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EDITOR’S PREFACE

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

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

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

These continue to be exciting times for the delivery of healthcare, with digital technologies, genomic personalised medicine and the eradication of certain diseases through vaccination. Patients, data and providers are moving globally and the pace of development is relentless. This year has seen a recognition of the real value of data in the provision of care and the development of healthcare technology; this has been coupled with new legislation including the European General Data Protection Regulation, which has impacted not just on data controllers in Europe but on many of the international providers caring for EU citizens. Younger healthcare economies are offering exciting new opportunities in a market where healthcare professionals can be a scarce resource; more mature markets are having to address ageing infrastructure and a pressing need to reform to meet today’s challenges.
Each chapter has been written by leading experts who describe succinctly their own country’s healthcare ecosystems. I would like to thank them for the time and attention they have given to this project and also the wider team at Law Business Research for their support and organisation.

Sarah Ellson
Fieldfisher
Manchester
July 2018
Chapter 1

AUSTRIA

Valerie Hohenberg and Maren Jergolla-Wagner

I OVERVIEW

The central characteristic of the Austrian healthcare system is that responsibilities are split between several different bodies, and their tasks are regulated in several laws and regulations. This makes the topic of healthcare in Austria highly complex. Another peculiarity is that there are many social security funds that are connected under one umbrella organisation. It is also noteworthy that the relations between the public health insurance institutions and the providers of healthcare services are regulated by civil law contracts.

II THE HEALTHCARE ECONOMY

i General

Access to healthcare services in Austria is independent of factors such as nationality and age; rather, it is a matter of the type of health insurance in place.

Public healthcare services (i.e., services available to persons who have statutory health insurance) include:

a medical, therapeutic and psychologists’ services:
  • consultation with doctors, who have a contractual relationship with a public health insurance institution (contract doctors);
  • consultation with non-contract doctors;3
  • consultation with healthcare centres of the respective health insurance institution; and
  • if prescribed by a doctor, treatment by psychotherapists, speech therapists, occupational therapists or masseurs, and, if prescribed or ordered by a doctor or psychotherapist, a diagnosis by a clinical psychologist;

b remedies, which include the necessary medicinal products and other means to cure or alleviate the illness or to ensure the success of the treatment;

c medical aids, such as glasses and orthopaedic insoles;

d hospital care and medical treatment at home;4

e dental services;5

1 Valerie Hohenberg is a partner and Maren Jergolla-Wagner is a senior associate at Wolf Theiss Rechtsanwälte GmbH & Co KG.
2 E.g., Sections 135 ff of the General Social Insurance Act (ASVG) re items (a) to (c).
3 This is not free of charge for patients in the public health system; please see below, subsection iii.
4 E.g., Sections 144 to 151 ASVG.
5 E.g., Sections 153 and 153a ASVG.
as an optional service, which the health insurance fund may deny for financial reasons, stays at sanatoriums;\(^6\)

maternity services;\(^7\) and

preventive measures, such as yearly medical check-ups, yearly medical examinations of adolescents and certain vaccinations.\(^8\)

Public health insurance institutions do not pay for alternative health therapies, lifestyle drugs or dietary supplements.

Private healthcare services, by contrast, are not limited in any way. For instance, they comprise, in addition, consultation with private doctors (i.e., doctors who operate a private practice in parallel to being a contract doctor or doctors who do not invoice their services in compliance with the requirements of the public health insurance system).

### The role of health insurance

For the vast majority of the Austrian population, health insurance is mandatory pursuant to statutory law. This applies to:

- employees and apprentices;\(^9\)
- self-employed persons in the industry sector;\(^10\)
- public servants;\(^11\)
- persons working in the agriculture and forestry sector;\(^12\) and
- persons drawing a pension pursuant to the ASVG.\(^13\)

Family members of the main insured person who do not have health insurance of their own are generally included in the main insured person's insurance.\(^14\) Likewise, statutory health insurance is generally provided for unemployed persons.\(^15\)

The Austrian public health insurance institutions are nine regional health insurance funds (i.e., one in each federal province), currently five company health insurance funds and four professional social insurance institutions.

All public health insurance institutions are combined in the Main Association of the Austrian Social Insurance Institutions.\(^16\)

The fees due to the health insurance institutions are, for example, for employees 7.65 per cent of their salary and for apprentices 3.35 per cent of their salary, which are paid

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\(^{6}\) E.g., Section 155 ASVG.

\(^{7}\) E.g., Sections 157 to 168 ASVG.

\(^{8}\) E.g., Sections 132a to 132c ASVG.

\(^{9}\) Sections 4 ff ASVG.

\(^{10}\) Sections 2 ff GSVG.

\(^{11}\) Sections 1 ff of the Public Servants’ Health and Accident Insurance Act (B-KUVG).

\(^{12}\) Sections 2 ff of the Social Insurance Act for Farmers (BSVG).

\(^{13}\) Section 8(1) No. 1a ASVG.

\(^{14}\) E.g., Section 123 ASVG.

\(^{15}\) Article II, Section 6 of the Unemployment Insurance Act (AlVG).

\(^{16}\) Section 31(1) ASVG.
in virtually equal parts by the employee or apprentice and the employer. The fees to be paid for health insurance under the Industrial Social Insurance Act (GSVG) are 7.65 per cent of the insured person’s income.

As regards the remaining parts of the Austrian population (i.e., persons not covered by mandatory statutory health insurance), various professional associations have their own health insurance regimes, which provide for voluntary participation in the statutory health insurance or choosing health insurance provided by private insurers.

iii Funding and payment for specific services

The public healthcare system

With regard to the costs of consulting a doctor, the services provided by a contract doctor are paid for directly by the appropriate health insurance fund; the same applies to services provided by the specialists and therapists mentioned in subsection (i) above, based on a prescription or order.

If a patient consults a non-contract doctor, the insured person has to pay for the doctor’s services first and, subject to certain restrictions, can ask for a refund by the public health insurance fund of 80 per cent of the costs that the health insurance fund would have had to pay to a contract doctor for the same services. This controversial 80 per cent rule has been confirmed by the constitutional court of Austria.

As regards medicinal products and other remedies prescribed by contract doctors, patients do not have to pay for medicinal products as such, prescribed to them by contract doctors, provided that the medicinal products can be prescribed pursuant to the Reimbursement Code. Instead, the insured person, in general, merely has to pay a prescription fee, which is currently €5.85 per remedy; however, payment of these fees is capped at 2 per cent of the insured person’s yearly net income. Exemptions from these fees apply in relation to contagious diseases that require notification, as well as to particular socially vulnerable persons. The same regulations may apply to certain non-contract doctors subject to specific conditions.

As regards medical aids, reimbursement relating to hospital care is regulated separately by the various hospital carriers. In relation to services by established doctors, the Competence Centre for Medical Aids (CC-HBHI) decides on reimbursement and determines the prices in respect of certain products for most social insurance carriers. In general, 10 per cent of the costs of medical aids prescribed to patients have to be borne by the insured person.

As regards hospital care, most hospitals in Austria, both public and private, are financed via the Procedure and Diagnosis-Related Groups (PDRG) system, (LKF-System), namely,
a DRG system adapted to the Austrian framework, namely including procedures as well as diagnoses.\textsuperscript{28} In addition, patients have to pay moderate fees for inpatient and outpatient hospital care.\textsuperscript{29}

**Private sector**

The costs of services provided by private doctors are not refunded (not even partly) by the public health insurance institutions. In addition, the price of such services is not bound to a lower or an upper limit. Such services can only be paid for by private insurance companies on the basis of individual private insurance contracts.

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

#### i Legal frameworks and the care pathways

According to the latest available study, the healthcare access and quality index of Austria, based on mortality from causes amenable to personal healthcare from 1990 to 2015, is at 88, ranking at number 14 globally.\textsuperscript{30} With over 270 hospitals and another approximately 900 outpatient clinics, Austria offers a comprehensive network of medical treatment.\textsuperscript{31}

The Hospitals and Sanatoriums Act (KAKuG) regulates the scope of practice of such institutions. It states in Sections 1 to 2a that hospitals shall provide first diagnoses and further surveillance by medical checks and operations, services for prophylaxis, healing, maternities and organ transplants. The same is applicable for outpatient clinics, with the exemption of only carrying out small surgeries.\textsuperscript{32}

However, for primary healthcare, most Austrians prefer a visit to their family doctor first. Unlike in many other European jurisdictions, Austria offers direct access to medical consultants. The legal framework is the Physicians Act (ÄrzteG). General practitioners may, among other medical services, prescribe medicine, therapies or further medical examinations, or carry out regular checks. Furthermore, social care is mainly regulated in the Healthcare and Nursing Act (GuKG).

All of the above-mentioned treatments require an individual medical treatment contract between the patient and either the institution providing the care, or the responsible or chief physician. This is the foundation of the physician–patient relationship, which is influenced by various legal regulations and provides the basis of numerous rights and obligations for the parties, such as the obligation to carry out therapies on the practitioner's side as well as paying the medical fee on the patient's side. The treatment contract is qualified as a free service contract according to the Austrian prevailing doctrine as well as judicature. It is a mixed contract combining elements of a service and a work contract. This differentiation is not only important for labour or social law-related issues but also for the limitation of liabilities.\textsuperscript{33}

\textsuperscript{28} Section 148(3a) ASVG.

\textsuperscript{29} Section 144(6) and Section 31(5a) ASVG and Sections 26 and 27a KAKuG.


\textsuperscript{31} See: https://www.bmgf.gv.at/home/Gesundheit/Krankenanstalten/Krankenanstalten_und_selbststaendige_Ambulatorien_in_Oesterreich/, 11 April 2018.

\textsuperscript{32} Füssl in Aigner/Kletečka/Kletečka-Pulkert/Memmer, Handbuch Medizinrecht für die Praxis III/26: IV.1 Krankenanstaltrecht, p. 4, 44.

\textsuperscript{33} Jesse-Huš in Resch/Wallner, Handbuch Medizinrecht: Zivilrechtliche Fragen des Arzt-Patienten-Verhältnisses, p. 82–90.
On 28 June 2017, a new law regulating and improving primary healthcare and its institutions was adopted in Austria and entered into force on 3 August 2017. The aim of the Primary Healthcare Act (PrimVG) is to offer better and easier access to family healthcare with more extensive medical services and longer opening hours. So far, three primary healthcare institutions have been established in Austria. While those first institutions are still facing difficulties in the initial phase, there are plans to establish 75 primary healthcare institutions all over Austria by 2021. These institutions shall be in the form of group practices or independent outpatient clinics staffed with a core team of general practitioners and nurses. Focusing on the needs of citizens in certain areas, additional health and social care professionals shall be added to the teams (i.e., psychologists and midwives).

Another purpose of this reform was to relieve hospitals and their outpatient clinics as well as to up-value the work of family doctors in the countryside. Most students do not favour a career as ‘just’ a general practitioner, and by 2025 more than 50 per cent of the general practitioners in Austria will be retired. With the new institutions, the access to healthcare outside of cities and bigger villages shall nevertheless be maintained. Moreover, the merging of various medical areas in these institutions, and thus extending the medical work field of former family doctors, shall make their profession more attractive again.

ii Electronic health records

In 2012, a system for electronic health records (EHR) was introduced in Austria, known as ‘ELGA’. It is an information system facilitating certain healthcare providers looking up medical records, independent of location and time, as a basis for their own treatment and is regulated in Chapter IV of the Health Telematics Act (GTelG 2012).

According to Section 2(10) GTelG 2012, healthcare providers under this law include members of the medical and dental professions, pharmacies, hospitals and healthcare institutions. In general, the participants are all natural persons insured in Austria and need not hold Austrian citizenship. It is, however, necessary that these natural persons are registered with the Patient Index and have not opted out of ELGA. An objection can only be made in written form at the ‘opt-out offices’.

Because of the personal data that is saved in ELGA, the main goal of the statutory regulations is to foster and extend data security when using EHRs in direct or indirect communication by setting up uniform federal minimum standards. The data is also classified as ‘sensitive data’ according to the Data Protection Act (DSG 2000) and is therefore also protected under this law.

Only providers that have a valid treatment contract with the patient may look up the data, after authorising their own identity, up to 28 days after signing. In general, the data and protocols of these encrypted transactions are stored decentralised for a maximum of 10 years and thereafter shall be deleted. If there is a suspicion of data abuse, one can contact the ELGA

34 BGBl. I No. 131/2017 – PrimVG.
ombudsman’s office for support. The punishment is imprisonment for up to six months or a financial penalty of tens of thousands of euros. Last but not least, it has to be stressed that medical confidentiality also applies to the knowledge gained through EHR.

As of 2018, in addition to medical records, prescribed medicine shall also be saved under ELGA: ‘eMedicine’ is a new tool in the ELGA system that saves prescribed and, in a pharmacy, purchased medication in an online list for one year. Healthcare providers as well as pharmacies and the patients themselves have secured access to this list. As the main goal of eMedicine is to detect potential interactions between various drugs and treatments, healthcare providers are legally obliged to fill in the prescribed medication in the system.\(^{38}\)

As a result, already over 160 healthcare providers in Austria successfully use ELGA and more than 12 million electronic medical records are available in the system as per the end of January 2018. The eMedicine tool shall be implemented in all federal states in Austria by the end of 2018. Since its implementation, only 266,000 persons insured in Austria opted out of ELGA.\(^{39}\)

### IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

#### i Regulators

The key licensing bodies in relation to hospitals and independent outpatient clinics, irrespective of whether they are being operated as public or private institutions, are the provincial governments. As regards sanatoriums, the key licensing bodies are the regional administrative authorities.

Public and private hospitals, as well as independent outpatient clinics, need a licence issued by the respective provincial government for their establishment and operation.\(^{40}\) Sanatoriums need a licence for their operation only, issued by the respective regional administrative authority.\(^{41}\)

Licensing of doctors and dentists is the task of their professional bodies (i.e., the Medical Chamber and the Dentists’ Chamber). Apart from certifying the personal and academic qualification of doctors and dentists, the Medical and the Dentists’ Chambers are, inter alia, in charge of registering doctors and dentists in the Austrian List of Doctors or in the List of Dentists, respectively. Such registrations are mandatory requirements for working as an independent doctor or dentist in Austria.\(^{42}\) As to prohibiting a doctor’s or dentist’s medical practice, the competent body is the governor of the respective federal province.\(^{43}\)

As regards nurses, pursuant to a law adopted in 2016, the Act on the Registry of Healthcare Professions, persons who are licensed to work as nurses and who provide nursing services on 1 July 2018 have to apply for and obtain their registration in this Registry by 30 June 2019 at the latest. As of 1 July 2018, persons who qualify as a nurse and who wish to provide nursing services in Austria need to apply for their registration in this registry

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40 Section 3 and Section 3a KAKuG.
41 Section 42b KAKuG.
42 Sections 4 and 27 ÄrzteG and Sections 6, 11 and 12 ZÄG.
43 Section 62 ÄrzteG and Section 46 ZÄG.
before providing nursing services. The registering authorities are the Federal Chamber of Labour with respect to employed nurses, and Gesundheit Österreich GmbH with respect to independent nurses.44

The responsibility for licensing with respect to pharmacists is divided between the locally competent district administrations and the Chamber of Pharmacists.45 The district administrations are, \textit{inter alia}, in charge of administering applications for operating new public pharmacies, whereas the Chamber of Pharmacists handles applications for operating existing public pharmacies.46


dii Institutional healthcare providers

Licences for operating a hospital, independent outpatient clinic or sanatorium comprise all services carried out in these institutions. More specific regulations on the prerequisites for obtaining a licence for establishing or operating such institutions as well as regulations on closures of such institutions operating without fulfilling the requirements for obtaining a licence to operate are in place on the provincial level rather than on the federal level.

As regards licences for establishing hospitals, apart from personal and qualitative aspects, in general, the provincial governments to a large extent focus on the prerequisite of a need for this new hospital or, with respect to independent outpatient clinics, whether the new clinic can bring about a substantial improvement of the healthcare provision in the catchment area.47

Licences for establishing or operating hospitals are to be modified or revoked if any of the prerequisites for obtaining the licence are not or no longer fulfilled. In addition, licences for operating hospitals can be revoked if any other serious defects are not remedied within a set period, despite a request to do so.48

In 2016, the Austrian Administrative Court had to decide on an appeal lodged by a company whose application for a pre-filing declaration of an existing need for a public rehabilitation clinic for children in a town in the province of Salzburg was dismissed by the provincial government of Salzburg. The government had argued that there was no need for this clinic because a different company had previously applied for and obtained a similar pre-filing declaration of an existing need for a private rehabilitation clinic for children close to the town in which the applicant wished to establish its public clinic. Furthermore, the other company had, on the basis of the declaration granted, applied for a licence to establish the clinic, but it had not yet begun to set it up. The Austrian Administrative Court granted the appeal against the dismissal of the declaration for two reasons. First, a private rehabilitation clinic for children could not be considered hindering the need for a public rehabilitation clinic for children. Second, a licence for establishing a (private or public) clinic could not, when examining the need for a new clinic, be treated like the clinic itself; that is, a clinic that is merely planned but has not yet been established cannot remove the need for a new clinic.49

44 Health Professionals Register.
45 E.g., Sections 44 and 46 of the Pharmacy Act.
46 Sections 46 and 51 of the Pharmacy Act.
47 Sections 3 and 3a KAKuG.
48 Section 12 KAKuG.
iii Healthcare professionals

Doctors and dentists

The ÄrzteG contains the requirements for licensing of doctors (i.e., the general personal and respective educational requirements). In addition, as mentioned above, in order to work as an independent doctor in Austria, any doctor needs to be registered in the Austrian List of Doctors. If the Medical Chamber finds that the conditions of being admitted to the medical profession in Austria are not met, it has to render an administrative decision stating this, thereby refusing to register the doctor in the Austrian List of Doctors.50

Several provisions of the ÄrzteG concern setting up and operating a doctor’s medical practice. For instance, starting to work as a self-employed doctor requires evidence of a valid insurance contract with a licensed Austrian insurer, covering patients’ claims for damages of at least €2 million per insured event, and this insurance has to be maintained during the entire duration of the doctor’s medical practice.51

Doctors may, subject to precautionary measures and on a case-by-case basis only, delegate certain medical activities to laypersons (e.g., relatives of the patient or personal care assistants).52

If a doctor is no longer apt or allowed to pursue his or her profession (e.g., as a result of a disciplinary offence), the Medical Chamber has to declare via an administrative decision that the doctor must not pursue the medical profession any longer and has to arrange for the doctor being deleted from the Austrian List of Doctors; the doctor has the right to appeal such administrative decisions in an administrative court.53

In cases of imminent danger and if public well-being so requires, the governor of a federal province has to order a preliminary prohibition of a doctor’s further medical practice if a judicial procedure on: imposing legal guardianship on the doctor; or serious misconduct in the course of his or her medical practice, which triggers criminal or administrative fines, has been instigated. Such prohibitions are valid until the final termination of the respective judicial procedures.54

Practising as a doctor without being licensed to do so is an administrative offence and sanctioned by a fine of up to €3,630.55

The provisions in the Dentists Act (ZÄG) regarding dentists are rather similar to the ones relating to doctors.

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50 Section 27(10) ÄrzteG. Such decisions can be appealed by the doctor in an administrative court.
51 Section 52d ÄrzteG.
52 Sections 50a and 50b ÄrzteG.
53 Section 59 ÄrzteG.
54 Section 62(1) ÄrzteG.
55 Section 199(1) ÄrzteG.
Nurses
The requirements for working as a nurse include personal suitability and trustworthiness, proof of qualification and a command of German.\textsuperscript{56} As regards the mandatory registration of nurses in the Registry of Healthcare Professions mentioned above,\textsuperscript{57} the competent registering authority has to deny registration via an administrative decision if the applicant does not fulfil all conditions required; the applicant may appeal this decision in an administrative court.\textsuperscript{58}
A registration in the Registry of Healthcare Professions is valid for five years and may be renewed upon application.\textsuperscript{59} If the competent district administration finds that a nurse does not fulfil, or no longer fulfils, the prerequisites for lawfully pursuing this profession (e.g., proof of qualification and trustworthiness), it has to withdraw the nurse’s licence\textsuperscript{60} and remove the nurse from the Registry of Healthcare Professions by Gesundheit Österreich GmbH.\textsuperscript{61}
Working as a nurse without being entitled to do so is sanctioned as an administrative offence by a fine of up to €3,600. The same offence and sanction are imposed on anybody who engages a person not entitled to work as a nurse to pursue this profession. In both cases, an attempt to commit these offences is also punishable.\textsuperscript{62}

Pharmacists
In general, a licence for operating a (new or existing) public pharmacy in Austria requires the pharmacist’s personal suitability, which includes, \textit{inter alia}, reliability, an adequate health status proved by a medical officer, professional qualification, a sufficient command of German and payment of a fee.\textsuperscript{63} As regards pharmacies to be newly established, the licence also requires that a doctor’s permanent practice is in the community where the pharmacy is supposed to have its seat, and that there is a need for a new public pharmacy.\textsuperscript{64} Persons who already have a licence for operating a pharmacy in Austria, in the EEA or in Switzerland may not obtain another licence.\textsuperscript{65} The owner of a public pharmacy is obliged to operate it continuously.\textsuperscript{66}
The insurance obligation of pharmacists is virtually identical to the one applicable to doctors.\textsuperscript{67}
A pharmacist’s licence has to be withdrawn if the prerequisites for granting it are not or are no longer fulfilled; a pharmacist’s licence can be withdrawn if the pharmacy has not been opened within five years from the effective date of the licence or if the operation of the pharmacy has stopped and not been resumed within six months.\textsuperscript{68} A public pharmacy that is operated without a licence is to be closed immediately by the authorities, and no regular

\textsuperscript{56} Section 27 GuKG.
\textsuperscript{57} See Section IV.i above regarding the effective dates of the GBRG.
\textsuperscript{58} Section 16 GBRG.
\textsuperscript{59} Section 18 GBRG.
\textsuperscript{60} Section 40(1) GuKG.
\textsuperscript{61} Section 25(1) GBRG.
\textsuperscript{62} Section 105(1) No. 1 and No. 2 and Section 105(2) GuKG.
\textsuperscript{63} Sections 3 to 3b and Section 11 Pharmacy Act.
\textsuperscript{64} Sections 9 and 10 Pharmacy Act.
\textsuperscript{65} Section 2 Pharmacy Act.
\textsuperscript{66} Section 13 Pharmacy Act.
\textsuperscript{67} See above, (a); Section 4a Pharmacy Act.
\textsuperscript{68} Section 19 Pharmacy Act.
remedy is available against such administrative decision.\textsuperscript{69} Infringements of the provisions of the Pharmacy Act are sanctioned as administrative offences and trigger fines of up to €4,360.\textsuperscript{70}

\textbf{International graduates}

For all professionals mentioned above, Austria has implemented the provisions of EU directive 2005/36/EC. That is to say, in respect of, for example, doctors, professional qualifications from other EU or EEA Member States or from Switzerland will be recognised automatically, unless the qualifications do not comply with directive 2005/36/EC. In the latter case, if the Austrian Medical Chamber does not consider the candidate’s qualification to be sufficient because of substantial differences in the professional training, which differences cannot be counterbalanced by the professional experience gained, the candidate will need to take an aptitude test. Candidates holding qualifications from third countries need to have their degrees recognised (‘nostrification’) by an Austrian university, in other words they need to pass one or more additional exams, unless (1) their diplomas have been recognised as equivalent in any EEA country or Switzerland and (2) the candidates have worked there legally in this profession for three years.\textsuperscript{71} In addition, sufficient command of German is a precondition for admission in any case.

\section{NEGLIGENCE LIABILITY}

In Austria, both public and private healthcare providers are subject to the same provisions on medical liability. The general rules of the Austrian Civil Code and the Austrian Criminal Code determine the civil and criminal liability of healthcare professionals, respectively. Whereas criminal proceedings according to the relevant provision in the Austrian Criminal Code dealing with unauthorised medical treatment (Section 110 of the Austrian Criminal Code) are rather seldom, civil cases dealing with the improper performance of physicians or the healthcare institution have been continuously increasing in recent years. Consequently, Austrian case law established by the Supreme Court covering civil cases related to medical malpractice is very advanced.

The majority of patients are treated based on contractual relationships with the physician or surgery, the hospital or the healthcare institution. As a result, most civil claims are based on a damage claim for the violation of contractual provisions and on Austrian tort law. Note, the Austrian Civil Code only provides for one basis for a tort law claim, which is perhaps most closely related to the tort of negligence.

In practice, a damage claim for medical malpractice usually includes a medical treatment that was not performed lege artis or a poor pre-operation discussion causing a lack of the patient’s informed consent. Further, court cases dealing with medical malpractice in Austria very often involve a medical court expert for questions raised in relation to the causality of a non-lege artis performed medical treatment or for assessing the amount of damages in case the claim is granted by the court.

When it comes to remedies, the harmed patient can claim for pecuniary losses, such as for medical treatment, medication, nursing and rehabilitation, and for loss of income.

\begin{enumerate}
\item Section 19a Pharmacy Act.
\item Section 41 Pharmacy Act.
\item Sections 5, 5a, 27 and 28 ÄrzteG.
\end{enumerate}
Apart from these expenses, inured patients are further entitled to compensation for pain and suffering, which are usually granted in the form of a lump sum. Generally speaking, Austrian court orders on damage claims for non-pecuniary loss as a result of medical malpractice do not reach extensive amounts. The maximum compensation is currently around €370,000. In any case, most cases in Austria are settled out of court.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

There are not many rules and laws dealing with the ownership of healthcare businesses in Austria. The main Act addressing this issue is the KAKuG. It states that in general any natural or legal person can be the owner of a healthcare business. At present the following legal persons are owners of healthcare businesses in Austria: the federal government, the governments of the federal states and provinces in Austria, local authorities, public enterprises, social insurance agencies, clerical entities, clubs and commercial enterprises. From this it can be seen that ownership is not limited to bodies of the public sector, but – theoretically – open to anyone.72

At this point, an important distinction may be mentioned briefly before continuing with the explanation of the few exemptions to the general rule. In Austria, the differentiation between public and private healthcare businesses does not depend on the form of ownership, but, rather, meeting certain requirements set out in the KAKuG in order to be qualified and offered the status as a public healthcare business. The requirements that need to be met are: (1) being a non-profit organisation; (2) the assurance of continued existence and appropriate business operation; (3) ownership by a legal person; (4) the fulfilment of certain obligations under the KAKuG; and (5) meeting the requirements of the plan set out by the respective federal state of Austria. However, there is no right to be granted the status of a public hospital, even if all requirements are met.73

The significance of this distinction might have been recognised already; public entities may only be owned by legal persons. Therefore, the simple general rule of any person, no matter if natural or legal, to be the owner only applies to private healthcare businesses. Moreover, because of another requirement that needs to be fulfilled, only owners of private healthcare businesses are free to decide whether they want to operate as a non-profit or as a profit-oriented business.

Despite the division into private and public bodies, there is one other exemption to the general rule, based on the type of healthcare business. The ownership of group practices is not regulated under the KAKuG, but in Section 52a ÄrzteG. Therein it is set forth that these institutions may only be owned by persons who collaborate in the form of a general partnership or who have established a limited liability company for this purpose. These are all restrictions to ownership of healthcare businesses in Austria.74

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72 Füssl in Aigner/Kletečka/Kletečka-Pulkert/Memmer, Handbuch Medizinrecht für die Praxis III26: IV.1 Krankenanstaltenrecht, p. 10a.
74 Schneider in Aigner/Kletečka/Kletečka-Pulkert/Memmer, Handbuch Medizinrecht für die Praxis III26: IV.2 Zusammenarbeit, Reformgestaltung, Gruppenpraxen, p. 66.

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VII COMMISSIONING AND PROCUREMENT

The relations between the social security funds represented by the Main Association of the Austrian Social Insurance Institutions and the providers of healthcare services, including pharmacies and most hospitals, as well as primary healthcare institutions, are governed by civil law contracts. That is to say, providers of healthcare services in the public sector, in general, need to conclude a contract with the Main Association of the Austrian Social Service Institutions. Doctors, dentists and pharmacists are to be represented by their professional associations in the general contracts, and doctors and dentists conclude special contracts with the respective health insurance institutions, pursuant to the provisions of the general contracts.

The above provisions do not apply to providers of private healthcare services who, by contrast, only need to obtain their respective licences and may then enter into healthcare service contracts with the patients directly. It is rather common, though, for private hospitals to have concluded ‘direct settlement agreements’ with several social insurance institutions and private insurers regulating payment of the services rendered to the patients directly by the respective insurers.

VIII MARKETING AND PROMOTION OF SERVICES

The owners of hospitals must not, by themselves or via other individual or legal persons, provide unobjective or false information in connection with the operation of a hospital. This general prohibition is substantiated further by the respective implementing provisions in the nine federal provinces.

Doctors must not, in connection with their professional practice, provide any information that is unobjective, is false or affects the reputation of their profession. In addition, doctors may not promise, grant, accept or have promised to themselves any remuneration for assigning patients to themselves or to other doctors. The statutory regulations on advertising and promotion of the services of dentists are almost identical to those relating to doctors. These prohibitions applicable to doctors and dentists are extended to any other individual and legal persons as well (i.e., any other third party must comply with these prohibitions too).

These statutory provisions on marketing and promotion of services of doctors and dentists are complemented and substantiated by the doctors’ professional rules, the regulation of the Austrian Medical Chamber on the manner and types of admissible information in

75 See Section III above.
76 Sections 338 ff ASVG.
77 Sections 341, 342 and 343 ASVG.
78 Section 13(1) KAKuG.
79 Section 53(1) ÄrzteG.
80 Section 53(2) ÄrzteG.
81 Sections 35(2) and (3) ZÄG.
82 Section 53(3) ÄrzteG and Section 35(4) ZÄG.
public. Likewise, the Dentists Chamber’s advertising guidelines for dentists pursuant to Section 35(5) ZÄG contain more specific regulations on inadmissible advertising and promotion practices.

For mentioning just a few of these regulations, both the professional rules of doctors and dentists prohibit, *inter alia*, advertising medicinal products, medical aids or other medical products, as well as the manufacturers or suppliers of such products. In addition, both sets of rules oblige doctors and dentists to reasonably prevent third parties, in particular the media, from publishing any inadmissible information or advertisements.

Doctors and dentists, as well as any third parties, who contravene the above-mentioned provisions on advertising and promotion are subject to disciplinary measures or administrative fines, as the case may be.

Independent nurses may not advertise their services in a way that is detrimental to the reputation of their profession; in particular, they have to abstain from any comparative, discriminatory or unobjective advertising.

The Austrian courts are rather strict as regards the restrictions on advertising regarding doctors or dentists, and hospitals. We would like to briefly outline two cases to illustrate this.

The Austrian Supreme Court (OGH) recently ruled that flyers distributed in Upper Austria regarding an ‘information event’ taking place in an inn, and the information event itself, advertising bus trips to a dental clinic in Hungary, at which at the same time a famous Hungarian spa situated close to the dental clinic was advertised as well, were in breach of Section 13 KAKuG and the corresponding provincial provision in connection with Section 1 of the Austrian Act on Unfair Competition (UWG) because the combination of advertising both the dental clinic and the spa was considered unobjective. Interestingly, the Supreme Court held that the tour operator itself had breached the advertising prohibitions of Section 13 KAKuG and the corresponding provincial provision, although the addressees of these provisions are the owners of hospitals only.

In 2015, the Austrian Administrative Court had to rule in a disciplinary proceedings case concerning two surgeons who had placed advertisements for their newly opened medical practice in a magazine displayed in waiting rooms of doctors. Because the medical practice was supposed to focus on sports accidents, the advertisements showed pictures of the two surgeons in their medical clothing and with their medical equipment, and at the same time wearing sport equipment such as ski goggles, a Tyrolean hat, a hiking rucksack and ski poles. Because the advertisements did not contain any factual information on the two surgeons’ practice, apart from the terms ‘Sports accidents, foot and hand surgery, vein treatment, MRI – X-ray, ultrasound’ at the side of the advertisements, the Court held that the advertisements

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84 ‘Werberichtlinien gemäß § 35 Abs. 5 Zahnärztegesetz’, in their latest version of 12 June 2015.
85 Section 3 of the Regulation ‘Arzt und Öffentlichkeit 2014’ and Article 3d of the ‘Werberichtlinien gemäß § 35 Abs. 5 Zahnärztegesetz’.
86 Section 5(1) of the Regulation ‘Arzt und Öffentlichkeit 2014’ and Article 5a of the ‘Werberichtlinien gemäß § 35 Abs. 5 Zahnärztegesetz’.
87 Sections 136(1) and 193(9) ÄrzteG and Section 89(5) Nos. 2 and 3 ZÄG.
88 Section 38 of the Nursing Act (Gesundheits- und Krankenpflegegesetz – GuKG).
89 OGH, 28 March 2017, file No. 4 Ob 241/16v – Zahnarzttwerbung VII.
90 VwGH, 25.11.2015, file No. Ra 2015/09/0045.
were not informative, but gimmicky, and therefore affected the reputation of the medical profession. The Court thus upheld the disciplinary fines imposed on the two surgeons by the Austrian Medical Chamber.

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

i Dr Google and mHealth

In light of the digital age, a whole new way of receiving information regarding one’s health has become possible. An increasing number of people are using search portals such as Google to receive a first diagnosis. At first sight, this might seem to be a negative development because of possible false information or misinterpretations. However, this can also create an ‘informed patient’. Patients can now look up symptoms before a medical appointment, make medical appointments according to this information and afterwards look up any technical vocabulary used by the doctor, resulting in a faster, better and clearer treatment. Having said that, for this to have an effect it is necessary for the Austrian government to provide websites and portals with reliable information placed by professionals.

An even more promising future trend is mobile health. The trend of ‘mHealth’, as referred to by the WHO, has been revolutionising ways of monitoring one’s health, sport activity, nutrition and medication. This not only benefits the user, but is also linked to a very profitable market and broad data collection.

As there are over 100,000 mHealth applications on the market, with an upward trend, collecting personal data about one’s daily activities has become an easy task. It is evident that there needs to be comprehensive data protection regulations to protect users from data protection infringements. It is just a matter of time until the Austrian lawmakers – probably initiated by European regulations – have to act in order to keep this personal data safe. However, the broad health data collection also creates great opportunities concerning epidemiological research.

ii Compulsory vaccination

Another topic that will be the subject of many discussions in the upcoming years is the introduction of compulsory vaccinations. As a result of the trend of receiving medical advice online, the spreading of conspiracies and the advertising of dreadful side effects connected to vaccinations has reached a new level. It can already be seen that fewer and fewer people, especially children, are being vaccinated, as a result of belief in these anti-scientific theories.

In Austria there is no obligation to be vaccinated. But merely providing optional clarification and further information to citizens is no legitimate way for the state to stop the decrease. The widespread growth of dangerous infections such as measles as a result of this is a problem that must be taken seriously. Based on the latest reports of the OECD, Austria shows the second-highest rate in registered measles cases in Europe.

There is no general legal barrier preventing the introduction of compulsory vaccination in Austria. The state only has to provide for a proportionate and infection-differentiating

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92 Kopetzki, Impfpflicht und Verfassung, RdM 2017/42.
statutory vaccination obligation, also taking into account that interference in a person’s right to a private life can be justified by the right to protect health in case of a potential risk – without having to wait for a real outbreak.93

As the state is obliged to ensure and secure the well-being of its citizens and their health, a first step could already be an obligatory medical consultation regarding vaccinations or connecting vaccinations to social welfare benefits.

iii Automatic organ donors94

As post-mortem organ donations are still of ultimate concern, it is necessary to address this topic. In general, every state, even within the European Union, may set out the rules regarding post mortem donations independently. Over the years, two different main schemes have evolved: the dissent solution and the consent solution.

Since 2012, the dissent solution has been codified in the Austrian Transplants Act. It sets forth that in any case of a cerebral death of a person within the territory of Austria, the organs of this person may be taken if there is no explicit dissent to the donation of organs. The dissent must be expressed explicitly by the person in a pre-prepared form. To ensure the form’s documentation, it should be filed in the dissent registry. All hospitals and doctors are obliged to look into the registry before removing organs.

Because of the small number of drafted dissenting statements, this solution leads to many organ donations. Thus, in the international context, Austria is at the top of conducted organ transplants, with 91.6 transplants per million inhabitants in 2015, whereas Germany, applying the consent solution, only recorded 46.4 transplants per million inhabitants.95 As a result, the Austrian regulation shall be taken as a role model for states that have not yet implemented the dissent solution.

X CONCLUSIONS

Although the Austrian healthcare system is among the best-developed systems worldwide, there are still several points of criticism pertaining to it. Among these, the split responsibilities between several different bodies and the abundance of laws and regulations regulating their tasks and duties, as well as the large number of health insurance institutions, are most prominent, and periodically evoke calls for amendment and some sort of consolidation. In response to this, the federal government currently plans a reform of the social insurance system. Although there is no draft law yet to date, it has become known that the amendment aims at reducing the individual public health insurance institutions from the current 18, combined in the Main Association of the Austrian Social Insurance Institutions, to only four. Unlike the present situation, the benefits granted by these respective new health insurance institutions shall be uniform throughout Austria. The government expects considerable savings from this reform. Details are yet to be determined.

93 ECHR, Solomakhin case, 24 September 2012.
Chapter 2

BRAZIL

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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). The SUS’s legal basis is composed mainly of: (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 the 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 the SUS’s constitutional directives, the first of them is the directive of ‘decentralisation 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 of by the municipalities.7 Pursuant to this directive, not only federal and state hospitals shall be managed by municipalities, but also the relationship between the SUS and private healthcare providers shall be implemented through the municipalities.

The other two of the 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 the SUS in a complementary manner (i.e., to complement certain treatment needs when the SUS’s availabilities are insufficient to ensure adequate coverage in a certain area), and (2) outside the SUS, with supplementary character.

Any time the private enterprise participates in healthcare in a complementary manner, namely, 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 the SUS, this is designated supplementary healthcare. Even if independent from any formal agreement with the SUS, supplementary healthcare remains, nonetheless, bound to the SUS’s legal scheme in that the SUS’s ethical principles and rules issued by the 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 the 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 the SUS Basic Operational Norm (NOB 1/96), among others.

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7 This obligation is further detailed in Law No. 8,080/90, Article 17, I and in the SUS Basic Operational Norm (NOB 1/96).
At a national level, the Brazilian Ministry of Health is the highest sanitary authority, responsible for ultimately resolving health issues in Brazil.\(^8\) The Ministry of Health counts in its organisational structure with 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).

The CNS operates as the highest decision-making body of the 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.

The ANS, created by Law 9,961/2000, is the agency competent for regulating, standardising, managing and inspecting activities that guarantee supplementary healthcare. The ANS, thus, regulates, controls and supervises private entities that operate health plans or insurance, or render private services that are not legally bound to the 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 the 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 do so, lacking hospitals, laboratories and clinics. Thus, the partnership with private parties is a relevant means of pursuit of its constitutional goals.\(^9\)

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

According to the CNS’s data, in January 2018, the total number of hospitals in Brazil amounted to 6,805, 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.\(^10\)

As reported by the ANS, in April 2018, the rate of the Brazilian population covered by private insurance plans (with and without dentistry coverage) was 22.7 per cent,\(^11\) 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, the 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 the ANS’s regulations. In relation to the coverage of health treatments or medical appointments, the 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 the 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

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13 Decree No. 7,508, of 28 June 2011, which regulates the Organic Health Law.
14 See Dallari, Sueli Gandolfi et al., Direito Sanitário, São Paulo, p. 83-84.
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 by the ‘entry doors’ 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).

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 the SUS’s regulatory agencies (ANVISA and the 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 the CNS, ANVISA and the ANS. Both ANVISA and the 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.15 The 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 Consolidation Resolution No. 04/2017 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.

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

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.\(^\text{16}\)

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.

The law ensures a proper administrative proceeding for a refusal to grant or withdrawal of licences and authorisations.

iii Healthcare professionals

The regulation with regard 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 regard 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. 564/2017 set the main legal framework with respect to the compulsory registration of nurses.

\(^{16}\) Ministry of Health Ruling No. 511 of 2000.
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 imprisonment from six months to two years.

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).18 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, as 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.19

Hospitals, laboratories, clinics and other healthcare providers (including those operated by the state directly or indirectly)\textsuperscript{20} 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.\textsuperscript{21} 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.\textsuperscript{22} In this scenario, because the patient can be qualified as a consumer according to the CDC, healthcare providers (e.g., physicians and the hospital) will be jointly liable for the damages. However, the corresponding healthcare provider has 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.\textsuperscript{23} 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 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).

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 the SUS (complementary healthcare) and outside the 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).

\textsuperscript{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 the 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 in February 2014).

\textsuperscript{21} For instance, a hospital was held liable for damages caused to a patient because of 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 in June 2011).

\textsuperscript{22} The Superior Court of Justice recognised a hospital’s strict liability because of its physician on duty’s fault (misdiagnosis), who was a member of the clinical body (Superior Court of Justice, lawsuit No. 696.284/RJ, ruled in December 2009).

\textsuperscript{23} As seen in: Superior Court of Justice, lawsuit No. 696.284/RJ, ruled in December 2009.

\textsuperscript{24} Article 88 of the Consumer Defence Code (Law No. 8.078/1990).
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.

VII COMMISSIONING AND PROCUREMENT

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 preceded by a public bid. Law No. 8,666/1993 is, currently, the main federal public bids and contracts statute. The requirements to participate in a public bid or to execute a public contract are usually set forth in each ‘request for proposal’ presented by the Administration; they include legal, tax and labour regularity, as well as proper technical and financial requirements. As the bill of law has recently made significant progress in the National Congress, the federal system of public bids and contracts is likely to be substantially remodelled in the near future.

Relevant contracts for the supply of services and medications, however, have also been signed as a consequence of Law No. 10,973/2004 (the Federal Science, Technology and Innovation Framework). Based on such statute, Decree No. 9,245/2017 has recently established the National Policy of Health Technological Innovation, under which public entities were authorised to execute two contract modalities with private parties: (1) Partnerships for Productive Development (PDPs) and (2) Technological Orders (ETECs). PDPs are a combination between a technology transfer agreement and a supply agreement – involving products deemed strategic for the SUS. ETECs, differently, involve the execution of research, development and innovation activities for the solution of a specific technical problem or for the development of innovative products, services and practices.

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) and 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:

- the cure of diseases that have no proper treatment according to proven scientific knowledge;
- methods of treatment and diagnosis still not scientifically approved;
- specialisation still not approved by the respective professional career;
- offer of diagnosis or treatment at distance; or
- prosthetic products that require tests and diagnoses of specialised doctors.

Also, healthcare professionals shall not promote:

- the exercise of more than two specialisations; or

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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:

- it must be in accordance with the rules of the professional and governmental bodies applicable to the matter;
- it shall mention the medical management in charge;
- it shall contain a clear and adequate description of the type of treatment or diet;
- it shall not contain testimonials given by laymen; and
- 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.

Claims can be brought before CONAR by competitors affiliated with CONAR, groups of consumers or even members of CONAR’s board; which puts advertisements under heavy surveillance. For instance, CONAR’s Superior Committee started an investigatory procedure – based on concerns raised by the São Paulo State Health Council to the general public – to scrutinise advertisements of paracetamol-based medicines that led consumers to believe that those products could treat the symptoms of dengue and other diseases caused by the aedes aegypti mosquito. Even though pharmaceutical companies – who had long been exploiting this topic in Brazil – tried to present scientific studies and demonstrate that the advertisements show proper disclaimers, CONAR recommended in a decision of December 2017 the modification of the advertisement.

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 with regard 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

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25 CONAR’s decision are not mandatory, but tend to be followed by the companies to demonstrate good marketing practices.
Ethics Code forbids the prescription of treatment and other procedures without the direct examination of the patient, except in case of emergency or urgency and proven impossibility of rendering the examination (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 regard to telemedicine may represent a relevant change to healthcare practice in Brazil.

In a scenario of constant modernisation of the health sector in Brazil – as seen by the implementation of digital systems and massive databases, such as the public DATASUS (the SUS Informatics Department) – it is also important to rethink how to reconcile technological innovation with the rights and guarantees of patients concerning privacy, such as the confidentiality of their information and the protection of their data. For instance, the Brazilian jurisdiction supports the use of electronic or digital medical records and 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. However, it is a challenge to implement easily accessible universal records and still efficiently secure sensitive data and ‘protected health information’ contained in patient records.

Moreover, with regard to privacy regulations, Brazil is about to enact a national privacy law (the General Data Protection Law) that follows a European trend for more restricted data protection regulation. As far as health and medical data is concerned, the Brazilian General Data Protection Law lists these types of information as ‘sensitive data’ together with information about race, ethnicity, religious or political beliefs, or sexual life, which demand a higher level of protection and more restricted rules for processing; not only because of privacy concerns, but also in order to avoid targeting or discrimination. Except for certain specific scenarios in which the Law authorises treatment of sensitive data, to be able to process sensitive information companies will now have to obtain specific consent from the data owner, and properly delimit the purposes for which that data will be used in each and every case. The Law also prohibits health and medical data, particularly, to be commercialised, except for the purpose of portability and with the owner’s explicit consent.

In the view of this up-and-coming enactment, it is likely that the Brazilian healthcare scenario will experience some changes, especially concerning the handling of personal sensitive data.
X CONCLUSIONS

As we tried to describe in this article, healthcare regulation in Brazil is extremely sparse and complex, in part because of the myriad of legislative and infra-legal entities competent to govern health matters. Navigating such regulatory landscape may prove to be a challenging exercise, especially when the call is innovation, thanks 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.26

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.27 The enactment of Law No. 12,846/2013 (the Brazilian Anticorruption Law) was another signal of the commitment of the countries’ authorities in this matter. Private practices have also been enhancing their internal policies concerning, among others, compensation models and ethical supply chains.28

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.

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

27 Partially as an indirect consequence of the car wash massive process to fight corruption.

28 The topic of the 2016 three-day Congress of ANAHP was ‘Ethics: Sustainability of Healthcare in Brazil’.
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 was the subject of between 34 (Quebec) and 43 (Ontario) per cent of the provincial governments’ budgets in 2017. 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 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 a federal statute, 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 federal government sets out a number of conditions that must be met annually in order for the provinces to be entitled to their full share of the Canada Health Transfer for that year. Aggregating billions of dollars, 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:

- publicly administered;
- comprehensive;
- universal;
- portable; and
- accessible.

To be accessible, provincial health insurance plans must prohibit extra billing and user charges for medically necessary healthcare services.

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. In fact, all persons other than the provincial health insurance plans – including hospitals and healthcare providers, for example – 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.

Although the term ‘medically necessary’ is not necessarily used in provincial health insurance statutes, it 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).

iii Funding and payment for specific services

Provincial health insurance statutes prohibit private insurance companies from selling insurance for medically necessary healthcare services delivered to Canadians. Nonetheless, a limited private insurance market exists, including for example:

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6 In 2018–2019, the provinces will receive, in the aggregate, approximately $38.5 billion as part of the Canada Health Transfer.

7 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.
Canada

a dental services (as 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 (as, with limited exceptions including in the case of drugs prescribed
to seniors, to those under the age of 25 in Ontario, and to those living below specified
income levels, only drugs administered in hospital are covered by the provincial health
insurance plans); and
c non-medically necessary services (e.g., most physiotherapy, chiropractic services and
home care).

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

i Access to and delivery of healthcare services

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 nurse practitioners.

Nearly all other practising physicians in Canada are specialists (e.g., surgeons,
oncologists). 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, because not all patients have
family physicians, and because family physicians are not always accessible in a timely manner,
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 and telemedicine
solutions are emerging to meet patient demands stemming from, among other things, the
inaccessibility of their family physician.

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;
f private homes or seniors homes: where patients receive ‘home care’, including clinical
and non-clinical care, and respite care for family caregivers;
g hospitals: of which there are many types – acute, chronic, tertiary, community, etc.; and
h long-term care (nursing) homes.
It should be noted that because not all healthcare services are medically necessary and thus, not insured services under provincial health insurance plans, services in a number of the above settings may be paid for privately, including by the individuals receiving such services and their private insurers.

ii Electronic Health Record (EHR)

For a number of years, Canada has been developing a national 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 patient records are readily accessible by healthcare providers across the country and to increase compatibility across different provincial or regional systems.

The national EHR initiative is supplemented by other provincial electronic health record initiatives. For example, provinces have provided support in respect of the conversion of paper-based systems to electronic systems at family physicians’ offices and hospital systems, and have also independently 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, secure connectivity between sites and large-scale application is still on the horizon.

iii Services to support seniors

As Canada’s population continues to age, services and programmes to support the health needs and social well-being of seniors continue to be necessary components along the continuum of care. The majority of the provincial governments offer or provide services and programmes to benefit the health and social needs of seniors. For example, home care services and community support services are generally funded, at least in part, by the provinces and aim to keep seniors living within their residences for as long as possible, thereby reducing unnecessary hospital admissions and lengthy hospital stays. Many of the services offered by the provincial governments are provided for or coordinated in partnership with community agencies.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

Healthcare professions are regulated by profession-specific ‘colleges’, each of which is a not-for-profit corporation established by profession-specific statutes. In Ontario, for example, there are currently 26 colleges, including the College of Physicians and Surgeons of Ontario, which governs the profession of medicine in the province.

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 partial operating funding from the government.

The provincial legislation that is applicable to healthcare professions sets out to protect the public by, among other things, establishing the scope of the practice of the profession and restrictions on who can practice the profession. Colleges are required by such legislation to, among other things, ensure that the public has access to qualified, skilled and competent healthcare professionals. Colleges seek to uphold such obligation by, for example, developing, establishing and maintaining standards of practice, quality assurance programmes, and
standards of professional ethics. The profession-specific legislation also generally provides colleges with authority to investigate complaints regarding their members’ conduct and to impose disciplinary measures on their members in prescribed circumstances.

ii  Institutional healthcare providers

Professionals within institutional healthcare providers

Employers in Canada have vicarious liability for certain of their employees. Thus, healthcare providers are diligent in ensuring that the healthcare professionals they employ are qualified and licensed to practise. Where healthcare providers deliver healthcare services in a hospital, long-term care home or other healthcare institution on a non-employed basis (e.g., physicians and dentists as independent contractors to hospitals), 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.

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 long-term care homes and 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 are subject to accreditation or licensure by the College governing the medical profession.

iii  Healthcare professionals

As noted above, the requirements for registration or licensure8 as a member of a healthcare profession are set out in the various provincial health profession Acts described in Section IV.i above. In general terms, the registration requirements for healthcare professionals include:

(1) having a degree in his or her area of practice from an accredited school, or a degree that

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8 Many provinces in Canada are moving away from a licensing model to a registration model with a focus on harm prevention. For the purposes of this chapter, the term ‘registration’ will be used to refer to both licensing and registration models.
is determined to be equivalent by the relevant College; (2) successfully completing certain postgraduate training or education; and (3) passing certain qualifying examinations or assessments. It is also a general registration requirement that an applicant’s past and present conduct afford reasonable grounds for the belief that the applicant will practise the profession competently and with integrity.

Healthcare professionals are required to have professional liability insurance, generally as a requirement of registration with a college.

The health profession Acts also often provide a means by which healthcare professionals who are members of colleges 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 registration or certification (e.g., student class, practitioner class), each of which attract distinct qualification 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 (e.g., limitations on ability to provide healthcare independently).

Where the registrar of a college has doubts as to whether an 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 given an opportunity to make submissions in response to same.

The health profession Acts provide that a member’s contravention of a term, condition or limitation imposed on his or her certificate of registration constitutes an act of professional misconduct.

Where a healthcare professional is found by the court to have contravened a health profession Act, he or she may be subject to sanctions established by the applicable health profession Act (e.g., suspension or revocation of the member’s certificate of registration, a fine or imprisonment). Examples of actions that are likely to contravene health profession Acts include:

\[a\] Except in the case of certain limited exceptions, it is an offence to perform a controlled act (i.e., an activity that can cause harm if it is performed by an unqualified person) unless the controlled act is performed by a member authorised by a health profession Act to perform the controlled act, or the performance of the controlled act has been delegated by an authorised person to another person.

\[b\] It is also an offence for someone other than a healthcare professional acting within the scope of his or her practice to treat or advise a person where it is reasonably foreseeable that serious bodily harm may result from the treatment or advice.

\[c\] It is also an offence to commit an act of professional misconduct.

The health profession Acts also incorporate procedural fairness provisions that give members an opportunity to be heard and challenge decisions regarding their conduct, including through a court process.

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9 For example, in Ontario, in 2017, legislative amendments were introduced to strengthen the penalties for healthcare professionals found to have sexually abused a patient.
V NEGLIGENCE LIABILITY

i Overview

Negligence claims are pursued through proceedings in court. In order to succeed 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 care, the plaintiff suffered damages, there is a causal connection between such damages and the negligence, and the damages were reasonably foreseeable.

It is legally established that healthcare providers owe a duty of care to their patients. The duties owed by healthcare professionals have broadened in scope over time to include, for example, the duty to obtain informed consent. Healthcare professionals are held to the standard of a normal and prudent professional of similar experience, expertise and standing. Damages for negligence may include general damages for pain and suffering, loss of income, expenses incurred as a result of the negligence, and the cost of future care. Close family members may also be entitled to damages for loss of care, guidance and companionship, as well as compensation for services they have provided to the plaintiff. Causation is proved by demonstrating that the injury would not have occurred ‘but for’ the defendant’s negligence on a 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 damages 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 physicians, as physicians are typically not employees of the facility, other healthcare professionals, such as registered nurses).

ii Notable cases

R v. John Doe, 2016 FCA 191

Privacy class actions involving healthcare providers are an emerging area. A class action was recently certified on behalf of participants in the Marijuana Medical Access Program (MMAP) after letters were sent by Health Canada to the participants with the programme’s name on it (thereby revealing the participants’ association with the programme). The class action followed a finding by the Office of the Privacy Commissioner of Canada that Health Canada had 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.

As of February 2018, the parties were still waiting for the Federal Court to issue the remaining portion of its decision with respect to certification, following which a notice of certification will be circulated.

Paur (Committee of) v. Providence Health Care, 2017 BCCA 161

In this case, the British Columbia Court of Appeal 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 province’s 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, however, 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 decision underscores the need for hospitals to ensure that their facilities and staffing protocols reasonably protect patient safety and limit the risk of suicide.

The Christian Medical and Dental Society of Canada et al v. College of Physicians and Surgeons of Ontario, 2018 ONSC 579

In 2018, the Divisional Court in Ontario upheld the constitutional validity of two policies of the College of Physicians and Surgeons of Ontario (CPSO) requiring physicians who are unwilling to provide elements of care on moral or religious grounds to provide patients requesting that care with an effective referral to another healthcare provider. The crux of this challenge focused on the CPSO’s Medical Aid in Dying (MAID) policy, which was adopted by the CPSO after the Supreme Court of Canada struck down the legislation criminalising physician assisted suicide in 2015.

The Divisional Court considered the intersection between the provision of the Canadian Charter of Rights and Freedoms providing for individual health practitioners’ freedom of religion on the one hand, and the provision for equal treatment without discrimination based on characteristics such as mental or physical disability on the other hand. The Court concluded that although the policy does infringe on health practitioners’ freedom of religion, that infringement is justified because of the paramount importance of ensuring equitable access to healthcare, and because the policy impairs the religious freedom of the healthcare practitioners as little as possible.

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.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

While healthcare in Canada is generally paid for publicly, it is delivered in large part by those in private business, including physicians and operators of private clinics, long-term care homes, and, in Ontario, independent health facilities.

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 insured services. Private payment for insured services is at the centre 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 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 such as Cambie’s, in which a private clinic engages in extra billing in addition to receiving funding for insured services. While the trial has faced numerous procedural delays and is, as of June 2018, adjourned, it is anticipated that the decision of the court will be appealed to the Supreme Court of Canada, as the decision 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. 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. Provincial legislation and Colleges’ policies prescribe how professionals can market their services and describe their qualifications and education. Non-compliance may be considered professional misconduct.
Generally, legislation and policies prohibit:

a advertising that is false, misleading, or unprofessional;
b information that cannot be verified;
c claims of superiority, comparisons or guarantees;
d endorsements or testimonials; and

e reference to a specialisation unless certified by an official body.

It is generally acceptable to advertise fees for services that are not publicly funded; however, some policies restrict the use of promotional deals.

The prevalence of social media has raised new issues. The interactive nature of social media raises privacy concerns and the ease of sharing content can cause copyright infringement or plagiarism. Existing regulations apply to all means of communication, including print, oral or electronic. For example, prohibitions on inducements, such as coupons, continue to apply when using platforms such as mobile applications. Many regulatory bodies have developed specific social media use policies.

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\(^\text{10}\) 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 represents 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.

Canadians today are more easily accessing health information and are continuing to proactively manage their own health, particularly through the use of products they can choose and use on their own, such as natural health products (NHPs). Given the increased interest in these products, Health Canada recently invited stakeholders to comment on its proposed regulatory framework that seeks to modernise the oversight of consumer health products, including NHPs. Following a consultative process from April to June 2017, Health Canada’s efforts are currently focused on examining the feedback and finalising the regulatory proposal.

Recently, there has been an increasing focus on transparency about financial relationships within the healthcare system. Interest in such relationships stems from, among other things, the use of public dollars for payments within the healthcare system (e.g., payments from provincial health insurance plans to physicians), and the potential for conflicts of interest to arise where the relationship includes private sector payments to healthcare providers (e.g., payments from drug manufacturers to physicians).

For example, in 2017, Ontario was the first province to introduce legislation requiring public reporting of payments, including those made by the private sector, to specified healthcare organizations and professionals. In particular, once in force, the Health Sector Payment Transparency Act, 2017, will require the medical industry (e.g., pharmaceutical

companies, medical device companies) to report annually to the province’s Minister of Health and Long-Term Care on ‘transfers of value’ to prescribed recipients such as physicians (and their professional corporations), hospitals and laboratories. More recently, British Columbia announced upcoming consultations on a ‘health-sector transparency program’, which would, like the Health Sector Payment Transparency Act, compel the medical industry to report payments to healthcare organisations and professionals.
Chapter 4

CHINA

Min Zhu

I OVERVIEW

China’s healthcare system is mainly composed of the healthcare services sector, the healthcare insurance sector, and the drugs and medical equipment sector, which are supervised by three separate government departments. Specifically, the PRC National Health Commission (NHC) 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 State Drug Administration (SDA) 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.

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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.

2 The duties of the former PRC National Health and Family Planning Commission were merged into the newly established PRC NHC following the implementation of the Programme for the Reform of State Council Organs on 18 March 2018.

3 The SDA was newly established under the supervision of the State Administration for Market Regulation following the implementation of the Programme for the Reform of State Council Organs.
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.4

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.5

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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5 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 because 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.

Meanwhile, China is actively establishing and improving the healthcare services system for the elderly: community healthcare service centres provide continuous health management and medical care; general medical institutions provide convenience for the elderly to make appointments and consultations with doctors; in addition, elderly care institutions meeting certain conditions may establish geriatric disease hospitals, rehabilitation centres and nursing homes which, if qualified, may be designated within the scope of basic healthcare insurance for urban and rural residents.

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 PRC National Health and Family Planning Commission (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 Implementation), 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.

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6 Bluebook 2017 at page 16.
7 See Circular of the General Office of the State Council on Transmitting and Issuing the Guiding Opinions of the Health and Family Planning Commission and Other Departments on Promoting Integration of Medical and Elderly Care Services (No. 84, 2015).
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 Provisions of the Civil Law, 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 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. Additionally, Measures for Information Management of Population Health (for Trial Implementation) has also set basic requirements for the information management of population health such as categorised management, local storage systems and tracking, etc.

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 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.

Foreigners wishing to practice medicine in China (e.g., foreign-registered physicians) need to first obtain an invitation or employment from a domestic Chinese hospital before applying for a Temporary Licence for Foreign Physicians to Practice Medicine in the People’s Republic of China, which allows foreign physicians to perform clinical diagnosis and patient treatment in China for no more than one year. Foreigners who intend to become long-term physicians in China must pass the national medical practitioners licensing examination and obtain a practice certificate before registering as medical practitioners.

**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

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9 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 that results in harm to the patient will subject the 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 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\(^\text{10}\) 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, as 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, 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.

Medical institutions can be categorised into non-profit medical institutions and for-profit medical institutions according to their operating objectives. Non-profit medical institutions primarily serve the social public interest and generate revenues to cover the cost of healthcare services, with any amounts remaining only being used for the purpose of improving the institution, such as improving medical treatment conditions, importing technologies, and developing new healthcare service programmes. Conversely, for-profit medical institutions return economic profits to investors. Public medical institutions and socially funded medical institutions are generally non-profit medical institutions, while private medical institutions can voluntarily choose to be non-profit or for-profit. The Chinese government manages non-profit and for-profit medical institutions according to their categorisation and is inclined to support non-profit medical institutions through taxation, pricing and other policies.

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 stipulates the total amount of investment, the minimum proportion of Chinese capital or equity and the term of operations 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. Foreign capital or equity is not allowed to exceed 70 per cent in a foreign-invested medical institution.

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

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11 See the latest statistics of April 2017 at www.moh.gov.cn/mohwsstjxx/tjxx/s7967/201706/41573016be1b4 1719c8ca68dfb05e9d.shtml.
12 Bluebook 2017 at page 16.
13 Non-profit medical institutions established by the government enjoy financial subsidies from the government of the corresponding level. Other non-profit and for-profit medical institutions do not enjoy such subsidies. Non-profit medical institutions price their healthcare services according to the direction of the government and enjoy corresponding preferential tax policies. For-profit medical institutions enjoy freedom to set the prices, carry out autonomous operation and pay taxes according to laws and regulations. See this in Proposals for the Categorised Management of Medical Institutions in Urban and Rural Areas, No. 233, 2000.
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.14 Advertising review organs include SDA, NHC and State Administration for Market Regulation.

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.

According to Law of the People’s Republic of China Against Unfair Competition (2017 Revision), effective in January 2018, discounts or transfers of profits between transaction parties in selling drugs and medical equipment do not undermine the interests of third parties or customers and thus are considered market behaviour rather than bribery under the law.15 When a transaction party intends to give a discount to the other party or pay a commission to middlemen, the party should express its intentions clearly and enter the items truthfully in its accounting records.

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15 Note: if the transaction parties involve state-owned entities (e.g., public hospitals), such transfers of profits may damage the value of state-owned assets. Therefore, under the framework of Criminal Law, if a transaction party gives benefits to another party that is a state-owned enterprise, public hospital or other state-owned entity, the act may constitute the crime of offering bribes to entities, and the act of accepting such benefits by a state-owned enterprise or public hospital may constitute a crime of accepting bribes by the entity.
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. Government regulators are gradually opening and expanding the application of internet and big data technology in medical services. On 12 April 2018, the State Council promulgated Opinions on Promoting the Development of ‘Internet plus Healthcare’, promoting a comprehensive ‘Internet plus Healthcare’ service system, encouraging medical institutions to apply internet and other information technology in developing the scope and content of healthcare services, allowing medical institutions to develop ‘internet hospitals’ which provide online diagnosis of common disease and follow-up consultations for chronic diseases, supporting medical institutions to cooperate with third-party organisations to establish internet information platforms for long-distance healthcare consultations, health management and other services, and increasing the exchange of medical resources and information. It is expected that ‘Internet plus Healthcare’ will soon be a target growth area for many mobile healthcare companies.

Furthermore, with respect to the fast-developing field of gene detection and diagnosis, the most recent Guidance Catalogue of Foreign Investment Industries provides that the ‘development and application of human stem cells, gene diagnosis and treatment technology’ still falls within the catalogue of prohibited industries for foreign investment, and therefore foreign capital continues to be blocked from gene detection and diagnosis projects in China.

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.
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’. The 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 England, healthcare is currently provided distinctly from personal, non-medical (‘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. 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\(^4\) (known as NHS England). Funding pressures in 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.

There is an increasing role for private healthcare provision, either directly to the NHS (i.e., by running specific NHS-provided services) or by providing privately available services directly to patients. A recent answer to a Parliamentary question indicated that NHS spending with private sector providers in England was just over £9 billion in the 2016–2017 financial

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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.
year, representing 7.7 per cent of the Department of Health’s revenue budget.\(^6\) While this has been politically contentious,\(^7\) 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 cover is not usually provided for accidents and emergency. 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.\(^8\) 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.\(^9\) There are a range of exemptions from these charges available on the basis of age, income or certain medical conditions. These 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 EU member state as if they were a national of that state,\(^10\) and this is reciprocated for EU nationals in the UK. It is uncertain whether such provisions will remain after Brexit.

As of 21 August 2017, those exempt from charges for NHS services are no longer able to receive NHS medical, surgical or obstetric services provided for the diagnosis or treatment of infertility. The regulations that set the legal framework for cost recovery from chargeable overseas visitors changed in October 2017;\(^11\) it is now mandatory to collect payment, in full and in advance of providing any services, unless doing so would prevent or delay the provision of immediately necessary or urgent services to the patient. The new regulations also extended the scope of the rules to include private and voluntary providers supplying NHS services.

The role of voluntary or third-sector providers in healthcare in England is limited, given the availability of NHS care, but one particular area of charitable provision is hospice care.

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\(^6\) https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2017-12-18/120099.


\(^8\) Regulation 3(1), National Health Service (Charges to Overseas Visitors) Regulations 2015/328.

\(^9\) 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.


\(^11\) The National Health Service (Charges to Overseas Visitors) Regulations 2015 were amended by the National Health Service (Charges to Overseas Visitors) (Amendment) Regulations 2017.
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. EU nationals living in the UK and not employed are required to have comprehensive sickness insurance,\(^\text{12}\) however in December 2017 the government announced that EU citizens who apply for post-Brexit settled status in the UK will not be required to have such insurance.\(^\text{13}\) In addition, those applying for certain types of entry clearance or leave to remain in the UK must pay a compulsory surcharge of £150–£200 a year to use NHS services.\(^\text{14}\)

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. 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.\(^\text{15}\)

Funding and payment for specific services

NHS services are commissioned at a local or national level by either the local CCG or NHS England; what services are routinely commissioned is substantially informed by evidence-based guidance and advice issued by the National Institute for Health and Care Excellence (NICE).

NICE has various powers to produce guidance and recommendations to NHS bodies on care pathways and technologies they are expected to provide.\(^\text{16}\) NHS bodies are legally obliged to fund medicines and treatments recommended by NICE’s technology appraisal recommendations,\(^\text{17}\) however, other forms of guidelines do not have the same level of authority.\(^\text{18}\)

For example, NICE guidelines (as opposed to technology appraisal recommendations) 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, with three cycles offered to women under 40 and one for those aged 40–42. 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. Another example is the very limited availability of acupuncture on the NHS in the absence of NICE recommendations.

\(^\text{12}\) Immigration (European Economic Area) Regulations 2016.
\(^\text{14}\) The Immigration (Health Charge) Order 2015/792.
\(^\text{15}\) www.gov.uk/cma-cases/private-healthcare-market-investigation#final-report.
\(^\text{16}\) 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.
\(^\text{17}\) Regulation 7(6) National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.
\(^\text{18}\) The obligations to comply with different types of NICE guidance, guidelines and recommendations were most recently explored in *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).
NICE’s role is to assess the clinical and financial efficacy of the technology. In addition, the Cancer Drugs Fund (CDF) is a third option at the end of the NICE technology appraisal process. The CDF acts as a managed access fund for cancer drugs where it is considered that more information is required to determine clinical effectiveness. In April 2017 a controversial budget impact test for certain technologies was introduced to assess the financial impact of a technology over the first three years of its use in the NHS. If the budget impact exceeds £20 million, in any of the first three years, NHS England may engage in commercial discussions with the company. These discussions are designed to mitigate the impact that funding the technology would have on the rest of the NHS.

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 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 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.19

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

The UK healthcare system is 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.20

GP providers 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), many of the provisions are required under the National Health Service (General Medical Services Contracts) Regulations 200421 or the National Health Service (Personal Medical Services Agreements) Regulations 2015, respectively.

NHS hospitals and secondary services are run by local trusts or foundation trusts. While these are still NHS bodies, they are independent of CCGs or 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

19 National Health Service (Charges for Drugs and Appliances) Regulations 2015 and the National Health Service (Dental Charges) Regulations 2005 (as amended).
20 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.
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. However, there has been an increasing movement in recent years towards the integration of both different health services and of health and social 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. A recent development has been the government’s proposal to introduce ‘Accountable Care Organisations’, which would be commissioned by CCGs to take responsibility for the healthcare of a population. However, this has been controversial and faced two legal challenges, both of which were defeated.

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 the rest of the UK) healthcare records are held at a local level with the patient’s GP and 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 as a result of 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 government previously announced a plan to launch a digital service allowing people to see who had accessed their Summary Care Record by December 2018, but no further information has been released.

The UK’s data protection law (which regards information about a person’s health to be a special category of personal data) has been significantly strengthened by the introduction of the new Data Protection Act and EU General Data Protection Regulation in 2018, which came into force on 25 May 2018. Alongside this, NHS Digital has launched a new data security toolkit to measure and publish their performance against the National Data Guardian’s data security standards, which is required to be completed annually.

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. 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 CQC. 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 the 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;
- treatment for a disease, disorder or injury by or under the supervision of a healthcare professional;
- surgical procedures carried out by a healthcare professional;
- diagnostic and screening procedures; and
- medical advice or triage, over the telephone or by email.

In order to be registered, a new provider must register with the 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:

- safeguarding policy and procedures document;
- building regulation document;
- registered manager’s supporting evidence; and
- 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 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:

- compliance with the fundamental standards, including person-centred care, dignity and respect, consent, and safe care and treatment;
- management and safeguarding; and
- whether the provider’s directors are of good character and have the necessary competence and qualifications.

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. 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.

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27 Section 10(1) and (4), Health and Social Care Act 2008.
29 Section 11, Health and Social Care Act 2008.
30 Known as the ‘fit and proper person test’, this is currently subject to an independent review by Tom Kark QC.
31 Section 32, Health and Social Care Act 2008.
32 Sections 17 and 18, Health and Social Care Act 2008 and the Care Quality Commission (Registration) Regulations 2009.
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’.33

iii Healthcare professionals

Healthcare professionals in England are usually required to be registered with one of the eight different regulators, including the General Medical Council (GMC),34 the Nursing and Midwifery Council (NMC),35 the General Dental Council (which regulates the wider dental team)36 and the General Pharmaceutical Council.37 Some of these operate on a UK-wide basis, while others only operate in certain nations. In particular, a new profession of nursing associates is being created in England only. Nursing associates will be regulated by the NMC from early 2019. These regulators are overseen by the Professional Standards Authority for Health and Social Care (PSA).38 The PSA also 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. The requirements for registration with a regulator typically vary according to whether an applicant is coming from the UK, the EU or overseas. As regulators are typically involved in setting the requirements of UK qualifications leading to registrant, an overseas applicant will normally need to demonstrate how their qualifications and training meet the requirements of an applicant with a UK qualification. This may be done either by their overseas registration, qualification or further training being recognised by the UK regulator, by the applicant undergoing testing, or by a period of supervised practice in the UK. There was a consultation in late 201739 about reform of the regulation of professionals in the UK.40 There is an expectation of a government response in autumn 2018 but at present, no indication has yet been given for when legislation might be submitted to parliament.

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33 Sections 54 to 56, Care Act 2014 and the Care and Support (Market Oversight Criteria) Regulations 2015.
34 Medical Act 1983.
37 Opticians Act 1989.
38 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 patients’ rights in cross-border healthcare, all of the professional regulators require their registrants to have indemnity or insurance arrangements providing appropriate cover for their practice.41 In the vast majority of circumstances, this 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, although this is currently the subject of legal debate.

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 Board42 (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 doctor–patient relationship. The 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’ (Paragraph 75). This has 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’.43 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).

Much controversy has been generated by the case of Dr Hadiza Bawa-Garba, a trainee paediatrician who was found guilty of gross negligence manslaughter in November 2015, following the death of a child after delays in diagnosing septic shock. Dr Bawa-Garba had only recently returned to practice following an extended period of maternity leave and the errors were made towards the end of a 12-hour shift. In addition to her criminal conviction, in June 2017 the Medical Practitioners Tribunal suspended her from the GMC’s register of medical practitioners for one year, however the GMC appealed this and in January 2018 the

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41 For example, Section 44C, Medical Act 1983 and Article 12A, Nursing and Midwifery Order 2001.
42 Montgomery v. Lanarkshire Health Board (Scotland) [2015] UKSC 11.
43 Montgomery v. Lanarkshire Health Board (Scotland) [2015] UKSC 11, paragraph 82.
High Court instead erased her name from the register. This decision was then overturned by the Court of Appeal, which reinstated the original one-year suspension. The matter has also sparked a review into such cases and further changes to the law are being considered.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

As discussed above, the Regulated Activities Regulations require directors of registered providers to comply with a range of requirements, although these requirements are currently under review. These include that the directors: 44

a are of good character;
b have the qualifications, competence, skills and experience necessary;
c have not been responsible for or contributed to any serious misconduct or mismanagement while carrying out a regulated activity; and
d have not been convicted of an offence or erased from a register of health professionals.

There is no prohibition on internationally owned or non-national businesses being CQC-registered, however, there must be a registered premises in the UK from which the service is provided.

Between April 2012 and April 2014, the Competition and Markets Authority concluded that features of the privately funded healthcare market in the UK prevented, restricted or distorted 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 financial interest in:

a that hospital;
b the hospital operator that owns or operates that hospital; or
c 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.

At present, the UK government is very keen to welcome new investment in the UK healthcare space, which is particularly seen in 2017’s Life Sciences Industrial Strategy.45

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 or CCGs, supported by local Commissioning Support Units, depending on the nature of the service and how commonly those services are required (routine services would be commissioned on a local basis by the CCG, whereas complex, rare procedures would be commissioned by NHS England). The commissioned services may be provided by NHS providers 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,\textsuperscript{46} which sets out the standard terms to be expected for the commissioning of all health services except primary care. The terms of the contract are mandated each year by NHS England.

Since 18 April 2016, procurement of healthcare services by all publicly funded or controlled NHS bodies is subject to open and transparent competitive tendering under the ‘light-touch regime’ in the Public Contracts Regulations 2015 (PCR 2015). In addition, procurement of healthcare services by CCGs and NHS England is subject to its own specific procurement regime under the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013, which is overseen by NHS Improvement. These two procurement regimes may overlap in some instances.

For the procurement of supplies (as opposed to services), competitive tendering under the PCR 2015 is normally required. There is a general trend for NHS procurement of supplies (ranging from sophisticated medical equipment to non-medical supplies) to be aggregated into larger ‘hubs’ in order to secure economies of scale in purchasing. For similar reasons, there is a move towards greater clinical and price standardisation of medical supplies across the NHS and centralised contracting for some higher value products. Patented pharmaceuticals are generally procured directly from the originating manufacturer. Prices of drugs are (indirectly) controlled through the Pharmaceutical Price Regulation Scheme, a voluntary scheme agreed between the Department of Health and the Association of British Pharmaceutical Industries (ABPI).

\textbf{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 logo is a 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, placing 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. 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\textsuperscript{47}.

The ASA's advertising codes prohibit misleading, harmful or offensive advertising and require that all advertising must be legal, decent, truthful, deal fairly with consumers and not be misleading or offensive. The ASA 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 marketing authorisation and there are separate requirements for marketing to the public and prescribers. Prescription-only medicines cannot be advertised at all. Therefore, the promotion of health services that specify a treatment with a

\textsuperscript{46}  \url{www.england.nhs.uk/nhs-standard-contract/17-18/}.

\textsuperscript{47}  Under Regulation 20A of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
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.

The Association of British Healthcare Industries and the ABPI also publish codes of practice, which regulate the medical devices and the pharmaceutical industries’ interactions with healthcare professionals, including all marketing and training activities. Even though these codes are binding only on the corporate members of those associations, they are widely considered to reflect industry best practice, and compliance with them (as well as various NHS policies and codes, such as its Managing Conflicts of Interest in the NHS) is often required contractually.

The Bribery Act 2010 applies to all market participants. It establishes general bribery offences, which apply to individuals who offer or receive a financial or other advantage with the intention to induce or reward improper performance of any function or activity (including activity performed as part of a public duty or commercial operations). Improper performance is understood as performance in breach of an expectation of good faith, impartiality or trust associated with that function or activity. There are also corporate offences of failure to prevent bribery and bribing a foreign public official. A body corporate may be prosecuted for failure to prevent bribery anywhere in the world, and the foreign public official offence may apply to interactions with healthcare professionals in countries where those professionals are also public officials.

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.

There is an increasing number of online services being promoted, many of which have been welcomed in terms of speed of access, increased access for those in remote areas and potentially lower-cost services. Many of these are private services, although some have gone on to partner with NHS organisations. However, there is concern to ensure patient safety in these settings, with the CQC subjecting such providers to close inspection and guidance from bodies such as the professional regulators and new guidance from the Royal College of General Practitioners for patients.48

The Department of Health currently has a number of major inquiries ongoing in relation to English patients: into the use of infected blood;49 following the conviction of surgeon Ian Paterson for unlawful wounding during unnecessary breast surgery;50 and an

49 https://www.infectedbloodinquiry.org.uk/.
50 https://www.patersoninquiry.org.uk/.
independent review of apparent failures in breast cancer screening. Each of these has the potential to generate recommendations on the delivery of certain services and the role of various NHS bodies.

The UK continues to lead the world in its genomics work. The Department of Health set up Genomics England in 2013, which by June 2018 had sequenced over 60,670 genomes\(^51\) from NHS patients with rare diseases and common cancers, creating a unique platform for research and delivery of personalised care; from October 2018, the NHS is intending to conduct genetic screening of new cancer patients to gather personalised medicine. In addition, 2018 saw the first licences to allow mitochondrial donation in embryos that will be transferred for pregnancies in the coming months.

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.

**X 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.

\(^{51}\) www.genomicsengland.co.uk/the-100000-genomes-project-by-numbers/.
Chapter 6

FINLAND

Kirsi Kannaste, Terhi Kauti and Leena Lindberg

I OVERVIEW

Under Finnish law, municipalities are currently primarily responsible for organising healthcare and social services. Municipalities can also purchase social welfare and healthcare services from other municipalities, organisations or private service providers. Private healthcare services thus supplement municipal services. In addition, employers have a statutory obligation to arrange occupational healthcare for employees. Despite the recent considerable growth of the private sector’s share in the provision of services, healthcare and social services are at present still mainly provided by public entities.

The Finnish healthcare and social services system is currently undergoing a major reform, which if materialised would be implemented gradually as of 2021 onwards. This would drastically change the structure and organisation of healthcare services in Finland. Therefore, while this chapter describes the current state of the healthcare system in Finland, it should be borne in mind that the reform is likely to change the system significantly in the near future.

On a general level, the purpose of the reform is to obtain costs savings and to enhance efficiency in public healthcare. One of the main changes would be that the responsibility for providing public healthcare services would be transferred from the currently responsible 311 municipalities to 18 new larger autonomous regions (counties). The state would be primarily responsible for financing the new autonomous regions. The customers’ freedom of choice would be enhanced by allowing the customers to choose where they want to receive services by the payment of the basic user charge. This reform would also further integrate private operators into the healthcare and social services system and would thus likely enhance the growth of the private healthcare companies.

As for the relevant national bodies in the Finnish healthcare sector, the Finnish Ministry of Social Affairs and Health is in charge of the planning, steering and implementation of social and health policy and preparing legislation. The Social Insurance Institution of Finland is a government agency that provides basic economic security for everyone living in Finland and is responsible, for example, for paying various social benefits, such as family benefits and basic unemployment security. The National Supervisory Authority for Welfare and Health guides, supervises and runs the licensing administration of social and healthcare while the Finnish Medicines Agency (Fimea) does the same for the pharmaceutical sector. The Regional State Administrative Agencies are responsible for supervising healthcare on a regional level.

1 Kirsi Kannaste, partner, Terhi Kauti, counsel, and Leena Lindberg, partner, jointly head Krogerus Attorneys Ltd’s healthcare and pharmaceuticals group.
II THE HEALTHCARE ECONOMY

i General
The constitutional obligation for providing adequate social, health and medical services to all is enforced primarily via municipalities, who are responsible for offering primary healthcare services to their residents. Moreover, specialised medical care is assigned to five regional hospital districts, which together cover all Finnish municipalities.

The municipalities are free to choose how they carry out the required primary healthcare operations, as long as they fulfil the requirements set by law. Also specialised medical care may be procured from third parties.

Permanent residents of Finland are insured against illness by the National Health Insurance scheme, which covers a share of medication costs, private medical expenses as well as certain sickness and parental allowances.

In addition to the above, employers are required to offer occupational healthcare services to their employees. Employers may choose to use either public or private service providers.

Hence, both public and private options for health and medical care are available, although the most demanding medical care is typically carried out by public specialised hospitals. While the National Health Insurance covers a small share of private medical expenses, it remains considerably more expensive than the fees collected by public service providers.

ii The role of health insurance
The National Health Insurance scheme generally applies to every permanent Finnish resident, meaning persons who are domiciled and spend most of their time in Finland. The scheme is financed by mandatory premiums paid by employers, employees and the state.

The premiums paid by employees and employers are both set as a percentage of the employee's annual salary. The employer's premiums are mandatory for any employer or self-employed person where their operations in Finland last longer than four months (irrespective of where the self-employed person resides). In addition, employers shall take out an insurance against occupational accidents and diseases for their employees. Employers may also choose to take out excess coverage for all or key employees.

Private health insurance functions as an addition to the existing public health insurance and does not limit the statutory insurance coverage. Typically, private policies cover private medical expenses wholly or partly. Moreover, insurance companies may typically conclude agreements with certain private healthcare service providers on services for its policy holders.

iii Funding and payment for specific services
Municipalities may charge fees for the primary healthcare services they provide. The maximum level of fees is set in legislation and typically covers only a fraction of the services'
Finland

Moreover, fees for public services have an upper limit per calendar year per person, beyond which services are free of charge. Similarly, patients bear only a fraction of the costs of public specialised medical care by paying publicly determined fees, while the bulk is covered by public funds.8

The National Health Insurance is funded by beneficiaries’ and employers’ mandatory health insurance premiums as well as state subsidies. It covers a share of certain expenses, such as private doctor fees, examinations and treatments prescribed by private doctors, private dentist fees and examinations prescribed by the same, costs of prescribed medications and illness-related transport. Persons covered by National Health Insurance are also entitled to sickness allowance owing to long-term incapacity to work, rehabilitation allowance and parental allowance (separate from maternal and paternal allowance). These reimbursements and allowances are granted by the Social Insurance Institution of Finland.

Using private healthcare services is almost entirely at the individual’s expense, as the National Health Insurance only covers a minor share of private medical costs. Private operators are free to fix the price of services at the desired level, which is normally notably higher than in the public sector.

III PRIMARY/FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

The provision of private healthcare and social care is subject to licence, the conditions of which are set in legislation.9 Currently private licensed entities may provide all the same services as public entities. Within public sector healthcare, patients shall, in case of illness, primarily contact their own designated health centre to make an appointment with a general practitioner or a nurse. Appointments on short notice are possible for illnesses that require urgent care, while the waiting time for non-urgent healthcare may be rather long. It is also possible to consult a nurse or a general practitioner ad hoc at a local public health centre during duty hours. Outside the opening hours of a public health centre, urgent cases are directed to emergency clinics located in connection with hospitals.

For both pre-booked appointments and ad hoc visits to the health centre, it is evaluated, based on the patient’s symptoms, whether treatment by a nurse or a general practitioner is required. Appointments with specialists may thus not be booked directly. Instead, general practitioners refer patients to specialists where necessary.

Private healthcare providers are typically able to provide appointments to both generalist practitioners and specialist medical consultants with rather short notice. Private healthcare providers typically may make referrals also to public laboratories, but private referrals are not valid for public sector X-rays, ultrasound and magnetic resonance imaging.

In Finland, medical records are restored electronically by the healthcare institutions. This platform as emergency medical care, outpatient care, home nursing, at-home hospital care and inpatient care, mental health services, and substance abuse services where these are not covered by social services or specialised medical care (See Health Care Act, 1326/2010).

See Act on Social and Healthcare Client Fees (734/1992) and Decree on Social and Healthcare Client Fees (912/1992).

Specialised medical care entails specialised medical and dental healthcare, services pertaining to preventing, diagnosing and treating illnesses, emergency medical service, emergency medical care and medical rehabilitation.

Finland offers individuals the possibility to study all personal medical records in one place. It requires the consent of the individual for different institutions to be able to use information provided in the register by other institutions where the patient has already been treated.

Sharing identifiable patient data constitutes processing of personal data and therefore the provisions of data protection legislation need to be taken into account, especially the EU General Data Protection Regulation (GDPR) and the Finnish Data Protection Act along with Finnish sectoral legislation (which is fairly plentiful in the field of healthcare). The Finnish sectoral legislation is currently under review by the relevant Ministries and changes to the healthcare-related legislation are also expected. One interesting topic is the future of the Finnish Biobank Act under the regime of the GDPR. The biobank legislation in Finland has had a rather permissive approach for the use of data in connection with biobanks and has allowed for a broad consent to be obtained, which among other issues is now being discussed thanks to the GDPR.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

The Regional State Administrative Agencies have been entrusted with guiding and monitoring municipal and private social welfare and healthcare services and evaluating the availability and quality of basic services provided by municipalities in their respective regions. They are also responsible for granting licences to private service providers in the region. Meanwhile, the National Supervisory Authority for Welfare and Health guides, monitors and manages the administration of licences for the social welfare and healthcare sector. It is also responsible for granting the right to practise as a licensed or authorised healthcare professional and for authorising the use of occupational titles.

ii Institutional healthcare providers

Municipalities, who provide statutory basic social welfare and healthcare services either alone, or form joint municipal authorities with other municipalities, do not require a licence. Similarly, hospital districts provide medical care services without the need for a licence.

Private service providers must obtain a licence to operate health, medical or social care services. Where the service provider operates in one region only, the licence is granted by the Regional State Administrative Agency in the respective region and where the service provider operates in several regions, the licence is granted by the National Supervisory Authority for Welfare and Health. Exceptionally, where employers themselves organise statutory occupational healthcare for their employees, no licence is required for the employer itself but the healthcare professionals are of course subject to the same requirements as described below.

Unlicensed provision of healthcare services is criminally sanctioned and may lead to fines or imprisonment. A licence may also be revoked following gross negligence of the laws concerning the provision of healthcare.

Operating a pharmacy is also subject to licence. A pharmacy licence can be granted to qualified pharmacists having obtained a Master of Science degree in Pharmacy. Fimea grants pharmacy licences based on applications, taking into account, among other factors,

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10 Section 3 of Chapter 44 of the Criminal Act (39/1889).
11 Section 22 of the Private Health Care Act (152/1990).
the demand for pharmacy services at the location of the pharmacy. As an exception, certain universities may operate pharmacies by virtue of special legislation. Unlicensed operation of a pharmacy is criminally sanctioned. Fimea may also issue a written or oral warning to a pharmacist for undue conduct as well as revoke a licence, for instance if the pharmacist is unable to maintain operations because of bankruptcy, illness, or substance abuse, or if the pharmacist is otherwise clearly unfit to operate a pharmacy.\textsuperscript{12}

\textbf{iii Healthcare professionals}

Practising the professions of a doctor, dentist and nurse in Finland is subject to licence.\textsuperscript{13} Unlicensed provision of healthcare services is sanctioned in criminal law. Recently, an unlicensed person was sentenced to five years of unconditional imprisonment for having practised medicine for roughly 10 years without a valid permit.\textsuperscript{14} Moreover, all healthcare operators must take out statutory patient insurance providing primary insurance coverage for patients’ personal injuries.

As a member of the EU, Finland guarantees the free movement of healthcare professionals from other EU Member States, who may practise their profession in Finland upon receiving the required professional licence. In general, the National Supervisory Authority for Welfare and Health grants the licence, upon application, to doctors, odontologists and nurses from other Member States in accordance with the principle of automatic recognition.

Granting nationals of non-EU or non-EEA states authorisation to practise as licensed professionals in Finland is subject to stricter requirements. In principle, the National Supervisory Authority for Welfare and Health may grant the authorisation only for special reasons and on conditions prescribed by it. These conditions may include, among others, additional studies and examinations as well as mandatory training periods.

In order to obtain a licence, healthcare professionals must possess adequate language proficiency to practise their profession in Finland. The required level of proficiency is in connection with managing the profession adequately in either of the two official languages in Finland: Finnish or Swedish.

All information on up-to-date licences of authorised healthcare professionals is available to the public on an internet portal provided by the National Supervisory Authority for Welfare and Health.

\textbf{V NEGLIGENCE LIABILITY}

\textbf{i Overview}

All healthcare providers, including self-employed healthcare professionals, companies that offer healthcare or emergency medical services, pharmacies, hospital districts, and government agencies and public bodies must have patient insurance as set out in the Patient Injuries Act.\textsuperscript{15} Negligence liability cases are primarily covered by this patient insurance system. The insurance covers bodily injury arising from malpractice, infection, accidents, accidents caused by medical devices, damages caused by the treatment rooms and apparatus, harm caused by

\textsuperscript{12} See the Medicines Act (395/1987).
\textsuperscript{13} See the Act on Health Care Professionals (559/1994).
\textsuperscript{14} Helsinki Court of Appeal, judgment 112532, 30 March 2017.
\textsuperscript{15} The Patient Injuries Act (585/1986).
delivery of medicaments and other unreasonable damage. The insurance does not cover risks inherently contained in the treatment, nor is compensation available when an appropriately applied treatment does not give the desired results. Minor damages are also not covered.

The Act on the Status and Rights of Patients primarily sets out requirements for the quality of healthcare services to be provided by both public and private operators in Finland. Furthermore, there is legislation regulating specific situations. While the violation of these Acts does not directly affect the compensation to be granted by the Patient Insurance Centre, the Finnish entity responsible for handling all personal injuries that have occurred in connection with healthcare activities in accordance with the Patient Injuries Act, the Acts provide a backdrop for assessing the acceptable quality level of healthcare services. The level of compensation paid on the basis of negligence in the healthcare context is relatively moderate on a global scale and punitive damages, for example, are not allowed under Finnish law.

If the injured patient is entitled to receive compensation from the party that caused the injury, the insurer has a right of recourse towards that party. In rare cases where the damage is not covered by the statutory patient insurance, the patient may have a right to claim compensation for injuries directly from the healthcare provider (e.g., under the Tort Liability Act or the Product Liability Act). Claims for material damage caused in connection with medical treatment may also be filed against the party causing the damage. It is also noteworthy that under the Tort Liability Act the employer is primarily liable for damages caused by an employee or a public official through an error or negligence at work.

In the most severe cases, healthcare professionals may bear criminal liability. Negligent homicide and negligent bodily injury are the most probable offences in this context. Sanctions for these offences vary from fines to imprisonment for at most six years. However, damages resulting from incorrect treatment rarely lead to criminal liability, in particular because of challenges in demonstrating intent or negligence.

Other measures protecting patients’ rights include the right to submit an objection to the director of a healthcare unit or a complaint to the competent Regional State Administrative Agencies, the National Supervisory Authority for Welfare and Health, the Parliamentary Ombudsman or the Chancellor of Justice. In addition, patients have the right to appeal against decisions concerning involuntary treatment. The competent supervisory authority may, for example, give administrative guidance, in the form of warnings, to the healthcare professionals. In severe cases, the professional’s licence to practise can be limited or removed. Similar restrictions can be imposed to the service provider functioning as the employer.

ii Notable cases

Liability and compensation for treatment injuries or other healthcare-related damages are often dependent on whether the injured party can prove causality between the injury and the treatment, and negligence. However, the threshold for reimbursement from the patient injury insurance under the Patient Injuries Act is somewhat lower, as its precondition is a ‘probable’ causality between treatment and injury, and because no demonstration of wilful conduct or negligence is required. Instead, the patient’s right to compensation depends on

17 E.g., the Mental Health Act (1116/1990) and the Communicable Diseases Act (583/1986).
19 Chapter 21, Sections 8–11 of the Criminal Code of Finland (39/1889).
whether an experienced healthcare professional would have examined, treated or otherwise dealt with the patient in a different manner and would thereby probably have avoided the injury.

A recent case on personal injury from the healthcare sector concerns vaccinations against swine flu distributed with government support in 2009. After the pandemic had passed, narcolepsy cases were found to have increased among vaccinated individuals, leading to the precautionary suspension of the vaccines in 2010. Compensation was eventually paid to patients from the non-statutory Pharmaceutical Injuries Insurance, which covers injuries caused by all medicines distributed, manufactured, imported or marketed by entities who are members of the Finnish Cooperative for the Indemnification of Medicine-Related Injuries.

A landmark criminal case relating to liability in the healthcare sector is the Supreme Court ruling KKO 1994:101 dealing with manslaughter of a child. A, who had claimed to be a naturopathy expert, had advised parents whose child suffered from diabetes to replace insulin treatment by a treatment based on hot baths. The child’s condition had aggravated while A was treating him, but A did not give the child insulin nor take him to a hospital. The Supreme Court held that A should have understood that the provided treatment was not proper for the child and A was thus liable for the child’s death. A was sentenced to conditional imprisonment of six months for manslaughter.

The Supreme Court case KKO 2010:67 concerned compensation based on the Patient Injuries Act. The Supreme Court considered whether a fracture in the patient’s hip allegedly caused by the installation of an endoprosthesis could have been avoided if a specialised and experienced professional had treated the patient. The Supreme Court held that in this case the level of expertise and care had been adequate and consequently no injury was to be compensated. Furthermore, no weight was given to the fact that the risk of fracture had not been explained to the patient, because it did not influence the avoidability of the injury.

Issues relating to data protection have also been topical in Finland. An exemplary case was KKO 2014:86 where a physician in a psychiatric outpatient clinic had read his spouse’s relative’s patient information, even though the patient was not in his care. The court considered this action unnecessary and wilful misconduct and, thus, a violation of official duty. The court also maintained the lower court’s decision making the physician liable for damages to the injured party.

Furthermore, in a recent case of data leakage, personal data and laboratory test results of around 6,000 persons were accidentally made available online by the National Institute for Health and Welfare. The National Supervisory Authority for Welfare and Health has also investigated cases where patient information system issues have potentially endangered patient safety. Currently no information on sanctions or follow-up claims is available.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

The public sector is under a statutory obligation to provide adequate healthcare services and, consequently, most healthcare services are provided by publicly owned entities. Non-profit organisations are active in the social welfare sector, but less so within healthcare. In addition, self-employed persons and private businesses provide healthcare services. The ownership
of private healthcare businesses is rather highly concentrated when it comes to nationwide chains. All healthcare provision is regulated by law, but more regulation and monitoring is applied to private service providers to ensure the safety and quality of the services.

There are no sector-specific limitations on the ownership of healthcare businesses, and major players in the sector include listed companies as well as companies wholly or partly owned by foreign entities. As an exception, pharmacies can generally not be operated by a company, but only by a licensed pharmacist. Moreover, the Act on the Monitoring of Foreigners’ Corporate Acquisitions (623/1999) may have an impact on foreign ownership, should the acquisition be considered to jeopardise an extremely important national interest.

EU and national competition laws may restrict the possibility to create large concentrations within the sector. This will be true in particular if the planned healthcare reform is successful, as new sector-specific regulation on merger control is likely to be proposed. Private healthcare service providers are governed by the Private Healthcare Act.\textsuperscript{21} As mentioned above, private healthcare providers are required to apply for a licence either from the competent Regional State Administrative Agency or the National Supervisory Authority for Welfare and Health. The Private Healthcare Act does not include any specific criteria for financial viability, but sets requirements, such as for appropriate facilities and equipment, proper training of staff, quality of medical services and patient safety. The service provider has to, among other things, have a healthcare service manager who has been approved by the licensing authority and a patient ombudsman who enforces the patient’s rights.

\section*{VII \ COMMISSIONING AND PROCUREMENT}

Municipalities may provide primary healthcare services in-house, form joint municipal authorities, or procure them partly or wholly from third parties, such as other municipalities, NGOs and private sector service providers. Several municipalities have outsourced the provision of their entire healthcare services to private companies by long-term contracts. Some municipalities have also established joint ventures with private companies. Moreover, hospital districts and university hospitals may procure specialised medical care from third parties.

Municipalities may also decide to provide social and healthcare services by granting service vouchers to local residents. In this case, the Act on Public Procurement and Concession Contracts does not apply. If service vouchers are used, all service providers fulfilling certain objective criteria must be accepted onto a list from which residents may choose a service provider of their liking.

Where healthcare and medical care is procured from third parties, Finnish public procurement law applies.\textsuperscript{22} Tenderers must fulfil the qualification criteria set out by the contracting authority in the contract notice or invitation to tender. The criteria to be chosen are at the discretion of the contracting authority, as long as the criteria comply with the principles of openness, non-discrimination and proportionality.

The procurement of healthcare services has been reviewed in several court cases. The cases have mainly concerned compliance with public procurement rules, in particular as regards ambiguity of award criteria and evaluation of tenders. In addition, a large-scale

\textsuperscript{21} The Private Healthcare Act (152/1990).
\textsuperscript{22} The Act on Public Procurement and Concession Contracts (1397/2016).
outsourcing project within the healthcare sector was appealed against before the Market Court in December 2017. The estimated value of the contract was €1 billion. However, the appeal was withdrawn.23

The ongoing reform of the Finnish social and healthcare system would change the commissioning of these services. According to the Finnish Competition and Consumer Authority, which also supervises public procurement, the upcoming reform has already affected the nature and volume of procurement of these services. In 2017, out of all sectors, social and healthcare services as well as procurement of medical devices gave rise to the largest number of opened procurement cases at the authority.24

VIII MARKETING AND PROMOTION OF SERVICES

At present, the applicable regulation and monitoring of marketing is mainly directed at private healthcare service providers in Finland. Marketing and promotion of private healthcare services is primarily regulated under the general consumer protection laws and unfair business practice legislation. No specific legislation in the field of marketing or promotion of health services exists.

The Consumer Protection Act regulates that any marketing that is inappropriate or otherwise unfair from the point of view of consumers is prohibited.25 Marketing must clearly indicate its commercial purpose and on whose behalf the marketing is carried out. A general prohibition to use false or misleading information applies.

The Unfair Business Practices Act prohibits practices that are unfair to other entrepreneurs as well as sets out general provisions on marketing.26 The Act requires compliance with good business practice and prohibits the use of misleading comparative marketing. The marketing provisions in the Unfair Business Practises Act correspond to a great extent with the provisions in the Consumer Protection Act.

Marketing offences are also criminalised under the Criminal Code of Finland. Criminal sanctions can be imposed on the marketing entity where false or misleading information conveyed in marketing is significant from the point of view of the target group.

In addition to the aforementioned legislation, the healthcare industry practises self-regulation on marketing. This includes general marketing guidelines and guidelines on marketing on social media provided by The Finnish Medical Association as well as the monitoring of marketing of health services conducted by a supervisory board under the Finnish Medical Association. Moreover, the Code of Advertising and Marketing Communications Practice by the International Chamber of Commerce applies to marketing of healthcare services as well.

The general marketing guidelines by the Finnish Medical Association emphasise the truthfulness, appropriateness, reliability and fair practice of marketing. The severity of an illness or a symptom is not allowed to be used for intimidation nor is the use of superlatives allowed in marketing. The guidelines prohibit the use of any type of anonymous marketing

23 The Market Court, case MAO:315/18, 11 June 2018.
on the internet, social media or search engines. Moreover, the private service provider shall not market other services outside its field nor shall the medical services be connected to product marketing.

For the time being, there are no specific regulations on the marketing of health services conducted by public entities or third-sector service providers, nor is there an authority supervising overseeing such marketing. Private and public service providers are thus treated differently with respect to the marketing of health services, and public service providers may market public healthcare services in ways prohibited from private entities. The Finnish Competition and Consumer Authority has deemed this an issue in the current system, and emphasis will be given to said issue in future reforms. Despite the lack of specific marketing regulations for public or third-sector service providers, public entities are nevertheless subject to principles of good administration such as the service principle, which sets a requirement for the marketing of public health services to be appropriate.

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

Having regard to the ongoing major health and social services reform, it is hard to predict how the healthcare sector will look in the near future. The reform package has been highly politicised and, thus, the detailed content of the reform is still subject to changes. As mentioned above, if successful, the reform would change the structure and organisation of the whole Finnish healthcare system and result in significant changes in legislation. It is expected that the reform would facilitate the entry and expansion of privately produced healthcare services.

Technological advances over recent years have also created new opportunities for healthcare service providers. For instance, new biobank legislation was introduced in late 2013, which has provided for a new field to emerge in the health sector.27 In the field of e-health, a personalised health programme is envisaged by a network of public sector actors to pursue the creation of international business and innovation for personalised healthcare platforms by utilising data from different sources, such as biobanks or lifestyle data collected by the individuals themselves.28 The ambitious goal for the programme is for Finland to become the global pioneer in the provision of personalised health by 2025.

X CONCLUSIONS

The current healthcare service system in Finland is heavily based on public funding and healthcare services are mainly provided by the public sector. Meanwhile, the role of private insurance is supplementary to the statutory scheme. The responsibility for organising healthcare is delegated to municipalities, which can provide basic social welfare and healthcare services independently, together with other municipalities, or purchase social welfare and healthcare services from third parties. The health and social services reform would, however, transfer these responsibilities from municipalities to counties, which would be created as part of the reform.

Despite the strong position of public healthcare in Finland, the number of private service providers has considerably increased in the 21st century. Demand of private healthcare

27 The Biobank Act (688/2012).
services is partly explained by the employers’ responsibility to arrange basic healthcare for its employees. The private sector is expected to take on an even greater importance as part of the healthcare system once the health and social services reform may open up the market to new players.

Because the final scope of the health and social services reform is still unclear and is likely to change owing to conflicting political visions, it is yet impossible to forecast how exactly the reform would affect current legislation.
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 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 2.55 per cent of the yearly salaried income or pension of the insured, with employers and employees each paying half of the total premium.\(^4\)

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 is 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 €59,400 in 2018) have an opt-out option if they choose private insurance instead.\(^5\)

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

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\(^3\) Data published by vdek under www.vdek.com/presse/daten/b_versicherte.html.

\(^4\) Data published by vdek under www.vdek.com/vertragspartner/arbeiggeber/beitragssaezte.html.

\(^5\) Reference is made to www.pkv.de/themen/krankenversicherung/so-funktioniert-die-pkv/ wer-kann-sich-privat-versichern/.
circumstances – treatment in rehabilitation facilities. These services also include screening tests, necessary vaccinations (not travel vaccinations) and medical care related to pregnancy and birth.

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 policymaking 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.6

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 a 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.

6 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.7

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

7 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:

- 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;
- 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
- 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

Since 2012, the German healthcare system has been undergoing a period of active reform in several areas. The year 2018 will also bring changes in the healthcare system. These generally include more health benefits, relief for supplementary payments (e.g., for medication or hearing aids), the right to the opinion of a second doctor and additional preventive check-ups for better dental health. Infants, people in need of care and people with disabilities will benefit from the new range of services offered by the statutory health insurance funds.8

Other than that, Germany passed a bill for secure digital communication and healthcare applications (the E-Health Act) in December 2015, which provides for concrete deadlines for implementing infrastructure and electronic applications and introduces incentives and sanctions if schedules are not adhered to. From 1 January 2017, statutory health insurance physicians receive additional fees for transmitting electronic medical reports, and receive additional fees for collecting and documenting emergency records (since 2018) and managing and reviewing basic insurance claims data online. As of July 2018, statutory health insurance physicians who do not participate in online review of the basic insurance claims data receive reduced remuneration.9

Furthermore, despite the legal mandate to have health insurance, it has been estimated that about 0.1 per cent of the population did not have insurance in 2015. A population group with a higher risk of being uninsured are low-income self-employed individuals, as it can be difficult for them to afford statutory health insurance (SHI) contributions or private health insurance (PHI) premiums. Indeed, independent of their actual income, the self-employed pay a contribution based on an expected minimum income of €2,284 per month, which is unmanageable for a large proportion of small business owners. The bill to reduce the mandatory contributions that insured individual must pay into the SHI system (SHI-Contribution Relief Law; bill of the German Federal Ministry of Health of 19 April 2018) plans to halve the reference amount used to calculate the minimum contribution. This measure will lead to an estimated loss in revenue for the SHI of €800 million, which will be compensated for by the current financial reserves.10

8 Reference is made to https://www.vdek.com/politik/was-aendert-sich/gesundheitswesen-2018.html.
9 Reference is made to http://international.commonwealthfund.org/countries/germany/.
10 Reference is made to http://www.hsppm.org/countries/germany/28082014/countrypage.aspx; and https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/
On 25 June 2018, the German Federal Ministry of Health submitted a draft bill to strengthen the nursing staff (Nursing Staff Strengthening Act). This act is intended to enter into force on 1 January 2019, and aims to achieve tangible improvements in the daily lives of nursing staff through better staffing and working conditions in nursing and care for the elderly. In order to improve staffing facilities in hospital care, in future every additional nursing position will be completely refinanced by the payers.11

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, there will be a particular focus in this area. 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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I OVERVIEW

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

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

II THE HEALTHCARE ECONOMY

i General

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

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

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1 Tom Hayes is a partner and head, and Rebecca Ryan and Michael Finn are partners, of 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 46 per cent of the Irish population holds private health insurance, a key benefit of which is avoiding public waiting lists for elective procedures.

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

iii  Funding and payment for specific services

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

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

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

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

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

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

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

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

Doctors

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

The main functions of the IMC are to:
a maintain a register of doctors;
b ensure high standards of medical education and training;
c specify standards of practice for doctors, including the areas of professional competence and ethics;
d provide guidance to doctors on compliance with standards of practice;
e promote good medical practice;
f investigate complaints made about doctors and, where necessary, conduct disciplinary procedures. The IMC has the power to suspend, attach conditions to registration or erase a doctor’s name from the register; and
g advise the Minister for Health on matters relating to doctors and patient safety.5

Nurses and midwives

The Nurses and Midwives Act 2011 regulates nurses and midwives in Ireland and requires all nurses and midwives working in Ireland to register with the Nursing and Midwifery Board of Ireland (NMBI). The NMBI’s main functions are to:
a establish procedures and criteria for the assessment and registration of nurses and midwives;
b act as the competent authority for the mutual recognition of professional qualifications of nurses and midwives awarded in or recognised by EU Member States;
c specify standards of practice for registered nurses and midwives;
d specify criteria for specialist nursing and midwifery posts;
e establish committees to inquire into complaints; and

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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:

- establish, maintain and publish a Register of Dentists, Dental Specialists, Dental Hygienists and Dental Nurses;
- regulate the dental education and training provided in Irish dental schools and to set standards required for primary qualifications;
- 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;
- make, with approval of the Minister for Health, schemes for the establishment of classes of auxiliary dental workers; and
- advise the dental profession and the public on all matters relating to dental ethics and professional behaviour.

**Health and social care professionals**

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

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

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

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

**ii Direct access to medical consultants**

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

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

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\(^6\) www.ihca.ie/information/information.386.html.
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.

Data protection laws

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

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

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

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

The IMC Ethical Guidelines8

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

7 https://www.hse.ie/eng/gdpr/gdpr-faq/.
is necessary as part of the care and treatment of the patient, the Ethical Guidelines permit disclosure to the appropriate person on the basis that they understand that the information is confidential.

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

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Doctors

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

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

Complaints

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

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

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

\(a\) an advice, admonishment or censure in writing;
\(b\) a censure in writing and a fine not exceeding €5,000;
\(c\) the attachment of conditions to the doctor’s registration, including restrictions on the practice of medicine that may be engaged in by the doctor;
\(d\) the transfer of the doctor’s registration to another division of the register;
\(e\) the suspension of the doctor’s registration for a specified period;
\(f\) the cancellation of the doctor’s registration; and
g  the prohibition from applying for a specified period for the restoration of the doctor’s registration.\(^9\)

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

**Medical indemnity insurance**

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

**ii  Nurses and midwives**\(^{11}\)

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

**Complaints**

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

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

**Medical indemnity insurance**

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

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

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\(^{9}\) [www.medicalcouncil.ie/Public-Information/Making-a-Complaint-/Fitness-to-Practise-Inquiries/Medical-Council-Sanctions.html](http://www.medicalcouncil.ie/Public-Information/Making-a-Complaint-/Fitness-to-Practise-Inquiries/Medical-Council-Sanctions.html).


\(^{11}\) [www.nmbi.ie/Registration](http://www.nmbi.ie/Registration).


\(^{13}\) [www.inmo.ie/Home/Index/7581/9869](http://www.inmo.ie/Home/Index/7581/9869).
iii Dentists
The dental profession in Ireland is regulated by the Dental Council of Ireland, a statutory body created under the Dentists Act 1985. Only dentists listed on the Irish Register of Dentists can legally practise dentistry in Ireland. Dentists must hold appropriate professional indemnity cover.14

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

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

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

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

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

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

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

The choice of committee will depend on the nature of the complaint. Complaints that concern matters of professional misconduct or poor professional performance will normally be referred to the Professional Conduct Committee. Complaints that concern impairment of a pharmacist’s ability to practise because of a physical or mental ailment, emotional disturbance or an addiction to alcohol or drugs will normally be referred to the Health Committee.\(^{17}\)

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

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**Institutional healthcare providers**

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

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

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

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

- on summary conviction, a fine not exceeding €5,000, or imprisonment for up to one year, or both; or
- on conviction or indictment, a fine up to €70,000, or imprisonment for up to two years, or both.

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\(^{17}\) www.thepsi.ie/gns/making-a-complaint/complaints-process.aspx.
V NEGLIGENCE LIABILITY

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

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

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

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

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

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

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

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

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

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

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

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

VI OWNERSHIP OF HEALTHCARE BUSINESSES

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

VII COMMISSIONING AND PROCUREMENT

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

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

Universal Health Insurance (UHI) is a new system of healthcare, which the government revealed in a 2014 White Paper on UHI that it plans to adopt and introduce by 2019.23 UHI aims to eliminate Ireland’s current two-tier health system and create in its place a single-tier health service that merges the public and private systems, where access to services is based on need and not on ability to pay. This means:

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

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

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

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

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

The All-Party Oireachtas Committee on the Future of Healthcare considered this issue and published its findings in its Sláintecare Report.24 The report encourages a shift away from the current hospital-centric model, which it states will enable the system to better respond to the challenge of chronic disease management and provide care closer to home for patients.

The OECD in its Economic Survey of Ireland in March 2018 suggested Ireland ‘move towards providing universal access to health and social services and incentivise patients to access care outside of hospitals’.25 This is discussed further at the end of this chapter.

**i) Procurement in the Irish healthcare system**

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

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

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

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

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VIII  MARKETING AND PROMOTION OF SERVICES

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

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

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

IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

Organ donation – opt in or opt out

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

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

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

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

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

**ii The future of healthcare in Ireland**28

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

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

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

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

**X CONCLUSION**

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

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

Over the next 10 to 15 years, the HSE has planned to make a number of significant changes to the way healthcare services are provided in Ireland. The HSE plans to roll out a national Electronic Health Record that will enable patient information to be instantly accessed by approved medical personnel. Further, there are proposals to provide free medical care for all, changes to the laws governing organ donation and the phasing out of the provision of private care services in public hospitals.
I \hspace{1em} \textbf{OVERVIEW}

\textbf{The national health insurance system}

Japan is recognised worldwide as a society of health and longevity at relatively low costs. Like most developed countries, it has a universal health insurance, referred to as the national health insurance system (NHIS), which was established in 1961 (see Section II below), but Japan also has a privately initiated medical care provision system. These two systems are sometimes called the ‘publicly funded and privately delivered’ system.

However, the sustainability of the NHIS has been questioned because of the rapid rise in healthcare costs due to the low fertility rate, ageing population, growing use of expensive technologies and Japan’s general economic slump for the past two decades.

To tackle those challenges, Japan adopted several reforms, including the following:

\begin{enumerate}
  \item The Medical Care Plan (see Section II below) was adopted in 1985.
  \item The Long-term Insurance System, which is a social insurance system for those aged 65 and over who require long-term care and social services, was introduced in 2000. This system is reviewed and revised every three years in order to maintain sustainability.
  \item The concept of the Integrated Community Care System, which is a comprehensive system at the community level that integrates the provision of healthcare, nursing care, prevention, housing and livelihood support, to enable the elderly to live self-sufficiently in environments that are familiar to them, was widespread as a matter of national policy from 2012.
  \item The Comprehensive Reform of Social Security and Tax was started in 2012. This reform consisted of joint reforms of the social security and taxation systems to improve the fiscal sustainability of Japan’s social security system. This cross-system reform plan includes measures for the support of children and child-raising, the employment of young people, the reform of medical and long-term care services, pension reform, measures against poverty and income inequality, and measures for low-income earners.
  \item The Regional Healthcare Vision (see Section II below) was started in 2015.
\end{enumerate}

Moreover, Japan’s privately initiated medical care provision system has been gradually shaped by a planned economy approach to make the healthcare economy more efficient.

\footnote{Noboru Suwa is a partner at, and Fumiharu Hitomoto is counsel to, Mori Hamada & Matsumoto. Noboru Suwa is also a healthcare management consultant registered with the Japan Association of Healthcare Management Consultants. Our thanks go to our colleague Jane Pardinas.}
Hot issues to be tackled with assistance from professionals
The following are some of the hot issues that we believe will eventually require the support of financiers as well as lawyers, accountants and other professionals.

Uneven distribution of physicians
The phenomenon of karoshi (death caused by overwork or job-related exhaustion) is a reality in Japan, even in the medical industry. In 2017, the karoshi of medical interns in 2015 and 2016 in severe working environments were determined as workers’ accidents. Although it is anticipated\(^2\) that supply and demand of physicians will balance out around 2028 (on the premise of 60 working hours a week and other conditions) or 2033 (on the premise of 55 hours a week and other conditions), the uneven distribution of physicians, in both geography and practice areas, and their severe working environment remain a major problem. See Section IX below.

Ageing and deterioration of medical institutions
The number of medical facilities rapidly increased from the late 1970s to the early 1980s in anticipation of the introduction of restrictions on the number of hospital beds in 1985. The statutory depreciation period for steel-reinforced concrete buildings of 39 years, which apply to these facilities, is expiring. In addition, these facilities do not satisfy the latest earthquake resistance standards. Therefore, we anticipate that a considerable number of medical facilities will need large-scale repairs, if not complete reconstruction. See Section IX below.

Family-oriented governance of medical corporations
Medical corporations are corporate bodies that are operated by administrative bodies for medical care service programmes without losing the non-profit status of the medical practice. The seventh major revision of the Medical Care Act (the ‘7th Revision’) promulgated in 2016 and enforced in April 2018 statutorily obligated a certain scale or category of medical corporations to comply with the Japan GAAP for medical corporations, accept external audit procedures, and publish written reports on transactions of a certain scale with their directors, close relatives or other specified persons. As a result, a review of corporate governance systems, especially in family-owned medical corporations, is anticipated. See Sections VI and IX below.

New industrial technologies
Ultra-expensive pharmaceutical, radiotherapy facilities, ICT, AI, robotic surgery and other industrial technologies have evolved and will keep evolving. These technologies increase and deepen inter-relations between the medical industry and for-profit corporations and organisations that confront the conventional philosophy on the non-profit status of medical practice in Japan. See Section IX below.

\(^2\) See ‘The Third Interim Report’ from 31 May 2018, prepared by the Physicians Supply and Demand Subcommittee under the Healthcare Providers Supply and Demand Review Committee (set up by the Health Policy Bureau of the MHLW).
II  THE HEALTHCARE ECONOMY

i  General
Although Japan residents avail themselves of private health insurance, Japan boasts of a working NHIS for its residents. The NHIS possesses the following features, namely, (1) legal residents in Japan are required to enrol in the public health insurance system, (2) there is freedom of choice of medical institutions (so called ‘free access’), and (3) medical services, medication and medical devices that are covered by NHIS are available at a low cost under a nationwide uniform price system.

ii  The role of health insurance
As long as Japan legal residents pay the required insurance premiums, they are entitled to medical services covered by the NHIS. The insured co-pay 10–30 per cent of the service fees to the medical provider. While NHIS coverage is wide and includes most basic medical services and conditions, there are medical services, such as heavy particle beam therapy or certain new experimental therapies, that are not covered. The NHIS does not allow NHIS-covered medical treatment to be provided alongside uncovered treatment, and considers the entire NHIS-covered and uncovered medical treatments as not covered by NHIS at all, except in very limited circumstances. Thus, many individuals opt to take out private health insurance for medical services not covered by the NHIS.

iii  Funding and payment for services
The NHIS has allowed Japan to enjoy the world’s highest level of life expectancy and healthcare standards, but because it allows free access to medical facilities and providers, an enormous amount of public subsidy is required to maintain the universal health insurance coverage. Thus, its sustainability is heavily affected by tax revenues and other public funds.

To control the supply and demand of medical resources, Japan adopted the Medical Care Plan in 1985, under which the Ministry of Health, Labour and Welfare (MHLW) obligates each prefectural government to make periodic reports on its prefecture-specific healthcare system. These reports must include an estimate of future supply and demand of hospital beds in the ‘secondary medical service areas’3 and their medical functions (such as acute phase function and recovery phase function), basically targeting (1) cancer, cerebral apoplexy, cardiovascular diseases, diabetes and mental disorders, referred to as the ‘five diseases’; (2) emergency medical care, medical care in case of disasters, medical care in remote areas, perinatal medical care, and paediatric medical care (including paediatric emergency medical services), referred to as the ‘five services’; and (3) home medical care. The reports used to be required every five years, but from 1 April 2018, the reports must be submitted once every six years with provisional revisions to be made every three years. If the number of existing hospital beds with certain medical functions exceeds the standard number of that

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3 Secondary medical service areas are areas determined by each prefectural government in its Medical Care Plan as enabling the provision of relatively highly specialised medical services including hospitalisations.
On the other hand, primary medical service areas are those for the provision of daily medical services that generally correspond to minimum administrative districts, and tertiary medical service areas are those determined by each prefectural government in its Medical Care Plan as enabling the provision of advanced medical services that generally cover the said prefecture, except Hokkaido Prefecture and Nagano Prefecture, which are large and are divided into multiple tertiary medical service areas.
type of hospital beds in the secondary medical service areas set out in the Medical Care Plan, the prefectural governor can directly or indirectly refuse applications for additional hospital beds.

From 2015, the MHLW further obligated each prefectural government to create, within its Medical Care Plan, a prefecture-specific vision called the Regional Healthcare Vision. This vision requires the use of a newly adopted reporting system (introduced from 2014) on medical functions of hospital beds to estimate supply and demand for healthcare for 2025 (when the baby boomers will reach the age of 75) and establish region-specific healthcare systems by 2025.

Medical service fees payable to medical institutions and pharmacies for insured medical services, medication and devices are determined every two years by the MHLW based on discussions within the Central Social Insurance Medical Council. The FY 2018 revision of medical fees covered by the NHIS applicable for two years from 1 April 2018 showed an average decrease of 1.19 per cent from the previous fees. That average decrease represents an increase in medical service fees but a decrease in the prices of drugs and supplies.

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

Unlike some countries where patients are required to first see a general practitioner even for insurance-covered medical services or have no direct access to high-functioning hospitals, Japan’s free access policy allows patients to directly access high-functioning hospitals for medical services covered by the NHIS. In order to cope with increasing medical costs, however, public policy guides patients and physicians to seek a general practitioner first. For example, in the FY 2018 revised fees, medical fees are increased for medical institutions that strengthen its general practitioner practice. Generally, patients without a referral from a general practitioner have to pay ¥5,000 as a first consultation fee to visit hospitals with at least 400 beds.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

The MHLW regulates the licensing and overall practice of healthcare professionals including physicians and dentists.

Licensed physicians and licensed dentists, however, are not automatically registered with the NHIS. They need to register as insurance physicians or insurance dentists with the Local Bureau of Health and Welfare where they are located.

Prefectural governments are also responsible for overseeing the management and operation of medical institutions on a regional basis.

As can be seen in the adoption of the Medical Care Plan and the Regional Healthcare Vision, there is a tendency to shift administrative powers over medical practitioners and institutions from national government to prefectural governments.

ii Institutional healthcare providers

Under the Medical Care Act, medical practice can only be performed in medical institutions that are categorised as ‘hospitals’ (with 20 or more beds) and ‘clinics’ (with zero to 19 beds). The Medical Care Act also provides for requirements for establishment permits (e.g., staff deployment standards, facility standards, and responsibilities of managers) for each
category of hospitals (such as ‘general hospitals’, ‘special functioning hospitals’, ‘regional medical care support hospitals’, ‘clinical research core hospitals’, ‘psychiatric hospitals’ and ‘tuberculosis hospitals’) and the names that hospitals can use.

The setting up of clinics requires notification if the applicant is a physician or dentist, or a permit if the applicant is a corporate body or is neither a physician nor a dentist.

In addition to the licensing requirement, medical institutions must be separately registered as insurance medical institutions to be included in the NHIS system.

### iii Healthcare professionals

Healthcare professionals such as (1) physicians, (2) dentists, (3) pharmacists, (4) public health nurse, midwives, nurses and assistant nurses, and (5) others are regulated under:

- the Medical Practitioners Act;
- the Dental Practitioners Act;
- the Pharmacists Act;
- the Act on Public Health Nurses, Midwives and Nurses; and
- other laws, respectively.

A graduate of a medical school (or medical department of university) outside Japan, or a physician licensed outside Japan must be accredited by the MHLW in order to take the National Examination for Medical Practitioners. However, (1) a physician, dentist or nurse licensed outside Japan who visits Japan for purposes of acquiring medical knowledge and skills, or (2) a physician or dentist licensed outside Japan who visits Japan for purposes of teaching or researching medicine or dental medicine, may provide medical services to the extent that such services are rendered within the said purposes by special permit from the MHLW.

To our knowledge, foreign entities who approach the Japanese medical industry sometimes involve foreign medical practitioners in their R&D or commercial activities. But the performance of any medical act in Japan always requires a licence or its equivalent under the Medical Practitioners Act.

### V NEGLIGENCE LIABILITY

#### i Overview

Because of an information asymmetry between medical practitioners and their patients, as well as the physicians’ expertise, the medical hierarchy or the locked-room nature of the medical profession, medical practitioners do not typically lose medical malpractice cases. In 2016, the average trial period of medical malpractice cases was approximately 24.2 months and their settlement rate was approximately 53.3 per cent, while the average trial period

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4 See ‘Accreditation of Qualification for Taking National Examination for Medical Practitioners’ (Notification No. 0324007 of 24 March 2005) issued by the Chief of the Health Policy Bureau of the MHLW.

5 See Act on the Exceptional Cases of Article 17 of the Medical Practitioners Act regarding Advanced Clinical Training of Foreign Medical Practitioners, etc. (Act No. 29 of 1987).

6 Under Article 17 of the Medical Practitioners Act, no person but a licensed medical practitioner may engage in medical practice.
of civil cases (other than overpayment claims) was approximately 8.8 months and their settlement rate was approximately 34.7 per cent.\(^7\) This means that medical malpractice cases tend to end in settlement in over 50 per cent of the cases, after prolonged trial periods.

Technically, a ‘reasonable causal relationship’ between a negligent conduct and damages or death is not easy to establish. Therefore, Japanese courts have eased the plaintiff’s burden of proof under various theories, such as ‘violation of patient’s expectation right’ and ‘possibility of patient’s survival to a reasonable extent at the time of death’, among others.

Moreover, it is important to mention that no punitive damages are allowed under Japanese law, and the amount of damages paid to the elderly is generally not large.

### ii Notable cases

In a decision issued on 22 September 2000, the Supreme Court adopted the concept of ‘possibility of patient’s survival at the time of death to a reasonable extent’ by holding that in cases where the causal relationship between a doctor’s negligent medical act and a patient’s death is not proved, but the possibility of the patient’s survival to a reasonable extent at the time of death if medical services satisfying fair medical standards were rendered is proved, the doctor shall be liable.

There have been two recent high-profile medical malpractice incidents in Japan. The first is the use of propofol, which is banned for use on children, on 63 children at the Tokyo Women’s Medical University Hospital in 2014. The second is the high incidence of deaths in patients who underwent complex liver surgery by laparoscopic operation at the Gunma University Hospital in 2015. Both hospitals involved are ‘special functioning hospitals’ that provide advanced medical care, develop and evaluate advanced medical technologies, and provide advanced medical research. These incidents led to the eighth major revision of the Medical Care Act (the ‘8th Revision’), which became effective on 1 June 2018, which reformed the governance of special functioning hospitals, including requiring due procedures for the appointment of hospital managers, establishment of an audit committee to ensure the safety of medical care, and establishment of a compliance system.

### VI OWNERSHIP OF HEALTHCARE BUSINESSES

Various entities including the government, public medical organisations, social insurance related entities, medical corporations, public benefit corporations, private school corporations, social welfare corporations, general corporation associations or foundations, stock corporations and individuals can operate medical facilities such as hospitals and clinics; however, approximately 68.6 per cent of the hospitals in Japan are operated by medical corporations (as of 31 March 2018).\(^8\) A medical corporation is either a medical corporation association, which is an assembly of people, or a medical corporation foundation, which is an assembly of funds. A medical corporation association may be with or without equity. When a member (and equity holder in almost all cases) of a medical corporation association with equity leaves the medical corporation by resignation or death, that member or his or her heir has the right to request for the return of that member’s equity. When a medical corporation association with equity is dissolved, the residual assets will be distributed to the equity holders.

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\(^7\) See the ‘Report on Verification of the Expediting of Trials (7th)’ published by the Supreme Court on 21 July 2017.

\(^8\) See ‘Vital Survey of Medical Institutions (Approximate Number as of 31 March 2018)’.
proportionately to their equity holdings. On the other hand, when a medical corporation association without equity is dissolved, the residual assets will be distributed to the national government, local governments or other medical corporations without equity.

As of 31 March 2018, out of the 53,944 medical corporations, there were 39,716 medical corporations with equity. As mentioned above, if a member of a medical corporation association with equity resigns or dies, he or she, or his or her heirs, can ask for the return of the equity. The amount to be returned is calculated by multiplying the then net asset value of the medical corporation with the equity ratio. This calculation was upheld by the Supreme Court in a decision issued on 8 April 2010. As can be expected, the operation of a medical corporation association with equity is adversely affected when the association must accommodate a request to return a member’s equity. Thus, the government encourages medical corporations with equity to convert into medical corporations without equity by providing time-limited tax incentives.

More specifically, a conversion is done by the voluntary relinquishment by all members of their right to request for the return of their equity. Therefore, the members need a lot of convincing to give up that right. The government hopes to do this through tax incentives, such as the deferral of and exemption from inheritance tax (on deceased member’s heirs) and deemed gift tax (on the members who do not relinquish that right at the time of conversion, or even if they do relinquish, on the medical corporation itself that acquires benefits from the relinquishment by all the members), for conversions made from 1 October 2014 to 30 September 2017 (under certain strict requirements), and from 1 October 2017 to 30 September 2020 (with a relaxation of such strict requirements). Once a medical corporation with equity converts into a medical corporation without equity, however, it cannot reconvert into a medical corporation with equity.

One of the major policies of the Medical Care Act is that medical practice must be non-profit. The reasons given for this non-profit policy include (1) Japanese medical services are supported by the universal healthcare insurance backed by public funds and, thus, medical services should not be provided for profit and (2) non-profit organisations have fewer incentives to take advantage of the information asymmetry between physicians and patients for profit and are, thus, a cost-effective way to monitor fraud by medical service providers. Because of the non-profit status of medical services:

\[ \begin{align*}
\text{a} & \quad \text{a licence to operate medical facilities is generally not given to for-profit organisations (with limited exceptions)}; \\
\text{b} & \quad \text{medical corporations are prohibited from making dividend distributions (including } \textit{de facto} \text{ dividend distributions like rents proportionate to earnings); in other words, any surplus of medical corporations can only be used for medical expenditures such as maintenance and improvement of medical facilities and salaries of the employees and any remaining balance must stay within the medical corporations}; \\
\text{c} & \quad \text{the directors general of medical corporations must be physicians or dentists, with exceptions under specific permit from the relevant prefectural governor; and} \\
\text{d} & \quad \text{for-profit organisations such as stock corporations may make monetary contributions to medical corporations but cannot become members thereof (with limited exceptions).}
\end{align*} \]

In addition, directors of entities operating a medical facility are prohibited from concurrently serving as directors or employees of other for-profit entities with an interest in the establishment or operation of that medical facility.
Because of the foregoing restraints, for-profit organisations are less incentivised to make contributions to medical corporations, especially in the context of M&A to revitalise distressed ones. Prohibition of rents proportionate to the earnings of a hospital restrains the flexible structuring of attractive products in the area of securitising hospital real estate.

Specific to family-owned medical corporations, a for-profit organisation, called a ‘medical services corporation’ or an ‘MS corporation’, is often established by a family, and provides to the medical corporation such services as laundry of linen, leases of medical devices and hospital/clinic building, procurement of medical goods and drugs, and provisions of accounting and other administrative services. There are suspicions that surpluses from medical services are paid to MS corporations for those services to circumvent the principle of non-profit status of medical institutions. The current arrangement with MS corporations is expected to be affected by the requirement of the 7th Revision for the auditing of the financial statements of medical corporations and filing requirements for, and public disclosure of, transactions with closely related entities.

VII COMMISSIONING AND PROCUREMENT

Commissioning is a process where the delivery of certain public services to be provided by the public sector is commissioned to the private sector, whereas procurement is a process where the public sector procures from the private sector goods and services it needs to deliver public services. In Japan, medical services are provided by private entities, which are not subject to commissioning and procurement procedures applicable to governmental entities.

VIII MARKETING AND PROMOTION OF SERVICES

Restrictions on advertisement of medical services

Before the 8th Revision, there were two different sets of restrictions on the advertisement of medical services: (1) one for advertising media such as advertising inserts, TV commercials and signboards under the Guidelines for Advertisements on Medical Services, and (2) another for advertisements on websites under the Guidelines for Home Pages of Medical Institutions.

Before the 8th Revision, generally, no-one may advertise any matter with respect to medical services other than certain limited information (such as the name of a physician or dentist, his or her clinical department name, and medical services to be rendered). False advertising was subject to penalties (so called ‘direct penalties’), while comparative advertising, exaggerated advertising, objective-truth-not-proven advertising and advertising with contents in violation of public orders and morality (collectively, ‘exaggerated advertising’) were subject to orders for suspension or correction from the relevant prefectural governor but only subject to penalties in violation of such orders (so called ‘indirect penalties’). In any event, if there was a threat of false or exaggerated advertising, the prefectural governor was entitled to request the submission of a report and to have its officials enter and inspect the sites. Advertising on the websites of medical institutions was not treated as ‘advertisement’, which was prohibited under the Medical Care Act, and therefore no penalties were imposed on the violation of the Guidelines for Home Pages of Medical Institutions.

However, because numerous consumer problems related to aesthetic medical services arose from advertising on the medical providers’ websites, the 8th Revision defined advertising under both items (1) and (2) above as statutory ‘advertisement’ subject to direct penalties
for false advertising, indirect penalties for exaggerated advertising (to which definition the 8th Revision added advertising by use of patients’ experiences on a subjective or hearsay basis and advertising by use of misleading pictures before and after medical treatments), and site inspection by the relevant prefectural governor. The 8th Revision also clarified the limited cases that are not subject to the aforementioned limitations on advertisement, taking into account medical treatments that are not covered by the NHIS or other information that patients need to know. The Guidelines for Home Pages of Medical Institutions were integrated into the Guidelines for Advertisements on Medical Services on 1 June 2018.

Healthcare providers and their commissioned advertising agencies and affiliate marketers may also be subject to other advertisement regulations under other laws of more general application, such as the Act against Unjustifiable Premiums and Misleading Representations, the Pharmaceuticals and Medical Devices Act,9 the Health Promotion Act, and the Act on Unfair Competition Prevention.

**Restrictions on marketing and promotion activities toward healthcare providers and professionals**

Medical institutions and universities (including healthcare professionals) not only buy from pharmaceutical and medical device companies, but also collaborate with these companies for medical and pharmaceutical research, safety measures, and reliefs from adverse drug reactions, and arrangements are often accompanied by monetary payments in return for their contribution.

The MHLW and the Pharmaceuticals and Medical Devices Agency10 are the principal regulatory authorities under the Pharmaceuticals and Medical Devices Act. In addition, the Fair Trade Commission and the Consumer Affairs Agency oversee those relations through the relevant self-regulatory organisations11 pursuant to the Fair Competition Code Concerning Restrictions on Premium Offers in the Ethical Pharmaceutical Drugs Marketing Industry and the Fair Competition Code Concerning Restriction on Premium Offers in the Medical Devices Industry, both of which are based on the Act Against Unjustifiable Premiums and Misleading Presentation.12

At an industry self-regulation level, pharmaceutical and medical device companies have made efforts to make such relations more transparent through their industry associations and industry regulations based on high ethical standards. These industry regulations include corporate activity charters, compliance programme guidelines, codes of practice, promotion codes and transparency guidelines. It should be noted, however, that these industry regulations are not legally binding and violations thereof are not penalised.

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9  The Act on Ensuring Quality, Efficacy and Safety on Pharmaceuticals, Medical Devices, Etc.
10  It is an Incorporated Administrative Agency sponsored by the MHLW, engaged in approval reviews, safety measures and health damage control in relation to pharmaceuticals, medical devices and regenerative pharmaceutical products.
11  They are the Fair Trade Council of the Ethical Pharmaceutical Drugs Marketing Industry, and the Fair Trade Council of the Medical Devices Industry. These further consist of member organisations, such as the Japan Pharmaceutical Manufacturers Association (JPMA) and the Japan Federation of Medical Devices Association (JFMDA).
12  For instance, the provision of food and drink to healthcare providers and professionals is permissible to the extent that it is not determined to be an ornate or excessive method for inducing the selection or purchase of pharmaceuticals or medical devices under socially accepted standards. There are safe-harbour rules, however, such as ¥5,000 (excluding consumption taxes) per person not being determined as such method.
Some groups within the MHLW are pushing to partially elevate such industry self-regulations into official MHLW notifications that are subject to ‘indirect penalties’ if violated.  

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

Discussed below are possible solutions currently being considered or in progress to the hot issues pointed out in Section I above.

Uneven distribution of physicians in regional areas and among departments

A bill for amendments to the Medical Care Act and the Medical Practitioners Act was submitted to the Diet in March 2018 and if enacted, will be enforced on 1 April 2019 or 2020. The main features of the bill are:

a Introduction of a new system on MHLW’s accreditation of physicians with certain working experiences in regional areas facing a shortage of physicians, as managers of ‘regional medical care support hospitals’;

b Establishment of ‘plans to procure physicians’ in the ‘Medical Care Plans’, based on a PDCA cycle by prefectural governors, and enhancement of the cooperative functions of councils for regional medical services in prefectures;

c Reinforcement of measures for procuring physicians through training programmes, including having regional quota for admissions to medical schools in universities; and

d Promotion through conferences and setting up of policies for functional differentiation and cooperation among healthcare providers and professionals inside and outside of each medical service area.

Ageing and deterioration of medical facilities

Solutions to ageing and deteriorating medical facilities include complete reconstruction and large-scale repairs (including renovation for earthquake-resistant structures) of these facilities. We anticipate that these necessary repairs or construction will be financed primarily through debt financing by the Welfare and Medical Service Agency or other financial institutions and secondarily through asset financing, rather than equity funding, because of the low return on investment due to the non-profit status of medical practice.

As to asset financing such as securitisation of real estate for hospitals, on 26 June 2015 the Ministry of Land, Infrastructure and Transport issued the ‘Guidelines Concerning REITs Investing In Real Estate For Hospitals’, which took effect on 1 July 2015. The guidelines were issued after discussions with various interested parties including the MHLW and the Japan Medical Association (JMA) and placed importance on healthcare business operators and

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13 See ‘Report on FY 2016 Surveillance Activities of Advertisement and Promotion of Pharmaceutical Drugs’ prepared by the Compliance and Narcotics Division, Pharmaceutical Safety and Environmental Health Bureau of the MHLW.

14 This is an Incorporated Administrative Agency sponsored by the MHLW, which provides low-interest long term loans to private social welfare institutions (e.g., intensive care homes for the elderly, support facilities for persons with disabilities, and nurseries) and private medical institutions (e.g., hospitals, clinics and long-term care facilities) for construction, maintenance and operation of facilities.

15 It is the largest physicians’ organisation, consisting of approximately 167,000 members from 47 prefectural medical associations in Japan.
internal management systems in the licensing requirements for asset management companies of REITs. It bears mentioning that the securitisation of hospital real estate essentially requires a separation of the ownership of fundamental assets and the operation of the healthcare business, which is different from the traditional view by originators of hospital real estate that medical assets should be owned and operated by medical practitioners.

Despite the said guidelines, however, there has not been much progress in investments in hospital real estate so far. The first deal made by a healthcare REIT listed on the Tokyo Stock Exchange was the acquisition by Healthcare and Medical Investment Corporation of Niigata Rehabilitation Hospital by purchasing trust beneficial interest on 10 October 2017. But no other listed REITs have acquired hospital real estate since, and it seems private REITs that are preparing to acquire hospital real estate have not been listed yet. In our view, one reason is that the JMA continues to be vigilant against the entry of ‘funds’ that represent for-profit entities, which are inconsistent with the non-profit status of the medical practice. This approach creates anxiety among healthcare business operators about the possible discontinuation of their business because of the loss of hospital real estate in the event of non-payment of rent.

New approaches to connect the healthcare industry and the ‘fund’ industry are crucial. These approaches include (1) eliminating the old-fashioned view that the ownership of hospital assets and the practice of medicine should be one and the same, (2) encouraging healthcare business operators to establish and implement a more enhanced and transparent governance system, and (3) encouraging ‘fund’ investors not to seek excessive returns through ‘ESG investing’, ‘SRI’ or ‘impact investing’.

Family-oriented governance of medical corporations

On 2 April 2017, Japan started a new corporate system called ‘Corporations Promoting Regional Medical Cooperation’ under the 7th Revision. Under this system, general incorporated associations that meet certain criteria may be accredited by prefectural governors as ‘Corporations Promoting Regional Medical Cooperation’. These criteria include (1) establishing a policy of providing functional differentiation of, and cooperation among, healthcare services within a healthcare service area and (2) engaging in activities involving non-profit organisations who agree with the said policy and participate in meeting hospital bed quota and cooperative purchasing of pharmaceuticals and medical devices, exchange of personnel, and R&D among those organisations.

However, as of 1 April 2018, there are only six such accredited corporations. Of those, a corporation called Japan Sea Healthcare Net Corporations Promoting Regional Medical Cooperation was accredited on 1 April 2018. This corporation is unique in that it is managed by an independent administrative agency that was established in April 2008 as a result of a merger of two hospitals that were sponsored by different local governments. This merger represents a ‘hard-type’ business integration initiated by medical organisations that are sponsored by and reliant on local governments. It bears studying whether that kind of ‘hard-type’ business integration will become a preferred choice of local-government-
sponsored medical organisations, given that, according to the latest survey reports, approximately 90 per cent of them were in deficit without local government funding and ‘hard-type’ business integration may be unavoidable.

On the other hand, for private medical corporations, we expect that ‘soft-type’ solutions will be more easily employed than ‘hard-type’ solutions because the integration of varied human resources and payroll systems generally takes considerable time and effort. These soft-type solutions include (1) business alliances or management integrations of medical corporations and (2) M&A transactions where the purchaser acquires controlling power (and if the target is a medical corporation with equity, the purchaser also acquires the equity).

We also expect that, like many other legal entities in Japan, medical institutions will start enhancing their governance systems such as safety, compliance and whistle-blower systems.

**New industrial technologies**

The most recent major amendments to the primary data protection law in Japan, the Act on the Protection of Personal Information (APPI) completely came into effect on 30 May 2017. The amended APPI strictly restricts the utilisation of patients’ medical history and other sensitive information referred to as ‘special care-required personal information’. In this regard, a special but related law, the Act on Anonymised Medical Data to Contribute to R&D in the Medical Field came into effect on 11 May 2018 with the aim of balancing industrial needs and privacy protection. Another recent law, the Act On Clinical Research, which came into effect on 1 April 2018, safeguards the quality of, and protects data subjects in, certain types of clinical research called ‘Specified Clinical Research’, by requiring the researchers to comply with certain clinical research standards, submit research implementation plans and be reviewed by certified clinical research review committees, and by requiring the marketing authorisation holder to disclose conflicts of interest arising from the provision of research grants.

It is hoped that these new laws, which aim to address issues arising from new industrial technologies, will not only create legislative and administrative regulations but also strengthen self-regulation and cooperation between the non-profit healthcare industries and the for-profit industries.

**Possibility of inbound or outbound investments into or from, or business partnerships with, healthcare providers**

Inbound investment by foreign entities by way of contributions in medical corporations in Japan is not likely to be permissible in the near future. The JMA has taken the view not only that profit organisations should not have any controlling power over medical corporations but also that foreign entities should not have such power.

Inbound investment by way of shares of peripheral profit companies (usually family-owned companies) is possible under certain procedures under the Foreign Exchange and Foreign Trade Act, except where national security is affected. In any case, M&A

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16 One of them is the Summary of Survey Analysis Report on Hospital Management Conditions 2017 (Survey on June 2017) jointly prepared by the Japan Hospital Federation and the Japan Hospital Association on 1 March 2018.
purchasers who have their own R&D or commercial activities that involve medical practice in Japan must have the necessary licence under the Medical Practitioners Act before they may perform medical acts on legal residents in Japan.

On the contrary, outbound investments by Japanese medical corporations into shares of foreign medical entities are permissible, subject to compliance with notifications issued by the MHLW, as long as (1) their overseas operations will not adversely affect their original business of running hospitals, clinics, long-term-care health facilities or long-term-care medical centres, (2) the aggregate investments in local entities are within their retained earning reserves on their latest balance sheet prepared in accordance with the ‘Medical Corporation Accounting Standards’, and (3) they make prescribed prior and periodic reports to the MHLW.

X CONCLUSIONS

The world has been watching Japan as it faces enormous and unprecedented challenges in healthcare ahead of any other country because of Japan’s twin population problems of inevitable ageing and persistent population decline. As Japan continues to confront and overcome these mounting and increasing difficulties, the medical, healthcare, nursing care and related industries will need the ever increasing and ever crucial support, resourcefulness and initiative investors, innovators and professionals, including lawyers, especially in the context of M&A, financing, governance, restructuring and rehabilitation to navigate the growing needs of Japan’s citizens.

17 See ‘Regarding Overseas Operation of Medical Corporations’ (Notification No. 0420 (7th) of 20 April 2016 Issued by the Chief of the Health Policy Bureau of the MHLW).
I OVERVIEW

The healthcare industry of South Korea is mainly governed by the Ministry of Health and Welfare (the MOHW) and the Ministry of Food and Drug Safety (the MFDS). These governmental authorities are concerned with the healthcare service at large, including the enforcement of healthcare-related laws and regulations, administrative review of healthcare professionals, certification of medical institutions, mediation of medical disputes, sanctions on illegal rebates involving pharmaceutical products and medical devices, national health insurance, pricing and reimbursement, safety management of pharmaceutical products and medical devices, and the overall management of clinical trials. The MOHW and the MFDS work together with related organisations, including the National Hospital, the National Health Insurance Service (the NHIS), the National Medical Center, the Korea Institute of Drug Safety and Risk Management, and the Health Insurance Review and Assessment Service (HIRA).

Healthcare services can be provided by a variety of healthcare providers, including clinic-level medical institutions and hospital-level medical institutions, and citizens can choose the providers from which they wish to receive their healthcare services. The licensing, establishment and operation of healthcare providers are also governed by the MOHW and the MFDS pursuant to relevant laws and regulations.

The National Health Insurance is the central component of the operation and funding of healthcare services in South Korea. Under the National Health Insurance system, insurance enrolment and payment of insurance contribution is mandatory, and the amount of insurance contribution is determined based on the respective income level of the insured.

II THE HEALTHCARE ECONOMY

i General

Healthcare related laws in South Korea include (1) the Pharmaceutical Affairs Act (PAA), (2) laws and regulations relating to medical devices, (3) the Medical Service Act (MSA) and (4) the laws and regulations relating to health insurance.

There are various stakeholders involved in the healthcare industry in South Korea, which include:

a medical institutions;

b healthcare professionals;

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1 Soon-Yub Samuel Kwon and Eileen Jaiyoung Shin are both partners at Lee & Ko.
The roles played by the various government authorities in relation to the National Health Insurance are as follows.

**a. The MOHW:** The MOHW is ultimately responsible for making policy decisions regarding the National Health Insurance system. For example, the MOHW determines the insurance contribution rate, the standards for imposition of insurance contribution, and the scope of healthcare benefits subject to insurance, and approves the budget and regulations of the NHIS, which is the authority managing and operating the National Health Insurance system.

**b. The NHIS:** As the insurer of the National Health Insurance, the responsibilities of the NHIS include:
- the management of qualification criteria of health insurance subscribers and their dependants;
- the imposition and collection of insurance contribution;
- the management of insurance benefits;
- the implementation of national health check-ups, disease prevention and health promotion related work;
- payments to medical institutions;
- the determination of drug prices through negotiations with pharmaceutical companies; and
- the execution of pricing contracts with pharmaceutical companies.

**c. HIRA:** The responsibilities of HIRA include (1) the assessment of medical care costs and the appropriateness of the healthcare benefits and (2) the development of such review and assessment criteria.

**d. The Health Insurance Policy Deliberative Committee:** As a committee under the MOHW, the Health Insurance Policy Deliberative Committee makes decisions on long-term comprehensive planning for the National Health Insurance system, the implementation, timing and method of such comprehensive plans, and the various standards applicable to benefit qualifications and the level of insurance contributions and benefits.

**ii. The role of National Health Insurance**

**National Health Insurance under the National Health Insurance Authority**

The National Health Insurance programme in South Korea is a public insurance system that spreads the burden of medical expenditure to all residents under the mandatory National Health Insurance coverage. The resources required to run the National Health Insurance programme are derived from insurance contributions paid by the insured and their employers (as applicable), government subsidies and other income (such as fees for delinquent payments and other penalties).

The National Health Insurance programme is governed by the National Health Insurance Act and the key features of this statute are as follows:
the National Health Insurance programme is compulsory when certain legal requirements are met, and the payment of insurance contribution becomes mandatory;

- insurance contribution is imposed based on the capability to pay the contribution, such as the income level;

- regardless of the level of insurance contribution, the insurance benefits are paid equally with regard to the scope and level of insurance coverage.

Non-resident foreign patients are not eligible for National Health Insurance coverage under the National Health Insurance Act.

**Medical benefits**

The medical benefits system is a public assistance system that provides support with respect to medical problems of low-income citizens. It is a social security system that works together with the National Health Insurance system to support public health. Specifically, the medical benefits system is under the responsibility of the MOHW, and provides medical cost assistance to the low-income class pursuant to the Medical Care Assistance Act.

In principle, the medical benefits system provides support for medical expenses for items specified in the National Health Insurance Medical Benefits Criteria published by the MOHW. Certain co-payment requirements may apply as well as restrictions on the number of days during which medical benefits or treatment procedures can be received.

**Private insurance**

Citizens may also enroll into private insurance in addition to the National Health Insurance system. Private insurance differs from public insurance in that (1) enrolment is optional, (2) insurance contribution is imposed by the private insurance provider based on their risk analysis, (3) insurance benefits are paid differently based on the level of insurance contribution of the insured, and (4) the insurance contribution is collected pursuant to private contracts rather than by requirement of laws and regulations. In South Korea, insurance companies offer a variety of insurance products, such as cancer insurance, death insurance and co-pay expense insurance.

**Funding and payment for specific services**

Under the National Health Insurance system of South Korea, the insured usually pays a part of the healthcare expense as co-payments, and the insurance proceeds are reimbursed directly to the medical institutions and pharmacies that provide healthcare services to insured patients. The co-payment rate of the insured is affected by multiple factors, such as, the type of treatment (for example, inpatient service or outpatient service) and the identity of the medical facility providing the treatment.

Certain treatments are non-benefit items, which are not covered by the National Health Insurance programme. These include medicine, medical material, or medical service that is provided or used for a disease that does not seriously affect a patient’s daily life, and residents must pay for the cost of such non-benefit items, either personally or through enrolment in private insurance. Medicine, medical material or medical service that does not improve essential bodily functions, such as cosmetic surgery, freckle treatment and snoring treatment, are examples of non-benefit items that are not covered by the National Health Insurance programme.
III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

i Classification of medical institutions

Medical institutions are classified as follows:

a Clinic-level medical institution:
- outpatient care for simple and common diseases;
- patient care for those who do not need to be hospitalised for a chronic disease requiring long-term treatment;
- simple outpatient surgical operation or treatment; and
- treatment of patients who have returned after treatment of general care at a general hospital or tertiary hospital (advanced-care general hospital).

b Hospital or general hospital:
- general hospitalisation and surgical treatment;
- patient care that requires more specialised management by area;
- patients with chronic disease requiring long-term care and hospitalisation;
- patients who have been hospitalised at the medical institution concerned and need direct observation of progress at such medical institution after discharge; and
- medical treatment for patients requiring long-term hospitalisation.

c Tertiary hospital (advanced-care general hospital):
- treatment of serious diseases that require highly specialised treatment techniques;
- treatment of patients with a condition carrying a high risk of mortality and complications;
- treatment for patients involving multiple medical specialty areas and the use of special facilities and equipment;
- treatment of patients with a rare or incurable disease;
- operation of specialised medical treatment centres for specialised medical services for severe diseases;
- treatment of patients who have been hospitalised at the medical institution concerned and need direct observation of progress at such medical institution after discharge; and
- performance of medical training of healthcare professionals and research and development of medical services.

Although, in principle, a patient should be transferred to a general hospital or a tertiary hospital pursuant to a referral from a physician at a clinic, there are no direct restrictions preventing a patient from initially visiting a general hospital or tertiary hospital without such referral from a clinic. That said, if the subject treatment is covered by the National Health Insurance, the patient’s copayment may increase upon such direct visit to a general or tertiary hospital.

ii Primary/family medicine

In Korea, a family doctor or individual doctor system is not prevalent. The proportion of specialists is very high, and doctors who open clinics are either specialists or those who practice medicine for only certain diseases. Therefore, patients choose their doctor according to their symptoms and receive primary care from the clinic with the relevant specialisation.

On the other hand, Korean medicines are classified as either over-the-counter drugs, which do not require the prescription of a doctor, or ethical drugs that require prescription
by a physician. Additionally, medicines can be sold only by pharmacists in principle; however, certain over-the-counter drugs designated as home emergency drugs under relevant regulations can be sold in 24-hour convenience stores.

### iii Social care

According to the Regional Public Health Act, public health centers are established in municipal units and form a part of government agencies. Doctors and nurses at these public health centers are in charge of vaccination, treatment and patient education in the local community. A patient must pay a prescribed fee in order to visit a public health center, but this fee is less than the cost of visiting a private clinic or hospital.

Medical assistance is provided to the low-income class pursuant to the Medical Care Assistance Act. If you are covered by the Medical Care Assistance Act, this fee for visits to public health centers may be exempted or discounted under the National Health Insurance Act.

### IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

#### i Regulators

The MOHW regulates the social welfare and healthcare systems through the enforcement of relevant laws, such as the MSA, the PAA, the Medical Care Assistance Act, the National Health Insurance Act and the National Basic Living Security Act. For reference, the government authorities working together with the MOHW include the MFDS, National Health Insurance Service, and the National Medical Center, and institutions under the MOHW include the National Hospital for each district, and the South Korea Centers for Disease Control and Prevention.

The MFDS enforces the PAA together with the MOHW, and the enforcement of the Medical Devices Act is also under the responsibility of the MFDS. Institutions under the MFDS include the Medical Device Information Support Center.

#### ii Institutional healthcare providers

**General**

According to the MSA, medical institutions in South Korea are classified under the following categories: (1) clinic-level medical institutions, (2) midwifery clinics and (3) hospital-level medical institutions. Clinic-level medical institutions consist of medical clinics, dental clinics, and oriental medical clinics, and hospital-level medical institutions consist of hospitals, dental hospitals, oriental medical hospitals, intermediate care hospitals and general hospitals.

On the other hand, if classified by function, medical institutions can be classified as general hospitals or advanced care hospitals, as explained above.

**Establishment of medical institution**

A healthcare professional cannot engage in healthcare service business without establishing a medical institution, and except for certain specified exceptions, all medical services must be performed within such medical institution. The qualification criteria of those who can open a medical institution in accordance with the MSA are limited. Medical institutions can be established only by licensed healthcare professionals, local governments or entities of public nature specifically permitted under the MSA.
The procedure for opening a medical institution can be roughly classified into filing a ‘report of establishment’ for medical institutions at the clinic level, and the application for an ‘establishment permit’ for medical institutions at the hospital level. Any person who intends to open a medical institution must file a ‘report of establishment’ or apply for an ‘establishment permit’, as applicable, to the relevant local municipality depending on the type of medical institution.

Prohibition on the establishment of medical institutions
Non-healthcare professionals are prohibited from establishing medical institutions. The penalty for violating this restriction may include the invalidation of relevant contracts and administrative as well as criminal sanctions.

iii Healthcare professionals
The MSA prohibits, in principle, any person who is not a healthcare professional from engaging in medical activities, and any medical professional from engaging in medical activities other than those for which they are licensed. A person who violates the above may be subject to criminal sanctions, and if a healthcare professional has caused a non-healthcare professional to perform medical activities, such healthcare professional may be disqualified. In order to become a healthcare professional, a person must pass a national examination and obtain a licence from the MOHW after completing their studies in the relevant healthcare field at a qualified institution.

The MSA and the Pharmaceuticals Affairs Act sets forth instances where a healthcare professional’s licence may be suspended or revoked. Grounds of suspension or revocation include the violation of relevant laws and regulations and ethical rules.

V NEGLIGENCE LIABILITY
i Overview
In the case of claims for medical negligence, case law provides that, in order to be liable for breach of the duty of care in medical practice, a causal relationship between the breach of duty of care in medical practice and the damages incurred must be found. Case law further provides that, in order to find such causal connection, the plaintiff has the burden of proving that: (1) medical malpractice has occurred and (2) there are no causes other than the medical malpractice for the resulting damage at case.

On the other hand, if a medical treatment may result in negative consequences to the patient, physicians have the obligation to explain the symptoms of the disease, the details of the treatment method and the necessity of the treatment and the risks associated with such treatment to the patient (or the legal representative of the patient), such that the patient is able to sufficiently compare the necessity or risks of the treatment and make an informed decision whether or not to receive the medical treatment. In the event of a serious negative consequence of a treatment for which the relevant physician failed to properly inform the patient, the physician may be liable for damages. In this case, if the patient claims only damages for the lost opportunity to make a choice, the patient is only required to prove that it had lost such opportunity because of lack of explanation by the physician. If the patient claims compensation for damages as a result of the serious negative consequence, the patient has to prove causality as well. In practice, patients are required to sign a prior consent form describing, for example, the details of treatment and the risks associated with the treatment.
ii Notable cases

Recently, there was a case in which a nine-year-old who visited an emergency room at a university hospital died because of the failure to receive an emergency blood transfusion and treatment from the paediatric haematologic tumour/paediatric neurology, and a case in which a celebrity died of perforation in the small intestine and pericardium in the process of receiving a gastrointestinal adhesiolysis. In the case of the former, civil and criminal lawsuits are both ongoing and final judgment of the Supreme Court is pending. In the latter case, the civil lawsuit is still in progress, but the criminal lawsuit was concluded by the Supreme Court decision in May 2018, in which a sentence of one year’s imprisonment by the trial court was confirmed by a finding of professional malpractice resulting in death.

As a result of the above cases, issues relating to the dispute procedure for medical accidents were raised, and in consequence, an amendment to the Act on Remedies for Injuries from Medical Malpractice and Mediation of Medical Disputes was passed. Pursuant to the amended Act on Remedies for Injuries from Medical Malpractice and Mediation of Medical Disputes, effective as of 30 November 2016, if the medical accident results in death or unconsciousness for more than a month, the mediation process will be initiated regardless of the consent of the hospital.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

i Medical institutions

Both private parties and public parties (entities) can establish medical institutions such as hospitals and dental clinics, but as above-mentioned, the qualifications of those who can establish medical institutions are limited pursuant to the MSA. In other words, medical institutions can be established only by licensed healthcare professionals, local governments or entities of public nature specifically permitted under the MSA.

ii Pharmacies

Similar restrictions apply to pharmacies. That is, according to the PAA, no person, other than pharmacist or oriental medicine pharmacist, can establish a pharmacy. According to the above provision, it can be construed that only a pharmacist or oriental medicine pharmacist who is a natural person can open a pharmacy and that a corporation or an entity cannot open a pharmacy. In this regard, the Constitutional Court explained that, while the above provision does not permit the establishment and operation of a pharmacy by a general person or regular corporation who is not a pharmacist, the prohibition of establishing a pharmacy even to a corporation whose members are all pharmacists unduly violates the freedom of occupation of such pharmacists. However, despite this decision of the Constitutional Court, it is still controversial whether a corporate pharmacy is permitted.

VII COMMISSIONING AND PROCUREMENT

In Korea, all citizens are enrolled in National Health Insurance, and all medical institutions must provide medical services under this National Health Insurance system. However, there are also medical services that are not covered by the National Health Insurance. In the case of these services, (1) the patient directly pays or (2) a private insurer will bear the costs if the patient has private health insurance coverage. However, in the case of the medical
services covered by the National Health Insurance system, the patient pays a small amount of co-pay to the medical institution and the remaining amount is paid directly to the medical institution by the National Health Insurance Corporation. In the case of medical services covered by National Health Insurance, the price is controlled by the state, and although prices are determined through consultation between the state, medical organisations and civil groups, there is always a conflict among the respective interests of stakeholders.

Also, in the case of medicines that the patient purchases or that which is prescribed according to a physician’s prescription, the benefits are provided according to the National Health Insurance Act. Whether or not the drug can be covered by the National Health Insurance is determined by the Health Insurance Review and Appraisal Center, and drug prices are determined based on negotiations between the National Health Insurance Corporation and the relevant pharmaceutical company. Because drug prescription is not practicably possible unless covered by National Health Insurance, the original drug manufacturer pays great attention to National Health Insurance coverage and pricing negotiation. For reference, Korean drug prices are usually determined at less than 75 per cent of the OECD average price.

VIII MARKETING AND PROMOTION OF SERVICES

i General
In South Korea, marketing and promotion of healthcare services and products are mainly regulated by the MSA, the PAA, the Medical Devices Act (the MDA) and supervised by the MOHW and the MFDS. In addition, the Fair Labelling and Advertising Act that governs advertising activities in general and the Monopoly Regulation and Fair Trade Act that governs fair competition in the market, both of which are supervised by the Korea Fair Trade Commission (the KFTC), may also apply.

ii Medical services advertisement
The MSA prohibits advertising of medical services of a non-healthcare professional or non-medical corporation/institution. In addition, advertisements consisting of the following are prohibited: (1) guaranty of treatment effect, (2) comparison of the quality of treatment with treatments by other medical institutions or professionals, (3) criticism of other medical institutions or healthcare professionals, (4) direct exposure of treatment process and (5) omission of important information. Further, if a medical institution or healthcare professional intends to advertise using newspapers, outdoor advertisements, electronic signboards, etc., such person or institution needs to obtain prior review from the MOHW regarding the content and method of the advertisement.

iii Pharmaceutical advertising
In the case of pharmaceuticals, the PAA prohibits false advertising or exaggerated advertising regarding the name, manufacturing method, effectiveness of the pharmaceutical product. In addition, the advertising of products that have not obtained MFDS approval, the use of news articles or media publication that may be misunderstood as providing a guarantee of the effectiveness of the drug by a healthcare professional, and the advertisement using photographs or articles that suggests effectiveness or performance are all prohibited.
Furthermore, when a manufacturer, importer or the market authorisation holder of a pharmaceutical product intends to advertise the pharmaceutical product manufactured or imported by such person, review and approval of the advertisement by the MFDS is required. Finally, in the case of ethical drugs, direct-to-consumer advertising is prohibited.

iv Advertisement of medical devices
The MDA regulates the advertising of medical devices. Specifically, the following information should not be indicated anywhere on the product or its packaging: (1) any false or misleading information, (2) information on the effectiveness or performance of the product for which approval or certification has not been obtained and (3) information on the method of use or period of use that may cause health or hygiene issue. The following types of medical device advertisements are also prohibited: (1) false or exaggerated advertising of the name, manufacturing method, effectiveness or performance of the medical device, (2) advertisement that uses news articles or media publication that may be misunderstood as suggesting that a healthcare professional is guaranteeing or recommending the medical device in relation to its effectiveness or performance and (3) advertisements which use articles, photographs or drawings that suggest performance or effectiveness of the medical device. Those who wish to advertise medical devices are required to obtain review from the MFDS.

v Marketing activities of pharmaceuticals and medical devices
Unless specifically permitted by the PAA or the MDA (such as sample provision, clinical trial, post-market surveillance, product presentation, sales call, sponsorship of academic congress or otherwise), the provision of hospitality or economic benefit for marketing purposes is prohibited.

The MOHW has the general authority under the PAA, the MDA and the MSA to regulate these marketing activities. However, the KFTC can investigate pharmaceutical companies, medical device companies and healthcare professionals under Article 23 of the Monopoly Regulation and Fair Trade Act, which prohibits unfair inducement of customers, such as the provision of kickbacks. In addition, given that certain criminal sanctions can be imposed, the Prosecutors’ Office can also conduct an investigation into these activities.

If a pharmaceutical company or medical device company provides undue economic benefit to healthcare professionals, administrative sanctions (which may consist of revocation of product approval of the drug or medical device at issue) or criminal sanctions can be imposed. Healthcare professionals who are provided with such illegal rebate are also subject to criminal penalties and the economic benefits obtained via such rebate must be disgorged, and where disgorgement is not possible, the equivalent amount must be paid.

vi K-Sunshine Act
The PAA and the MDA have been amended to adopt record-keeping requirements similar to the US Physician Payments Sunshine Act. Under the amendments, drug providers (including market authorisation holder, importer, wholesaler of drugs) and medical device providers (including manufacturer, importer, seller or lessor of medical device) are now required to keep records of economic benefits given to medical institutions and healthcare professionals beginning 1 January 2018 (regardless of when their accounting year begins) through sample provision, clinical trial, post-market surveillance, product presentation, sales call, sponsorship
of academic congress or otherwise. Companies must maintain such records for five years. Companies must maintain a template expense form prepared by the MOHW for each expense item and must submit such records to the Ministry upon request.

IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

The South Korean government released the Health Insurance Protection and Enhancement Measures in August 2017 aimed at raising the National Health Insurance coverage rate from approximately 60 to 70 per cent. To this end, the government has considered converting non-salaried employees into salaried persons, mitigating the medical burden of vulnerable groups such as the elderly, children and women, and institutionalising disaster-related medical expenses support and expanding the target of health insurance. The necessary funding is planned to be covered by the cumulative reserve of health insurance contribution and the increase of contribution rates. However, there is a view that that medical expenditure may increase more than expected considering the increase in the use of medical services when the patients’ own burden falls. And in this regard, the predominant view is that effective management of medical expenditure and the reorganisation of the medical payment system must accompany the change to the health insurance system.

Recently, the MOHW announced an amendment proposal that includes an expansion of the coverage of National Health Insurance to include epigastric ultrasonography. However, many stakeholders have differing views with respect to such expansion of coverage, and as such, it is uncertain whether this amendment proposal will be signed into law.

X  CONCLUSIONS

The healthcare industry of South Korea is an industry in which government regulations affect various aspects of the industry, such as National Health Insurance coverage, commercial activities and advertising. As such, there are many cases in which regulations change according to government policy, and as a result, conflicts among stakeholders such as healthcare professionals, patients, the NHIS and the government authorities often arise. As discussed above, various issues relating to the current healthcare system, including dispute resolution in case of medical accidents and the scope of health insurance coverage, are being discussed, and as a result, the healthcare system of South Korea may change considerably in the near future.
Chapter 11

MEXICO

José Alberto Campos-Vargas

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, and is expected to slightly increase for this year.

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.

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 authority to issue regulations that clarify or specify existing laws passed by Congress, and specifically 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

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

Additionally, medical and health-related services are also subject to Mexican Official Standards (NOMs), administrative guidelines establishing technical specifications and characteristics for 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 the 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), a programme developed to render health services for specific maladies to those outside 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.

Particular attention has been given during the last couple of years to health services rendered through telemedicine services, which although not well regulated, has provided the possibility to grant individuals living in isolated communities with better medical and health services, as well as incarcerated individuals. The operation of these telemedicine services is operated not only by the MH but also by the IMSS, ISSTE, SEDENA and the Mexican Oil Company (PEMEX).
ii  The role of health insurance

Insurance is compulsory to users of healthcare services who are employees, as employees, together with their employers, must contribute certain amounts to the public institutions that render health services (the 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;

d. social welfare; and

e. other health-related 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 drugs and medicines required by patients.

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

Individuals covered by private insurance are subject to the benefits and coverage contracted and agreed with the insurance company.

iii  Funding and payment for specific services

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

For individuals covered by ISSSTE, SEDENA and SEMAR, the employer is the government itself, whereas in the case of private individuals and entities, 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 agreed amounts and concepts.

Public health coverage only includes 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, and although not formally forbidden, in most cases, are not recognised, nor do they receive public approval or coverage.

III  PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

There are approximately 25,000 premises registered to provide health services, of which approximately 4,500 are hospitals (1,200 public institutions and 3,200 in 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.

Receiving the necessary health services from public institutions is 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, and based upon it a physician determines if the patient requires specialised analysis, tests and procedures, or whether he or she can provide the applicable treatment and medicines.

The patient will be required to schedule the visits to the specialist doctors and laboratory or analysis procedures needed, which may take months to complete.

This system is inefficient and time-consuming, resulting in an untimely rendering of the required treatment and medicines, having direct impact on the patient’s health. Because of the lack of proper infrastructure and equipment, it is not possible to render the required services in all premises operated by public institutions, being necessary for patients to receive such services in premises away from their domicile or in Mexico City. This situation may be corrected through a greater use of telemedicine services.

Public institutions professionals are restricted in the scope of their activities by three main legal bodies: the Health Law, the Services Regulations and the Professional Practice Law. However, these are 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, only authorised to carry out the specific services and procedures included in the corresponding licences and authorisations, thus it is not 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 as are included in NOM-004-SSA3-2012 – that 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, implements, coordinates, verifies and controls 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.

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

These services regulations 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.

Generally, 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. Currently, a Sanitary Alert regarding premises where cosmetic procedures are carried out has been issued by COFEPRIS, and over 250 premises where these kind of services are rendered were subject to administrative procedures bound for their foreclosure.

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 the 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.

iii 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 requires 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, orthopaedics, 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 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 be required to file a technical and an economic proposal that will be analysed and, as the case may be, awarded.

Under this Law, the 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 expenditure by the authorities being the 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. Because 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 OECD 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.

Obesity and diabetes are considered as an epidemic that affects 33 per cent of the child population and at least 72.5 per cent of the adult population in accordance with the National Institute for Public Health. As this is such an epidemic, the authorities and private sector have implemented programmes to avoid obesity and being overweight, including the National Strategy for the Prevention and Control of Overweight and Obesity, which intends to change processes and principles within the public health services and sanitary regulations through the promotion of a healthy lifestyle, education campaigns and monitoring of maladies associated with this problem, federal education reform regarding nutrition in education institutions, an increase in the population’s physical activity and sports, creation of the Center for the Attention of Diabetic Patients, and the implementation of the ‘nutritional quality’ stamp for food products with high nutritional quality.

Likewise, diverse premises bound for the attention of diabetes have been opened in the country, providing advice and treatment to individuals with this sickness in a gratuitous manner in connection with internal medicine, psychology, nephrology, cardiology, ophthalmology, nutrition, etc.

The private sector has also participated in these efforts through the creation of the Nutrition Health Alliance that has proposed specific actions bound to be included in a General Law Against Overweight and Obesity that will control special programmes and integral policies in this area.

In connection with rare diseases, Mexico now has 24 hospitals authorised for treatment of 14 of the most common of these maladies, out of the 7,000 rare diseases worldwide.

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 3,669.

The reported number of chikungunya cases was 722 during 2016, according to the 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.
NEW ZEALAND

Jonathan Coates, Aisling Weir and Andrea Lane

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.

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.

In May 2018, Health Minister Dr David Clark announced a major review designed to future-proof New Zealand’s health and disability sector. An interim report is due in July 2019, with the final report due in early 2020.

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. Under the previous centre-right National government, the
New Zealand

amount New Zealand is spending on its public health system dropped to around 6 per cent of GDP. In its first budget, the new Labour-led coalition government has increased health spending by NZ$2.2 billion.

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.  

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. 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. 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).

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5  Paterson, see footnote 2, at [1.2.1(2)].

6  See the NZPHD Act, Section 48(a).
Services that are not subsidised include optometry, orthodontics and most adult dental care.

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

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, particularly since the 2018 budget, where the Labour-led coalition government introduced initiatives to extend eligibility and access to subsidised services.

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.

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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. Because 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).
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). This is not expected to change with the new Privacy Bill, introduced to Parliament in March 2018.

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.

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.

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11 This legislation is predominantly comprised of the Privacy Act 1993, the Health Information Privacy Code 1994 and parts of the Health Act 1956.

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.
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.

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. In order to gain (and retain) certification, these providers must meet relevant service standards and are audited for compliance. If the provider does not meet the requisite standards, their certification may be cancelled or a cessation or closure order issued.

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. A licensing regime also governs providers that use ionising radiation for medical purposes.

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.

### iv 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

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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.

14 See the Health and Disability Services (Safety) Standards Notice 2008 and the Health and Disability Services (Safety) Standards Notice 2010.

15 HDSS Act 2001, Sections 48 and 49.

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 June 2018, drafting of the Therapeutic Products Bill continued to progress, although the 2017 election and resulting change of government has had an impact on the time lines for the consultation phase.

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.
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. 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; although even non-registered health professionals will need to comply with the HDC Act and the Code of Rights.

Once registered, healthcare professionals must work within a prescribed scope of practice when performing a healthcare service that is part of their profession and obtain and maintain an annual practising certificate while doing so. 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.

V NEGLIGENCE LIABILITY

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 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. 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.

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18 See HPCA Act, Section 7.
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.
20 See HPCA Act, Section 8.
21 Ibid.
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.
or provider organisation in the Human Rights Review Tribunal (HRRT). 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 and NZ$15,000).

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; a decision holding that the delivery of a stillborn baby was a personal injury to the mother; 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).

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) 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’. 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.

Another case that has been influential is the decision in Baigent’s case, 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.

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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/.
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 NZS10,000 were awarded against a psychiatrist who engaged in a sexual relationship with a vulnerable and former patient; R v. Eade DC Auckland NP3604/97, 12 May 2000, where NZ$27,500 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 NZ$85,000 in exemplary damages was made against a doctor, although this involved private rather than professional conduct (spousal abuse and violence).
Since that decision, public law damages have been successfully sought against government entities in a number of cases involving personal injury, but unsuccessfully in a claim relating to risperidone treatment provided by a DHB.  

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 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).

The Medicines Act 1981 establishes a licensing regime for pharmacies and imposes significant restrictions on the ownership of pharmacy businesses. 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; 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; and prescribers are generally not permitted to hold interests 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. Finally, pharmacy

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34 PF v. Capital and Coast District Health Board [2013] NZHC 1792.
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 55F.
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.

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. 46 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) 47 along with a range of generic business and public sector statutes. 48 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

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.
other countries no less favourably than New Zealand suppliers\textsuperscript{49} 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.\textsuperscript{50} 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.\textsuperscript{51} There are various exceptions to this requirement, however, including where the procurement is of ‘health services provided by government for the public good’.\textsuperscript{52} Accordingly, a good proportion of the procurement of healthcare services by DHBs may not be undertaken using a publicly advertised, competitive process.

In the recent case of \textit{Attorney-General v. Problem Gambling Foundation of New Zealand},\textsuperscript{53} 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.

\section*{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\textsuperscript{54} 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.\textsuperscript{55} 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.\textsuperscript{56} There are also guarantees to provide services, where not otherwise agreed, for a reasonable price and within a reasonable time.\textsuperscript{57} 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);\textsuperscript{58} or (2) is a panacea or infallible. It also prohibits endorsements by doctors, nurses and pharmacists.\textsuperscript{59}

\begin{itemize}
\item[49] Rule 4(1).
\item[50] Rule 4(3).
\item[51] See Rule 13 and the definition section.
\item[52] 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).
\item[53] \textit{Attorney-General v. Problem Gambling Foundation of New Zealand} [2016] NZCA 609.
\item[54] Fair Trading Act 1986, Section 9.
\item[55] Fair Trading Act, Section 40.
\item[56] Consumer Guarantees Act 1993, Section 28 and 29.
\item[57] Consumer Guarantees Act 1993, Section 30 and 31.
\item[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.
\item[59] Medicines Act 1981, Section 58.
\end{itemize}
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.

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.60 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.61 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.62 In view of the need to provide healthcare services

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).
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.

On 29 May 2018, Dr David Clark, Health Minister in the new Labour-led government announced a wide-ranging review of the health system, aimed at future-proofing the sector. An interim report is due by the end of July 2019, with the final report to follow by 31 January 2020.

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 the minds of 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.

Potential opportunities and risks associated with rapidly emerging technologies forms part of the core considerations set out in the draft terms of reference for the current review of the New Zealand health and disability sector announced in May 2018.

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 are currently in the process of being introduced to support innovative and efficient practices, and to maximise the use of health practitioners’ skills. These changes include registered nurse prescribing and the commencement of a number of provisions that 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).63

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, although the 2017 election and resulting change of government has had an impact on the time lines for the consultation phase. 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

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63 The provisions bring the legislation that resulted from the Health Practitioners (Replacement of Statutory References to Medical Practitioners) Bill into force. This was an omnibus Bill which amending eight statutes. The first seven amendments commenced in January 2018. The final amendment will commence in November 2018.
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. The new Labour-led government’s 2018 budget has seen a funding boost for health, which has been met with approval by both the public and private health sectors. Money allocated to reduce surgical waiting lists in particular is likely to have a flow effect for the private sector.

Finally, health policy continues to be vigorously debated in Parliament. 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.

X CONCLUSIONS

The New Zealand healthcare system is largely stable. While there has been a change of government, there is unlikely to be wholesale changes over the coming year.

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.

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.

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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.
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.2

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.3

The Ministry of Health is responsible for issuing the National Health Plan4 and the National Strategy for Quality in Health.5 Five regional health authorities (ARS) (which are public entities and 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.

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1 Francisco Brito e Abreu is a partner and Joana Mota is a managing associate at Uría Menéndez – Proença de Carvalho. The authors would like to acknowledge the contribution of their colleagues José Maria Rodrigues (senior associate), Rita Canto e Castro and Sebastião de Carvalho Lorena (both trainee lawyers) in the preparation of this review.
2 Article 64 (2) of the Constitution of the Portuguese Republic.
3 The organisation chart of the Ministry of Health: www.sns.gov.pt/institucional/entidades-de-saude/.
5 The main guidelines of the strategy: www.dgs.pt/ms/8/pagina.aspx?js=0&codigoms=5521&codigono=0203 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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, while it slightly decreased in 2016 to 1.22 million.

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, 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.

Healthcare services are also be provided, on a more limited scale, by non-profit private operators with a charitable background, known as Holy Houses of Mercy. Anyone can access the healthcare services provided by the Holy Houses of Mercy (e.g., hospitals, Clinics of Physical Medicine and Rehabilitation, etc.), as they have agreements with both the SNS, as well as with health subsystems and insurers. In the case of agreements with the SNS, the Holy Houses of Mercy have agreements with the Ministry of Health for the provision of healthcare services also be provided, on a more limited scale, by non-profit private operators with a charitable background, known as Holy Houses of Mercy.
healthcare services, integrating them into the national healthcare network. In the case of subsystems (e.g. ADSE) and insurers, the user will have to be a beneficiary of one of these subsystems and the Holy Houses of Mercy must have an agreement in place with them to allow these beneficiaries to access healthcare services. There are currently 23 hospitals, 120 nursing homes, and other healthcare activities managed by the Holy Houses of Mercy.\(^{10}\)

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.\(^{11}\)

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.\(^{12}\)

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 entities in Portugal, profit and non-profit, 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.

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\(^{10}\) https://www.ump.pt/Home/uniao/areas-de-atuacao/linhas-de-servico/grupo-misericordias-saude/


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.

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, setting a fixed fee for consultations (primary care and hospital outpatient visits), emergency visits, home visits, diagnostic testing and therapeutic procedures. Moderating fees are only due in ambulatory care.

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 that 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., infants and adolescents, pregnant women, the elderly, and AIDS and HIV patients) are entitled to certain specific additional benefits. In the specific case of the elderly, this group of beneficiaries can access additional benefits, such as co-funding for...
glasses up to a certain limit (under the Solidarity Supplement for the Elderly\textsuperscript{13} or exemption from payment of moderating fees. Furthermore, the Holy Houses of Mercy – in the context of the National Network of Integrated Continuous Care\textsuperscript{14} – provide the elderly with a set of mechanisms to give them adequate care, such as residential structures, day centres, home support services and continuous care units.

**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.\textsuperscript{15}

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\textsuperscript{13} Additional information on the beneficiaries entitled to this social benefit can be found here: https://www.sns.gov.pt/sns-saude-mais/comparticipacoes/.

\textsuperscript{14} This national network was enacted by Decree-Law No. 101/2006, of 6 June, as amended, and is operated by the SNS and the Social Security System, consisting of a set of institutions, public and private, that provide continuous care and social support for people in situations of dependency, both in their homes and in inpatient units.

\textsuperscript{15} 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/.
IV  THE 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 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.

It is possible, under Decree-Law 341/2007 of 12 October, to obtain automatic recognition of foreign academic degrees that are of the same level and nature as and have objectives that are identical to the degrees of licenciado, mestre and doutor awarded by Portuguese higher-education institutions. Under this legal framework only public higher-education institutions are entitled to recognise a foreign degree as the corresponding referred to degrees. Following this recognition, international graduates can request their registration with the Portuguese College of Medical Doctors.
The practice of medicine without registration in the Portuguese College of Medical Doctors is considered as the crime of usurpation of functions under the Portuguese Penal Code, 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 the SPMS, a public entity, created in 2010 to operate under the Ministry of Health and Finance. 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.

16 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/.
The process related to public purchases in the health sector is processed in a single electronic contracting platform, centrally managed by the SPMS. 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. 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 (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. Previously, in 2014, ERS issued a recommendation and an alert on advertising practices of healthcare providers, aimed at ensuring that any and all advertising messages referring to health services – regardless of format, form or medium of disclosure – should abide by the principles of lawfulness, truth, transparency and completeness.

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 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.

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17 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?SkinName=SPMS.
18 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.
19 And further regulated by Regulation 1058/2016 of 24 November.
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), which has been extended until 2020, is a basic element in defining health policies in Portugal and 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).22

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.23

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 positive signs. The Health Data Platform, launched in 2012, is a centralised system that records and shares clinical information, being duly authorised to do so by the Portuguese Data Protection Authority.24 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). This digital project has already been recognised by Portugal (it won the President of the Republic distinction in 2015 as well as the annual eGov Award) as a high-added-value project for citizens.25

Another important innovation worth emphasising is the implementation of the electronic prescription, which, as of 1 April 2016, is mandatory across the entire SNS. Another important change in the digital transformation of the SNS is telehealth, that is, the provision of healthcare services through teleconsultations, which allows the NHS to speak

22 The full version of the Plan may be found here: http://1nj5ms2llihdggbe3mm7ms5.wpengine.netdna-cdn.com/files/2015/06/Plano-Nacional-de-Saude-Revisao-e-Extensao-a-2020.pdf.pdf.
24 The authorisation can be found at: www.cnpd.pt/bin/diciseos/Aut/10_940_2013.pdf.
with all citizens, eliminating any geographical barriers. There are already several Local Health Units equipped with webcams and microphones that are prepared to provide medical services through teleconference.

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.\(^{26}\) The SNS launched its new website\(^{27}\) in February 2016, on which it provides information on waiting times regarding outpatient consultations for several specialties.\(^ {28}\)

Finally, the Portuguese government approved the National Strategy for the Ecosystem of Information 2020 (ENESIS 2020),\(^ {29}\) 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\(^ {30}\) 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.

### X CONCLUSIONS

As mentioned in Section I above, despite the significant 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 joint report issued by the Ministry of Health of Portugal, the European Observatory on Health Systems and Policies, and the Regional Office for Europe of the World Health Organization in April 2018,\(^ {31}\) Portugal has a strong record of developing coherent and well-focused health plans, but there are significant weaknesses in linking and implementing plans at the national, regional and local levels. The future vision for healthcare delivery will need better facilities, and better equipment to improve the delivery of healthcare services and provide staff motivation. The increase in the use of information technology is also an aspect that will bring significant benefits as it contributes to improving health literacy and access to care, increasing accountability and better informing the planning and management of health services. Periodic analysis by the different agents of the healthcare system on the weaknesses of the system, as well as focused action and careful monitoring and evaluation will make it possible to meet Portuguese healthcare needs more effectively and efficiently.

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30 See Section III above.
Chapter 14

SAUDI ARABIA

Nabil A Issa

I OVERVIEW

The Kingdom of 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 an 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. Abu Dhabi-based NMC Healthcare recently announced a joint venture with a governmental entity to own and operate numerous healthcare facilities in Saudi Arabia. A new healthcare city is currently being developd in Riyadh. Also, foreign private equity groups and operators such as Investcorp, NBK Capital, TVM Healthcare, Audacia, KIMS Healthcare, Global Investment House, BlueApple and others have recently announced healthcare investments or intentions to invest in the Kingdom. The Ministry of Health has previously 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

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1 Nabil A Issa is a partner at King & Spalding LLP, which operates in cooperation with the Law Office of Mohammad Al-Ammar in Riyadh.

privatising certain aspects of its healthcare sector. Saudi Arabian Airlines recently announced it has awarded a preferred bidder to privatise its Jeddah-based medical centre. Currently, there are a number of foreign investment restrictions, which will be discussed in this chapter.

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 relatively new regulations, the insurance coverage becomes invalid only in case of the beneficiary’s death, cancellation or expiry 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;
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;
h 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
i 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,3 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 shariah4 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’ 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

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3 The Basic Law of 1992 declared the Holy Koran 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 is the predominant school in Saudi Arabia.
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.

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 and 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 100 beds. We are, however, seeing an increasing willingness by the MoH to provide exceptions. 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 more formalised 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. Saudi Arabia is also actively working towards ‘corporatising’ government healthcare assets and preparing the same to be privatised.

In addition, the MoH has recently published an update to the Private Healthcare Institutions Regulations that explicitly permits non-GCC nationals to own companies
that operate (i.e. not own) polyclinics, clinics, radiology centres, etc., provided that such operating company qualifies with a number of requirements and has otherwise been approved by the MoH. Non-GCC nationals can also own entities providing ancillary services such as waste management, IT support and sterilisation services. Consistent with Saudi Arabia’s desire to encourage in-country manufacturing, parties manufacturing medical devices and pharmaceutical products (and directly selling such manufactured medical devices and pharmaceutical products) can also be non-GCC national owned, though they will have to comply with SAGIA’s requirements in order to receive a foreign investment licence for manufacturing.

Please note the following in regard 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 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 that 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. We understand both contracts will be retendered in the near future, creating opportunities for new foreign parties to participate in this sector. 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.

xi Potential exceptions
Foreign investors should consider alternative, enforceable structures to access the healthcare sector. For example, to date some foreigners have accessed the Saudi Arabian healthcare sector by investing in certain healthcare investment funds established pursuant to the Saudi Arabian Capital Market Authority’s Investment Funds Regulations. Such investment funds have invested in sectors as diverse as pharmacies and clinics to small, medium-sized and large hospitals. In addition, we are aware that the MoH and the Capital Market Authority has, to date, not objected to investors who meet the qualified foreign financial institutions requirements acquiring listed securities of entities operating in the healthcare sector.

VII COMMISSIONING AND PROCUREMENT
The MoH and the Saudi Central Board for Accreditation of Healthcare Institutions (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 the CBAHI. Pharmaceutical companies are also required to obtain licences from the 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.

Investors are often surprised by the number of regulators involved with the licensing of a business operating in the healthcare sector. In addition, parties acquiring hospitals or clinics have found that such hospitals or clinics (particularly if more than 10 to 15 years old) sometimes have outstanding issues and reports with the local civil defence, municipality or health department and are operating on temporary licences. Healthcare facilities that do not comply with the latest regulations could face costly and lengthy processes to bring their facilities into compliance.

Quite often such issues arise when facilities were constructed before purpose-built healthcare facilities were the norm. At one point it was not unusual for parties to operate out of converted villas and other facilities that were not purpose-built to service the healthcare sector. It should come as no surprise that many older medium-sized or regional medical centres also started life as something other than a hospital and, over time, were slowly expanded. Often, such facilities will not fully comply with the latest rules issued by the relevant health regulator, civil defence or municipality relating to ingress/egress, fire safety, ventilation, width of hallways, number and size of elevators, size of patient rooms, waiting rooms, sanitation, and waste disposal requirements for each medical facility. We have seen various acquisitions halted once a potential buyer understands the significant cost of making the necessary changes if a new owner will not be grandfathered under a previous exception.

If an investor is considering a first-time acquisition in the regional healthcare sector, often it is advisable to appoint an expert consultant to evaluate the condition of the target facility and to determine whether any expense to upgrade the facility will be needed in order to comply with regulatory requirements, so that such expenses and requirements can be taken into consideration as the opportunity is assessed.
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 privatise 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.
Chapter 15

SWITZERLAND

Markus Wang and Jonas Bornhauser

I  OVERVIEW

The Swiss healthcare ecosystem is rather complex, as 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 2,352 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.3

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.4 The most important piece of legislation by which the Swiss Confederation steers the Swiss healthcare system is the Federal Health Insurance Act (HIA),5 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

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1 Markus Wang is a partner and Jonas Bornhauser an associate at Bär & Karrer AG.
2 The information contained in this chapter is accurate as of August 2017.
4 Articles 95, 117 and 118 of the Swiss Constitution; De Pietro et al., Switzerland: Health system review, 19.
5 De Pietro et al., Switzerland: Health system review, 19.
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.\textsuperscript{6}

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\textsuperscript{7} 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.\textsuperscript{8}

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).\textsuperscript{9} 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 upfront 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.\textsuperscript{10} Insurance is offered

\textsuperscript{6} The Swiss healthcare system, Verband der forschenden pharmazeutischen Firmen der Schweiz (interpharma), accessible online at www.interpharma.ch/fakten-statistiken/4561-swiss-healthcare-system (accessed on 19 July 2017) (cited: The Swiss healthcare system).
\textsuperscript{7} Article 1a HIA.
\textsuperscript{8} The Swiss healthcare system, Financing healthcare.
\textsuperscript{9} Articles 1a and 6 of the Federal Act concerning Accident Insurance.
\textsuperscript{10} Article 3 HIA.
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.

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

11 Article 4 HIA.
14 Sturny, 156.
15 Article 32 HIA.
16 The Swiss healthcare system, Financing healthcare; Sturny, 155.
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. The Swiss cantons are responsible for the organisation of long-term care, and may delegate responsibility to municipalities.

18 Article 64, paragraph 2 HIA.
19 Sturny, 156.
20 The Swiss healthcare system, Financing healthcare.
21 Article 41 para. 1 HIA.
22 De Pietro et al., Switzerland: Health system review, 155.
23 Article 41 para. 1 bis HIA.
24 De Pietro et al., Switzerland: Health system review, 186 f.
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 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.25

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 fulfills the licence requirements defined in cantonal legislation. Requirements cover in particular issues such as medical supervision, hygiene, structure, hospital pharmacy and quality management.26

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.27 Any applicant

25 Sturny, 160.
26 De Pietro et al., Switzerland: Health system review, 57.
27 Article 36 AMP.
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. 28Licensed university-trained health professionals have the right to practice without supervision and to run their own practice. Healthcare professionals have to be re-accredited by cantons every 10 years (and every three years after the age of 70). 29Physicians 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. 30Employed 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. 31

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 it, however, to the cantons’ discretion whether and to what 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). 32

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. 33A register for psychological professionals (similar to the register of medical professionals) is planned; 34the corresponding implementing ordinance has, however, not yet been enacted.

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

28 Article 51 et seq. AMP.
29 De Pietro et al., Switzerland: Health system review, 56.
30 Article 40 (h) AMP.
31 Article 35 AMP.
33 Article 24 APP.
34 Article 38 APP.
of 2020. An important role for the training and qualification of non-university-trained health professionals is played by the guidelines issued by OdASanté, an organisation founded by the cantons and the federal employer associations in the health sector.\textsuperscript{35}

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.\textsuperscript{36} 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 be asserted by the patient, also in the framework of the public proceedings.\textsuperscript{37}

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, the SPO and the 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.\textsuperscript{38}

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,\textsuperscript{39} 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 any other 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,\textsuperscript{40} the court held that it is up to the treating physician to prove that he has

\textsuperscript{35} De Pietro et al., Switzerland: Health system review, 62–63.
\textsuperscript{37} Gächter/Rütsche, marginal note 391 et seq.
\textsuperscript{38} De Pietro et al., Switzerland: Health system review, 75.
\textsuperscript{39} Decision of the Swiss Federal Supreme Court dated 26 September 2016, 4A_216/2016.
\textsuperscript{40} Decision of the Swiss Federal Supreme Court dated 19 August 2015, 4A_137/2015.
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 an 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.

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 a legal entity (i.e., as limited liability company or joint stock company) if, in particular, the following requirements are fulfilled:

\( a \) each physician employed by a limited liability company or joint stock company needs a professional licence for physicians;

\( b \) each of the employed physicians is obliged to perform the healthcare services personally (no delegation of responsibilities);

\( c \) the employed physicians remain functionally responsible towards the patients;

\( d \) corporate bodies may not give professional instructions;

\( e \) the employed physicians have to take appropriate professional liability insurance either directly or via the legal entity they work for; and

\( f \) 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.

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41 Article 36a HIA.
42 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.
43 De Pietro et al., Switzerland: Health system review, 172.
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.

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. In the fields of highly specialised medicines, the cantons are even obliged to plan on a country-wide level. 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. Sanctions may include warnings, reprimands and fines up to an amount of 20,000 francs. Public and private hospitals, as well as emergency departments, on the other hand, are authorised to advertise their services without such restrictions. Because the distinction between self-employed physicians and hospitals can hardly be justified, part of the doctrine considers similar restrictions on hospital advertising adequate.

45 De Pietro et al., Switzerland: Health system review, 170.
46 Article 39, paragraph 2 HIA.
47 Article 39, paragraph 2 bis HIA.
48 Articles 40 (d) AMP and 27 (d) APP.
49 Article 43, paragraph 1 (a–c); Article 30, paragraph 1 (a–c) APP.
IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

The 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 donors 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 donors 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 donors. Furthermore, the SwissPOD study is continued in an improved way and is expanded on the emergency departments. 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.

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 an analysis of

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.
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-Qaiwain 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’.2

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, the Department of Health (DOH), the Dubai Health Authority (DHA) and the 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 the 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 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.

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1 Andrea Tithecott is a partner and head of regulatory practice at Al Tamimi & Company.
2 Article 19 UAE Constitution of 1971, as amended.
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, and 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 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.

³ Emirates NBD Research, 17 July 2017, IMF annual Article IV report.
⁴ BMI UAE pharmaceuticals and healthcare report Q3 2017.
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 DOH 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 2016.5 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,6 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 (with its subsidiaries the Healthcare Corporation and the Dubai Healthcare Insurance Corporation (DHIC)), the Abu Dhabi Health Services Company (SEHA) and the 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.

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.

SEHA7 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

5 DOH Standard for Primary Health Care in Emirate of Abu Dhabi HAAD/PHC/SD/0.9.
6 Dubai Regulation No. 30 of 2017 regulating telehealth; DOH Standards on teleconsultation, TC/SD/0 2014.
7 Established by Abu Dhabi Emiri Decree No. 10 of 2007.
public healthcare services, also catering for privately insured or high net worth self-paying patients. Projects include the Cleveland Clinic-Abu Dhabi, Healthpoint Hospital, the Imperial College London Diabetes Centre and the 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 (PPP)). 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 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 DOH Data Standard 2008 requires that healthcare providers in the emirate of Abu Dhabi develop and institute policies and procedures relating to ‘Confidential Health

8 Federal Decree Law No. (1) of 1972 concerning the Competences of the Ministries, as amended.
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 DOH 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.

There are two subsidiaries of the DHA that assist in the management of healthcare in the Emirate of Dubai. Created in accordance to Dubai Decree by Law No. 17 of 2018, the Healthcare Corporation and DHIC support the DHA in managing public health facilities in Dubai and overseeing health insurance services respectively. These two subunits, along with the new changes created under Dubai Law No. 8 of 2018, create a more comprehensive healthcare system for the inhabitants of Dubai.

Dubai Healthcare City Authority

The DHCC free zone is regulated by Dubai Healthcare City Authority (DHCA), which is a public corporation established to promote the status of the emirate as an international

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10 Dubai Law No. 9 of 2011 (concerning Dubai Healthcare City).
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 the DHCA, and is responsible for healthcare facility licensing and healthcare professionals licensing.

**Department of Health (Abu Dhabi)**

The DOH was established pursuant to Abu Dhabi Law No. 1 of 2007 (on Establishing Health Authority – Abu Dhabi). The DOH 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**

The 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 through the Healthcare Corporation, the DHCA or the DOH, 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 the 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 approve 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.

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 DOH 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 DOH 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 DOH 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.

With regard 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

i Overview
The UAE is a civil law jurisdiction with statutory codes governing most areas of substantive law.\textsuperscript{11} The Constitution provides that all laws in the UAE are subject to the overlay of the shariah (principles of Islamic law).\textsuperscript{12} 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.

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.

\textsuperscript{11} The Federal Law No. 5 of 1985 (Civil Code).
\textsuperscript{12} Article 7 UAE Constitution 1971, as amended.
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.13

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.

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.14 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).15

13 Articles 282, 292, 389 Federal Law No. 5 of 1985 (Civil Code).
14 Federal Law No. 2 of 2015 regulating Commercial Companies.
15 Executive Regulations (Council of Ministers’ Resolution No. 37 of 2014) Cabinet Resolutions (Resolution Nos 13 and 22 of 2016).
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 DOH 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 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.

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.

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17 Cabinet Resolution No. 7 of 2007 (regarding Health Advertisements Regulation).
IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

i  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.

ii  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 DOH 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).19

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18   UAE Vision 2021 World Class Healthcare.
19   Rule No. 1 Concerning Permitted Activities and Licensing Categories for Dubai Healthcare City Effective 1 December 2016 RU/RL/002/01.
Organ donation – opt-in or opt-out

Federal Law No. 5 of 2016 (regulating organ transplants) further progressed the existing legal framework\textsuperscript{20} 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.

Public-private partnerships (PPPs)

With the rapid growth in both population and the diversification of the economy, the UAE, and more particularly the DHA, have begun to discuss how to promote the introduction of more PPPs into the healthcare system. The DHA had created an Investment Strategy that wishes to ‘promote Dubai as a viable and competitive hub for investment in healthcare that address the needs of the Emirate and the future opportunities, and provide the best service for investors and enable sustainable public-private model in Dubai’\textsuperscript{21}.

Initiatives range from creating incentives to promote PPP investment to reviewing and implementing regulatory changes that might encourage investment. A new piece of legislation is expected to be decreed this year regarding PPPs in healthcare. These new and rapid changes are creating an enticing opportunity for foreign investment.

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.

\textsuperscript{20} Federal Law No. 15 of 1993 Regulating the Transfer and Transplant of Human Organs.
Chapter 17

UNITED STATES

Lawrence W Vernaglia and Anna S Ross

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’ (initially as a pejorative, but, later, sincerely), 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, with the election of Donald Trump as US President in 2016, even greater changes to the US healthcare system may be on the horizon. Although Trump’s efforts to completely ‘repeal and replace’ the legislation have not yet succeeded, the current administration has spearheaded a number of efforts to significantly weaken the programme as envisioned by President Obama. Significantly, the tax reform legislation passed at the end of 2017 repealed the individual mandate, a cornerstone of the ACA. The Trump administration has also taken other actions to dismantle key components of the legislation, including introducing regulations to provide for short-term health insurance plans, allowing states to impose work requirements for Medicaid, and positioning the Justice Department to undermine the constitutionality of the provisions of the law related to pre-existing conditions.

Thus, although President Obama’s signature domestic achievement remains the law of the land, it has not emerged from such legislative battles completely intact, and indeed now bears a number of scars. Moreover, although the efforts of President Trump and congressional Republicans have not yet been able to completely overturn the legislation, many are still determined to further weaken if not destroy the programme. The significance

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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.
of overturning such legislation is apparent, should their efforts ultimately be successful. 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. This chapter thus addresses the ACA as it stands today, noting where there have been significant changes to the programme.

Notwithstanding these challenges, the US healthcare system has continued to experience 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, which has only intensified since the most recent edition of this publication. One factor that continues to drive 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 further encourage 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).

### 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.

### 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

Because 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). The CMS is a division of the Department of Health and Human Services (HHS), 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. The Trump administration proposed a restructuring of the federal government in June 2018. In a 132-page document, entitled ‘Delivering Government Solutions in the 21st Century’, the administration offered several changes to the regulation of healthcare, including renaming the HHS the Department of Health and Public Welfare and consolidating several functions within the agency.\(^2\) As of the time of publication, this proposal had yet to be implemented.

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:

- enterprises that operate hospitals and health systems;
- manufacturers and developers of medical devices, pharmaceuticals and other biotechnology products;
- academic institutions that provide care while training healthcare professionals;
- information technology firms, construction companies and other infrastructure providers;
- insurance companies, self-insured employers and other third-party payors;
- labour unions representing the employees of healthcare organisations;
- medical entrepreneurs and investors (including private equity and venture capital) who finance the healthcare system;
- 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, health maintenance organisations (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, such as 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.\(^3\) The federal government contributes roughly half of the reimbursement for the Medicaid programmes, though some US states with struggling economies receive much higher reimbursement than others. 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.

Under the ACA, the rules governing Medicaid eligibility were 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. However, recent changes under the Trump administration may roll back some of these protections, as the HHS announced a new policy in January 2018 to promote work among Medicaid beneficiaries, allowing states to pursue demonstration projects that impose work requirements as part of their Medicaid plan. At the time of this update, 12 states had either received or were in the final stages of seeking federal approval to advance a work requirement. Notably, such requirements have been challenged in court in at least one state, with opponents of the work incentive demonstration projects arguing that no evidence exists to indicate that imposing such requirements will strengthen the health insurance system and that such work incentives will destroy Medicaid’s purpose as a safety net for some of the most vulnerable Americans.

**Commercial and 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

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\(^3\) See The Henry J. Kaiser Family Foundation, Medicaid Pocket Primer (updated 9 June 2017; last accessed 19 July 2017), www.kff.org/medicaid/fact-sheet/medicaid-pocket-primer/. See also The Henry J. Kaiser Family Foundation, Total Number of Medicare Beneficiaries (Timeframe: 2015), www.kff.org/medicare/state-indicator/total-medicare-beneficiaries/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.
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: 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 of 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 ‘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$3,450 for an individual and US$6,900 for a family in 2018). 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 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.

Funding and payment for specific services
Healthcare reform, including the ACA and any new healthcare legislation that may ultimately 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 was 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.

However, with the passage of the Tax Cuts and Jobs Act, which was signed into law by Trump on 22 December 2017, the individual mandate has been repealed effective in 2019. The mandate, which subjects individuals without health insurance coverage to steep tax penalties ($695 or 2.5 per cent of household income, whichever is greater), has long been seen as a cornerstone of the ACA, as the expanded coverage provisions of the programme are subsidised by requiring all individuals to pay into the system. Given the delay in the implementation of change, it may take some time before the effects of the repeal are fully borne out. Early projections by the nonpartisan Congressional Budget Office (CBO) indicate that elimination of the mandate will cause 4 million people to drop health insurance coverage in 2019, with 13 million more becoming uninsured by 2027. The CBO’s estimate projects savings to the government in the range of $300 billion, stemming from fewer people receiving subsidies or Medicaid, though it also anticipates a 10 per cent rise in the cost of insurance premiums following repeal of the individual mandate.

Another important development includes the introduction of alternative healthcare plans into the US healthcare market. As background, the ACA 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.4

Despite these requirements, changes to the ACA introduced under the Trump Administration have cut away at other features of the ACA. For instance, in February 2018, HHS proposed regulations allowing for alternative health plans in the form of short-term plans lasting just under one year (under the previous administration, the duration of such short-term plans was limited to 90 days, making them exceptionally unattractive to potential

consumers). Such short-term plans are likely to create a competitive, lower-priced alternative to the plans available under Obamacare because they are not subject to the same requirements as full-scale health plans.

Critically, the short-term plans may exclude people with pre-existing conditions, undercutting one of the most popular (and expensive) protections of the ACA. The short-term plans are also not required to offer the same comprehensive coverage as other plans under the ACA, and indeed typically do not provide benefits such as free preventive care, maternity care, prescription coverage and mental health services. Further, the short-term plans may impose annual or lifetime limits, meaning that policyholders will be responsible for the cost of care beyond such caps (typically around $1 million), and are not required to cap consumers’ cost-sharing burdens.

Another recent change introduced by the Trump administration in June 2018 is the option for ‘association health plans,’ which permits small businesses to join forces to purchase the types of coverage available to large employers. The new rule allows such companies to band together based on common geography or industry, and collectively purchase health insurance as a much larger employer might. Although the association health plans would not be able to discriminate based on an employee’s health status or any ‘health factor,’ they may be able to offer health insurance that does not include all of the essential health benefits required by the ACA. While proponents of this new measure say it will allow small businesses to provide care that is more affordable and more tailored to their employees’ needs, and help ‘level the playing field’ between large and small businesses, critics of the rule warn that it will roll back the protections of the ACA, opening the door to ‘junk health insurance’ and allowing association health plans to write their membership rules in such a way that discriminates against or avoids high-cost areas or high-risk professions.

Although these reforms to the ACA have created a number of different options for consumers (albeit with increased risks), there nonetheless remains 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 with 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. However, despite Republicans’ current control of both houses of Congress, efforts to ‘repeal and replace’ Obamacare have been generally unsuccessful, partly because of the popularity of many of Obamacare’s requirements related to exclusions and discrimination. There is thus an inherent tension between conservatives’ desire to limit the role that government plays in healthcare with the more popular features of the law, one that is likely to lead to further legislative battles in the coming years.
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.

There have recently been other developments in this area as well, as innovators from other sectors of the economy become more involved in the delivery of healthcare. For instance, there has been a growing movement towards telemedicine, whereby providers and patients interface virtually rather than through an in-person office visit. Such opportunities can capitalise on improvements in technology to help offer increased access to primary care services, particularly in areas where providers are scarce or patients are not easily able to travel to provider offices. Another example is the announcement by business leaders Jeff Bezos of Amazon, Jamie Dimon of JPMorgan Chase, and investor Warren Buffett of a new health venture that aims to transform the delivery of healthcare to be headquartered in Boston, Massachusetts with noted author and physician, Atul Gawande as the chief executive officer, but with a promise of no profit motive.

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, imposes 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.

In 2018, US companies (both healthcare and non-health-related) devoted significant efforts to meeting the requirements of the European Union General Data Protection Regulation (GDPR), applicable to companies that monitor or process the personal data of European citizens. Many US companies rushed to meet the GDPR’s strict requirements as to how such personal data is collected, stored and maintained.

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 centres, healthcare clinics (though the specific types of licensure and restricted activities can vary widely from state to state), pharmacies and other similar healthcare facilities.

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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 CONs 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 Organisations, 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 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 hundreds of thousands of dollars per year. Some smaller organisations, seeking to reduce their expenses, forgo 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 the 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.

### iii 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.

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5 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.’).
or certification. Similarly, hospitals, health plans and certain other providers or professional 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 ‘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.6

VI OWNERSHIP OF HEALTHCARE BUSINESSES

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 ‘co-management agreements’. These are contractual arrangements under which certain physicians in a particular specialty (e.g., cardiology, oncology, gastroenterology) agree

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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.

As the proposed $69 billion merger between health insurance giant Aetna and pharmacy chain CVS indicates, other areas of the healthcare industry have also been swept up in the move toward greater consolidation. Under the terms of the proposed merger, Aetna would become a subsidiary of CVS, which the companies argue would provide for better coordination and continuity of care by helping patients to adhere to their medication regimens. Given the size of the deal, the merger requires federal approval, and a number of antitrust experts and other groups – including, most recently, the American Medical Association, the largest provider association in the country – have spoken out against it. They argue that the combination would lessen competition and increase insurance premiums.

ii Restrictions on ownership

A number of states prohibit ‘corporate practice 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 such as 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.

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, such as 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.
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 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 HHS 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 harbour 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.

**The future of the Stark rules?**

In June 2018, the CMS published a Request for Information (RFI) seeking ‘input from the public on how to address any undue regulatory impact and burden of the physician self-referral law’. It appears that the CMS is particularly concerned with ‘removing unnecessary government obstacles to care coordination’ and is especially interested in responses that address ‘the structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements,’ but more wide-ranging responses from the industry are expected in response to the RFI. This move by the agency is consistent with the Trump administration’s overall push toward deregulation. The budget proposed by Donald Trump for fiscal year 2019 also included a legislative proposal to establish a new exception to the Stark Law for arrangements that arise because of providers’ participation in alternative payment models, so change to the Stark Law may be multifaceted.

### 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 of 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 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 continues to be a target for Trump and many congressional Republicans, despite their numerous failures to completely overturn the law and challenge its constitutionality. Their current strategy has been to chip away at the specific features of the law on a piece-by-piece basis. As discussed above, this slow dismantling of Obamacare has taken place in several parts since the inception of Trump’s administration, with the repeal of the individual mandate through the 2017 tax reform legislation representing the biggest blow.

The cumulative effect of these efforts remains to be seen, although early projections indicate that by stripping out several of the ACA’s most important provisions, millions of Americans will be without healthcare coverage. What is not yet clear is whether the healthcare system designed by the law can withstand these reforms, as the requirement for all individuals to maintain coverage was intended to underpin the expanded access to care and protections offered by Obamacare. Further, some of the other changes introduced by Donald Trump, such as the short-term health plans and association health plans, may also affect the overall structure of the system if increasing numbers of Americans opt for such limited, less expensive coverage. Importantly, diminished access to care affects not only patients but providers as well, particularly if growing numbers of patients are not able to afford care or delay preventive care, exacerbating other health conditions.

Probably the single largest challenge of the US healthcare system continues to be 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, and it is not yet clear whether the reforms to the system under the Trump administration will improve these features of the healthcare system. 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 introduced by the Republican majority despite repeated failures to completely 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, the full impact of the changes brought about in the new administration under Donald Trump has not yet been realised.

Both the ACA and the recent reforms to 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 such as 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 into 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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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, corporate governance, due diligence, and licensing and permit issues. For governments, she has contributed to the development of new law and policy. She has been instrumental in developing the firm’s healthcare practice group.

Her regulatory work was shortlisted for the Corporate Counsel Middle East awards consecutively in 2014 and 2015, and won the award for 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.

LAURIE TURNER
Fasken Martineau DuMoulin LLP

Laurie Turner is an associate in the business law group at the Toronto office of the law firm Fasken Martineau DuMoulin LLP, with a focus on health law. 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.

LAWRENCE W VERNAGLIA
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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 national healthcare 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; 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 US counsel to international healthcare and life science companies doing business in the United States.

MARKUS WANG
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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 in the life sciences and healthcare field. Dr Wang lectures intellectual property law at the University of Fribourg.

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.

MIN ZHU  
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Mr Zhu concentrates his practice on general corporate and commercial matters, foreign direct investment, mergers and acquisitions, corporate restructuring and private equity investment. Mr Zhu has provided legal services for dozens of multinational corporations, foreign companies and Chinese companies with respect to their establishment, domestic and overseas investments, and dispute resolution. Mr Zhu is experienced in the fields of investment, mergers and acquisitions, regulation and compliance of food, drugs, medical devices and medical service industries.
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THE BANKING LITIGATION LAW REVIEW
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THE CARTELS AND LENIENCY REVIEW
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