new system introduced in the 1990s:

While the number of healthcare professionals has grown, the years required to complete university courses has reduced: new three-year university courses have been introduced, and currently, the former six-year course is only required for the main healthcare professionals.

The professional practice, after the enrolment, can be carried out throughout the national territory.

Appeal against enrolment in the relevant professional roll or register should be brought before the administrative courts.

Nonetheless, the practice of each one of the aforementioned professions is subject to the possession of the professional qualification, and sanctions are provided for offenders.

Unlicensed practise of a profession is a crime sanctioned by Section 348 of the Italian Criminal Code. The crime is applicable to any professional activity for which it is required a degree, licence and registration in the relevant professional roll. The applicable sanction is imprisonment up to six months or a fine from €103 to €516. Since the sanctions are very low and infringements are frequent, a bill of law addressed to increase applicable sanctions is pending before the Italian parliament, but an approval is not expected before the end of the legislature.

V NEGLIGENCE LIABILITY

The phenomenon of medical malpractice in Italy during the past decades has increased significantly, causing an increase of the cost of medical insurance (both for public health structures and medical practitioners) and of ‘defensive medicine’, such as additional diagnostic tests and redundant therapeutic interventions as a defensive mechanism, resulting in higher costs for the NHS and for the medical professionals belonging to the NHS.

In case of malpractice, Italian physicians may face both civil and criminal liability. They would respond for negligent personal injuries and negligent manslaughter in criminal court, and for damages caused to patients and their relatives in civil courts.

Very recently, in order to face the increasing number of malpractice cases, the parliament approved Law 8.3.2017 No. 24 (the Gelli Law), introducing significant changes to the existing rules, with respect to both criminal and civil liability.

Regarding the criminal liability for death (Article 589, Criminal Code) and bodily injuries (Section 590, Criminal Code) in healthcare, the Gelli Law introduced Section 590-sexies of the Italian Criminal Code, entitled ‘Liability in negligence for death or personal injury in a healthcare environment’. Under such new rule, the healthcare professional who treated the injured or dead patient can avoid liability if he or she can provide evidence that he or she complied with recognised and published scientific societies’ guidelines or good clinical care practices. The modifications of the criminal code with the introduction of the aforementioned

4 The new professional figures were identified and implemented by several decrees issued by the Ministry of Health pursuant to Article 6 of Legislative Decree No. 502/1992.
impunity is to be considered an important step to reduce the claims for medical malpractice, despite the fact that the criteria to identify the ‘recognised guidelines’ and ‘good clinical practices’ have still to be identified by the competent authorities.

Regarding civil liability, the Gelli Law introduced a rule in favour of healthcare professionals employed by public healthcare structures recognising the civil liability for causing harm to patients as a non-contractual liability, which implies a shorter limitation period (five years instead of 10 years) and the burden of proof upon the patient harmed instead of the professional.

The Gelli Law has also introduced the mandatory obligation for private healthcare professionals (practising without employment relationship with a public or private healthcare structure) to take an insurance policy for professional liability. Furthermore, the law recognised the direct action of the damaged patient against the insurance company.

Another important reform introduced by the Gelli Law is the mandatory attempt at conciliation imposed on the party willing to bring a claim for damages arising out of healthcare liability to file a request for mandatory conciliation. All parties, including the insurers, must attend to such conciliative proceedings, and failure is sanctioned with a fine and with costs liability.

The most relevant cases regarding liability for damages to patients concern the claims brought in recent years by patients who underwent blood transfusion and contracted serious diseases (hepatitis and the HIV virus) through infected blood.

The Italian courts established the liability of the Ministry of Health for damages suffered by patients for not having fulfilled the duty of vigilance and control in the public interest. The claims were based on the special liability clause under Section 2050 of the Civil Code (tort liability for dangerous activity). The court decisions concerning such claims are numerous because an enormous number of patients was involved in the infections. In consideration of the significant number of patients affected, the parliament, with Law 210/92, introduced an indemnification mechanism in favour of the damaged parties. A subsequent decree law (DL No. 90/2014) set forth the amounts and funds for the settlement of the outstanding claims in the range of €100,000 per person (about 6,500 persons to be indemnified). A recent decision of the Court of Appeal of Rome (No. 2270/2017) in a civil litigation brought by hundreds of claimants rejected the appeal of the Ministry of Health and established the right of the patients to obtain, in addition to the indemnification, restoration of additional damages suffered.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

Suppliers of healthcare services can be either public (i.e., hospitals directly managed by local health authorities) or private, such as hospitals and other healthcare facilities (accredited or otherwise). Pursuant to Article 38 of the Italian Constitution, private sector assistance may be freely provided.

However, in order to start an healthcare business such as nursing home, specialty outpatient clinic, dental practice, home care practice, medical practice or diagnostic structure, an authorisation issued by the region where the healthcare structure is located is required (see Section IV, supra). Requirements for issuance of authorisation are set forth in the applicable regional law and are generally focused on compliance with safety measures and satisfaction of technical requirements depending on the activity carried out by the healthcare structure.
Accreditation of the healthcare business to the NHS is a more complex process, and it is extremely difficult for newcomers to obtain accreditation. The accreditation system has been revised by Legislative Decree No. 502/1992 and by Law No. 191/2009, which imposed that the regions reorganise the accreditation programme. The system has been criticised by the Italian antitrust authority since 1999 (Note AS 175/1999), which outlined that the traditional organisation of the health service is in itself a major limit to the competitiveness of the sector. In fact, due to the great number of structures that have already been accredited, access to the accreditation system has become increasingly difficult for new private operators. In addition, the quality of the service is not going to improve as the local health authorities, which are in charge of the accreditation system, are providing the service themselves. The refusal of access to accreditation is usually submitted to judicial review by the Italian Administrative Court, which often rules in favour of newcomers, and against the region when the region did not complete the reorganisation determining the updated need in the relevant region (TAR Lazio, III quarter, 27 March 2015 No. 4703).

Pharmacies have been traditionally subject to intense restrictions: under the previous Law (see Law No. 362/1991) pharmacies could be owned only by individuals or partnerships and up to a maximum of four pharmacies each. In the past few years, the Italian legislator has been trying to amend that law in order to remove the barriers to the entry of new operators and favour the development of competition. A first attempt was made in 2006, with the introduction of para-pharmacies and the liberalisation of the sale of over-the-counter drugs, formerly reserved to pharmacies only. Secondly, in 2012, the authorised number of pharmacies was increased ‘in order to facilitate access to pharmacy ownership by a wider range of applicants, who have legal requirements, and to facilitate procedures for the opening of new pharmacies, while ensuring a wider presence in the territory of pharmaceutical service’ (see the decisions of Cons. St. Nos. 270/2017 and 2851/2014).

Finally, a new amendment, which is expected to eliminate the surviving restrictions, has recently been adopted.

According to the new Market and Competition Law approved by the Senate on 2 August 2017, to increase the competition in pharmaceutical distribution, the former limit of four pharmacies, as well as the restriction on the ownership by companies, will be cancelled. However, two new restrictions have been added: (1) incompatibility between the exercise of medical professions or any other activity in the field of promotion and manufacturing of medicinal products and the holding in a corporate entity owner of a pharmacy; and (2) the prohibition to control, directly or indirectly, more than 20 per cent of pharmacies located in the same region.

**VII COMMISSIONING AND PROCUREMENT**

The procurement of goods and services by public healthcare structures is subject to Legislative Decree No. 50/2016 (the Public Procurement Code), which implemented Directives 2014/23/EU, 2014/24/EU and 2014/25/EU. Whereas in the past the tenders were usually handled by the single contracting authority, nowadays they tend to gather in bigger contracting entities (at both regional and national level) in order to have more contractual power and obtain lower prices. The new Public Procurement Code allows contracting authorities to conduct independent tenders without using central contracting authorities for supplies with a value of less than €40,000.
One of these entities is Consip SpA, a public company totally owned by the Ministry of Economy and Finance established in 1997 with the duty to implement a programme for the rationalisation of public procurement. To accomplish its task, Consip has put in place several activities over the years, culminating in the implementation of new public procurement procedures and in the use of computer technologies and innovative tools.

Under the Italian Procurement Code, not all the procurements are subject to a tender: the Code provides for specific thresholds, above which the contract is considered relevant and, therefore, subject to public tender; otherwise, the contracting entity can use simplified procurement procedures.

A significant number of disputes brought before the administrative courts every year indicates a malfunctioning system. In this regard, Anac, the national anti-corruption authority, pursuant to Article 36 of the new Public Procurement Code is in charge of issuing guidelines to support contracting entities in defining the detailed measures and improving the quality of procurement procedures. Furthermore, since 2016, Anac is acting as the body responsible for reviewing procedures and can issue new pre-litigation advices, in addition to the traditional judicial remedies, as an optional and ancillary non-judicial remedy.

VIII MARKETING AND PROMOTION OF SERVICES

The issue of advertising by physicians and dentists has been the subject of debate and of several decisions after the entrance into force of Law Decree No. 223/2006 (the ‘Bersani Decree’), which, in compliance with the EU principle of free competition and free circulation of persons and services, abolished all the previous laws and regulations regarding the prohibition for professionals to carry out informative advertising regarding titles, professional specialisation, characteristics of the offered professional services, as well as price and cost of their services. According to Section 2.1 of the Bersani Decree, the limit to such advertising is that ‘it should be in accordance with transparency and truthfulness criteria whose compliance is verified by the Professional Order’. The position of the Professional Orders has been, in general, very strict, with the aim to limit as much as possible the freedom of advertising introduced by the Bersani Decree. The Code of Ethics of the Professional Association of Physicians and Dentists contained several restrictions to advertising, which have been considered in violation of the UE and domestic liberalisation rules and, therefore, sanctioned by the Italian Antitrust Authority. The sanction to the Professional Association has been appealed before

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5 Recently, Consip has concluded a contract worth €36 billion for the supply of needles and syringes, obtaining a discount of the 70 per cent of the original offer.
6 A public tender is mandatory in case the value of the contract is more than:
   a) €5,225 million in case of contracts for public works;
   b) €135,000 in case of contracts for the supply of good and services commissioned by the state (including Consip);
   c) €209,000 in case of contracts for the supply of good and services commissioned by non-state bodies; or
   d) €750,000 in case of contracts for the supply of social and care services.
7 The Guidelines are available at the link: www.anticorruzione.it/portal/public/classic/AttivitaAutorita/ContrattiPubblici/LineeGuida.
8 About the new quasi-judicial role assigned to ANAC in 2016 see F. Aperio Bella, Il nuovo parere precontenzioso vincolante ANAC: la tutela giustiziale nei confronti della pubblica amministrazione tra procedimento e processo, in www.rivistaaic.it, 4/2016.
the administrative courts: the dispute ended in January 2016 with the annulment of the sanction by the Council of State (Judgment 167/2016), but the decision was based on the elapse of the time bar period, not on the merits.

In general, the decisions of the Civil and Administrative Courts regarding disciplinary sanctions applied by the Professional Order to physicians and dentists for allegedly unlawful advertising are in favour of the professionals confirming the liberalisation. The Supreme Court in 2014 (No. 870 of 17 January 2014), with respect to advertising of a dentist, stated that the position of the disciplinary commission of the relevant professional order was not correctly grounded: the sanction can be applied only when the advertising is not transparent or untrue.

IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

What is expected to take place in the future is a review of the payback system introduced in 2013 to control the expense of medicinal products utilised by the hospital structures. The complexity of the rules for calculation of company’s budget and amount of over-expenditure generated several litigations before the administrative courts, and the government still has to recover about €900 million of excess budget.

Developments are expected also from new collaboration between the Italian Drug Agency (AIFA) and the Italian Antitrust Authority (AGCM). Such collaboration was set forth in an agreement executed on 19 January 2017, pursuant to which, inter alia, the two public bodies shall cooperate by exchanging information in case of violation of rules concerning negotiation of prices of medicinal products, counterfeit medicines and illegal distance sale of medicines. The aim is to avoid possible conflicts between the positions of the AIFA and AGCM as occurred in 2014 for the Avastin–Lucentis case, and in 2016 for the price increase of an old oncological medicine owned by the company Aspen.

Furthermore, an increase of recourse to private health insurance is expected and legislation addressed to incentivise such insurance coverage is likely to be issued. Recourse to private insurance for prevention, diagnosis and programmed hospitalisation could significantly reduce the public healthcare costs.

X  CONCLUSIONS

The Italian NHS is considered one of the most efficient health systems in the world because Italy’s population has the third-longest life expectancy (a few months less than Sweden and Japan), despite the fact that its cost over the GDP is generally lower than UK, France and Germany. In 2012, according to Istat data, Italy’s public health expense was 7 per cent of GDP, while Germany spent 8.5 per cent, France spent 8.7 per cent and the UK spent 7.9 per cent. However, the economic crisis caused the concern that the cost of the NHS could no longer be afforded by future generations, and starting in 2012 with the Mario Monti Cabinet, a number of measures to reduce the cost of healthcare have been introduced. In 2016, the total cost of healthcare in Italy was €149.5 billion, equivalent to 8.5 per cent of GDP, of which, 54.9 per cent was used for hospitalisation and rehabilitation, 20.8 per cent for pharmaceutical products and 22.4 per cent for outpatient assistance. Throughout the past few years, reduction measures have been directed to cut the costs of healthcare personnel and medicinal products. The cost cuts regarding personnel were obtained by stopping turnover, thus, the number of healthcare professionals was also cut in emergency and urgent
care structures, with consequent burnout of personnel. This will not be without effect on efficiency and quality of the hospital system, and it is likely to increase malpractice claims. In respect to cuts affecting the expense of medicinal products, the industry is pressing for a reform of payback based on a company’s budget; for innovative and orphan drugs, specific measures, such as dedicated funds, have recently been introduced in order not to deprive patients of new medicinal products, such as hepatitis C drugs. The aim is to change the governance of public health expense by taking into account any innovation that could lead to cost reduction, for example, in terms of reduced hospitalisation of patients.

Finally, it is important to point out that despite the crisis, manufacturing of medicinal products is a sector that is expected to continue to grow: in the past years, industry reached important results with investments by national and international companies. Attention to the pharma sector has also been proven by the significant efforts addressed by the central and local government and by the industry to support Milan as candidate town to host the European Medicines Agency after Brexit.
LITHUANIA

I OVERVIEW

The structure and the main principles of the Lithuanian health system are set in the Law on the Health System. According to this Law, the health system consists of governance institutions (the government, ministries and municipalities, as well as other control bodies), providers of healthcare services, health system resources and services. The health system in Lithuania is predominantly funded by the National Health Insurance Fund (which consists of contributions from employers and employees and from revenue created through state and social insurance activity), and supplemented by state contributions on behalf of those who are economically incapable of contributing. Accordingly, Lithuania provides free state-funded healthcare to all citizens and registered long-term residents. Providers of such healthcare (both state or municipal entities and private ones) shall conclude a contract with the National or Territorial Health Insurance Fund and become a part of Lithuanian National Health System. Purely private healthcare (i.e., based on private medical insurance or payments for the services) is also available in the country.

The Ministry of Health directly controls the national healthcare institutions, as well as being responsible for implementing government policy, licensing healthcare personnel, and keeping the register of medical professionals. The Ministry of Health also establishes the prices for services provided by institutions that are a part of the Lithuanian National Health System. The prices for services provided by institutions that do not belong to the Lithuanian National Health System are established by their management bodies or owners in accordance with the procedure established by the laws of these institutions.

In order to provide healthcare services, institutions and healthcare professionals must obtain healthcare licences from the State Healthcare Accreditation Agency, which are of indeterminate duration.

Healthcare in Lithuania is divided into three levels: (1) primary (healthcare provided by family doctors or their assistants, nurses, obstetricians, or midwives, etc.); (2) secondary; and (3) tertiary. Primary and secondary healthcare services are organised by municipalities, while the Ministry of Health organises the tertiary level of healthcare. Secondary and tertiary level healthcare institutions provide specialised care of two types – outpatient and inpatient care. Unless it is a case of emergency, both secondary and tertiary level healthcare services require that the patient had been issued with a referral by a family practitioner or specialist.

If the healthcare institution is not a part of the Lithuanian National Health System, it is less restricted to the state control as the national inspectorate bodies are able to control

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1 Rūta Pumputienė is the founder of and a partner at Rūta Pumputienė Law Firm.
healthcare institutions that have received funding from the national or municipal budgets. However, not being a part of the National Health System may mean restrictions to the activities that can be performed by such institutions.

II THE HEALTHCARE ECONOMY

i General

Health expenditure as share of GDP fell between 2010 and 2013 from 6.82 per cent to 6.14 per cent, and grew to 6.52 per cent between 2014 and 2015. Just as in the two other Baltic countries – Latvia and Estonia – the healthcare financing system in Lithuania is focused on curative health, which receives 49 per cent of all health spending. In 2015, there were 5.1 hospitals per 100,000 people in Lithuania, compared with 3.4 hospitals in Latvia and 4.2 hospitals in Estonia per 100,000 people. In 2015, there were 430 healthcare institutions of primary level in the National Health System, 260 of which were private institutions and 168 public. The total number of hospital beds per 10,000 of the population in 2015 was 87.9, compared with 55.6 Latvia and 55.6 in Estonia. Compared with 2005, in 2015, the number of physicians’ visits per person increased in Lithuania by almost 30 per cent.

ii The role of health insurance

In Lithuania, like in many other European countries, health insurance is compulsory, which means that residents of Lithuania are obliged to pay compulsory health insurance contributions. The Compulsory Health Insurance Fund (CHIF) is regulated by the Law on Health Insurance and is an autonomous fund separated from the state and municipalities funds. The Ministry of Health implements the state’s health insurance policy and the Compulsory Health Commission (an advisory Ministry of Health body), National Health Insurance Fund and territorial health insurance funds administer the compulsory health insurance.

Those healthcare institutions that have entered into a contract with the National Health Insurance Fund are compensated from the CHIF for the provided healthcare services to insured people. The CHIF also covers expenses of pharmacies for the reimbursed medicinal products, medicinal devices, preventive medicinal programmes, rehabilitation, care and social services, etc. The health insurance system is based on two principles of solidarity and universality. The latter principle means that every citizen of Lithuania and foreign nationals permanently residing in Lithuania, also foreign nationals temporarily residing and legally employed in Lithuania must pay compulsory health insurance contributions and, therefore, are entitled to receive healthcare services that are compensated from the budget of the CHIF. The principle of solidarity means that the insurance contribution ranges depending on the practical abilities of the payer, while the CHIF will guarantee that the healthcare services will be provided regardless of the paid contribution. Therefore, persons who are insured may be divided into two groups: (1) persons who pay compulsory health insurance contributions (by themselves or by their employer), and (2) persons who are insured with state funds (retired

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3 According to data in Health in Baltic Countries 2015.
4 Ibid.
persons, disabled persons, mothers on maternity leave, registered unemployed, minors, etc.).
The Law on Health Insurance states that the supplementary health insurance is also possible
to cover expenses for the healthcare services that are not covered by the CHIF.

### iii Funding and payment for specific services

Lithuanian regulations ensure that all persons who are insured with compulsory health
insurance are provided with free-of-charge healthcare services. The CHIF covers individual
healthcare services provided on the primary, secondary and tertiary levels of healthcare
institutions; covers medical rehabilitation, nursing care and social services; and reimburses
expenses related to medicinal products and medical devices, etc. If the patient is entitled to
free healthcare services, healthcare institutions are not allowed to introduce co-payments
for reimbursed healthcare services, except in cases when a patient personally chooses more
expensive services, materials, or procedures, or if the patient asks for additional services and
agrees to them in writing. In this case, these services will not be reimbursed by the state or
municipal authorities, but rather paid by the patient himself or herself, by a particular legal
person (i.e., employer) or by the supplementary health insurance.

Emergency medical services are provided free of charge to all patients, including
non-residents. The Ministry of Health approves a list of paid healthcare services and prices
for such services. As the public healthcare institutions are non-profit organisations, they are
not allowed to include a profit margin in their pricing.

The institutions that provide primary healthcare services are paid depending on the
number of residents that are registered to the institution – this is the main funding source,
which is also called the base payment. Moreover, these institutions receive extra payments for
the registered residents of rural areas, good healthcare results, and for special services (there
are 13 groups of special services, e.g., low-risk pregnancy care, healthcare for disabled people,
early diagnosis of malignant tumours and child immunoprophylaxis). Since 1 January 2012,
the diagnosis-related groups (DRG)-based reimbursement of healthcare services system
has been used in Lithuania at hospital level. Clinically and economically similar services
are classified into groups. Different reference prices are approved for each group. After
assessment of the patient’s diagnosis, interventions carried out during the treatment episode
and any complications, the healthcare service is assigned to a DRG group. The price paid to
hospitals depends on the DRG group to which the particular service has been assigned. The
costs of expensive examinations and procedures performed during the episode of the active
inpatient treatment are included in the total cost of healthcare service and are not reimbursed
separately. The actual cost of the service increases if expensive blood components, medical
aids or chemotherapy pharmaceuticals are used.

Those healthcare institutions that do not belong the Lithuanian National Health System
provide healthcare services that are paid for by citizens personally. Offices of obstetricians and
gynaecologists are not usually a part of the National Health System.

Furthermore, there are paid healthcare services that are not reimbursed by the CHIF,
even though they are provided by healthcare institutions that belong to the system. The
Minister of Health approves a list of such paid healthcare services and it includes preventive
health examination for those who are going abroad, cosmetic surgeries, and dental prosthetics
and implants.
III PRINCIPAL / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

As mentioned above, healthcare is divided into three levels: (1) primary, (2) secondary and (3) tertiary. The primary level is healthcare services provided by family doctors and other qualified specialists that provide personal, comprehensive care for individuals and provide referral to specialized institutions (secondary and tertiary level healthcare) when needed. The referral from the primary healthcare specialists is a prerequisite for patient to receive free-of-charge healthcare. Without the referral, unless it is an emergency case, the healthcare services would be paid by the patient himself or herself, or a supplementary insurance fund. The patient is free to choose primary healthcare institutions or specialists according to his or her preference, and this also applies to both private and public institutions, although healthcare will be paid only for those services that were provided in an institution that had entered into a contract with the National Health Insurance Fund or territory health insurance funds.

As stated in the Law on the Health System, Lithuania supports the use of an e-health system, which has the following priorities: (1) general access to e-health services for patients and health professionals; (2) cooperation between the healthcare sector participants; (3) general access to the healthcare sector information resources – the Electronic Health Record (EHR), registers and classifications; (4) general access to public administration information resources and e-government services; and (5) the creation of conditions for more efficient, more qualitative and accessible health services via continuous information gathering, data exchange, interoperability and information security. However, the progress of the e-health system coming into use has not been promising. Since the end of 2015, the obligation has been imposed on only 170 of 500 state healthcare institutions who took part in e-health projects to start using certain information systems; for those that did not take part in these projects, the mandatory obligation will begin from 2018.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

The obligation for the institutions that are planning to provide healthcare to obtain a licence for healthcare services is set in the Law on Health Institutions. This law also sets rules on establishing institutions that provide healthcare, both those institutions that belong to the National Health System and those that do not, both private and public. Moreover, this law indicates rights and obligations of the healthcare-providing institutions as well as sets the monitoring body for such institutions. The key body for licensing healthcare institutions and individual professionals is the State Healthcare Accreditation Agency (SHAA). The SHAA is mainly engaged in licensing healthcare providers and professionals (i.e., medical doctors, nurses, midwives and public healthcare specialists, except for dental services) and public health institutions, laboratories and pathology services; it also has a role in the assessment and control of medical devices. Only after receiving a licence from the SHAA can an institution provide healthcare. The rules of the licensing process are set in the Order of the Health Minister No. V-156. (the Licensing Rules). The SHAA also supervises whether the healthcare institutions are providing healthcare services according to the national legislation and whether the terms and conditions of the licence are being complied with.
ii Institutional healthcare providers

As mentioned above, the SHAA is responsible for issuing licences for healthcare institutions in line with the Law on Healthcare Institutions and the Licensing Rules. Under the Licensing Rules, the SHAA can not only issue licences, but also revoke licences (or parts of licences), withhold licences and refuse to issue licences. A licence is issued after 30 calendar days from the submission date. The submission for the licence can also be made via e-registration. When a healthcare institution is applying for the healthcare services licence, it must comply with the requirement of the institutions that are set in the national legislation (such as civil liability insurance for damage to patients, the institutions are in line with hygiene requirements, etc.) and have enough specialists, as well as equipment to provide the healthcare services.

iii Healthcare professionals

Healthcare professionals are also required to obtain a licence from the SHAA to provide healthcare services and be named on the practitioners’ list. After receiving a licence, they can enter into contracts with healthcare institutions that have licences to provide the particular healthcare service that the professional holds the licence for. There are few licence categories for healthcare professionals issued by the SHAA: medical doctors, nurses, midwives and public health specialists. Licences for dentists and oral care specialists are not issued by the SHAA, but by the Lithuanian Dental Chamber.

According to the Law on medical practice regarding the licence of medical doctors, medical doctors are allowed to provide healthcare services only in institutions that also have a licence for healthcare service provision. Therefore, it is illegal for a medical doctor to practise in any other institution, regardless of its legal form, if the institution is not licensed by the SHAA. This principle applies to all healthcare professionals as it is set in the Law on the Health System. According to the Code of Administrative Offences of the Republic of Lithuania, persons illegally engaged in healthcare activities are to receive a fine of between €600 and €1140. Also, there is a provision in the Penal Code that imposes criminal liability on a medical doctor who has the right to perform the abortion procedure, but carries out the procedure outside of a healthcare institution.

V NEGLIGENCE LIABILITY

As mentioned above, institutions willing to provide healthcare services and obtain a licence must be insured with civil liability insurance for the damage caused to patients (both pecuniary and non-pecuniary damage). The law on the Rights of Patients and Compensation for the Damage to their Health sets the mechanism of the health damage compensation. Under this law, a mandatory pre-litigation procedure exists, as the patient who suffered damage due to the fault of the healthcare institution or staff of this institution must firstly refer to the Commission for the establishment of the damage caused to the patients under the Ministry of Health. If the patient does not agree with the decisions made by these institutions, it possible to seek compensation through legal proceedings.

i Overview

As the mandatory pre-litigation procedure exists, not so many cases reach the national courts. The current model of damage compensation means that the patient must prove that he or she suffered damage as a result of fault by the healthcare institution or its staff, therefore, the patient must prove that there are all four mandatory conditions for the responsibility to arise:
negligence or malpractice, damage (pecuniary, non-pecuniary), the fault of the person who has caused the damage and causality between the damage and wrongful actions. The case law in Lithuanian national courts shows that fault of the healthcare professional is presumed and the injured person must prove the other mentioned conditions. According to the case law, the healthcare professional’s mistake when diagnosing an illness or patient’s condition will not be viewed as a negligence if he or she did his or her utmost and what was necessary under particular circumstances. Thus, the burden of proof will be on the patient to prove that the doctor had not done everything he or she could and should have done.

The process of compensation is difficult and it is often criticised by patients and healthcare professionals. The compensations for the injured persons are usually very little and sometimes regarded as inadequate.

ii Notable cases

One of the most famous cases regarding compensation for damage to a patient’s health in Lithuania was in regard to seriously injured newborn twins. Although not so recent, this case is famous for the non-pecuniary damages awarded from the healthcare institution for both parents and twins, which was 500,000 litai (around €145,000), and is still the highest amount of compensation awarded for damage to patients’ health since 2005. The healthcare professionals whose negligence resulted in injuring the newborn twins were included in the case as a third party. The Supreme Court of Lithuania rejected the arguments that as a result of the amount of the compensation the hospital would go bankrupt, as there was no real evidence to indicate this, also the financial state of the subject that caused the damage for the patients cannot be the decisive criterion for the damages awarded. The main criteria for non-pecuniary damages are negligence and the consequences for health and sufferance as a result of such negligence.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

According to the Law on Healthcare Institutions, there may be few legal forms of the public healthcare institution. The public healthcare institution may be: (1) a budgetary institution, (2) an enclosed budgetary institution, or (3) a public non-profit institution. Budgetary institutions include sports medicine centres, addiction centres, centres for infants with developmental delays and the national transplant bureau. Budgetary institutions are owned either by municipalities or the state. Enclosed budgetary institutions are special budget institutions also owned by the state or municipalities, and are used for convicted imprisoned persons, persons with mental illnesses, and officers and cadets. The Ministry of Health establishes enclosed budget institutions. Finally, the public institutions are non-profit healthcare institutions established by the Ministry of Health, municipalities, higher education institutions or educational and scientific institutions altogether with Ministry of Health with the consent of the government. The great majority of healthcare providers are not budgetary institutions but public non-profit institutions.

There are no restrictions on foreigners owning companies. Also, for private healthcare institutions, the same regulation applies as to any other private legal body, in addition to obtaining a licence from the SHAA.
VII COMMISSIONING AND PROCUREMENT

As mentioned above, emergency medical services are provided free of charge to all residents. Secondary and tertiary healthcare services are provided to the insured by compulsory health insurance. To receive healthcare services, a patient should turn to his or her family practitioner first. If the family practitioner decides that it is necessary, then he or she will give a referral to a specialist and that consultation will be covered by CHIF. The admission to the hospital takes place with the referral issued by a family practitioner or specialist. Only in the case of an emergency can a patient go directly to the hospital.

Healthcare services payment procedure is regulated by Personal Healthcare Services’ Payment Order No. V-1113, approved by the Minister of Health. Healthcare institutions that have entered into a contract with the National Health Insurance Fund are paid for providing healthcare services according to approved basic prices of services, which is reimbursed from the CHIF budget.

Since 1 January 2012, the DRG-based reimbursement of healthcare services in the hospital level of the system has been used in Lithuania. Clinically and economically similar services are classified into groups. Different reference prices are approved for each group. After assessment of the patient’s diagnosis, interventions carried out during the treatment episode and any complications, the healthcare service is assigned to a DRG group. The price paid to hospitals depends on the DRG group to which the particular service has been assigned. The costs of expensive examinations and procedures performed during the episode of the active inpatient treatment are included in the total cost of healthcare service and are not reimbursed separately. The actual cost of the service increases if expensive blood components, medical aids or chemotherapy pharmaceuticals are used. As far as medicinal products are concerned in the outpatient sector, the Ministry of Health approves a list of conditions for which medical treatment would be reimbursed by the CHIF. In order for a medicinal product to be reimbursed, it must meet the legal criteria (i.e., requirements for medicinal benefits, pharmaeconomic value, reimbursement impact to the budget). Only then are medicinal products included on the A-list and with the approval of the Ministry of Health included on the Price List of Reimbursable Medicinal Products. The National Health Insurance Fund reimburses the price by paying pharmacies according to the prescriptions. Only a certain compensation level of the base price of the medicinal product is reimbursed (either 100 per cent, 90 per cent, 80 per cent or 50 per cent). With regard to the inpatient sector, there are two possible ways of commissioning medicinal products: (1) the National Health Insurance Fund procures medicinal products through the Central Procurement Organisation (nevertheless, medicinal products still need to be included into the A-list); or (2) the healthcare institutions (hospitals) procure medicinal products through hospital tenders. Inpatient services are fully reimbursed and no co-payments from insured patients are needed. The situation with medical devices is similar, as medical devices are also reimbursed only if they are included on the List of Diseases and Reimbursable Medical Devices for their Treatment (the ‘C-List’) and the Price List.

VIII MARKETING AND PROMOTION OF SERVICES

There is only one particular restriction regarding the advertisement of healthcare services, which is set in the Law on Advertising. It prohibits using a patient’s first name, surname, image, and relying on recommendations of healthcare institutions or professionals. Moreover,
the general rules on advertisement also apply, which prohibit degrading a person’s dignity and honour, inciting hatred and discrimination and promoting behaviour that poses a threat to health, as well as prohibiting misleading advertising.

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

One of the major unresolved issues in Lithuanian healthcare is the implementation and use of e-health. The Lithuanian National Electronic Health System was only launched in 2015. If it becomes fully operational, it may improve the efficiency and quality of healthcare, and make it easier for different institutions to exchange data. The introduction of electronic methods to make the funding process more transparent is also expected.

Lithuania is working to strengthen long-term care. As society ages, and employment rates rise, there will be an increasing demand for long-term care services. With the help of EU funds, Lithuania is putting in place and modernising its long-term care infrastructure (such as day-care centres), establishing new community-based care homes for the elderly and developing the provision of social and nursing care at home. The establishment of an efficient and effective long-term care system will require close coordination between the Ministry of Health and the Ministry of Social Affairs.5

While there are no fiscal sustainability problems in the Lithuanian health system in the medium or long term, Lithuania could support future sustainability by linking expenditure increases to improvements in cost-effectiveness.

However, limited progress has been made in the recent past on improving the performance of the healthcare system. Several challenges remain. The primary care system needs strengthening so that more patients are treated instead of being referred to a specialist, which will also require a change in attitude by patients. Transparency and accountability need to be increased in resource allocation, including financing of capital investment and in the payer–provider relationship. In addition, out-of-pocket payments remain high (in particular, for pharmaceuticals) and could threaten health access for vulnerable groups. Finally, population health, albeit improving, remains a concern, and major progress can be achieved by reducing the burden of amenable and preventable mortality.6

X CONCLUSIONS

Lithuania has a modern state healthcare system, funded by the government through a national health insurance scheme. Like many other European states, Lithuania has put in place the compulsory health insurance system, which means that residents of Lithuania are obliged to obtain health insurance coverage (i.e., pay compulsory health insurance contributions). With respect to the insured, the state guarantees healthcare services compensated by the CHIF. In other words, all employers must register employees to the scheme, and they will then automatically be covered. Disadvantaged groups, such as the elderly and the long-term sick, do not have to contribute, but are still covered by the scheme.

Healthcare, including emergency treatment, is free at the point of delivery, with the standard system of family doctors (GPs) providing referrals for non-urgent cases.

The standard of some local hospitals may still be poor; however, the city hospitals tend to be far better, and the general standard of healthcare facilities in Lithuania is improving as the government prioritises funding for health. Naturally, the private healthcare facilities, especially those aimed at the medical tourist market, are even better.

Public financing of the health sector has gradually increased since 2013 to 6.14 per cent, and grew in 2014–2015 to 6.51 per cent; however, this number is still one of the lowest in the EU, and the future government’s plans in public health spending is a cause for concern. Many challenges remain ahead.
Chapter 9

MEXICO

José Alberto Campos-Vargas¹

I OVERVIEW

Mexico has a population of approximately 110 million individuals, 75 per cent of which may be considered as urban population, and whose life expectancy has increased from 34 years in 1930 to 76 years in 2016.

This fact, among others, leads to specific risks and health requirements prevalent in urban populations, which are subject to non-transmittable sicknesses, maladies and accidents, rather than infectious and undernourishment maladies that are more common to rural communities, which have less access to basic infrastructure and services.

This situation means a great challenge to the Mexican government in terms of rendering and regulating health services for an older population.

The Mexican government has acknowledged in several official documents the relevance of health as a fundamental human right and the obligation of the state to provide extensive healthcare to all individuals in the country – a situation that is, in reality, far from the official position of the authorities.

The Mexican Federal Constitution (the Constitution) establishes health as a fundamental right and provides the basis for the government to enact provisions regarding, inter alia, health services and medical attention.

The main law regulating these matters is the Mexican General Health Law (the Health Law) and its diverse Regulations, which establish health services as a matter of public policy and interest subject to sanitary control.

Under these provisions, the authorities in charge of health and medical-related services include the President of Mexico, the General Health Board, the Ministry of Health (MH) and state governments, among others.

The MH, through the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), has the broadest jurisdiction regarding the control and supervision of these services and activities.

The Constitution also provides the Executive Branch with the authority to issue regulations that clarify or specify the content of existing laws passed before Congress, which in the specific case of health-related services include the Regulations For Medical Services Rendering (the Services Regulations), the Regulations in Health Research Matters and the Regulations in Publicity Matters (the Publicity Regulations), as well as those provisions

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governing the National Institute of Social Security (IMSS), the Social Security Institute for Governmental Employees (ISSSTE), the Public Administration Organic Law and a considerable number of other legal provisions.

In addition, medical and health-related services are also subject to Mexican Official Standards (NOMs), which are administrative guidelines establishing technical specifications and characteristics, among other requirements applicable to the premises, systems, activities, methods, etc.

Provisions governing these services also include official communications and guidelines issued by the health authorities, which may or may not be published in the Federal Official Gazette.

II THE HEALTHCARE ECONOMY

i General

Health services can be classified into two main sectors: public and private.

Within the public sector, the most relevant health institutions are IMSS and ISSSTE, together with the Mexican Armed Forces (SEDENA) and the Navy (SEMAR) medical services and facilities, the MH hospitals and clinics, and local state authorities.

The private sector includes hospitals and clinics, independent services providers, private and independent medical personnel and health professionals, and to some extent, insurance companies.

The population groups entitled to medical and health services may be divided into three main groups:

a formally employed workers and their families;
b self-employed individuals, private practitioners, informal employees, unemployed individuals and other individuals not considered as part of the formal employment group subject to social security; and
c individuals choosing to use independent health services.

The first group, whether belonging to the public or private sector, are entitled to social security services. These services currently cover a considerable percentage of the Mexican population.

The second group has traditionally been dependent on health services directly provided by the MH on a public assistance and welfare basis, as well as services rendered under the Popular Insurance Programme (PIP). The latter is a programme developed to render health services for specific maladies to those who are not part of the first group.

The last group will normally use private medical insurance and health services through direct payment, without depending on the state’s social security structures.

ii The role of health insurance

Insurance is compulsory to users of healthcare services who are employees, since employees, together with their employers, must contribute certain amounts to the public institutions that render health services (IMSS or the National Workers Housing Fund Institute (INFONAVIT)).

Health services generally provided by the IMSS and INFONAVIT include:

a health and maternity insurance;
b work risk insurance;
c retirement and old age insurance;
Individuals not considered as ‘workers’ for purposes of compulsory insurance may voluntarily request an affiliation to the IMSS that may provide them with part of health and maternity insurance.

Individuals not enrolled in the above institutions may be subject to the PIP, which provides only specific health-related services (including some surgical procedures) and the corresponding drugs and medicines required by patients.

The part of the population not covered by any of the above programmes or medical protection may receive some health services from federal or local agencies, however, these are mainly emergency and basic services.

In case of individuals covered by private insurance, they will be subject to the benefits and coverage contracted and agreed with the insurance company, which may be considerably diverse and varied.

iii Funding and payment for specific services

Health services rendered by the above institutions are financed through the ‘social security contributions’ paid by the employer and the employee.

In case of individuals covered by ISSSTE, SEDENA and SEMAR, the employer would be the government itself, whereas in case of private individuals and entities having workers, part of the contribution is paid by the employer and part by the employee.

Other health services may be funded by direct budget from the federal or local governments and through payment of ‘fees’ collected from the users of such services.

In case of private parties rendering these services, funding is obtained either through direct charging of services or through payment by insurance companies in the percentages and based on the coverage agreed with the health services user.

Public health coverage does not include any and all kinds of procedures, but rather, only those concepts formally considered within the specific coverage of such institutions. Concepts such as ‘wellness’ and ‘alternative health therapies’ are outside the scope of the services rendered by these institutions. Although these concepts are not formally forbidden, in most cases, they are not recognised, nor do they receive public approval or coverage.

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

In Mexico, there are approximately 25,000 premises registered to provide health services, of which, approximately 4,500 are hospitals (1,200 corresponding to public institutions and 3,200 to the private sector).

Access to health services in private hospitals and institutions is subject to the contractual obligations established by the parties giving and receiving such services, with the competent governmental agencies only responsible for regulating the premises, and the characteristics and quality of the services.

Exceptions to the above may be made in very rare cases of disaster situations or medical emergencies. However, such situations must be formally established by the governmental entities.

In case of public health institutions, receiving the necessary health services may be a cumbersome and time-consuming process.
Except for the SEDENA and SEMAR services, most public agencies require preliminary medical review at the hospital or clinic corresponding to such individual’s registered domicile.

Based on such prior review, a general doctor will determine whether the patient requires further analysis by a specialist, or specific analysis and procedures, or whether he or she can provide the applicable treatment and medicines.

If necessary, the patient will be required to schedule the visits to the specialist doctors as well as the laboratory or analysis procedures needed, which may take up to a couple of months to complete.

This system may be extremely inefficient and time-consuming, resulting in an untimely rendering of the required treatment and medicines, which ultimately has a direct impact on the patient’s health, however, owing to the lack of proper infrastructure and equipment, it is not possible to render the required services in all health premises operated by public institutions, being in cases necessary for the patient to receive such specialist services in premises located in other states or even only in Mexico City.

Public institutions professionals are restricted in the scope of their activities by three main legal bodies, which are: the Health Law, the Services Regulations and the Professional Practice Law. However, these are also further clarified through internal regulations, procedures and structures implemented by each specific institution.

It should be noted that public and private health institutions are heavily regulated, by being only authorised to carry out the specific services and procedures included in the corresponding licences and authorisations, thus not being possible, for example, to carry out clinical analysis at premises lacking the specific authorisation.

These authorisations and licences depend on the available infrastructure and certification of processes formally requested before COFEPRIS or other competent authorities.

Among the relevant regulated activities are nursing services, general medical services, surgery procedures, medical procedures involving radiation sources, health services entailing investigation, psychiatric-related services, dental services, medical consultation, laboratory and medical samples, and organ and tissue preservation.

The specific technical requirements and conditions for the rendering of these services are generally set forth in NOMs rather than in Laws or Regulations, and may be of a very varied nature.

In case of clinical records and information obtained during the course of these services, special provisions exist – the same that are included in NOM-004-SSA3-2012 – which are subject to particular provisions regarding confidentiality and privacy protection provisions, many of which, in practice, are unlikely to be enforced by virtue of the lack of the necessary infrastructure.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

The federal government, through the MH and COFEPRIS, is in charge of the implementation, coordination, verification and control of all human health-related matters.

Among the MH activities is strategic planning of the health services, health priorities determination, coordination with different governmental bodies, health attention regulation and supervision, and evaluation of services, programmes, policies and systems, etc.
COFEPRIS is the specific authority in charge of regulating and controlling any sanitary or health risks, including those related to premises, services, activities, tissue disposal, organ transplants, etc., as well as issuing the necessary licences, authorisations or certifications required for rendering health-related services.

In certain cases, these authorisation or certification activities may be executed together with other governmental bodies, non-governmental organisations, educative institutions and civil organisations, etc.

These services regulation include mechanisms and structures to certify education centres imparting medical, nursing, therapy, rehabilitation and other health-related education.

Certification of health professionals is controlled by the education institutions providing this knowledge, as well as the Public Education Ministry through its General Professional Practices Directorate.

As a general rule, health professionals must have a degree issued by a recognised education centre, and a federal professional practice licence issued by the Directorate. Additional certifications may be issued by specialised organisations coordinated by the National Academy of Medicine and the Mexican Surgery Academy.

Most of the approximately 80 medical schools in Mexico are associated with the National Association of Medicine Universities and Schools, and around half of them are recognised by the Mexican Counsel for Medical Education Certification, institutions that, although not authorities by themselves, are recognised as institutions that may validly certify the quality of medical education.

Likewise, nursing and related practices certification is in charge of the Mexican Counsel for the Certification of Infirmary.

In case of institutions, the operating licences and authorisations are governed by COFEPRIS based on the specific provisions of the Health Law and applicable NOMs.

Premises certification and authorisation will require the due compliance with technical and formal requirements established by NOMs and the internal criteria and requirements set forth by COFEPRIS.

ii Institutional healthcare providers

Under Article 34 of the Health Law, rendering of health-related services requires a licence or authorisation depending on the type of services rendered or premises operated. In other cases, such as private practice and consultation premises, it is only necessary to file a premises operation notice.

Generally, formal licences and authorisations are required for premises where some sort of technical activity is rendered, for example, analysis laboratories, rehabilitation centres, premises where surgical procedures are rendered and premises where x-ray or similar technologies are operated.

Possibly some of the most complex authorisations and heavily regulated services are those related to cosmetic and other kinds of procedures not necessarily related with maladies or sicknesses, but that represent a clear health risk for individuals receiving these services.

Although the authorisation and licensing processes for specific premises operation are apparently straightforward and clear, in practice, a considerable number of issues are left to the governmental official criteria, a situation that may practically complicate securing the necessary licences and authorisations, as well as raising the possibility of corruption acts.
The general rule is that these licences and authorisations may be secured through the filing of the corresponding application, payment of federal (or local) governmental fees and evidence of due compliance with the technical and formal requirements, together with possible inspections and on-site visits.

Licences and authorisations may be revoked or suspended by the health authorities in case the corresponding requirements cease to be met during the course of the operation of such premises or it is determined that the operation of such premises may represent a sanitary risk for the population.

These revocation or suspension procedures are subject in all cases to the formal requirements for verification procedures set forth by the Health Law and its Regulations, and Federal Law on Administrative Procedures, which in essence implies the formal serving of a notice stating the review, scope of the review, authorised officials, preliminary determinations, preliminary arguments and evidence in charge of the visited party and a final resolution by the authority.

Any party affected by an unfavourable resolution issued by the competent health authorities may file, as a general rule, an administrative appeal before the same authority that carries out the determination or a nullity petition before the Administrative Justice Court. In very specific cases involving direct constitutional provisions, it is possible to file a constitutional remedy or *amparo* petition.

These alternatives present specific challenges and requirements and their filing will greatly depend on the nature of the resolution, imposition of fines and penalties, and particular issues of the resolution.

Lack of securing the applicable licence or authorisation or filing the corresponding notices may, under the Health Law Articles 373, 375, 419, 420, et al, derive fines and penalties ranging from temporary and definitive closure of premises and fines ranging from approximately US$8,000 to US$25,000.

In some cases, operation and providing services without the proper or required licences and authorisations may also represent a criminal offence subject to criminal procedures under the Federal Criminal Code.

### Healthcare professionals

Health and medical professionals’ authorisation and licensing are subject, in principle, to the issuance of the corresponding degrees or titles by duly authorised education institutions or third parties recognised by the MH and COFEPRIS as entitled to certificate professional capability in health-related matters.

Under Article 79 of the Health Law, exercise of professional activities related to medicine, dentistry, biology, bacteriology, infirmary, social work, chemistry, psychology, nutrition, pathology and other related professions require a degree recognised by the education authorities and duly registered with the latter when health or medical-related activities are carried out by such individuals.

In this same connection, technical and auxiliary activities that require specific knowledge related to medical attention, dentistry, clinical laboratory, infirmary, physical therapy and rehabilitation, prosthesis, orthopedics, biostatistics, pharmacist, etc., require a degree issued by a recognised institution.

Individuals carrying out these activities without the proper certifications or degrees may be subject to fines and imprisonment under Article 250 of the Federal Criminal Code.
Under the Mexican statute, it is not necessary that these individuals have professional or malpractice insurance. However, based on recent developments regarding damages arising from negligence and malpractice, this kind of insurance is being more commonly implemented and contracted.

Some healthcare-related services may be carried out by non-professional individuals, on the general condition that they do not appear or present themselves as being professionals. In addition, some specific exceptions are applicable, as could be traditional medicine and similar practices.

V NEGLIGENCE LIABILITY

i Overview
Under Mexican law, there is no specific procedure or system for the compensation of possible injuries or damage arising from the improper or incorrect medical services and procedures. Individuals affected or harmed by a medical procedure or service may file a lawsuit (ordinary civil procedure) to request the compensation of damages.

Until recently, only direct damages could be requested, however, recent jurisprudential criteria have opened the possibility for affected parties to file for punitive and consequential damages, as well as moral damages arising from medical negligence and malpractice.

In 1996, the National Commission for Medical Arbitration was created, whose main purpose is to solve in an amicable manner controversies between medical services suppliers and patients in an instance prior to judicial procedures. However, from a practical perspective this instance is generally ignored or non-efficient to achieve such agreements.

From a criminal perspective, medical negligence may derive in diverse criminal offences, ranging from physical harm all the way to murder.

ii Notable cases
Because of social media and technology, a significant number of cases regarding medical negligence and malpractice in public health institutions have recently been brought to public attention, and have been analysed by institutions responsible for protecting human rights through the applicable mechanisms (the Federal and Local Human Rights Ombudsman).

These cases include the denial of services for childbirth to individuals not formally registered with IMSS or other institutions, the denial of health services to the indigenous population or poor or homeless individuals, incorrect limb amputations, incorrect organ removal and violation of privacy of patients through exposure on social networks.

Although health professionals involved in these situations have argued that in most cases there is no malpractice or negligence, the fact is that there is a greater awareness of these situations and a greater interest by the public and diverse governmental institutions to better control or even eradicate and provide assurances of non-repetition and satisfaction in these situations.

Although these situations have been politicised, in most cases it has been determined that there exists an authentic malpractice or negligence by many health professionals in public institutions.

Likewise, there exists a trend that actually permits punitive and moral damages to be granted to the victims of these situations, as well as direct punishment of the individuals carrying out such malpractice or negligence, together with the institution.
On the other hand, doctors and other health professionals have carried out a series of demonstrations and complaints regarding the poor or limited technical and logistics situation prevailing in several governmental health institutions, including lack of personnel and equipment, lack of formal processes, political involvement in health services matters, lack of opportunities, and extremely low wages and salaries.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

Ownership of a healthcare business is not restricted to a specific kind of legal entity or individuals holding determined degrees or similar qualifications, nationality, financial viability, etc.

The ownership of the business itself is not restricted or regulated, however, as above, the technical characteristics and conditions of the premises where services are rendered, as well as the technical qualifications of the individuals rendering the services, are subject to certain conditions and requirements.

It should even be noted that the possibility exists for health professionals holding titles and degrees in other countries to render these services in Mexico, a situation that may more often be seen in cases of, for example, cosmetic procedures, with 'medical tourism’ a booming industry in some parts of the country.

VII COMMISSIONING AND PROCUREMENT

Procurement of health services is generally carried out by governmental entities rendering the services directly or indirectly. The procurement and, when it occurs, the bidding procedure are carried out directly by the entity or institution requiring the services.

These processes may be on a federal, local or, in some cases, municipal basis, the most relevant provisions being those included in the Federal Law on Acquisitions, Leasing and Services of the Public Sector.

Under this Law, participants in a public procurement or bidding procedure will require to file a technical and an economic proposal that will be analysed and, as the case may be, awarded.

Under this Law, kinds of public procurement may be diverse, including national and international goods and services procurement procedures.

In some very isolated cases there may be restricted procedures of three or more specific suppliers, however, the requesting entity must duly evidence the need for such limited number of participants.

Finally, in some specific cases, among which are national security and emergency, the governmental agencies may carry out a direct assignment of the services procurement.

It is worth noting that in case of national services procurement processes, legal entities resident in countries with which Mexico has entered into a free trade agreement may participate and be considered as a domestic supplier, if the corresponding agreement has specific clauses in this regard.

Likewise, it is possible that as of the entry into force of the new national anti-corruption system and provisions (June 2017) new requirements in this regard will be included in the clauses and conditions for public procurements and biddings.
This will be particularly sensitive to entities rendering services to public health institutions in Mexico as a result of the amount of services required and the necessary controls for this type of services rendering that, in practice, may be required.

VIII  MARKETING AND PROMOTION OF SERVICES

The rules regulating the advertising of health-related services are far less restrictive than those regulating the advertising of pharmaceutical products and medical devices, however, this marketing and promotion must meet specific requirements and controls established in the Publicity Regulations.

The concept of ‘publicity’ for health-related matters included in the above Regulations is defined as any activity that includes all creation, planning, playing and broadcasting processes of advertisements in communications media with the purpose of promoting the sale or consumption of products or services.

Under the Health Law, there is a difference between publicity intended for health professionals and for the public at large.

The first refers to information regarding characteristics of services, procedures and scientific information used for publicity or promotional purposes but restricted to specialised media given to health professionals.

The second is more restrictive and, in general, requires specific licences and authorisations prior to the actual broadcasting or publication of such publicity.

Although the existing provisions are specifically applicable to goods and products rather than services, the general principles regarding the availability of scientific information and hard data sustaining the claims included in this publicity are applicable to that related to services as well.

Because of obesity currently being a major health concern in Mexico, particular attention is paid by the health authorities to services related to aesthetic procedures, reduction of body size, amendments or modifications to body parts and cosmetic surgery.

IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

Health is a major concern for the Mexican government, and not only because of the number of individuals in the country and costs associated with it.

Owing to the lack of the necessary human and economic resources, the Mexican government has implemented diverse programmes intended to provide the greatest possible number of services to the greatest amount of the population under the most cost-efficient structures.

A considerable number of the challenges faced by health services will greatly depend on the existence of the necessary funding and efficient expense by the authorities’ reason why new technologies have been implemented and recognised by the authorities from a legal or practical perspective.

Many of these have as a main purpose the possibility of rendering services to the most isolated and poorest communities in the country. In connection with this, we expect new procedures and use of technology to be recognised by the authorities as well as regulated (for good or bad) in the short term.
The use of many of these technologies is part of the ‘National Digital Strategy’ implemented by the Executive Branch since 2014, which intends to have more agile procedures through the use of technology and remote access.

For instance, COFEPRIS has developed various online projects that will allegedly permit up to one-third of the different procedures followed before them to be electronically filed rather than under traditional formal written procedures. Because of the nature of the information that some of these procedures require, special attention has been provided to the data privacy and security of these systems by the competent authorities.

One of the most relevant issues for 2017 is the potential implementation of new provisions regulating telemedicine services. Under the Health Law and specific NOMs, health service providers may use ‘Practical Clinical Guides and electronic media’ to support their activities.

This has permitted the issuance of a NOM draft to regulate health services through electronic media, and including topics such as data protection and confidentiality, professional liability of health service providers; however, very relevant issues such as specific requirements for online medical advice at premises having no physical presence of health professionals (home, offices, etc.) or international services have not yet been considered.

The main purpose of these provisions is to support complete and economic health coverage, particularly to isolated communities and high-poverty areas.

As a consequence of the aforementioned new anti-corruption laws, the business structures implemented by most companies engaged in governmental sales and services rendering will require substantive review and the implementation of new mechanisms. Since a considerable number of services may be outsourced or procured from private entities, this will be of particular relevance to the health services industry, especially when providing services directly or indirectly to governmental entities or other entities subject to these kinds of controls.

On the other hand, one of the most relevant issues in connection with health in Mexico is the epidemic of obesity affecting the population, and particularly the urban and child population.

In accordance with the OECD ‘Fit Not Fat’ publication, Mexico is the member with the second-greatest number of obese individuals. Three out of 10 individuals are considered obese, and almost seven out of 10 are overweight, with one out of three children in the country being either obese or overweight.

Diabetes is one of the most common and direct consequences of obesity, and has a constant and very fast growth in Mexico, representing one of the largest health costs for the Mexican authorities. Close to 10 per cent of the Mexican population has some degree of diabetes, one of the greatest percentages in OECD countries.

According to the MH data, in 2013, 55,992 people died from type-2 diabetes, and during the same period, 148,681 died from cardiovascular diseases. The above developments are a consequence of concerns regarding obesity, lack of access and inequality, among others, and aim at improving the health of the population through improvements in the regulation of the health services industry. This is possibly the greatest challenge in health matters for the authorities during the years to come.

In connection with infectious disease and maladies, the most urgent threats according to the Pan American Health Organization are infectious diseases such as dengue and zika, which are still present in Mexico because of its geography, vast regions for mosquito reproduction, lack of health services and absence of preventive actions.
During 2016, 19,510 cases of dengue, followed by 19 deaths, were confirmed, and in the case of zika, of particular concern has been the risks for pregnant women owing to the possibility of microcephaly in babies. The number of pregnant women formally registered as having this malady during 2016 was 3669.

The reported number of chikungunya cases was 722 during 2016, according to Pan American Health Organization.

Mexico has, in accordance with the OECD, a significant inequality and lack of access to the health system, which together with inadequate preventive actions has led to the lowest life expectancy of all OECD countries.

X CONCLUSIONS

Health is one of the most relevant human rights contemplated in the Mexican legal statute and is a very relevant cost and matter of public policy for the government to consider.

From a strict legal perspective, a very detailed and robust regulatory regime has been implemented in connection with the rendering of services that may affect health and well-being in any manner; however, from a practical perspective, very relevant constraints exist for the authorities in relation to the human and monetary resources required to correctly implement and enforce these provisions.

Corruption is a major issue when dealing with authorisations, licences and similar issues in connection with health services because of the position of the authorities, and in many cases, the lack of public information regarding the position or rules of application of the applicable provisions by the authorities.

Obesity and diabetes represent some of the most relevant health concerns and thus are a primary focus of the Mexican health authorities from the direct and indirect perspective. Services and processes related with these maladies tend to be particularly focused on by the authorities, although with a more punitive perspective than a preventive perspective.

The formal authorisation of certain substances, such as THC and plant derivatives, to be used as recognised medicines or legal drugs will probably represent an important challenge for the authorities in connection with their therapeutic use and rendering of services related to the use of such products.
I OVERVIEW

The New Zealand healthcare system has undergone significant changes over recent decades. The market, insurance and regulatory reforms have resulted in a healthcare system that is truly unique internationally.

Perhaps the most unique aspect of the system is the no-fault compensation scheme for personal injury caused by accident – overseen and run by the Accident Compensation Corporation (ACC). In exchange for no-fault national insurance cover, the right to sue for compensatory damages for personal injury – including injury caused in the provision of health services – has been removed. In the absence of clinical negligence litigation, a number of other regulatory processes have emerged.

New Zealand spends around 9.5 per cent of GDP on its public health system. The public system is overseen by the Ministry of Health – with the funding and provision of services largely devolved to 20 District Health Boards (DHBs) responsible for the services in their districts. The publicly funded system is supplemented by a well-established private health sector – funded by private health insurers, state funders (DHBs and ACC) and private paying patients.

There will be a general election in New Zealand in 2017. It is not anticipated that there will be significant structural change – regardless of whether the new government is formed by the incumbent National Party or the centre-left Labour Party.

II THE HEALTHCARE ECONOMY

i General

New Zealand’s healthcare system is fundamentally a centrally funded, tax-based system, with the large majority of healthcare being publicly funded (i.e., free or subsidised). Publicly funded services are available to all ‘eligible persons’ (which includes New Zealand citizens, certain types of permanent residents and people on work permits) and include hospital care, primary care, maternity services, community mental health services and a range of other health and disability services.

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1 Jonathan Coates is a partner, Aisling Weir is a consultant and Catey Boyce is a solicitor at Claro.
2 Ron Paterson ‘Regulation of Health Care’ in Peter Skegg & Ron Paterson (eds) Health Law In New Zealand (Thomson Reuters, Wellington, 2015) at [1.2.1(1)].
3 See Ministry of Health’s Health and Disability Services Eligibility Direction 2011, which describes the groups of people who are eligible for publicly funded health and disability services in New Zealand.
New Zealand also has a well-established network of private health providers ranging from major surgical hospitals to private cancer-treatment facilities, small one-person providers and aged care facilities. In most geographical areas, patients have a choice of accessing publicly funded or privately funded services (or a mixture of both). Healthcare services provided by private providers are paid for in a number of ways, including by health insurers, the patients themselves and, in some cases, by public funders.

ii The role of health insurance
Central to New Zealand’s healthcare economy is the state-run ACC, which provides comprehensive, ‘no-fault’ personal injury insurance cover for people who are injured in New Zealand. The ACC is the sole and compulsory provider of accident insurance cover in New Zealand and is funded mainly by mandatory levies.

Private health insurance is not mandated under New Zealand legislation. Currently, around 35 per cent of adults and 28 per cent of children have private health insurance.4

iii Funding and payment for specific services
The New Zealand Public Health and Disability Act 2000 (the NZPHD Act) provides the legislative framework for the public funding and provision of healthcare services. Under the NZPHD Act, most public funding is devolved to 20 DHBs, which are publicly owned statutory organisations responsible for providing or funding healthcare services in their geographical areas. Each DHB operates at least one public hospital and funds the majority of public healthcare services within its district.

Apart from services provided by DHBs, some ‘nationally important’ services are funded directly by the Ministry of Health (for example, some screening programmes, mental health services, elective services and primary maternity services).

The range of publicly funded services that are fully or partially funded is fairly comprehensive. The government subsidises primary healthcare services (discussed below) and dental care for children up to 18 years. Inpatient and outpatient public hospital care is provided free of charge, with prioritisation used to manage demand for elective services.5 In some cases, alternative health therapies are eligible for government subsidies (for example, the ACC may subsidise the costs of acupuncture provided to treat personal injuries). Means-tested subsidies are available for elderly people in long-term residential care facilities. The government also subsidises pharmaceuticals included in the New Zealand Pharmaceutical Schedule.6 Pharmaceutical Schedule items are free for inpatients and provided at a capped price when prescribed and purchased in the community (although items prescribed for children under six years old are free).

Services that are not subsidised include optometry, orthodontics and most adult dental care.

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5 Paterson, see footnote 2, at [1.2.1(2)].
6 See the NZPHD Act, Section 48(a).
Since the release of New Zealand’s Primary Healthcare Strategy in 2001, essential primary healthcare services have been coordinated through not-for-profit bodies called primary health organisations (PHOs). PHOs receive capitated funding from DHBs, and work with general practices and other contracted providers to provide comprehensive primary healthcare services for their enrolled populations. Although patients are not required to enrol with a PHO, and providers are not required to affiliate with a PHO, there is a strong incentive to do so in order to access government funding.

Another key player is the ‘third sector’, which refers to the non-profit, non-governmental organisations that offer primary healthcare, community-based health services and disability support services (many of which are fully or partially publicly funded).

In terms of patient care pathways, unwell people will usually seek advice from community pharmacists or contact their GP in the first instance. In emergencies or after hours, people may visit an emergency department at their local public hospital (where services are generally free) or an after-hours clinic (where services attract a fee).

Generally, referrals from GPs are required in order for a patient to be seen by a specialist working in a publicly funded hospital or, alternatively, patients can choose to see a specialist working privately and pay for the appointment themselves (or through insurance). The patient may then be re-referred to the public system or continue to be treated privately by the specialist. Although this system is largely governed by a contractual rather than legislative framework, New Zealand’s Code of Health and Disability Services Consumer’s Rights and human rights legislation have been interpreted to support rights to fair and efficient systems for handling patient referrals (particularly by DHBs), appropriate coordination of care between primary and secondary or tertiary providers, and to information about the availability of, and waiting times for, publicly funded healthcare.

To ensure continuity of care between primary, secondary and tertiary healthcare providers, New Zealand’s data protection laws do not restrict the appropriate sharing or disclosure of patient information (although they generally require providers to inform patients of such sharing or disclosures and to take reasonable security safeguards to protect health information from loss and unauthorised access, use, modification or disclosure).

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7 Currently there are 32 PHOs in New Zealand, which vary widely in size and structure. The Ministry of Health’s website reports on quarterly progress towards achieving agreed primary care health targets for each PHO.
8 As above, the New Zealand government provides subsidies to lower the cost of general practice visits for people enrolled in a PHO. Patients can only be enrolled in one PHO at a time, and the practice in which the patient is enrolled will receive funding for that patient. Since PHO subsidies do not usually cover the full cost of delivering care, general practitioners (who operate private businesses) often charge a patient co-payment. Higher fees are charged for casual patients (which are patients who visit the practice who are not enrolled).
9 The Code of Health and Disability Services Consumers’ Rights is a legally binding set of regulations issued under the Health and Disability Commissioner Act 1994. It grants a number of rights to all consumers of health and disability services in New Zealand, and places corresponding obligations on providers of those services.
10 For example, the Human Rights Act 1993 prohibits discrimination in the provision of health services on the basis of a prohibited ground (such as age or disability).
11 This legislation is predominantly comprised of the Privacy Act 1993, the Health Information Privacy Code 1994 and parts of the Health Act 1956.
New Zealand does not currently have a single, unified approach to electronic health records for patients. Instead, a range of patient management systems and electronic health records programmes and information technology systems are used by healthcare providers and within DHBs, and many still maintain hard copy records alongside electronic patient records. One of the central aims of the Ministry of Health in recent years has been to improve access to patients’ health information and to support the coordinated development of IT capabilities across the health sector, and an indicative business case for the use of a single electronic health record for all patients in New Zealand is expected to be completed by the Ministry in 2017.12

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Overview
The safety and quality of health services in New Zealand, including who may offer such services, is regulated by various sector-specific statutes and regulations, notably the Health and Disability Services (Safety) Act 2001 (HDSS Act); the Health Practitioners Competence Assurance Act 2003 (HPCA Act); and the Health and Disability Commissioner Act 1994 (HDC Act).

ii Regulators
The Ministry of Health plays a central role in administering, implementing and enforcing legislation and regulations relevant to the healthcare sector, including administering public health legislation, overseeing the performance of DHBs, certifying some types of healthcare providers and regulating the licensing of pharmacies.

Individual health professionals are largely regulated by 16 statutorily independent ‘responsible authorities’ (RAs) appointed under the HPCA Act. The powers and functions of RAs include prescribing the qualifications necessary for scopes of practice for each regulated profession, maintaining a register of practitioners, conducting competence reviews and quality assurance activities in relation to registered practitioners, and (through independent committees) investigating complaints about conduct.

Other key regulators include the Health and Disability Commissioner, a statutory ombudsman appointed under the HDC Act to assess and investigate complaints about healthcare services; and the Privacy Commissioner, appointed under the Privacy Act 1993 to investigate complaints about breaches of privacy (including in relation to health information).

The responsibility for professional discipline sits with the Health Practitioners Disciplinary Tribunal. The Tribunal hears charges of professional misconduct and other disciplinary matters and has the power to suspend or cancel a health practitioner’s registration.

iii Institutional healthcare providers
Some, but not all, healthcare providers are covered by specific licensing or approval regimes.

12 A number of other initiatives to use technology to deliver better health outcomes for New Zealanders are included in the Ministry of Health’s ‘Digital Health 2020’ strategy, which sets out the key strategic digital investments that are expected to occur across the health and disability sector in New Zealand in the next three to five years.
Under the HDSS Act, providers of hospital care, rest home care, residential disability care and fertility services must be certified by the Ministry of Health.\textsuperscript{13} In order to gain (and retain) certification, these providers must meet relevant service standards and are audited for compliance.\textsuperscript{14} If the provider does not meet the requisite standards, their certification may be cancelled or a cessation or closure order issued.\textsuperscript{15}

Pharmacies are required to be licensed under the Medicines Act 1981 and there are restrictions on who can hold a licence to own and operate a pharmacy – although this may soon change.\textsuperscript{16} A licensing regime also governs providers that use ionising radiation for medical purposes.\textsuperscript{17}

All healthcare providers are regulated by the HDC Act and associated regulations – most notably the Code of Health and Disability Services Consumers’ Rights (Code of Rights). Under the Code of Rights, healthcare providers have a legal duty to provide services that are safe and of an appropriate standard, and that duty means that providers are required to ensure that all people, including medical specialists, who undertake work at the healthcare provider’s premises are qualified, safe and competent to do so. This is achieved, in a large part, through internal credentialing processes that are designed to ensure medical specialists are safe to perform their clinical responsibilities within a designated service environment.

\textbf{iv \quad Healthcare professionals}

New Zealand regulates most healthcare professionals by way of a certification regime under the HPCA Act. In effect, any healthcare professional who wishes to provide services using one of a specified list of titles must be registered under the HPCA Act with the relevant RA. Those titles include ‘medical practitioner’, ‘nurse’, ‘midwife’, ‘dentist’ and ‘pharmacist’. However, registration under the HPCA Act is not a prerequisite to providing healthcare services in New Zealand, as individuals who are not certified can offer services in competition with certified professionals, provided they use a different title.\textsuperscript{18} With the exception of a few ‘restricted’ clinical interventions, there are no overarching prohibitions on non-registered health professionals providing healthcare services in New Zealand;\textsuperscript{19} although even non-registered health professionals will need to comply with the HDC Act and the Code of Rights.

\textsuperscript{13} A provider who provides these services while not certified commits an offence under the HDSS Act, and may be liable for a fine of up to NZ$50,000. See HDSS Act, Sections 9 and 54. In relation to fertility services, Section 80 of the Human Assisted Reproductive Technology Act 2004 deems fertility services to be ‘specified health and disability services’ for the purposes of the HDSS Act.

\textsuperscript{14} See the Health and Disability Services (Safety) Standards Notice 2008 and the Health and Disability Services (Safety) Standards Notice 2010.

\textsuperscript{15} HDSS Act 2001, Sections 48 and 49.

\textsuperscript{16} A new therapeutic products regime has been proposed to replace the Medicines Act 1981, and is expected to remove pharmacy ownership restrictions and replace them with appropriate licensing requirements. As at July 2017, consultation on an Exposure Draft of the Therapeutic Products Bill is expected before the end of 2017.

\textsuperscript{17} Users of radiation sources must either hold a licence under the Radiation Safety Act 2016; be authorised in regulations; be authorised in a source licence; or act under the supervision or instructions of someone who is authorised. They must also satisfy a number of requirements set out in the Radiation Protection Regulations 2016 and Codes of Practice issued by the Director for Radiation Safety.

\textsuperscript{18} See HPCA Act, Section 7.

\textsuperscript{19} These clinical interventions are deemed to be ‘restricted activities’ under Section 9 of the HPCA Act, and include surgical and operative procedures, orthodontic procedures and ophthalmic procedures. These interventions can only be undertaken by health practitioners with a relevant scope of practice.
Once registered, healthcare professionals must work within a prescribed scope of practice when performing a healthcare service that is part of their profession\textsuperscript{20} and obtain and maintain an annual practising certificate while doing so.\textsuperscript{21} RAs also have significant powers under the HPCA Act to take action to assure the competence and safe practice of registered health practitioners. There are established appeal and review processes for practitioners to challenge decisions of the RAs.

\section{V NEGLIGENCE LIABILITY}

\subsection{i Overview}

A key aspect of the New Zealand healthcare system is its compulsory accident compensation scheme (the ACC Scheme). The ACC Scheme was established in 1974 as a result of a Royal Commission of Inquiry into compensation for personal injury\textsuperscript{22} and provides compensation for personal injuries (including those suffered while receiving treatment) on a ‘no fault’ basis. However, in exchange for the benefits of the ACC Scheme, people have significantly limited rights to sue for compensatory damages arising out of any personal injury, and for that reason, New Zealand has little medical negligence litigation.\textsuperscript{23} We note, however, that claims for exemplary damages and other remedies may still be available, and we return to this point below.

Notwithstanding the prohibition on claims for compensation in relation to personal injuries, there are a number of avenues that recipients of healthcare services can pursue in order to hold healthcare providers and professionals to account. Complaints may be made to the Health and Disability Commissioner, who has responsibility for promoting and protecting patients’ rights as set out in the Code of Rights. In serious cases, the Commissioner can investigate a complaint to determine whether or not a provider has breached the Code of Rights. Although a breach finding by the Commissioner is not directly ‘actionable’ in the general courts, it can have significant implications for individual healthcare professionals and providers. For example, it could lead to disciplinary proceedings against the registered health practitioners involved or open the door to proceedings against an individual practitioner or provider organisation in the Human Rights Review Tribunal (HRRT).\textsuperscript{24} The latter is a statutory tribunal that has the power to award damages to patients in respect of a breach of the Code of Rights (such as punitive damages in respect of any action that was in ‘flagrant’ disregard of a patient’s rights, or damages for injury to feelings and loss of dignity, regardless of whether there was a personal injury). In practice, however, HRRT proceedings in relation to breaches of the Code of Rights are rare and awards are typically modest (usually between NZ$5,000 to NZ$15,000).\textsuperscript{25}

\textsuperscript{20} See HPCA Act, Section 8.
\textsuperscript{21} Ibid.
\textsuperscript{23} See Accident Compensation Act 2001, Section 317. This prohibition applies even where a person chooses not to lodge a claim or is not entitled to compensation.
\textsuperscript{24} For a discussion of the HRRT jurisdiction, see T Baker ‘Human Rights Review Tribunal: The role of the tribunal in upholding the rights of consumers of health and disability services in New Zealand’ (2009) 16 JLM 85.
\textsuperscript{25} See HDC Act, Sections 55 and 57, and the schedule of damages awarded by the HRRT published online at www.justice.govt.nz/tribunals/human-rights/damages-and-costs-awarded/.

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ii Notable cases

As noted above, medical negligence litigation is rare in New Zealand. The relevant jurisprudence has tended to focus on the ambit of coverage under the ACC Scheme and the circumstances in which a common law action for damages is statute-barred. Notable cases include a decision allowing cover under the ACC Scheme for pregnancy arising from a failed sterilisation;\(^\text{26}\) a decision holding that the delivery of a stillborn baby was a personal injury to the mother;\(^\text{27}\) and a decision holding that cover is available to a mother in relation to a child born with spina bifida (following a failure to detect that condition during an ultrasound scan).\(^\text{28}\)

Several important cases have also considered the availability of other forms of remedies in circumstances where the ACC statutory bar does or is likely to apply. The decision in *Couch v. Attorney General (No. 2)*\(^\text{29}\) confirmed that exemplary damages are available in respect of conduct that has caused a personal injury, but set a very high threshold for such awards; that is, only where it can be established that the defendant either intended to cause harm or was ‘subjectively reckless’.\(^\text{30}\) To date, exemplary damages have only been awarded against healthcare professionals in cases of intentional sexual misconduct; and none have been awarded against healthcare professionals or providers since the judgment in *Couch*.\(^\text{31}\)

Another case that has been influential is the decision in *Baigent’s case*,\(^\text{32}\) which confirmed that public law damages are available where financial compensation is necessary to vindicate the state’s breach of an individual’s rights under the New Zealand Bill of Rights Act 1990. Since that decision, public law damages have been successfully sought against government entities in a number of cases involving personal injury,\(^\text{33}\) but unsuccessfully in a claim relating to risperidone treatment provided by a DHB.\(^\text{34}\)

VI OWNERSHIP OF HEALTHCARE BUSINESSES

In New Zealand, business ownership structures include limited liability companies, partnerships, limited partnerships, trusts, joint ventures and sole traders. With the exception

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\(^{27}\) *Harrild v. Director of Proceedings* [2003] 3 NZLR 289 (CA).

\(^{28}\) *Cumberland v. Accident Compensation Corporation* [2011] NZAR 389.


\(^{30}\) That is, the defendant ‘consciously appreciated the risk the impugned conduct posed to the plaintiff’s safety and went ahead deliberately and outrageously to run that risk, causing harm to the plaintiff’: *Couch v. Attorney General* as cited in *White v. Attorney General* [2010] NZCA 139 at [214].

\(^{31}\) See *L v. Robinson* [2000] 3 NZLR 499, where exemplary damages of NZ$10,000 were awarded against a psychiatrist who engaged in a sexual relationship with a vulnerable and former patient; *R v. Eade DC Auckland NP 3604/97*, 12 May 2000, where NZS27,500 in exemplary damages was awarded for breach of fiduciary duty as a result of a primal therapist’s sexual relationship with a vulnerable client with a history of sexual abuse; and *G v. G* (1996) 15 FRNZ 22 (HC), where an award of NZS85,000 in exemplary damages was made against a doctor, although this involved private rather than professional conduct (spousal abuse and violence).

\(^{32}\) *Simpson v. Attorney General* [Baigent’s case] [1994] 3 NZLR 667.

\(^{33}\) For examples of awards of public law compensation in personal injury cases, see *Greenwood v. Attorney-General* [2006] DCR 586 (DC); and *Falwasser v. Attorney-General* [2010] NZAR 445 (HC).

\(^{34}\) *PF v. Capital and Coast District Health Board* [2013] NZHC 1792.
of pharmacy businesses (which we return to below), New Zealand law does not impose any limitations or requirements on the ownership of healthcare businesses over and above what would apply to any other kind of business.

There are a number of generic pieces of legislation that regulate business in New Zealand and may be particularly relevant to non-domestic organisations considering establishing a business, or investing in an existing business, in New Zealand. These pieces of legislation include the Overseas Investment Act 2005 (which sets out restrictions on overseas persons establishing or acquiring a New Zealand business including requirements of the individuals in control of the overseas person); the Commerce Act 1986 (which is New Zealand’s competition legislation, and among other things, prohibits contracts, arrangements, understandings and the purchase of shares or assets that have the purpose, effect, or likely effect of substantially lessening competition in a market); and the Companies Act 1993 (which imposes various requirements on companies incorporated outside of New Zealand and operating in New Zealand and requires that each New Zealand registered company has at least one New Zealand resident director or one Australian resident director who is also a director of an Australian company, and a New Zealand registered office or address for service).35

The Medicines Act 1981 establishes a licensing regime for pharmacies and imposes significant restrictions on the ownership of pharmacy businesses.36 For example, natural persons may only be granted a licence to operate a pharmacy or own a majority interest in a pharmacy if they are registered pharmacists;37 a company may only be granted a licence to operate a pharmacy if its majority shareholding capital is owned by one or more registered pharmacists and those pharmacists must have effective control of the company;38 and prescribers39 are generally not permitted to hold interests40 in pharmacies. In addition, companies may not operate more than five pharmacies, and individual pharmacists may not operate or hold a majority interest in more than five pharmacies.41 Finally, pharmacy licences will only be granted where the applicant is a ‘fit and proper’ natural person or a body corporate of ‘good repute’,42 and has not been disqualified.43 New Zealand does not place any restrictions on the distribution of pharmacies;44 although pharmacy licences are granted in respect of a particular site.45 Importantly, a new therapeutic products regime has been proposed to replace the Medicines Act 1981; and is expected to remove pharmacy ownership restrictions and replace them with appropriate licensing requirements.

37 Medicines Act 1981, Section 55E (the exception to this is hospital pharmacies).
38 Medicines Act 1981, Section 55D (the exception to this is hospital pharmacies).
39 Prescriber is a defined term under the Medicines Act 1981.
40 ‘Interest’ is broadly defined and includes a beneficial interest in a shareholding of a holding company, being the lessor to the pharmacy and being a party to a commercial agreement involving key money or profit sharing. See Medicines Act 1981, Sections 5A and 42C.
41 See Medicines Act 1981, Section 55E.
42 See Medicines Act 1981, Section 51(1)(b).
43 See Medicines Act 1981, Sections 51(1)(c) and 83.
45 Medicines Regulations 1984, reg 45A.
VII COMMISSIONING AND PROCUREMENT

In New Zealand, the large majority of healthcare is publicly funded, and most public funding is devolved to 20 DHBs via Crown funding agreements with the Ministry of Health. Each DHB is responsible for providing healthcare services in its district and is free to do so in the way that it sees fit (including continuing to provide existing services and introducing new services), provided that it meets its obligations under its Crown funding agreement and the NZPHD Act. The Ministry of Health also introduces new services from time to time and either directly funds the rolling out of these services itself or requires and funds the DHBs to roll them out on a district-by-district basis.

DHBs procure a wide range of goods and services including healthcare-related goods and services (such as hospital supplies and diagnostic testing services) and general goods and services (such as office equipment and courier services). The basis on which these goods and services are procured varies depending on whether other DHBs or public sector agencies also need the relevant goods and services. Public sector agencies (which include DHBs) are required to purchase from a range of supply agreements that have been established to cover the entire public sector. In addition, various third-party agencies have been established to procure goods and services on behalf of DHBs (either on a national or regional basis). Currently, the most significant of these agencies is New Zealand Health Partnerships Limited. Other than that, DHBs procure goods and services on a local (i.e., district) basis or regionally in concert with other geographically proximate DHBs. The Ministry of Health predominantly procures goods and services on a national basis.

Public sector agencies in New Zealand are required to conduct procurement activity in accordance with the Government Rules of Sourcing (the Rules) along with a range of generic business and public sector statutes. The Rules predominantly focus on the sourcing process, rather than imposing mandatory pre-qualification or other requirements on potential providers. We note, however, that the Rules expressly require agencies to treat suppliers from other countries no less favourably than New Zealand suppliers and prohibit discrimination on the grounds of the country that the goods, services or works come from or the degree of foreign ownership or foreign business affiliations of the supplier.

The key Rule is that agencies must undertake any procurement of goods or services or refurbishment works with a total estimated value of NZ$100,000 or more using a publicly advertised, competitive process. There are various exceptions to this requirement, however, including where the procurement is of ‘health services provided by government for the public good’. Accordingly, a good proportion of the procurement of healthcare services by DHBs may not be undertaken using a publicly advertised, competitive process.

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49 Rule 4(1).
50 Rule 4(3).
51 Rule 7. The requirement to use a publicly advertised, competitive process also applies to procurements relating to new construction works with a total estimated value of NZ$10 million or more (see Rule 8).
52 See Rule 13 and the definition section.
In the recent case of Attorney-General v. Problem Gambling Foundation of New Zealand, the Court of Appeal held that judicial review of commercial contracting decisions by public sector agencies will only be available if the agency failed to follow a statutory requirement, where there was fraud, corruption, or bad faith on the part of the agency or where the procurement has some extra public law feature.

VIII MARKETING AND PROMOTION OF SERVICES

The generic law that regulates advertising and promotion in New Zealand is set out in the Fair Trading Act 1986 (FTA) and the Consumer Guarantees Act 1993 (CGA). The FTA prohibits false, misleading or deceptive advertising and penalties for breach can be in the order of NZ$200,000 in respect of an individual, and NZ$600,000 in respect of a body corporate. The CGA imposes a guarantee that services are provided with reasonable care and skill, that they are reasonably fit for the particular purpose, and that they are of such a nature and quality that it can reasonably be expected to achieve the (expressly desired) result. There are also guarantees to provide services, where not otherwise agreed, for a reasonable price and within a reasonable time. A party can bring civil proceedings for damages for breach of guarantees in the CGA.

The Medicines Act 1981 also sets out specific legal requirements relating to medical advertisements. Notably, it prohibits the publication of advertisements to the public that claim, indicate or suggest that a medicine, medical device or treatment (1) will prevent, alleviate or cure any of a list of diseases and physiological conditions (which include cancer, diabetes and infertility); or (2) is a panacea or infallible. It also prohibits endorsements by doctors, nurses and pharmacists.

In addition, the Therapeutic and Health Advertising Code (Health Advertising Code) covers all words and visual depictions in all advertising for health services, methods of treatment, medicines and medical devices. It includes the key principles that advertisements should observe a high standard of social responsibility as consumers often rely on medical-related products and services for their health and well-being, and they should not mislead, deceive or confuse consumers, abuse their trust, exploit their lack of knowledge, or, without justifiable reason, play on fear. The Health Advertising Code also requires that any scientific information in an advertisement should be presented in an accurate manner, and that scientific terminology should be appropriate, clearly communicated and able to be readily understood by the audience to whom it is directed. In addition, advertisements should not claim or imply endorsement by any government agency, professional body or independent agency unless there is prior consent, the endorsement is current and verifiable, and the agency or the body is named. If a complaint that an advertisement breaches the Health Advertising Code is upheld, then the advertiser is required to withdraw the advertisement immediately.

54 Fair Trading Act 1986, Section 9.
55 Fair Trading Act, Section 40.
56 Consumer Guarantees Act 1993, Section 28 and 29.
58 Note that the Medicines Act does state that it will be a good defence in a prosecution based on a breach of this prohibition if the defendant proves that the matter claimed, indicated or suggested in the advertisement is true.
59 Medicines Act 1981, Section 58.
The Code of Rights may also come into play with regard to medical advertising – for example, the right to freedom from coercion and exploitation, the right to effective communication and the right to be fully informed.

In terms of professional regulation, many of the responsible authorities that regulate different types of health professionals have either stand-alone codes for advertising practice that apply to their profession or incorporate standards relating to advertising in their general code of ethics. One notable characteristic of some of these codes and standards is the detailed provisions concerning when different professional titles can be used. Failure to comply with these codes and standards may result in the health professional being referred to a professional conduct committee or the Health and Disability Commissioner, which may lead to a charge being laid before the Health Practitioners Disciplinary Tribunal.

IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

Like many other countries, New Zealand’s healthcare sector continues to be shaped by increasing demand and associated health spending; growing prevalence of non-communicable and chronic diseases; the development of new, more costly technologies and pharmaceuticals; and a more educated and consumerist population. In addition, the global recession and the costs of rebuilding Christchurch following two major earthquakes in 2010 and 2011 continue to have an impact on the New Zealand economy, with flow-on effects to health, including social impacts such as unemployment and overcrowded housing, and budgetary constraints on all government spending. In view of the need to provide healthcare services in a way that meets current public demand and expectations, health organisations are under more pressure than ever to make smarter use of existing resources, people, facilities and funding to drive better, cheaper and more efficient care.

With these challenges in mind, a key trend that will continue to influence the delivery of healthcare services in the years to come is the development and use of ‘telehealth’ and other technology-enabled health services. The introduction of patient portals; increasing use of digital health apps and smartphones as diagnostic tools; proposals to use online videoconferencing and related communication technologies to provide online consultations, prescriptions and other telehealth services; and the proposed development of a ‘single’ electronic health record are just some examples of the ways in which technology is increasingly being used to help reduce the overall cost of healthcare delivery and increase accessibility in New Zealand. Of course, a shift towards digitalisation also means that patient privacy and cybersecurity issues will be top of mind for providers and consumers of health services, particularly with recurring incidences of health professionals inappropriately accessing patient health records and increased cybersecurity risks in the form of malware, viruses and ‘ransomware’ threats.

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60 See, for example, Statement on Advertising (Medical Council of New Zealand, November 2016); Code of Practice on Advertising (Dental Council of New Zealand, March 2011, available at www.dcnz.org.nz/assets/Uploads/Consultations/2012/Advertising-COP.pdf); and Aotearoa New Zealand Physiotherapy Code of Ethics and Professional Conduct (Physiotherapy Board of New Zealand, October 2011, at Section 10.4).


New technologies and treatments, together with increasing demand for health services, have also been drivers for adaptation and diversification across New Zealand’s health workforce. To this end, a number of key regulatory and legislative changes were introduced over 2015–2016 to support innovative and efficient practices, and to maximise the use of health practitioners’ skills. These changes include registered nurse prescribing and the Health Practitioners (Replacement of Statutory References to Medical Practitioners) Bill,63 which will enable a range of health practitioners to undertake certain statutory functions that are currently only able to be carried out by doctors (such as issuing sickness certificates and taking blood samples to test blood alcohol levels of drivers).

Elsewhere in the legislative arena, new regimes for medicines and natural health products have been proposed. In relation to therapeutic products, drafting of the Therapeutic Products Bill is well under way, with a consultation draft expected to be released before the end of 2017. As well as replacing and modernising the current regulatory arrangements for medicines and pharmacy businesses under the Medicines Act 1981, this new regime will provide for the regulation of all therapeutic products, including medical devices and cell and tissue therapies (which are currently not fully regulated in New Zealand). A separate regime for natural health products is also set to be implemented in the near future, with the Natural Health and Supplementary Products Bill currently awaiting its third (and final) reading in Parliament. The Bill is designed to address a range of problems with the current piecemeal regulatory regime for natural health products, including inadequate controls on safety and quality, inadequate information about risks and benefits, and enforcement difficulties.64

Finally, and as noted above, 2017 is an election year for New Zealand. Although it is not anticipated that this will result in significant structural change to the sector, health policy will, as is always the case in the lead up to an election, be vigorously debated by all parties. Issues such as medical cannabis and a number of public health initiatives relating to childhood obesity, smoke-free policy, a sugar tax and plain packaging for tobacco are all likely to be key areas of interest, in addition to the ever-present concerns of health spending and inequalities in access to care. The contentious issue of assisted dying and euthanasia also remains topical, after ACT Leader David Seymour’s End of Life Choice Bill was drawn from the ballot for debate in Parliament.65

X CONCLUSIONS
The New Zealand healthcare system is largely stable and is unlikely to see wholesale changes over the coming year. A general election in late 2017 does increase uncertainty, but significant structural change of the publicly funded system seems unlikely.

On the legislative front, a proposed new therapeutic products regime (with fewer restrictions relating to pharmacy ownership), and reforms of public health legislation, are two matters that will be closely watched.

63 The Bill passed its third reading in November 2016, and will be brought into force in parts by Order in Council.
64 The full regulatory scheme will be phased in over three years after the legislation comes into force.
65 While previous Bills on assisted dying have been defeated at first reading (or withdrawn from the ballot out of concern the issue would become a political football during election year), cross-party backing and widespread public support in favour of a law change suggest that rigorous debate will continue in this area.
There will be continued focus on innovation – and trying to do things differently so that limited public health resources can keep up with demand. Any health sector organisation – public or private – that can come up with new and innovative ways of providing healthcare services will be well received.
Chapter 11

PORTUGAL

Francisco Brito e Abreu and Joana Mota

I OVERVIEW

In Portugal, there is a fundamental right to health protection specifically set forth in the Chapter dedicated to fundamental rights in the Constitution of the Portuguese Republic. The right to health protection must be guaranteed: (1) by means of a universal and general national health service, which, with particular regard to the economic and social conditions of the citizens who use it, will tend to be free of charge; and (2) by creating economic, social, cultural and environmental conditions that particularly guarantee the protection of children, the young and the elderly; systematically improving living and working conditions, and promoting physical fitness and sport at schools and among the general population; and developing the public’s health and hygiene education and healthy living practices.

Healthcare services in Portugal are provided through three coexisting and overlapping systems: (1) the National Health Service (SNS), (2) special health insurance schemes for certain professions (health subsystems) and (3) voluntary private health insurance.

The SNS was established in 1979 in the context of the enactment of the Constitution of the Portuguese Republic in 1976 and is managed by the Ministry of Health.

The Ministry of Health is divided into three sectors: (1) the direct administration; (2) the indirect administration; and (3) the Public Enterprise Sector, comprising the Shared Services of the Ministry of Health (SPMS), local health units, hospital centres and public enterprise hospitals.

The Ministry of Health is responsible for issuing the National Health Plan and the National Strategy for Quality in Health. Five regional health authorities (ARS) (which are public entities part of the indirect administration of the state under the supervision of the Ministry of Health) are responsible for the implementation of the national health objectives set forth in said documents and have financial responsibility for primary and hospital care.
Despite the universal coverage of the SNS, there are other forms of financing the provision of healthcare services, which are specific to particular categories of citizen. There are groups of citizens with specific sickness schemes, usually designated as ‘health subsystems’. These systems, which constitute the second vector of the healthcare system in Portugal, are formed by entities of a public or private nature that, by law or under contract, provide health benefits to a group of citizens or financially reimburse them for the corresponding charges. Membership of these subsystems is based on professional categories and covers beneficiaries who are still in work, retired workers and their family members. These subsystems are financed through the beneficiaries’ contributions.

Until 2005, there were six health subsystems operating in the public sector that were integrated in that same year into the main subsystem, ADSE. ADSE comes under the indirect administration of the Ministry of Health (and is also subject to financial control from the Ministry of Finance) and now covers the provision of healthcare services to all public servants in a standardised form. At the end of 2015, the number of ADSE beneficiaries amounted to 1.25 million, including active staff, pensioners and family members.6

Private health subsystems consist of entities of a private nature that, under contract, provide healthcare to a group of citizens or contribute financially to the corresponding charges. Such a contract is compulsory, resulting from a compulsory intra-group solidarity mechanism (with a professional or business matrix). The largest private subsystems are PT-ACS (the health subsystem for the employees of the telecommunications company Portugal Telecom) and SAMS (the health subsystem for banking and insurance employees).

Finally, the private insurance sector, the third vector of the healthcare system in Portugal,7 which is based on voluntary individual affiliation, operates under a free-market regime and is subject to the general legislation of the insurance sector. Since the early 1990s, the number of beneficiaries of health insurance has increased at a rate of more than 10 per cent per year, and in 2015, almost 2.7 million Portuguese citizens had health insurance. There are some cases where people can benefit from triple coverage: from the SNS, from a health subsystem and under private health insurance.8

Healthcare services are also be provided, on a more limited scale, by non-profit private operators with a charitable background, known as Misericórdias.

The healthcare system landscape has undergone changes in recent years. Portugal’s bailout in 2011 and recourse to European Union mechanisms to avoid defaulting on its debts resulted in the execution of a memorandum of understanding (MoU) with the ‘troika’ of the European Commission, the International Monetary Fund and the European Central Bank. One of the most evident effects of the crisis involved the recessionary measures that governments were obliged to implement to reduce their sovereign debt.

To meet the purposes of the MoU, the Portuguese government initiated in 2011, among other reforms, a comprehensive reorganisation of the healthcare system to accomplish the MoU’s objectives within the proposed time frames.9

As a result of these reforms, the Portuguese health system has been able to successfully balance the twin priorities of financial consolidation and continuous quality improvement. Despite these advances, a number of challenges remain in order to improve the quality of care in Portugal.10

II THE HEALTHCARE ECONOMY

i General

In addition to what is stated in the Constitution of the Portuguese Republic regarding the right to health protection, the general policy guidelines regarding the healthcare sector in Portugal are set out in Basic Law No. 48/90 of 24 August, as amended (the Healthcare Basic Law).

In addition to a network of public hospitals and primary healthcare facilities covering the entire Portuguese territory, there is a broad range of private healthcare services offered in Portugal, including private clinics of varying dimensions and private hospitals. There are several private groups in Portugal operating networks of multiple private hospitals and clinics.

ii The role of health insurance

As mentioned in Section I above, there is no obligation for users of healthcare services to acquire healthcare insurance. This activity is governed by law and other instruments regulating insurance in Portugal. The insurance sector in Portugal is governed by the Authority for the Supervision of Insurance and Pension Funds.

iii Funding and payment for specific services

Pursuant to the Healthcare Basic Law, the SNS is financed primarily through transfers from the Portuguese state budget. Furthermore, pursuant to the Healthcare Basic Law, the Statutes of the SNS approved by Decree-Law No. 11/93, of 15 January, as amended, and Decree-Law No. 113/2011, of 29 November, as amended (Decree-Law 113/2011), which regulate access to the SNS services on the basis of moderating fees. Healthcare units of the SNS may also receive the following income:

- payment of healthcare services provided in particular rooms or other types or services not available for the majority of users;
- payment of healthcare services by third parties that have the legal or contractual responsibility to pay for healthcare such as healthcare subsystems or insurers;
- payment of healthcare services provided to non-beneficiaries of the SNS;
- donations; and
- moderating fees paid by users.

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Moderating fees are charged to SNS users (with some exceptions applicable to certain categories of users as well as to certain types of healthcare services) with a view to incentivising a rational use of SNS resources and the control of public expenditure. Such fees are governed primarily by Decree-Law No. 113/2011 and by Ministerial Order No. 306-A/2011 of 20 December, as amended.

Moderating fees will ideally be charged upon the provision of healthcare services, unless the user is unable to pay as a consequence of his or her health situation or a lack of financial means. Whenever the fees are not paid immediately, the user will be instructed to pay the relevant amount within 10 days. Non-payment of moderating fees is not a cause for refusing healthcare services.

The Portuguese government reimburses purchasers of prescription pharmaceutical products. The rules governing the reimbursement of prescription pharmaceutical products are set out in Decree-Law 97/2015 of 1 June 2015 (Decree-Law 97/2015). The decision to reimburse purchasers of pharmaceutical products must be made taking into account technical and scientific criteria as well as criteria of economic rationality, among other factors. Additional benefits are given to certain categories of patients, notably, pensioners who do not meet certain income thresholds and patients who suffer from certain types of illnesses.

Owing to mismatches between supply and demand, waiting lists in the SNS for surgery or consultations for certain medical specialties are often long. The SNS’s offering of dental services is also limited, although Ministerial Order No. 301/2009, of 24 March, introduced the National Oral Health Promotion Programme, pursuant to which certain categories of patients are entitled to vouchers which are exchangeable for dentistry services. For these reasons there is strong demand for private sector services in certain areas (e.g., dentistry or medical specialties).

Wellness services, alternative therapies and optics are usually funded by individuals, with the possibility of co-funding by private insurers or by the health subsystems. Certain types of beneficiaries (e.g., elderly people receiving benefits for the elderly) are entitled to certain specific additional benefits, such as co-funding for glasses up to a certain limit.

### III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

Primary care is currently organised in Portugal on a geographical basis. The Group of Healthcare Centres (ACES), introduced under Decree-Law No. 28/2008, of 22 February, as amended, was created as a decentralised service of the ARS (which have directive powers over it) as a new way to guarantee improved direct access to healthcare for Portuguese citizens, which was previously assured by the healthcare centres regime, enacted by Decree-Law No. 60/2003 of 1 April. ACES is made up of healthcare providers with administrative autonomy, which agglomerate one or more healthcare centres. They are responsible for providing primary healthcare to the population of a specific geographic area. Even though ACES is intended to be the primary source of healthcare services, hospitals continue to be citizens’ first choice.

It is also possible to receive basic primary healthcare through the Local Healthcare Systems (SLS), introduced by Decree-Law No. 156/99, of 10 May, which are made up of healthcare centres, hospitals and any other healthcare service providers or institutions, public or private, which operate within a certain local region. The SLS are created by means of an administrative order from the Minister of Health, following a proposal from the ARS and after consulting the local authorities.
Despite the international financial crisis in 2007, which limited public expenditure in the healthcare system, the private sector managed to find a way to keep its market share within the healthcare sector. One of the most important reforms within the hospital sector in Portugal in recent years was the development of public–private partnerships, enacted by Decree-Law No. 111/2012, of 23 May, as amended. Although the investment and operation of these healthcare units is private, they are nevertheless integrated into the SNS, which means that all SNS users have the same rights and duties as in any other public hospital or healthcare unit. Currently, there are four hospitals under this regime.\(^\text{11}\)

In the context of the administrative modernisation of the public sector, which has been a strong commitment of Portuguese governments in recent years, the healthcare system also provides good examples. The Health Data Platform, launched in 2012, is a centralised system that records and shares clinical information, duly authorised by the Portuguese Data Protection Authority.\(^\text{12}\) This platform provides access to information for citizens who are SNS users and healthcare professionals within the SNS (hospitals, emergency rooms, primary care, continuing care network).

Another important innovation worth emphasising is the implementation of the electronic prescription, which, as of 1 April 2016, is mandatory across the entire SNS.

### IV LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

**i Regulators**

As mentioned in Section I above, the Ministry of Health is the central government entity responsible, among other things, for the execution and evaluation of the national health policy, for regulating and overseeing healthcare services and activities developed by the private sector and for the regulation, evaluation and inspection of the SNS.

Meanwhile, the ARS are the bodies responsible for supervising healthcare providers from the public, private or social sectors, with the exception of the pharmacy sector.

**ii Institutional healthcare providers**

The ARS, apart from being the bodies responsible for supervising healthcare activities, are also responsible for the entire licensing process of institutional healthcare providers. In accordance with Decree-Law No. 127/2014 of 22 August, as amended, the opening and functioning of a healthcare unit depends on the verification of the technical operating requirements applicable to each type of healthcare provider.

For an entity to operate as a healthcare provider it must obtain a licence for that purpose, except in the specific cases set forth in the law (in which case, a mere declaration of conformity is sufficient for the healthcare unit to function).

Without prejudice to criminal, disciplinary and civil liability and any other administrative sanctions that may apply, operating a healthcare unit without a licence is an administrative offence punishable with fines ranging from €4,000 to €44,891.81. In addition to this, and depending on the seriousness of the offence, additional sanctions may

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\(^{11}\) Hospital Beatriz Ângelo, Hospital de Braga; Hospital Cascais Dr. José Almeida and Hospital Vila Franca de Xira. Additional information on the contracting model of the PPP can be found at: www.acss.min-saude.pt/2016/10/12/parcerias-publico-privadas/.

\(^{12}\) The authorisation can be found at: www.cnpd.pt/bin/decisoes/Aut/10_940_2013.pdf.
be imposed, such as the suspension of the activity of the healthcare unit subject to licensing for a maximum period of two years. If the licensing procedure is not settled, the healthcare unit may be definitively closed.

### iii Healthcare professionals

The practice of medical doctors in Portugal is regulated by the Statutes of the Portuguese College of Medical Doctors, approved by Law No. 282/77 of 5 July, as amended.

The Portuguese College of Medical Doctors is a public professional association representing the medical doctor class in Portugal. To practise as a doctor, it is necessary to be registered with the Portuguese College of Medical Doctors. Registration can only be rejected on the basis of (1) a lack of required academic qualifications, (2) prohibition from practising the medical profession dictated by a court of law (if the decision can no longer be appealed), and (3) failure to pass a medical communication test that foreign doctors must comply with in order to assess their Portuguese language skills. The applicant is entitled to appeal the decision of the Portuguese College of Medical Doctors to a superior council or to the Portuguese administrative courts.

The practice of medicine without inscription in the Portuguese College of Medical Doctors is considered a crime of usurpation of functions under the Portuguese Penal Code, being punishable with a prison sentence of up to two years or a fine of up to 240 days.

Dentistry, nursing and pharmacy are all also regulated professions that require prior inscription with a public association. Inscription in each of the respective public colleges governing the dentistry, nursing and pharmacy professions is governed by similar principles to those that govern inscription with the Portuguese College of Medical Doctors, notably in terms of academic requirements and the need to undertake adequate training in each of the aforementioned professions.

### V NEGLIGENCE LIABILITY

#### i Overview

Law 67/2007 of 31 December sets forth the rules applicable to the state and other public entities’ extra-contractual civil liability. Under this legal framework, the state and other legal entities governed by public law are exclusively liable for damages resulting from unlawful actions or omissions committed negligently by members of their bodies, officials or agents, in the performance of their administrative duties and resulting from that performance. This means that if the individuals working for the healthcare institution act with the expected level of diligence and in accordance with the technical rules of medical science, there will be no liability, regardless of the final outcome of the treatment (i.e., the obligation concerns the means and not the outcome).

The state and other legal persons governed by public law will also be liable in cases where the damage has not resulted from the conduct of a particular individual or whenever it is not possible to demonstrate liability for any act or omission, but must be attributed to the abnormal provision of the service. The law further clarifies what is considered an abnormal provision of the service.

Individuals will only be liable under this legal framework when their acts or omissions are caused by fault or when their diligence and care is significantly lower than what is expected for the position they hold. The public healthcare provider remains, nevertheless, jointly and severally liable.
Where private healthcare providers are concerned, and in the absence of specific legislation, the rules of contractual liability set forth in the Portuguese Civil Code will apply. Despite this, the rules of tort liability may also apply whenever it is not possible to resort to the rules of contractual liability in cases where it is not possible to demonstrate the existence of a contractual relationship between the patient and the doctor. Similarly to the public healthcare service providers, the obligations of private healthcare units (and their providers) concern the means and not the outcome.

ii Notable cases

*Lisbon Court of Appeal (Case 1573/10.5TJLSB)*

This case dates back to 2010 and relates to a civil action filed by a private hospital against the heirs of a patient who died. The hospital sought the payment of health expenses arising out of the patient’s treatment while she was hospitalised. The defendants argued that they were not responsible for the payment of the fees, claiming that instead the hospital should pay compensation for damages arising from the patient’s death, which happened as a result of a misdiagnosis.

The court considered this to be a situation of defective performance, and the defendants had to prove that there was an objective divergence between the acts carried out by the hospital and those that were deemed adequate for a certain result to be produced (in this case, to avoid the death of the patient). The court ruled that the hospital violated the general duties of care and that the misdiagnosis was a direct cause of the patient’s death.

The novelty of this decision lies in the nature of the damages awarded to the defendants; there is no evidence that, even if the patient had been correctly diagnosed, the chances of survival would have been different. However, the defective performance of the hospital’s duties (the court considered that the hospital had the contractual obligation to have acted differently, to have performed certain tests that would have allowed a correct diagnosis and adequate treatment) removed any possibility of the patient surviving. The theory of the ‘loss of opportunity’ refers to acts or omissions that have led to the loss of the opportunity of obtaining a benefit or avoiding an injury. There is a causal link between the hospital’s conduct and the damage caused to the patient and, therefore, the hospital was liable for the damages caused to the patient and the heirs.

The court also decided that the expenses that the hospital claimed from the heirs were only incurred in an attempt to remedy the patient’s condition, which was itself caused by the previous omissions and defective performance and, therefore, were not to be paid.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

As already mentioned in Section IV.ii above, the opening and functioning of a healthcare unit depends on the verification of the technical operating requirements applicable to each type of healthcare provider. In addition to the technical operating requirements, the healthcare providers must also comply with hygiene, safety and public health requirements and their professionals must abide by the applicable ethical rules. Also, healthcare units must have an insurance policy in place covering all the inherent risks of the activity and the activity of its professionals.

There are no particular restrictions regarding the nationality of healthcare business owners.
Where competition issues are concerned, in the absence of specific rules applicable to the healthcare sector, the general rules of the Portuguese Competition Act (enacted by Law 19/2012 of 8 May) will apply.

VII COMMISSIONING AND PROCUREMENT

The procurement for the provision of healthcare services is made, at a national and centralised level, by SPMS, a public entity, created in 2010 to operate under the Ministry of Health and Finance.\(^{13}\) The rules applicable to the formation, as well as to the substantive regime of administrative contracts in the context of the acquisition of products and services in the healthcare sector are set forth in Decree-Law 18/2008 of 29 January, as amended, which introduced the Public Contracts Code. Other rules also apply, such as the Administrative Procedure Code and the Procedure Code of the Administrative Courts.

The process related to public purchases in the health sector is processed in a single electronic contracting platform, centrally managed by SPMS.\(^{14}\) The SPMS publishes on the platform a Public Health Supply Catalogue, which provides, among other things, updated information on existing goods and services under public procurement contracts and allows for the online consultation of the ongoing public tenders, as well as the online submission of supply proposals.

There are four main types of procurement procedures and two possible award criteria (the most economically advantageous tender and the lowest price). As a general rule, the choice of procedure is determined by the value of the contract, i.e., by the maximum value of the economic benefit, which, depending on the procedure adopted, can be obtained by the contractor. In some cases, the procedure to be followed is determined by the verification of specific circumstances provided by law.\(^{15}\) It is possible to challenge the procurement decisions either at an administrative or a judicial level.

As a final note, it is worth pointing out that the Minister of Health issued, on 16 January 2017, Order No. 851-A/2017 with recommendations aimed at preventing the violation of the principles of transparency, competition and pursuit of public interest in the area of public procurement.

VIII MARKETING AND PROMOTION OF SERVICES

The promotion and advertising of healthcare services and businesses was not formally regulated until 2015 with the enactment of Decree-Law 238/2015 of 14 October\(^{16}\) (Decree-Law 238/2015), which established the legal regime for health advertising practices and the general principles they must follow, and set out the practices considered to be misleading in this regard. With the exception of matters governed by special legislation, such as advertising for medicinal products and health products and state institutional advertising, this Decree-Law...

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13 It was formally incorporated under Decree-Law 19/2010, of 22 March. Further information about the SPMS can be found at: http://spms.min-saude.pt/en/spms/.
14 In accordance with Ruling 227/2014, of 6 November, as amended. The electronic contracting platform is available at: https://community.vortal.biz/PRODSTS/Users/Login/Index?Skin=SPMS.
15 Further information on the procurement process can be found at: http://spms.min-saude.pt/wp-content/uploads/2016/01/Manual-de-Contratação-Pública.pdf.
16 And further regulated by Regulation 1058/2016 of 24 November.
covers all advertising practices relating to conventional and non-conventional methods, complementary means of diagnosis and therapy, any treatments or therapies, namely those involving the use of cells.

This legal framework applies to any public or private entity that provides healthcare services or advertises products, regardless of the forms and means, related to the prevention and treatment of diseases, including the provision of diagnoses and any treatments or therapies.

All health advertising practices which, for any reason, induce or are likely to mislead the user as to whether to acquire a product or service, are forbidden by law. These advertising practices constitute an administrative offence punishable by fines ranging from €3,000 to €44,891.81. Additional sanctions, such as temporary prohibition (up to two years) from practising a professional or advertising activity and the loss of rights or benefits granted by regulatory authorities or public services (up to two years), may also be imposed depending on the seriousness of the offence and its potential impact.

The rules of the Portuguese Advertising Code, approved by Decree-Law 330/90, of 23 October are applicable, on a subsidiary basis, to these advertising practices.

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

The National Health Plan (2012–2016) (the Plan), a basic element in defining health policies in Portugal, provides the main strategies for public health action to be implemented in the coming years. The Plan’s main goals for the coming years are the decrease of premature (before the age of 70) mortality by 20 per cent, the increase of healthy life expectancy at age 65 by 30 per cent, the reduction of smoking in the population over 15 years old and the elimination of exposure to environmental smoke, as well as controlling the incidence and prevalence of obesity in young people and schoolchildren (with no quantitative objective attached).

Another recent change regarding health promotion was the termination in 2012 of the four national vertical programmes on HIV/AIDS, oncological diseases, cardiovascular diseases and mental health, which were replaced with priority health programmes. Those resulted from the reorganisation of the four existing national vertical programmes as mentioned above and existing initiatives on respiratory diseases, tobacco control, healthy nutrition, control of antimicrobial resistance and diabetes.17

Further to this, some measures have been recently approved to improve patient choice across SNS hospitals. From May 2016, SNS users can be referred to a hospital outside their local area, as long as waiting times for a given procedure or outpatient consultation are shorter than in their local area.18 The SNS launched its new website19 in February 2016, on which it provides information on waiting times regarding outpatient consultations for several specialties.20

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Finally, the Portuguese government approved the National Strategy for the Ecosystem of Information 2020 (ENESIS 2020),\textsuperscript{21} which is aimed at improving access and information sharing by simplifying and dematerialising processes and documents, such as electronic prescriptions and the dispensing of drugs, processes associated with death and sick leave, the availability of data and services through the Health Data Platform\textsuperscript{22} and related portals and also providing public access to open data on the SNS website and at www.dados.gov.pt. The coordination and supervision of ENESIS 2020 are the responsibility of SPMS, under guidance of the respective ministry, ensuring its operationalisation and promotion within the scope of the SNS.

\section*{X CONCLUSIONS}

As mentioned in Section I above, despite the relevant reforms that have been carried out by the Portuguese government in recent years, particularly after 2011, a number of challenges are yet to be overcome. According to a report issued by the OECD,\textsuperscript{23} the following topics have been identified as priorities to be considered by the government in order to improve the quality and financial efficiency of the healthcare system in Portugal: (1) strengthening the quality of the Portuguese healthcare system – e.g., by gathering and making a better use of patient feedback, considering ways to move to more provider- and doctor-level feedback to improve patient involvement, increasing accountability to patients and as a central quality improvement model; (2) improving the provision of primary care service – e.g., by maximising the dividends of a sophisticated data system, through improving data linkage, and promoting the use of data by physicians to evaluate the quality of their own care; (3) improving the quality of hospital care – e.g., by reducing non-essential emergency department visits and managing the demand for emergency care more efficiently by experimenting with models of emergency care delivered in primary care settings; and (4) increasing value for money while improving quality – e.g., by ensuring that the gains obtained from a more effective purchase policy of pharmaceutical products are not lost and are accompanied by regular audits.

These recommendations are also in line with the main conclusions drawn from a report issued in 2014 by the Gulbenkian Foundation.\textsuperscript{24} It is also worth pointing out that this report outlines some topics regarding the financial sustainability of the SNS.\textsuperscript{25}

\begin{flushleft}\footnotesize
\textsuperscript{21} Resolution of the Council of Ministers 62/2016, of 17 October.
\textsuperscript{22} We refer to Section III (Primary/family medicine, hospitals and social care) above.
\textsuperscript{23} The full version of the report can be found at: www.oecd.org/health/health-systems/Review-of-Health-Care-Quality-Portugal-Executive-Summary.pdf.
\textsuperscript{24} Fundação Calouste Gulbenkian is a Portuguese private foundation of public utility, established in 1956, with statutory aims in the fields of the arts, charity, science and education. It supports several investigative programmes aimed at developing Portuguese society in order to foster the country’s sustainable growth. In the health sector, it has developed an initiative called Innovation in Health, with the purpose of discussing several topics regarding a sustainable healthcare system, healthcare models, systems and services. More information can be found at: https://gulbenkian.pt/en/initiatives/innovation-in-health/.
\textsuperscript{25} The full version of the report can be found at: https://gulbenkian.pt/wp-content/uploads/2016/03/Summary-The-Future-for-Health.pdf.
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Chapter 12

SAUDI ARABIA

Nabil A Issa

I OVERVIEW

Saudi Arabia has witnessed dramatic economic changes in recent years. With the introduction of compulsory health insurance for those working in the private sector, the healthcare landscape has opened up for a wide range of healthcare players, such as laboratories, pharmaceutical companies, insurers and healthcare providers, all of whom are still looking to take advantage of the growing market. There is also continuous improvement in education, which is leading to increase in healthcare awareness.

Saudi Arabia is the largest economy in the Middle East and, while oil wealth has brought new opportunities, it has led to a growing occurrence of lifestyle diseases, such as diabetes and heart disease. Saudi Arabia is challenged by a population demanding the latest technology and is establishing new medical colleges and partnering with international players. For example, Saudi Aramco Medical Services teamed up with Johns Hopkins to form Johns Hopkins Aramco Healthcare. The Ministry of Health has awarded significant contracts to Diaverum and DaVita to operate dialysis clinics in Saudi Arabia. The hospitals of Saudi Arabia are often performing some of the world’s most complicated medical procedures, including organ transplants, separation of conjoined twins and neurosurgery.

The Ministry of Health is the regulator for most of the healthcare sector in Saudi Arabia. The Ministry of Defence, including the National Guard, maintains its own standards.

The government of Saudi Arabia has established certain regulatory reforms to encourage investment in the healthcare sector by the private sector. The healthcare sector is undergoing constant change because of its high importance to Saudi Arabian nationals, and certain agencies have overlapping responsibilities, as described below. Moreover, as part of Saudi Arabia’s well-publicised Vision 2030, it is transforming its public sector and exploring privatising certain aspects of its healthcare sector. Currently, there are a number of foreign investment restrictions, which will be discussed in this chapter.

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II THE HEALTHCARE ECONOMY

i General
The Council of Cooperative Health Insurance has made it mandatory for all business owners to cover their workers with medical insurance from the date of their arrival and hand them insurance cards within 10 days of their arrival in the Saudi Arabia. According to the council’s new regulations, the insurance coverage becomes invalid only in case of the beneficiary’s death, cancellation or expiration of his or her insurance documents, or if he or she leaves Saudi Arabia on an exit-only visa. Married workers’ medical insurance should cover pregnancy and childbirth. Article 7 of the Cooperative Health Insurance System also requires owners of private hospitals to provide medical insurance to their foreign workers.

The first stage of this compulsory insurance was introduced in 2006 and covered all workplaces with more than 500 people. This was followed by the next stage, introduced in the second half of 2007, which mandated all workplaces with fewer than 500 employees to also adopt the policy. Now, all companies with fewer than 500 employees that are renewing business licences must provide proof that expatriate medical insurance is available for all staff. This policy was a major shift in the Saudi market, although the main players in the industry – pharmaceutical companies, insurers and healthcare providers – are still at odds as to who benefits the most in the new landscape.

Eventually, all Saudi citizens will need to be covered by medical insurance, as the free medical healthcare programme is under stress from a large population with lifestyle diseases in an age of dwindling public resources. In preparation of the privatisation of public hospitals, Saudi Arabia is looking to create a form of insurance for those in the public sector.

The introduction of mandatory health insurance for expats, and insurance reform in general, has certainly shaken up the healthcare market in Saudi Arabia, providing a great amount of potential for pharmaceutical companies, laboratories, insurers and healthcare providers.

All Saudi Arabian insurance companies are required to be listed companies in Saudi Arabia. There are a number of insurance companies that are partly owned by foreign parties such as BUPA, Munich RE and AXA.

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE
Privately owned healthcare institutions, which offer treatment, diagnostic, laboratory, rehabilitation and nursing services (private healthcare institutions), are classified under the relevant regulations as one of the following:

a hospitals that are equipped to diagnose, treat and admit patients on an inpatient basis;
b general health centres prepared to diagnose and treat patients that offer at least three medical specialisations;
c specialised healthcare centres that focus on one medical specialty or more;
d physician office (clinics) prepared for treatment and diagnosis of patients;
e radiology centres for diagnostic imaging and radiology treatment;
f medical laboratories;
g same-day surgical facilities (i.e., ambulatory surgery centres) that are licensed to admit patients for minor and medium surgeries, provided that patients are discharged on the same day of admission;
supporting medical services facilities that provide complementary medical and technical
services and include: physical therapy centres, vision, nutrition centres, artificial limbs,
or any other facilities that are classified as a supporting medical facility by the Ministry
of Health; or

medical transport services that include transport and first-aid for patients before
admission to hospitals in accordance with the standards and requirements of the Saudi
Red Crescent Society.

The premises of all private healthcare institutions must be compliant with the medical
and technical requirements historically designated by the Ministry of Health and must
be equipped with the necessary medical equipment and furniture. In addition, a private
healthcare institution must have appropriate systems for medical waste disposal, prevention
of infection and medical records filing.

There is a wide range of both medical clinics and hospitals in Saudi Arabia. It is normally
possible to obtain direct access to hospitals without the need for a referral.

There are strict data privacy laws that do not permit the storage of patient information
outside of Saudi Arabia without the written permission of the concerned patient.

There are some unusual approvals that may be required by a woman’s husband
or guardian prior to undertaking certain medical procedures. For example, a woman is
required to obtain written permission from her husband or guardian prior to undertaking a
hysterectomy, unless it is required in a life-threatening situation.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

Medical staff, including doctors and pharmacists, must be properly licensed by the Ministry
of Health and the General Directorate of Health Affairs in accordance with the Healthcare
Profession Practice Regulations, including any regulations or circulars published by the Saudi
Commission for Health Specialties, which is the regulatory body responsible for licensing
doctors.

In respect of employment, please note the following:

a each hospital must appoint a locally qualified doctor of Saudi nationality as a medical
   manager for the hospital (exceptions might be given for hospitals located in rural and
   remote areas);

b each hospital must appoint a pharmacist of Saudi nationality as a manager of the
   hospital’s internal pharmacy on a full-time basis;

c the pharmacist officer responsible for drugs in the hospital’s internal pharmacy, who is
   subject to surveillance, shall be a full-time pharmacist assistant of Saudi nationality. The
   internal pharmacy manager might hold this position; and

d each hospital must appoint an administrative manager of Saudi nationality, holding a
   university degree, to manage the hospital on a full-time basis.

V NEGLIGENCE LIABILITY

The area of liability is still under development in Saudi Arabia. Saudi law consists of
two types: the shariah or Islamic law (God-made law); and the government regulations,
ministerial decrees and implementation rules (man-made law). Although the government
regulations, decrees and rules are deemed to be subservient to the shariah, in practice, the two types of law are sometimes in conflict. Further, as there is no recognised system of legal precedent in Saudi Arabia, the ability to resolve any conflict between the shariah and the government regulations remains problematic. In court cases, both types of law are usually applied, and the courts’ rulings may be supported by principles or regulations of either type – or a combination of the two. This makes it exceedingly difficult to predict with any degree of certainty the outcome of legal cases, including liability for medical negligence. The facts of the particular case, therefore, are perhaps more relevant to the dispute than would ordinarily be the case in Western jurisdictions.

Despite the generally unpredictable nature of the Saudi civil justice system, several important principles are nonetheless helpful in analysing claims in Saudi litigation or arbitration. A fundamental principle in Hanbali shariah is that a contract between two parties constitutes the law between those parties – except to the extent it violates the shariah or public policy.

The shariah also contains many equity principles similar to those found in the common law of England and the United States. This includes a presumption of good faith in contract matters. It also includes the concepts of unjust enrichment and the voiding of contracts owing to incapacity, fraud and duress. The shariah, however, lacks many of the equitable remedies found in the common law, such as injunctive relief, which is exercised only in rare circumstances.

The shariah concept of damages is also important in determining potential liability in a commercial dispute. Under the shariah, only direct, proven damages are recoverable in cases involving tort or breach of contract. Thus, incidental and consequential damages will not be recognised. In addition, lost profits are generally not recoverable on the ground that they are speculative; only God could know what would, in fact, occur in any given situation. Thus, some of the consequential damages in a lawsuit in a Western jurisdiction may not be applicable in Saudi Arabia.

In general, there is the concept of blood money. We note that under Saudi Arabian law, the maximum civil liability for wrongful death is 120,000 riyals for an adult Muslim male. This is established by General Organisation of Social Insurance, which provides workers’ compensation coverage to employees.

In Saudi Arabia, the concept of ‘blood money’ or diya exists with respect to homicide, in which a crime victim’s family may demand a sum of money in order to spare the life of a killer. This may arise in a situation in which an employee of a medical institution were found to have intentionally killed a person (rather than the death being deemed an accident). This would, of course, involve the Saudi Arabian criminal justice system. As a general rule, corporate criminal responsibility does not exist in Saudi Arabia, particularly for crimes such as homicide. The individuals responsible for the homicide rather than the corporation would be held accountable. We understand there are instances of medical professionals being held criminally liable for being grossly negligent and such action resulting in a death.

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3 The Basic Law of 1992 declared the Holy Qur’an and the sunnah (traditions and sayings) of the Prophet Mohammed to be the Kingdom’s Constitution.

4 The Hanbali school of Islamic jurisprudence is one of the four major schools, together with the Maliki, Hanafi and Shafi’i schools. The Hanbali shari’a is the predominant school in Saudi Arabia.
VI OWNERSHIP OF HEALTHCARE BUSINESSES

Currently, Saudi law treats foreign-owned entities in a manner that dramatically differs from local and Gulf Cooperation Council (GCC)-owned entities. Foreign-owned entities are entities that have any non-GCC foreign shareholders, even if such entities are incorporated in the GCC. Examples of some differences are demanding additional procedural steps during formation, restricting the activities of the foreign entity, demanding higher share capital to conduct business in certain sectors and imposing a higher income tax than local or GCC-owned entities. Foreigners and foreign-owned entities are taxed at 20 per cent of profit versus zakat at 2.5 per cent.

When Saudi Arabia joined the World Trade Organization (WTO) in December 2005, the Saudi government agreed to open to foreign investment several areas that were previously closed. As per Royal Decree No. M/54 dated 21/09/1426H, the documentation in relation to Saudi Arabia’s accession to the WTO was approved. In terms of the WTO, medical services are generally open. Technically, the Saudi Arabian General Investment Authority (SAGIA) maintains the only restrictions in terms of foreign investment in the healthcare sector are ‘services provided by midwives and nurses, physical therapy services and quasi-medical services internationally classified at CPC 93191’, which are on the Negative List. As per the WTO, the ownership of entities engaged in medical care was meant to be open if the foreign entity entered into a joint venture with a properly licensed Saudi party. We understand Saudi Arabia has not yet complied with such commitment, so will require new implementing regulations prior to Saudi Arabia opening up most areas of healthcare.

In addition to the above restrictions as per the Negative List, the Ministry of Health (MoH) and Saudi Food & Drug Authority (SFDA) have their own set of rules and restrictions. The Council of Ministers Resolution No. 683151 dated 10/03/1436 H (1 January 2015 G) is the most current version of the Regulations for Private Healthcare Institutions (the Private Healthcare Regulations). The Private Healthcare Regulations provide that essentially all areas of healthcare, other than hospitals, are reserved for Saudi Arabian nationals. We have been advised by the MoH that non-Saudis are only allowed to own hospitals with a minimum of 100 beds and provided the medical director of the hospital is a Saudi national. In our experience, the MoH generally grants licences to foreigners only if the foreign-owned hospital has at least 150 beds, or at least 100 beds if the foreign party is acquiring an existing hospital or it is a specialty hospital, which the MoH agrees is focused on an area of importance to Saudi Arabia. The hospital medical director must be a qualified Saudi physician. The head of the pharmacy must also be a Saudi Arabian pharmacist. Further, the application for private hospitals requires that the Administrative Director be a Saudi Arabian national. Note that a hospital with even 1 per cent foreign ownership is required to obtain a SAGIA licence and falls under the Private Healthcare Regulations. We understand that SAGIA and the MoH may soon announce a relaxation allowing for partial foreign investment of up to 75 per cent of medical centres on a case-by-case basis, and if such meets certain minimum foreign investment guidelines.

Please note the following in regards to healthcare sectors that are and are not currently open to foreign investment.

i Private clinics or centres
Owners of private clinics or centres must be 100 per cent Saudi parties. These include dialysis clinics, radiology clinics and polyclinics.
ii  Dental clinics
Owners of dental clinics must be 100 per cent Saudi parties. We understand individual non-Saudi GCC national dentists may also potentially be licensed to own and operate dental clinics.

iii  Foreign ownership in other healthcare-related arenas
Non-Saudis are allowed to have 100 per cent ownership in managing and operating companies engaged in medical maintenance, non-medical maintenance, hygiene, sterilisation, security, IT services, leasing of medical equipment, medical waste management and monitoring clinical trials.

iv  Medical device manufacturers
Foreign investment in medical device manufacturing is generally permitted. Approvals are required from the SFDA.

v  Pharmaceutical manufacturers
Pharmaceutical manufacturers are regulated by the Institutions Pharmaceuticals Regulations, under which foreigners can establish manufacturing plants (pharmaceuticals and medical devices) in Saudi Arabia, with 100 per cent ownership under an industrial licence. Approvals are required from the SFDA.

vi  Pharmacies
Only Saudi Arabian nationals are permitted to own pharmacies and pharmaceutical establishments in Saudi Arabia, and such must be at least partly owned by a Saudi Arabian pharmacist. The regulations set forth certain conditions that pharmacy owners must satisfy. These include:
   a  being licensed by the MoH to practise as a pharmacist;
   b  employing a Saudi national as a manager; and
   c  meeting the specifications for a pharmacy that were historically set out by the MoH.

The regulations also limit the number of pharmacies that can be owned by one individual or company to no more than 30 pharmacies.

vii  Laboratories
As per the Law on Private Laboratories issued pursuant to Council of Ministers Decision No. 29 dated 25/01/1423H (7 April 2002 G), which provides that licensing may be granted for laboratories provided that: (1) the applicant for the licence is 100 per cent Saudi, (2) the applicant undertakes to assign a Saudi to be the laboratory technical manager, and (3) the applicant undertakes to provide necessary academically qualified specialists and use proper equipment and instruments.

viii  Foreign ownership of property
A non-Saudi entity may not own real estate in Saudi Arabia before it establishes a commercial presence in the country. The ownership rules applicable to GCC nationals are regulated in
Saudi Arabia by the Ownership of Real Estate by GCC Nationals Regulations; non-Saudi, non-GCC nationals' ownership of real estate is regulated by the Regulation on the Ownership and Investment of Real Estate by Non-Saudis.

Additionally, property ownership by a company that is wholly or partially owned by non-Saudi nationals within the boundaries of the designated holy cities of Mecca and Medina is not permitted.

Finally, individual foreigners who hold residency permits (iqamas) in Saudi Arabia are permitted to acquire a residential property for their personal accommodation upon the approval of the Saudi Arabian Ministry of Interior.

ix Barriers to market access

There are a number of barriers to market access by foreign investors in the healthcare and pharmaceutical sector in Saudi Arabia. Chief among them are the following:

a. Price controls: Pharmaceutical products can be sold only after their prices have been approved and undergone registration requirements. Such, however, also applies to 100 per cent Saudi-owned entities.

b. Tendering procedures: The two principal buyers of pharmaceutical products in Saudi Arabia are the SFDA and the General Directorate of Healthcare Affairs (SGH). GCC member countries, including Saudi Arabia, practise collective purchasing of pharmaceuticals, vaccines and other healthcare products through the SGH tender – this process allows GCC countries to buy in bulk and benefit from significant cost savings from multinational drug-makers. Companies that wish to participate in the SGH tender must have already registered products in at least three GCC member states or be directly registered with the Gulf General Committee for Drug Registration.

c. Certain aspects of agency and commercial law: Unless a product is produced in Saudi Arabia, all foreign companies must sell their products through licensed distributors or agents in Saudi Arabia.

x TCR

We are aware the MoH is permitted to waive in part or in whole its restriction on ownership and provision of services. If the MoH believes an area of healthcare is underserved, it can award a government contract. The foreign entity can then obtain a temporary commercial registration (TCR). For example, because of the high rates of diabetes and need for dialysis care, the MoH awarded substantial contracts separately to DaVita and Diaverum. Both entities have 100 per cent foreign-owned TCR branches to provide dialysis care to MoH patients. We also understand another foreign company was permitted to establish a laboratory in partnership with the Saudi Arabian National Guard by establishing a TCR.

VII COMMISSIONING AND PROCUREMENT

The MoH and CBAHI are the primary parties involved in the commissioning of a new hospital.

The registration process and procedural steps for obtaining a sector-specific regulatory licence to set up a hospital in Saudi Arabia can be divided into three key steps: (1) obtaining MoH's preliminary approval; (2) obtaining the approval of the Ministry of Commerce and
Investment (MoCI); and (3) obtaining final approval from the General Directorate of Health Affairs and CBAHI. Pharmaceutical companies are also required to obtain licences from MoH and the MoCI.

Investors must first obtain a preliminary approval from the MoH. At this stage, the MoH requires information about the applicant investors, including, in the case of corporate investors, the constitutive documents (i.e., the commercial registration and articles of association) of each applicant. The MoH also requires information describing in brief the investment plan (including number of hospitals and beds, proposed project sites, construction plan, management structure, expertise of the involved parties and the implementation plans). The MoH will review the application and may request further documents or clarifications. This process will normally take one to two weeks from the date of submitting the required documents.

After successfully obtaining the MoH’s initial approval, the corporate entity must be incorporated in Saudi Arabia to conduct the intended licensed activities (e.g., developing and operating hospitals). At this stage, the investors must obtain the necessary approvals from the MoCI.

After incorporation of the appropriate investment vehicle, the MoH will request copies of the constitutive documents of the investment vehicle (i.e., articles of association and the commercial registration) and a land-ownership deed for the project site. The MoH will then refer the application to the relevant General Directorate of Health Affairs (GDHA).

Construction plans and other sketches for each hospital must be submitted to the relevant GDHA for approval. Construction work cannot commence before obtaining the approvals from the Projects and Maintenance Department at the MoH, the relevant municipality, and the Civil Defence. A technical study must be submitted to the Civil Defence certifying the compliance of sites with the related technical specifications and requirements. This study must be prepared by an engineering consultancy office, accredited by the Civil Defence, and specialised in safety and fire protection. The Civil Defence Regulations set out the required specifications in respect of project sites, structures and equipment. The hospital will also be expected to enter into a contract with a specialised licensed entity for the safe disposal of medical waste, and obtain a report from a specialised licensed entity evidencing (1) the installation of the safety measures of radiation and other necessary measures for the radiation departments in the hospital; (2) its compliance with the specifications and standards; and (3) the availability of protection measures from radiation and measures for early detection of radiation leakage. Upon completion of the construction work, the relevant MoH committee will inspect the hospital buildings and preparations work and issue an inspection report within two weeks from the date of the application, and the applicant will be provided with a reference letter to the Ministry of Labour to apply for recruitment visas. The MoH will issue the final approvals after the necessary number of staff have been recruited and after the hospital has obtained the necessary professional licences and approvals for professionals hired in Saudi Arabia. A hospital is required to recruit a certain number of resident doctors, specialists, consultants, pharmacists, technicians, nurses and medical staff, based on its size.

VIII FUTURE OUTLOOK AND NEW OPPORTUNITIES

We continue to see a tremendous interest in telemedicine, particularly in the field of dermatology. There has been a focus on this area as the Saudi public continues to desire best-in-class services.
We continue to see tremendous interest by medical providers and private equity houses focusing on Saudi Arabia. Ashmore recently raised a significant fund to invest in hospitals in Saudi Arabia. Investcorp recently invested in Al Borg Laboratories based in Jeddah and a number of hospitals, dental clinics, etc., are expanding through raising new funds or through IPOs.

Furthermore, Saudi Arabia has been looking to increase foreign investment in large hospitals. There are also a number of privatisations occurring in this sector. Saudi Arabian Airlines is currently entertaining bids to privatisate its medical centre and create a new medical centre to serve its employees and the general public.

IX CONCLUSIONS

Saudi Arabia is currently liberalising its regulations to encourage more foreign participation in the healthcare sector in Saudi Arabia. There continues to be tremendous opportunity for investment in this sector. We expect such to further accelerate, with the expected announcement of medical centres and hospitals that the government hopes to partially or wholly privatise.
I OVERVIEW

The healthcare regulatory framework in Singapore broadly comprises the Ministry of Health (MOH) and its statutory boards and the public and private healthcare providers.

The MOH manages the public healthcare system, which is designed with the twin aims of: ensuring that Singaporeans have access to good and affordable healthcare; and promoting health, as well as preventing and reducing illness. The public healthcare system is currently structured as vertically integrated delivery networks, and is organised by region. As part of the MOH’s Healthcare 2020 Masterplan, some of the public sector healthcare institutions in Singapore will be merged and restructured into three integrated clusters, namely, the central, eastern and western regional health systems. Each regional health system will have acute general hospitals, which will cooperate closely with long-term and other integrated care providers, such as community hospitals, nursing homes, home care and day rehabilitation providers, as well as polyclinics and private general practitioners in the region, to provide holistic healthcare to patients.

Healthcare facilities such as hospitals, clinics (including dental clinics), nursing homes and clinical laboratories are regulated by the MOH under the Private Hospitals and Medical Clinics (PHMC) Act and its subsidiary legislation.

Healthcare professionals are self-regulated by their respective professional bodies, which are established under legislation regulating the practice of healthcare (medicine, dentistry, pharmacy, nursing and midwifery, among others) in Singapore.

Health products such as pharmaceuticals, medical devices, cosmetics and complementary medicines are regulated by the Health Sciences Authority under the Health Products Act, the Medicines Act, the Medicine (Advertisement and Sale) Act, the Poisons Act, the Sale of Drugs Act and their subsidiary legislation, as well as guidelines promulgated by the Health Sciences Authority and the MOH.

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1 Benjamin Gaw is the director and co-head of the healthcare and life sciences practice group at Drew & Napier LLC.
2 The reorganisation is expected to be completed by early 2018.
3 Medical Registration Act (Cap. 174).
4 Dental Registration Act (Cap. 76).
5 Pharmacists Registration Act (Cap. 230).
6 Nurses and Midwives Act (Cap. 209).
II THE HEALTHCARE ECONOMY

i General
In Singapore, healthcare services are offered through a mixed delivery model, with primary healthcare services, acute hospital services and dental services being offered by healthcare institutions in both the public and private sectors.

Singapore's healthcare operates on a mixed financing system and is anchored on the twin philosophies of individual responsibility and affordable healthcare for all. The Singapore government's healthcare expenditure averages about 2 per cent of Singapore's gross domestic product (GDP). Singaporeans are afforded multiple tiers of protection through a combination of government subsidies, mandatory medical savings for working Singaporeans (Medisave), risk pooling via insurance schemes (such as MediShield Life, Integrated Shield Plans, ElderShield), and a government endowment fund that provides healthcare financial assistance for needy Singaporeans (MediFund).

ii The role of health insurance
It is mandatory for all working Singaporeans to contribute a portion of their income to Medisave, which is a national medical savings scheme administered by the Central Provident Fund (CPF) Board. Employees contribute a portion of their monthly wages into their personal Medisave account. The savings in the Medisave account can be used by the account holder to pay his or her own hospital bills and those of his or her immediate family members.

Apart from Medisave, all Singapore citizens and permanent residents are also automatically enrolled into MediShield Life, which is a basic national health insurance plan administered by the CPF Board. MediShield Life provides lifelong coverage to help Singaporeans pay for large hospital bills and selected costly outpatient treatments, such as dialysis and chemotherapy for cancer. Coverage can be supplemented by additional private insurance coverage, under Medisave-approved Integrated Shield Plans, which are managed by private insurers.

The MediShield Life Scheme Act 2015 (No. 4 of 2015) provides for the establishment and administration of the MediShield Life scheme. The MediShield Life Scheme Act further provides for the establishment of a MediShield Life Council, whose functions include making recommendations on the policy and scheme to ensure the continued provision of effective protection for Singapore citizens and permanent residents in an affordable and sustainable manner, and reviewing the administration of the scheme.

iii Funding and payment for specific services
Singapore's healthcare ecosystem adopts a mixed financing model, which broadly comprises the following tiers of protection: (1) government subsidies; (2) Medisave; (3) MediShield Life; and (4) MediFund.

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7 According to statistics compiled by the MOH and published by the Department of Statistics, over the past 10 years (FY06 to FY15). In Singapore, the total health expenditure is approximately 4.6 per cent of the GDP (The World Bank, 2016).
8 Self-employed persons who earn more than S$6,000 a year in net trade income are also required to make contributions to Medisave, based on their previous year's net trade income.
9 Section 8(2), MediShield Life Scheme Act.
The first tier consists of subsidies from the Singapore government of up to 80 per cent of the total bill for acute healthcare services rendered through the public hospitals.

The second tier of healthcare financing is via the Medisave scheme, which is a compulsory individual medical savings account scheme, to which all working Singapore citizens and permanent residents contribute a portion (between 8 per cent and 10.5 per cent\(^{10}\)) of their monthly wages. Withdrawals can be made by the account holder to pay for hospitalisation and selected outpatient expenses incurred at any hospital in Singapore (e.g., conditions under the Chronic Disease Management Programme, such as diabetes, hypertension, lipid disorders, stroke, asthma, chronic obstructive pulmonary disease, Parkinson’s disease and osteoporosis; certain outpatient vaccinations; and health screenings, such as mammogram and colonoscopy screenings), whether for the account holder or his or her immediate family members.

The third tier consists of MediShield Life and ElderShield, both of which are automatically provided to all Singapore citizens and permanent residents.

MediShield Life is a basic health insurance plan that provides lifelong coverage, including for any serious pre-existing conditions. It is designed to help Singaporeans pay for subsidised treatment in class B2 or class C wards in public hospitals, though Singaporeans can choose to supplement their basic MediShield Life coverage with Integrated Shield plans (IPs), which they can purchase from private insurers. IPs can provide additional coverage and benefits to cover the costs of treatment at private hospitals, or class B1 or class A wards in public hospitals. MediShield Life premiums can be paid for using money from a person’s Medisave account. Where a person opts to purchase an IP, the premiums paid to the private insurer already includes the premiums for the MediShield Life component.

ElderShield is a severe disability insurance scheme intended to provide basic financial protection to Singaporeans requiring long-term care. ElderShield is offered to all Singapore citizens and permanent residents who have a Medisave account when they reach 40 years of age, unless they choose to opt out of the scheme. Enrolment is automatic and a person will be automatically covered by one of the private insurers appointed by the MOH to run ElderShield. Premiums are payable annually upon the policy renewal date, until the person reaches 65 years of age or becomes severely disabled, whichever is the earlier. Policyholders may purchase ElderShield Supplements to gain additional disability benefits coverage.

The fourth tier, Medifund, is a medical endowment fund set up by the government to assist needy Singapore-citizen patients that have financial difficulties paying their remaining medical bills, even after receiving government subsidies and drawing on other means of payment such as Medisave, MediShield Life, and cash. It is intended to provide a safety net to ensure that no Singaporean is denied access to basic healthcare solely because of affordability issues.

In addition to the above, the Singapore government also administers various other subsidy schemes, such as the Community Health Assist Scheme (CHAS) (formerly known as the Primary Care Partnership Scheme) and the Interim Disability Assistance Programme for the Elderly (IDAPE).

Under the CHAS, participating general practitioners and dental clinics will provide common outpatient medical treatment and basic dental services to needy patients who are Singapore citizens at subsidised rates. The CHAS covers 19 chronic conditions, namely, anxiety, asthma, benign prostatic hyperplasia, bipolar disorder, chronic obstructive pulmonary disease

\(^{10}\) Depending on age group.
Singapore

(COPD), dementia, diabetes, epilepsy, hypertension, lipid disorders (e.g., high cholesterol), major depression, nephritis and nephrosis, osteoarthritis, osteoporosis, Parkinson's disease, psoriasis, rheumatoid arthritis, schizophrenia and stroke.

Separately, the IDAPE assistance scheme provides disability financial assistance to a limited group of elderly Singapore citizens who were not eligible to be enrolled in ElderShield at the time of its launch, either because they had exceeded the maximum entry age or had pre-existing disabilities.

Apart from subsidies for the costs of healthcare treatment and services, the MOH also provides drugs subsidies for drugs prescribed through public sector hospitals and clinics (which include specialist outpatient clinics and polyclinics) that are approved under the Standard Drug List (SDL) and the Medication Assistance Fund (MAF). Drugs may be listed on the SDL if they are assessed to be both clinically effective and cost-effective. The MOH regularly reviews and updates the list of drugs on the SDL, taking into account changes in clinical practice, advances in medical science and evolving needs of patients. Drugs approved under the MAF are generally newer and more expensive drugs and financial assistance provided under the MAF is subject to the use of the drug for only those specific clinical conditions for which the drug is assessed to be clinically effective and cost-effective.

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

Generally, healthcare services in Singapore are available through a broad network of primary, acute, and step-down care providers, from both the public and private sectors. In the primary care sector, private sector providers account for about 80 per cent of the market. In the acute care sector, public sector institutions deliver approximately 80 per cent of the care to patients. In the step-down care sector (which comprises nursing homes, community hospitals and hospices, among others), the majority of services are provided by voluntary welfare organisations, and costs of such service provision are mostly funded by the Singapore government.

Primary care and acute care providers are typically general practitioners, who must be licensed under the Medical Registration Act (in the case of medical practitioners) or under the Dental Registration Act (in the case of dental practitioners). Primary care providers are often patients' first point of contact under Singapore's healthcare system. Patients can generally receive outpatient medical treatment, immunisation, health screening and obtain other diagnostic and pharmaceutical services from their primary care providers. Patients who require specialised medical attention may be referred to other healthcare professionals with the necessary expertise.

Step-down care services are available for patients or individuals who require intermediate and long-term care. Such services may be home-based, centre-based, or residential. Home-based services are rendered to patients in their homes, and may include medical, nursing and palliative care. Centre-based services are offered at centres located within the community, and they may include community rehabilitation, dementia day care, and social day care services. Residential intermediate and long-term care services are generally provided by community hospitals, chronic sick hospitals, nursing homes, inpatient

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hospices and sheltered homes. The Agency for Integrated Care, which is established as an independent corporate entity under MOH Holdings (the holding company of Singapore’s public healthcare assets), is the coordinating agency that facilitates referrals to nursing homes receiving subsidies from the MOH.

To facilitate the delivery of integrated healthcare services across the network of providers, all patients who have sought medical treatment from a clinician or healthcare professional at a public healthcare institution since February 2011 will have an electronic medical record (EMR) created and uploaded to the National Electronic Health Record (NEHR) system. This is regardless of the patient’s residency or citizenship status. The NEHR system receives different data types from healthcare institutions and national registries, and these data are consolidated in the EMR of individual patients. A patient’s EMR can be accessed by clinicians and healthcare professionals at public healthcare institutions, community hospitals, nursing homes and hospices, as well as government agencies and general practitioner clinics that have requested to participate in the NEHR, who are authorised to access the NEHR, and who are providing the particular patient with medical care.

The access, security and management of patient data under the NEHR system is protected under a patchwork of legislation which include the Computer Misuse and Cybersecurity Act (Cap. 50A) (CMCA), the Personal Data Protection Act 2012 (Act 26 of 2012) (PDPA) and the PHMC Act, as well as under professional ethical codes that apply to registered healthcare professionals.

Under the CMCA, unauthorised access or modification of patient records under the NEHR system is an offence, which may attract a fine of up to S$100,000 or jail of up to 20 years or both.14

The PDPA, which is the baseline personal data protection law in Singapore, imposes obligations relating to the collection, use, disclosure, access, protection, retention and transfer of personal data. Organisations are required to make reasonable security arrangements to prevent unauthorised access, collection, use, disclosure, copying, modification, disposal or similar risks to personal data in their possession or under their control.15

Pursuant to the PHMC Act and its subsidiary legislation, licensees of healthcare institutions are required to ensure that there are adequate safeguards in place (whether by means of their administrative, technical or physical systems and processes) to protect the medical records of patients against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification.16

Registered healthcare professionals are bound by law and their respective professional ethical obligations to maintain patient confidentiality. For instance, doctors are bound by the provisions of the Medical Registration Act and its subsidiary legislation, in addition to professional ethical obligations under the Singapore Medical Council Ethical Code and Ethical Guidelines.

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14 Section 9, CMCA.
15 Section 24, PDPA.
16 Regulation 12, PHMC Regulations.
IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

The MOH oversees the regulation of healthcare in Singapore, including the licensing and regulation of all institutional healthcare providers in Singapore.

Healthcare professionals are generally self-regulated by their respective professional bodies:

a the Singapore Medical Council, which is established under the Medical Registration Act;

b the Singapore Dental Council, which is established under the Dental Registration Act;

c the Singapore Nursing Board, which is established under the Nurses and Midwives Act;

d the Singapore Pharmacy Council, which is established under the Pharmacists Registration Act;

e the Traditional Chinese Medicine Practitioners Board, which is established under the Traditional Chinese Medicine Practitioners Act (Cap. 333A);

f the Optometrists and Opticians Board, which is established under the Optometrists and Opticians Act (Cap. 213A); and

g the Allied Health Professions Council, which is established under the Allied Health Professions Act (Cap. 6B).

ii Institutional healthcare providers

Under the PHMC Act, any premises that are used as a private hospital, medical clinic, clinical laboratory or healthcare establishment must be licensed by the MOH.\(^\text{17}\) The PHMC Act and its subsidiary legislation also detail the requirements with regard to the types of services that may be carried out at private hospitals, medical clinics and clinical laboratories, as well as the qualifications of persons who manage these healthcare institutions.

Types of licences

The relevant licences and approvals required will depend on the scope of practice proposed to be carried out at the premises.

For instance, a medical clinic licence should be obtained if the premises are intended to be used by a doctor, dentist or other person for: (1) the diagnosis or treatment of persons suffering from, or believed to be suffering from any disease, injury or disability of mind or body, or (2) curing or alleviating any abnormal condition of the human body by the application of any apparatus, equipment, instrument or device requiring the use of electricity, heat or light.\(^\text{18}\) Medical clinics that offer certain special care services as listed in the Third Schedule of the PHMC Regulations will, additionally, require prior approval from the MOH to offer those services.\(^\text{19}\)

A private hospital licence will generally be required if the premises are to be used for the reception, lodging, and treatment and care of persons who require medical treatment or

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\(^\text{17}\) Section 2, PHMC Act.

\(^\text{18}\) Section 2, PHMC Act. There are certain exclusions, for instance, in respect of premises that are maintained by the Singapore government or the National University of Singapore, or which form part of the premises of a licensed private hospital.

\(^\text{19}\) Regulation 37, PHMC Regulations.
suffer from any disease.\(^{20}\) All private hospitals (with certain exceptions) will generally also need to offer the following types of services: blood services (including having facilities for the proper storage and administration of blood and blood products), dietetic services, emergency services and nursing services.\(^{21}\) Private hospitals that offer certain specialised procedures or services as listed in the Second Schedule of the PHMC Regulations will, similarly, require additional prior approvals from the MOH to offer those procedures or services.\(^{22}\)

Licensees of healthcare institutions must comply with all terms and conditions of their licences, as well as all relevant provisions of the PHMC Act and its subsidiary legislation.\(^{23}\) Failure to obtain the requisite licence or comply with licence terms and conditions is an offence, for which every person having the management or control of the healthcare institution will be liable on conviction to a fine not exceeding S$20,000 or imprisonment for a term of up to two years, or both.\(^{24}\)

**Application for licence**

Applications for the issue of a licence under the PHMC Act must be made through the MOH’s electronic licensing system (eLis) at http://elis.moh.gov.sg.\(^{25}\) The application must be submitted no less than two months before the intended date of commencement of practice. For new licence applications, supporting documents including the following must also be submitted within seven days of the licence application: a fire safety certificate,\(^{26}\) and a floor plan of the new premises (drawn to scale). If the proposed licensee intends to share the premises with other healthcare institutions, additional supporting documents may be required.

The relevant person who must apply for the licence under the PHMC Act depends on the type of healthcare institution licence that is being applied for. There are restrictions on the persons to whom a licence may be issued. A licence for a private hospital will generally only be issued to its owner, or the person having the management or control of the hospital.\(^{27}\) Medical clinic (or dental clinic) licences are generally issued to a medical practitioner or dentist.\(^{28}\) A clinical laboratory licence will generally only be issued to: (1) a Singapore-registered medical practitioner who has the relevant higher qualification and training in certain specified disciplines,\(^{29}\) (2) a person who has a degree in medicine, or (3) any other higher qualification in certain specified disciplines\(^{30}\) that is acceptable to the MOH’s Director of Medical Services.

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\(^{20}\) Section 2, PHMC Act.
\(^{21}\) Sections 21, 22, 23, PHMC Act. Nursing homes, psychiatric hospitals, convalescent hospitals, and maternity homes may not need to.
\(^{22}\) Regulation 18, PHMC Regulations.
\(^{23}\) Section 5(1), PHMC Act.
\(^{24}\) Section 5(2), PHMC Act.
\(^{25}\) Regulation 3(1), PHMC Regulations.
\(^{26}\) Regulation 20, Fire Safety Act (Cap. 109A).
\(^{27}\) Regulation 13, PHMC Regulations.
\(^{28}\) Regulation 35, PHMC Regulations.
\(^{29}\) The relevant disciplines are those listed in Regulation 56 of the PHMC Regulations.
\(^{30}\) The relevant disciplines are those listed in Regulation 56 of the PHMC Regulations.
and who has at least five years’ relevant working experience in a clinical laboratory acceptable to the MOH’s Director of Medical Services.\textsuperscript{31} For an x-ray laboratory licence, the applicant or licensee should be a radiologist who is registered with the Singapore Medical Council.\textsuperscript{32}

It is possible for a corporate entity to be the applicant of a licence under the PHMC Act. In the case of a private hospital licence, where the proposed licensee is a company, the applicant applying on behalf of the company must be a person holding a senior position in the company, for instance, the chief executive officer, chief operating officer, chief financial officer, or a director (who is listed as a director in the company profile\textsuperscript{33}).

As part of the application, it is necessary to name the person who will be the manager of the healthcare institution. For private hospitals, the manager should be a person who is responsible for the administration or management of the hospital, such as the chief executive officer or general manager.\textsuperscript{34} For a maternity home, the manager should be a Singapore-registered medical practitioner, nurse or midwife;\textsuperscript{35} and for a nursing home, the manager should be a Singapore-registered medical practitioner or nurse.\textsuperscript{36} The manager of a medical clinic and a dental clinic should be a Singapore-registered medical practitioner and dental practitioner, respectively.\textsuperscript{37} The manager of a clinical laboratory should be a person who either: (1) has a degree in medicine or a basic degree in a relevant science subject that is acceptable to the MOH’s Director of Medical Services, or (2) has at least five years’ relevant working experience in a clinical laboratory acceptable to the MOH’s Director of Medical Services.\textsuperscript{38} The manager of an x-ray laboratory should be a qualified radiographer.

For the licensing of new premises, the applicant will also be required to arrange for the premises to be inspected by the MOH’s Licensing, Inspection & Audit Branch, when the premises and facilities are operationally ready. This typically follows the submission of all necessary licence application documents and application fees to the MOH, after the premises have been prepared in accordance with the ‘Guide for Preparation of Medical & Dental Clinics’ (if applicable), and the facilities meet the checklist of requirements set out on eLis.

Depending on the type of licence sought, the MOH may typically require approximately one to two weeks after inspection to process, carry out administrative checks and confirm compliance with the relevant licensing requirements. Delays can be expected if there are deficiencies that need to be rectified.

Other additional licences or requirements may be required prior to the commencement of operation of a healthcare institution. These include licences for certain equipment, such as ultrasound machines, to be used in the healthcare institution, advertising licences for the display of advertisements, and Medisave accreditation.

**Risk-based licensing framework**

The MOH adopts a risk-based licensing framework, under which all healthcare institutions are categorised as ‘high-risk’, ‘moderate-risk’ or ‘low-risk’. This framework is intended

\textsuperscript{31} Regulation 47, PHMC Regulations.
\textsuperscript{32} MOH’s elis website, https://elis.moh.gov.sg.
\textsuperscript{33} As maintained by the Accounting and Corporate Regulatory Authority.
\textsuperscript{34} Regulation 10(2), PHMC Regulations.
\textsuperscript{35} Regulation 10(1)(a), PHMC Regulations.
\textsuperscript{36} Regulation 10(1)(b), PHMC Regulations.
\textsuperscript{37} Regulations 10(1)(c), 10(1)(d), PHMC Regulations.
\textsuperscript{38} Regulations 10(1)(e) and 49, PHMC Regulations.
to incentivise licensees to be compliant with licensing requirements. Subject to certain exceptions, licensees that are compliant may qualify for a five-year licence, unless they opt for a standard two-year licence. Hospitals, nursing homes, and medical clinics providing special care or specialised procedures are not eligible for a five-year licence. The MOH may conduct random audits to ensure licensees’ regular compliance with the applicable licensing requirements.

**Appeal for refusal to issue a licence**

Where the MOH refuses to issue or renew a licence under the PHMC Act, the applicant may lodge an appeal to the Minister for Health, within 21 days of receipt of the notice informing him of such refusal. The appeal will be referred to and considered by an advisory committee consisting of three members of the Singapore Medical Council or Singapore Dental Council (depending on whether the appeal is made by a medical or dental practitioner in relation to his or her clinic). The report of such advisory committee will be taken into account by the Minister in his or her decision-making.

**Suspension or revocation of licence**

The circumstances under which a licence issued under the PHMC Act may be suspended or revoked include the following:

- the issue of the licence has been obtained by fraud or misrepresentation;
- the person to whom the licence has been issued is contravening or has contravened or failed to comply with: (1) the PHMC Act or its subsidiary legislation; (2) any term or condition of the licence; or (3) any direction given to him by the MOH or an authorised officer under the PHMC Act or its subsidiary legislation;
- the MOH has concerns over the character or fitness of the licensee (or, where the licensee is a corporate entity, of the members of the board of directors or committee or board of trustees of the licensee), the ability of the licensee to operate and maintain the healthcare institution in accordance with the prescribed standards, or the suitability of the premises licensed for use as the healthcare institution, or the adequacy of the nursing and other staff that are employed at the healthcare institution’s premises;
- the private hospital, medical clinic, clinical laboratory or healthcare establishment in respect of which the licence was issued has ceased to operate as such; or
- it is in the public interest to do so.

Before suspending or revoking the licence, the MOH will generally: (1) give written notice to the licensee of the proposed suspension or revocation; and (2) in the notice, call upon the licensee to show cause within a specified time as to why the licence should not be suspended or revoked. If the licensee fails to show cause within the specified time (including any extensions of time that may be granted), or fails to show sufficient cause, the MOH would then give written notice to the licensee as to the date from which the suspension or revocation of the licence will take effect.

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39 Section 10(1)(a), PHMC Act.
40 Section 10(2), PHMC Act.
41 Section 9(1), PHMC Act.
42 Section 9(2), PHMC Act.
43 Section 9(3), PHMC Act.
Any person aggrieved by the decision to suspend or revoke a licence may, within 21 days of the date of receipt of the written notice informing of the suspension or revocation, appeal in writing to the Minister for Health, whose decision shall be final. Before making a decision, the Minister shall refer the matter to an advisory committee consisting of three members of the Singapore Medical Council or Singapore Dental Council (as appropriate), and the Minister will consider the report of such advisory committee in his or her decision-making.

iii Healthcare professionals

Doctors

All medical practitioners must be registered with and hold a valid practising certificate issued by the Singapore Medical Council to practise medicine in Singapore. A person applying for registration as a medical practitioner in Singapore may be eligible for one of four types of registrations, depending on his or her educational qualification, knowledge, skill and experience: (1) full, (2) conditional, (3) temporary or (4) provisional registration.

Medical practitioners that wish to practise as specialists must, additionally, be accredited by the Specialists Accreditation Board and registered under the relevant specialty by the Singapore Medical Council. To practise as a family physician in Singapore, a medical practitioner must be accredited with the Family Physicians Accreditation Board and also be registered as a family physician with the Singapore Medical Council.

Subject to certain limited exceptions, the Medical Registration Act makes it an offence for a person to practise medicine, or to advertise or hold himself or herself out as a medical practitioner, otherwise than in accordance with the relevant requirements. It is also an offence for a person to wilfully and falsely pretend to be a duly qualified medical practitioner. Each of these offences may, in the case of a first conviction, attract a fine of up to S$100,000 or imprisonment for a term of up to 12 months, or both. For second or subsequent convictions, the offence may attract a fine of up to S$200,000 or imprisonment for a term of up to two years, or both.

44 Section 10(1), PHMC Act.
45 Section 10(2), PHMC Act.
46 Section 13, Medical Registration Act.
47 Sections 20, 21, 23 and 24 of the Medical Registration Act provide for full, conditional, temporary and provisional registration, respectively.
48 Section 22, Medical Registration Act. As at the time of writing, the Specialist Accreditation Board recognises 35 specialities (anaesthesiology, cardiology, cardiothoracic surgery, dermatology, diagnostic radiology, emergency medicine, endocrinology, gastroenterology, general surgery, geriatric medicine, haematology, hand surgery, infectious diseases, internal medicine, medical oncology, neurology, neurosurgery, nuclear medicine, obstetrics and gynaecology, occupational medicine, ophthalmology, orthopaedic surgery, otorhinolaryngology/ENT, paediatric medicine, paediatric surgery, pathology, plastic surgery, psychiatry, public health, radiation oncology, rehabilitation medicine, renal medicine, respiratory medicine, rheumatology and urology) and five sub-specialties (aviation medicine, intensive care medicine, neonatology, palliative medicine and sports medicine).
49 Section 17(1), Medical Registration Act.
50 Section 17(1), Medical Registration Act.
Any person who is refused registration (as a medical practitioner, specialist or family physician) may, within one month of the written notice given by the Singapore Medical Council informing him or her of such refusal, submit a written appeal to the Minister for Health, whose decision is final.\(^51\)

All registered medical practitioners are required to observe the pronouncements on professional matters and professional ethics issued from time to time by the Singapore Medical Council.\(^52\) These include the Singapore Medical Council Ethical Code and Ethical Guidelines, and the Handbook on Medical Ethics. Failure to comply with any professional ethical obligations or the serious disregard of, or persistent failure to meet the standards of ethics prescribed by the Singapore Medical Council may result in disciplinary proceedings being taken against the medical practitioner.\(^53\)

Existing medical practitioners must renew their practising certificates, which are typically granted for no more than two years at a time.\(^54\) Medical practitioners must fulfil the requisite number of continuing medical education points, which is statutorily prescribed, in order to renew their practising certificates.\(^55\)

There is no strict statutory requirement for medical practitioners in Singapore to maintain medical indemnity insurance. However, it is customary for medical practitioners in Singapore to take up such insurance.

**Dentists**

A person who wishes to practise dentistry in Singapore will generally need to be registered with, and must hold a valid practising certificate issued by the Singapore Dental Council.\(^56\) A person applying for registration as a dental practitioner in Singapore may be eligible for one of three types of registrations, depending on his or her educational qualification, knowledge, skill and experience: (1) full, (2) conditional or (3) temporary registration.\(^57\)

Dental practitioners that wish to practise any of the recognised dental specialties must have obtained accreditation from the Dental Specialist Accreditation Board and be registered as a dental specialist with the Singapore Dental Council.

The unauthorised practise of dentistry is an offence, which may attract a fine of up to S$25,000 in the case of a first conviction, and in the case of a second or subsequent conviction, a fine of up to S$50,000 or imprisonment for a term of up to six months, or both.\(^58\)

It is also an offence for any person other than a registered dentist having in force a practising certificate to take or use the title of dentist, dental surgeon, registered dentist, qualified dentist, doctor of dental surgery, professor of dentistry, surgeon dentist, any prescribed title under Section 31(5),\(^59\) or any name, title, addition or description implying,

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\(^{51}\) Section 28(5), Medical Registration Act; Regulations 20(7) and 20A(7), Medical Registration Regulations.

\(^{52}\) Regulation 26, Medical Registration Regulations 2010.

\(^{53}\) See generally, Part 7 of the Medical Registration Act, and Part V of the Medical Registration Regulations.

\(^{54}\) Regulation 25(1), Medical Registration Regulations 2010.

\(^{55}\) Regulation 24(1) and the Fourth Schedule, Medical Registration Regulations 2010.

\(^{56}\) Section 22, Dental Registration Act.

\(^{57}\) Sections 14, 14A and 14B of the Dental Registration Act provide for the full, conditional and temporary registration, respectively.

\(^{58}\) Sections 22(1) and 22(2) read with Section 28, Dental Registration Act.

\(^{59}\) Section 31(5) of the Dental Registration Act empowers the SDC to make regulations to prescribe appropriate titles and conditions under which the titles may be used, if the SDC is of the opinion that
whether in itself or in the circumstances in which it is used, that that person is qualified to heal or treat dental disorders or derangement, whether by dentistry or other means of any kind or description whatsoever.60

Any person who is refused registration (whether as a dental practitioner or specialist) may, within one month of the written notice given by the Singapore Dental Council informing him or her of such refusal, appeal to the Minister for Health, whose decision shall be final.61

All dentists are required to observe the professional pronouncements on professional matters and professional ethics issued from time to time by the Singapore Dental Council, for instance, the Singapore Dental Council Ethical Code and Guidelines.62 Serious disregard or failure to meet the standards of professional conduct and ethics prescribed by the Singapore Dental Council may lead to disciplinary proceedings against the dental practitioner.63

Registered dental practitioners must renew their practising certificates, which are typically granted for no more than two years at a time.64 Dental practitioners must fulfil the requisite number of continuing professional education points, which is statutorily prescribed, in order to renew their practising certificates.65

The Singapore Dental Council strongly encourages all dental practitioners in Singapore to maintain adequate professional indemnity insurance coverage, though there is presently no strict statutory requirement to do so.66

Nurses

Generally, a person must be registered or enrolled as a nurse under the Nurses and Midwives Act and hold a valid practising certificate issued by the Singapore Nursing Board in order to carry out an act of nursing.67

Depending on the nursing course that the applicant has successfully completed, he or she may be registered as a registered nurse, or enrolled as an enrolled nurse, provided that he or she has also fulfilled all other applicable conditions for such registration or enrolment.68 In addition, any registered nurse who wishes to be an Advanced Practice Nurse must separately apply to be certified as such, subject to the applicant meeting all relevant requirements under the Nurses and Midwives Act.69

any branch of dentistry has become so distinctive that it would be for the convenience of the public or of the dental profession that registered dentists qualified to practise, or practising, in that branch of dentistry should use a distinctive title, subject to the approval of the Minister for Health.

60 Section 26(1) read with Sections 26(2), and 28, Dental Registration Act.
61 Section 15(7), Dental Registration Act, and Regulation 14, Dental Registration Regulations.
62 Regulation 16, Dental Registration Regulations.
63 Paragraph 1 (Introduction), SDC Ethical Code and Guidelines.
64 Section 17(3), Dental Registration Act.
65 Regulation 15I and Third Schedule, Dental Registration Regulations.
66 Paragraph 4.1.10, SDC Ethical Code and Guidelines.
67 Section 26, Nurses and Midwives Act.
68 Sections 14(1) and (2), Nurses and Midwives Act.
69 See generally, Sections 32(2) and (4), Nurses and Midwives Act.
Subject to certain limited exceptions, the unauthorised carrying out of any act of nursing for a fee or reward is an offence, which may attract a fine of up to S$10,000 (in the case of a first conviction) or a fine of up to S$20,000 or imprisonment of up to six months (in the case of a second or subsequent conviction), or both.

It is also an offence for a person who is not a qualified nurse to take or use the name or title of nurse in any language, either alone or in combination with any other words or letters, or any name, title, addition, description, uniform or badge, implying that he or she is a qualified nurse or that he or she is qualified to carry out an act of nursing. This may attract a fine on conviction of up to S$10,000.

Any person who is refused registration or enrolment as a nurse, or refused certification as an advanced practice nurse may, within one month of the written notice given by the Singapore Nursing Board informing him or her of such refusal, submit a written appeal to the Minister for Health, whose decision shall be final.

All registered and enrolled nurses, as well as advanced practice nurses are required to observe the Singapore Nursing Board’s pronouncements on professional practice, professional conduct and professional ethics issued from time to time. These include the Singapore Nursing Board Code of Ethics and Professional Conduct (for nurses and midwives), and a Standards of Practice for Nurses and Midwives. Nurses may face disciplinary action by the Singapore Nursing Board for professional misconduct, for instance, in the case of breaches of the professional values and standards set out in the Code of Ethics and Professional Conduct and the Standards of Practice for Nurses and Midwives.

Nurses must renew their practising certificates annually. Renewal of the practising certificate is subject to the nurse making a declaration of his or her fitness to continue nursing practice, and payment of the relevant fee for the renewal of the practising certificate.

**Pharmacists**

All pharmacists must generally be registered with and hold a valid practising certificate issued by the Singapore Pharmacy Council to practise pharmacy in Singapore. A person applying for registration as a pharmacist in Singapore may be eligible for one of three types of registrations, depending on his or her educational qualification, knowledge, skill and experience: (1) full, (2) conditional or (3) temporary registration.
Registered pharmacists who wish to practise as specialists must, additionally, be accredited by the Pharmacy Specialists Accreditation Board and registered under the relevant specialty by the Singapore Pharmacy Council.  

Subject to certain limited exceptions, the Pharmacists Registration Act makes it an offence for a person to practise pharmacy, or to advertise or hold himself or herself out as a pharmacist, otherwise than in accordance with the relevant requirements. It is also an offence for a person to wilfully and falsely pretend to be a duly qualified pharmacist. Each of these offences may, in the case of a first conviction, attract a fine of up to S$25,000. For second or subsequent convictions, the offence may attract a fine of up to S$50,000 or imprisonment for a term of up to six months, or both.

Any person refused registration as a pharmacist may, within 30 days of the written notice given by the Singapore Pharmacy Council informing him or her of such refusal, submit a written appeal to the Minister for Health, whose decision is final.

All registered pharmacists are required to comply with, among others, the standards of professional conduct set out in the Code of Ethics issued by the Singapore Pharmacy Council. Serious disregard or persistent failure to meet the Code of Ethics could lead to disciplinary proceedings against a pharmacist for professional misconduct.

Further, registered pharmacists must renew their practising certificates, which are typically granted for no more than two years at a time. Pharmacists must fulfil the statutorily prescribed continuing professional education requirements in order to renew their practising certificates.

Others
Apart from the above, allied health professionals (which include occupational therapists, physiotherapists, speech-language therapists, diagnostic radiographers, audiologists, clinical psychologists and dieticians), optometrists and opticians, and oral health therapists, among others, are also subject to registration and other requirements.

V NEGLIGENCE LIABILITY

i Overview
In general, a patient alleging negligence against a doctor must establish that the doctor breached one or more of his or her duties of care owed to the patient, and further that this caused damage to the patient.

The Singapore courts have recognised that the duties of care owed by a doctor to a patient comprise three aspects: (1) diagnosis (establishing what the patient’s medical need is), (2) advice (providing information regarding alternative treatments and the risks attendant on various possible treatments, etc.) and (3) treatment and care.
The relevant standard of care owed by doctors to their patients in relation to the three aspects mentioned above was laid down by the Singapore Court of Appeal in *Gunapathy*, and more recently, in *Lucien Ooi*. In respect of the diagnosis and treatment of patients, the applicable standard is the *Bolam* test, subject to the *Bolitho* addendum. In respect of advice given by a doctor to his or her patients, the applicable standard is a modified version of the *Montgomery* test, as laid down by the Singapore Court of Appeal in *Lucien Ooi*.

In assessing whether a doctor is liable to his or her patient in the tort of negligence, the courts will have regard to whether the negligence was causative of damage. In medical negligence cases, compensatory damages are typically awarded by the courts to a plaintiff patient for pecuniary losses (such as expenses for medical or nursing care) and non-pecuniary losses (such as pain and suffering, and loss of amenities) that the patient has suffered. Aggravated damages, which also serve a compensatory function, may be awarded for the enhanced hurt suffered by a plaintiff patient due to the aggravation of the injury by the manner in which the doctor committed the wrong or by his motive in so doing, either or both of which might have caused further injury to the patient’s dignity and pride. In rare instances, the courts may award provisional damages, that is, an award of damages that is contingent on reassessment of the plaintiff patient’s situation at a prescribed future date. The courts in Singapore are generally reluctant to award punitive or exemplary damages in medical negligence cases.

### ii Notable cases

**Hii Chii Kok v. Ooi Peng Jin London Lucien and another**

The patient in this case had undergone certain diagnostic scans that revealed lesions in his pancreas. On the advice of his surgeon and certain other doctors associated with the National Cancer Centre of Singapore (NCCS), the patient underwent a surgical procedure called the Whipple procedure. The patient suffered life-threatening complications as a result, and had to undergo further operations to overcome these complications. Post-operative tests revealed that the lesions were not in fact cancerous. The patient brought proceedings against his surgeon and the NCCS for, among other things, negligent diagnosis and negligent advice.

The Singapore Court of Appeal took the view that ‘although the law as it was stated in *Gunapathy* still applies in the contexts of diagnosis and treatment, a different, more patient-centric test is now required in the context of information and advice that doctors provide to their patients’. In this regard, the court held that the standard of care applicable to advice given by a doctor to his or her patient should be that under a modified version of the *Montgomery* test.

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89 *Khoo James and another v. Gunapathy d/o Muniandy and another appeal* [2002] 1 SLR(R) 1024.
91 *Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 582.
92 *Bolitho v. City and Hackney Health Authority* [1998] AC 232.
93 *Khoo James and another v. Gunapathy d/o Muniandy and another appeal* [2002] 1 SLR(R) 1024.
94 See, for example, *Koh Sin Chong Freddie v. Chan Cheng Wab Bernard* [2013] 4 SLR 629 at [75]-[77]; *ACB v. Thomson Medical Pte Ltd* [2017] 1 SLR 918 at [156].
95 See, for example, *Koh Chai Kwang v. Teo Ai Ling* [2011] 3 SLR 610.
96 See, for example, *ACB v. Thomson Medical Pte Ltd* [2017] 1 SLR 918 at [170]-[209].
97 *Hii Chii Kok*, at [51].
In other words, the test of whether a doctor has discharged the relevant standard of care in the advice given to his or her patients now involves, broadly, a three-stage inquiry:

a) first, what was the information alleged to have been omitted by the doctor in advising the patient, and was such information: (1) relevant and material to a reasonable patient situated in the particular patient’s position, or (2) information that a doctor knows is important to the particular patient in question;\(^9\)

b) second (assuming the court is satisfied that the information needed is relevant and material), was the doctor in possession of the information, and if not, ought he to have been in possession of the information (as assessed under the standard applicable to diagnosis or treatment, i.e., applying the Bolam test and the Bolitho addendum);\(^10\) and

c) third (assuming the doctor did possess the information), whether there is any reasonable justification why the information, though material and in the doctor’s possession, was nevertheless withheld.\(^11\) If the doctor was justified in withholding the information, then the doctor would not be found to have breached the standard of care in relation to his duty to communicate the information.

However, in relation to the diagnosis and treatment by doctors to their patients, the relevant standard of care applicable continues to be the Bolam test, subject to the Bolitho\(^12\) addendum. This means that a doctor would not generally be found to be negligent, in relation to the diagnosis or treatment of his or her patient, if he or she had acted in accordance with a practice that has been accepted as proper by a responsible body of medics skilled in the particular area, but only provided that the body of opinion was logically defensible.

**ACB v. Thomson Medical Pte Ltd and others**\(^13\)

The appellant in this case had undergone in vitro fertilisation (IVF) treatment at a fertility clinic operated by Thomson Medical Pte Ltd. After the child’s (Baby P) birth, the appellant and her husband discovered that Baby P had been conceived with the appellant’s ovum and an unknown third-party’s sperm rather than the husband’s.

The appellant sued the clinic as well as a senior embryologist and chief embryologist who were employed by the clinic, and sought to claim damages for, *inter alia*, the upkeep costs for raising Baby P. One of the principal legal issues in the appeal was whether such upkeep costs were a compensable head of damage. Other issues that the court considered in the appeal proceedings included whether the appellant could seek damages for loss of autonomy suffered, and whether the court was entitled to award punitive damages in the circumstances.

On account of the circumstances, the court denied the claim for upkeep costs as being against public policy considerations. Such a claim depended upon the recognition of the obligations of parenthood as actionable damage. However, the responsibilities of parenthood were, in the eyes of the law, obligations of a legal and moral character. Such responsibilities were incapable of valuation as ‘loss’ in any meaningful sense and could not be the subject of a claim for damages. The parents would have had to prove that the child represented a net

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\(^9\) Hii Chii Kok v. Ooi Peng Jin London Lucien [2017] SGCA 38 at [132].

\(^10\) Hii Chii Kok v. Ooi Peng Jin London Lucien [2017] SGCA 38 at [133].


\(^12\) Bolitho v. City and Hackney Health Authority [1998] AC 232.

\(^13\) [2017] 1 SLR 918.
loss to them. Such an exercise would, in the court’s view, encourage the exaggeration of any
infirmities and the diminution of benefits as might exist in the child, thereby giving rise to a
potential conflict of interest between the parents’ private interests in the litigation and their
responsibilities as parents.

In relation to the damages claimed for ‘loss of autonomy’, the court held that such
a head of damage was not to be recognised as an actionable damage in its own right. The
concept of ‘autonomy’ was not only a nebulous one, but the notion of ‘autonomy’ also did not
cohere with the requirement of ‘damage’ in the law of negligence which required claimants
to prove objective detriment in order to make out a cause of action. Further, the recognition
of loss of autonomy would mean that claimants may be able to circumvent existing control
mechanisms in the tort of negligence. While the court declined to award damages for loss of
autonomy in this case, it left open the possibility that a loss of autonomy could underlie a
more specific award of damages in the context of a negligent interference with the plaintiff’s
reproductive plans.

Importantly, however, the court recognised that the ‘loss of genetic affinity’ could be
seen as an element of non-pecuniary loss, which was akin in some ways to an award for
pain and suffering. The court acknowledged that the appellant’s desire to have a child of
her own, with her husband, was a basic human impulse, the loss of which would be keenly
and deeply felt. The court also noted that the loss of genetic affinity could lead to social
stigma and embarrassment arising out of others’ misperceptions, as was the case on the facts.
In this regard, the court considered that the appropriate amount of damages in each case
would depend on the unique types of harm suffered by the plaintiff who has had his or her
reproductive plans disrupted. The harm would, in turn, depend on the precise motivations of
each plaintiff in seeking fertility treatment, as well as other relevant case-specific factors, such
as the precise manner in which the negligence took place and the personal circumstances of
the plaintiff. In the present circumstances, where the court noted an absence of comparable
local and foreign precedents, the appellant was awarded damages for her loss of genetic
affinity benchmarked as a percentage (30 per cent) of the financial costs of raising Baby P.

As can be seen from the above, public policy considerations are an important aspect
in medical negligence cases, whether in the establishment of liability for medical negligence
or the award of damages for medical negligence. The Singapore courts are generally slow
to award damages for negligence by individual and institutional healthcare providers, even
in cases where liability has been established, if doing so would be against public policy
considerations.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

As discussed above, the public healthcare system is currently structured as vertically integrated
delivery networks, and is organised by region. Currently, all acute hospitals and specialty
centres in the Singapore public sector are run as private companies that are wholly owned
by the government, but their management resembles that of not-for-profit organisations.
Public sector hospitals receive an annual government subvention or subsidy for the provision
of subsidised medical services, and are subject to broad policy guidance by the Singapore
government through the MOH. This model allows the public sector hospitals in Singapore
to have the management autonomy and flexibility to respond more promptly to the needs
of the patients.
There are no statutory prohibitions against the ownership of healthcare providers in Singapore. However, there are restrictions on the persons to whom a licence under the PHMC may be issued, that is, for the operation of a private hospital, medical or dental clinic, clinical or x-ray laboratory or other types of healthcare establishments. In determining whether to issue or refuse to issue a licence under the PHMC Act to an applicant, the MOH will have regard to, among others, the following matters:

a. the character and fitness of the applicant to be issued with a licence or, where the applicant is a body corporate, the character and fitness of the members of the board of directors or committee or board of trustees or other governing body of the body corporate; and

b. the ability of the applicant to operate and maintain a private hospital, medical clinic, clinical laboratory or healthcare establishment, as the case may be, in accordance with the prescribed standards.

Consolidations in the healthcare sector may be subject to the provisions of the Competition Act (Cap. 50B), which include a prohibition against anticompetitive mergers. In 2015, the Competition Commission of Singapore, which enforces the Competition Act, took a provisional decision to block a proposed transaction involving the acquisition of an equity stake by one healthcare provider of another healthcare provider.

VII COMMISSIONING AND PROCUREMENT

On a broader level, the MOH has oversight over the healthcare ecosystem in Singapore, in terms of not only the public healthcare infrastructure but also healthcare manpower, and the development and implementation of policies and programmes across the public and private sectors to ensure accessible, affordable, quality and sustainable healthcare.

In the public sector, all acute hospitals and specialty centres currently operate as private companies that are wholly owned by the government through an entity called MOH Holdings. These public healthcare institutions generally have management autonomy in their day-to-day operations, including in the procurement of appropriate healthcare manpower to meet demand. Public healthcare institutions may also procure manpower from recruitment agencies to meet short-term and temporary manpower needs. In contrast to private sector healthcare institutions, however, those in the public sector are managed akin to not-for-profit organisations and they also receive an annual government subvention or subsidy for the provision of subsidised medical services to patients. The public healthcare clusters also pool their long-term reserves (which they need only to use in the medium to long term) into a common pool and these funds are managed through MOH Holdings.

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104 See Section IV above.
105 Section 6(3), PHMC Act.
106 Section 54, Competition Act.
107 CCS media release dated 16 March 2015, 'CCS's Provisional Decision to Block Parkway Holdings Ltd's Proposed Acquisition of Radlink-Asia Pte Ltd'.
108 MOH Holdings Pte Ltd is the holding company of Singapore's public healthcare clusters.
The SingHealth Group Procurement Office (GPO) has responsibility over the procurement of drugs, and medical, surgical and other supplies for public healthcare institutions. The GPO functions as an agent for individual healthcare institutions. This means that the GPO will despatch the relevant requests for proposal to potential vendors, review replies therefrom, conduct negotiations and then select ‘strategic vendors’ on behalf of all the individual healthcare institution entities. Each hospital or clinic has its own internal department that manages the specific institutional needs for purchases and inventory of products and services, and will take delivery of the products and services that they require directly from the vendor.111

VIII MARKETING AND PROMOTION OF SERVICES

There are regulatory restrictions on both institutional and individual healthcare providers in relation to the marketing and promotion of the services that they offer.

i Healthcare institutions

Healthcare institutions that are licensees under the PHMC Act are required to comply with the Private Hospitals and Medical Clinics (Publicity) Regulations (the PHMC Publicity Regulations), among others.

The Publicity Regulations sets out restrictions in relation to, inter alia, the content of publicity in Singapore, and the advertising media in which publicity may appear. For instance:112

a information contained in the publicity must be factually accurate and capable of being substantiated, and must not be exaggerated, false, misleading or deceptive;
b the publicity must not be offensive, ostentatious or in bad taste such as to undermine the honour and dignity of the medical, dental or nursing profession;
c the publicity must not contain any information that: (1) implies that the healthcare institution can obtain results from treatment not achievable by other healthcare institutions or create an unjustified expectation from the treatment provided; or (2) compares and contrasts the quality of the services of the healthcare institution with those provided by other healthcare institutions or deprecate the services of other healthcare institutions;
d the publicity must not contain any laudatory statements (including statements of prominence or uniqueness) or superlatives to describe the services of the healthcare institution;
e the information contained in the publicity must not contain any testimonial or endorsement of the services, including the services of any employee of the healthcare institution; and
f the publicity must not provide information to the public in such a manner so as to amount to soliciting or encouraging the use of the services provided by or at any healthcare institution.

Permitted advertising media in which publicity may appear are: newspapers, directories, medical journals, magazines, brochures, leaflets, pamphlets and the internet.113 This is,

112 Regulation 4, PHMC Publicity Regulations.
113 Regulation 5(1), PHMC Publicity Regulations.
however, subject to certain restrictions. For instance, the internet must not be used for patient consultation with any employee of the healthcare institution if the patient is not an existing patient of the healthcare institution.\textsuperscript{114} Publicity brochures, leaflets or pamphlets must contain the date of publication.\textsuperscript{115}

There are also restrictions in relation to the following types of activities involving healthcare institutions:

\begin{itemize}
\item[a] the publicity of a healthcare institution’s services in conjunction with any person;\textsuperscript{116}
\item[b] media interviews where the licensee or an employee of the healthcare institution consents to be interviewed;\textsuperscript{117}
\item[c] public acknowledgement of contributions (e.g., donations, sponsorships or subscriptions) to good causes, by a healthcare institution;\textsuperscript{118}
\item[d] filming on the premises of a healthcare institution;\textsuperscript{119} and
\item[e] publicity of public workshops, seminars or symposiums organised by a healthcare institution.\textsuperscript{120}
\end{itemize}

\section*{ii Healthcare professionals}

The ethical codes and guidelines issued by the relevant professional bodies in the healthcare sector set out restrictions on advertising by healthcare professionals of their services.

For instance, the Singapore Medical Council Ethical Code and Guidelines provide, in relation to doctors’ advertisement of their services, for matters such as the standards of information contained in the advertisements, requirements when giving talks, interviews or writing articles, associations with healthcare organisations (whether professionally or in business), dissemination of professional announcements, and overseas advertisements.

Similarly, the Singapore Dental Council Ethical Code and Guidelines, which apply to dental practitioners, contains guidance in relation to the provision of information about dentists’ services. The guidance relates to matters including content standards (including information provided at public talks, broadcasting and publications), platforms on which dentists may list their service information, association with healthcare organisations, provision of information through websites, electronic communications with patients, use of personal name cards and stationery, as well as professional announcements.

For nurses, the Code of Ethics and Professional Conduct and the Standards of Practice for Nurses and Midwives issued by the Singapore Nursing Board provides, generally, that nurses (and midwives) must refrain from any form of canvassing or advertising that is incompatible with the ethical standards of the profession.\textsuperscript{121}

In respect of pharmacists, the Singapore Pharmacy Council Code of Ethics contains a section relating to the Ethical Code on Advertising. This sets out general principles on

\begin{footnotes}
\item[114] Regulation 5(2), PHMC Publicity Regulations.
\item[115] Regulation 5(3), PHMC Publicity Regulations.
\item[116] Regulation 6, PHMC Publicity Regulations.
\item[117] Regulation 7, PHMC Publicity Regulations.
\item[118] Regulation 8, PHMC Publicity Regulations.
\item[119] Regulation 9, PHMC Publicity Regulations.
\item[120] Regulation 10, PHMC Publicity Regulations.
\item[121] Paragraph 10.6, Section II, SNB Code of Ethics and Professional Conduct.
\end{footnotes}
advertising by pharmacists, and it also details permissible and prohibited advertising activities in various contexts (such as public speaking and broadcasting, and the provision of information about their services through websites and other media platforms).

IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

The MOH takes an active approach in the regulation of healthcare issues in Singapore. The Healthcare 2020 Masterplan was unveiled by the MOH in March 2012, and has since been progressively implemented. One of the key areas under the masterplan is the ageing population in Singapore, which was projected to be a strong driver for healthcare demand.

In recognition of the fact that telemedicine can assist to meet the healthcare demands of an ageing population and potential shortages of healthcare professionals and caregivers, the MOH introduced the National Telemedicine Guidelines in 2015 to provide leadership and direction in the area of telemedicine. These guidelines are targeted at healthcare professionals and organisations, patients and caregivers. They are intended to provide guidance on best practices in telemedicine interactions, including the respective responsibilities of healthcare organisations and healthcare professionals in relation to: (1) clinical standards and outcomes, (2) human resources, (3) organisation matters, and (4) technology and equipment.

Under the Healthcare 2020 Masterplan, the MOH has worked in tandem with healthcare stakeholders to ensure that its policies, financing structure, support system and programmes support the shift from healthcare provision to the promotion of health upstream, by enabling Singaporeans to take personal responsibility for their health, and empowering patients (and their caregivers) to participate in self-care and management of their medical conditions. In addition to raising awareness among the population of common diseases and health concerns, the MOH also intends to strengthen early screening and intervention, as well as provide support for better disease control measures.

Following the introduction of the Healthcare 2020 Masterplan, the MOH has tackled the issue of seeking to increase accessibility to healthcare by expanding capacity across various sectors of the healthcare ecosystem. This includes opening new acute and community hospitals, as well as progressively adding more beds to these hospitals and to other institutions such as nursing homes. Expansions of polyclinics offering primary healthcare services are also either under way or expected.

Regulatory reforms have also been implemented by the MOH to help ensure that the cost of healthcare remains affordable, and that care is effective and good value for money. For instance, the MOH introduced the MediShield Life scheme (to replace the Medishield scheme) to provide lifelong basic health insurance coverage for all Singapore citizens and permanent residents.

X  CONCLUSIONS

The healthcare regulatory landscape in Singapore is ever evolving. Given the increasing use of telemedicine, and other advances in medicine and technology, changes to the regulations governing the provision of healthcare services in Singapore are to be anticipated. Further developments within the healthcare ecosystem can also be expected under the MOH’s Healthcare 2020 Masterplan, which focuses on three strategic objectives of enhancing the accessibility, quality and affordability of healthcare.
Chapter 14

SWITZERLAND

Markus Wang and Jonas Bornhauser

I OVERVIEW

The Swiss healthcare ecosystem is rather complex, since it combines aspects of managed competition and corporatism in a decentralised regulatory framework. The system is characterised by the allocation of decision-making or decision influencing powers to (1) the three different levels of government (the Swiss Confederation, the 26 Swiss cantons and the 2352 municipalities in Switzerland); (2) the recognised private healthcare organisations, such as Swiss Red Cross, Swiss Patient Organisation, Swiss Cancer League and the organisation of the mandatory health insurance (MHI) providers; and (3) the Swiss citizens who can veto against or demand a reform through public referenda and plebiscite.

The Swiss Confederation (i.e., the federal state) is only permitted to act in those fields in respect of which it is granted powers to do so by the Swiss Constitution. The most important fields are (1) the funding of the health system (through the MHI and other social insurances); (2) ensuring quality and safety of medicinal products and medical devices; (3) ensuring public health (control of infectious diseases, food safety, health promotion); and (4) research and training (third-level education) of non-physician health professionals. The most important piece of legislation by which the Swiss Confederation steers the Swiss healthcare system is the Federal Health Insurance Act (HIA), which sets the legal framework of the MHI system and in particular defines which services are to be paid by such system.

The Swiss federal government, the so-called Federal Council, and the Swiss parliament enact laws and ordinances that are to be implemented by the Swiss cantons. On a governmental level, the Federal Office of Public Health (FOPH), which is part of the Federal Department of Home Affairs (FDHA), is responsible for the development of national health policies. The responsibilities of the FOPH include other tasks, such as the supervision of mandatory health insurance, decisions on the reimbursement and the prices of therapeutic products and the regulation of university-educated medical and healthcare professions. It also represents the health policy interests of Switzerland in international bodies and with regard to other states.
The responsibility for the provision of healthcare services lies mainly with the 26 Swiss cantons. The cantons maintain and, together with the MHI, finance hospitals and nursing homes, which they also supervise. In addition, they are also competent to issue and implement certain health-related legislation. The cantons further finance a substantial part of inpatient care, provide subsidies to low-income households enabling such households to pay for insurance, and coordinate prevention and health promotion activities. The Swiss cantons work together on an institutional level through the Swiss Conference of the Cantonal Ministers of Public Health.

The competences and responsibilities of municipalities in the fields of healthcare and other social support services vary across Switzerland, depending on the related allocation of powers and tasks in the cantonal constitutions.

II THE HEALTHCARE ECONOMY

i General

Free healthcare services are available to all persons resident in Switzerland on the basis of the MHI system, irrespective of whether such residents are Swiss citizens or not, are employed or not, or work in the public or private sector. The MHI system, the basic social insurance covering the risk of illness, maternity and (if not covered by another insurance) accidents is regulated by the HIA, which entered into force in 1996. The basic principle set forth in the HIA provides that all persons resident in Switzerland have guaranteed access to good medical care. The basic MHI aims to ensure that the costs of required medical treatments are covered by the insurance.

Every person employed in Switzerland is further covered by the mandatory accident insurance scheme for the health and economic consequences of work-related and non-work-related accidents, as well as occupational diseases (i.e., diseases that are caused in the course of occupational activity solely or principally by harmful substances or certain types of work according to a list issued by the federal government). Not covered by mandatory accident insurance are non-employed persons, such as children, students and pensioners. For these persons, coverage for accident is available as part of MHI.

Temporary non-resident visitors have to pay up front for care and must reclaim reimbursement under insurance coverage they may have in their home country.

ii The role of health insurance

Residents are legally required to insure themselves with an MHI provider. Persons moving to Switzerland have to do so within three months as from their arrival. Insurance is offered by about 60 competing non-profit MHI companies that are supervised by FOPH. Contrary to private insurers providing complimentary health insurance coverage, the MHI providers must accept all applicants, irrespective of age and irrespective of whether they are already ill or not.


6 Article 1a HIA.
7 The Swiss healthcare system, Financing healthcare.
8 Articles 1a and 6 of the Federal Act concerning Accident Insurance.
9 Article 3 HIA.
10 Article 4 HIA.
The largest share of the health costs is funded by the MHI system. In 2015, the share covered by the MHI system amounted to 35.3 per cent of the total health costs. Costs are further covered by direct financing of healthcare providers through the tax-financed budgets of the Swiss Confederation, the cantons and municipalities. The largest portion of such direct financing is made in the form of cantonal subsidies to hospitals providing inpatient acute care. In 2015, the share paid by the cantons amounted to 18.2 per cent of the total health expenditure. A further share of the costs is covered by the contributions to other social insurances also providing coverage for health-related risks, such as accident insurance, old-age insurance, disability insurance and military insurance.

### iii Funding and payment for specific services

The healthcare services and products (medicinal products, medical devices and ancillary materials) payable by the MHI are defined by the FDHA. In doing so, it has to evaluate whether the services and products are (1) effective, (2) appropriate, and (3) cost-effective.

The MHI system pays the costs of most general practitioners (GPs) and specialists, hospital care, home care services (Spitex), physiotherapy (if prescribed), and certain preventive services, including selected vaccinations, general health examinations and screenings for early detection of diseases for certain risk groups. Also covered are the cost of a comprehensive range of medicinal products and medical devices. Care for mental illness is paid by the MHI, if provided by certified physicians. The services of non-physician professionals, such as psychotherapy by psychologists, are only covered if prescribed by a qualified medical doctor and provided in its practice. Long-term care is only paid to the extent necessary medicinal services are concerned. Glasses, to the extent medically required, are partly paid. Procedures and methods used in complementary medicine (such as homeopathy) are covered by the MHI to some extent. Broadly excluded from the MHI is dental care.

Premiums vary for three different age categories and for different geographical regions, but are otherwise the same for every Swiss resident insured with a particular MHI company, independent of gender or health status. In addition, the premiums are not dependent on income. In principle, the insured persons have to pay the premiums themselves. There are no employer contributions. However, people with low income may request a premium reduction, which is subsidised by the Swiss Confederation and the canton of domicile.

In 2016, cantonal average annual MHI premiums for adults with a minimum franchise of 300 Swiss francs per year and the standard insurance model with accident coverage ranged from 3,920 francs to 6,547 francs. The insurers offer specific insurance models, such as health maintenance organisation (HMO) models, which the insured persons may select to benefit from reduced premiums. Insured persons may also reduce the premiums by accepting

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13 Sturny, 156.

14 Article 32 HIA.

15 The Swiss healthcare system, Financing healthcare; Sturny, 155.

a higher franchise than 300 francs (presently franchises of up to 2,500 francs for adults and up to 600 francs for children are admissible). Chosen insurance models and selected franchises can be changed every year.

The insured persons have to pay 10 per cent of the cost of services received (above the franchise), including GP consultations, on their own, up to an annual cap of 700 francs for adults and 350 francs for children up to age of 18. Where generic drugs are available, patients have to pay 20 per cent of the price themselves if they want the original medicinal product. For hospital stays, patients have to pay an amount of 15 francs per inpatient day.

Supplementary health insurance plans may be concluded on a voluntary basis and cover benefits that are not paid by the MHI, such as greater freedom with respect to the choice of doctor or hospital, payment of certain methods of complementary medicine that are not reimbursed by MHI or single room accommodation in hospitals. Such complementary insurances are offered by private insurers as well as by MHI insurers.

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

The MHI system allows patients to go directly to specialists (i.e., free choice of doctor), unless they have opted for a special insurance model, such as HMO or Managed Care. (In 2012, approximately 20.8 per cent of all insured people were estimated to be insured by either an HMO plan or a physician network plan.) However, traditionally, the family doctor or GP is the first point of contact for patients. If the GP is not able to treat a disease, the patient is referred by the GP to a specialist or hospital. Patients are free to choose to receive their treatment in any hospital listed on the ‘hospital list’ of the canton in which they are domiciled or in which the hospital is located. Specialists often work in both hospitals and their own private practices. In some cantons, GPs and specialists are allowed to sell medicinal products to their patients; in others, they have to refer their patients to pharmacies in this respect.

Residential (institutional) long-term care is provided by medical nursing homes or nursing departments of old-age or disability homes, while home-care nursing services are provided by the Spitex services. The contributions of the MHI system for care in nursing homes depend on the level of need determined in assessments and do not necessarily cover the total costs. The amount paid by the system for Spitex services depends on the type and duration of the care provided. Responsible for the organisation of long-term care are the Swiss cantons, which may delegate responsibility to municipalities.

In April 2017, a new act governing the national electronic patient record entered into force. The act aims to increase care coordination, quality of treatment, patient safety and efficiency in the healthcare system. Insured persons may voluntarily opt for such a record and decide who shall have access to information pertaining to their treatment-related information. The records are being stored in decentralised form. Health service providers will have to take

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17 Article 64 para. 2 HIA.
18 Sturny, 156.
19 The Swiss healthcare system, Financing healthcare.
20 Article 41 para. 1 HIA.
21 De Pietro et al., Switzerland: Health system review, 155.
22 Article 41 para. 1 bis HIA.
23 De Pietro et al., Switzerland: Health system review, 186 f.
part in certified communities to be able to read the records. While hospitals and long-term care institutions are legally required to join and offer their services using an electronic patient record, ambulatory providers are not.24

**IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS**

**i Regulators**

In Switzerland, licensing and supervision of institutional healthcare providers and health professionals is mainly the responsibility of the cantonal authorities.

**ii Institutional healthcare providers**

Each hospital and other inpatient service provider (rehabilitation, psychiatric, geriatric and long-term care) requires an operating licence granted by the canton in which it operates. Licences are granted if the hospital or inpatient service provider fulfils the licence requirements defined in cantonal legislation. Requirements cover in particular issues such as medical supervision, hygiene, structure, hospital pharmacy and quality management.25

In addition, hospital and inpatient service providers need a permission to provide services that are reimbursable by the MHI system. The related requirements that need to be fulfilled are defined in Article 39 of the HIA. Such requirements include, in particular, organisational requirements (such as, sufficient personnel and adequate medical equipment), the obligation to treat all patients in need of care and the inclusion in the cantonal hospital list, which is the main instrument of the cantons to steer sufficient, but cost-efficient provision of inpatient and acute care services by hospitals and other inpatient service providers.

**iii Health professionals**

In Switzerland, generally three groups of health professionals need to be distinguished: (1) university-trained health professionals (physicians, dentists, pharmacists, chiropractors and veterinary surgeons); (2) psychological professionals, including psychotherapists and clinical psychologists; and (3) non-university trained health professionals, including nurses and midwives.

*University-trained health professionals*

The cantonal departments of health are responsible for the licensing of university-trained health professionals in independent practice. The general conditions for licensing are set forth in the Federal Act on Medical Professions (AMP). The licence requirements defined in the AMP include a university diploma, a recognised specialisation title, a good personal reputation, proficiency in a national language and good health condition.26 Any applicant fulfilling these requirements is entitled to obtain the cantonal licence. The cantons are obliged to register licensed university-trained health professionals in the national register of medical professionals.27 Licensed university-trained health professionals have the right to practice without supervision and to run their own practice. Healthcare professionals have

24 Sturny, 160.
25 De Pietro et al., Switzerland: Health system review, 57.
26 Article 36 AMP.
27 Art. 51 et seq. AMP.
to be re-accredited by cantons every 10 years (and every three years after the age of 70).\textsuperscript{28} Physicians further need a cantonal approval and register number to practise at the expense of the MHI (ZSR-Number). Moreover, self-employed physicians are required to take out professional liability insurance.\textsuperscript{29} Employed physicians, in particular, physicians in hospitals, are insured via their employer.

University-trained health professionals with qualifications obtained abroad may provide their services without special licence under the conditions outlined in Annex III of the treaty between the Swiss Confederation and the European Union concerning the Free Movement of Persons dated 2 June 1991 or Annex K of the EFTA treaty of 4 January 1960.\textsuperscript{30}

With the object to control increasing healthcare costs by limiting the number of newly practising physicians, a temporary ban on the opening of new practices was implemented back in 2001. After being lifted for a short period in 2012, it has been re-enacted until 2019, leaving, however, the cantons discretion whether and to which extent they want to enforce it. As a result, some cantons do not apply the ban at all, and others restrict admission of new providers only in certain special fields (e.g., only GPs and paediatricians). Cantons may choose to restrict physicians only in private practice or also in the outpatient departments of hospitals (see also Section VI in this regard).\textsuperscript{31}

\textbf{Psychological professionals}

Pursuant to the Federal Act on Psychological Professions (APP), the cantons are further responsible for the licensing of psychological professionals. Comparable to the AMP, the APP stipulates the requirements of education, specialisation, cantonal licensing and continuing education.\textsuperscript{32} A register for psychological professionals (similar to the register of medical professionals) is planned;\textsuperscript{33} the corresponding implementing ordinance has, however, not yet been enacted.

\textbf{Non-university trained health professionals}

Presently, no specific regulations exist for non-university health professionals (i.e., nurses, midwives, nutritionists, physiotherapists, occupational therapists, medical laboratory officers, specialists in medical radiology, dental hygienists, podiatrists and ambulance officers). Currently, these professions are regulated as any other profession by the State Secretariat for Education, Research and Innovation, which belongs to the Federal Department of Economic Affairs, Education and Research. A draft for a Federal Act on Health Professions has been passed by the Swiss parliament, but is not expected to enter into force before the beginning of 2020. An important role for the training and qualification of non-university trained health professionals play the guidelines issued by OdASanté, an organisation founded by the cantons and the federal employer associations in the health sector.\textsuperscript{34}

\begin{flushright}
\begin{tabular}{l}
28 De Pietro et al., Switzerland: Health system review, 56. \\
29 Article 40 let. h AMP. \\
30 Article 35 AMP. \\
31 De Pietro et al., Switzerland: Health system review, 56-57. \\
32 Article 24 APP. \\
33 Article 38 APP. \\
34 De Pietro et al., Switzerland: Health system review, 62-63.
\end{tabular}
\end{flushright}
V NEGLIGENCE LIABILITY

i Overview

The relationship between a healthcare professional in private practice and the patient is qualified under Swiss law as a mandate, governed by the provisions of the Swiss Code of Obligations. In case of a mistreatment, the acting private healthcare provider is liable to the patient for any damage suffered, provided the patient can prove that it has suffered a damage as a consequence of a mistreatment or lack of the required diligence owed by the treating health professional and provided the health professional acted with fault (which is assumed). Public law institutions, such as public hospitals and physicians employed by them, are liable based on public laws, namely the state liability acts. Substantive conditions for liability thereunder are similar to those under private law.\(^{35}\) In case of a split treatment relationship (e.g., where a self-employed physician operates in a public hospital assisted by health professionals employed by the hospital), the civil law claims may asserted by the patient also in the framework of the public proceedings.\(^{36}\)

In Switzerland, conflicts between harmed patients and healthcare institutions and professionals respectively are often resolved by out-of-court-settlements. In this regard, the Swiss Patient Organisation (SPO) and the Swiss Patient Federation (DVSP) play an important role. For their members, SPO and DSVP provide legal advice and support in filing complaints and negotiating settlements. Pursuant to the DVSP, nearly 95 per cent of all patient complaints are resolved out of court.\(^{37}\)

ii Notable cases

In two recent cases, the Swiss Federal Supreme Court has further clarified the question regarding the burden of proof with respect to the failure of the treating physician to act diligently when treating a patient and, thus, one of the key requirements of negligence liability. In a decision rendered in 2016,\(^{38}\) it reiterated the principle that the treating physician does not owe a success (restoration of the patient’s health), but only a treatment that is in line with the rules of acknowledged medical standards and diligence. Lack of success does not imply a lack of diligence and, therefore, lack of diligence must be proved by the patient. This also applies if the treatment results in another physical damage. While a physician is under an obligation to take all measures reasonably required to avoid such other physical damage and the occurrence of such new damage may suggest a maltreatment, it is still up to the patient to prove that the physician has not complied with his or her obligation to act diligently. In another case,\(^{39}\) the court held that it is up to the treating physician to proof that he has adequately informed the patient of the risks of a treatment and obtain the patient’s consent for the treatment. However, in those cases in which the physician may rely on a implied or hypothetical consent (e.g., in cases of urgency), it is up to the patient to show that it would have rejected the treatment had it been aware of the risks the treatment entails.

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\(^{36}\) Gächter/Rütsche, marginal note 391 et seq.

\(^{37}\) De Pietro et al., Switzerland: Health system review, 75.

\(^{38}\) Decision of the Swiss Federal Supreme Court dated 26 September 2016, 4A_216/2016.

\(^{39}\) Decision of the Swiss Federal Supreme Court dated 19 August 2015, 4A_137/2015.
VI OWNERSHIP OF HEALTHCARE BUSINESSES

Traditionally, independent physicians in Switzerland were self-employed. However, as a result of the trend towards group practices, physicians started to organise themselves as unregistered partnerships, and since 2001, due to a revision of the HIA, it is permissible for physicians to practise (together with other physicians) organised as legal entity (i.e., as limited liability company or joint stock company) if, in particular, the following requirements are fulfilled:

- each physician employed by a limited liability company or joint stock company needs a professional licence for physicians;
- each of the employed physicians is obliged to perform the healthcare services personally (no delegation of responsibilities);
- the employed physicians remain functionally responsible towards the patients;
- corporate bodies may not give professional instructions;
- the employed physicians have to take appropriate professional liability insurance either directly or via the legal entity they work for; and
- a cantonal approval to practise at the expense of the MHI system and a ZSR-Number must be obtained.

In some cantons, to organise a medical practice in the form of a legal entity, operating the practice additionally requires a licence for medical practices. Legal entities holding such an operating licence are obliged to notify changes regarding the operationally and professionally responsible persons (i.e., the responsible body) as well as changes of the legal entity.

i Hospitals

Public hospitals are mainly owned and operated by the cantons or the municipalities. However, more and more public hospitals are operated by independent institutions (about 34 per cent of all public hospitals in 2013) or joint stock companies (about 31 per cent). Also, privately owned hospitals may be included in cantonal hospital lists and are then allowed to provide services reimbursable by the MHI system. As result, private hospitals are (at least in theory) able to compete on a level playing field with public hospitals, and patients have the choice to be treated in private hospitals included in the cantonal hospital lists. However, (new) private organisations that intend to operate a hospital can find it hard to get in local cantonal lists. Private hospitals may be managed either on a profit-making or not-for-profit basis.

Almost 70 per cent of general acute inpatient hospitals in Switzerland are publicly owned or subsidised. Specialised hospitals, on the other hand, such as hospitals for surgical, gynaecological or paediatric care, are mainly privately owned. Emergency services are provided by public or subsidised non-profit hospitals. There is a tendency to form larger (public and private) hospital organisations with several sites to increase efficiency in management and purchasing in both public and private hospitals.

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40 Article 36a HIA.
41 Kaufmann Markus, Die Arztpraxis als Aktiengesellschaft oder GmbH – Zulässigkeit und Vorteile, in: Der Luzerner Arzt, Ausgabe 2010/2 (Nr. 81), 32; De Pietro et al., Switzerland: Health system review, 56.
42 De Pietro et al., Switzerland: Health system review, 172.
44 De Pietro et al., Switzerland: Health system review, 170.
VII COMMISSIONING AND PROCUREMENT

Commissioning and procurement of care services is mainly in the responsibility of the Swiss cantons. As far as inpatient care is concerned, the cantonal hospital planning and eventually the hospital list are the major instruments for steering sufficient, but cost-effective, institutional healthcare provisions in the respective cantons. The cantons are required to coordinate their planning.\(^{45}\) In the fields of highly specialised medicines, the cantons are even obliged to plan on a country-wide level.\(^{46}\) The hospital lists are reviewed and updated periodically by the cantons. Commissioning and procurement of non-institutional healthcare services by physicians have hardly been regulated in Switzerland to date, but are essentially left to the market, subject to the above-mentioned temporary restrictions regarding the opening of new practices (see Section IV.iii). However, this may change, in particular, with respect to GPs in some remote regions of Switzerland, where interest to open a new practice or take over an existing practice is low, and it is likely that no sufficient coverage will exist in the foreseeable future.

The main instrument for ensuring that new specific services and treatments are introduced and made available to the patients is the list of healthcare services and products reimbursable by the MHI system, which is maintained on a federal level by the FDHA (see Section II.ii above).

VIII MARKETING AND PROMOTION OF SERVICES

In Switzerland, the restrictions on advertising applicable to healthcare services differ depending on the person of the advertiser. Specifically, the AMP and APP stipulate that advertisements of healthcare professionals governed by the respective acts (see Section IV.iii) need to be objective and meet a public need and must not be misleading or obtrusive.\(^{47}\) Sanctions may include warnings, reprimands and fines up to an amount of 20,000 francs.\(^{48}\) Public and private hospitals, as well as emergency departments, on the other hand, are authorised to advertise their services without such restrictions. Since the distinction between self-employed physicians and hospitals can hardly be justified, part of the doctrine considers similar restrictions on hospital advertising adequate.\(^{49}\)

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

Coming years will bring new developments in Switzerland, in particular, in the fields of organ donation and pre-implantation diagnostics.

In Switzerland, the demand for organs for transplantations is by far higher than the number of available organs. While the proportion of deceased donators tends to remain at the same level, the number of individuals waiting for an organ is constantly rising. Therefore, the federal government launched an action plan in 2013, named ‘More Organs for Transplantations’. With this plan, the federal government aims to increase the number of

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45 Article 39 para. 2 HIA.
46 Article 39 para. 2 bis HIA.
47 Articles 40 let. d AMP and 27 let. d APP.
48 Article 43 para. 1 lets. a – c; Article 30 para. 1 lets. a – c APP.
donators from 13 to 20 per million inhabitants by 2018. This goal shall be achieved through a collective implementation of various measures. By now, some measures have already been realised, namely the development of the ‘Swiss Donation Pathway’, which describes the donation process and helps to create checklists for quick detections of donators. Furthermore, the SwissPOD study is continued in an improved way and is expanded on the emergency departments.\textsuperscript{50} Finally, general awareness of the public shall be increased with the aim of significantly increasing the number of persons who opt-in for a donation by introducing a donation pass.

Pre-implantation genetic diagnosis (PID) is a medical procedure in which embryos are genetically analysed before inserting them into the uterus. In Switzerland, PID was generally forbidden. However, in 2016, the Swiss people accepted in a referendum a change in the respective legislation, the Federal Act concerning Medically Supported Reproduction (AMSR), providing for a liberalisation of PID. The revised law shall, in particular, ensure that couples involving a person in respect of which the risk exists that a child may, as a result of genetic reasons, become ill or handicapped, can make use of PID on favourable terms. Furthermore, it shall help couples that are incapable of getting pregnant naturally to have children. The revised AMSR, as well as the implementing ordinance, will enter into force on 1 September 2017.

\textbf{X CONCLUSIONS}

The Swiss MHI system and the combination of managed competition and corporatism has helped to create and maintain a healthcare system at a very high level, covering the entire country and ensuring that all people resident in Switzerland have free access to first-class medical treatment. On the other side, the split responsibilities between the different government levels, as well as the fact that demand for medical services is, due to the MHI system, hardly influenced by cost considerations, make it difficult to control healthcare costs, which have significantly increased over the past years. Therefore, the focus of the policy and legislative initiatives will continue to be on measures to stop, or at least slow down, cost increases in the fields of healthcare. While already-implemented measures mainly focused on the prices of medicinal products, one may expect that in the near future reimbursement of specific medical treatments with questioned efficiency will be re-assessed and eventually excluded from reimbursement. Further, the federal government has announced to analyse the methods by which other European countries, in particular, Germany and the Netherlands, try to steer the increased demand for healthcare services, namely by the means of budgets or measures controlling the amount for services provided.

\textsuperscript{50} Aktionsplan mehr Organe für Transplantationen im Rahmen der Bundesrätlichen Strategie Gesundheit 2020, Bundesamt für Gesundheit BAG, www.g2020-info.admin.ch/de/create-pdf/?project_id=54 (visited on 20 July 2017).
Chapter 15

UNITED ARAB EMIRATES

Andrea Tithecott

I OVERVIEW

The United Arab Emirates (UAE) is a confederation of seven emirates. The most well known are Dubai and Abu Dhabi. The other emirates are Sharjah, Ajman, Fujairah, Umm Al Quwain and Ras Al Khaimah, often collectively referred to as the 'Northern Emirates'. At the federal level, the UAE operates within a constitutional framework, which makes provision for the health and welfare of the population in that 'the community shall provide all the citizens with medical care and means of prevention and treatment from diseases and epidemics and shall promote the establishment of public and private hospitals, clinics, and treatment houses.'

The healthcare sector is regulated at federal level, but with certain emirates having established their own health authorities with powers to adopt local policy, laws, rules and codes of practice. The complex relationship between federal government and local government means that for practical purposes there are multiple regulators with responsibilities that sometimes overlap.

The Federal Ministry of Health and Prevention (MOH) oversees the implementation of federal government policy in relation to the provision of comprehensive healthcare for all UAE citizens and residents, and works in collaboration with all health authorities to ensure that all public and private hospitals are accredited according to clear national and international quality standards of medical services and staff.

The emirates of Abu Dhabi, Dubai and Sharjah have established their own health authorities, Health Authority – Abu Dhabi (HAAD), Dubai Health Authority (DHA) and Sharjah Health Authority, respectively, and have the most developed rules and regulations among the seven emirates with respect to healthcare matters. The emirates of Dubai and Sharjah have also made provision for healthcare investment by establishing healthcare sector free zones, such as the Dubai Healthcare City (DHCC) and Sharjah Healthcare City. The remaining Northern Emirates rely on the MOH to act as their regulator to oversee delivery of healthcare services.

The UAE has always looked to other jurisdictions for inspiration in creating a legal framework for the healthcare sector. The priorities are to ensure adherence with international best practice and to support delivery of high-quality medical care to the population. The drive to achieve continuing improvements in healthcare services throughout the UAE is...

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2 Article 19 UAE Constitution of 1971, as amended.
intended to reduce the need for people to travel abroad for specialised treatment, encourage medical tourism, and is a key driver in widening the scope of services provided and building a healthcare sector that is supported by private sector and insurance investment.

II THE HEALTHCARE ECONOMY

i General
The status of the healthcare economy in the UAE is inextricably linked to the general economy and the government’s diversification policy away from the oil and gas sector. The indications for the general economy optimistically set in Q1 of 2017 for significant growth in 2017 and 2018 driven by improved oil prices and a continuation of the focus on developing non-oil sectors range from GDP growth of 2.8 per cent in 2017 and 3.3 per cent in 2018, have since been downgraded by the IMF at the half-year point to 1.3 per cent.3

The healthcare sector has been identified by the government as a key sector for development. The private healthcare expenditure continues to be driven by medical tourism, and the continued roll-out of compulsory health insurance, with recent figures suggesting that the sector is expected to increase in value from US$16.1 billion in 2016 to US$16.96 billion in 2017, representing an increase of 5.3 per cent.4

ii The role of health insurance
The Insurance Authority was established under Federal Law No. 6 of 2007 (on regulating the insurance sector). Mandatory health insurance has begun to be introduced across the UAE. The UAE national Emirati population (and those of similar status) are covered by a government-insured scheme named ‘Thiqa’, which is administered by the UAE national insurance company, Daman, and provides for a comprehensive range of health insurance cover.

Abu Dhabi was the first emirate to fully implement mandatory health insurance for the expatriate population by Law No. 23 of 2005 (on Abu Dhabi Health Insurance), which provides a basic level of cover for all employees and their families. A similar scheme is currently being implemented in Dubai by Law No. 11 of 2013 (on Dubai Insurance Law) implemented from February 2014 over three phases according to employer workforce size, the last phase being completed in June 2016. Mandatory health insurance for expatriates has yet to reach every emirate in the UAE.

As the government reduces financial commitment to publicly funded services, which are largely accessed only by the Emirati population, the role of health insurance is critical to the ability of the remaining expatriate population to afford and access private medical services and medicines.

iii Funding and payment for specific services
Health insurance does not cover all healthcare needs. While the Thiqa cover for the Emirati population is reasonably comprehensive, recent cutbacks in spending have meant that access to certain Thiqa services has been withdrawn, and similarly, the expatriate population who benefit only from a basic level of cover must pay themselves for many services that are

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4 BMI UAE pharmaceuticals and healthcare report Q3 2017.
excluded from most policies. The extensive list of uninsured services means that expatriate patients must pay themselves, and in some cases, access services abroad, where they can be significantly cheaper.

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

i Primary/family medicine

UAE patients can directly access medical specialist consultants without first transitioning through a primary care service. Direct access to specialist services is responsible for pushing up the costs of healthcare for both the government and insurers, with patients ‘shopping’ for services and seeking advice from a number of specialists for the same complaint.

Direct access is now being curtailed, with primary care becoming an increasing focus for healthcare regulators, in order to improve the coordination of treatment throughout a continuum of care enabling the delivery of healthcare through the entire life-cycle, as well the process from initial visit to a primary care physician, throughout the referral process, to the completion of treatment. Such initiatives should result in the development of using the expertise of primary care professionals through care pathways, and coordinated care between primary, secondary and tertiary healthcare services.

The concept of family medicine and primary care physicians is now included in the healthcare professional licensing requirements under the specialty title of ‘family medicine’, and the concept of ‘social worker’ included as a sub-speciality of ‘allied health professional’.

The HAAD identified the need for primary care gateways as part of the emirate master plan for delivery of healthcare services, and recently issued a standard for primary healthcare services in 2016. Similarly, the DHA has approved licences for 20 healthcare centres and clinics around the emirate providing primary healthcare services.

Insurers are increasingly taking the lead on adjusting health insurance policy terms and conditions to require patients to access primary care services and to have appropriate referrals from primary gateway providers before approving fees. In terms of future developments, as the UAE rolls out licensing for telehealth services, we also expect the ability of patients to access teleconsultation pathways.

ii Hospitals

Public sector

The main public sector institutions that oversee delivery of healthcare services and quality are the DHA, Abu Dhabi Health Services Company (SEHA) and MOH. Within the scope of secondary care services provided by public hospitals are trauma facilities, obstetrics and gynaecology, orthopaedic, surgical services and the treatment of lifestyle diseases. The policy aim is to overlay these with more specialised services.

5 Healthcare Professionals Qualification Requirements 2014.
6 HAAD Standard for Primary Health Care in Emirate of Abu Dhabi HAAD/PHC/SD/0.9.
7 Dubai Regulation No. 30 of 2017 regulating telehealth; HAAD Standards on teleconsultation, TC/SD/0 2014.
The DHA operates Dubai’s public healthcare facilities, including Dubai Hospital, Rashid Hospital, Latifa Hospital and Hatta Hospital. It is currently building new facilities and expanding the range of services, including gastroenterology, a kidney transplant centre and specialist paediatric services.

SEHA is an independent public joint stock company that owns and operates all public hospitals and clinics across Abu Dhabi, consisting of 12 hospitals, 46 primary healthcare clinics, 10 disease prevention and screening centres, along with mobile clinics, a school clinic, blood banks, dental centres and a vaccination centre.

Mubadala Healthcare, a division of the Abu Dhabi government investment vehicle Mubadala Development Company, has also played a prominent role in the provision of public healthcare services, also catering for privately insured or high net worth self-paying patients. Projects include the Cleveland Clinic-Abu Dhabi, Healthpoint Hospital, Imperial College London Diabetes Centre and Abu Dhabi Telemedicine Centre.

The MOH manages public healthcare services in the Northern Emirates, overseeing 16 hospitals and over 60 clinics. While historically servicing the Emirati population, MOH will soon extend services to all residents, such as through Ras Al Khaimah’s flagship Sheikh Khalifa Specialist Hospital under the management of Seoul National University Hospital, and which now offers specialist cancer services.

**Private sector**

The expansion of the private sector is well advanced and expected to play a significant role in the provision of healthcare in the future, with recent amendments to the Federal Law No. 4 of 2015 (on Private Health Facilities) and Dubai Law No. 22 of 2015 (regulating Private Public Partnership Projects). For further details pertaining to private sector hospitals, see Section IV.

**iii Social care**

The Ministry of Social Affairs was created to oversee social care in the UAE, and largely focuses on development projects for Emirati families and persons with special needs. Since social care laws were first introduced in the 1970s, the concept of social care remains immature. There is very little focus on geriatric or dementia care services, and an underdeveloped network supporting the transition of elderly or vulnerable patients from hospital care to home care with appropriate social care support. This burden is typically left to families.

**iv Data and patient health information**

The UAE does not have a comprehensive data protection law. Privacy obligations stem from legal duties under the Penal Code as to the use or disclosure of ‘secrets’ without the consent of the person to whom the secret relates. However, we now see the development of new provisions that apply specifically in a healthcare context.

Federal Law No. 7 of 1975 (concerning the Practice of Human Medicine Profession), which governs doctors licensed in the UAE, provides that in the absence of the patient’s

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8 Established by Abu Dhabi Emiri Decree No. 10 of 2007.
9 Federal Decree Law No. (1) of 1972 concerning the Competences of the Ministries, as amended.
10 Article 379 Penal Code Law No. 3 of 1987.
consent, no doctor has the right to divulge a private secret, either if the patient has directly confided it to him or her, or if he or she has come to know it by him or herself in the course of his or her work.

The MOH Code of Conduct 1988 governing medical practitioners, pharmacists and other healthcare professionals licensed in the UAE requires complete confidentiality of information related to patients (including medical records and personal information related to the patient) and prohibits disclosure without the patient’s prior informed consent.

DHCC Regulation No. 7 of 2013 (on Health Data) regulates the use and disclosure of ‘Patient Health Information’ (including personal information and medical information relating to a patient’s physical or mental health) by entities licensed in the DHCC.

The HAAD Data Standard 2008 requires that healthcare providers in the emirate of Abu Dhabi develop and institute policies and procedures relating to ‘Confidential Health Information’, which includes information that can be used to identify a patient. Policies developed pursuant to the Data Standard are required to ensure that only the minimum necessary personnel have access to confidential health information, and such information must be kept from unauthorised access.

The DHA introduced the ‘Salama Electronic Medical Record System’ in 2017. This is a unified electronic medical record system currently connecting the government hospitals: Rashid Hospital, Barsha Health Centre, Airport Medical Centre, Dermatology Centre and Dubai Physiotherapy and Rehabilitation Centre. In the long term, this scheme will be rolled out to all hospitals in the emirate of Dubai. The HAAD is currently working on a similar scheme, but is yet to introduce the necessary law, policy or information technology platform.

IV  THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i  Regulators

Ministry of Health and Prevention

The MOH is the federal authority focused on creating a unified set of healthcare policies across the emirates. The MOH also plays the role of the primary health regulator for the Northern Emirates. In general, the MOH’s activities include licensing and monitoring healthcare providers and healthcare professionals, administering health prevention and awareness training programmes, and regulating the registration and control of pharmaceuticals and medical devices.

Dubai Health Authority

The DHA was established pursuant to Dubai Law No. 13 of 2007 (on Establishing the Dubai Health Authority) and is the health authority regulating healthcare services, healthcare providers and healthcare insurance in the Emirate of Dubai, and certain free zones. Included under the purview of the DHA is regulation of medical education and research.

While the DHA owns and manages public healthcare facilities in Dubai, it is the primary regulator for facilities licensing to the private sector. Facility licence categories include hospitals, day surgical centres, outpatient care facilities (which includes polyclinics, general clinics, dental clinics and specialty clinics), clinical laboratories, diagnostic imaging centres, home healthcare facilities, dental laboratories, school clinics, community pharmacies, optical centres, and complementary and alternative medicine centres.
**Dubai Healthcare City Authority**

The DHCC free zone is regulated by Dubai Healthcare City Authority (DHCA),\(^\text{11}\) which is a public corporation established to promote the status of the emirate as an international medical and healthcare hub and which regulates healthcare establishments in the free zone by developing policies and procedures, granting licences and with power to enforce sanctions against violations of the law.

The Dubai Healthcare City Authority – Regulatory (DHCR) is an independent regulatory arm of DHCA, and is responsible for healthcare facility licensing and healthcare professionals licensing.

**Health Authority – Abu Dhabi**

The HAAD was established pursuant to Abu Dhabi Law No. 1 of 2007 (on Establishing Health Authority – Abu Dhabi). The HAAD owns and operates public healthcare services and is the primary regulator for the private sector, granting facility licences, regulating health insurance providers and healthcare professionals.

**Sharjah Health Authority**

Sharjah Health Authority was established by Sharjah Emiri Decree No. 12 of 2010 (amended by Emiri Decree No. 33 of 2016) and regulates Sharjah’s healthcare system.

**Institutional healthcare providers**

In this section, we focus on the licensing and approval regime for private healthcare facilities. All private healthcare facilities must operate under a licence granted either by their governing regulator, typically the DHA, the DHCA or the HAAD, or by the MOH (as delegated to the local emirate municipality) in the case of the Northern Emirates.

Federal Law No. 4 of 2015 (on Private Health Facilities) regulates the licensing of private healthcare facilities (except in DHCC, which operates its own licensing system). The procedure for obtaining a licence entails making an online application to the regulator providing basic information in order to obtain an initial approval.

It is a requirement of the law that the facility licence be issued in the name of a UAE national person rather than a corporate entity. The application process then dives into further detail, with the applicant having to follow and conform to hospital or clinic planning, design and commissioning requirements applicable to the emirate and ensure the facility is constructed to approved local standards.

The applicant must choose from a range of permitted activities, such as hospital, clinic, dental clinic and rehabilitation clinic. The activity categories can vary slightly in each emirate.

The application will be subject to stringent scrutiny with a number of physical inspections of the facility while under development (or refurbishment) before the grant of the final licence. Time frames can vary significantly depending on the complexity of the project.

The process of appealing against the refusal to grant a licensing application entails issuing an appeal in writing to the Minister of Health or the head of the health authority within 30 days as of the date of notifying of the denial decision. A further grievance may be appealed to a competent court.

\(^{11}\) Dubai Law No. 9 of 2011 (concerning Dubai Healthcare City).
There are no exceptions to the requirement to obtain a facility licence. The licence must then be renewed periodically, the renewal period can vary and can be from one to five years. A breach of the licence conditions empowers the regulator to take disciplinary action, which usually takes the form of additional conditions being placed on a licence, suspension or revocation of the licence.

A penalty may also be applied against a general manager of a private facility, with potential sanctions including imprisonment for a period of no less than six months and a fine of no less than 100,000 dirhams.

iii Healthcare professionals

No person may practise a healthcare profession in the UAE without first being licensed by the respective health authority. A healthcare professional’s licence is directly linked to a healthcare facility. All practising health professionals must have a designated facility sponsor whose name appears on their health professional licence. Thus, healthcare professionals who are not affiliated with a facility may apply for licensure at the relevant authority and receive a letter of eligibility while seeking employment, but may not practise the profession until a final licence is issued in connection with an employing healthcare facility.

If an individual is discovered to be practising a health profession without the appropriate licence from the appropriate authority, civil and criminal penalties may be issued to the individual and the facility at which the individual is carrying out such activities.

In the Emirate of Dubai, the DHCR and the DHA have purview to regulate healthcare professionals in the emirate. The DHA is the sole authority authorised to issue a licence to practise medicine and other healthcare professionals operating in Dubai, outside of the DHCC. Within the DHCC, the DHCR is responsible for regulating the facilities and professionals operating therein. Each authority, the DHCR and the DHA, has the charge to supervise, regulate and discipline healthcare professionals operating in its jurisdiction. Overseas visiting healthcare professionals are also required to obtain a DHA licence to practise their profession in the emirate of Dubai.

The HAAD regulates healthcare professionals practising in the emirate of Abu Dhabi and maintains a similar online portal and applications process as the DHA. The MOH regulates health professionals practising in the Northern Emirates and in certain facilities regulated by the MOH.

Unified qualification requirements

The framework for healthcare professional licensure has been brought under a unified process by virtue of the Healthcare Professionals Qualification Requirements 2014 (PQR), jointly issued by the MOH, the DHA and the HAAD in order to standardise healthcare professional requirements across the emirates. While the PQR has been adopted across the authorities, each authority still maintains its individual regulatory purview to approve and issue licences in its respective emirate. Consequently, the PQR acts as a baseline for the authorities to assess the documents submitted by healthcare professionals within their geographical jurisdiction, but does not unify the licensing approvals. Thus, if a healthcare professional practising in Abu Dhabi with a HAAD licence moves to Dubai, an application will need to be made to the DHA for transfer of the licence, or granting of a new licence, by the DHA.

The PQR identifies the licensure category, minimum qualifications for such licensure, and the experience and other applicable requirements that must be met in order to be granted
a health professional licensure. Applicants with educational qualifications not mentioned in the PQR may still be awarded licensure, subject to the evaluation and review of the respective health authorities committee.

With regards to foreign licences, healthcare professionals who successfully complete one of the international examinations listed in the PQR, or hold an active registration or licence to practice with certain regulatory bodies, will be exempt from the assessment required to obtain the professional licence. A valid ‘Certificate of Current Status’ confirming good standing registration of the applicant issued by the registration or licensing authority at the time of application will be required. The other requirements will also still apply, however, including credentialling, experience and primary source verification. If a healthcare professional exceeds two years of gap of practice, the assessment exemption policy will not apply.

V NEGLIGENCE LIABILITY

Overview

The UAE is a civil law jurisdiction with statutory codes governing most areas of substantive law.12 The Constitution provides that all laws in the UAE are subject to the overlay of the shariah (principles of Islamic law).13 Judicial authority is vested in its courts. A federal judiciary is based in Abu Dhabi and administered by the Ministry of Justice. The emirates of Abu Dhabi, Dubai and Ras Al Khaimah have each elected to maintain their own local judicial systems. The courts follow the Civil Procedure Code, which provides very broad grounds for the courts’ jurisdiction. All cases are tried before judges. Civil matters are dealt with by way of written submissions. There is no full trial with oral testimony.

The courts can (and often do) refer cases that involve technical issues or complex fact situations to court-appointed experts. These experts conduct investigations and provide reports to the courts on the issues within their scope of work.

The official language of the UAE (and the courts) is Arabic, and all documentation brought before the courts in respect of any dispute must be in Arabic or accompanied by certified Arabic translations.

Liability of healthcare providers

There are a number of ways in which healthcare providers are exposed to liability, potential legal claims and regulatory actions.

A patient is entitled to lodge a complaint with his or her regulator regarding the conduct of healthcare practitioners or providers. A complaint is investigated in accordance with the established procedure in the emirate in which the patient received healthcare services. There is variation in the process and approach in each emirate. The regulator may take disciplinary action against a provider or practitioner, with conditions imposed on a provider or professional licence, including suspension or revocation. In cases where there is sufficient evidence of malpractice, the regulator has further power to refer the matter to a medical liability committee convened under law, and ultimately to the courts.

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12 The Federal Law No 5 of 1985 (the, Civil Code).
13 Article 7 UAE Constitution 1971, as amended.
The Medical Liability Law
The Federal Law No. 4 of 2016 (on Medical Liability) has brought several changes to the previous law, Federal Law No. 10 of 2008, which has been repealed.

The Medical Liability Law requires all medical malpractice claims to be referred to a new Medical Liability Committee before they are reviewed by the judicial authorities. It also affords protection and relief to doctors in criminal proceedings by prohibiting their arrest, imprisonment, and investigation before the authorities until the Medical Liability Committee issues a final report. The Medical Liability Law also introduces stringent penalties against medical practitioners who commit gross medical errors.

The procedures established in the Medical Liability Law will ensure that healthcare professionals accused of malpractice are not prosecuted until the Medical Liability Committee or the Supreme Committee issues a final report, and will mandate that patients submit their claims to the health authority to be reviewed by the Medical Liability Committee in order for civil claims for compensation to be admissible to the courts. It also provides a grievance process that protects both patients and doctors by affording them with the right to have their appeals thoroughly reviewed by the Supreme Committee.

Civil court claims
Subject to the restrictions imposed upon pursuing a civil claim under the Medical Liability Law, a patient can take a medical complaint before the civil courts to claim monetary compensation against healthcare providers and professionals for material, moral and psychological damages.

The legal burden of proof requires that the patient must establish that the healthcare professional was at fault. When assessing damages, the court will examine the harm suffered by the patient, the healthcare professional’s actions or omissions, and the causal link. The criterion for the entitlement of an aggrieved party to compensation is that the damage should have been suffered as a direct result of the causal fault.14

When awarding compensation for damages, the guiding principle in accordance with the Civil Code is that compensation should be equal to the harm suffered. Damages are the remedy that is used to restore the victim to the position they were in prior to the harm suffered. Direct damages, loss of profit, loss of opportunity, consequential damages and moral damages are types of damages recognised under UAE law.

ii Notable cases
The UAE is a civil code jurisdiction where the concept of legal precedent does not apply. Judges are under no obligation to take previous court decisions into consideration in an action before them, although prior rulings of the appellate courts have persuasive authority and are routinely sited by litigants in their pleadings and by the courts in their judgments. As in other civil law jurisdictions, the courts also rely on scholarly writings. Court proceedings and judgments are not a matter of public record and there is no system of case reporting.

There are no precedents on the figures awarded by the courts in medical malpractice claims, accordingly, damages awards vary from case to case and are subject to the discretion of the judge.

14 Articles 282, 292, 389 Federal Law No. 5 of 1985 (Civil Code).
VI OWNERSHIP OF HEALTHCARE BUSINESSES

Statutory restrictions are in place that prevent foreign companies establishing wholly owned healthcare businesses, and require local partner involvement for most projects. Each company established in the UAE must have one or more UAE national partners who holds at least 51 per cent of the company’s capital. Companies established in free zones are exempt from the 51 per cent requirement, if the relevant free zone has special provisions regulating the company, in which case, where the services are established in a healthcare free zone, this would permit 100 per cent foreign ownership.

The UAE Federal Law No. 4 of 2012 (regulating competition) regulates anticompetitive practices, prohibiting: restrictive agreements, dominant position (market share of the establishment exceeds 40 per cent of the total transactions in the relevant market), and economic concentrations (application for approval should be submitted to a committee prior to concluding the relevant contract and applies to share acquisitions, transfers of assets and liabilities and should be made where the market share of the parties exceeds 40 per cent of the total transactions undertaken in the relevant market). The practical restrictions in terms of competition are concerned with the financial viability for the commissioning and development of new projects, the significant number of domestic and foreign companies already present in the UAE, and limitations on the healthcare insurance market affecting profitability.

VII COMMISSIONING AND PROCUREMENT

The commissioning of healthcare services is government-led in terms of the policy position. The MOH, Dubai and Abu Dhabi health authorities dictate policy, identify what services are required, and determine whether these should be provided by public or private sector investment.

The DHA has upgraded services at the government-owned Rashid Hospital and has also completed the development of a medical university, the University of Sheikh Mohammed bin Rashid for Medicine and Health Sciences, which will train medical students, along with establishing 40 primary healthcare centres and three new hospitals, as well as three new medical colleges and five nursing schools by 2025. The DHA now expects the private sector to either step in with operation and management agreements to run the existing facilities or proposals to develop the new facilities through public–private partnership.

In Abu Dhabi, Johns Hopkins Medicine has had a long association with the government hospitals operator SEHA and has worked with the HAAD in completing a master capacity plan, analysing a vast amount of population, demographic and healthcare data across the emirate to identify gaps in the provision of services and to prioritise what services will be required in future years. The private sector is expected to take a leading role in developing new services or re-commissioning existing provision, with international brands committing to significant investment in large healthcare infrastructure projects, such as the 364-bed

15 Federal Law No. 2 of 2015 regulating Commercial Companies.
16 Executive Regulations (Council of Ministers’ Resolution No. 37 of 2014) Cabinet Resolutions (Resolution Nos. 13 and 22 of 2016).
Cleveland Clinic in Abu Dhabi (a Mubadala project), which also supports the public sector through a long-standing relationship with the government hospital, Sheikh Khalifa Medical City.

The commissioning of large healthcare infrastructure projects can take many forms, increasingly so, by a local health authority putting a project out to tender under local procurement laws. The tender process can vary widely. There may be flexibility for the largest of projects, which will be opened up to ‘foreign’ bidders in order to encourage international investment. Smaller projects or contracts to operate and manage a facility, or the procurement of equipment, suppliers are required to register as a supplier on the local health authority procurement supplier list, and comply with obligations to have a local licensed entity or agent.

There is no one-size-fits-all for healthcare procurement. Foreign investors and healthcare providers should check the requirements carefully for each project and pay particular attention to the contract terms in order to minimise the possibility of disputes arising in the future or having to renegotiate the contract. While it is possible to mount a challenge to a government procurement decision, such challenges are few and far between, and can be very time-consuming and expensive.

VIII MARKETING AND PROMOTION OF SERVICES

All advertising must comply with the MOH Healthcare Advertising Regulation. The Healthcare Advertising Regulation contains a comprehensive list of matters that are relevant to healthcare advertising.

The MOH must formally approve all advertising content by way of an application and approval process, which leads to the MOH giving a reference number that must be cited on all advertising material.

The MOH will take into account prohibitions on advertisements in poor taste, misleading statements of a medical nature, misleading statements of a comparative nature, and misleading statements of a general nature, as well as on sales incentives directed to certain persons. The prohibitions of advertisements that breach good taste are basically couched in terms of prejudice to public morals, and violation of the customs and traditions of UAE society or Islamic values.

In particular, there are critical matters that the MOH will consider when reviewing the healthcare advertisement. Some of the more interesting and sometimes challenging points raised within this part of the Healthcare Advertising Regulation include the requirement that the advertisement shall avoid exaggerated wording such as ‘unique’, ‘incomparable’, ‘best quality’, ‘beware of counterfeiting’, etc. As these words are commonly used in jurisdictions outside of the UAE, such a prohibition means that foreign advertisements will not be able to be used in the UAE without amendment if such terms are used.


19 Cabinet Resolution No. 7 of 2007 (regarding Health Advertisements Regulation).
IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

i  E-health, telehealth and telemedicine
The term telehealth generally refers to the use of information and communications technology to transfer medical information from one person or place to another to improve a patient’s clinical health status.

There is no federal regulation governing telehealth, but both the HAAD and DHA have attempted to put in place regulation to govern this area of healthcare.

The HAAD has introduced regulations to define minimum standards for telemedicine as a means to provide healthcare services to patients in the Emirate of Abu Dhabi.

Since 2012, the DHA has regulated the use of the specific telemedicine service of ‘teleradiology’ under the DHA Diagnostic Imaging Services Regulation. More recently, Dubai Law No. 30 of 2016 (on regulating Telehealth Services) has now regulated telehealth in a wider context, enabling the licensing of providers and practitioners, enabling the establishment of telecentres, and providing for out-of-jurisdiction support.

The regulation of telehealth remains to be formally regulated at federal level, and the fragmented regulation that does exist could usefully be brought under the umbrella of a unified protocol. Many significant issues remain to be properly dealt with, including liability for out-of-jurisdiction healthcare advice, data protection issues, advertising of services from out of jurisdiction and insurance reimbursement. What is urgently needed is a consistent federal (and wider regional) approach to regulation governing the use of telemedicine services based upon internationally recognised standards.

ii  Fertility treatment services
Fertility treatment services are regulated pursuant to UAE Federal Law No. 11 of 2008 (concerning the licensing of fertilisation centres). Governmental approvals are contingent upon satisfaction of numerous requirements, including facilities, equipment and staffing with appropriate professional personnel.

The regulations lag significantly behind other mature jurisdictions governing similar services, such as in the United Kingdom, with restrictions upon the freezing and storing of embryos.

However, the UAE has already made significant advancements in a cultural change to allow such services to be offered in order to offer treatment services to the Emirati population, which it is hoped will boost numbers in view of the region having a high rate of infertility problems derived from levels of vitamin D deficiency, obesity and consanguineous family history, giving rise to a dwindling population. Government-controlled fertility clinics, such as the Al Ain Fertility clinic, are able to offer up to three fully funded cycles of treatment to Emirati families under the Thiqa insurance scheme with no co-payment element.

iii  Initiatives around wellness, obesity, diabetes and heart disease
A national agenda, the ‘Emirates Vision 2021’ emphasises the importance of preventive medicine to combat an increase in the prevalence of lifestyle-related diseases and to identify and treat cancer, which is the third-leading cause of death in the country, after heart disease and accidents.
There are a number of public, private and corporate sector initiatives to promote wellness and combat the prevalence of lifestyle diseases, obesity, diabetes and heart disease. In Abu Dhabi, the ‘Weqaya’ has been in place for many years and was created to target the Emirati population. The HAAD more recently introduced a wellness and prevention priority strategy in 2014.

The DHA has included within the scope of practice for licensed practitioners the responsibility for wellness visits. The DHA has run also pilot projects, collecting health data from fitness tracking devices and apps. Dubai residents who adopt healthy steps, such as eating healthily and exercising, are rewarded with incentives such as free or discounted gym membership.

The DHCC launched phase two of its free zone development in 2016, which saw an expansion into wellness, a focus on the continuum of care, and will drive wellness tourism, together with medical tourism, in line with the government’s health policy initiatives. The new facility licensing scheme will focus on providers of rehabilitation and wellness services that will be permitted to locate in a designated ‘wellness cluster’ with provision for the following categories of wellness services: personal care (which will include weight loss services), a wellness studio, medical tourism and residential care homes (assisted living in a retirement village environment).21

iv Organ donation – opt-in or opt-out

Federal Law No. 5 of 2016 (regulating organ transplants) further progressed the existing legal framework22 that enables the transplant of tissue or organs from either live or deceased patients. The law makes a provision equivalent to ‘opt-in’, in that cases are considered on a case-by-case basis. There is currently no system in place for carrying a donor card. The law makes provisions regarding the health, consent and will of the donor.

The law also prohibits trafficking of human organs, which is further prohibited under Federal Law No. 51 of 2006 (on Combating Human Trafficking Crime).

Over 100 kidney transplants have been performed at the Sheikh Khalifa Medical City hospital in Abu Dhabi, with the first kidney transplant carried out in Dubai at the Mohammad Bin Rashid University of Medicine and Mediclinic City Hospital in 2016.

X CONCLUSIONS

The UAE healthcare sector is expanding rapidly. Regulators have adopted a series of long-term initiatives to create a healthcare sector that will be fit for purpose and guide the sustainable growth of this sector, supported by a legal framework created with reference to equivalent laws in other international jurisdictions and creating an environment where private and foreign investment can thrive.

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21 Rule No. 1 Concerning Permitted Activities and Licensing Categories for Dubai Healthcare City Effective 1 December2016 RU/RL/002/01.
22 Federal Law No. 15 of 1993 Regulating the Transfer and Transplant of Human Organs.
I OVERVIEW

Overview of the US healthcare system

The US healthcare industry is at a crossroads. The healthcare reform legislation passed under President Barack Obama in 2010, officially called the Patient Protection and Affordable Care Act (ACA) but widely referred to in the United States as ‘Obamacare’, resulted in significant changes in the US healthcare system. These changes included a dramatic expansion in the number of insured patients, contributing to increased demand for services. Many of these newly insured are covered by the joint state–federal Medicaid programme, which generally covers low-income patients as an entitlement programme, and reimburses at the lowest rates in most markets. However, the ACA has created a number of challenges for the US healthcare system as well, owing to both increased demand driven by newly insured patients and a view by many providers that the rates paid by many payors for healthcare services are inadequate.

Further, even greater changes to the US healthcare system may be on the horizon, as Congress currently considers legislation that would create sweeping reforms to the programme and the US healthcare system as a whole. The dramatic turn of events in the 2016 US presidential election, with the surprise victory of Republican candidate Donald Trump over Hillary Clinton (a recognised defender of the policies embodied by the ACA), plus the Republican control of both houses of Congress, calls into question the long-term survival of the ACA and its benefits. Republican legislators have promised to ‘repeal and replace’ the ACA, and multiple bills have been presented. However, as of the completion of this Article, neither the ‘repeal’ nor the ‘replace’ legislation has been finalised, and defections from both the Republican right and more moderate factions appear to have doomed any immediate hopes of those driven to dismantle President Obama’s signature domestic achievement. The following discussion, therefore, addresses the ACA as it stands today. The significance of overturning such legislation is apparent. These changes would affect the many stakeholders in the US system, including providers, patients, vendors, private payors, as well as the government agencies that are involved in healthcare – Medicare, Medicaid and others that serve as both as payors and regulators.

1 Lawrence W Vernaglia is a partner and Anna S Ross is an associate at Foley & Lardner LLP. The authors would like to acknowledge the significant contributions of their friend and colleague R Michael Scarano for his work on several sections of this article. Mr Scarano was a preeminent healthcare lawyer in the San Diego office of Foley & Lardner who trained generations of healthcare lawyers and zealously served healthcare provider clients at the highest levels. Mike is sorely missed by his peers, and we dedicate this article to his memory and friendship.
Notwithstanding these challenges, the US healthcare system has experienced a period of sustained growth of approximately 6 per cent per year over the past several years. This growth has been coupled with a trend towards consolidation in recent years. One factor driving consolidation is that it is increasingly difficult for independent hospitals and medical groups to survive. As a result of these factors, healthcare presents an attractive area for investment in the United States. This will continue to drive consolidation, along with waning animosity by government towards for-profit healthcare in many markets, and an increasing acceptance of for-profit buyers and investors by state regulators and local communities.

The following sections seek to put the larger healthcare services sector in the United States into context, focusing on these and other broad business and regulatory trends, while also understanding the organisational fundamentals (US Health Care 101).

ii Delivery of healthcare in the United States
Hospitals with inpatient, outpatient and diagnostic capacities are the ‘work benches’ for the delivery of healthcare in the United States, although the physicians and other professionals who treat patients there are obviously critical parts of the care delivery system as well. Physicians are also sometimes referred to as the ‘captains of the ship’ in the hospital context, though other non-physician practitioners are gaining prominence in the institutional and community healthcare setting. Non-physician practitioners, sometimes called mid-level practitioners, include nurse practitioners, physician assistants, certified registered nurse anaesthetists, nurse midwives and others. These practitioners are licensed in their respective states by the state professional board, such as the medical board or the nursing board. Sometimes these practitioners are licensed by the state department of health or another agency within the government.

To help ensure that patients are adequately protected from substandard care provided by deficient practitioners, hospitals and other healthcare facilities in the United States are required by law to perform ‘peer review’ and ‘quality assurance’ activities. Compliance with specific procedures required by these laws qualifies the organisation and its physicians who participate in peer review for immunity from liability under antitrust and certain other laws. Physicians and other practitioners who are disciplined and do not prevail in their hearings are listed on a nationwide databank that warns other institutions and prospective employers regarding a practitioner’s professional shortcomings.

iii Payment for healthcare services
Healthcare services in the United States are paid for primarily by (1) governmental programmes such as Medicare and Medicaid and (2) private insurance organisations. These public and private organisations are collectively known as ‘third-party payors’ or simply ‘payors’. Most third-party payor arrangements have some element of ‘managed care’, which means that care is provided subject to utilisation review, such as primary care physicians acting as gatekeepers to specialists. Managed care plans typically enter into contracts with providers to provide services at a discounted rate, sometimes in exchange for an expectation of increased volume from the payor.

iv Regulation of healthcare
Since the government spends so much on Medicare, Medicaid and other programmes, it has taken aim at fraud and abuse and made concerted efforts to reduce provider misconduct and to recover funds inappropriately paid by these programmes. Such regulation is carried out
by a number of regulatory bodies. At the federal level, most laws affecting the structure and payment of healthcare are promulgated by the Centers for Medicare and Medicaid Services (CMS). CMS is a division of the Department of Health and Human Services, which has a separate enforcement arm – the Office of Inspector General (OIG). The OIG helps to fight fraud, abuse and other forms of waste in government healthcare programmes. The OIG provides oversight by carrying out audits, investigations, and evaluations and develops resources for the healthcare industry. At the state level, state government agencies oversee issues such as Medicaid rules and payment requirements along with provider licensing, and often also enforce state-level versions of some of the major federal compliance rules and regulations. This two-tiered structure creates a complicated patchwork of healthcare laws, often with significant variations among the 50 states and the District of Columbia.

II THE HEALTHCARE ECONOMY

i General
The US healthcare industry is one of the most closely watched and fastest growing sectors of the nation’s economy. There are many stakeholders in the US healthcare system, many of which have dramatically differing interests. These include, but are not limited to:

a enterprises that operate hospitals and health systems;
b manufacturers and developers of medical devices, pharmaceuticals and other biotechnology products;
c academic institutions that provide care while training healthcare professionals;
d information technology firms, construction companies and other infrastructure providers;
e insurance companies, self-insured employers and other third-party payors;
f labour unions representing the employees of healthcare organisations;
g medical entrepreneurs and investors (including private equity and venture capital) who finance the healthcare system;
h healthcare trade associations;
i patient advocates and special interest healthcare advocacy organisations; and
j patients and their families.

In addition, there is substantial governmental involvement in healthcare in the United States, with the government serving as a major payor, as well as a provider and regulator in various parts of the market.

ii The role of health insurance
Most medically necessary healthcare services in the United States are paid for by governmental or private third-party payors, including insurance companies, self-insured employer plans, HMOs, Medicare and Medicaid, Tri-Care, the Veterans Administration and workers’ compensation programmes. Most third-party payor arrangements are either managed care indemnity arrangements or involve monthly pre-payments known as ‘capitation’. Private third-party payors are heavily regulated by state insurance commissioners, or the United States Department of Labor with respect to employer sponsored plans, known as ERISA plans (short for the Employee Retirement Income Security Act).
Medicare and Medicaid

The two major governmental healthcare payment programmes in the United States are Medicare and Medicaid. Medicare is a federal programme that primarily provides coverage for individuals who are age 65 and over, disabled, or have end-stage renal disease. Medicare is currently the largest (in total dollars) federal healthcare programme, providing health insurance for the elderly and certain other individuals. Medicare offers a number of payment arrangements, including traditional indemnity fee-for-service coverage (Traditional Medicare) and Medicare HMOs, known as Medicare Advantage plans. Medicare beneficiaries may choose between the two types of plans.

Under Traditional Medicare, inpatient services for most hospitals (i.e., other than ‘excluded hospitals’ that have special status under the law because of their specific types of service, like cancer care), are reimbursed under the Inpatient Prospective Payment System (IPPS). Under the IPPS, hospitals are paid a prospectively determined case rate based on the patient’s diagnosis – a diagnosis-related group (DRG). There are certain add-on payments to the DRG, such as ‘outlier’ cases, where the patient requires medically necessary hospital services for a longer time than is normally the case. Provider-based hospital outpatient services under Traditional Medicare are reimbursed under the outpatient prospective payment system (OPPS), which is also based on a prospectively determined case rate. Outpatient services that are not ‘provider-based’ are reimbursed under the Medicare Physician Fee Schedule or the ambulatory surgical centre payment rules, which are less generous than the provider-based rules, discussed further below.

Some outpatient procedures can either be performed (1) outside of and independent of a hospital (e.g., in a freestanding clinic or physician’s office) and are reimbursed under the Medicare Physician Fee Schedule; or (2) in a hospital-affiliated and hospital-operated site included on the hospital’s licence and generally referred to as ‘provider-based’. Reimbursement for provider-based facilities under the OPPS methodology is generally higher than comparable rates for the same procedures if performed in a freestanding facility under the Physician Fee Schedule. However, to qualify for provider-based reimbursement, the outpatient site must meet a number of requirements, some of which are somewhat onerous. A hospital that operates a surgery centre also has the option of operating that facility as provider-based, thereby permitting use of the OPPS payment structure.

A significant change in Medicare policy affecting outpatient services was implemented through Section 603 of the Bipartisan Budget Act of 2015, capping the ability of hospitals to add new off-campus outpatient departments and have them reimbursed under the favourable OPPS rates. Unless grandfathered or meeting limited exception, these new off-campus facilities are reimbursed at lower, freestanding rates. Proposed payment policies for 2018 would cap those rates at 25 per cent of the current OPPS rates, a major hardship for land-locked hospitals or those in communities with changing demographics and geographies.

Medicaid is a joint state and federal programme traditionally for certain indigent or impoverished individuals who are aged, blind or disabled, or members of indigent families with dependent children that meet income and resource standards set by the state Medicaid agency. Medicaid today covers more individuals than Medicare, making it the largest single payment system in the United States, in terms of persons served. The federal government contributes roughly half of the reimbursement for the Medicaid programmes, though some

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2 See The Henry J. Kaiser Family Foundation, Medicaid Pocket Primer (updated June 9, 2017; last accessed 19 July 2017), www.kff.org/medicaid/fact-sheet/medicaid-pocket-primer/. See also The Henry J. Kaiser...
US states with struggling economies receive much higher reimbursement than others. Under the ACA, the rules governing Medicaid eligibility have been substantially relaxed, thereby making it possible for millions of additional Americans to qualify for the programme even though they do not meet these traditional criteria. Although the rates payable by Medicaid in most states are notoriously low (and in many cases fall far short of the provider’s costs), the rates will be increased for a number of years under the ACA, hopefully making the programme more attractive for primary care physicians and others who are either in scarce supply or simply do not wish to treat these low-income patients.

**Commercial/private insurance**

**HMOs and PPOs**

Although there remain some ‘pure indemnity’ arrangements (wherein the beneficiary is reimbursed for all healthcare expenses he or she incurred regardless of the provider who rendered the care), most third-party payor arrangements involve some element of ‘managed care’, meaning that the healthcare services are provided subject to utilisation review procedures such as a primary care physician serving as a ‘gatekeeper’ for specialists, and typically create certain constraints on the beneficiary’s choice of provider, usually as a result of network or panel arrangements established by the payor.

There are two primary types of managed care arrangements: health maintenance organisations (HMOs) and preferred provider organisations (PPOs). An HMO typically requires the beneficiaries or members to exclusively use providers that have signed a contract with the HMO to receive a discounted or capitated amount for its services. The HMO will not pay for services provided by a non-contracted provider except when the services were performed in an emergency or the HMO does not have a needed specialist in its contracted network.

PPOs are delivery systems wherein the plan assembles a contracted provider network from which the member can receive care on a discounted fee-for-service basis; however, the beneficiary also has the option of going outside of the network if he or she is willing to shoulder a greater share of the cost of care, typically in the form of a higher co-payment. There are also ‘point of service’ or ‘POS’ plans which are a hybrid between an HMO and a PPO. Under a POS plan, the member usually receives capitated care but has the option of receiving care from a non-contracted out-of-network provider if he or she is willing to pay a substantial portion of the provider’s fee-for-service charges.

**Consumer-driven health plans**

An increasingly popular type of insurance arrangement combines a so-called ‘high deductible health plan’ with a ‘health savings account’ (HSA). The HSA is similar to an individual retirement account in that it permits individuals to save, on a tax-sheltered basis, through the establishment of a special account. The member funds the HSA with up to the maximum permitted by law (US$3,400 for an individual and US$6,750 for a family in 2017). Those funds can only be used to pay for healthcare items and services that would be deductible under federal tax rules if incurred by a taxpayer, as well as to pay down the deductible, until

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[Family Foundation, Total Number of Medicare Beneficiaries (Timeframe: 2015), www.kff.org/medicare/state-indicator/total-medicare-beneficiaries/?currentTimeframe=0&sortModel=%7B%22colId%22:%22%22Location%22,%22%22sort%22:%22%22asc%22%7D.](www.kff.org/medicare/state-indicator/total-medicare-beneficiaries/?currentTimeframe=0&sortModel=%7B%22colId%22:%22%22Location%22,%22%22sort%22:%22%22asc%22%7D)
the funds in the HSA are exhausted. The beneficiary must exhaust the high deductible in the health plan and spend down the HSA, before receiving the full benefit of the health plan’s coverage. Once the HSA is exhausted and the deductible is met, the plan pays most or all of the beneficiaries’ remaining charges. These are sometimes called consumer-driven health plans because the beneficiary controls the expenditure of his or her healthcare dollars to a much greater extent than under a traditional plan. If the funds deposited in the HSA at the beginning of the year are not all used during the benefit year (which is the calendar year), the individual gets to carry the remaining amount in the HSA forward to the next year. The funds also earn interest or investment income until they are spent. The combination of HSAs and high deductibles essentially gives the individual what Americans call ‘skin in the game’, i.e., an incentive to find and use cost-effective providers. To the extent that those providers include domestic or overseas providers, these consumer-driven plans may be a catalyst for the growth of overseas medicine in the United States. Patient advocates are concerned that ‘high deductible’ plans, coupled with insufficiently funded HSAs, have caused a spike in consumer bankruptcy filings. Indeed, many view medical debt as one of the leading causes of personal bankruptcy in the United States.

### iii  Funding and payment for specific services

Healthcare reform, including the ACA and any new healthcare legislation that may be passed under the Trump Administration, has and will continue to have a major impact on healthcare delivery and expenditures. The ACA’s overarching objective is to expand coverage to 31 million currently uninsured Americans, primarily through the individual mandate, employer mandate, expansion of Medicaid and establishment of subsidies (i.e., tax credits) to purchase plans in the health insurance marketplace established by each participating state, or by the federal government. The law establishes a minimum of 10 categories of ‘essential health benefits’ for plans: (1) ambulatory patient services; (2) emergency services; (3) hospitalisation; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioural health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) paediatric services, including oral and vision care. However, other types of healthcare services for adults, such as dental care and vision care, are typically paid for individuals personally or through other types of private insurance plans that cover such services.

The ACA also amends the prior law to prohibit a health plan from establishing limits on the dollar value of these essential health benefits. It requires the plans to provide coverage for and to all individuals, and prohibits cost-sharing requirements for certain preventive services and immunisations. Further, it requires health plans that provide independent coverage of children to extend that coverage to adult children up to the age of 26. It establishes a minimum payment for primary care Medicaid services.

The ACA further looks to novel healthcare delivery models to reimburse providers based on improved health outcomes, prevent preventable hospital readmissions, improve patient safety and reduce medical errors, as well as promote wellness. Health plans are prohibited from imposing pre-existing condition exclusions or discriminating on the basis of any health status-related factor, including genetic factors.³

Despite these refinements, there is a widespread perception that the US healthcare system will continue to be inefficient and burdened with unnecessary administrative expenses and inflated prices. Problems with the healthcare infrastructure in the United States may continue to be a substantial drag on the nation's economic growth and development, notwithstanding the ACA and other reform measures. Indeed, early implementation problems, including but not limited to the serious defects in the ACA's enrolment website, have contributed to the view that the United States lacks the competence to reform its healthcare system.

These concerns, along a view shared by the Trump administration and the Republican congressional majority that espouses a fundamentally different role for government in the healthcare sector, have contributed to calls for further reform. Congressional Republicans, who were in the minority when the ACA was passed in 2010 but now enjoy majorities in both houses of Congress, have called for 'repeal and replace' of Obamacare for the past several years, and now are in a position to do so. However, there is widespread public support for many of the reforms created by the ACA, particularly the prohibition related to exclusions or discrimination based on pre-existing conditions, and such provisions may prove difficult to overturn.

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

i Hospitals and primary care

As noted above, hospitals are the ‘work benches’ for the delivery of healthcare in the United States. Further, the Emergency Medical Treatment and Labor Act, a federal law mandating that anyone who arrives at a hospital emergency department must be stabilised and treated, regardless of their insurance status, has contributed to the use of hospital emergency departments for all types of care. However, there has been an increased focus on primary care, particularly under the ACA. Not only has the ACA expanded the number of insured patients, thereby increasing the number of patients able to access primary care, but provisions of the law have also specifically addressed the types of primary care and other preventive services that must be covered by insurance and have set minimum payment rates for primary-care Medicaid services.

Further, under most types of third-party payment arrangements, there is an element of managed care, meaning that the healthcare services are provided subject to utilisation review procedures such as a primary care physician serving as a ‘gatekeeper’ for specialists. Such care arrangements typically place restrictions on the beneficiary’s choice of provider, usually as a result of network or panel arrangements established by the payor. Thus, although it is possible to have direct access to different healthcare providers, for many insureds, access to a specialist is only possible through a referral by that individual’s primary care provider.

ii Electronic health records and privacy

Although many healthcare facilities and providers in the United States are individually moving towards use of electronic medical records, there has not yet been a sustained effort to implement a universal electronic medical record.

Healthcare organisations are subject to a plethora of federal and state privacy and security laws pertaining to health information maintained by the organisation. The most comprehensive federal law that applies to healthcare organisations is the Health Information Portability and Accountability Act of 1996 (HIPAA), as modified by the Health Information Technology for Economic and Clinical Health Act. These laws and their implementing
regulations provide federal protections for the privacy of individually identifiable health information or protected health information (PHI) held by covered entities (e.g., health plans, healthcare clearinghouses and most healthcare providers) and give patients an array of rights with respect to such information. The HIPAA Security Rule specifies a series of administrative, physical and technical safeguards that covered entities must implement to ensure the confidentiality, integrity and availability of electronic PHI.

HIPAA, along with other federal and state privacy and security laws, impose liability on healthcare organisations for technical violations of the required privacy protections and security safeguards, and for any unauthorised access, use or disclosure (i.e., breach) of confidential health or medical information. If a healthcare organisation violates HIPAA, the Secretary of Health and Human Services may impose civil monetary penalties or corrective action plans on a covered entity and the business associates with which it contracts. The secretary may also refer criminal violations to the Department of Justice. State attorneys general also have a right to bring a cause of action on behalf of residents of their states under HIPAA. State laws vary considerably, but in some states, a healthcare organisation is also subject to state civil penalties and damages in any action brought by an individual whose privacy was compromised as the result of a violation of state privacy law. In addition to any potential liability for their own actions, healthcare organisations may also bear liability for the actions of their subcontractors for violations of state privacy laws.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

Licensure of healthcare providers and professionals is primarily regulated at the state level, typically by the state departments of health, departments of public health, or similarly titled agencies. Such agencies serve as the primary agency that promulgates and enforces licensure requirements for healthcare facilities and individual providers, including physicians, nurses, physician assistants, pharmacists and other healthcare professionals. In some states, accreditation by a private accreditation agency, discussed below, creates ‘deemed’ compliance status for the provider. Regulatory boards, usually made up of other licensed practitioners guard the ‘scope of practice’, often fighting to exclude new, competing professionals, like new categories of non-physician practitioners (referred to above).

Usually, licences are limited to a specified period of time (e.g., one to three years) and must be renewed on a periodic basis. Each type of healthcare facility and provider has its own set of licensure requirements, although there are some types of requirements that are common to all.

ii Institutional healthcare providers

Licensure

As indicated above, the licensing of hospitals and other types of healthcare facilities is regulated at the state level, resulting in at least 51 different sets of licensure requirements for institutional healthcare providers. Notably, even the types of healthcare facilities that require a licence to operate vary from state to state, which can become particularly challenging as more and more healthcare providers move towards consolidation. In general, states will require licensure of hospitals (both general and specialty), nursing homes, ambulatory surgical centers, healthcare clinics (though the specific types of licensure and restricted activities can vary widely from state to state), pharmacies and other similar healthcare facilities.
For hospitals and other health facilities, the licensure laws typically cover issues such as professional and non-professional staffing; physical plant requirements; required clinical services; administrative capabilities; and a vast array of other requirements. In most states, in addition to hospital licensure, full-service hospitals require other licences and permits, such as laboratory permits, permits related to hazardous wastes, food service permits, and transportation licences for hospital-affiliated ambulances. Other residential healthcare facilities, such as nursing homes or behavioural health homes, are typically subject to similar requirements.

States also generally impose sanctions for the provision of healthcare services without a licence by a facility, which often include penalties per violation or per day in operation without a licence. State licensure authorities also have individualised procedures for the issuance, suspension or termination of a facility licence, which typically provide for an appeal by a provider that is refused a licence or has its licence suspended or terminated.

**Certificate of need laws**

There are also a number of other healthcare-related restrictions that may preclude the construction of a hospital or other health facility. In this regard, many states have certificate of need (CON) (sometimes called determination of need) laws that regulate the construction and licensing of new hospitals and other types of healthcare facilities and the addition of new beds to existing facilities. These laws are aimed at avoiding excess capacity and inefficiencies in the delivery of healthcare.

A federal law enacted in 1974 provided for the establishment of CONs by the states. That law was repealed in 1986 and, since that time, a number of other states have repealed their CON laws or dialled back the types of healthcare facilities required a CON. However, despite the gradual fading of CON during the 1990s and 2000s, as states seek to find ways to contain costs as Medicaid and private employer spending on healthcare becomes a serious budgetary concern, some states are revisiting their CON laws.

**Certification and accreditation**

In addition to the licensure requirements administered by the states, Medicare, Medicaid and other governmental reimbursement programmes rely on the 'power of the purse' in regulating healthcare providers in their delivery of services. These programmes impose 'conditions of participation' and 'conditions of payment', which essentially mandate compliance with specified standards set forth in the government programme's regulations and policies. The process of Medicare, Medicaid, and other government reimbursement programmes determining compliance by a hospital or other healthcare provider with the programme’s rules is known as 'certification'. Certification is a right to participate in the governmental payment systems; it is distinct from state ‘licensure’ and private ‘accreditation’. In most cases, hospitals will possess all three: certification, licensure and accreditation, although there are examples of hospitals that do not.

Although they are ultimately responsible for granting certification, the Medicare and Medicaid programmes delegate much of this responsibility to private accreditation agencies and state 'survey agencies'. The two primary private accreditation bodies in the United States are the Joint Commission (TJC) (previously referred to as the Joint Commission on Accreditation of Health Care Organizations, or JCAHO), which surveys most hospitals and other healthcare institutions, and the American Osteopathic Association (AOA), which surveys osteopathic hospitals. Foreign healthcare organisations may be most familiar with
Joint Commission International (JCI), affiliated with TJC. Compliance with the TJC or AOA standards affords a hospital ‘deemed status’ as a certified provider under the Medicare programme, as well as the Medicaid programme, in most states. This means that a hospital is deemed to comply with the Medicare, and usually the Medicaid, requirements, if it complies with the applicable accreditation standards. Accreditation expires no later than three years from the date of the last survey of the hospital. The accreditation agencies can also resurvey hospitals on an unannounced basis. As noted above, accreditation also confers ‘deemed status’ for state licensure purposes in some jurisdictions.

Hospitals are not required to seek private accreditation. The process of seeking accreditation is lengthy and expensive. The accrediting bodies charge considerable fees for the survey process, and also sell a variety of consulting services to accredited hospitals. These fees will often run into the hundreds of thousands of dollars per year. Some smaller organisations, seeking to reduce their expenses, forego accreditation and rely on the surveys by the state survey agencies. The federal Medicare programme has contracted with the state healthcare agency in every state (usually the Department of Public Health) to be the official state survey agency for CMS. These state survey agencies will visit and approve the certification in the Medicare programme and do not charge the hospital, other than nominal licensing fees.

The OIG has criticised the relationship between TJC and hospitals as being too collegial, and a reaction has been somewhat harsher TJC surveys. Consequently, more hospitals are considering relying on the state survey rather than TJC accreditation status to achieve Medicare certification.

### Healthcare professionals

Health practitioners are subject to licensure by their respective state boards. These typically include the medical board for physicians, the nursing board for nurses, and other boards for other types of licentiates. In some states, the state department of health performs this function for some professional categories. These boards establish and enforce the criteria for initial and ongoing licensure, as well as a process for revoking such licensure or taking other disciplinary action, such as the imposition of probation.

Although each state issues its own licence, some states permit reciprocity by honouring each other’s licences. For example, there is a National Nursing Compact, under which 24 member states recognise the nursing licences granted by all of the other member states. In addition, some states honour each other’s medical licences or permit physicians who are licensed in another jurisdiction to practise medicine across their state lines using telemedicine.

In addition to governmental licensing and certification requirements, ‘credentialing’ of individual professionals occurs at the facility level. Compliance with standards and requirements established by individual health facilities permit individual licentiates to perform services within those facilities. Health plans, professional associations and licensed outpatient facilities usually also impose such requirements.

State and federal statutes applicable to physicians and certain other licentiates provide hearing and appeals rights when a state agency denies, or proposes to deny or revoke, licensure or certification. Similarly, hospitals, health plans and certain other providers or professional

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4 See ‘The External Review of Hospital Quality: A Call for Greater Accountability’, (July 1999 OEI-01-97-00050) (‘As the system increasingly tilts toward the collegial mode, however, it could result in insufficient attention to investigatory efforts intended to protect patients from questionable providers and substandard practices.’).
organisations are required by state and federal law to have formal ‘peer review’ and ‘quality assurance or quality improvement’ procedures in place whereby they determine whether to permit a new practitioner to provide services to their patients. These procedures also govern any adverse disciplinary actions against practitioners, such as the revocation or restriction of their clinical privileges. Under a federal law called the Health Care Quality Improvement Act (HCQIA), and under state laws in many jurisdictions, these organisations must follow specified procedures in making adverse decisions affecting a practitioner’s privileges. In most states, practitioners must go through or ‘exhaust’ these administrative appeal procedures before they can challenge the denial or revocation of privileges or other adverse action in court. Because failure to follow these rules can result in liability to the organisation, it is incumbent on hospitals and other healthcare organisations that are subject to these rules to have a compliant peer review and appeals process in place prior to commencing operations.

Pursuant to the reporting provisions of the HCQIA, practitioners who either do not challenge adverse actions or who are unsuccessful in their challenges are identified on the National Practitioner Data Bank so that other prospective employers or hospitals become aware of any competence or conduct issues before permitting such practitioners to join their staffs. The HCQIA also confers immunity on hospitals and certain other organisations that perform peer review and on the individuals who participate in that process. To qualify for immunity under the HCQIA, certain conditions must have been met, including adequate notice and an opportunity for the affected practitioner to be heard that meets certain criteria. The peer review action must also have been taken with the reasonable belief that the action was warranted based on the facts known.

As is the case with health facilities, individual healthcare licentiates enroll in Medicare and other government payment programmes if they want to participate in these programmes. They must also meet specified requirements, such as licensure under state law.

V NEGLIGENCE LIABILITY

One characteristic of the US healthcare system that is viewed by many as contributing to its exorbitant cost is professional liability (‘medical malpractice’). Under the US professional liability system, any patient who believes he or she has been damaged by the professional negligence or wilful misconduct of a healthcare provider is entitled to damages if he or she demonstrates that it is more likely than not that the negligence or wilful misconduct caused the patient’s damages.

It is believed by many providers and politicians on the right that fear of liability drives up the cost of US medicine because physicians order tests that are not medically necessary out of fear that the theory or failure to order the test will be second-guessed if the patient has a bad outcome. This is sometimes referred to as practising ‘defensive medicine’.

In addition, professional liability can arise from failure to obtain appropriate informed consent. If a practitioner fails to do so, the patient may argue that he or she would not have undertaken the procedure and its inherent risks had he or she been notified of those risks.

There are some basic steps providers can take to help reduce their risk of liability. These include careful documentation; obtaining consent from patients; using validated protocols, when available; and following up with patients after they receive their treatment. Some states, including California, have enacted caps on non-economic damages in professional liability cases. This reduces the exposure that practitioners face when performing medical
services. Fortunately, most states in the United States also have so-called ‘good Samaritan’ laws that permit physicians and other healthcare practitioners to render aid at the scene of an emergency, or to assist in the rescue of an individual, without incurring liability.

In addition to provider liability, medical devices and pharmaceuticals experience liability for patient injuries on some different theories, most notably ‘products liability.’

Despite some calls for reform, medical malpractice suits continue to be a frequent presence, based in part on real concerns regarding medical errors. A recent study by Johns Hopkins University found that more than 250,000 patient deaths per year in the United States are a result of medical error, making such errors the third leading cause of death in the country.5

VI OWNERSHIP OF HEALTHCARE BUSINESSES

i Types of ownership and management

The trend toward consolidation of the healthcare industry in the United States has created a number of different ownership and management models. Entities entering the healthcare market typically acquire a healthcare business though an asset acquisition, a stock or limited liability company acquisition, a merger, or a true consolidation that forms a new entity.

In addition to the foregoing organisational changes, control of a hospital can be transferred or shared through the formation of a joint venture or the establishment of a management or co-management relationship. Joint ventures are a common vehicle for extending the reach of an existing hospital into new neighbourhoods and markets, or for leveraging the assets of multiple (usually two) existing market participants in order to enhance the collective ability of those participants to serve their combined communities. Another vehicle for entering the marketplace, potentially with minimal assets, is a management agreement. Under the terms of a typical management agreement, one party with special expertise in the operation and management of a hospital will essentially assume control of the assets and personnel of an existing facility.

It has also become increasingly common over the past two decades for governmental hospitals to enter into management agreements with private parties with the private entity managing the governmental hospital. Such ‘public-private partnerships’ raise complex issues under the special laws that apply to governmental agencies. These include laws that: require most governing body meetings to be public; require public disclosure of most of the agency’s documents; provide special liability protections for the entity and its employees; and, similar to the laws protecting the assets of tax-exempt organisations, protect the assets of the governmental entity from exploitation by private parties, and prevent ‘gifts of public funds’ or the ‘lending of the government entity’s credit’.

Hospitals seeking to lawfully partner with their physicians may also enter into so-called ‘co-management agreements’. These are contractual arrangements under which certain physicians in a particular specialty (e.g., cardiology, oncology, gastroenterology) agree to provide certain management services to a service line of a hospital. The purpose of the agreements is to develop and manage the service line collaboratively, and to improve its quality and efficiency of delivery.

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ii \hspace{1em} \textbf{Restrictions on ownership}

A number of states prohibit ‘corporate practise of medicine’ (CPOM), which is generally defined as the operation of a medical practice, or the employment of physicians (or other licensed practitioners of the healing arts), by lay corporations and entities that are not themselves licensed to practise medicine. The US states have wildly divergent degrees of CPOM regulation, with states like California having the strictest prohibition on physician employment, and Florida having the most lax.

The CPOM is typically articulated in state statutes and regulations, case law, attorneys’ general opinions and medical board guidance. There are usually limited exceptions to the CPOM in those states that enforce the prohibition. The rationale for the CPOM is that commercial business issues (revenue generation, profit and loss, etc.) should not be permitted to intrude on the physician–patient relationship. In theory, the corporate practice prohibition ensures that physicians are able to put the medical interests of their patients above all other concerns, unfettered by the demands of a corporate entity employer. Depending on the state, violations of the CPOM can result in injunctive relief, civil penalties and criminal enforcement.

\section*{VII COMMISSIONING AND PROCUREMENT}

Because most hospitals are private (whether for-profit or not-for-profit), procurement and purchasing is handled on a local level, with each hospital (or other healthcare provider) making purchasing decisions individually with the manufacturers and distributors of medical supplies and products. The large federal systems, like the Veterans Administration hospitals, purchase through governmental procurement contracts.

To address the disparity of bargaining power by private hospitals, many hospitals have banded together in ‘group purchasing organisations’ (GPOs) that retain a percentage of the total spent (e.g., 3 per cent) and then negotiate large contracts of multiple hospitals. The GPOs retain significant influence in the healthcare industry, though commenters note that physicians’ preference for expensive technologies continues to drive needless expense and waste in the industry.

\section*{VIII MARKETING AND PROMOTION OF SERVICES}

There are a number of laws that restrict the promotion and advertising of healthcare services and business, particularly to the extent that any such arrangements involve ‘remuneration’ in exchange for a referral for particular types of healthcare services. In general, ‘remuneration’ means the payment or transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

i \hspace{1em} \textbf{The Federal Anti-Kickback Statute}

The Anti-Kickback Statute prohibits any person from ‘knowingly and wilfully’ paying, offering, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce the referral of, any item or service covered by a federal healthcare programme, or in exchange for arranging for or recommending purchasing, leasing or ordering any good, facility, service or item covered by a federal healthcare programme, including Medicare and Medicaid. Violation of the Anti-Kickback Statute is punishable by a US$25,000 fine, imprisonment for up to five years, or both, and may subject
a violator to civil monetary penalties as well. Moreover, violation of the Anti-Kickback Statute is also grounds for exclusion from participation in the Medicare and Medicaid programmes and other federal healthcare programmes. The ACA amended the Anti-Kickback Statute to provide that items or services resulting from a violation of the Anti-Kickback Statute can constitute false claims for the purposes of the False Claims Act (FCA), discussed below. Thus, violations of the Anti-Kickback Statute can also lead to substantial civil liability under the FCA.

The Anti-Kickback Statute is an intent-based statute. Consequently, whether an arrangement violates the statute depends on the facts and circumstances of a particular arrangement and, more specifically, whether the parties entered into the arrangement with the intent to induce referrals. Further, the Anti-Kickback Statute contains several exceptions. Given the breadth of the Anti-Kickback Statute, Congress authorised the US Department of Health and Human Services to promulgate regulatory safe harbours that would provide additional guidance regarding arrangements that are not subject to the Anti-Kickback Statute. There are a number of regulatory safe harbours, covering arrangements such as recruitments, electronic health records subsidies, discounts and certain investment interests.

Importantly, the OIG has stated that the failure of an arrangement to fit squarely inside a safe harbor does not mean that the arrangement is illegal; it means only that the arrangement does not have guaranteed protection and must therefore be evaluated on a case-by-case basis, taking into account the facts of the particular arrangement.

Thus, unlike the Stark Law (discussed below), the failure to comply with an Anti-Kickback Statute exception or regulatory safe harbour does not necessarily mean that an arrangement violates the statute. The absence of a bright-line rule regarding failure to comply with the Anti-Kickback Statute exceptions can make it particularly difficult to analyse whether certain arrangements comply with the law. If an arrangement does not comply with each and every requirement of an Anti-Kickback Statute exception or safe harbour, the exception or safe harbour will not apply to the arrangement. However, as noted, the arrangement does not automatically violate the statute simply because an exception or safe harbour does not apply.

ii The Federal Physician Self-Referral Law (the Stark Law)

The Federal Physician Self-Referral Law (commonly referred to as the Stark Law, after Congressman Fortney ‘Pete’ Stark, who introduced the legislation) prohibits a physician from referring Medicare beneficiaries for ‘designated health services’, including all inpatient and outpatient hospital services, to entities with which the physician has a financial relationship (and prohibits billing for services provided pursuant to such a referral), unless an exception applies. The Stark Law defines ‘physician’ as a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry or a chiropractor. Violations of the Stark Law may result in penalties that include denial of payment, civil monetary penalties of up to US$15,000 per service (and US$100,000 for schemes that are designed to circumvent the Stark Law), and exclusion from the Medicare and Medicaid programmes.

A financial relationship under the Stark Law can be created through a direct or indirect ownership or compensation arrangement between a hospital and physicians. There are several exceptions, covering arrangements such as space leases, bona fide employment relationships, isolated transactions, and recruitment arrangements. In addition, there are 23 regulatory
exceptions. Although each exception is different, most of the ‘compensation arrangement’ exceptions require that the arrangement be (1) in writing, (2) signed by the parties, (3) commercially reasonable without regard to referrals, and (4) at fair market value.

Unlike the Anti-Kickback Statute, the Stark Law is a strict liability law (i.e., the intent of the parties is irrelevant). If the elements of the Stark Law are met, namely that a financial relationship exists between a physician and a healthcare entity pursuant to which the physician makes referrals of designated health services that are payable by Medicare, then an exception must be met to avoid penalties. Because of its broad scope, the Stark Law can implicate many financial arrangements that may seem relatively innocuous. A number of practices present risk under the Stark Law (and potentially under the federal Anti-Kickback Statute, as well), and have been the source of government investigations, enforcement actions and settlements. Such practices as the giving of free items and services, undocumented arrangements, failure to adhere to contract terms, and lack of fair market value are all subject to a high degree of scrutiny.

Free items and services
Under the Stark Law, ‘compensation’ is broadly defined to include ‘any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind’. Free items and services provided to physicians are generally treated as ‘compensation’ to physicians, and, therefore, must meet a Stark Law exception to avoid compliance issues. For example, if a hospital administrator provides a physician with free football tickets, the physician is deemed to receive compensation because the free items and services have an independent value to the physician. Although the Stark Law contains a ‘non-monetary compensation’ exception that permits gifts of non-monetary items (e.g., meals and theatre tickets) valued at up to US$398 (in 2017) in the aggregate over the course of a year, this amount is relatively easy to exceed.

Lack of fair market value
An important requirement of many Stark Law exceptions is that payments under an arrangement constitute fair market value payment for goods or services. ‘Fair market value’ in this context generally means the price that an asset would bring, or the compensation that would be included in a service agreement, as the result of bona fide bargaining between well-informed parties to an agreement who are not otherwise in a position to generate business for the other parties on the date of acquisition of the asset or at the time of the service agreement. If a healthcare entity undercharges or overpays a physician, then the healthcare entity bestows a financial benefit on the physician that the government could view as being in exchange for patient referrals. Thus, it is very important that financial arrangements between a healthcare entity and a physician (e.g., space leases, professional services agreements, equipment leases and employment agreements) contain compensation that is fair market value.

iii Penalties

The Civil Monetary Penalty Law
The Civil Monetary Penalty Law (CMPL) is a civil statute that prohibits various forms of inappropriate activities, such as the submission of false claims, contracting with an
individual who has been excluded from federal or state healthcare programmes, violating the Anti-Kickback Statute, denying access to the OIG during an audit, or failing to return any overpayment.

One particular area of concern related to the CMPL is the prohibition on patient inducements. The CMPL prohibits the offering or transferring of ‘remuneration’ to any individual eligible for benefits under Medicare or Medicaid that the offeror ‘knows or should know’ is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under Medicare or Medicaid. ‘Remuneration’ is defined to include (among other things) the waiver of co-payments and deductible amounts. Violation of the CMPL is punishable by a monetary penalty of US$10,000 per item or service, damages of up to three times the amount claimed for the item or service, and potential exclusion from Medicare. Similar to the Anti-Kickback Statute, there are several exceptions to the CMPL that, if met, protect the arrangement. Advertising and other promotional materials to provided to patients present one example of potential risk under the CMPL’s patient inducement prohibition. Although such items or services can be structured to comply with an exception to the CMPL’s prohibition on patient inducements, such arrangements warrant particular attention from a compliance standpoint.

**The False Claims Act**

The FCA prohibits a variety of fraudulent conduct with respect to federal programmes, purchases or contracts. A person or entity can violate the FCA through a variety of methods, including knowingly: (1) submitting a false claim for payment, (2) making or using a false record or statement to obtain payment for a false claim, (3) conspiring to make a false claim or get one paid, or (4) making or using a false record material to an obligation to pay the government, or concealing or avoiding such an obligation. Either the attorney general or a private person through a private whistleblower action can bring a lawsuit for violation of the FCA. The FCA imposes penalties of US$11,000 to US$22,000 per claim, plus three times the amount of damages to the government. These penalties were most recently half as large, before a little known federal agency, the Railroad Retirement Board (the Board), which administers retirement-survivor and unemployment-sickness benefit programmes for railroad workers, published an interim final rule on 2 May 2016, nearly doubling the amounts of penalties ‘under the Board’s jurisdiction’ including the FCA.

Under recent changes in the law, providers also have an obligation under the FCA to refund and report Medicare and Medicaid overpayments by 60 days after the overpayment is identified or the date the corresponding cost report is due. In addition to potential FCA liability, failure to report and return overpayments within this timeline can result in civil monetary penalties of no more than US$10,000 for each item, plus three times the amount of damages to the government. This is a significant new source of liability and is considered a ‘reverse false claim’.

**IX FUTURE OUTLOOK AND NEW OPPORTUNITIES**

Although the ACA has brought about a number of important reforms to the US healthcare system, the law has long been a target for many congressional Republicans, who are against the law’s ‘individual mandate’ – the requirement that each individual purchase or otherwise maintain healthcare coverage, or pay a tax penalty. Republicans have supported a number of
legislative and legal challenges to the ACA since it was first enacted, including several votes to repeal the act between 2011 and 2015 and lawsuits challenging the constitutionality of the law.

To date, these efforts at ‘repeal and replace’ have not succeeded. However, with the 2016 election of President Trump, a major critic of the ACA, along with Republican majorities in both the Senate and the House, the right is now poised to implement significant reform. In May 2017, the House narrowly voted in favour of the American Health Care Act, which would eliminate tax penalties for people who go without insurance, roll back state expansions of Medicaid, and offer tax credits to aid the purchase of healthcare insurance instead of the government-subsidised insurance policies created by the ACA.

As of this writing, the Senate has released its own version of a healthcare reform bill, the Better Care Reconciliation Act, which also would eliminate the mandate, while allowing insurers to sell lower-cost healthcare plans with fewer benefits and expanding the use of tax-favoured health savings accounts. Like the House bill, it would also severely curtail spending on Medicaid, both by phasing out money provided by the federal government to expand Medicaid eligibility in the states and by placing limits on spending for the entire programme. However, the Senate bill faces a steep uphill climb, with several Republican senators indicating that they will not vote for the bill.

One challenge is that the bills considered by both the House and Senate have had low public approval ratings, with criticism being lobbied against the Senate bill in particular for being crafted mostly out of public view. The issue of pre-existing conditions has also drawn significant public concern and comment, since many voters favour the ACA’s prohibition on exclusion or discrimination based on pre-existing conditions. The House and Senate bills have taken different approaches to this issue. The House bill provides for waivers that permit states to allow insurers to charge people with pre-existing conditions higher premiums if the states meet certain conditions, such as setting up high-risk insurance pools. The Senate bill, on the other hand, does not permit states to use waivers to change federal regulations related to pre-existing conditions, but some critics have pointed out that under the proposed law, insurers could nonetheless use other loosened regulations to design policies that indirectly discriminate against those with pre-existing conditions.

Another sticking point for healthcare reform has been the proposed reductions to Medicaid. The House bill gradually eliminates the Medicaid expansion created by the ACA, and goes one step further to turn Medicaid into a programme providing a block grant to states to cover total spending, rather than providing guaranteed matching funds. Although Republicans have argued that these reforms will drive efficiencies in care, opponents have voiced concern that fewer funds will result in reduced eligibility, diminished provider payments and fewer benefits.

Not being able to carry out their promise to repeal and replace the ACA while in the majority would deal a significant blow to congressional Republicans, many of whom campaigned on a promise to overturn the law. However, following the setback of the Senate bill, President Trump issued a call to Republicans to simply repeal Obamacare and then work on replacement from a ‘clean slate’. The fate of the ACA thus remains to be seen, although there will almost certainly be significant changes to the law in one form or another.

Probably the single largest challenge of the US healthcare system is the management of cost. While beyond the scope of this chapter, it is well accepted that the cost per capita in the United States is significantly higher than in the other Western democracies and other countries discussed in The Healthcare Law Review. The causes for that cost increase
are many and complex, and often attributed to the core structural issues discussed above, such as the dependence on high-cost, bricks-and-mortar hospitals, achievements in high-end diagnostics, and expensive pharmaceuticals. Other causes are more uniquely American, such as the notion of the patient as an individual entitled to the best possible cure for disease and prolongation of life, as opposed to more communitarian notions that might look to the overall public health as the ultimate goal of the healthcare system. But whatever the cause, the result has been a materially more expensive system that has an arguably (questionably) superior outcome across the board. Thus, when the ACA was being debated, a 'triple aim' was proposed as a goal: reduced cost, increased access and improvement of the patient experience. The ACA addressed the patient access issue, but cost containment, and likely patient experience improvements, remain elusive. Innovators, disruptors or other investor-backed initiatives seeking to address cost are likely the most important frontier for new healthcare service businesses in the United States for the foreseeable future.

X CONCLUSIONS

The US healthcare system is made up of a complex set of provider types and payor types, and is set against a backdrop of overlapping federal and state laws. Further complicating the system are significant changes that may be on the horizon, as the Republican majority attempts to overturn the ACA, a law passed by the then-President Obama that ushered in sweeping reforms both to access to insurance and the delivery of care. Although the repeal and replace efforts have not yet been successful, change of one type or another appears inevitable.

Both the ACA and the legislation proposed to replace it address access to healthcare, through the type of insurance plans available and the type of benefits provided by such plans. Currently, insured Americans typically receive care either through the government – such as through a programme like Medicare or Medicaid – or through a private insurance plan.

Another important trend in the US healthcare industry is the move towards greater consolidation, with more and more facilities and medical groups coming in to common control. This movement has created a number of interesting types of ownership and management structures.

Relatedly, rising healthcare costs remain a significant issue for the US healthcare system. This has driven in part a number of laws targeting fraud and abuse in the provision of healthcare, particularly related to referral practices. The Anti-Kickback Statute and the Stark Law, and the related penalty provisions, can be difficult for providers to navigate when structuring financial arrangements. Nevertheless, given the complex causes for cost increases, the United States will likely need to look to innovators, disruptors, or other investor-backed initiatives to address rising costs in the healthcare system.
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Daniel Fabiano is a partner at the Toronto office of the law firm of Fasken Martineau DuMoulin LLP. His business law practice emphasises public procurement, privacy/information protection and technology. In his procurement practice, Daniel advises organisations on documenting the bidding process, drafting and negotiating contracts, and mitigating procurement risks and bid disputes. Daniel has both a ‘Certificate in Public Procurement Law and Practice’ and a ‘Certificate in Advanced Procurement Law and Practice: Major Projects and Tendering’ from Osgoode. He also advises the Healthcare Supply Chain Network on common tendering and contracting templates and guidance documents for healthcare organisations, and regularly speaks on health sector procurement. In his privacy/information protection practice, Daniel regularly assists clients in complying with Canada’s privacy and freedom of information laws. Together with other members of Fasken, he co-authored a compliance manual on the Freedom of Information and Protection of Privacy Act for Ontario hospitals.
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Ms Bertonha Felício is a senior associate of Veirano Advogados and has strong experience advising domestic and foreign clients in M&A, banking and finance, and capital markets transactions, including stock sales and purchases, asset sales and purchases, private equity investments, leveraged buyouts, joint ventures, debt restructurings and IPOs. She has also represented clients in connection with corporate integrity and compliance matters and has coordinated internal corporate investigations that involved not only anticorruption but also fraud issues. She has advised companies across a broad range of industries such as pharmaceutical, mining, manufacturing and insurance. Mrs Vanessa Bertonha Felício graduated at PUC-SP in 2008, obtained her postgraduate degree at Insper – Instituto de Ensino e Pesquisa in 2014 and an LLM degree at the University of Chicago Law School in 2015.

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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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Benjamin is a director in Drew & Napier's corporate and finance department and he is co-head of the healthcare and life sciences practice group.

He is recognised as a leading life sciences lawyer and has been listed in Who's Who Legal: Life Sciences for six consecutive years. Asia IP Experts 2016 lists Benjamin as a leading individual in pharma and biotech.

Benjamin has experience advising companies on a wide range of corporate and commercial matters including finance, mergers and acquisitions, and restructuring. He also advises on all aspects of employment law including employment agreements, secondment arrangements and termination of employment.

His particular focus is on the technology, biotechnology, health and pharmaceutical industries, where his experience includes reviewing and drafting clinical trial agreements, research and development agreements, licensing agreements and franchise agreements. Benjamin has also been involved in life sciences, pharmaceutical and healthcare regulations.

GIULIA GIGANTE
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Giulia graduated in business law in 2014 at Luiss Guido Carli University of Rome.
She has gained experience in insolvency and corporate law as well as in the field of regulatory and compliance issues regarding medical products and medical devices.

Giulia is also involved with general civil and commercial practice, and mergers and acquisitions.

She is also involved in advising pharma companies on compliance with the various legislative and regulatory requirements relating to the prevention of criminal liability of corporate bodies (DL 231/2001).

**LYNNE GOLDING**

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Lynne Golding leads the national health law group at the law firm of Fasken Martineau DuMoulin LLP. Out of their Toronto office, she has an active corporate-commercial practice principally in the health industry, which involves transactions dealing with public and private corporations in both regulated and unregulated industries. Her own practice focuses on corporate law, particularly structuring contractual arrangements between hospitals and private sector service providers and providing governance advice. Together with other members of Fasken, she co-authored the Ontario Hospital Association's Toolkit on the Freedom of Information and Protection of Privacy Act and advised Healthcare Supply Chain Network on the Common Tendering and Contracting Templates for healthcare organisations, including by preparing guides and annotations for their use. She has led large teams involved in the merger or integration of large, medium and small corporations involved in the delivery of healthcare.

**STEFANIE GREIFENEDER**

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Dr Stefanie Greifeneder is a partner in the Munich office of Fieldfisher (Germany) LLP. She provides regulatory law, intellectual property and commercial law advice for national and international companies from a wide range of industry sectors, with a specific focus on the pharmaceutical, biotech, medical devices and food sectors. She represents such companies in administrative proceedings and before the respective courts. She also focuses on IP and commercial law issues in the framework of international corporate transactions. Stefanie has extensive experience in court and out-of-court proceedings on patent infringement, trademark and unfair competition matters. She also advises clients in drafting and negotiating a broad range of agreements, such as licence agreements and R&D agreements, as well as distribution and supply agreements.

**TOM HAYES**

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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
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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, High Court, Court of Appeal and
Supreme Court in recent years.

He has a strong interest in clinical governance and has lectured extensively on
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professional disciplinary litigation generally.

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Nabil Issa specialises in private equity, funds and investment structures in the GCC and
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Nabil regularly represents clients on healthcare transactional matters in Saudi Arabia
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funds and investment structures for real estate and private equity investments in Saudi Arabia
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Nabil is ranked in Band 1 for his work on investment funds in the Middle East by
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Chambers Global 2017, in addition to being highly ranked for his corporate work in the
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The Legal 500: Europe, Middle East & Africa 2017.

LINDA LONGO

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Linda Longo has been a name partner at Biolato Longo Ridola & Mori, Rome, since 1992.
She was an associate at Studio Avv. Ercole Graziadei from 1979 to 1984.

She is the head of the life science department of the law firm.

She is involved in general counselling to companies with a special orientation to the
pharmaceutical, biotech, medical devices and food industries. She is familiar with regulatory
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Linda is a member of the surveillance body of pharmaceutical companies for the
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She is the co-author of the Italian chapter of EC Legal Systems: An Introductory
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MICHELE LYRA DA CUNHA TOSTES  
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Ms Lyra is experienced in litigation and has worked on a number of sophisticated commercial and corporate litigation matters. In more than 15 years of practice in litigation, she has assisted companies from different sectors, including clients in the banking, tobacco, pharmaceutical and mining industries. Ms Lyra has coordinated administrative and judicial litigation matters related to public bids and concessions. She offers clients extensive experience, helping with administrative and judicial cases in various regulated sectors, such as energy, ports, and oil and gas. Ms Lyra has also been involved in some of the firm’s most prominent litigation matters regarding antitrust and competition issues, including cartel cases. Brazilian and foreign clients value her ability to provide counsel in the areas of contracts, torts, consumer law, administrative law and commercial arbitration. Ms Lyra holds an LLM from the State University of Rio de Janeiro, awarded with honours, and has been a lecturer for universities in Brazil.

RENATA FIALHO DE OLIVEIRA  
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Mrs Fialho de Oliveira is a corporate partner of Veirano Advogados based in São Paulo and the co-leader of the healthcare practice area at the firm. Counsel to domestic and foreign clients on complex corporate, commercial and international law issues, representing private equity firms, private acquirers and target companies in a variety of Brazilian and cross-border acquisitions, dispositions, spin-offs and restructurings. In the area of mergers and acquisitions clients rely upon her advice on across the full spectrum of issues. She also regularly provides corporate governance advice, as well as general corporate and contractual counseling, with particular experience in agreements specific to the healthcare industry, including distribution, manufacturing, licence, supply and quality agreements. Mrs Fialho de Oliveira graduated at PUC-SP in 2001, obtained her master’s and PhD degrees with distinction at the Law Faculty of the University of São Paulo in 2006 and 2010, respectively, and an LLM degree at Columbia University in the City of New York in 2011.

JOANA MOTA  
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Joana Mota joined Uría Menéndez as a junior associate in February 2012 and became a senior associate in February 2014. Between 2006 and 2012, Joana worked as a lawyer in other prestigious law firms.

Joana focuses her practice on the acquisition, protection and maintenance of national and international IP rights and has represented parties in related litigation proceedings. She has also advised companies on personal data protection issues.

Joana has a postgraduate qualification in IP law, awarded by the Portuguese Association of Intellectual Property Law in conjunction with the Faculty of Law of the University of Lisbon. She also has an advanced qualification in data protection law from the University of Lisbon.
FÁBIO LUIZ BARBOZA PEREIRA
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Mr Pereira is the partner responsible for the Intellectual Property and Information Technology practices at Veirano Advogados in São Paulo. He holds an LLB from PUC-Rio, a postgraduate degree in civil law from the Escola Superior de Advocacia (ESA-RJ) and an LLM in intellectual property from Queen Mary and Westfield College, University of London (awarded the British Chevening Scholarship by the British Council/FCO). He is the co-coordinator for the Software, Informatics and Internet Commission of the Brazilian Intellectual Property Association (ABPI). Fábio has authored several articles and publications in the fields of IP and IT, and frequently lectures in national and international events. He has worked as in-house counsel for TV Globo and for the Roberto Marinho Foundation, and as legal affairs and intellectual property manager for the University College London Hospitals, in England. Fábio is recognised by Chambers and Partners as an ‘Expert Based Abroad’ for the UK in IP and by The Legal 500, Who’s Who Legal and Revista Análise da Advocacia as an expert in intellectual property and information technology.

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Ms Piccolo Brandão is a senior associate with Veirano Advogados, based in the Rio de Janeiro Office. As a litigator, she has worked in a number of sophisticated cases involving civil, corporate, contracts and consumer matters for companies from different sectors, including clients in the banking, pension fund, oil and gas, energy, logistics, entertainment and mining industries. She has drafted, reviewed and negotiated numerous commercial contracts. She has advised clients, including foreign outside counsel from major law firms, on the above-mentioned matters. Her current practice focuses on insurance law, working with senior partners to develop and improve this area of practice by writing legal opinions and advising foreign clients interested in the Brazilian insurance and reinsurance market. She graduated from PUC-Rio in 2005. She has a postgraduate degree in private law from PUC-RIO (2008). She also holds a master of laws degree from New York University – NYU, USA, issued in 2014, where she was awarded with an International Finance and Development (IFD) Fellowship. Currently Insurance and Reinsurance MBA candidate before Escola Nacional de Seguros (Foundation National School of Insurance) – Funenseg and member of the Consumer Relations Group of AIDA Brasil.

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Kimberly Potter is an associate in the litigation department of the law firm of Fasken Martineau DuMoulin LLP. She works out of the Toronto office.

Kimberly has advised clients on the implications of recent changes to healthcare legislation, and assisted in drafting regulations for a professional college. She has also represented clients who operate in the healthcare space in litigation matters. She recently co-authored an article on proposed changes to Ontario’s healthcare regime, which was published in Canadian Health Facilities Guide and Risk Management in Canadian Health Care by LexisNexis.
RŪTA PUMPUTIENĖ

Rūta Pumputienė Law Firm

Mrs Rūta Pumputienė is an attorney-at-law and the founder and managing partner of Rūta Pumputienė Law Firm, with over 12 years’ legal experience, mainly in the life sciences sector. Rūta continues her practice after working for 10 years as an associate partner in the biggest business law firm in the Baltics. She works with leading international life science companies in Lithuania within the pharmaceutical, food and other regulated industries sectors. She is widely considered one of the most experienced life sciences law and intellectual property experts in the Baltic States. Mrs Pumputienė graduated from Vilnius University Faculty of Law in 2004. In 2010, she obtained a master of law (LLM) degree in international intellectual property law from the University of London. Since 2013, Mrs Pumputienė has been the head of the Local American Working Group (LAWG), a standing committee established by the American Chamber in Commerce in Lithuania to tackle issues concerning the healthcare system and pharmaceutical industry in Lithuania. Recently, Rūta Pumputienė was announced as one of the top lawyers in Lithuania in biotechnology law, information technology law and intellectual property law in the seventh edition of Best Lawyers.

Mrs Pumputienė is also a frequent speaker in national and international conferences on medical law, intellectual property, and EU and domestic trade law spheres, and has authored and co-authored dozens of publications on medical law, pharmaceutical law, intellectual property and related law matters.

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David Rosenbaum is a partner in the litigation department at the law firm of Fasken Martineau DuMoulin LLP. He works out of the Toronto office. David has extensive experience in the health law area, which includes: acting for regulators of health professionals in discipline matters, prosecutions in the courts, drafting of regulations and advice on regulatory matters. He is a member of a panel of litigators at Fasken who act as counsel to the Discipline and Fitness to Practise Committees of the College of Physicians and Surgeons of Ontario. In addition to the work he has done for regulators, he has provided regulatory and liability advice to many institutions within the health care sector including hospitals, long-term care homes and laboratories. He regularly advises clients on compliance with the statutes and regulations that govern the healthcare system in Canada. David has written and spoken extensively on topics in health law, including recently participating in a panel discussion at Ryerson University on the legal implications of the Cambie Surgical case in British Columbia.

ANNA S ROSS

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Anna Ross is an associate and business lawyer in Foley & Lardner LLP’s Washington office. She focuses her practice on healthcare, FDA regulatory and public policy matters. Ms Ross counsels clients in the healthcare and pharmaceutical and medical device industries with respect to a wide range of regulatory, compliance, and corporate matters. In the scope of her healthcare practice, Ms Ross advises hospitals and health systems, post-acute care providers, physician groups, pharmacy benefit managers and health plans in all aspects of federal and state regulatory and compliance issues, including government and internal investigations.
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and audits, self-disclosures, Medicare and Medicaid reimbursement compliance, state and federal fraud and abuse issues, and state licensure issues, certificate of need requirements and change of ownership issues. She also provides clients with support related to their compliance programmes, including developing policies and procedures, creating training programmes and implementing compliance obligations in connection with a corporate integrity agreement. Ms Ross provides further assistance to clients with respect to preparing, reviewing and implementing hospital, physician and other provider contracts.

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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Mrs Sansone is a partner at Veirano practising product liability and consumer law and co-heading the dispute resolution practice area of the firm nationally. Priscila also joins the healthcare practice area advising several clients in the industry from a consumer law and civil liability standpoint. Mrs Sansone has more than 15 years of experience counselling Brazilian and international companies on issues related to prevention and resolution of disputes, litigation, commercial contracts law and product liability and torts. Priscila majored in law at PUC-RS in 2001 and holds an LLM degree in private law from UFRGS (2007). Mrs Sansone was also trained by the Center of American and International Law, attending the 2008 Academy of American and International Law. Mrs Sansone is the author of several articles, book and sessions of books on her areas of expertise. Priscila has obtained a distinction and won a prize on an article on Brazilian Consumer Law by the Brazilian Consumer Policies and Rights Institute (BRASILCON).

ANDREA TITHECOTT
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Andrea Tithecott is a partner and head of the regulatory practice. Andrea is also co-head of the healthcare practice group.

Andrea joined the firm in 2013 to establish the regulatory practice, which was quickly ranked by Chambers and Partners for significant expertise in regulatory and local compliance issues. Her practice area has focused upon regulatory compliance, investigations and disputes, risk management, crisis management, trade and customs, public policy and advocacy,
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Her regulatory work was shortlisted for the Corporate Counsel Middle East awards consecutively in 2014 and 2015, and awarded In-House Community Firm of the Year, 2016 for ‘Compliance and Regulatory UAE’ by Asian Mena Counsel. When based in the UK, she was ranked in tier 1 by The Legal 500 for her health and safety expertise.

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Laurie Turner is an associate in the business law group at the Toronto office of the law firm Fasken Martineau DuMoulin LLP, focusing primarily in the health industry. Laurie advises both for-profit and not-for-profit clients (including charities) in respect of a wide-range of matters including structuring, contractual arrangements, corporate governance, privacy, procurement and compliance.

Previously, Laurie was a full-time Executive Research Assistant to the Canada Research Chair in Breast Cancer at Sunnybrook & Women's College Health Sciences Centre and a Research Assistant for Professor Jurgen Rehm at the Centre for Addiction and Mental Health. During her legal career, Laurie has participated in numerous secondments in the health sector, including at two large teaching hospitals and a shared service organisation.

Together with other members of Fasken, she co-authored the Ontario Hospital Association's Toolkit on the Freedom of Information and Protection of Privacy Act.

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Lawrence Vernaglia is a partner and healthcare lawyer in Foley & Lardner LLP’s Boston office. He serves as chair of the firm’s healthcare practice and co-chair of the health care industry team – named ‘Health Law Firm of the Year’ by US News – Best Lawyers on the ‘Best Law Firms’ list (2012–2014). Mr Vernaglia represents hospitals, health systems and academic medical centres and a variety of other healthcare providers. Mr Vernaglia’s practice involves regulatory and transactional matters, including Medicare/Medicaid reimbursement compliance advice and appeals; mergers, acquisitions and financings; state regulatory issues including licensing, change of ownership and CoN/DoN; survey/certification appeals; fraud and abuse/Stark Law analyses; managed care contracting; and general corporate and business planning in healthcare. He runs strategic planning programmes for senior management and governing boards. He regularly serves as local counsel on healthcare transactions in New England for multi-state projects.

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Markus Wang studied law at the University of St Gallen (lic. iur.; Dr. iur.) and the London School of Economics (LLM) and was admitted to the Bar in 1996. He heads Bär & Karrer’s life sciences and intellectual property departments. His practice covers a wide range of contentious and non-contentious intellectual property issues, as well as regulatory matters.
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AISLING WEIR

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Aisling Weir is a senior commercial lawyer who specialises in health sector business law, contracting and procurement. She has practised both in-house (including at a manufacturer and distributor of medical devices) and in private practice, and has extensive experience in advising health sector businesses, public healthcare providers and health regulators. Aisling has an LLB/BA from Victoria University of Wellington.

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