ACKNOWLEDGEMENTS

The publisher acknowledges and thanks the following for their assistance throughout the preparation of this book:

AL TAMIMI & COMPANY
BÄR & KARRER AG
CLARO
FASKEN MARTINEAU DUMOULIN LLP
FIELDFISHER LLP
FOLEY & LARDNER LLP
HAN KUN LAW OFFICES
HERBERT SMITH FREEHILLS CIS LLP
HOGAN LOVELLS (SOUTH AFRICA) INC
KING & SPALDING LLP IN COOPERATION WITH THE LAW OFFICE OF MOHAMMED ALAMMAR
LEE & KO
MATHESON
MORI HAMADA & MATSUMOTO
PINHEIRO NETO ADVOGADOS
SÁNCHEZ DEVANNY
URÍA MENÉNDEZ – PROENÇA DE CARVALHO
## CONTENTS

**PREFACE**

*Sarah Ellson*

**Chapter 1**  
BRAZIL  
*Théra van Swaay De Marchi and Maria Silvia L de Andrade Marques*  
1

**Chapter 2**  
CANADA  
*Lynne Golding, David Rosenbaum, Daniel Fabiano, Kimberly Potter, Laurie Turner, Zohar Levy, Vanessa Mui and Sophie MacRae*  
12

**Chapter 3**  
CHINA  
*Min Zhu*  
23

**Chapter 4**  
ENGLAND  
*Holly Bontoft and Sarah Ellson*  
34

**Chapter 5**  
GERMANY  
*Stefanie Greifeneder*  
45

**Chapter 6**  
IRELAND  
*Rebecca Ryan*  
54

**Chapter 7**  
JAPAN  
*Noboru Suwa and Fumiharu Hiromoto*  
69

**Chapter 8**  
KOREA  
*Soon-Yub Samuel Kwon and Eileen Jaiyoung Shin*  
83

**Chapter 9**  
MEXICO  
*José Alberto Campos-Vargas*  
93

**Chapter 10**  
NEW ZEALAND  
*Jonathan Coates, Aisling Weir and Andrea Lane*  
105

© 2019 Law Business Research Ltd
Contents

Chapter 11 PORTUGAL......................................................................................................................118
Francisco Brito e Abreu and Joana Mota

Chapter 12 RUSSIA..............................................................................................................................129
Lola Shamirzayeva

Chapter 13 SAUDI ARABIA....................................................................................................................138
Nabil A Issa

Chapter 14 SOUTH AFRICA .............................................................................................................148
Mandi Krebs and Abrianna Marais

Chapter 15 SWITZERLAND......................................................................................................................158
Markus Wang and Jonas Bornhauser

Chapter 16 UNITED ARAB EMIRATES ..........................................................................................169
Andrea Tischcott

Chapter 17 UNITED STATES.............................................................................................................182
Lawrence W Vernaglia and Anna S Ros

Appendix 1 ABOUT THE AUTHORS.................................................................................................205

Appendix 2 CONTRIBUTORS’ CONTACT DETAILS........................................................................217
Welcome to the third edition of The Healthcare Law Review. The Review now provides an introduction to healthcare economies and their legal frameworks in 17 jurisdictions, with new contributions from Russia and South Africa in this edition. Our expert authors have also reviewed and updated their chapters to reflect the ever evolving situation in the jurisdictions covered in earlier editions. While a hugely diverse area of practice, it is possible to discern common challenges and similar approaches in very different countries.

Increasingly it appears that some aspects of healthcare are being delivered in ways that transcend usual requirements of co-location of the patient and provider, and traditional national boundaries. Regulators and legislative frameworks have struggled to keep pace and to reflect this new reality. In Germany, France and Russia we have seen recent new telehealth laws as countries seek to find a balance between, on the one hand, opening up new provision and meeting patient expectation and, on the other hand, commitments to ensure safety and quality and domestically appropriate regulation.

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. Integration between health and wider social care continues to be a key area, alongside a recognition of public health and wellness and a desire to relieve pressures by seeking to keep large ageing populations well for longer. Another rapidly developing area is personalised medicine and as countries gather more genomic data, and speed and costs of profiling reduce, payers look to the rapid identification of diseases, their causes and individualised cost-effective treatments.

The ways different countries are meeting the demands of healthcare 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 and I anticipate that the year ahead will witness far greater levels of comfort with digital and online involvement
in diagnosis and treatment, continued debates about the democratisation or elitism of new technology and a recognition of the impact of data in the sector. Each chapter describes a country’s healthcare ecosystems. I would like to thank the many leading experts 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 LLP
Manchester
August 2019
I OVERVIEW

The current Brazilian healthcare framework was defined in 1988 upon enactment of the Federal Constitution. Brazil has developed a dynamic and complex health system based on the principle of access to health as a fundamental right of every person and a duty of the state. The state is responsible for organising a set of initiatives and services to ensure universal, unconditional and unpaid access to healthcare for all citizens. The role of the state encompasses not only taking actions for promotion, protection and recovery of health, but also putting social and economic policies in place to reduce illnesses or their aggravation.

The Unified Health System (SUS) is one of the biggest and most complex public health systems in the world. Jointly with the Federal Constitution, Law 8,080 of 1990 (known as the Organic Health Law) and Law 8,142 of 1990 emphasise the SUS principles and guidelines and set the funding standards for public health initiatives and services.

The SUS operates according to the following principles:

a universality: all citizens have the right of access to all public health services (or services contracted by the public administration);

b non-discrimination: access to all services is warranted to everyone without discrimination based on race, gender, economic condition, social status, sexual orientation, political views or any social or personal characteristics;

c equity: all citizens have equal rights (in terms of access to and use of services) and will be attended to according to their health needs; and

d comprehensiveness: public initiatives and services at distinct levels of complexity must cover all actions for the promotion, prevention, protection and recovery of health, including their biological, psychological and social dimensions.

The state’s healthcare obligations are developed within the SUS by the Ministry of Health in the federal sphere and by the respective healthcare offices in the state and municipal spheres, on a basis of cooperative federalism. In general terms, the federal government sets national guidelines for health policy, the states coordinate their respective regional healthcare networks and municipalities plan out and implement health actions and services alongside other cities within the same region based on the population’s needs.

---

1 Théra van Swaay De Marchi is a partner and Maria Silvia L de Andrade Marques is a counsel at Pinheiro Neto Advogados.

Given this common authority, the bodies of the federation are jointly responsible for meeting healthcare demands and, in view of constitutional criteria of decentralisation and hierarchy, the judicial authority must direct compliance according to rules of division of powers and order the payment of compensation for those bearing the financial burden.3

The National Health Committee (CNS), a joint committee established by Law 8,142 of 1990, is responsible for the strategy and control of public health policies and their economic and financial aspects, thus acting as the highest decision-making body of the SUS.

The Federal Constitution also allowed the private sector to develop healthcare actions and services. Private institutions may participate in the national health system (1) on an accessory basis, by providing input or services or else by engaging in healthcare management with their own resources, following public administration guidelines and on the basis of administrative contracts signed with public entities, and (2) on a supplementary basis, by offering health services through companies operating private health plans and insurance.

Philanthropic and non-profit organisations take precedence over other private entities in providing services for the SUS. However, if the services of those entities cannot be retained or are not enough to meet the SUS demand, the public administration may contract those services for the SUS with private entities for a profit.

Supplementary health is an economic sector served by a significant number of private health plan and insurance operators.

The National Regulatory Agency for Private Health Insurance and Plans (ANS), established by Law 9,961 of 2000, is the agency established by the Brazilian government under the Ministry of Health that operates nationwide to regulate, standardise, control and inspect the private health insurance and plan sector.

Law 10,185 of 2001 provided for the specialisation of insurance companies in private healthcare plans becoming subject to regulation and oversight by the ANS.

The regulatory framework for this sector is found in Law 9,656 of 1998, which contains the regulations on private health and insurance plans.

The National Health Surveillance Agency (ANVISA), created by Law 9,782 of 1999, is the authority primarily responsible for public health control over the production and marketing of designated products and services, including pharmaceutical products and medical devices.

The Ministry of Health, the CNS, the ANS and ANVISA are the government bodies primarily tasked with enforcement of healthcare laws and rules.

The SUS serves approximately 75 per cent of the Brazilian population. The remaining citizens (circa 47.3 million Brazilians)4 have a private healthcare plan. Private healthcare is the asset third most desired by non-beneficiaries, behind only education and home ownership,5 and largely as a result of shortcomings in public sector healthcare provision due to, among other things, budgetary constraints and a shortage of skilled labour in the medical and dental

---

5 Research carried out by IBOPE Inteligência in 2017, at the request of Instituto de Estudos de Saúde Suplementar (IESS): http://www.ibopeinteligencia.com/noticias-e-pesquisas/cresce-satisfacao-de-beneficiarios-com-seus-planos-de-saude/.
areas, as well as the continental dimensions of the country. The process of ‘exclusionary universalisation’ established by the SUS has given a strong impulse to the private healthcare sector recently.

The line between public and private participants has always been somewhat blurred, with their coexistence resulting sometimes in overlapping and inefficiencies. Users may resort to either side of the system depending on their actual needs or financial resources. Although disparate and uncoordinated, these two sectors are interdependent. They do not exclude or replace each other, given the universal character of the SUS. However, the medical records for the same user of the public and private sectors are not integrated, which creates inefficiencies in the health system.

Patients regularly choose between the SUS and the private healthcare sector after considering their medical condition, treatment complexity, and proximity of available facilities, among other factors. Under Article 32 of Law 9,656 of 1998, private healthcare providers must reimburse the SUS for the public treatment costs of those covered by a private healthcare plan.

The Brazilian health system has also been affected by other global dilemmas. As identified by Willis Towers Watson, the population will age in the next decades at a faster rate, putting more pressure on the overburdened healthcare system. Unnecessary treatments, the incorporation of costly new technologies, the expansion of mandatory procedures to be covered by private health providers and judicial decisions obliging the state and private operators to cover unanticipated medical treatments are also key factors tipping the scale unfavourably for the Brazilian health system.

II THE HEALTHCARE ECONOMY

i General

The SUS struggles to overcome obstacles to fulfil the ‘free-and-available-to-all’ mission established in the Federal Constitution, with one of the most difficult obstacles being cost. Serving more than 200 million people, 80 per cent of whom are fully dependent on its services and resources, the SUS is heavily reliant on funding by the state.

As for funding of the public system, Law 8,142 of 1990 provides for the intergovernmental transfer of financial resources. Constitutional Amendment No. 29 (EC 29) aims to ensure the funding of public health initiatives and services by establishing minimum resources to be provided by the three spheres of government. Funding for the SUS comes from tax revenues and social contributions from the federal, state and municipal budgets.

According to a study carried out by the Federal Council of Medicine (CFM) in November 2018, the amount of funding remains below international standards and is insufficient to cope with the growing demands of the population, driven by changes in socioeconomic and epidemiological profiles. The fiscal austerity policies recently implemented by the government have aggravated the problem by freezing health service expenses for the next 20 years.

---

7 Constitutional Amendment No. 29 (EC 29), enacted on 13 September 2000 and further regulated by Supplementary Law 141 of 2012.
Brazil allocates only 3.8 per cent of its gross domestic product to the public health system, a very low percentage compared to other countries (e.g., Portugal 6.2 per cent, United Kingdom 7.6 per cent and France 9 per cent). The SUS funding mechanisms have not been adequate to the task of securing sufficient financial resources for the public system.

ii The role of health insurance

Given the shortcomings in the public service, the purchase of private health insurance, albeit not mandatory, appears an attractive alternative. In March 2019, the ANS reported the existence of approximately 47 million private plan beneficiaries.

Corporate health insurance plans serve the vast majority of these beneficiaries. Employers are the main source of funding for private healthcare participants, which offer health services – directly or indirectly (through full or partial funding) and through health plans managed by an operator or insurer – to their employees, who in turn represent approximately 70 per cent of private health plan beneficiaries.

Families and individuals also play a relevant role in the private health sector by financing directly the services rendered by healthcare service operators and providers or by acquiring medicines or medical devices.

Public and private systems coexist not only for funding and management, but also in the offer and use of health services. There is direct and indirect public subsidy for health plans, ranging from tax exemptions for operators, providers and clients of health plans (whether individuals or corporations) to the purchase of private plans for public servants and reimbursements paid to the SUS (when a beneficiary of a private health plan uses public services covered by the private healthcare plan). In 2018, the ANS made a record transfer of 383.38 million reais to the SUS.

iii Funding and payment for specific services

The National Commission for Incorporation of Technologies (CONITEC) advises the Ministry of Health on incorporation, exclusion or alteration of health technologies by the SUS, as well as on the creation or alteration of clinical protocols and therapeutic guidelines. In this context, legislation sets a period of 180 days (extendable for 90 days) for decision-making through a healthcare technology assessment (ATS), which includes evidence-based analysis and takes into account such aspects as efficacy, accuracy, effectiveness, safety of the technology and even its impact – not only from a financial perspective, but also from a social, organisational, ethical and legal point of view. CONITEC also undertakes economic evaluations of benefits and cost comparisons with existing technologies.

In terms of private healthcare, the scope of coverage – including transplants and highly complex procedures – is defined by the ANS, which also sets the corresponding rules of

10 Data related to the private sector provided by the ANS: http://www.ans.gov.br/perfil-do-setor/dados-gerais.
11 It is important to note that not all services rendered to beneficiaries of private health plans qualify for compensation; only those services provided by the operator of a private health plan established on the List of Medical Procedures and Events issued by the ANS or in the contractual conditions.
use. Every two years, the List of Healthcare Procedures and Events (the ANS List) is revised and updated and, from then on, all procedures and treatments qualifying for compulsory coverage by private health plans are made public, without prejudice to any additional coverage stipulated in private health contracts.

The extent of care coverage by public and private health systems has always been disputed in Brazilian courts, particularly the coverage of high-cost drugs and procedures not offered by public and private health systems and the off-label use of medical products or treatments (i.e., those used in the treatment of conditions for which the use of those products or treatments is not authorised by the government agency and accordingly is not indicated in the product labelling).

In 2018, the Superior Court of Justice (STJ) rendered landmark decisions on this matter, with the following being worthy of note:

a) REsp No. 1657156/RJ – considering the existence of multiple cases discussing the same matter in dispute, the STJ established as Topic 106 that ‘the granting of medicines not incorporated in SUS normative acts requires the cumulative presence of the following: (1) evidence, by means of detailed and substantiated medical report issued by a physician assisting the patient, of the need for the medication, and of the ineffectiveness, for treatment of the disease, of the drugs provided by the SUS, (2) financial inability to bear the cost of the prescribed drug, and (3) registration of the drug with ANVISA in line with the uses authorised by the agency’. The Court also determined that, on the judgment becoming final and conclusive, the Ministry of Health and CONITEC should be notified to carry out studies into the feasibility of incorporating the corresponding drug into the SUS system.

b) REsp No. 1712163/SP and REsp No. 1726563/SP – after hearing these two cases, the STJ also established as Topic 990 that ‘health plan operators are not obliged to provide a drug that is not registered with ANVISA’. According to the reporting judge, the judiciary cannot ‘trample over the whole existing system only to ensure health security to specific medicine users, at the risk of doing more harm than good’.

Those recent precedents illustrate the trend for the Brazilian higher courts to look favourably on the limits and standards established by the state and its existing regulations in providing health services to citizens.

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

The Federal Constitution determines that public health initiatives and services should together create a regionalised and hierarchical network. Following this guideline, health regions were created, which are, in brief, territorial administrative and sanitary divisions that allow the population access to treatment most suited to local needs. Under Decree 7,508 of 2011, these health regions should contain at least primary care, urgent and emergency care services, psychosocial care, specialised outpatient and hospital care and health surveillance.

---

13 Article 1,036 of the Brazilian Code of Civil Procedure provides that, when there is a multiplicity of appeals in course before the Superior Court of Justice based on the same dispute, the assessment of the merits may occur by sampling, through the selection of cases that adequately represent the dispute. A repetitive appeal is therefore one that represents a group of special appeals that have identical theses, that is to say, they have a basis in the same legal issue.
In 2017, the federal government instituted the National Primary Care Policy to expand clinical care and focus on primary care, while avoiding unnecessary medical appointments or procedures.

The National Primary Care Policy adopts the same principles as the SUS (universality, non-discrimination, equity, comprehensiveness) and should be the preferred reference entry point in relation to public health services.

Following the same public sector rationale, the ANS issued Normative Ruling 440/2018 establishing the Programme for Certification of Good Healthcare Practices of Private Healthcare Plan Operators (APS), which is a voluntary process to evaluate the adequacy of preset technical criteria for specific healthcare networks or of operators’ specific care lines, with the evaluation being carried out by health accreditation entities recognised by the ANS.

The APS certification proposes a model for reorganisation of the gateway based on primary healthcare, to induce change in the gateway and in the remuneration model for value generation. Based on the main structuring pillars for primary healthcare as provided in national and international scientific literature, the programme focuses on reception, patient care, coordination and integral care, recognition of the heterogeneity of demands, centrality in the family and community orientation.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

Companies that independently and exclusively provide healthcare services or coverage for healthcare costs, at a preset or post-set price, for an indeterminate period, are regarded as health plan carriers, for purposes of securing medical, hospital and dental care expenses without a financial limit.

Other activities are also equated by law to those of operators, when they present, in addition to the security for financial coverage of healthcare risks, other characteristics that differentiate them from an exclusively financial activity.

i Regulators

The Ministry of Health, the ANS and ANVISA are the government bodies primarily tasked with enforcing the laws and rules on delivery of healthcare at federal level.

The Ministry of Health is the highest public health authority and, as such, is responsible for establishing general rules to implement and organise the SUS, as well as for defining, monitoring and evaluating the national health surveillance policy; this authority is supplemented by local rules relating to healthcare initiatives and services targeting local interests.

The ANS is responsible for regulating, standardising, controlling and inspecting private health insurance and plans, and also for planning industry-level initiatives in Brazil.

Mergers, acquisitions or any corporate restructuring entailing a change or transfer of control of senior managers or insurers is subject to prior clearance from the ANS. In January 2019, the ANS and the Administrative Council for Economic Defence (CADE)14 signed a technical cooperation agreement consolidating their institutional relationship and aiming (1) to improve local monitoring of levels of concentration in the private health

---

14 The Administrative Council for Economic Defence (CADE) is an independent agency reporting to the Ministry of Justice tasked with assessing all corporate restructurings that could affect free competition in the national territory.
market thus protecting competition in this industry, and (2) to train staff through bilateral events and exchange of public servants for joint production of studies and research, among other initiatives.

ANVISA is responsible for public health control in relation to the production and marketing of designated products and services (including pharmaceutical products and medical devices), including in related environments, processes and technologies, and for ports, airports and borders.

Institutional healthcare providers and healthcare professionals are subject to licensing and rules issued by professional bodies such as the CFM, Federal Council of Dentistry (CFO) and Federal Council of Pharmacy and the corresponding regional councils for these professions.

ii Institutional healthcare providers

Companies must first obtain a licence for operation as a private healthcare insurer, subject to the documentary and other requirements established by Normative Ruling 85 of 2004 issued by the ANS. Once in possession of this licence, the healthcare operator may apply for registration of the products it intends to sell in the private health market.

The sanctions for private health insurers found to be in contempt of ANS determinations include fines, suspension of sales, supervisory intervention, mandatory portfolio transfer and cancellation of registration.15 Acting as a private health plan operator without a licence is one of the most serious infractions, punishable by a daily fine until cessation of the activity, compliance with the authorisation requirements or correction of an irregular and unlawful dissolution of a legal entity, or else until the date when in relation to the operator the ANS decrees the adoption of a technical or fiscal regime, liquidation or disposal of portfolio.

Supervisory intervention concerning financial, economic or technical matters is decreed (depending on the severity of the case) when the ANS detects poor financial backing or severe administrative, economic or financial anomalies in any private health insurer that may impair the continuity and quality of services rendered to beneficiaries.

No company with customers or in debt to the network of healthcare providers may cease its operations. The existence of customers also prevents the cancellation of product registrations. Any private health insurer wishing to cancel its licence must comply with all legal requirements established by the ANS.

iii Healthcare professionals

The regulation of healthcare professionals is extensive. All doctors, dentists, pharmacists and nurses must be licensed. In general, professional healthcare activity is regulated by federal councils, which in turn establish that these professionals must be registered with regional councils. Enrolment with the competent authorities is compulsory and infringement may translate into criminal sanctions, such as fines and detention from six months to two years.

Licensing of doctors is regulated by Federal Law 3,268, by Decree 44,045 and by the code of professional ethics. In brief, doctors must have their titles registered with the Ministry of Education and also be registered with the competent regional council of medicine.

15 Normative Ruling 124 of 2006 issued by the ANS.
Furthermore, all technical reports and patient records must contain the corresponding doctor’s number of registration with the competent regional council of medicine, under penalty of ethical sanctions.

The same requirement to register with a regional council applies to dentists (pursuant to Federal Law 4,324, Decree 68,704 and the Code of Ethics in Dentistry).

When it comes to nurses, mandatory registration with the regional councils is set by Federal Law 2,604, and the nursing ethics code emphasises that nurses can refuse to execute a prescription unless it contains the applicable doctor’s regional council of medicine registration number. The mandatory licensing of pharmacists is regulated by Federal Law 3,820.

In cases of breach of applicable laws, healthcare professionals can be punished with disciplinary sanctions, such as warnings, censorship, fines, suspension or withdrawal of the licence to practise. Professionals can appeal against any disciplinary decision. Unlicensed professionals cannot provide health services. However, unlicensed professionals can render some services related to the healthcare industry, if supervised by a licensed professional.

International graduates can be registered to render health services, but they must take the National Exam for Revalidation of Medical Degrees, established by Ordinance 278 of 2011 (Legislative Bill 4,067 of 2015 is intended to convert Ordinance 278 of 2011 into a federal law).

V NEGLIGENCE LIABILITY

A consumer relation exists between patients and healthcare providers, so the rules of liability established by the Civil Code and the Consumer Protection Code (CDC) apply.

Physicians must always act diligently, clearly informing patients about the characteristics of their pathology, treatment alternatives, risks of treatment or medical procedure (if any), and using all existing know-how for the patient’s care and treatment.

In fact, according to most court rulings, at-fault liability applies to doctors, who are held liable when guilt is proven in any of its modalities (recklessness, negligence or malpractice).

The STJ\textsuperscript{16} has already decided that a contractual relationship exists between healthcare professionals and patients, and the provision of services (according to the expertise and medical resources available under the circumstances) is part of the concept of obligation of means, except in the case of aesthetic plastic surgeries (obligation of result). Hospitals, laboratories, clinics and other healthcare providers (including those operated by the state, directly or indirectly) are subject to strict liability, based on Article 14 CDC and Article 927 of the Civil Code.

Healthcare operators are liable to the consumer, jointly and severally, for defective medical and diagnostic services, whether those provided through their own hospital and contracted doctors or through accredited doctors and hospitals (Articles 2, 3, 14 and 34 CDC).

VI OWNERSHIP OF HEALTHCARE BUSINESSES

Under Law 9,656 of 1998, individuals or legal entities resident or domiciled abroad may set up or hold equity interests in healthcare operators. After extensive discussions on the

\textsuperscript{16} Res No. 1,725,092/SP, Reporting Judge Nancy Andrighi, Terceira Turma, published in the Online Court Gazette on 23 March 2018.
matter, Law 13,097 of 2015 also established exceptions to the constitutional prohibition against direct and indirect participation of foreign capital in healthcare activities. As a result, significant foreign investments have been made more recently in this industry.

The opening of the market to foreign investment, the provision of national investment funds and the going public of healthcare companies boosted a strong movement of mergers and acquisitions in the private health market.

From 2003 to 2017, CADE analysed and judged 155 merger filings (termed ‘concentration acts’) involving companies in the healthcare industry. During this period, the growth and consolidation of certain economic groups that have since become industry leaders were monitored, and it was found that the merger and acquisition of companies had been adopted as the main strategy for expansion in the industry. Amil, Rede D’Or, Dasa, Fleury, Unimed, Qualicorp and NotreDame Intermédica were, in this order, the most active companies engaged in this trend, and were responsible for 80.98 per cent of the total number of deals.17

VII  COMMISSIONING AND PROCUREMENT

All purchases and contracts for services undertaken by the public administration must be preceded by public bidding procedures as established by Law 8,666 of 1993. The requirements for tendering bids or executing public contracts are usually established beforehand in the formal document prepared at the beginning of the bidding process.

VIII  MARKETING AND PROMOTION OF SERVICES

Several restrictions apply to the marketing and promotion of health services in Brazil. The main advertising watchdog in Brazil is the National Council for Advertising Self-Regulation (CONAR), but there are also restrictions imposed by the ANS, ANVISA and professional councils (the CFM and the CFO), and others set out in the CDC.

The Brazilian Code of Self-Regulation issued by CONAR establishes restrictions on the advertising of health-related services (in Annex G), prohibiting, among other things, advertisements or materials announcing: (1) cures for diseases for which no adequate treatment yet exists; (2) distance or remote diagnosis or treatment; and (3) treatment and diagnosis methods not yet scientifically established.

Between 2012 and 2018, CONAR commenced 396 proceedings involving health services and issued 99 decisions, of which only 18 moved to dismiss the case. In the other cases, CONAR ordered the advertising campaign to be changed or suspended.

Among the relevant cases analysed by the CONAR board, a decision issued in March 2019 ordered the suspension of a drug advertisement claiming that the product cured pain and fever caused by the dengue, zika and chikungunya diseases; this suspension is to remain in effect until official studies verify the accuracy of the reported indications.18

17 ‘Concentrations in the healthcare market, hospitals and diagnostic medicine’, published by CADE in July 2018.
18 Formal Complaint 029 of 2018; a description of the decision is available on the CONAR website.
In a supplement to the CONAR regulations, the CFM has banned doctors from posting selfies, images or aids characterised by ‘sensationalism, self-promotion, or unfair competition’. The CFO, for its part, prohibits the use of before-and-after images of procedures in advertisements.

IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

The Brazilian health system faces enormous challenges that have to be addressed if the system is to continue in the role assigned to it by the Federal Constitution. In this context, and particularly with regard to the supplementary health system, health market participants (including the ANS and ANVISA as the sector regulators) often come together to discuss strategic issues and opportunities, some of which are outlined below.

i  Telemedicine

As defined in Resolution 1,643 of 2002 issued by the CFM, telemedicine is the exercise of medicine through the use of interactive methodologies of audiovisual communication and data, with the objective of healthcare, education and research. On 6 February 2019, the CFM issued a new regulation on this matter defining and regulating telemedicine throughout the national territory and providing for procedures such as telediagnosis and telesurgery, and also determining the level of data security for patients served through telemedicine. This new regulation, however, was later revoked, but it will only be a matter of time until it is improved and republished so that health services can be provided to patients in distant and inaccessible areas at a more reasonable cost.

ii  Emergence of new products

‘New products’ are coming out in the private sector whereby the population is being provided with healthcare services that are not subject to oversight by the ANS and, by extension, to its minimum coverage requirements.

iii  Adoption of different remuneration models

Revamping the current system for remuneration to hospitals and laboratories is critical, since the variation in hospital and medical costs for healthcare providers represents one of the main factors for the soaring increase in annual costs. The adoption of alternative remuneration mechanisms, such as fees for performance, may help reduce both healthcare costs and cases of fraud involving medical devices and medicines.

iv  Focus on prevention and promotion of health programmes

Aiming to foster health and well-being rather than treating diseases alone, the ANS is seeking a paradigm shift by encouraging operators to rethink the management of plans to focus on actions to maintain the health of beneficiaries. This is a topic of the ANS Regulatory Agenda for 2019–2021, which is undergoing public consultation, and reflects a global trend. These efforts are expected to culminate in a guiding set of strategies and integrated programmes targeting risk reduction, compression of morbidity, and a better quality of life, leading to a more robust engagement by beneficiaries and ultimately reducing costs.

---

19  Resolution CFM 2,227.
Adaptation of health market participants to the General Law on Data Protection

Law 13,709 of 2018, known as the General Law on Data Protection, which enters into force in August 2020, will impact all relationships within the public and private health sectors, including health plan operators, service providers, plan contractors and other participants that have access to personal data on health insurance and plan beneficiaries. Sensitive health data, already protected by medical confidentiality, is to be shared with those in the private healthcare chain in charge of capturing information that can help improve the quality of life of beneficiaries. This measure will be highly beneficial to data subjects, will favour contractors who pay plan monthly fees and will also be used by health plan operators, who regulate the cost of plans offered to the market. This more effective management of care, including directing beneficiaries to more cost-effective providers for treating specific illnesses, will make it possible to focus on campaigns and actions against major chronic diseases.

CONCLUSIONS

In Brazil, the public and private healthcare systems coexist. However, the lack of policies and mechanisms for better coordination between the two sectors may explain some of the inefficiencies found in the health system and this lack deserves priority attention from all industry participants.

Like other systems in the world, the Brazilian health system has been affected by global dilemmas and faces great challenges, starting with the guarantee of effective access, better quality of healthcare, technology, the financial sustainability of the sector and health prevention and promotion for all. In this context, industry participants have been discussing the future of the health system in pursuit of concrete proposals that tackle these challenges and identify opportunities to improve the quality of services and reduce their increasing cost.
Overview
Canada is a federated country comprising 10 provinces and three territories, populated by over 37 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 35 (Quebec) and 41 (Ontario) per cent of the provincial governments' budgets in 2018. 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.

The Healthcare Economy

General

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

1 Lynne Golding, David Rosenbaum, Daniel Fabiano, Kimberly Potter, Laurie Turner, Zohar Levy, Vanessa Mui and Sophie MacRae are partners, and Vanessa Mui and Sophie MacRae are associates, at Fasken Martineau DuMoulin LLP. The authors would like to thank Kathryn Beck, Rosario Cartagena, Heather Whiteside and Jacob Wagner for their assistance with the writing of this chapter.
2 As the distinction between a province and a territory is not important for the purposes of this chapter, all will be referred to herein as provinces.
3 Statistic provided by Statistics Canada.
4 The government of Canada provides direct healthcare services to First Nations people living on reserves, Inuit populations, serving members of the Canadian Forces, eligible veterans, inmates in federal penitentiaries and some refugee claimant groups.
In it, the federal government sets out a number of conditions that must be met annually 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 or defined 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**

Most 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:

- 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);

---

6 In 2019–2020, the provinces will receive, in the aggregate, approximately C$40.3 billion as part of the Canada Health Transfer.

7 For example, 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.
prescription drugs (as, with limited exceptions, including in the case of drugs prescribed to seniors, to those under the age of 25 without private insurance in Ontario, those with specific conditions and to those living below specified income levels, only drugs administered in hospital are covered by most provincial health insurance plans); and 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. 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:

- private clinics: including the offices of physicians and other specialists;
- surgical centres, or in Ontario, independent health facilities: generally, for specialty day surgeries or diagnostic procedures;
- community health centres: clinics for marginalised or other specific populations;
- community centres: clinics for specialised procedures provided by allied health professionals, such as infusion clinics or for speech pathology or physiotherapy;
- hospices: for palliative or end-of-life care;
- private homes or seniors homes: where patients receive ‘home care’, including clinical and non-clinical care, and respite care for family caregivers;
- hospitals: of which there are many types – acute, chronic, tertiary, community, etc.; and
- long-term care (nursing) homes.

It should be noted that 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.

In response to challenges facing healthcare delivery, notably exceedingly long waiting times for necessary care, duplication and lack of coordination among care providers, the pressures of an aging population and the prevalence of chronic diseases, provinces are replacing institution-centred approaches with patient-centred approaches. Ontario, for example, is transitioning towards a more coordinated model for delivery of healthcare, through which patients within a specified geography will receive integrated care, including, for example, primary care, hospital services, mental health and addiction services, long-term care and community care from healthcare providers forming part of the same ‘Ontario Health Team’.
ii Electronic health record
For a number of years, Canada has been developing a national electronic health record (EHR) system, through a collaboration of the government of Canada, the 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 practise the profession. Colleges are required by this legislation to, among other things, ensure that the public has access to qualified, skilled and competent healthcare professionals. Colleges seek to uphold this 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.
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 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 (Ontario) (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, in most provinces, licences are not required to operate private clinics that are not engaged in surgical procedures. However, in several provinces, such as Alberta, British Columbia, Manitoba, Ontario, Quebec and Saskatchewan, private clinics providing surgical procedures are subject to accreditation or licensure by the college governing the medical profession.

Healthcare professionals

As noted above, the requirements for registration or licensure\(^8\) as a member of a healthcare profession are set out in the various provincial health profession statutes described in Section IV.i. 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 is determined to be equivalent by the relevant college; (2) successfully completing certain postgraduate training or education; and (3) passing certain qualifying examinations

---

\(^8\) 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.
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).9 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.

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. 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 damage, there is a causal connection between that damage and the negligence, and the damage was 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 damage to 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 motions judge of the Federal Court certified a class proceeding against the Crown brought by two anonymous plaintiffs on behalf of participants in the Marijuana Medical Access Program. The plaintiffs allege that Health Canada sent them oversized envelopes addressed with their names and with a return address to the Program (thereby revealing the plaintiffs’ association with the Program). The plaintiffs alleged a number of causes of action, including intrusion upon seclusion, and publicity given to private life. The class action followed a finding by the Office of the Privacy Commissioner that Health Canada had violated federal privacy laws.

The Federal Court of Appeal confirmed the certification order, but only with respect to the causes of action of negligence and breach of confidence. The Court overturned the certification order with respect to the claim for intrusion upon seclusion and publicity given to private life, because the plaintiffs had not pleaded the material facts in support of the necessary elements of those causes of action.

The Christian Medical and Dental Society of Canada et al v. College of Physicians and Surgeons of Ontario, 2019 ONCA 393
In 2019, the Ontario Court of Appeal (ONCA) upheld the Superior Court’s decision that two policies of the College of Physicians and Surgeons of Ontario (CPSO) regarding Medical Aid in Dying (MAID) are constitutional. The crux of this challenge focused on the CPSO’s
MAID policy, 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 CPSO argued that the policy was necessary to protect patients, while the plaintiff argued that the policy required healthcare practitioners to act in contravention of their sincerely held religious beliefs, breaching their right to freedom of religion. The policy was adopted by the CPSO after the Supreme Court of Canada struck down the legislation criminalising physician assisted suicide in 2015.

On appeal, the ONCA balanced the healthcare practitioners’ rights to freedom of religion, set out in the Canadian Charter of Rights and Freedoms, with the patients’ right to equal treatment without discrimination based on characteristics such as mental or physical disability. The Court concluded that although the policy does infringe on healthcare practitioners’ freedom of religion, that infringement is justified because of the paramount importance of ensuring equitable access to healthcare, and because the policy minimally impairs the religious freedom of the healthcare practitioners. Physicians have a duty not to abandon patients.

The courts showed some deference to the CPSO’s policy judgement on how to balance physician interests and patient needs because as a self-governing professional body with institutional expertise, the CPSO is better suited to decide the policy in balancing these interests. The fact that other jurisdictions have established policies that the appellants regarded as less impairing was not persuasive to the ONCA, since a right is ‘minimally impaired’ so long as the policy in question is within a range of reasonable alternatives to achieve the underlying policy goal but respect individuals’ rights.

**DD v. Wong Estate, 2019 ABQB 171**

In 2016, the Supreme Court of Canada clarified the law regarding causation in medical negligence cases. In its decision of *Benhaim v. St-Germain*, 2016 SCC 48 (CanLII), the Supreme Court stated that the approach to factual causation should be ‘robust and pragmatic’ and a trier of fact can draw inferences even without scientific expertise sufficient to arrive at a definitive conclusion. The Court of Queen’s Bench of Alberta has recently applied that decision in a medical malpractice lawsuit against a gynaecologist and an obstetrician. After a trial, the judge found that the doctors failed to identify intrauterine growth restriction quickly enough, failed to tell the patient about the risks of her pregnancy, including the risks of growth restriction, and failed to recommend that labour be induced early.

The trial judge held that, to prove causation, the plaintiffs had the burden to prove that injuries would have been avoided with proper diagnosis and treatment. The trial judge accepted the plaintiff’s evidence that she would have been induced if she had been provided with complete and timely information about her options. The trial judge also cited *Benhaim* for the proposition that where there is causal uncertainty created by the defendants’ negligence, it can but does not necessarily mean that the burden of proof is shifted from the plaintiffs to prove causation or that an adverse inference should be drawn against the defendants. Here, the trial judge found no such adverse inference necessary and concluded that the evidence was sufficient to prove causation. The defendants were found liable for the plaintiffs’ injuries.
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.

Although 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. In most provinces, physicians must hold all the voting shares of medical professional corporations, but their spouses or family members, or in some provinces other persons, may own non-voting shares of such corporations (provided that the physicians themselves remain liable for the professional services they provide). The same is true for certain other healthcare providers. A market exists for the purchase and sale of all such corporations, subject to applicable provincial law and the policies of each regulatory college, 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 the 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 (Attorney General)*.

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 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 (billing a patient directly for an insured service) in addition to receiving funding for insured services. While the trial has faced numerous procedural delays since it started in 2016, as at June 2019, the trial had resumed, after a long adjournment and dozens of evidentiary hearings, and was ongoing. It is anticipated that the decision of the court will eventually be appealed to the Supreme Court of Canada, as it could have a significant impact on how healthcare services are delivered and funded in Canada.

VII COMMISSIONING AND PROCUREMENT

Some Canadian healthcare providers (e.g., hospitals and health authorities) are subject to public procurement rules. These rules arise out of international trade agreements; national and regional domestic trade agreements; provincial statutes and procurement directives; and the specific policies of each public sector purchaser. Procurement rules are intended to ensure fairness, transparency and accountability in decisions about the use of public funds. They apply to contracts for the purchase of goods or services that meet or exceed certain value thresholds. Generally, these rules require those contracts to be awarded through an open
competitive process – that is, a process that is open to any person to submit a bid. They also require public sector purchasers to share material information with prospective bidders at the outset, and through particular communications channels; 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). Potential providers of healthcare goods and services should look to various online procurement portals for notices about pending and open competitive procurement processes.10

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.

Advertisement by email and similar electronic means (e.g., SMS text) is also subject to privacy laws, as well as to Canada’s anti-spam law, which requires a person sending an electronic marketing message of this kind to have prior consent or other authority to send that message. Canada’s anti-spam law also requires the message to identify the sender, the sender’s mailing address and other contact information, and to include an easy-to-use unsubscribe mechanism through which a person can request to no longer be sent electronic marketing messages.

10 See the webpage for the Canadian Free Trade Agreement for links to federal and provincial public procurement portals: https://www.cfta-alec.ca/doing-business/.

© 2019 Law Business Research Ltd
IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

Given Canada’s ageing population, the high percentage of the country’s GDP expended on healthcare, the comparatively poor health outcomes achieved\(^{11}\) 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, there is no national framework for telemedicine.

Canadians today are accessing health information more easily 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. Given the increased interest in these products, Health Canada engaged in extensive consultations beginning in 2016 to inform its new approach to regulating consumer health or ‘self-care’ products. Based on these consultation processes, Health Canada introduced the Self-Care Framework, which, among other things, aims to improve labelling of natural health products and, ultimately, expand the scope of Health Canada’s oversight over consumer and self-care products. This Framework will be rolled out over three years, with the first of three phases being targeted to begin in spring 2020.

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). Legislative efforts, however, have been delayed. In 2017, Ontario was the first province to introduce legislation requiring public reporting of payments (the Health Sector Payment Transparency Act 2017), including those made by the private sector, to specified healthcare organisations and professionals. However, a new Ontario provincial government, on coming into power in 2018, reopened consultations and has delayed implementation indefinitely. British Columbia announced consultations on a ‘health-sector transparency program’ in mid-2018, which would, like the Health Sector Payment Transparency Act, compel the medical industry to report payments to healthcare organisations and professionals. No proposed legislation has been tabled.

---

Chapter 3

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.

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 National Health Commission 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 the 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 the 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

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 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 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 that, if qualified, may be designated as being 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.

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).
iv Personal information protection

The Provisions on Administration of Medical Records in 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 and 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 1 June 2017, provide more solid protections for personal information by defining the constitutive elements for several criminal acts involving the infringement of personal information and significantly reducing the threshold for imposing criminal penalties on personal information infringement. Additionally, the Measures for Administration of Population Health Information (for Trial Implementation) has also set basic requirements for the administration of population health information, such as categorised management, local storage systems and tracking. The Measures for Administration of National Health and Medical Big Data Standards, Security and Services (for Trial Implementation) require local storage of health and medical big data. Furthermore, a voluntary national standard, the Information Security Technology – Guide for Health Information Security, which is being drafted, will provide detailed guidance on the use and protection of personal health information after the standard becomes effective.

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 the 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 Rules for Implementation of the Regulations on Administration 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'. In May 2019, NHC, together with four other authorities, jointly issued the Circular on Printing and Issuing the Opinions on the Pilot Programme for the Promotion and Development of Clinics, which encourages doctors who have practised for over five years with intermediate qualifications or higher to establish specialist clinics on a full- or part-time basis. This is regarded as a major signal of reforms in China that will permit doctors to freely practise medicine and establish private clinics.

### Healthcare professionals

In China, physicians, nurses and pharmacists must practise medicine in accordance with the Law on Licensed Doctors, the Regulations on Nurses and the Regulations on 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 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 practise 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 Practise 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. 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 for Registration of Medical Practitioners 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. Since the promulgation by the NHFPC\(^9\) of the new Measures for Administration of Registration of Medical Practitioners, doctors may practise medicine at multiple medical institutions 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

---

\(^9\) See footnote 2.
liability principle and, to some extent, in accordance with the presumption of fault principle.\footnote{10} In addition, the Regulations on Handling Medical Accidents also specify rules related to the prevention, handling, technical evaluation and administration of medical malpractice cases. When physical injury occurs, if the relevant liability is not provided for in the Tort Liability Law or the Regulations on Handling Medical Accidents, the relevant provisions may apply from the Interpretation of the Supreme People’s Court on Several Issues Concerning the Application of Law in Hearing Personal Injury Compensation Cases.

\section*{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.

\section*{ii Notable cases}

The dispute over medical damages between Shen Bo, Meng Xiaoxia and the Second Affiliated Hospital of Zhengzhou University in 2014\footnote{11} 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 argued 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 for that conduct.

\footnote{10} Tort Liability 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 institution to compensatory liability. Article 58 provides for the presumption of fault by the medical institution in cases where the medical institution conceals, refuses to provide, forges, tampers with or destroys case data in a dispute in violation of laws and regulations or other medical standards.

\footnote{11} Ref doc No.: (2014) Zheng Min Yi Zhong Zi No. 500.
VI OWNERSHIP OF HEALTHCARE BUSINESSES

China’s medical and healthcare system is established on the basis of the basic healthcare insurance system, whereby 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 Special Administrative Measures (Negative List) for the Access of Foreign Investment (2018), which restricts foreign investment in medical institutions to the form of a Sino-foreign equity or contractual joint venture. The Interim Measures for Administration of Sino-Foreign Joint Venture and Contractual Joint Venture Medical Institutions further stipulate the total amount of investment, the minimum proportion of Chinese capital or equity and the term of operations of Sino-foreign joint venture and contractual joint venture 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 foreign-invested medical institutions.

---

12 According to the latest statistics for April 2017.
13 Bluebook 2017 at page 16.
14 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.
VII COMMISSIONING AND PROCUREMENT

As mentioned above, China’s healthcare services are divided into basic healthcare services and special healthcare services. Basic healthcare services include public healthcare services and basic medical services. Public healthcare services are regarded as a form of public goods, which are mainly funded by government outlays and provided to urban and rural residents on an equal basis. Medical services for treating non-basic diseases, or those regarded as discretionary diagnosis and treatment measures are considered special healthcare services.

China is committed to optimising the price of medical services and drugs. Since the latter half of 2018, China has begun to carry out a pilot ‘centralised procurement policy’ for certain drugs in 11 cities, which centralised the procurement of drugs by public medical institutions across regions. Procurement will be made in large quantities and thus reduce transaction costs, encourage pharmaceutical companies to reduce drug prices, and relieve the burden on patients. After assessing the effect of enforcement of the pilot policy, China is contemplating expanding the coverage of this centralised procurement policy step by step and ultimately converting it to a stable, long-term policy.

VIII MARKETING AND PROMOTION OF SERVICES

In China, the publication of medical, pharmaceutical, medical equipment and health food advertising is subject to content reviews by the advertising authorities prior to publication. Advertising review organs include SDA, NHC and State Administration for Market Regulation.

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

- assertions or guarantees as to efficacy and safety;
- efficacy rates or cure rates;
- comparisons of the safety or effectiveness of drugs or medical devices with those of other medical institutions;
- the use of advertising spokespersons to endorse or provide testimonials; and
- medical advertising disguised as health and well-being advice.

According to the Law Against Unfair Competition, 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.

---

15 The cities included in the pilot centralised procurement policy are Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xi’an. The pilot drugs are chosen from the generic drugs that have passed a consistency evaluation for quality and efficacy. For details of the policy, please refer to the Circular of the General Office of the State Council on Printing and Issuing the Plan for the Government’s Pilot Organisation of the Centralised Procurement and Use of Medicine (Guo Ban Fa (2019) No. 2).

under the law. 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.

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’ that 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.

In September 2018, NHC and the State Administration of Traditional Chinese Medicine jointly promulgated three documents concerning Internet plus Healthcare, namely Measures for Administration of Online Medical Diagnosis (for Trial Implementation), Measures for Administration of Online Hospitals (for Trial Implementation), and Good Practices for Telemedicine Services (for Trial Implementation), which means the industry-focused ‘Internet Medical Policy’ has finally been implemented. However, as a new medical service model, these new Measures take a relatively conservative attitude to internet medical services from the following perspectives:

a  internet hospitals and internet-based diagnosis services must rely on bricks-and-mortar medical institutions, and be subject to advance market access administration and governmental approval;

b  a unified provincial-level supervision platform has to be established before implementing market access management of internet hospitals to ensure a baseline for medical quality and safety for the new internet medical services (also, all medical institutions that carry out internet-based diagnosis activities are required to keep traceable records during the whole process and provide administrative authorities with access to data);

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.
c internet-based diagnosis services are restricted to subsequent consultations for certain common diseases, chronic diseases and Internet-plus family doctor signing services. No internet-based diagnosis services may be provided to patients seeking initial medical consultations; and
d telemedicine services may only be carried out between bricks-and-mortar medical institutions.

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. At present, 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, piloting centralised procurement policy, 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.
Chapter 4

ENGLAND

Holly Bontoft and Sarah Ellson

I OVERVIEW

Healthcare in the UK is dominated by the National Health Service (NHS), a universal healthcare system 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 UK: 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.

Healthcare services are commissioned either at the local level by clinical commissioning groups (CCGs) made up of local general practitioners or, for more specialised commissioning, at a national level by the National Health Service Commissioning Board (known as NHS England). Funding pressures on the NHS have been political priorities and have been reflected in the latest NHS Long Term Plan, published in January 2019. The biggest impact of Brexit is likely to be the availability of healthcare professionals.

There is an increasing role for private healthcare provision, either directly to the NHS (i.e., by running NHS-provided services) or by providing private services directly to patients. In 2016–2017, NHS spending with private sector providers in England was 7.7 per cent of the Department of Health’s revenue budget. While this has been politically contentious, it is unlikely to change in the short term and private providers are as closely regulated as the NHS.

---

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 and Nicholas Pimlott.
2 Section 1I, National Health Service Act 2006.
3 Section 1H, National Health Service Act 2006.
5 https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/ Commons/2017-12-18/120099.
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 emergencies. Some people also pay for specific private treatment, such as elective surgery or physiotherapy, where there may be a wait to receive such treatment on the NHS.

In England, NHS hospital treatment and primary care is free at the point of use to those ordinarily resident in the UK. It is funded through general taxation and national insurance deducted from salaries. There are fixed charges for certain items of NHS care, such as prescription medicines and dental treatment. Exemptions from these charges are available on the basis of age, income or certain medical conditions.

As a current member of the European Union, UK nationals have reciprocal arrangements with European Union states. These arrangements will cease in the event of a no-deal Brexit, although the government has expressed a desire to maintain the current arrangements.

The regulations that set the legal framework for cost recovery from overseas visitors changed in 2017; it is now mandatory to collect payment, in advance of services, unless treatment is immediately necessary or urgent.

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.

ii The role of health insurance
Some UK citizens opt to have private health insurance, often as a tax-efficient employment benefit, but it is not compulsory. EU nationals living in the UK and not employed are required to have comprehensive sickness insurance, and those eligible for overseas visitor charges may rely on insurance. In addition, those applying for certain types of entry clearance or leave to remain in the UK must pay a surcharge of £300 to £400 a year to use NHS services.

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.

iii Funding and payment for specific services
Which services are routinely commissioned by NHS England or a CCG is substantially informed by evidence-based guidance and advice issued by the National Institute for Health and Care Excellence (NICE).

---

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 and National Health Service (Charges for Drugs and Appliances) Regulations 2015.
11 The National Health Service (Charges to Overseas Visitors) Regulations 2015 as amended.
12 Immigration (European Economic Area) Regulations 2016.
13 The Immigration (Health Charge) Order 2015/792.
NICE has various powers to produce guidance and recommendations to NHS bodies on care pathways and technologies they are expected to provide.\textsuperscript{14} NHS bodies are legally obliged to fund treatments recommended by NICE’s technology appraisal recommendations;\textsuperscript{15} however, other guidelines do not have the same level of authority.\textsuperscript{16}

For example, NICE guidelines recommend that three IVF cycles should be offered to women under 40 years of age who have been trying to get pregnant naturally for two years, or who have had 12 cycles of artificial insemination. However, the final decision about who can have NHS-funded IVF in England is made by local CCGs, whose criteria may be stricter than those recommended by NICE. NICE’s role is to assess the clinical and financial efficacy of the technology.\textsuperscript{17}

For cancer drugs, the Cancer Drugs Fund (CDF) is another option at the end of the NICE technology appraisal process. The CDF acts as a managed access fund where more information is required to determine clinical effectiveness. A budget impact test also applies for certain technologies over the first three years of a technology’s 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 to mitigate the impact on the rest of the NHS budget. The first reported example of this was Keytruda, where MSD agreed a substantial confidential discount before it was approved in 2018.

In some cases, further funding is available through Individual Funding Requests (IFRs). Where NHS England’s duty to provide health services\textsuperscript{18} is not met under NICE technology appraisal recommendations, individuals can request funding for treatment through an IFR. The law surrounding IFRs is discussed in the case of \textit{S v. NHS England}.\textsuperscript{19}

As set out above, standard charges apply to a number of NHS services.\textsuperscript{20}

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

The UK healthcare system is heavily reliant on primary care practitioners (general practitioners, or GPs) delivering family medicine and acting as gatekeepers to secondary and tertiary care, which in the NHS is rarely directly accessible, except in emergencies.\textsuperscript{21}

\textsuperscript{14} See, in particular, Regulations 5 and 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

\textsuperscript{15} Regulation 7(6) National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

\textsuperscript{16} The obligations to comply with different types of NICE guidance, guidelines and recommendations were most recently explored in \textit{R (Rose) v. Thanet CCG} [2014] EWHC 1182 (Admin), which confirmed that, although 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).

\textsuperscript{17} https://www.nice.org.uk/guidance/cg156.

\textsuperscript{18} Section 1H(3) of the 2006 Act.


\textsuperscript{20} National Health Service (Charges for Drugs and Appliances) Regulations 2015 and the National Health Service (Dental Charges) Regulations 2005 (as amended).

\textsuperscript{21} This position is slowly beginning to change, with the recent introduction in some areas of allowing patients to self-refer to NHS physiotherapy services or mental health services in certain situations.
GP providers are normally independent businesses, providing services to the NHS under contracts with NHS England. While these are private law contracts negotiated between NHS England and the British Medical Association (acting as the representative of all GPs), many of the provisions are required under the NHS (General Medical Services Contracts) Regulations 2015 or the NHS (Personal Medical Services Agreements) Regulations 2015. Similar arrangements are in place for NHS pharmacy and dental services.

NHS hospitals and secondary services are run by local trusts or foundation trusts, which are independent of CCGs or NHS England. The relationship between them 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 because of the high operating costs. However, secondary or hospital care may be provided by either the NHS or private providers. Private secondary care may either take place in separate private hospitals, or private patient units in NHS hospitals. While it is not usually possible for patients using the NHS to see a medical consultant without first being referred 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 both of different health services and of health and social care. In 2019, the government published the NHS Long Term Plan to focus on funding, staffing and the pressures of a growing and ageing population. A new service model is proposed with every patient having the right to online GP consultations. Expanded community health and social care teams are intended to create genuinely integrated teams, and new integrated care systems are to be in place nationally by 2021.

Healthcare in the UK benefits from a near universal Summary Care Record (SCR) 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 by the patient’s GP and the relevant hospital. Of GP practices in England, 98 per cent now use a system that automatically creates an SCR unless a patient has opted out. This can be accessed by professionals, and patients can see who has accessed their records.

The UK’s data protection law has been significantly strengthened by the EU General Data Protection Regulation. Alongside this, NHS Digital provides a data security toolkit for organisations to measure 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

Regulators

There are a range of healthcare regulators, including separate regulators for healthcare operators and professionals.

22 See generally the Care Act 2014 and specifically Section 18(1) of the Act.
23 Both the Secretary of State for Health and Social Care and local authorities have a duty to promote integration of health and social care services under Section 13N of the National Health Service Act 2006 and Section 3 of the Care Act 2014 respectively.
Institutional healthcare providers

The key regulator for institutional health providers in England is the Care Quality Commission (CQC). Whether a provider requires CQC regulation is dependent on the activities they provide; carrying out a ‘regulated activity’ without being CQC registered 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 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.

To be registered, a new provider must register with CQC, which will assess the suitability of the applicant. All registered providers must have a registered manager responsible for the overall management of the service, who also must be fit for the role. Among others, the following documents may be required:

- safeguarding policy and procedures document;
- buildings regulations document;
- registered manager’s supporting evidence; and
- governance document.

CQC anticipates that it will provide a decision within 10 weeks of an application. Registration can be either unconditional or with conditions. Appeals against a decision on registration are made to the First Tier Tribunal. When assessing an application, 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 CQC and notify it of changes in registered details or certain adverse incidents. CQC also operates a regime of both

26 Section 1, Health and Social Care Act 2008.
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 has recently been subject to an independent review by Tom Kark QC and implementation of the recommendations is awaited.
31 Section 32, Health and Social Care Act 2008.
announced and unannounced inspections of providers. 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.32

As a result of a financial failure in 2011 of Southern Cross, one of the largest care providers in England at the time, CQC also has limited market oversight powers in relation to the largest care providers.33

Healthcare professionals

Healthcare professionals in England are usually required to be registered with one of the eight different regulators, including the General Medical Council34 and the General Dental Council.35 Some regulators operate on a UK-wide basis, while others only operate in certain nations. A new profession of nursing associates has been regulated in England only since early 2019.36 These regulators are overseen by the Professional Standards Authority for Health and Social Care (PSA).37 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 under the direction of a registered healthcare professional.

Where a profession is regulated by a statutory regulator, registration is compulsory under the applicable legislation. Each regulator details its requirements for initial registration (i.e., qualifications, experience and good character), continued registration (i.e., standards and continuing professional development) and disciplinary procedures to address serious concerns about a registrant. The requirements for registration 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 registration, an overseas applicant will normally need to demonstrate how their qualifications and training meet the requirements of 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 following a Law Commission review.38 There was a consultation in late 201739 about reform of professional regulation in the UK. The government responded on 9 July 2019 proposing some amendments and further consultations. The government announced on 18 July 2019 that the General Medical Council will become the regulator for physician associates and anaesthesia associates.

32 Sections 17 and 18, Health and Social Care Act 2008 and the Care Quality Commission (Registration) Regulations 2009.
33 Sections 54 to 56, Care Act 2014 and the Care and Support (Market Oversight Criteria) Regulations 2015.
34 Medical Act 1983.
37 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 the professional regulators require registrants to have indemnity or insurance arrangements providing appropriate cover for their practice.\(^\text{40}\) This will usually be provided by their employer. In medical negligence claims the primary defendant will be the NHS trust 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, subject to the nature of the relationship between the practitioner and the institution and the connection between the wrongdoing and the relationship. This is currently the subject of legal (and political) 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 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 in *Montgomery v. Lanarkshire Health Board*,\(^\text{41}\) which revisited a patient’s right to information about the risks of a procedure in light of societal changes in the doctor–patient relationship. The judgment noted that patients are ‘now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession’ (Paragraph 75) as the duty of doctors is ‘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’.\(^\text{42}\)

Much controversy was 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 recently returned to practice following an extended period of maternity leave and the incident occurred towards the end of a 12-hour shift.\(^\text{43}\) The case has also sparked a review into such cases and further changes to the law of manslaughter as it applies to healthcare are being considered.

\(^{40}\) For example, Section 44C, Medical Act 1983 and Article 12A, Nursing and Midwifery Order 2001.
\(^{41}\) (Scotland) [2015] UKSC 11.
\(^{42}\) *Montgomery v. Lanarkshire Health Board (Scotland)* [2015] UKSC 11, paragraph 82.
\(^{43}\) In addition to her criminal conviction, Dr Bawa-Garba was suspended from the GMC’s register of medical practitioners for one year; however, the GMC appealed this and the 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. Sentencing guidelines increased sentences for gross negligence manslaughter from 1 November 2018.
VI OWNERSHIP OF HEALTHCARE BUSINESSES

As discussed above, the Regulated Activities Regulations require directors of registered providers to comply with a range of requirements. These include that the directors:

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 international or non-national businesses being CQC-registered; however, they must have 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, resulting in the Private Healthcare Markets Investigation Order (2014). Among wider prohibitions, the Order restricts the circumstances where a clinician can refer a patient to a private hospital where that clinician has a financial interest in:

a that hospital;
b the hospital operator or owner; or
c the 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 keen to welcome new investment in the UK healthcare space, which is particularly evident in 2017’s Life Sciences: Industrial Strategy.

VII COMMISSIONING AND PROCUREMENT

Since the reforms of the Health and Social Care Act 2012, provision of NHS services has been on a provider–commissioner basis. Services are commissioned by either NHS England or CCGs, depending on the nature of the service and how commonly it is required (routine services are commissioned on a local basis by the CCG, whereas complex, rare procedures are commissioned by NHS England). The services are commissioned from NHS providers or by private companies by means of the NHS Standard Contract, the terms of which are mandated each year by NHS England. The exact services to be commissioned will be based on recommendations by NICE and the available funding.

Procurement of services by NHS bodies is subject to 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 a specific procurement regime under the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013, which is overseen by NHS Improvement. Regimes may overlap in some instances.

45 Amended by the Private Healthcare Market Investigation (Variation and Commencement) Order 2017.
For the procurement of supplies (rather than services), competitive tendering under the PCR 2015 is normally required. There is a general trend for NHS procurement of supplies (from sophisticated medical equipment to non-medical supplies) to be aggregated into larger ‘hubs’ to secure economies of scale. There is also 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 a voluntary scheme agreed between the Department of Health and Social Care and the Association of British Pharmaceutical Industries (ABPI). 48

VIII MARKETING AND PROMOTION OF SERVICES

The presence of the NHS limits the role of marketing in UK healthcare, and the NHS logo is a widely recognised symbol. Private healthcare services can be marketed and promoted, provided this is in accordance with the codes provided by the regulator, the Advertising Standards Authority (ASA). 49

The professional regulators also provide guidance on the marketing of services, obliging 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 websites the rating given at the most recent CQC inspection. 50

The ASA’s advertising codes prohibit misleading, harmful or offensive advertising and require that advertising must be legal, decent, truthful, deal fairly with consumers and not be misleading or offensive. The ASA may make public rulings and impose sanctions. The advertising of medicinal products is regulated by Part 14 of the Human Medicines Regulations 2012. 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. Therefore, the promotion of services that specify a treatment with a product that is not authorised in the UK or by the EU, or for a use that is not on label or that is a prescription-only medicine will breach these strictly enforced laws. Commercial practices 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 that regulate the medical devices and the pharmaceutical industries’ interactions with healthcare professionals, including all marketing and training activities. The codes are binding only on the corporate members of those associations, but are widely considered to reflect industry best practice; compliance with them (as well as NHS policies and codes) 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 an advantage with the intention to

induce or reward improper performance of any function or activity. Improper performance is 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.

IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

Since 2008 there has been continuous pressure on NHS budgets, leading to innovation to drive cost efficiencies. This has 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. The NHS Long Term Plan sets out a number of priorities for the NHS, including cancer, mental health and healthy ageing. There is also a clearly articulated and funded programme to upgrade technology and digitally enabled care across the NHS. This builds on universal SCRs and care plans supported by artificial intelligence and access to genomic data.

An increasing number of online services are being promoted, many of which have been welcomed for speed of access, increased access for those in remote areas and potentially lower-cost services. These are mainly private services, although some partner with NHS organisations. However, there is concern to ensure patient safety, with the CQC subjecting the relevant service providers to close inspection and guidance from bodies such as the professional regulators and the Royal College of General Practitioners for patients.51 New apps can be included in the NHS Apps Library with an online tool now available for self-assessment.52

The Department of Health has a number of major inquiries ongoing: into the use of infected blood;53 following the conviction of surgeon Ian Paterson for unlawful wounding during unnecessary breast surgery;54 and into concerns about specific hospitals or providers. Each of these could generate recommendations on the delivery of 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 sequenced its 100,000th genome in December 201855 from NHS patients with rare diseases and common cancers, creating a unique platform for research and delivery of personalised care. The NHS offers genetic screening of new cancer patients to provide personalised treatment, and full genome analysis for children with rare diseases from 2020. In addition, 2018 saw the first licences to allow mitochondrial donation in embryos that will be transferred for pregnancies.

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

52  https://www.nhs.uk/apps-library/.
53  https://www.infectedbloodinquiry.org.uk/.
54  https://www.patersoninquiry.org.uk/.
55  www.genomicsengland.co.uk/the-100000-genomes-project-by-numbers/.
X  CONCLUSIONS

English healthcare is delivered in an environment dominated by the NHS. However, there are 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 and a desire for greater integration of care, in an environment that wants to embrace new technology.
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 this threshold can voluntarily choose 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.

---

1 Stefanie Greifeneder is a partner at Fieldfisher (Germany) LLP. The information in this chapter was accurate as at August 2018.

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 according to 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 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 insurance providers. The services covered include practice-based treatment by family doctors, specialists and psychotherapists, hospital-based treatment and – under certain

³ Data published by vdek under www.vdek.com/presse/daten/b_versicherte.html.
⁴ Data published by vdek under www.vdek.com/vertragspartner/arbeitgeber/beitragsaetze.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 hospital room, treatment by a senior consultant, or certain dental treatments – the patient has to pay for those costs. 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 hospitals to perform
a minimum number of those procedures to be reimbursed for them. 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 speciality 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 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 health authorities of the respective federal states 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. As corporations under public law, these bodies are responsible for the administration of all matters related to speciality training in Germany. The state laws governing the healthcare

6 Reference is made to http://international.commonwealthfund.org/countries/germany/.
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; for example, the doctor does not fully inform the patient of all possible risks. The mistake has to be causal in relation to the patient’s consent for the treatment. In the absence of effective consent, the treatment is considered illegal, irrespective 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 generally be 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 of 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 work of the doctor. Therefore, many decisions of the German courts have looked at the question of when it is justified to reverse the burden of proof by various presumptions.

7 Reference is made to www.bundesaerztekammer.de/weitere-sprachen/english/work-training/work-and-training-in-germany/.
For example, a treatment error was held to be presumed when an injury occurred that corresponded 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 had not recorded the course of treatment nor 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 was capable of causing the injury at issue. The findings from these cases have been implemented directly in the German Civil Code (Paragraph 630h).

VI OWNERSHIP OF HEALTHCARE BUSINESSES

Ownership of a hospital can be with:

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

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

\[c\] private for-profit companies and hospital chains.

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

Physicians either work in their individual, solely owned practice or in partnership with other doctors. In addition, a new legal form, the medical care centre (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 hospital healthcare services are provided by employees of the hospitals, although 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 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. As 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 (as from 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 premiums. Indeed, independent of their actual income, the self-employed pay a contribution based 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 system10 plans to

---

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 SHI- Contribution Relief Law; bill of the German Federal Ministry of Health of 19 April 2018.
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.\(^\text{11}\)

On 25 June 2018, the German Federal Ministry of Health submitted a draft bill, the Nursing Staff Strengthening Act, to strengthen the nursing staff workforce. 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. To improve staffing facilities in hospital care, in future every additional nursing position will be completely refinanced by the payers.\(^\text{12}\)

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 growth markets, is expected to be subject to profound changes over the course of the coming years. As digital healthcare becomes more and more important in ensuring sufficient healthcare provision for 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 in the number of elderly people.


\(^{12}\) https://www.bundesgesundheitsministerium.de/sofortprogramm-pflege.html.
Chapter 6

IRELAND

Rebecca Ryan

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.

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.

1  Rebecca Ryan is a partner at Matheson.
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 1994–2018. 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 (€124) (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.

© 2019 Law Business Research Ltd
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 hospitals to people living in the community; for example, by general practitioners, nurses and health clinics. Secondary healthcare is delivered in hospitals to patients normally living at home; for example, outpatient clinics, and accident and emergency clinics.

Doctors

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

The main functions of the IMC are to:

a maintain a register of doctors;

b ensure high standards of medical education and training;

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

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

e promote good medical practice;

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

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

Nurses and midwives

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

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

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

c specify standards of practice for registered nurses and midwives;

d specify criteria for specialist nursing and midwifery posts;

e establish committees to inquire into complaints; and

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

---

2 Section 37 of the Medical Practitioners Act 2007.
3 www.medicalcouncil.ie/Existing-Registrants/.
Dentists
The dental profession in Ireland is regulated by the Dental Council of Ireland (DCI) and only dentists registered with the DCI can practise dentistry in Ireland. The DCI was established under the provisions of the Dentists Act 1985 and its main functions are to:

a. establish, maintain and publish a Register of Dentists, Dental Specialists, Dental Hygienists and Dental Nurses;
b. regulate the dental education and training provided in Irish dental schools and to set standards required for primary qualifications;
c. inquire into the fitness of a dentist to practise dentistry and investigate any alleged professional misconduct. The Council has the power to suspend, attach conditions to registration or erase a dentist’s name from the Register;
d. make, with approval of the Minister for Health, schemes for the establishment of classes of auxiliary dental workers; and
e. advise the dental profession and the public on all matters relating to dental ethics and professional behaviour.

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

CORU currently maintains registers for dieticians, occupational therapists, radiographers and radiation therapists, social workers, speech and language therapists, optometrists and dispensing opticians, physiotherapists, medical scientists, podiatrists, psychologists and social care workers.

Members of these professions are required to register with CORU in their respective professional registers and 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
GP’s 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.

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

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

iv Data protection laws

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

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

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

The General Data Protection Regulation (GDPR) came into effect on 25 May 2018. The GDPR has ‘direct effect’ and therefore it does not require transposition into Irish law 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.5

v The IMC Ethical Guidelines

In accordance with the IMC Ethical Guidelines,6 a doctor can share information with other doctors in appropriate circumstances without the patient’s consent (e.g., the patient cannot give consent because of his or her medical condition). If disclosure of a patient’s information is necessary as part of the care and treatment of the patient, the Ethical Guidelines permit disclosure to the appropriate person on the basis that they understand that the information is confidential.

The Ethical Guidelines state that where a patient is capable of making his or her own decisions about his or her healthcare, a doctor must first obtain patient consent before

---

5 https://www.hse.ie/eng/gdpr/gdpr-faq/.
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 practitioners’ licences where there is a finding of misconduct or poor professional performance.

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

Complaints

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

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

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

- an advice, admonishment or censure in writing;
- a censure in writing and a fine not exceeding €5,000;
- the attachment of conditions to the doctor’s registration, including restrictions on the practice of medicine that may be engaged in by the doctor;
- the transfer of the doctor’s registration to another division of the register;
- the suspension of the doctor’s registration for a specified period;
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.7

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.8

ii Nurses and midwives

The NMBI is the independent, statutory organisation that regulates the nursing and
midwifery professions in Ireland.9 Its role is to protect the health and safety of the public, by
setting standards, ensuring that nurses and midwives are competent to practise. Its 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.10 The
Irish Nurses and Midwives Organisation Medical Malpractice Scheme provides cover for
members who are self-employed or employed outside the state sector.11

---

7 www.medicalcouncil.ie/Public-Information/Making-a-Complaint-/Fitness-to-Practise-Inquiries/Medical-
Council-Sanctions.html.
9 www.nmbi.ie/Registration.
11 https://new.inmo.ie/MagazineArticle/PrintArticle/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.12

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.13

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.14

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.15

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

v Institutional healthcare providers

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

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

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

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

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

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

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

ii Notable cases

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

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

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

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

c Causation: that the healthcare provider’s breach of duty caused the damage that the patient is complaining of, namely 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. This case established the principal test for establishing liability in medical negligence cases. In general, a medical practitioner will not be found negligent if he or she has followed a general and approved practice in his or her treatment or diagnosis. This practice need not be universally approved but must be approved by a substantial number of reputable practitioners holding

---

the relevant specialist or general qualifications. A medical practitioner will not be able to rely on a general and approved practice that has inherent defects that ought to be obvious to any person giving the matter due consideration.\textsuperscript{17}

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.\textsuperscript{18}

In relation to disclosure and informed consent of medical procedures, it was held in \textit{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.\textsuperscript{19}

\section{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.

\section{VII COMMISSIONING AND PROCUREMENT}

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

An \textit{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’.\textsuperscript{20}

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.\textsuperscript{21} 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:

$\begin{align*}
\text{a} & \quad \text{equal access for all to healthcare, based on need, not income;} \\
\text{b} & \quad \text{everyone insured for a standard package of curative health services;} \\
\text{c} & \quad \text{no distinction between public and private patients;} \\
\text{d} & \quad \text{universal GP care;}
\end{align*}$

\textsuperscript{18} \textit{Gottstein v. Maguire & Walsh} [2004] IEHC 416.  
\textsuperscript{20} \url{http://www.irishtimes.com/news/ireland/irish-news/commissioning-would-improve-health-service-says-hiqa-1.2959831}.  
universal hospital care to include independent, not-for-profit trusts and private hospitals;

social care services remaining outside 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.22 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’.23 This is discussed further at the end of this chapter.

**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).

---


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). 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

© 2019 Law Business Research Ltd
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, although consent is deemed, the next of kin will, in practice, always be consulted prior to removing any organ. If the next of kin objects to the organ donation, the donation will not proceed.

The Human Tissue Bill will address the giving of consent for the removal, retention, storage, use and disposal of organs and tissues from deceased persons in the context of post-mortems, transplantation, research or anatomical examination. It will also set out the details surrounding a person’s right to opt-out of the donation of his or her organs and tissues for transplantation and research. The government plans to publish the General Scheme of this Bill in the coming months, and the bill is expected to undergo pre-legislative scrutiny during the government’s Legislation Programme Summer Session 2019.

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

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 to implement the proposals outlined in the report. The recruitment process for the new ‘Sláintecare’ Programme began in January 2018. The Sláintecare implementation strategy is the government’s plan for delivering this substantive and equitable health and social service over the next 10 years. Sláintecare is an ambitious and complex reform programme that will take 10 years to implement.

CONCLUSIONS

In conclusion, healthcare services in Ireland are provided in a two-tier system, both private and public. There are a number of different regulatory bodies governing the provision of healthcare services in Ireland for both public and private patients alike. Regulatory bodies such as the Medical Council, Dental Council, CORU and the Pharmaceutical Society of Ireland play a pivotal role in ensuring a high standard of care is provided to all patients.

Over the next 10 to 15 years, the HSE has planned to make a number of significant changes to the way healthcare services are provided in Ireland. The HSE plans to roll out a national Electronic Health Record that will enable patient information to be instantly accessed by approved medical personnel. Further, there are proposals to provide free medical care for all, changes to the laws governing organ donation and the phasing out of the provision of private care services in public hospitals. The Department of Health has published the Sláintecare implementation strategy, which is the government's plan to deliver a world-class health service for Irish people over the course of the next decade.
Chapter 7

JAPAN

Noboru Suwa and Fumiharu Hiromoto

I OVERVIEW

i 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 universal health insurance, referred to as the national health insurance system (NHIS), which was established in 1961 (see Section II), 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 because of Japan’s low fertility rate, ageing population, growing use of expensive technologies and long-term primary budget deficit for nearly three decades.

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

a The Medical Care Plan (see Section II) was adopted in 1985.

b The Medical Care System for the Elderly in the Latter Stage of Life, which is a social insurance system for those aged 65 and over who require long-term care and social services, was introduced in 2000. To maintain sustainability, this system is reviewed and revised every three years.

c The Integrated Community Care System, which is a comprehensive community-level system that integrates healthcare, nursing care, prevention, housing and livelihood support to enable the elderly to live self-sufficiently in environments that are familiar to them, was promoted as a matter of national policy from 2012.

d 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, reforms of medical and long-term care services, pension reforms, measures against poverty and income inequality, and measures for low-income earners.

e The Regional Healthcare Vision (see Section II) was started in 2015.

f The Guidelines for the Appropriate Implementation of Online Medicine and the related question-and-answer (Q&A) documentation (see Section IX) were released by the Ministry of Health, Labour and Welfare (MHLW) in 2018.

g Measures for procuring physicians (see Section II), which started on 1 April 2019.

1 Noboru Suwa is a partner at, and Fumiharu Hiromoto 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.
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.

**ii Significant issues to be tackled with assistance from professionals**

The following are some of the significant issues that will eventually require the support of financiers, 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 that the 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 Sections II and IX).

**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 applies to these facilities, is now expiring. In addition, many of these facilities do not satisfy the latest earthquake-resistance standards. Therefore, a considerable number of medical facilities will need large-scale repairs, if not complete reconstruction (see Section IX).

**Family-oriented governance of medical corporations**

Medical corporations are corporate bodies that are operated by administrative bodies for medical care service programmes, and that retain the non-profit status required for medical practice in Japan.

Under the seventh major revision of the Medical Care Act (the 7th Revision) promulgated in 2016, almost all of a certain scale or category of medical corporations were statutorily obliged from April 2019 to comply with the Japan GAAP for medical corporations, accept external audits, and publish written reports on transactions of a certain scale with their directors, close relatives of directors, 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).

**New industrial technologies**

Ultra-expensive pharmaceuticals, radiotherapy facilities, ICT, AI, robotic surgery, telemedicine, and other industrial technologies have evolved and will keep evolving. These

---

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).
technologies increase and deepen inter-relations between the medical industry, for-profit corporations, and organisations that confront the conventional philosophy on the non-profit status of medical practice in Japan (see Section IX).

II THE HEALTHCARE ECONOMY

i General

Although Japan residents avail themselves of private health insurance, Japan boasts a working NHIS for its residents. Under the NHIS, (1) residents in Japan are required to enrol in the public health insurance system, (2) there is freedom of choice of medical institutions, and (3) the 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. Depending on age and income, the insured co-pay 10 to 30 per cent of the service fees to the medical provider. While the 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 disallows NHIS coverage of the entire NHIS-covered and uncovered medical treatments, 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 specific services

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

To control the supply of and demand for medical resources, Japan adopted the Medical Care Plan in 1985, under which the 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’ 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 the event 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, 3

---

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. In contrast, primary medical service areas provide 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 prefecture concerned, except Hokkaido Prefecture and Nagano Prefecture, which are large and are divided into multiple tertiary medical service areas.
the reports must be submitted once every six years with provisional revisions to be made every three years. If existing hospital beds with certain medical functions exceed the standard number of that type of hospital bed 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 in 2014) on medical functions of hospital beds to estimate healthcare supply and demand for 2025 (when the baby boomers will reach the age of 75) and establish region-specific healthcare systems by 2025. Furthermore, as of 2018, each prefectural governor can refuse applications for additional hospital beds if existing hospital beds with certain medical functions exceed the estimated number of that type of hospital bed in the Regional Healthcare Vision areas (which are areas similar to secondary medical service areas).

Medical service fees payable to medical institutions and pharmacies for covered 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. 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 were increased for medical institutions that strengthen their 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 (a number that legislators are considering lowering).

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 dentists, however, are not automatically registered with the NHIS and must 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 the 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) or 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, 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 nurses, midwives, nurses and assistant nurses, and (5) others are regulated respectively under:

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

A graduate of a medical school (or medical department of a university) outside Japan, or a physician licensed outside Japan must be accredited by the MHLW 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 those services are rendered within the scope of those purposes by obtaining a special permit from the MHLW.

To our knowledge, foreign entities who approach the Japanese medical industry sometimes involve foreign medical practitioners in their research and development (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.

---

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.
V NEGLIGENCE LIABILITY

i Overview
Because of the information asymmetry between medical practitioners and their patients, as well as the physicians’ expertise, the medical hierarchy and 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 of civil cases (other than overpayment claims) was approximately 8.8 months and their settlement rate was approximately 34.7 per cent. 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, punitive damages are not allowed under Japanese law, and the amount of damages paid to the elderly is generally not large.

ii Notable cases
In a decision issued in 2000, the Supreme Court adopted the concept of possibility of patient’s survival to a reasonable extent at the time of death, that is to say, where the causal relationship between a doctor’s negligent medical act or failure to 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 68.9 per cent of the hospitals in Japan are operated by medical corporations (as at 31 March 2019). 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. As at 31 March 2019, of 54,790 medical corporations, 39,263 were with equity.

When a medical corporation association with equity is dissolved, the residual assets will be distributed to the equity holders in proportion 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.

In addition, 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 the return of that member’s equity. The amount to be returned is calculated by multiplying the then net asset value of the medical corporation association 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 it must 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.

The conversion is done by the voluntary relinquishment by all members of their right to request for the return of their equity. The government hopes to convince members to give up that right through tax incentives, such as the deferral of and exemption from inheritance tax (on deceased members’ 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 the 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. In practice, it is typical for members to weigh the tax incentives against the hope of a future sale that will monetise their equity.

One of the major policies of the Medical Care Act is that medical practice must be non-profit because (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:

a licence to operate medical facilities is generally not given to for-profit organisations (with limited exceptions);

medical corporations are prohibited from making dividend distributions (including de facto dividend distributions like rents proportionate to earnings); thus, any surplus of

---

9 See ‘Vital Survey of Medical Institutions’ (approximate number as at 31 March 2019) released by the MHLW.
medical corporations can only be used for medical expenditures such as maintenance and improvement of medical facilities and salaries of employees and any remaining balance must stay within the medical corporations;

c) the directors general of medical corporations must be physicians or dentists, with exceptions under specific permit from the relevant prefectural governor; and

d) for-profit organisations such as stock corporations may make monetary contributions to medical corporations but cannot become members thereof (with limited exceptions).

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 also restrains the flexible structuring of attractive products to securitise hospital real estate.

In a structure 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 member of the founder physician, and provides to the medical corporation such services as laundry of linen, leases of medical devices and hospital or clinic buildings, 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

i) Restrictions on advertising of medical services

Before the 8th Revision, there were two different sets of restrictions on the advertising of medical services: (1) one for advertising media such as advertising inserts, TV commercials and signboards under the Guidelines for Advertisements for 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 was permitted to 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, and medical services to be rendered). False advertising was subject to penalties (direct penalties), while comparative advertising, exaggerated advertising, objective-truth-not-proven advertising and advertising with content in violation of public order and morality (collectively, exaggerated advertising) were subject
to orders for suspension or correction from the relevant prefectural governor but only subject to penalties for violation of such orders (indirect penalties). 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 constituting ‘advertisements’, which were prohibited under the Medical Care Act, and therefore no penalties were imposed for violations of the Guidelines for Home Pages of Medical Institutions.

However, because numerous consumer problems related to aesthetic medical services arose from advertising on medical providers’ websites, the 8th Revision defined advertising under both items (1) and (2) above as statutory ‘advertisements’ subject to direct penalties for false advertising, indirect penalties for exaggerated advertising (to the definition of which 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 advertisements, 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 for Medical Services on 1 June 2018.

Healthcare providers and their commissioned advertising agencies and affiliate marketers may also be subject to other advertising regulations under other laws of more general application, such as the Act against Unjustifiable Premiums and Misleading Representations, the Pharmaceuticals and Medical Devices Act (PMDA),\(^\text{10}\) the Health Promotion Act, and the Act on Unfair Competition Prevention.

### ii 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 Agency\(^\text{11}\) are the principal regulatory authorities under the PMDA. In addition, the Fair Trade Commission and the Consumer Affairs Agency oversee those relations through the relevant self-regulatory organisations\(^\text{12}\) pursuant to the Fair Competition Code Concerning Restrictions on Premium Offers in the Ethical Pharmaceutical Drugs Marketing Industry and the Fair Competition

---

\(^{10}\) The Act on Ensuring Quality, Efficacy and Safety on Pharmaceuticals, Medical Devices, Etc.

\(^{11}\) 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.

\(^{12}\) 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 and the Japan Federation of Medical Devices Association.
Code Concerning Restrictions on Premium Offers in the Medical Devices Industry, both of which are based on the Act Against Unjustifiable Premiums and Misleading Presentation (AUPMP).  

At an industry self-regulation level, pharmaceutical and medical device companies have made efforts to make these 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 statutorily penalised.

On 19 March 2019, a bill to amend the PMDA and other relevant laws covering the following, inter alia, was submitted to the Diet:

- establishment by proprietors of pharmacies and pharmaceuticals and medical device companies of a system to ensure compliance with laws and regulations on pharmaceuticals and medical devices;
- enhancement of the existing system for importation certificates for unauthorised medicines and medical devices from overseas, and strengthening the authority of drug enforcement officers; and
- introduction of a surcharge system for false or exaggerated advertising regarding pharmaceuticals and medical devices, which will (1) impose a surcharge equal to 4.5 per cent of the related sales of violators, (2) deduct 3 per cent of the related sales from that 4.5 per cent surcharge, if the same advertising is also subject to another surcharge system under the AUPMP, and (3) enable violators who file a leniency application with the MHLW under certain conditions to receive a 50 per cent deduction of the surcharge.

IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

The following possible solutions to the significant issues pointed out in Section I are currently in progress or being considered.

i  Uneven distribution of physicians in regional areas and among departments

On 6 July 2018, the Act on the Arrangement of Related Acts to Promote Work Style Reform was promulgated, setting maximum limits on overtime hours. However, its application to physicians has been deferred until April 2024. When the new law is applied, physicians’ overtime hours will be limited to 960 hours per year, with certain exceptions up to 1,860 hours per year, where a physician’s duty to respond to emergencies, the public nature of medical care, the unpredictability of diseases, the physician’s expertise and training, and innovations in medical treatments are balanced.

On 1 April 2019, to tackle the uneven distribution of physicians in regional and practice areas, the following amendments to the Medical Care Act and the Medical Practitioners Act took effect:

---

13 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 a lavish or excessive method for inducing the selection or purchase of pharmaceuticals or medical devices under socially accepted standards. In this context, ‘safe-harbour’ rules apply; for example, expenditure of up to ¥5,000 per person (excluding consumption taxes) at a client dinner accompanying business talk is considered not to be lavish or excessive.
introduction of a new system regarding the MHLW’s accreditation of physicians with certain working experience in regional areas facing a shortage of physicians and the evaluation of such physicians as managers of ‘regional medical care support hospitals’;

b establishment of ‘plans to procure physicians’ under the Medical Care Plans, through a PDCA cycle by prefectural governments, and enhancement of the cooperative functions of the councils for regional medical services in the 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 of functional differentiation and cooperation among outpatient hospitals inside and outside each secondary medical service area.

ii 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. It is anticipated that these necessary repairs or reconstruction will be financed primarily through debt financing by the Welfare and Medical Service Agency14 or other financial institutions and secondarily through asset financing, rather than equity funding, because of the low return on investment because of the non-profit status of medical practice in Japan.

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),15 and placed importance on healthcare business operators and 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 held by originators of hospital real estate that medical assets should be owned and operated by medical practitioners.

Notwithstanding the Guidelines, there has not been much progress in investments by REITs listed on the Tokyo Stock Exchange in hospital real estate. The first two deals (namely the acquisitions of Niigata Rehabilitation Hospital and Senri Chuo Hospital, both in the form of trust beneficial interest) were made on 10 October 2017 and 11 January 2019 respectively, by Healthcare and Medical Investment Corporation. But no other listed REITs have acquired hospital real estate. One possible reason for this is the JMA’s constant vigilance against the entry of ‘funds’ that represent for-profit entities, which is not consistent with the non-profit status of medical practice in Japan. 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. On the other hand, REITs

---

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.
themselves may not be prepared to accept risks associated with advanced acute or acute care facilities, including the possibility that medical revenues may be less stable compared with those from recovery phase facilities and medical accidents, which may harm their reputation.

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 to understand the healthcare industry and not seek excessive returns through environmental, social and governance investing, socially responsible investing or ‘impact investing’.

iii 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 that agree with this policy and participate in meeting hospital bed quotas and cooperative purchasing of pharmaceuticals and medical devices, exchange of personnel, and R&D among those organisations.

However, as at 1 April 2019, there are only eight such accredited corporations. They include Japan Sea Healthcare Net Corporations Promoting Regional Medical Cooperation, which 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, \(^{16}\) 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 may 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.

---

\(^{16}\) One of them is the Summary of Survey Analysis Report on Hospital Management Conditions 2018 (Survey on June 2018) jointly prepared by the Nationwide Public and the Private Hospital Federation on 26 February 2019.
iv 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), became completely effective 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, became effective on 11 May 2018 with the aim of balancing industrial needs and privacy protection. Another recent law, the Act On Clinical Research, which became effective on 1 April 2018, safeguards the quality of, and protects data subjects in, certain types of clinical research called ‘Specified Clinical Research’, by requiring 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.

In March 2018, the MHLW released the Guidelines for the Appropriate Implementation of Online Medicine, followed by the related Q&A, and the Notification of the Handling of Inappropriate Medical Practice of Online Medicine on 26 December 2018. These guidelines cover the minimum standards and recommendations for (1) online medicine (i.e., telemedicine on a real-time basis), including medical examination, diagnosis, and provision of diagnostic results and prescription through information and communication electronics devices on a real-time basis, and (2) online encouragement of visits to physicians who possess the minimum required medical judgement to refer patients to appropriate specialists by using information gathered through interviews or medical questionnaires using information and communication electronics devices on a real-time basis, but without, in any event, making a medical diagnosis, prescribing medicine or otherwise conducting medical practice. They will be revised every year, in light of the progress in technologies and other developments. In January 2019, LINE Corporation and M3, Inc announced a joint investment to launch LINE Healthcare Corporation to develop online healthcare businesses.

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.

v 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 for-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. In any case, M&A 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.

In contrast, 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 the 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 of 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 (MOHW) and the Ministry of Food and Drug Safety (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 (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.

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 contributions are mandatory, and the amount of the insurance contributions is determined based on the income level of the relevant 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) laws and regulations relating to health insurance.

There are various stakeholders involved in the healthcare industry in South Korea, including the following:

a medical institutions;

b healthcare professionals;

c patients;

1 Soon-Yub Samuel Kwon and Eileen Jaiyoung Shin are partners at Lee & Ko.
manufacturers, importers and sellers of medical devices and pharmaceutical or biotechnology products;

insurance companies;

government authorities, including the MOHW, the NHIS, the HIRA and the MFDS; and

academic institutions for healthcare professionals.

The roles played by the various government authorities in relation to the National Health Insurance are as follows.

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 the imposition of insurance contributions, and the scope of healthcare benefits subject to insurance. The MOHW also approves the budget and regulations of the NHIS, which is the authority managing and operating the National Health Insurance system.

The NHIS: as the insurer of the National Health Insurance system, the responsibilities of the NHIS include:

- the management of qualification criteria of health insurance subscribers and their dependants;
- the imposition and collection of insurance contributions;
- 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.

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

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 these 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 Act

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:

a. the National Health Insurance programme is compulsory when certain legal requirements are met, and the payment of insurance contributions becomes mandatory;

b. insurance contributions are imposed according to ability to pay (i.e., depending on income level); and

c. regardless of the level of the insurance contributions paid, 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 MOHW has responsibility for the medical benefits system, and provides medical costs assistance to those on low incomes 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 enrol 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 contributions are imposed by the private insurance provider based on the provider’s risk analysis, (3) the insurance benefits paid out vary according to the level of insurance contributions made by the insured, and (4) the collection of insurance contributions is governed by private contracts rather than by laws and regulatory requirements. In South Korea, insurance companies offer a variety of insurance products, such as cancer insurance, death insurance and co-pay medical expenses insurance.

### iii 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 services or outpatient services) and the nature 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 medicines, medical materials, or medical services that are 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. Medicines, medical materials or medical services that do 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 the 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 the 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 following 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 a referral from a clinic. That said, if the subject treatment is covered by the National Health Insurance, the patient’s co-payment may increase following such a 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 practise 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 centres are established in municipal units and form a part of government agencies. Doctors and nurses at these public health centres are in charge of vaccination, treatment and patient education in the local community. A patient must pay a prescribed fee to visit a public health centre, 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 centres 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, the NHIS, and the National Medical Center, and institutions under the MOHW include the National Hospital for each district, and the 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 institutions

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 that 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 a 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.

Prohibitions 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 the professional is licensed. A person who violates this prohibition may be subject to criminal sanctions, and if a healthcare professional has caused a non-healthcare professional to perform medical activities, the healthcare professional may be disqualified. 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 set out 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

As regards claims for medical negligence, case law provides that, 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 damage incurred must be found. Case law further provides that, to establish that causal connection, the plaintiff has the burden of proving that (1) medical malpractice has occurred, and (2) there are no causes for the damage in question other than the medical malpractice.

On the other hand, if a medical treatment may result in negative consequences to the patient, physicians have an obligation to explain the symptoms of the disease, details of the treatment method, the necessity for the treatment and the risks associated with the treatment to the patient (or the legal representative of the patient), such that the patient is able to sufficiently compare the necessity for the treatment and the risks inherent, and make an
informed decision whether or not to receive the medical treatment. In the event of a serious negative consequence of a treatment the possibility of which the relevant physician failed to properly inform the patient, the physician may be liable for damages. In this situation, if the patient claims only damages for the lost opportunity to make a choice, the patient is only required to prove that the opportunity to make a choice was lost because of lack of explanation by the physician. If the patient claims compensation for damage or harm 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.

There have been instances where physicians were held to be criminally liable when found to have committed medical malpractice. For this reason, it is quite common for patients who have had negative treatment results to file simultaneously both a criminal claim and their civil claims against the relevant physician. However, civil liabilities and criminal liabilities are differentiated under relevant laws, and the courts view criminal liability as being subject to a much higher burden of proof.

**Notable cases**

Recently, an eight-year-old child experiencing abdominal pain visited an emergency room, and this was followed by subsequent paediatric department visits and another emergency-room visit; the child ultimately died of hypovolemic shock due to diaphragmatic hernia and hemothorax while being treated for a diagnosis of constipation. The relevant physicians (one physician from the initial emergency-room visit, one paediatrician at the paediatric department and one physician present at the second emergency-room visit) were all found to be criminally liable and were sentenced to imprisonment at the trial-court level. There was an impassioned outcry from the Korean doctors’ association and healthcare provider communities criticising the decision for excessive punishment of medical negligence. The court of appeal found the physician from the initial emergency-room visit not guilty, and found that the other two physicians were guilty but imposed probation periods of three years on each. The prosecutors submitted the case to the Supreme Court but the Supreme Court dismissed the case on 30 May 2019. This case was the centre of much public attention because of its focus on criminal liability for physician malpractice.

**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 mentioned above, 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 a public nature specifically permitted under the MSA.

**ii Pharmacies**

Similar restrictions apply to pharmacies. That is, according to the PAA, no person other than a 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 by a regular corporation that is not a pharmacist, applying the prohibition on establishing a pharmacy to a corporation whose members are all pharmacists would unduly violate the freedom of occupation of those pharmacists. However, despite this Constitutional Court decision, the fact of whether a corporate pharmacy is permitted is still subject to debate.

VII COMMISSIONING AND PROCUREMENT

In Korea, all citizens are enrolled in the National Health Insurance programme, and all medical institutions must provide medical services under this system. However, there are also medical services that are not covered by National Health Insurance. In the case of these services the patient either pays directly or, if the patient has private health insurance coverage, a private insurer bears the costs. However, in the case of medical services covered by the National Health Insurance system, the patient pays a small co-payment to the medical institution and the remaining amount is paid directly to the medical institution by the NHIS. 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 conflict between stakeholders over their respective interests.

Also, in the case of medicines prescribed by a physician, the drug price is reimbursed according to the National Health Insurance Act. Whether or not the drug can be covered by National Health Insurance is determined by the Health Insurance Review and Assessment Service, and drug prices are determined based on negotiations between the NHIS and the relevant pharmaceutical company. Because drug prescription is not practicable unless covered by National Health Insurance, the original drug manufacturer pays great attention to National Health Insurance coverage and pricing negotiation.

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 (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 (KFTC), may also apply.

ii Medical services advertising

The MSA prohibits the advertising of medical services by a non-healthcare professional or non-medical corporation or institution. In addition, advertisements consisting of the following are prohibited: (1) guarantees of treatment effect; (2) comparisons of the quality of treatment with treatments by other medical institutions or professionals; (3) criticism of other medical institutions or healthcare professionals; (4) direct expositions of the treatment process; and (5) omission of important information. Further, a medical institution or healthcare professional intending to advertise using newspapers, outdoor advertisements, electronic signboards, etc. must obtain prior approval from the MOHW regarding the method and content of the advertising.
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 publications that may be misunderstood as providing a guarantee of the effectiveness of the drug by a healthcare professional, and advertising using photographs or articles that are suggestive of effectiveness or performance capabilities 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 that person, review and approval of the advertising by the MFDS is required.

Finally, in the case of ethical drugs, direct-to-consumer advertising is prohibited.

iv Advertising 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 issues. 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) advertising that uses news articles or media publications 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 that use articles, photographs or drawings that are suggestive of the effectiveness or performance capabilities of the medical device. Those who wish to advertise medical devices are subject to approval by 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 illegal rebates of this kind are also subject to criminal penalties and the economic benefits obtained through the rebate must be disgorged, and where disgorgement is not possible, the equivalent amount must be paid.
vi  **Korean Sunshine Act**

Under the Korean Sunshine Act, drug providers (including market authorisation holders, importers and wholesalers of drugs) and medical device providers (including manufacturers, importers, and sellers or lessors of medical devices) are required to keep records of economic benefits provided to medical institutions and healthcare professionals through sample provision, clinical trials, post-market surveillance, product presentations, sales calls, academic congress sponsorship or otherwise. Companies must maintain these records for five years. Companies must maintain a template expenses form prepared by the MOHW for each expenses item, and must submit these records to the MOHW upon request.

**IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES**

In April 2019, the MOHW released its four-year plan for National Health Insurance, with the following central ideas: (1) reimbursement expansion, (2) adequate compensation of medical services for quality increase, and (3) strengthening of National Health Insurance fund management. As regards reimbursement expansion, the current administration continues to transition non-reimbursables to reimbursables in accordance with the MOHW’s Plan for National Health Insurance Expansion released in August 2017. Under this Plan, coverage is being expanded in relation to magnetic resonance imaging and ultrasound examinations, medical services and medication provided at emergency rooms and intensive care units, and for various cancer and cerebrovascular patients.

Given the relatively low compensation of medical services, non-reimbursed examinations traditionally served as a source of supplemental income for healthcare providers. And for this reason, physician communities tend to oppose the expansion of National Health Insurance coverage to the historically non-reimbursed areas. The administration aims to address these concerns in the medical community by ensuring appropriate consideration for medical services.

Finally, the administration aims to strengthen its financial management of National Health Insurance funds by actively monitoring and re-examining current reimbursement status and drug prices.

**X  CONCLUSIONS**

Government regulations affect various aspects of the healthcare industry in South Korea, including National Health Insurance coverage, commercial activities and advertising. There are therefore many cases in which regulations change according to government policy, and as a result, conflicts often arise between stakeholders such as healthcare professionals, patients, the NHIS and the government authorities. As discussed above, various issues relating to the current healthcare system, including dispute resolution in cases of medical accidents and the scope of health insurance coverage, are currently the subject of debate, and as a result, the healthcare system of South Korea may change considerably in the near future.
I OVERVIEW

Mexico has a population of approximately 112 million individuals, 75 per cent of which may be considered urban population, and whose life expectancy has increased from 34 years in 1930 to 76 years in 2016 and is expected to increase slightly again this year.

This fact, among others, leads to specific risks and health requirements particular to urban populations, which are prone to non-communicable sicknesses, diseases and accidents, rather than the infectious and diet-related diseases that are more common in rural communities, where there is 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 implementing 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 (MoH) and state governments, among others.

The MoH, through the Federal Committee for Protection from 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 details of, existing laws passed by Congress, including, in particular, the Regulations on Rendering Medical Services (the Services Regulations), the Regulations on Health Research Matters and the Regulations on Publicity Matters (the Publicity Regulations), as well as provisions governing the National Institute of Social Security (IMSS), the Social Security Institute for Governmental Employees (ISSSTE), and the Public Administration Organic Law, among other legal provisions.
Additionally, medical and health-related services are also subject to Official Mexican 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 MoH 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 part of the formal employment group subject to social security; and

c individuals choosing to use independent health services.

The people in the first of these groups, whether in 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 MoH on a public assistance and welfare basis, as well as services provided under the Popular Insurance Programme (PIP), a programme developed to provide health services for specific diseases to those outside the first group.

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

During the past couple of years, particular attention has been given to the development of telemedicine services, which, although not well regulated, have offered the possibility of extending better medical and health services to individuals living in isolated communities, as well as to incarcerated individuals. These telemedicine services are operated not only by the MoH, but also by the IMSS, ISSTE, SEDENA, and PEMEX, the Mexican state-owned petroleum company.

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 provide health services (the IMSS or the National Workers Housing Fund Institute (INFONAVIT)).
Health services generally provided by the IMSS and INFONAVIT include:

- health and maternity insurance;
- work-risk insurance;
- retirement and old-age insurance;
- social welfare; and
- other health-related insurance.

Individuals not considered ‘workers’ for purposes of compulsory insurance may voluntarily request an affiliation to the IMSS that may provide them with partial 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.

Those sections of 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 ‘fees’ collected from the users of such services.

In the case of private parties rendering these services, funding is obtained either through direct charging of services or through payment by insurance companies on the terms and for the amounts agreed.

Public health coverage only extends to those areas of healthcare formally specified as being within the scope of the public institutions. Concepts such as ‘wellness’ and ‘alternative health therapies’ are outside the scope of the services provided by these institutions and, although not formally forbidden, in most cases they are not recognised nor do they receive public approval or coverage.

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

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 the 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, such as disaster situations or medical emergencies. However, such exceptions must be formally established by the appropriate governmental entities.
Accessing essential health services from public institutions is a cumbersome and time-consuming process.

With the exception of services provided by SEDENA and SEMAR, most public agencies require preliminary medical review at the hospital or clinic corresponding to the individual’s registered domicile, and on the basis of the review a physician determines whether he or she can provide the applicable treatment and medicines or whether the patient requires specialist analysis, tests or procedures. If necessary, the patient will be required to schedule visits to specialist doctors or laboratory or analysis procedures, which can take months to complete.

This system is inefficient and time-consuming, resulting in delays in the provision of required treatment and medicines, and this has a direct impact on patients’ 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, making it necessary for patients to travel to access services in premises at a distance from their domicile or in Mexico City. Further issues in this regard have arisen under the new administration following its general budgetary reduction, affecting health services and other areas.

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, and are 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 that specific authorisation.

These authorisations and licences are only issued subject to the specific formal procedures for applications submitted to 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 provision of these services are generally established in NOMs rather than in laws or regulations, and may vary greatly.

There are special legal provisions on confidentiality and privacy protection (set out in NOM-004-SSA3-2012) regarding clinical records and information obtained in the course of the provision of health services; however, in practice, many of these are unlikely to be enforced on account of a lack of necessary administrative infrastructure.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

The federal government, through the MoH and COFEPRIS, implements, coordinates, certifies and controls all human health-related matters.

Among the MoH 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 and organ transplants, 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 Medical Faculties and Schools of Medicine, and around half of them are recognised by the Mexican Council for the Accreditation of Medical Education; although not authorities themselves, these institutions are recognised as being qualified to certify the quality of medical education.

Similarly, the certification of nursing and related practices is the responsibility of the Mexican Council of Nursing Certification.

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

Premises certification and authorisation is subject to compliance with technical and formal requirements established by NOMs and the criteria and requirements stipulated by COFEPRIS.

**ii Institutional healthcare providers**

Under Article 34 of the Health Law, rendering of health-related services requires a licence or authorisation according to 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 concerning cosmetic surgery and other kinds of procedures not necessarily related to diseases or medical conditions, but which present 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 procedures for the operation of specific premises appear clear and straightforward, in practice, a considerable number of issues are left to the personal perception of governmental officials, which can lead to practical complications in securing these authorisations, as well as raising the possibility of corrupt acts.

The general rule is that these licences and authorisations may be secured by filing the corresponding application, paying the applicable federal or local government fees and demonstrating compliance with the technical and formal requirements, and they may be subject to inspections and on-site visits.

Licences and authorisations may be revoked or suspended by the health authorities if the corresponding requirements fail to be met during the course of the operation of the premises, or if it is determined that the operation of the premises may present a sanitary risk to the population.

In all cases, these revocation or suspension procedures are subject to the formal requirements for verification procedures set out by the Health Law and its implementing regulations and the Federal Law on Administrative Procedures; essentially this implies the formal service of notice of a review, including the scope of the review, authorised officials, preliminary determinations, preliminary arguments and evidence provided by the party under review, and upon conclusion of the review a final resolution issued by the authority.

Any party affected by an unfavourable decision issued by the competent health authorities may, as a general rule, file an administrative appeal with the same authority that carried out the determination, or file a nullity petition with the administrative court of justice. 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.

Pursuant to the Health Law Articles 373, 375, 419, 420, et al., failure to secure the applicable licence or authorisation, or to file the corresponding notices, may result in penalties ranging from temporary to definitive closure of premises, and fines ranging from approximately US$8,000 to US$25,000.

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

### Healthcare professionals

In principle, the authorisation and licensing of health and medical professionals are conditional on presentation of corresponding degrees or titles issued by duly authorised educational institutions or third parties recognised by the MoH and COFEPRIS as entitled to certify professional capability in health-related matters.

Under Article 79 of the Health Law, individuals exercising professional activities related to medicine, dentistry, biology, bacteriology, infirmary care, social work, chemistry, psychology, nutrition, pathology and other related professions require a degree recognised by and duly registered with the education authorities when health or medical-related activities are carried out by those individuals.
Similarly, the exercise of technical and auxiliary activities that require specific knowledge related to medical care, dentistry, clinical laboratory, infirmary care, physical therapy and rehabilitation, prostheses, orthopaedics, biostatistics, pharmacy, etc., is also conditional on possession of a relevant degree issued by a recognised institution.

Individuals carrying out these activities without the proper certification or degrees may be subject to fines and imprisonment under Article 250 of the Federal Criminal Code.

Under Mexican law, it is not necessary for these individuals to have professional or malpractice insurance. However, in view of 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 professionals. In addition, there are specific exceptions, such as traditional medicine practitioners 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 raised the possibility of affected parties filing 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, the main purpose of which is to solve, in an amicable manner and in a process undertaken prior to judicial procedures, disputes between medical services suppliers and patients. However, from a practical perspective this option is generally ignored or proves ineffective in achieving settlements.

From a criminal perspective, medical negligence may result in a number of possible criminal offences, ranging from physical harm all the way up 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 National Human Rights Commission and local human rights civil organisations).

These cases include the denial of childbirth health services to individuals not formally registered with the IMSS or other institutions, the denial of health services to the indigenous population or poor or homeless individuals, incorrect limb amputations, incorrect organ removals and violations 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 in controlling or, even better, eradicating them, and in securing assurances that they will be resolved satisfactorily and will not be repeated.

Although these situations have been politicised, from the evidence available from most cases of this type, it has been determined that actual malpractice or negligence by health professionals is not uncommon in public institutions.

In this context, there has been a trend for the award of punitive and moral damages to the victims in these situations, and for direct punishment of both the individuals responsible for the malpractice or negligence and the institution.

On the other hand, doctors and other health professionals have staged a series of demonstrations about political involvement in health-service matters and lodged complaints regarding the poor or limited technical and logistical resources in several governmental health institutions, including lack of personnel and equipment, lack of formal processes, 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 specific degrees or similar qualifications, nor on the basis of nationality, financial viability, etc.

The ownership of the business itself is not restricted or regulated; however, as noted 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 also be noted that the option exists for health professionals holding titles and degrees in other countries to provide services in Mexico – and this is most often seen in relation to, for example, the provision of 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 responsible for the provision of 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, with 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 procedures are required to file a technical and an economic proposal that will be assessed and, as the case may be, result in an award.

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, the procurement procedures may be restricted to three or more specific suppliers; however, the procuring entity must justify the imposition of a limit on the number of participants.

Finally, in some specific cases, including cases of national security or emergencies, governmental agencies may carry out the services procurement by direct assignment.
It is worth noting that in cases 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 domestic suppliers, if the corresponding agreement has specific clauses to this effect.

In this context, the entry into force (in June 2017) of the new national anti-corruption system and provisions may result in the introduction of new anti-corruption clauses and conditions into the requirements for public procurement and tenders. Developments of this kind would be of particular relevance for entities providing services to public health institutions in Mexico given the scale of the service provision required and the practical implications of monitoring this provision.

Although no new legal provisions regarding the public procurement of goods have been enacted, very important policies and practical measures have been implemented by the Mexican authorities in this area. Many of these policies and practical measures are, to say the least, contrary to the existing provisions regarding public procurement. A considerable number of acquisitions of medical devices, services, pharmaceutical products and other goods related to health services have been approved under the ‘exception’ categories of the applicable laws; these exceptions include the use of restricted invitations to tender, and the direct assignment of goods and services.

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 publicity intended for the public at large.

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

Publicity intended for the public at large is more restricted under the Health Law, 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 publicity for goods and products rather than services, the general principles regarding the availability of scientific information and hard data supporting the publicity’s claims are also applicable to publicity for services.
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 a lack of necessary human and economic resources, the government implemented various programmes to provide the greatest possible number of services to the greatest amount of the population under the most cost-efficient structures; many of these programmes have recently been repealed or restructured following the new administration’s focus on costs and budgetary restrictions, many of which have had a direct effect on health programmes for specific conditions and diseases.

Health services face a considerable number of challenges and how they tackle these will greatly depend on the availability of necessary funding and efficient expenditure by the authorities. Considering the general policies being implemented, with drastic budgetary cuts to governmental expenditure in all areas, including those related to health services, it will be a very challenging year for this sector; these new policies have similarly difficult implications for the practical acquisition of human health-related goods and services.

The main purpose of many of these programmes was to render services to the poorest and most isolated communities in the country. However, it now seems possible that the procedures and technologies that were to be introduced as a result of these programmes will not be implemented at least for several more years.

The use of many of these technologies – which formed part of the National Digital Strategy undertaken by the executive branch of government since 2014 to facilitate the introduction of more efficient and responsive procedures, including by means of remote access – will most likely be left until a future time.

Many of the COFEPRIS online projects (which have the potential to replace up to one-third of the various traditional formal written procedures with electronic filing) may be delayed or possibly cancelled.

As a consequence of the aforementioned new anti-corruption laws and the federal government’s strategies and policies regarding reduction of expenses, the business structures implemented by most companies engaged in governmental sales and the provision of services will have to undertake substantive reviews and implement new mechanisms. Because a considerable number of services that would have been outsourced or procured from private entities are likely to be dispensed with, this will be of particular relevance to the health services industry, especially for entities providing services directly or indirectly to governmental entities or other entities subject to these kinds of controls.

Diabetes, one of the most common and direct consequences of obesity, has seen constant and very fast growth in Mexico and represents one of the largest health costs for the Mexican authorities. Close to 10 per cent of the Mexican population has some degree of diabetes, among the highest percentages in the Organisation for Economic Co-operation and Development (OECD) countries.

According to MoH data, in 2013, 55,992 people died from type 2 diabetes and during the same period 148,681 died from cardiovascular diseases. These developments produced serious concerns regarding obesity, lack of access and inequality, among others, and prompted moves to tackle the population’s health problems through better regulation of the health services industry. This is possibly the greatest challenge in health matters that the authorities will face in the coming years.

Obesity and diabetes are considered an epidemic in Mexico, affecting 33 per cent of the child population and at least 72.5 per cent of the adult population according to the
National Institute for Public Health. As this is such an epidemic, the authorities and private sector have implemented programmes to prevent obesity and being overweight, including the National Strategy for the Prevention and Control of Overweight, Obesity and Diabetes (ENPCSOD). ENPCSOD aims to change processes and principles within the public health services, and improve health and hygiene through the promotion of healthy lifestyles and education campaigns and by monitoring medical conditions associated with this problem. Other ENPCSOD measures include federal education reform regarding nutrition in education institutions, an increase in the population's physical activity and sports, the creation of specialist centres for the care of diabetic patients, and the implementation of a 'nutritional quality' stamp for food products of a high nutritional quality.

Notwithstanding the significance of obesity and diabetes in the general context of national health, several of the programmes for its prevention and treatment have been cancelled or put on standby by the federal government subject to assessment of previous programmes and their results to determine whether these were properly implemented by prior administrations.

Various diabetes-related centres dealing with internal medicine, psychology, nephrology, cardiology, ophthalmology, nutrition, etc. that were opened throughout the country to provide free advice and treatment to individuals with diabetes have been closed or their services cancelled by the new administration.

The private sector has also participated in these efforts through the creation of the Nutrition Health Alliance, which has proposed specific actions for inclusion in a General Law against Overweight and Obesity to introduce special programmes and key policies in this area.

As regards rare diseases, Mexico now has 24 hospitals authorised for treatment of 14 of the most common of the 7,000 illnesses considered worldwide to be rare diseases.

According to the Pan American Health Organization, the most urgent threats presented by infectious diseases and illnesses include dengue and Zika, which are still present in Mexico because of its geography, with vast regions suitable for mosquito reproduction, and the lack of health services and absence of preventive action.

During 2016, 19,510 cases of dengue were confirmed in Mexico, with 19 subsequent deaths. Zika has also been a particular concern in view of the risks of microcephaly in babies that the virus presents for pregnant women. The number of pregnant women formally registered as having this virus during 2016 was 3,669.

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

According to the OECD, Mexico suffers from significant inequality and lack of access to health systems, which together with inadequate preventive action has led to the lowest life expectancy of all OECD countries.

X CONCLUSIONS

While health is one of the most important human rights enshrined in Mexican law, it represents an area of very significant cost and presents challenging issues 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 significant constraints exist for the authorities in relation to the human and monetary resources required to correctly implement and enforce these regulatory 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 are among the most pressing national health concerns and are thus a primary focus of the health authorities, from both a direct and an indirect perspective. Furthermore, although they are particularly focused on the services and processes that attend these conditions, the authorities’ emphasis tends to be more punitive than preventive.

The formal authorisation of certain substances, such as THC and plant derivatives, to be used as recognised medicines or legal drugs will probably present an important challenge for the authorities regarding the therapeutic application of these products and the provision of related services.

Very significant changes to policies on the provision of health services and related activities will have direct effects on the population that uses public health services, as the sums originally budgeted for expenditure on particular programmes tackling the most socially pressing conditions and diseases have either been cancelled, put on standby or considerably reduced. This situation that will have a direct economic effect on the health of the considerable number of Mexicans who depend on public health services.
Chapter 10

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).\(^2\) Publicly funded services are available to all ‘eligible persons’ (which includes New Zealand citizens, certain types of permanent residents and people on work permits)\(^3\) and include hospital care, primary care, maternity services, community mental health services and a range of other health and disability services. In April 2019, the Labour-led coalition government released the ‘Wellbeing Budget’, which is aimed at the health of people, communities and resources,

\(^1\) Jonathan Coates is a partner, Aisling Weir is special counsel and Andrea Lane is a solicitor at Claro.


\(^3\) See Ministry of Health’s Health and Disability Services Eligibility Direction 2011, which describes the groups of people who are eligible for publicly funded health and disability services in New Zealand.
as well as economic growth. Notably, the budget allocated an extra NZ$1.9 billion over the next five years for mental health initiatives and NZ$1.7 billion over the next two years for capital investment in health-sector assets such as hospitals.

New Zealand also has a well-established network of private health providers ranging from major surgical hospitals to private cancer-treatment facilities, small one-person providers and aged care facilities. In most geographical areas, patients have a choice of accessing publicly funded or privately funded services (or a mixture of both). Healthcare services provided by private providers are paid for in a number of ways, including by health insurers, the patients themselves and, in some cases, by public funders.

ii The role of health insurance

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

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

iii Funding and payment for specific services

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

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

The range of publicly funded services that are fully or partially funded is fairly comprehensive. The government subsidises primary healthcare services (discussed below) and dental care for children up to 18 years. Inpatient and outpatient public hospital care is provided free of charge, with prioritisation used to manage demand for elective services. 5 In some cases, alternative health therapies are eligible for government subsidies (for example, the ACC may subsidise the costs of acupuncture provided to treat personal injuries). Means-tested subsidies are available for elderly people in long-term residential care facilities. The government also subsidises pharmaceuticals included in the New Zealand Pharmaceutical Schedule. 6 Pharmaceutical Schedule items are free for inpatients and provided at a capped price when prescribed and purchased in the community (although items prescribed for children under 13 years old are free).

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

---

5 Paterson, see footnote 2, at [1.2.1(2)].
6 See the NZPHD Act, Section 48(a).
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 to access government funding, particularly since the 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 usually attract a fee).

Generally, referrals from GPs are required 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 Consumers’ Rights (the Code of Rights) and human rights legislation have been interpreted to support rights to fair and efficient systems for handling patient referrals (particularly by DHBs), appropriate coordination of care between primary and secondary or tertiary providers, and to information about the availability of, and waiting times for, publicly funded healthcare.

To ensure continuity of care between primary, secondary and tertiary healthcare providers, New Zealand’s data protection laws do not restrict the appropriate sharing or disclosure of patient information (although they generally require providers to inform

---

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 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).
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 the Ministry is exploring the use of a single electronic health record for all patients in New Zealand.

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 the scope of practice for each regulated profession, maintaining a register of practitioners, conducting competence reviews and quality assurance activities in relation to registered practitioners, and (through independent committees) investigating complaints about conduct.

Other key regulators include the Health and Disability Commissioner, a statutory ombudsman appointed under the HDC Act to assess and investigate complaints about healthcare services; and the Privacy Commissioner, appointed under the Privacy Act 1993 to investigate complaints about breaches of privacy (including in relation to health information). In 2019, the government announced it will establish a new Mental Health and Wellbeing Commission to strengthen leadership and oversight of mental health and addiction treatment.

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.
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.\(^{13}\) To gain (and retain) certification, these providers must meet relevant service standards and are audited for compliance.\(^{14}\) If the provider does not meet the requisite standards, their certification may be cancelled or a cessation or closure order issued.\(^{15}\)

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

All healthcare providers are regulated by the HDC Act and associated regulations – most notably the 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 credentialling 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 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.\(^{18}\) With the exception of a few ‘restricted’

---

\(^{13}\) 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 Bill is currently being drafted to replace the Medicines Act 1981 and may remove pharmacy ownership restrictions and replace them with appropriate licensing requirements.

\(^{17}\) 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.

\(^{18}\) See HPCA Act, Section 7.
clinical interventions, there are no overarching prohibitions on non-registered health professionals providing healthcare services in New Zealand;\textsuperscript{19} although even non-registered health professionals will need to comply with the HDC Act and the Code of Rights.

Once registered, healthcare professionals must work within a prescribed scope of practice when performing a healthcare service that is part of their profession\textsuperscript{20} and obtain and maintain an annual practising certificate while doing so.\textsuperscript{21} RAs also have significant powers under the HPCA Act to take action to assure the competence and safe practice of registered health practitioners. There are established appeal and review processes for practitioners to challenge decisions of the RAs.

\section{NEGLIGENCE LIABILITY}

\subsection{Overview}

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

\textsuperscript{19} These clinical interventions are deemed to be ‘restricted activities’ under Section 9 of the HPCA Act, and include surgical and operative procedures, orthodontic procedures and ophthalmic procedures. These interventions can only be undertaken by health practitioners with a relevant scope of practice.

\textsuperscript{20} See HPCA Act, Section 8.

\textsuperscript{21} ibid.


\textsuperscript{23} See Accident Compensation Act 2001, Section 317. This prohibition applies even where a person chooses not to lodge a claim or is not entitled to compensation.
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). Recently, the High Court ruled that ACC cover is available for injuries suffered when undergoing medical treatment where such injuries occur in less than 50 per cent of cases; ACC has been granted leave to appeal.

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 awards of 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

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/.
29 Accident Compensation Corporation v. Ng [2018] NZHC 2848.
30 Accident Compensation Corporation v. Ng [2019] NZHC 207.
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*.33

Another case that has been influential is the decision in *Baigent’s case*,34 which confirmed that public law damages are available where financial compensation is necessary to vindicate the state’s breach of an individual’s rights under the New Zealand Bill of Rights Act 1990. Since that decision, public law damages have been successfully sought against government entities in a number of cases involving personal injury,35 but unsuccessfully in a claim relating to risperidone treatment provided by a DHB.36

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 is discussed 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 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).37
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 licences will only be granted where the applicant is a ‘fit and proper’ natural person or a body corporate of ‘good repute’, and has not been disqualified. New Zealand does not place any restrictions on the distribution of pharmacies, although pharmacy licences are granted in respect of a particular site. Importantly, the Medicines Act 1981 is likely to be replaced with the Therapeutic Products Bill, which may 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. In addition, various third-party agencies have been established to procure goods and services on behalf of DHBs (either on a national or regional basis). Currently, the most significant of these agencies is New Zealand Health Partnerships Limited. Other than that, DHBs procure goods and services on a local (i.e., district) basis or regionally in concert with other geographically proximate DHBs. The Ministry of Health predominantly procures goods and services on a national basis.

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

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

In the recent case of Attorney-General v. Problem Gambling Foundation of New Zealand, the Court of Appeal held that judicial review of commercial contracting decisions by public sector agencies will only be available if the agency failed to follow a statutory requirement, where there was fraud, corruption, or bad faith on the part of the agency or where the procurement has some extra public law feature.

VIII MARKETING AND PROMOTION OF SERVICES

The generic law that regulates advertising and promotion in New Zealand is set out in the Fair Trading Act 1986 (FTA) and the Consumer Guarantees Act 1993 (CGA). The FTA prohibits false, misleading or deceptive advertising and penalties for breach can be in the order of

51 Rule Procurement Charter, Section 1.
52 Rule 3(1).
53 Rule 3(3).
54 Rule 6. The requirement to use a publicly advertised, competitive process also applies to procurements relating to new construction works with a total estimated value of NZS9 million or more (see Rule 7).
55 See Rule 12 and Section 7.
57 Fair Trading Act 1986, Section 9.
NZ$200,000 in respect of an individual, and NZ$600,000 in respect of a body corporate.\textsuperscript{58} 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{59} There are also guarantees to provide services, where not otherwise agreed, for a reasonable price and within a reasonable time.\textsuperscript{60} 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{61} or (2) is a panacea or infallible. It also prohibits endorsements by doctors, nurses and pharmacists.\textsuperscript{62}

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.\textsuperscript{63} One notable characteristic of some of these codes and standards is the detailed provisions concerning when different professional titles can be used. Failure to

\textsuperscript{58} Fair Trading Act, Section 40.
\textsuperscript{59} Consumer Guarantees Act 1993, Sections 28 and 29.
\textsuperscript{60} Consumer Guarantees Act 1993, Sections 30 and 31.
\textsuperscript{61} 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.
\textsuperscript{62} Medicines Act 1981, Section 58.
\textsuperscript{63} 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).
comply with these codes and standards may result in the health professional being referred to a professional conduct committee or the Health and Disability Commissioner, which may lead to a charge being laid before the Health Practitioners Disciplinary Tribunal.

IX    FUTURE OUTLOOK AND NEW OPPORTUNITIES

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

On 29 May 2018, Health Minister Dr David Clark announced a wide-ranging review of the health system, aimed at future-proofing the sector. An interim report is due by the end of August 2019, with the final report to follow by 31 March 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

---


© 2019 Law Business Research Ltd
undertake certain statutory functions that are currently only able to be carried out by doctors (such as issuing sickness certificates and taking blood samples to test blood alcohol levels of drivers).  

Elsewhere in the legislative arena, a new regime for medicines, the Therapeutic Products Bill, is well under way. 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).

The new Wellbeing Budget is likely to result in a boost for capital investment in health-sector assets, such as hospital buildings and other facilities, and the expansion of mental health services and initiatives, 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, with the End of Life Choice Bill being due for its second reading in Parliament. In addition, the government is delivering on an election promise to examine abortion law with the aim of removing abortion from the Crimes Act.

X CONCLUSIONS

The New Zealand healthcare system is largely stable.

On the legislative front, a proposed new therapeutic products regime, abortion law reform, the End of Life Choice Bill and reforms of public health legislation are 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.

---

66 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 amending eight statutes. The first seven amendments commenced in January 2018. The final amendment will commence in November 2018.

67 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 out 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 Plan\(^4\) and the National Strategy for Quality in Health. 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 out in those documents and have financial responsibility for primary and hospital care.

Despite the universal coverage of the SNS, there are other forms of financing the provision of healthcare services, which are specific to particular categories of citizen. There are groups of citizens with specific sickness schemes, usually designated as ‘health subsystems’.

---

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 junior associates) 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/](http://www.sns.gov.pt/institucional/entidades-de-saude/).

These systems, which constitute the second component of the healthcare system in Portugal, are formed of 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, the Institute for Disease Protection and Disease Control (ADSE). The 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 2016, the number of ADSE beneficiaries amounted to 1.22 million, including active staff, pensioners and family members, while it slightly decreased in 2017 to 1.21 million.5

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 component of the healthcare system in Portugal,6 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 also under private health insurance.7

Healthcare services are also provided, on a more limited scale, by non-profit private operators with a charitable background, known as Holy Houses of Mercy.8 Anyone can access the healthcare services provided by the Holy Houses of Mercy (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, integrating them into the national healthcare network. In the case of subsystems (e.g. the ADSE) and insurers, the user will have to be a beneficiary of one of these subsystems and the

5 https://www.pordata.pt/Portugal/Benefici%C3%A1rios+da+ADSE-612.
8 ‘Holy Houses of Mercy are brotherhoods of laymen inspired by the Catholic faith, whose objective is to help victims of any form of misery, and whose work includes feeding the hungry, curing the sick, and other types of social work.’ The role of private non-profit healthcare organisations in NHS Systems: implications for the Portuguese hospital devolution Program, 2016, Álvaro S Almeida: http://wps.fep.up.pt/wps/wp577.pdf.
Holy Houses of Mercy must have an agreement in place with them to allow these beneficiaries to access healthcare services. There are currently 21 hospitals, 120 nursing homes, and other healthcare activities managed by the Holy Houses of Mercy.9

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, among other reforms, the Portuguese government initiated in 2011 a comprehensive reorganisation of the healthcare system to accomplish the MoU’s objectives within the proposed time frames.10

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 to improve the quality of care in Portugal.11

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, both for profit and non-profit, operating networks of multiple private hospitals and clinics.

ii The role of health insurance

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

iii Funding and payment for specific services

Pursuant to the Healthcare Basic Law, the SNS is financed primarily through transfers from the Portuguese state budget. Furthermore, in this regard, there are provisions of the Healthcare Basic Law, the Statutes of the SNS approved by Decree-Law No. 11/93 of

9 https://www.ump.pt/Home/uniao/areas-de-atuacao/linhas-de-servico/grupo-misericordias-saude/.
15 January, as amended, and Decree-Law No. 113/2011 of 29 November, as amended (Decree-Law No. 113/2011), that 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. These 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 grounds 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 No. 97/2015 of 1 June 2015 (Decree-Law No. 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 opticians are usually funded by individuals, with the possibility of co-funding by private insurers or health subsystems. Some 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 specified limit (under the Solidarity Supplement for the Elderly12 or exemption from payment of moderating fees). Furthermore, the Holy Houses of Mercy – in the context of

12 Additional information on the beneficiaries entitled to this social benefit can be found here: https://www.sns.gov.pt/sns-saude-mais/complicaciones/.
the National Network of Integrated Continuous Care\textsuperscript{13} – 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.

\section*{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 has 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. The 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. Although the 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 (SLSs), 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, whether public or private in nature, that operate within a certain local region. The SLSs are created by means of an administrative order from the Minister of Health, following a proposal from the ARS and consultation with 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{14}

\section*{IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS}

\subsection*{i Regulators}

As mentioned in Section I, 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.

\textsuperscript{13} This national network was instituted 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, of a public and private nature, that provide continuous care and social support for people in situations of dependency, both in their homes and in inpatient units.

\textsuperscript{14} Hospital Beatriz Ângelo, Hospital de Braga, Hospital Cascais Dr. Josá 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/.
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 out 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 Medical Association, approved by Law No. 282/77 of 5 July, as amended.

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

It is possible, under Decree-Law No. 66/2018 of 1 January, 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 foreign degrees as the corresponding above-mentioned degrees. Following this recognition, international graduates can request registration with the Portuguese Medical Association.

The practice of medicine without registration with the Portuguese Medical Association constitutes 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.15

Dentistry, nursing and pharmacy are all also regulated professions that require prior inscription with a public association. Inscription in each of the respective public associations

---

15 Fines may be imposed in daily units, with the court determining the number units on the basis of the personal and financial circumstances of the defendant.
governing the dentistry, nursing and pharmacy professions is governed by principles similar to those for the Portuguese Medical Association, notably in terms of academic qualifications and the requirement to undertake adequate training in each of the aforementioned professions.

V  NEGLIGENCE LIABILITY

i  Overview

Law No. 67/2007 of 31 December sets out 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 a fault on their part or when their level of diligence and care is significantly lower than what is expected for the position they hold. Nevertheless, the public healthcare provider remains jointly and severally liable.

Where private healthcare providers are concerned, and in the absence of specific legislation, the rules of contractual liability set out 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 had 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 was 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 for 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. It was held that there had been a causal link between the hospital’s conduct and the damage caused to the patient and, therefore, the hospital was liable for the damage 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 mentioned in Section IV.ii, 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 Law (enacted by Law No. 19/2012 of 8 May) will apply.

VII COMMISSIONING AND PROCUREMENT

The procurement for the provision of healthcare services is carried out, 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 out in Decree-Law No. 18/2008 of 29 January, as amended, which introduced the Public Contracts Code. Other rules also apply, such as the Administrative Procedure Code and the Procedure Code of the Administrative Courts.

The process related to public purchases in the health sector is carried out through a single electronic contracting platform, centrally managed by the SPMS. The SPMS publishes a Public Health Supply Catalogue on the platform, which provides, among other

---

16 It was formally incorporated under Decree-Law No. 19/2010 of 22 March. Further information about the SPMS can be found at: http://spms.min-saude.pt/en/spms/.
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.
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.\(^\text{18}\) 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 on 16 January 2017, the Minister of Health issued Order No. 851-A/2017 with recommendations aimed at preventing the violation of the principles of transparency, competition and the pursuit of the 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 No. 238/2015 of 14 October\(^\text{19}\) (Decree-Law No. 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, the ERS issued a recommendation\(^\text{20}\) and an alert\(^\text{21}\) on the 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, and 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 used, related to the prevention and treatment of diseases, including the provision of diagnoses and any treatments or therapies.

All health advertising practices that, 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 (for up to two years) from

---

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 No. 1058/2016 of 24 November.
practising a professional or advertising activity and the loss of rights or benefits granted by regulatory authorities or public services (for 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 No. 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 mortality (i.e., before the age of 70) 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. For the year 2020, the government has established priority health programmes in the following areas:23 chronic diseases; healthy nutrition; promotion of physical activity; prevention of diabetes; brain and cardiovascular diseases; oncological diseases; respiratory diseases; transmissible diseases; control of antimicrobial resistance; and mental health.24

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 prior to the entry into force of the General Data Protection Regulation.25 This platform provides access to information for citizens who are SNS users and healthcare professionals within the SNS (in hospitals, emergency rooms, primary care and the 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.26

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

22 The full version of the Plan may be found here: http://1nj5ms2lli5hdggbe3mm7/ms5.wpengine.netdna-cdn.com/files/2015/06/Plano-Nacional-de-Saude-Revisao-e-Extensao-a-2020.pdf.pdf.
25 The authorisation can be found at: www.cnpd.pt/bin/decisoes/Aut/10_940_2013.pdf.
26 Additional information regarding the platform can be found here: https://www.epsa-projects.eu/index.php?title=The_Portuguese_Health_Data_Platform_(PDS)#tab=Case_description.
speak 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 teleconferences.

Further to this, some measures have recently been 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. The SNS launched its new website in February 2016, on which it provides information on waiting times regarding outpatient consultations for several specialties.

Finally, the Portuguese government approved the National Strategy for the Ecosystem of Information 2020 (ENESIS 2020), which is aimed at improving access and information sharing by simplifying and dematerialising processes and documents, such as electronic prescriptions and the dispatch of drugs, processes associated with death and sick leave, the availability of data and services through the Health Data Platform 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 the guidance of the relevant ministry, ensuring its operationalisation and promotion within the scope of the SNS.

X CONCLUSIONS

As mentioned in Section I, despite the significant reforms that have been carried out by the Portuguese government in recent years, particularly after 2011, a number of challenges have yet to be overcome. According to a 2018 ranking of European health systems, Portugal has been ranked as the 13th best healthcare system in Europe.

Moreover, a recent study published in the Portuguese Journal of Public Health argued that in Portugal the future vision for healthcare delivery cannot be exclusively focused on the economic and financial sustainability of the SNS in the short term, but rather it must address the issues identified by patients, healthcare providers and health services in general. The study indicates a set of four essential problems that should be dealt with by public health policies in the next decade. These essential problems mainly relate to patients’ difficulties in accessing the SNS; healthcare professionals’ great dissatisfaction with the organisational climate of the SNS; healthcare administrators’ critique regarding the loss of status of health planning in the Ministry of Health; and the need to foster integrated health promotion programmes to increase life expectancy, the average of which is lower in Portugal than in other European countries. A change of focus based on these recommendations would certainly contribute to a more effective and efficient integrated approach to meet Portugal’s healthcare needs in the coming years.

32 Thinking ahead: Portugal’s Health in 2027, Alexandre Abrantes, Jorge Simões. The full study is available here: https://www.karger.com/Article/Pdf/488336.
Chapter 12
RUSSIA

Lola Shamirzayeva

I OVERVIEW

Russia's current healthcare market is characterised, on the one hand, by the dominant role of public healthcare providers operating under the state-run healthcare system (the public healthcare system) and providing free-of-charge medical help and, on the other hand, by the gradual development of private healthcare providers. In practice, the public healthcare system often seems to be overburdened and underfunded, which can lead to a gap between the declared and actual possibility of obtaining all necessary medical help on a free-of-charge basis.

The private healthcare sector is growing and playing an increasingly prominent role in the healthcare system. Notably, the number of investment projects in infrastructure (e.g., construction of high-technology centres, and laboratory, diagnostic and medical radiation centres), including those being implemented under the public–private partnership model, is rapidly increasing in Russia.

The development of telemedicine should also be mentioned among recent trends. On 1 January 2018, legislation regulating telemedicine entered into effect. Although the legislation currently contains a number of substantial restrictions on rendering many types of medical services, the telemedicine market is considered to be highly promising in Russia.

II THE HEALTHCARE ECONOMY

i General

Broadly speaking, the Russian healthcare ecosystem consists of various actors, depending on the type of activities they perform. Each type of key activity (healthcare services provision, pharmaceuticals provision, medical equipment and devices provision, etc.) is subject to a specific regulatory regime and has its own peculiarities. In this chapter we will mainly focus on a general overview of Russian healthcare law in terms of medical services provision.

---

1 Lola Shamirzayeva is an associate at Herbert Smith Freehills CIS LLP.
3 This chapter does not cover life sciences, pharmaceutical, biotechnology and medical device issues, nor transplantation, donorship and other specific topics.
The fundamental right to health protection is provided by the Constitution.4 Thus, according to Article 41 of the Constitution:

a everyone has the right to health protection and healthcare;

b healthcare in state and municipal health institutions for individuals must be free, at the expense of the relevant budget, insurance contributions and other funds;

c federal programmes for the protection and improvement of the population’s health shall be financed by the state;

d measures shall be taken to develop state, municipal and private health services; and

e efforts that facilitate the improvement of health, development of physical culture and sport, and ecological and sanitary–epidemiological well-being shall be promoted.

One of the key pieces of legislation regulating the healthcare sector is Federal Law No. 323-FZ on the Basics of Health Protection of Citizens in the Russian Federation, dated 21 November 2011 (the Healthcare Law).

Foreign citizens living and staying in the territory of the Russian Federation have a right to medical care in accordance with the Russian legislation and relevant international treaties to which the Russian Federation is a signatory.

The Ministry of Healthcare (MoH) is the main regulatory body for the sector, responsible, for, among other things, the execution and evaluation of national health policy, regulation and oversight of healthcare services and activities developed by the private sector.5 The Federal Service for Surveillance in Healthcare (Roszdravnadzor) is the enforcement authority that, in particular, oversees the quality and safety of medical activity and the turnover of medicines.

ii The role of health insurance

The Russian healthcare system has a highly complex nature and is based on a budget–insurance financing model.6

According to Article 19 of the Healthcare Law, everybody has the right to receive (1) medical help to the extent guaranteed under the programme of state guarantees for the free-of-charge provision of medical care to citizens (the State Guarantee Programme) and (2) paid-for medical services, and other services such as those provided under a voluntary medical insurance (DMS) contract.

The principal legislation regulating compulsory medical insurance (termed ‘compulsory health insurance’ (OMS)) is Federal Law No. 326-FZ, dated 29 November 2010, on Compulsory Medical Insurance in the Russian Federation (the OMS Law). The OMS is a type of compulsory social insurance aimed at providing guaranteed free-of-charge medical help to insured persons. This help is paid for from OMS funds, within the limits of the particular OMS territorial programme (the Territorial OMS Programme) and, where stipulated by the OMS Law, within the limits of the basic OMS programme (the Basic OMS Programme).

---

5 Regulation of the medical devices and equipment sector, as well as production of pharmaceuticals, fall within the competence of the Ministry of Industry and Trade of the Russian Federation. One key piece of legislation in this area is Federal Law No. 488-FZ on the Industrial Policy of the Russian Federation, dated 31 December 2014.
6 Under this model, some types of medical help are subject to financing from the Federal Fund of Medical Insurance and its related territorial funds while others are financed from the state budget.
The Basic OMS Programme is approved by the government and stipulates the following:

a. the types of medical help available (including a list of high-tech medical help);

b. a list of insured events;

c. the tariff structure for medical service payments and means of payment; and

d. medical help access and quality criteria.\(^7\)

The Basic OMS Programme guarantees the same rights to insured persons within the whole Russian territory and establishes the requirements for the Territorial OMS Programme, which must be adopted in every Russian constituency.\(^9\)

The Basic OMS Programme covers primary healthcare, prophylactic help, emergency medical help, specialised medical help (including high-technology help) and other areas. Territorial OMS Programmes may include types of help, and terms, in addition to those provided by the Basic OMS Programme. The extent of medical help, and tariffs, vary from region to region depending on the specific situation in the region and availability of funds.

Healthcare providers under the Territorial OMS Programme may be either public healthcare institutions or private companies (the latter should be included in the applicable register of organisations providing help under the OMS regime).

It is important to note that the structure of medical help tariffs is strictly regulated by Article 35 of the OMS Law, which sets out a list of permitted expenditures (including, in particular, salaries, purchases of medicines, costs for provision of laboratory services where a medical organisation does not have laboratory and diagnostic equipment, transport and lease costs, costs for operation of the property, and other expenditures).

It should be noted that currently the OMS tariffs do not cover any capital expenditures and, depending on the type of medical help, may differ significantly from the market prices.\(^10\)

### iii Funding and payment for specific services

In practice, most visits to doctors and basic diagnostic tests are free. Owing to mismatches between supply and demand under the public healthcare system, waiting lists for some types of services are often long (e.g., surgery or consultations for certain medical specialities). The dental package offering under the State Guarantee Programme is often limited in practice and many people opt for private dental medicine.

Certain types of beneficiaries (e.g., infants and adolescents, pregnant women, the elderly, and AIDS and HIV patients) are entitled to a number of additional rights with respect to provision of medical services on a free-of-charge basis.

Wellness services and alternative therapies are not covered by the state-run healthcare programmes and are usually funded by individuals themselves.

In some cases, citizens are entitled to pharmaceutical products free of charge (e.g., if pharmaceuticals are included in the approved list of essential medicines) or with a 50 per cent discount (e.g., retired pensioners receiving help at the ambulatory care level).

---

7. The Basic OMS Programme is part of the State Guarantee Programme.


9. Russia is a federative state with 85 constituencies.

10. Exceptions often relate to high-technology types of services and some others.
III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

Provision of primary healthcare to the adult population is regulated by Order No. 543n of the MoH. Primary healthcare includes measures for the prevention, diagnosis and treatment of diseases, medical rehabilitation, monitoring of pregnancy, the formation of a healthy lifestyle and the sanitary hygiene of the population. Primary healthcare is provided by medical and other institutions of the state, municipal and private systems of healthcare, and by individual entrepreneurs with a medical licence.

The Healthcare Law envisages different types of primary healthcare (pre-doctor, doctor, specialised). Primary healthcare is usually provided as outpatient care (ambulatory care) and day inpatient care.

In the context of OMS-related services, the key primary healthcare provider is a multi-speciality facility (polyclinic) combining doctors of different specialisations. Polyclinics often operate under the legal form of state-budget healthcare institutions. Polyclinics provide mostly primary (including specialised) care for non-communicable diseases, preventive and palliative care.

Primary doctor healthcare is provided by general physicians, district general physicians and general practitioners (family doctors). There are plans to further develop the institution of general practitioners and general practice medical nurses in Russia.

The social care sector is governed by a separate federal law, Law No. 442-FZ on the Fundamentals of Social Services for Citizens in the Russian Federation, dated 28 December 2013, and by other legislative acts.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

Licensing of different types of activities is governed by Federal Law No. 99-FZ on Licensing Specific Types of Activities, dated 8 August 2011, and subordinate legal acts. As a general rule, medical activity (except for specified activities carried out by medical organisations and other organisations within the private healthcare system in the territory of the Skolkovo Innovation Center), the use of ionising radiation sources, production and technical operation of medical equipment, the use of pathogens of infectious diseases of humans and animals (with the exception if this activity is carried out for medical purposes) and genetically modified organisms of certain degrees of potential danger are subject to licensing.

Roszdravnadzor, which is subordinate to the MoH, carries out licensing of:

a medical and other organisations subordinate to the federal executive bodies;

b organisations of federal executive bodies, in which military and equivalent service is done in accordance with federal laws; and

c medical and other organisations engaged in providing high-tech medical care.

---


12 Polyclinics for adults and children are separate.
Authorised executive bodies of the Russian constituencies\textsuperscript{13} carry out licensing of:

\begin{itemize}
\item[a] activity of medical and other organisations, except for those whose activities are licensed by Roszdravnadzor; and
\item[b] individual entrepreneurs.
\end{itemize}

\textbf{ii Institutional healthcare providers}

The procedure for obtaining a medical licence is regulated by Decree No. 291 of the Government of the Russian Federation, dated 16 April 2012 (the Decree).

The establishment and operation of a medical organisation depends on the provision and maintenance of relevant licences and other approvals. To obtain a medical licence, the applicant must confirm, in particular, that it has relevant premises, medical equipment, and internal control of the quality and safety of medical activity. The Decree also specifies requirements related to staff and management of medical organisations. The licensing authority must review the application within 45 working days of the submission date and decide to issue or refuse the licence. Licences issued for medical activities are valid for an unlimited time.

In addition to criminal and civil liability, and any other administrative sanctions that may apply, the carrying on of a medical activity by a legal entity without a licence or in breach of licensing requirements is an administrative offence punishable with different sanctions depending on the subject, type and gravity of the breach. Fines can range from 30,000 Russian roubles to 250,000 roubles.\textsuperscript{14} Depending on the gravity of the breach, suspension of the activity of the healthcare unit for up to 90 days may apply. Failure to carry out the licensing procedure may result in the liquidation of the healthcare organisation.

\textbf{iii Healthcare professionals}

According to Article 69 of the Healthcare Law, only individuals who have completed medical education or other education in the Russian Federation in accordance with the federal state educational standards and hold a specialist’s accreditation certificate are allowed to pursue medical practice in Russia.

Accreditation of specialists (which should be done no less than once every five years) is regulated by Order No. 334н of the MoH.\textsuperscript{15}

Individuals who have completed medical education in foreign states are admitted to pursue medical practice or pharmaceutical activities based on compliance with certain requirements established by law (after recognition in Russia of the education or qualification received in a foreign state according to the established procedure, or unless otherwise envisaged by international agreements to which Russia is a party).

\textsuperscript{13} For example, in Moscow, the licensing entity is the Moscow Healthcare Department.

\textsuperscript{14} Articles 14.20 and 19.20 of the Russian Code for Administrative Offences.

\textsuperscript{15} Order No. 334н of the Ministry of Healthcare on the Approval of the Regulation on the Accreditation of Specialists, dated 2 June 2016. The transition from the procedure of certification to accreditation of specialists (with a more complex set of requirements) is to be carried out in a number of stages from 1 January 2016 to 31 December 2025 inclusive.
V NEGLIGENCE LIABILITY

The Healthcare Law stipulates that medical organisations, medical professionals and pharmaceutical workers are responsible for harm to life or health caused during the provision of medical care to citizens.\textsuperscript{16} The harm caused to life or health of citizens during the provision of medical care must be compensated by medical organisations in the amount and manner established by legislation. The obligations of healthcare professionals are established in Article 73 of the Healthcare Law, which provides that they shall perform medical activity in accordance with Russian legislation and be guided by the principles of medical ethics\textsuperscript{17} and deontology.

As regards civil liability, the Russian Civil Code provides a compensation regime for harm to citizens’ life and health caused by performance of contractual and other obligations. According to Article 1085 of the Russian Civil Code, in cases of harm or damage to health, the earnings or income that the injured person lost, or to which he or she would definitely have been entitled in the absence of the injury, shall be reimbursed. In certain cases, the injured person has a right to additional expenses compensation (including expenses for treatment, purchasing medicines, etc.).

As regards criminal liability, different provisions of the Russian Criminal Code may apply to healthcare professionals; these include provisions regarding failure to render help to a sick person (Article 124), infliction of death by negligence (Article 109), infliction of grave injury by negligence (Article 118), neglect of duty (Article 293) and rendering of services that do not meet safety standards (Article 238).\textsuperscript{18} Most of the above-mentioned Articles provide for sanctions of imprisonment for up to four years with disqualification for up to three years, among other penalties.

VI OWNERSHIP OF HEALTHCARE BUSINESSES

Healthcare institutions under public ownership (e.g., state-budget healthcare institutions) currently represent the largest part of all healthcare providers in Russia, although the number of private medical organisations is constantly increasing.

The private medicine market in Russia is characterised by a low degree of consolidation. Most of the current market is taken by commercial departments of state medical institutions, as well as thousands of small private clinics and offices. However, there are a number of large holdings successfully operating in Russia in the area of private medicine (including in the DMS sector), mostly in the area of multi-profile, laboratory and reproductive-related activities.

\textsuperscript{16} The rights of patients as consumers of paid-for medical services are regulated by Federal Law No. 2300-1 on Consumer Protection, dated 7 February 1992, allowing patients to protect their rights under consumer protection legislation.


\textsuperscript{18} Overall, the practice of finding healthcare professionals criminally liable in accordance with these Articles is haphazard, although the number of criminal cases opened has increased in recent years. There are many terms in medical legislation that are not clearly determined (‘doctor’s fault’, ‘defect of medical care’, etc.), which in turn leads to different interpretations in the courts.
As mentioned above (see Section IV.ii), the establishment and operation of a healthcare organisation depends on compliance with different licensing and other requirements. In addition to technical operating requirements, healthcare providers must also comply with safety, hygiene, public health and other requirements.

According to current legislation, there are no particular restrictions regarding the nationality of private healthcare business owners.

VII COMMISSIONING AND PROCUREMENT

The process related to public purchases in the health sector (e.g., supply of medical devices, equipment, pharmaceuticals and some types of medical services) is regulated primarily by Federal Law No. 44-FZ\(^1\) and Federal Law No. 223-FZ,\(^2\) applicable to public healthcare providers depending on their type of organisational form. There is a single information platform for procurement in the public sector containing updated information on the existing goods and services under public procurement contracts, ongoing public tenders and other information.\(^2\)

Generally, tender rules apply, although the legislation provides an opportunity to use other procurement methods or a single-supplier procedure.\(^2\) Note that some restrictions may apply to foreign companies willing to participate in tenders under Federal Law No. 44-FZ, although some of the prohibitions or limitations do not apply to suppliers coming from the Eurasian Economic Union Member States.

As a general rule, the determination of the winner is based on the value of the contract (i.e., by the maximum value of the economic benefit that can be obtained by the contractor, depending on the procedure adopted); however, certain exceptions apply to healthcare-related procurements.

It is possible to challenge procurement decisions either at the administrative level (e.g., through the Federal Antimonopoly Service (FAS)) or the judicial level.

VIII MARKETING AND PROMOTION OF SERVICES

Advertising issues are governed by Federal Law No. 38-FZ on Advertising, dated 13 March 2006 (the Advertising Law). Where competition issues are concerned, in the absence of specific rules applicable to the healthcare sector, the general rules of Federal Law No. 135-FZ on the Protection of Competition, dated 26 July 2006 (the Competition Law), will apply. The FAS is the regulatory body with responsibility for enforcing compliance with competition and advertising legislation.

The Advertising Law provides detailed rules for advertising medicines, medical services and medical devices, including, in particular, the following restrictions:

---

22 For more information about the regulation of government procurement in Russia see the Russian chapter in *The Government Procurement Review* (Law Business Research, 2019), by Olga Revzina, Lola Shamirzayeva and Olga Vasilyeva.

© 2019 Law Business Research Ltd
Russia

a advertising must not give an impression that it is unnecessary to visit doctors;
b advertising must not contain allegations or assumptions that consumers have certain
diseases or impairments of health; and
c advertising must not contribute to making an impression of the necessity for a healthy
consumer to use the advertised item.

Advertisements must not guarantee a positive effect, safety, effectiveness or lack of side effects. The advertisement must contain a warning about contraindications to the advertised product’s use, and about the necessity for patients either to familiarise themselves with instructions or to receive expert advice.

Note that a bill banning advertising of medicines and medical services in children’s television and radio programmes was submitted to the State Duma in July 2019.

IX  FUTURE OUTLOOK AND NEW OPPORTUNITIES

In accordance with Presidential Decree No. 204 on the National Aims and Strategic Goals for Development of the Russian Federation up to 2024, dated 7 May 2018, the National Healthcare Project (NHP) was developed by the MoH for the period 2019–2024. The NHP aims to achieve, in particular, the following national goals: ensuring sustainable natural growth of the population of the Russian Federation and increasing life expectancy to 78 years by 2024, and 80 years by 2030.

The NHP represents one of the key Russian healthcare policy documents and provides the following eight sub-projects:

a development of primary healthcare;
b control of cardiovascular diseases;
c control of oncological diseases;
d development of children’s healthcare, including the creation of a modern infrastructure for provision of medical care to children;
e staffing of healthcare organisations with qualified personnel;
f development of a network of national medical research centres and the introduction of innovative medical technologies;
g creation of a single digital circuit in healthcare on the basis of a unified state health information system; and
h development of export of healthcare services.

The NHP includes a detailed description of the planned measures to be undertaken with respect to each subsector. It is expected that future development of the Russian healthcare system will be focused on these areas.

23 It should also be noted that, overall, a lot has already been done in Russia with respect to digitisation of the healthcare system, including in state healthcare institutions (introduction of systems of electronic appointments, electronic medical records, electronic prescriptions for medicines, etc.), and this process is ongoing in the Russian medical sector.
The total estimated budget for the implementation of the NHP is around 1.7 trillion roubles. For the purpose of implementing the NHP, the Russian state-budget programme now includes the rules for provision of subsidies for different projects falling within the NHP.24

The process of digitisation of the Russian healthcare system and the development of telemedicine and other information technologies will continue. To raise quality and improve accessibility for medical help, centralisation of certain types of medical services and expansion of private healthcare providers, as well as development of different types of investment projects in the sector, may also be expected in the upcoming years.

X CONCLUSIONS

Russian healthcare law is complex and consists of many pieces of legislation, each governing a particular healthcare subsector. Significant reforms have been carried out by the Russian government in recent years with respect to modernisation of the Russian healthcare system and the related legislation. However, a number of challenges have yet to be overcome, both at the federal and regional levels. Some issues hindering the mass implementation of investment projects are still in place, although there are plans to continue developing a legal framework to attract more investors in the Russian healthcare sector.

Chapter 13

SAUDI ARABIA

Nabil A Issa

I OVERVIEW

The Kingdom of Saudi Arabia has continued to witness dramatic cultural and legal changes in recent years. The Ministry of Health and the Saudi Arabian General Investment Authority (SAGIA) have made various announcements in relation to opening almost all areas of healthcare to foreign investors.

Saudi Arabia is a critical sector for any party investing in the Middle East, partly because it 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. Although Saudi Arabia is working hard on a campaign to encourage daily exercise and is expected to impose tougher standards on imported food in relation to sugar and salt, it is not believed these lifestyle diseases will dramatically change in the short term. 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 developed in Riyadh. Also, foreign private equity groups and operators such as Investcorp, NBK Capital, Gulf Capital, TVM Healthcare, Audacia, KIMS Healthcare, 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 Ministry of Health has retained a number of the world’s leading consultants to explore implementing public–private partnerships and privatisations in the healthcare sector. Some of the world’s most complicated medical procedures, including organ transplants, separation of conjoined twins and neurosurgery, are often performed in the hospitals of Saudi Arabia.

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, but we understand this is expected to change soon and this responsibility will fall within the purview of the Ministry of Health.

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

---

1 Nabil A Issa is a partner at King & Spalding LLP, which operates in cooperation with the Law Office of Mohammed AlAmmar.

undergoing constant change because of its high importance for Saudi Arabian nationals, and certain agencies have overlapping responsibilities, as described below. Moreover, as part of Saudi Arabia’s well-publicised Vision 2030, it is transforming its public sector and exploring privatising certain aspects of its healthcare sector. Saudi Arabian Airlines recently announced it has awarded a contract to a preferred bidder to privatise its Jeddah-based medical centre, but implementation appears to be awaiting finalisation of Saudi Arabia’s privatisation programme. Currently, there are a number of foreign investment restrictions, but a number of liberalisations are expected shortly.

II THE HEALTHCARE ECONOMY

General
The Council of Cooperative Health Insurance previously made it mandatory for all business owners to have medical insurance cover for their workers from the date of their arrival, and to hand them insurance cards within 10 days of their arrival in Saudi Arabia. According to the council’s relatively new regulations, the insurance coverage becomes invalid only in the event 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 expatriates, 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 speciality or more;

d) physician office (clinics) prepared for treatment and diagnosis of patients;

e) radiology centres for diagnostic imaging and radiology treatment;

f) medical laboratories;

g) same-day surgical facilities (i.e., ambulatory surgery centres) that are licensed to admit patients for minor and medium surgeries, provided that patients are discharged on the same day of admission;

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 Saudi Arabia without the written permission of the patient concerned.

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.

For certain procedures, it is common for Saudi Arabian nationals to obtain government approval and funding from the Ministry of Health for treatment outside Saudi Arabia. The United States and Germany are two of the most common destinations for treatment of Saudi Arabian nationals.

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);
each hospital must appoint a pharmacist of Saudi nationality as a manager of the hospital's internal pharmacy on a full-time basis;
c. the pharmacist officer responsible for drugs in the hospital's internal pharmacy, who is subject to surveillance, shall be a full-time pharmacist assistant of Saudi nationality. The internal pharmacy manager might hold this position; and
d. each hospital must appoint an administrative manager of Saudi nationality, holding a university degree, to manage the hospital on a full-time basis.

V NEGLIGENCE LIABILITY

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

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

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

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

---

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.
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 for sparing the life of the killer. This may arise in a situation in which an employee of a medical institution was found to have intentionally killed a person (rather than the death being deemed an accident). This would, of course, involve the Saudi Arabian criminal justice system. As a general rule, corporate criminal responsibility does not exist in Saudi Arabia, particularly for crimes such as homicide. The individuals responsible for the homicide rather than the corporation would be held accountable. We understand there are instances of medical professionals being held criminally liable for being grossly negligent where the negligence resulted 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 the 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. Pursuant to 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, SAGIA maintains that 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. In accordance with 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.

In addition to the above-mentioned restrictions in accordance with 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. In the recent past, the MoH has generally granted licences to foreigners if the foreign-owned hospital has at least 30 beds and this reflects an increasing willingness by the MoH to allow exceptions to the previously stricter requirements; for example, NMC Healthcare was recently permitted to own various hospitals with fewer than 100 beds. 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 or complete foreign investment on a case-by-case basis where certain minimum foreign investment guidelines are met. Saudi Arabia is also actively working towards ‘corporatising’ government healthcare assets and preparing these 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 the operating company meets 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 to receive a foreign investment licence for manufacturing.

The foreign investment status of healthcare sectors is outlined below; note that those sectors not currently open to investment are expected to be opened and may be open to investment subject to special permission from SAGIA and the MoH on a case-by-case basis.

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, which must be at least partly owned by a Saudi Arabian pharmacist. The regulations set out 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 on condition 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.
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.

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.

**Temporary commercial registration**

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.

**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 Investment Funds Regulations of the Saudi Arabian Capital Market Authority (CMA). These funds have invested in sectors as diverse as pharmacies, clinics and small, medium-sized and large hospitals. In addition, we are aware that the MoH and the CMA has, to date, not objected to investors who meet the qualified foreign financial institutions’ requirements for acquiring listed securities of entities operating in the healthcare sector.

**New joint venture structures**

Foreign investors often prefer to undertake a joint venture with a local partner but are uncomfortable with Saudi Arabian law. Foreign investors are increasingly using the new Abu Dhabi Global Market (ADGM) jurisdiction to incorporate an English law special purpose vehicle (SPV) and then have the SPV own the operating company in Saudi Arabia. It is now possible to deem the ADGM SPV a Saudi Arabian tax resident, making it attractive to Saudi Arabian parties, who pay lower tax than foreign parties, while giving foreign parties English law certainty for their joint ventures in Saudi Arabia. Other parties are using CMA funds and ADGM/Dubai International Financial Centre funds as joint venture vehicles and currently these provide significant tax advantages to the foreign party.

**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 and approval by SAGIA will also be required if the company is partly foreign owned.

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 specialising 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 radiation safety measures and other necessary measures for the hospital radiotherapy departments; (2) compliance with specifications and standards; and (3) the availability of radiation protection measures and measures for early detection of radiation leakage. Upon completion of the construction work, the relevant MoH committee will inspect the hospital buildings and preparatory work and issue an inspection report within two weeks of 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 the hospitals or clinics (particularly if more than 10 to 15 years old) sometimes have outstanding issues or reports from 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 these 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, these facilities will not fully comply with the latest rules issued by the relevant health regulator, Civil Defence or municipality relating to ingress or 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, it is often advisable to appoint an expert consultant to evaluate the condition of the target facility and to determine whether any expenditure on upgrading the facility will be necessary for compliance with regulatory requirements, so that this 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. A number of hospitals, dental clinics, etc. are expanding through raising new funds or through initial public offerings.

Following the recent steps to liberalise the healthcare sector, we expect to see growing foreign investment in medical centres, radiology clinics and other types of medical facilities throughout Saudi Arabia.

Furthermore, Saudi Arabia has been looking to increase foreign investment in large hospitals. There are also a number of privatisations expected in this sector.

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 opportunities for investment in this sector and we expect this will only accelerate with the expected announcement by the government of medical centres and hospitals that are to be partially or wholly privatised.
I OVERVIEW

The Constitution of the Republic of South Africa (the Constitution) provides that everyone has the right to access to healthcare and requires that the state take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of this socioeconomic right. The National Health Act 61 of 2003 (the National Health Act) was promulgated to achieve this objective and to, inter alia, regulate national health and the establishment of a national health system.

The National Health Act provides a framework for a structured uniform health system within South Africa, by taking into account the obligations imposed by the Constitution and other laws on the national, provincial and local governments with regard to health services and making provision for related matters.

The regulation of health services is a concurrent legislative competence, and both the national legislature and the nine provincial legislatures have jurisdiction to regulate healthcare-related matters. The regulation of the different facets of the South African healthcare ecosystem is entrusted to the national and provincial departments of health, statutory bodies, professional bodies and other voluntary associations.

II THE HEALTHCARE ECONOMY

i General

In light of the above-mentioned entrenched constitutional right, everyone in South Africa, irrespective of nationality, has the right to access healthcare. In addition, no healthcare provider, health worker, or health establishment may refuse a person emergency medical treatment.

A prominent characteristic of the South African healthcare system is its two-tiered nature, comprising a public health sector and a private health sector. The National Health Act explicitly makes provision for the regulation of public and private providers of health services.
The South African government has stated that certain inequities between the public and private health sectors can be attributed to this two-tier healthcare system, which essentially allows the wealthy to pool their healthcare funds separately from the poor.  

ii The role of health insurance

Medical schemes

In South Africa, a medical scheme is a not-for-profit organisation that belongs to its members, the objective of which is to pool member contributions to pay for member healthcare expenses from a common risk pool. The contributions of a medical scheme's members are only dependant on the level of cover purchased (i.e., the benefit option) and not risk factors such as age or health status.

The Medical Schemes Act 131 of 1998 (the Medical Schemes Act) was enacted to consolidate the laws relating to registered medical schemes, to provide for the establishment of the Council for Medical Schemes (CMS) and the appointment of a Registrar of Medical Schemes, among other provisions.

As at 31 March 2018, it was reported by the CMS that there are about 80 medical schemes in South Africa. It is estimated that around 9.4 million individuals have medical aid cover in South Africa. The South African medical scheme market is highly concentrated, with two medical schemes holding approximately 50 per cent of both the open medical scheme market and the restricted medical scheme market.

Pursuant to the Medical Schemes Act, all medical schemes must be registered and are subject to regulatory oversight by the CMS.

Health insurance

For-profit insurance companies are generally allowed to sell short-term and long-term insurance policies in respect of health-related risks. Insurance companies are subject to the regulatory oversight of the Financial Services Board.

It has been recognised that appropriately designed and marketed health insurance policies can assist in protecting against unanticipated health events, but it is important that such insurance policies do not undermine the objectives of medical schemes.

The Minister of Finance, in consultation with the Minister of Health, in 2017 gazetted regulations to the Long-Term Insurance Act 58 of 1998 and the Short-Term Insurance Act 53 of 1998 (the Demarcation Regulations) to enhance the legislative framework relating to

---

8 Paragraph 58 of the National Health Insurance Policy, National Department of Health.
12 Annual Report 2017/2018 of the CMS.
13 Paragraph 1 of the Explanatory Memorandum to the Second Draft Demarcation Regulations made under Section 70(2b) of the Short-Term Insurance Act, No. 53 of 1998, National Treasury.
the demarcation between insurance business, providing products such as ‘health policies’ and ‘accident and health policies’ (collectively, health insurance policies) and the business of a medical scheme.\textsuperscript{15}

The effect of the Demarcation Regulations is that insurance companies are restricted from selling insurance policies that constitute the business of medical schemes and that are not specifically permitted under the Demarcation Regulations.

iii Funding and payment for specific services

Public health sector

The National Health Act provides for the establishment, by the Minister of Health, of conditions subject to which certain categories of persons are eligible for free health services at a public health establishment.\textsuperscript{16}

In addition, the National Health Act obliges the state and state-funded clinics and community health centres to provide:\textsuperscript{17}

\begin{enumerate}[	extit{a}]
\item pregnant and lactating women and children below the age of six years who are not members or beneficiaries of medical aid schemes with free health services;
\item all persons, except members of medical aid schemes and their dependants and persons receiving compensation for compensable occupational diseases, with free primary healthcare services; and
\item women with free termination of pregnancy services.
\end{enumerate}

The National Department of Health publishes annually a Uniform Patient Fee Schedule of Paying Patients Attending Public Hospitals (UPFS). The UPFS must be considered in conjunction with the relevant provincial department of health fees manual.

The UPFS was developed and introduced to provide for a simpler charge mechanism for public health sector hospitals.\textsuperscript{18} UPFS patients are categorised as follows:

\begin{enumerate}[	extit{a}]
\item full-paying patients – who are liable for the full UPFS fee as listed in the relevant tariff schedules;
\item fully subsidised patients – who receive all services free of charge, subject to certain exceptions; and
\item partially subsidised patients – who receive subsided services, with the level of subsidisation based on an income assessment (i.e., a means test).
\end{enumerate}

Private health sector

Pursuant to the regulations to the Medical Schemes Act (the Medical Schemes Regulations), medical schemes are generally required to pay in full, without co-payment or the use of deductibles, for the diagnosis, treatment and care costs of prescribed minimum benefit conditions (PMBs).\textsuperscript{19} This obligation in respect of PMBs is not affected by the medical scheme member’s benefit option, or the amount of that member’s medical scheme contributions.

\textsuperscript{15} Paragraph 1 of the Explanatory Memorandum to the Second Draft Demarcation Regulations made under Section 70(2b) of the Short-Term Insurance Act, No. 53 of 1998, National Treasury.

\textsuperscript{16} Section 4 of the National Health Act.

\textsuperscript{17} Section 4 of the National Health Act.


\textsuperscript{19} Regulation 8 of the Medical Schemes Regulations.
Approximately 270 PMBs are listed in Annexure A to the Medical Schemes Regulations and are set out in the form of Diagnosis and Treatment Pairs. The PMBs include conditions such as cancers, heart attacks and strokes.

PMBs were introduced to, inter alia, avoid incidents where individuals lose their medical scheme cover in the event of serious illness, with a consequent risk of unfunded utilisation of public hospitals, and to encourage improved efficiency in the allocation of private and public healthcare resources.

For all other conditions that are not PMB conditions, the medical scheme member’s benefit option will dictate the rate at which the cost of health services are covered or reimbursed by the relevant medical scheme.

In addition to the medical schemes, various insurance companies offer insurance products to cover health-related risks, including the following:

\( a \) medical expense shortfall policies – which cover the shortfall between medical scheme benefits and the rates charged by private medical service providers;

\( b \) non-medical expense cover as a result of hospitalisation policies – which pays out benefits upon hospitalisation; and

\( c \) primary healthcare insurance policies – which provide for certain, limited, medical service benefits (e.g., general practitioner visits, dentistry).\(^{20}\)

Medical expenses that are not covered, or are only partially covered, by medical schemes or health insurance products must be funded out of pocket.

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

South Africa suffers from a high burden of disease, including non-communicable diseases. As part of the National Department of Health’s strategic objectives and vision for 2030, the government has set out to, inter alia, significantly reduce the burden of disease and to raise the life expectancy of South Africans to at least 70 years of age.

Access to public healthcare is a challenge, as the public health sector faces various difficulties, including a lack of resources and general capacity constraints.

One of the primary challenges facing the public health sector is the inadequate supply of well-trained nurses and specialist practitioners. Nationally, and in the public sector, there are numerous vacant posts for nursing positions and also for doctors and specialists.

The South African government has placed an emphasis on developing a reliable primary care-centred and community-based healthcare system; however, in the absence of an optimally functioning public health sector, patients in the private health sector are often able to access a better quality and standard of healthcare.

Because of the high costs of private healthcare, individuals in the middle and high-income earning brackets in South Africa often opt to secure medical scheme coverage; however, the high costs mean that most South Africans are unable to afford medical scheme membership.

Limited coverage is provided through public social insurance schemes such as the Compensation Fund and the Road Accident Fund (RAF).

---

The Compensation Fund pays for medical care for workers who sustain injuries during the course of their work, or who suffer occupation-related illnesses. The RAF provides partial compensation for medical costs (and related compensation) in respect of persons who suffer injuries in motor vehicle accidents.

These funds offer partial coverage in respect of occupational injuries and partial coverage for road accidents.

Only basic primary healthcare services are provided in the public health sector. A primary healthcare clinic is the first step in the provision of public healthcare and includes services such as immunisation, family planning, antenatal care and treatment of common diseases.

If a patient cannot be assisted at a primary healthcare clinic, he or she will be referred to a community healthcare centre, which provides substantially the same services as a primary healthcare clinic, with the addition of a maternity service, emergency care and casualty ward.

Patients may also be referred to district or regional hospitals for treatment. The third level of healthcare in South Africa is provincial tertiary hospitals, which receive referrals from regional hospitals, as these establishments are generally staffed by specialists and generalists.

The fourth and highest level of healthcare comprises central centres or specialised hospitals; however, these establishments cater specifically for patients suffering from certain illnesses, including chronic psychiatric disorders, tuberculosis, spinal injuries and acute infectious diseases.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

Healthcare institutions include hospitals, clinics and other treatment facilities that provide a combination of acute, sub-acute, general and specialised services. Healthcare practitioners include general practitioners, specialists, nurses and pharmacists.

The relevant regulatory authorities include the Department of Health, the Health Professions Council of South Africa (HPCSA), the South African Nursing Council, the Allied Health Professions Council, the South African Pharmacy Council and the South African Dental Technicians Council.

ii Institutional healthcare providers

The National Health Act defines a ‘health establishment’ as including the whole or part of a public or private institution, facility, building or place that is operated or designed, whether for profit or not, to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, or rehabilitative, palliative, convalescent, preventative or other health services.

Although the National Health Act provides that a certificate of need (the Certificate of Need) must be obtained prior to the establishment, construction, modification or acquisition of a private health establishment, the provisions relating to Certificates of Need are not yet in effect and consequently the practice is not being enforced by the Department of Health.

The licensing of private health establishments takes place at a provincial level, through the applicable provincial department of health, and pursuant to provincial legislation or the General Licensing Regulations, which govern private hospitals and unattached operating theatre units under the National Health Act.
Subject to certain exclusions, a ‘private hospital’ is broadly defined in the General Licensing Regulations and includes an institution, building, or place that provides treatment and care in cases requiring medical treatment.

Under the General Licensing Regulations, no person may erect, alter, equip or in any other way prepare any premises for use as a private hospital without first having obtained the written approval of the relevant provincial department of health.

It is anticipated that, going forward, the requirement to obtain a Certificate of Need will be enforced in respect of all health establishments and that the licensing framework in respect of private healthcare facilities will be implemented at the level of the National Department of Health.

Under the Medical Schemes Regulations, all healthcare providers who issue accounts to members of medical schemes must include their practice code numbers (Practice Codes) on their accounts.

Practice Code Numbers (PCNs) are issued to private health establishments by the Board of Healthcare Funders of Southern Africa (BHF). The BHF can only issue PCNs to private health establishments that are duly licensed with a relevant provincial department of health.

iii Healthcare professionals

The Health Professions Act 56 of 1974 (HPA), and the regulations defining the scope of the profession of medicine published pursuant to the HPA (the HPA Regulations), set out the requirements for a medical practitioner to provide medical care in South Africa.

The HPA provides that no person shall be entitled to practise any registrable health profession within South Africa unless he or she is registered in accordance with the HPA.\(^{21}\)

The HPA Regulations set out the particular acts deemed to pertain to the medical profession in South Africa, including the physical medical or clinical examination of any person, managing the health of a patient (prevention, treatment and rehabilitation) and prescribing, administering or providing any medicine, substance or medical device.

The HPA Regulations specifically require any person who wishes to perform any of the above-mentioned acts to apply in the prescribed manner to the Medical and Dental Professions Board as a medical practitioner and submit proof of having complied with the registration requirements.\(^{22}\)

The application must include the qualification entitling the applicant to registration, together with such proof of identity and good character, and of authenticity and validity of the qualifications submitted, as may be required by the professional board concerned.

The HPA deals with, inter alia, the recognition by the Minister of Health, after consultation with the HPCSA, of foreign qualifications for purposes of registration as a South African medical practitioner.\(^{23}\)

\(^{21}\) Section 17 of the Health Professions Act 56 of 1974 (HPA).
\(^{22}\) Regulation 4 of the regulations published pursuant to the HPA.
\(^{23}\) Section 25 of the HPA.
V NEGLIGENCE LIABILITY

i Overview

In South Africa, liability for medical malpractice depends on whether there was intentional or negligent wrongful conduct by the parties concerned, or whether they were vicariously liable for the wrongful acts or omissions of others.

These legal principles apply equally to the public and private healthcare sectors. The National Department of Health, provincial departments of health and private sector hospital bodies will be liable for the wrongful conduct of their administrators where, through maladministration, they have harmed patients by intentionally or negligently deviating from the standard of care that is required of them.

Malpractice

Medical malpractice embraces professional medical misconduct committed either intentionally or negligently. It includes the concept of ‘professional medical negligence’, but goes further to include intentional conduct. The principles of delict govern medical malpractice claims.

To bring a successful delictual action, the plaintiff must prove that:

a there was a voluntary act or omission by the defendant;

b the conduct was unlawful or wrongful (i.e., the infringement of a lawful right, such as the right to life or bodily integrity);

c the defendant had legal capacity;

d the defendant was at fault in the form of intention or negligence;

e the act or omission caused the loss to the plaintiff; and

f the plaintiff suffered loss or damage.

Negligence in general

Negligence in general means that a reasonable person would have foreseen the likelihood of harm and taken steps to guard against it. As a consequence, the conduct of the person in question falls short of the standard that the law expects of a reasonable person in the particular circumstances of the case.

Professional negligence

Professional negligence occurs when medical practitioners or other healthcare professionals, acting negligently, fail to exercise the degree of skill and care of a reasonably skilled practitioner in their field of practice.

Greater skill and care is expected of specialists and particularly in more complicated medical procedures. Therefore, general practitioners would be negligent if they undertook work for which they did not have the required specialist skills, unless it was an emergency, when the standard of care may be relaxed. In emergencies, the test would be whether the practitioner reacted as a reasonable practitioner in that branch of the profession would have reacted in a similar situation; this only applies if the emergency was not created by the practitioner concerned.

ii Notable cases


This case has produced South Africa’s most controversial decision relating to healthcare exemption clauses, sparking debate in many quarters. The relevant exemption clause
indemnified the hospital, its employees and agents against all liability for damage or loss of any nature whatsoever, including consequential damages or special damages arising from any direct or indirect injury caused to the patient by act or omission. This exclusionary clause was upheld by the South African Supreme Court of Appeal and, in short, the Court held that such clauses were the norm, not the exception, and, as such, were sound business practice and not contrary to public policy.

**MEC for Health and Social Development, Gauteng v. DZ obo WZ 2018 (1) SA 335 (CC)**

The South African Constitutional Court was recently called upon to consider the application of the 'once-and-for-all' rule in the context of damages for medical negligence. The crisp legal question was whether this rule allows for payment of future expenses as and when the need arises, or by means of future provision of actual medical services. The Constitutional Court was also required to consider whether, alternatively, the rule should be developed or abolished. In response to these questions, the Court in its majority judgment confirmed that:

- damages due by law are to be awarded in money;
- the once-and-for-all rule requires that past and prospective damages be claimed and quantified in one action and that future damages may therefore not be paid in instalments; and
- a plaintiff may not be compensated by means of the actual rendering of medical services.

**VI OWNERSHIP OF HEALTHCARE BUSINESSES**

A healthcare professional may acquire a financial interest in a healthcare establishment, provided that all commercial terms related to the interest are negotiated on an arm's-length basis. The commercial agreement must be submitted to and approved by the HPCSA.

No conditions may be imposed in such agreements that would put healthcare professionals purchasing the interests into conflict with the Ethical Rules of Conduct issued by the HPCSA.

Financial or other rewards cannot be based upon admissions or specific targets for servicing patients. The healthcare professional may not participate in advertising or promotion of the healthcare establishment and may not advocate its preferential use.

Healthcare practitioners may only refer patients to any health establishment in which he or she, or a close family member or business associate has a financial interest if the interest has been declared to and approved by the HPCSA. In addition, the healthcare practitioner must disclose and discuss the interest with the patient before the referral. The referral will then be subject to the patient consenting.

**VII COMMISSIONING AND PROCUREMENT**

i **Public health sector**

Procurement in the public health sector is, inter alia, governed by the provisions of the following pieces of legislation:

- the Constitution;
- the Public Finance Management Act 1 of 1999 – at national and provincial government level;
The overarching requirement is that all public procurement must be in accordance with a system that is fair, equitable, transparent, competitive and cost-effective.\textsuperscript{24}

The procurement of pharmaceutical products, medical devices and other services at national, provincial and local government level generally requires that either:

\begin{itemize}
  \item \textit{a} \quad a written quotation be obtained from as many suppliers as possible; or
  \item \textit{b} \quad a competitive bid process be undertaken.\textsuperscript{25}
\end{itemize}

An additional consideration in the public health sector is the Broad-Based Black Economic Empowerment status of services providers, which may have an impact on their ability to contract with the state.

\textbf{ii \quad Private health sector}

It must be noted that in the private health sector, and especially where health services are funded by medical schemes, many medical schemes have entered into agreements with hospital groups and other service providers (also referred to as Designated Service Providers or DSPs), in an attempt to better manage and contain the costs of health services. Medical scheme members that choose to use healthcare service providers other than one of their medical scheme DSPs may be required to make co-payments.

\section*{VIII \quad MARKETING AND PROMOTION OF SERVICES}

Under the HPCSA Ethical Rules of Conduct, a practitioner may advertise his or her services, provided that the advertisement is not unprofessional, untruthful, deceptive or misleading, or causes consumers unwarranted anxiety that they may be suffering from any health condition.\textsuperscript{26}

A practitioner shall not be permitted to canvass or tout or allow canvassing or touting to be done for patients on his or her behalf.

The Guidelines on Over-Servicing, Perverse Incentives and Related Matters, published by the HPCSA, state that healthcare professionals shall not advertise or endorse or encourage the use of any health establishment or orthodox medicine, complementary medicine, veterinary medicine, medical device or scheduled substance or health-related product or health-related service in a manner that unfairly promotes the practice of a particular healthcare practitioner or a healthcare facility for the purpose of financial gain or other valuable consideration.

A healthcare practitioner may not refer his or her patients to any health establishment or to any other healthcare professionals if that referral would constitute over-servicing.

\section*{IX \quad FUTURE OUTLOOK AND NEW OPPORTUNITIES}

Over the coming months and years it is expected that significant healthcare reforms will be formulated and adopted in South Africa. A key consideration is the current national

\begin{itemize}
  \item \textsuperscript{24} \quad \text{Section 217(1) of the Constitution of South Africa.}
  \item \textsuperscript{25} \quad \text{National Treasury Practice Note No. 8 of 2007/2008 and Regulation 12(1) of the regulations published pursuant to the Municipal Finance Management Act 56 of 2003.}
  \item \textsuperscript{26} \quad \text{Item 3 of the Ethical Rules of Conduct issued by the Health Professions Council of South Africa.}
\end{itemize}
government’s efforts to move South Africa towards universal health coverage by formulating and implementing a National Health Insurance (NHI) scheme. The aim of the NHI scheme is to establish a single-payer and single-purchaser fund for all patients in South Africa.

Following its publication as a draft in 2018 and subsequent comments received from stakeholders, the National Health Insurance Bill (the NHI Bill) is in the process of being revised by the government.

It is understood that the NHI Bill will apply to public and private health establishments, including institutions, facilities, buildings or places, whether for profit or not, that are operated or designed to provide in-patient or outpatient treatment, diagnostic or therapeutic interventions, nursing, or rehabilitative, palliative, convalescent, preventative or other health services.

The Medical Schemes Amendment Bill was published for comment in 2018. This Bill proposes doing away with PMBs (see Section II.iii) and replacing them with ‘basic benefits’, but little guidance has been provided as to what these benefits would comprise.

In addition to the above, the South African Competition Commission is due to finalise its market inquiry into the public health sector and publish its final report and recommendations later this year. It is expected that various, and potentially far-reaching, recommendations for regulatory reforms in respect of public health sector funders, facilities and practitioners may be made.

X CONCLUSIONS

South Africa is one of the most industrialised countries in Africa. As illustrated above, the structure of the South African health sector provides unique challenges and opportunities. Many South African corporates in the private healthcare sector have developed innovative business models and products, which have allowed these companies to expand into developed jurisdictions in Europe and the Middle East.

Given the expected changes in the South African healthcare regulatory landscape, there is a unique opportunity for all stakeholders, including business, to have an impact on the reforms and developments that will shape the South African healthcare system.
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 the 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 or demand a reform through public referenda and plebiscites.

The Swiss Confederation (i.e., the federal state) is only permitted to act in those fields in respect of which it is granted powers 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. For the Swiss Confederation, the most important piece of legislation governing the Swiss healthcare system is the Federal Health Insurance Act (HIA), which establishes the legal framework of the MHI system and in particular defines which services are to be paid for by this system.

The Swiss federal government, namely the 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

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

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 competence 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 the 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\footnote{Article 1a HIA.} is regulated by the HIA, which entered into force in 1996. The basic principle set out 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.\footnote{The Swiss healthcare system, Financing healthcare.}

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).\footnote{Articles 1a and 6 of the Federal Act concerning Accident Insurance.} Not covered by mandatory accident insurance are non-employed persons, such as children, students and pensioners. For these persons, coverage for accident is available as part of MHI.

Temporary non-resident visitors have to pay up front for care and must reclaim reimbursement under insurance coverage they may have in their home country.

ii The role of health insurance

Residents are legally required to insure themselves with an MHI provider and persons moving to Switzerland have to do so within three months of their arrival.\footnote{Article 3 HIA.} Insurance is offered by

© 2019 Law Business Research Ltd
about 60 competing non-profit MHI companies, which are supervised by FOPH. In contrast to private insurers providing complementary health insurance coverage, the MHI providers must accept all applicants, irrespective of age and irrespective of whether they are already ill.

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 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 this 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 total health expenditure. A further share of the costs is covered by contributions to other social insurance schemes that also provide 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 meets the cost 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 is the cost of a comprehensive range of medicinal products and medical devices. Care for mental illness is paid for 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 the course of the doctor's practice. Long-term care is only paid for to the extent necessary medicinal services are concerned. Glasses, to the extent medically required, are partly paid for. Procedures and methods used in complementary medicine (such as homeopathy) are covered by the MHI to some extent. Dental care is broadly excluded from the MHI.

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 on low incomes 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

---

10 Article 4 HIA.
13 Sturny, 156.
14 Article 32 HIA.
15 The Swiss healthcare system, Financing healthcare; Sturny, 155.
from 3,920 francs to 6,547 francs. The insurers offer specific insurance models, such as health maintenance organisation (HMO) models, which the insured persons may select to benefit from reduced premiums. Insured persons may also reduce the premiums by accepting a higher franchise than 300 francs (presently franchises of up to 2,500 francs for adults and up to 600 francs for children are admissible). Chosen insurance models and selected franchises can be changed every year.

The insured persons have to pay 10 per cent of the cost of services received (above the franchise), including GP consultations, on their own, up to an annual cap of 700 francs for adults and 350 francs for children up to age of 18. Where generic drugs are available, patients have to pay 20 per cent of the price themselves if they want the original medicinal product. For hospital stays, patients have to pay an amount of 15 francs per inpatient day.

Supplementary health insurance plans may be concluded on a voluntary basis and cover benefits that are not provided by the MHI, such as greater freedom with respect to the choice of doctor or hospital, payment for certain methods of complementary medicine that are not reimbursed by MHI or single-room accommodation in hospitals. Such complementary insurance plans 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.

---

17 Article 64, paragraph 2 HIA.
18 Sturny, 156.
19 The Swiss healthcare system, Financing healthcare.
20 Article 41 paragraph 1 HIA.
21 De Pietro et al., Switzerland: Health system review, 155.
22 Article 41 paragraph 1 bis HIA.
23 De Pietro et al., Switzerland: Health system review, 186 f.
In April 2017, a new act governing national electronic patient records 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 to have 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. Although hospitals and long-term care institutions are legally required to join the scheme and offer their services using electronic patient records, ambulatory care providers are not.24

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators
In Switzerland, licensing and supervision of institutional healthcare providers and health professionals is mainly the responsibility of the cantonal authorities.

ii Institutional healthcare providers
Each hospital and other inpatient service provider (rehabilitation, psychiatric, geriatric and long-term care) requires an operating licence granted by the canton in which it operates. Licences are granted if the hospital or inpatient service provider fulfils the licence requirements defined in cantonal legislation. Requirements cover in particular issues such as medical supervision, hygiene, structure, hospital pharmacy and quality management.25

In addition, hospital and inpatient service providers require permission to provide services that are reimbursable by the MHI system. The requirements for this are defined in Article 39 of the HIA and include, in particular, organisational requirements (such as sufficient personnel and adequate medical equipment), the obligation to treat all patients in need of care, and inclusion on the cantonal hospital list (which is the main cantonal instrument for managing 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 must 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 out in the Federal Act on Medical Professions (AMP). The licence requirements defined in the AMP include a university diploma, a recognised specialisation title, a good personal reputation, proficiency in a national language and good health condition.26 Any applicant

24 Sturny, 160.
25 De Pietro et al., Switzerland: Health system review, 57.
26 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. Licensed university-trained health professionals have the right to practise 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). Physicians also require a cantonal approval and a register number (ZSR-Number) to practise at the expense of the MHI. Moreover, self-employed physicians are required to take out professional liability insurance. Employed physicians, in particular, physicians in hospitals, are insured via their employer.

University-trained health professionals with qualifications obtained abroad may provide their services without special licence under the conditions outlined in Annex III of the treaty between the Swiss Confederation and the European Union concerning the Free Movement of Persons dated 2 June 1991, or Annex K of the EFTA treaty of 4 January 1960.

With the object of controlling 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. This was lifted for a short period in 2012 but has been re-enacted with effect until 2019; however, it is left 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).

Psychology professionals
Pursuant to the Federal Act on Psychology Professions (APP), the cantons are further responsible for the licensing of psychology professionals. Similarly to the AMP, the APP stipulates the requirements of education, specialisation, cantonal licensing and continuing education. A register is planned for psychology professionals (similar to the register of medical professionals), the 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 like any other profession by the State Secretariat for Education, Research and Innovation, which is part of the Federal Department of Economic Affairs, Education and Research. A draft Federal Act on Health Professions has been passed by the Swiss parliament but is not expected to enter into force before the beginning of 2020. An

27 Article 51 et seq. AMP.
28 De Pietro et al., Switzerland: Health system review, 56.
29 Article 40 (h) AMP.
30 Article 35 AMP.
32 Article 24 APP.
33 Article 38 APP.
important role in 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{34}

V \hspace{1em} NEGLIGENCE LIABILITY

i \hspace{1em} 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 cases of mistreatment, the acting private healthcare provider is liable to the patient for any damage suffered, provided the patient can prove that it has suffered damage as a consequence of mistreatment or lack of the diligence required of 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{35} In the 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{36}

In Switzerland, conflicts involving harmed patients, healthcare institutions and health professionals 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. The SPO and the DSVP provide legal advice and support with filing complaints and negotiating settlements for their members. According to the DVSP, nearly 95 per cent of all patient complaints are resolved out of court.\textsuperscript{37}

ii \hspace{1em} 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{38} it reiterated the principle that the treating physician does not owe a success (restoration of the patient's health), but only a treatment that is in line with the rules of acknowledged medical standards and diligence. Lack of success does not imply a lack of diligence and, therefore, lack of diligence must be proved by the patient. This also applies if the treatment results in any other physical damage; although a physician is under an obligation to take all measures reasonably required to avoid such physical damage and the occurrence of such damage may suggest maltreatment, it is still up to the patient to prove that the physician had not complied with his or her obligation to act diligently. In another case,\textsuperscript{39} the court held that it is up to the treating physician to proof that he or

\textsuperscript{34} De Pietro et al., Switzerland: Health system review, 62–63.
\textsuperscript{36} Gächter/Rütsche, marginal note 391 et seq.
\textsuperscript{37} De Pietro et al., Switzerland: Health system review, 75.
\textsuperscript{38} Decision of the Swiss Federal Supreme Court dated 26 September 2016, 4A_216/2016.
\textsuperscript{39} Decision of the Swiss Federal Supreme Court dated 19 August 2015, 4A_137/2015.
she has adequately informed the patient of the risks of a treatment and obtain the patient’s consent for the treatment. However, in cases where 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 he or she would have rejected the treatment had he or she been aware of the risks the treatment entailed.

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, because of a revision of the HIA, it has been 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 the following requirements are fulfilled:

- each physician employed by a limited liability company or joint-stock company must have a professional physician licence;
- each of the employed physicians is obliged to perform the healthcare services personally (no delegation of responsibilities);
- the employed physicians remain functionally responsible towards the patients;
- corporate bodies may not give professional instructions;
- the employed physicians have to take appropriate professional liability insurance either directly or via the legal entity they work for; and
- a cantonal approval to practise at the expense of the MHI system and a ZSR-Number must be obtained.

In some cantons, where a medical practice is organised in the form of a legal entity, an additional operating licence is required. Legal entities holding such an operating licence are obliged to provide notice of any changes regarding the operationally and professionally responsible persons (i.e., the responsible body) as well as changes to the legal entity.

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 a 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 onto local cantonal lists. Private hospitals may be managed either on a profit-making or not-for-profit basis.

40 Article 36a HIA.
41 Kaufmann Markus, Die Arztpraxis als Aktiengesellschaft oder GmbH – Zulässigkeit und Vorteile, in: Der Luzerner Arzt, Ausgabe 2010/2 (Nr. 81), 32; De Pietro et al., Switzerland: Health system review, 56.
42 De Pietro et al., Switzerland: Health system review, 172.
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 the responsibility of the Swiss cantons. As far as inpatient care is concerned, cantonal hospital planning and ultimately the hospital list are the major instruments for managing sufficient, but cost-effective, institutional healthcare provision in the 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 and 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, particularly with respect to GPs in some remote regions of Switzerland, where interest in opening a new practice or taking over an existing practice is low, and it is likely that coverage will be insufficient 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).

VIII MARKETING AND PROMOTION OF SERVICES

In Switzerland, the restrictions on advertising applicable to healthcare services differ depending on the advertiser. Specifically, the AMP and APP stipulate that advertisements by healthcare professionals governed by these laws (see Section IV.iii) must be objective and meet a public need, and must not be misleading or obtrusive. Sanctions may include warnings, reprimands and fines of up to 20,000 francs. On the other hand, public and private hospitals, as well as emergency departments, are authorised to advertise their services without these restrictions. Because there is no definitively established distinction between self-employed physicians and hospitals, some legal doctrine considers the restrictions on hospital advertising to be adequate for both.

44 De Pietro et al., Switzerland: Health system review, 170.
45 Article 39, paragraph 2 HIA.
46 Article 39, paragraph 2 bis HIA.
47 Articles 40 (d) AMP and 27 (d) APP.
48 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 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 organs is constantly rising. Therefore, in 2013, the federal government launched an action plan 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. Some of these measures have already been realised, namely the development of the ‘Swiss Donation Pathway’, which describes the donation process and helps create checklists for quick detection of donors. Furthermore, the Swiss Monitoring of Potential Organ Donors study is to be continued in an improved way and expanded to include emergency departments.\footnote{Aktionsplan mehr Organe für Transplantationen im Rahmen der Bundesrätlichen Strategie Gesundheit 2020, Bundesamt für Gesundheit BAG, www.g2020-info.admin.ch/de/create-pdf/?project_id=54 (visited on 20 July 2017).} Finally, general public awareness will be increased with the aim of significantly increasing the number of persons who opt in for donation by introducing a donation pass.

Pre-implantation genetic diagnosis (PID) is a medical procedure in which embryos are genetically analysed before being inserted into the uterus. In Switzerland, PID was generally forbidden. However, in a referendum in 2016, the Swiss people accepted a change in the relevant legislation, the Federal Act concerning Medically Supported Reproduction (AMSR), providing for a liberalisation of PID. In particular, the revised law ensures that couples can make use of PID on favourable terms where, for genetic reasons affecting the couple, the risk exists that a child may become ill or handicapped. Furthermore, it will help couples who 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 hand, because responsibilities are split between different government levels, and the MHI system means demand for medical services is hardly influenced by cost considerations, it is difficult to control healthcare costs and these have significantly increased over the past years. Therefore, policy and legislative initiatives will continue to focus on measures to stop, or at least slow down, cost increases in the field of healthcare. While measures already implemented have mainly focused on the prices of medicinal products, reimbursement of specific medical treatments of questionable efficiency
is likely to be reassessed in the near future and eventually excluded from reimbursement. Further, the federal government has announced it will undertake an assessment of the methods other European countries, in particular Germany and the Netherlands, employ to tackle the increased demand for healthcare services, namely budgets or other measures controlling expenditure for services provided.
Chapter 16

UNITED ARAB EMIRATES

Andrea Tithecott

I OVERVIEW

The United Arab Emirates (UAE) is a confederation of seven emirates. The most well-known are Dubai and Abu Dhabi. The other emirates are Sharjah, Ajman, Fujairah, Umm al-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.

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

© 2019 Law Business Research Ltd
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 2005,5 which provides a basic level of cover for all employees and their families. A similar scheme is currently being implemented in Dubai pursuant to Law No. 11 of 2013,6 implemented from February 2014 over three phases according to employer workforce size, with the final phase 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.

4  BMI UAE pharmaceuticals and healthcare report Q3 2017.
5  Law No. 23 of 2005 concerning Health Insurance in the Emirate of Abu Dhabi and the Implementing Regulation.
6  Law No. 11 of 2013 regarding Health Insurance in the Emirate of Dubai.
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, with a view to improving the coordination of treatment throughout a continuum of care. The goal is the delivery of healthcare throughout the entire life cycle, in a process extending from the initial visit to a primary care physician, through the referral process, to the completion of treatment. Initiatives such as these should produce developments in the use of 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’s master plan for delivery of healthcare services, and recently issued a standard for primary healthcare services in 2016. Similarly, the DHA has approved licences for 20 healthcare centres and clinics around the emirate providing primary healthcare services.

Insurers are increasingly taking the lead on adjusting health insurance policy terms and conditions to require patients to access primary care services and to have appropriate referrals from primary gateway providers before approving fees. In terms of future developments, as the UAE rolls out licensing for telehealth services, we also expect the ability of patients to access teleconsultation pathways.

ii Hospitals

Public sector

The main public sector institutions that oversee delivery of healthcare services and quality are the DHA (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.

SEHA is an independent public joint stock company that owns and operates all public hospitals and clinics across Abu Dhabi, consisting of 12 hospitals, 46 primary healthcare clinics, 10 disease prevention and screening centres, along with mobile clinics, a school clinic, blood banks, dental centres and a vaccination centre.

Mubadala Healthcare, a division of the Abu Dhabi government investment vehicle Mubadala Development Company, has also played a prominent role in the provision of

---

7 DOH Standard for Primary Health Care in Emirate of Abu Dhabi HAAD/PHC/SD/0.9.
8 Dubai Regulation No. 30 of 2017 regulating telehealth; DOH Standards on teleconsultation, TC/SD/0 2014.
9 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 Federal Law No. 4 of 2015 (on Private Health Facilities) and Law No. 22 of 2015 Regulating Partnership between the Public Sector and the Private Sector in the Emirate of Dubai. For further details pertaining to private-sector hospitals, see Section IV.

**iii Social care**

The Ministry of Community Development 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 has remained immature. There has been very little focus on geriatric or dementia care services, resulting in an underdeveloped network supporting the transition of elderly or vulnerable patients from hospital care to home care with appropriate social care support. This burden was typically left to families to bear, but they will now benefit from additional support being made available through new initiatives by this Ministry and through the establishment of a Community Development Authority in Dubai, and a Department of Community Development in Abu Dhabi.

**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, there have been developments regarding new provisions that apply specifically in a healthcare context.

Federal Law No. 2 of 2019, concerning the Use of Information and Communications Technology in Health Fields, regulates the uses of information and communications technology in the areas of health in the country. This Law was published in February 2019. The executive regulations supplementing the law are expected to be published in August 2019. The Law will achieve (among other things) the following objectives:

a require health authorities to set standards for the confidentiality and control of electronic patient records;

b create a central health record storage system; and

c restrict the transfer of patient health data outside the country without permission granted by the health authority.

---

10 Federal Decree Law No. 1 of 1972 concerning the Competence of the Ministries, as amended.
11 Article 379 Penal Code Law No. 3 of 1987.
The following laws also make provision for patient confidentiality, and remain in place alongside the new law.

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 Information’, which includes information that can be used to identify a patient. Policies developed pursuant to the Data Standard must 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 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. 10 of 2018 (on Establishing the Department of Health – 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.

### ii 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 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 of the date of notification 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 applicable 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 where the individual is carrying out the 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 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 practise 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 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 particular 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 practise 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 there is a gap of more than two years in a healthcare professional’s 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. The Constitution provides that all laws in the UAE are subject to the overlay of the shariah (principles of Islamic law). 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

13 The Federal Law No. 5 of 1985 (Civil Code).
14 Article 7 UAE Constitution 1971, as amended.
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.

**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 damage.

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.\(^\text{15}\)

When awarding compensation for damage or harm, the guiding principle in accordance with the Civil Code is that compensation should be equal to the harm suffered. Damages are the remedy used to restore the victim to the position the victim was 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.\(^\text{16}\) Each company

---

15 Articles 282, 292, 389 Federal Law No. 5 of 1985 (Civil Code).
16 Federal Law No. 2 of 2015 regulating Commercial Companies.
established in the UAE must have one or more UAE national partners who holds at least 51 per cent of the company’s capital. A recent law allowing 100 per cent foreign ownership of companies has not yet been fully implemented and foreign investors cannot yet create a foreign wholly owned legal entity to establish a healthcare facility. However, 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).17

VII COMMISSIONING AND PROCUREMENT

The commissioning of healthcare services is government-led in terms of the policy position.18 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.

17 Executive Regulations (Council of Ministers’ Resolution No. 37 of 2014) Cabinet Resolutions (Resolution Nos. 13 and 22 of 2016).
VIII  MARKETING AND PROMOTION OF SERVICES

All advertising must comply with the MOH Healthcare Advertising Regulation.\(^{19}\) 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.

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 those governing similar treatment services in other mature jurisdictions, such as in the United Kingdom, with restrictions upon the freezing and storing of embryos.

However, in a cultural shift, the UAE has already made significant advancements to allow such treatment services to be offered to the Emirati population. It is hoped that this will boost dwindling population figures, given the region’s high rate of infertility problems derived from levels of vitamin D deficiency, obesity and consanguineous family history. 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,\(^{20}\) 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.

\(^{19}\) Cabinet Resolution No. 7 of 2007 (regarding Health Advertisements Regulation).
\(^{20}\) UAE Vision 2021 World Class Healthcare.
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).

iii Organ donation – opt in or opt out

Federal Law No. 5 of 2016 (regulating organ transplants) further developed the existing legal framework, enabling the transplant of tissue or organs from either live or deceased patients. The Law contains the equivalent of an opt-in provision, 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 the 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 Mohammed Bin Rashid University of Medicine and Mediclinic City Hospital in 2016.

iv Public–private partnerships

With Law No. 22 of 2015, the emirate of Dubai was the first to promulgate a law to govern public–private partnership (PPP) projects. This Law was aimed at a wide range of PPP projects, but its application has been slow because of the absence of detailed procedures; these procedures are expected to be issued by the government soon.

Notwithstanding the absence of regulatory guidance, the DHA has begun to discuss how to promote the introduction of more PPPs into the healthcare system. The DHA has created an investment strategy promoting Dubai as a viable and competitive hub for investment in healthcare that addresses the needs of the emirate, while providing future opportunities and the best service for investors to enable development of a sustainable public–private model in Dubai.

More recently, the emirate of Abu Dhabi has followed suite with the issuance of Law No. 1 of 2019 regulating PPP projects to encourage the private sector to participate in development projects and to maximise investment in the various relevant fields in a way that helps economic and social development in the emirate of Abu Dhabi. This Law is still very newly enacted and has yet to be put into practice.

21 Rule No. 1 Concerning Permitted Activities and Licensing Categories for Dubai Healthcare City Effective 1 December 2016 RU/RL/002/01.
22 Federal Law No. 15 of 1993 Regulating the Transfer and Transplant of Human Organs.
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.
Chapter 17

UNITED STATES

Lawrence W Vernaglia and Anna S Ross

I OVERVIEW

i Overview of the US healthcare system

The US healthcare industry remains 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.

Several years into the administration of Donald Trump as US President, the future of the US healthcare system remains uncertain. Trump, a Republican, campaigned on a promise to ‘repeal and replace’ the ACA legislation, and his administration has spearheaded a number of efforts to significantly weaken the programme as envisioned by President Obama, although his efforts to completely repeal the law have not been successful. Still, his efforts have had some impact, most 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 these legislative battles completely intact, and indeed now bears a number of scars. Moreover, although the efforts of 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. Notably, however, the focus

---

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 pre-eminent 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 US politics has shifted to the upcoming 2020 presidential election, in which a number of Democratic challengers to Trump have emerged. The majority of the major Democratic presidential candidates – at the time of writing, a crowded field – have expressed the need to expand healthcare coverage for more Americans, although they are split on how to do it. One of the most dramatic changes in healthcare financing and delivery being considered is the potential expansion of the federal Medicare programme (see Section II.ii) to all Americans: the ‘Medicare for All’ position advocated by the majority of the Democratic presidential candidates in the spring of 2019. At the time of writing this chapter, none of the candidates had articulated a detailed method to pay for a programme of this type, and health economists are divided on whether such a change would cost or save money for the United States. Legislation such as this would be impossible to pass in the present political climate in the United States, but shows how notions of a national health insurance programme, such as that in the United Kingdom (see Chapter 4), once a fringe consideration in the United States, are now embraced by mainstream candidates.

This dynamic places the US healthcare system in a tenuous position. Trump, running for re-election himself, needs to be able to demonstrate how his administration has been successful in improving the healthcare system, if not in repealing the ACA outright. Yet, nearly 10 years into Obamacare, the programme’s most popular features (including mandatory coverage of pre-existing conditions and expansion of coverage for certain populations) have become firmly entrenched, and it is difficult to imagine a programme succeeding without these aspects. The Democrats’ victories in the 2018 midterm elections further suggests that many Americans value the party’s overall approach towards healthcare.

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.

Another major trend in the US healthcare system is a drive towards value-based care and reducing costs in other ways. This has spurred the development of several alternative payment models, which intend to compensate providers based on the outcomes – or value – of the care they provide, rather than the volume of services. Government and private healthcare payors alike are increasingly turning towards these alternative payment models in an effort to reduce the overall costs associated with healthcare while improving the outcomes associated with such care. This trend has also resulted in increased scrutiny on certain aspects of the healthcare system that are some of the biggest cost drivers, such as drugs, and in novel ways of providing care, such as through telehealth services.

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.

---

ii  Delivery of healthcare in the United States

Hospitals with inpatient, outpatient and diagnostic capacities are the ‘work benches’ for the delivery of healthcare in the United States, although the physicians and other professionals who treat patients there are obviously critical parts of the care delivery system as well. Physicians are also sometimes referred to as the ‘captains of the ship’ in the hospital context, though other non-physician practitioners are gaining prominence in the institutional and community healthcare setting. Non-physician practitioners, sometimes called mid-level practitioners, include nurse practitioners, physician assistants, certified registered nurse anaesthetists, nurse midwives and others. These practitioners are licensed in their respective states by the state professional board, such as the medical board or the nursing board. Sometimes these practitioners are licensed by the state department of health or another agency within the government.

To help ensure that patients are adequately protected from substandard care provided by deficient practitioners, hospitals and other healthcare facilities in the United States are required by law to perform ‘peer review’ and ‘quality assurance’ activities. Compliance with specific procedures required by these laws qualifies the organisation and its physicians who participate in peer review for immunity from liability under antitrust and certain other laws. Physicians and other practitioners who are disciplined and do not prevail in their hearings are listed on a nationwide databank that warns other institutions and prospective employers regarding a practitioner’s professional shortcomings.

However, there is a growing trend towards services provided in other care settings, coupled with a drive towards lower costs. This has spurred on the presence and success of telehealth services, which may offer increased efficiency and also lower the total cost of care.

iii  Payment for healthcare services

Healthcare services in the United States are paid for primarily by (1) governmental programmes such as Medicare and Medicaid and (2) private insurance organisations. These public and private organisations are collectively known as ‘third-party payors’ or simply ‘payors’. Most third-party payor arrangements have some element of ‘managed care’, which means that care is provided subject to utilisation review, such as primary care physicians acting as gatekeepers to specialists. Managed care plans typically enter into contracts with providers to provide services at a discounted rate, sometimes in exchange for an expectation of increased volume from the payor. Governmental and private healthcare payors alike in the United States are increasingly focused on the value of services, which has contributed to the rapid expansion of alternative payment models that offer incentives to providers for better care outcomes, and in some cases penalise poor outcomes through reduced payments.

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. This 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.3 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:

a enterprises that operate hospitals and health systems;
b manufacturers and developers of medical devices, pharmaceuticals and other biotechnology products;
c academic institutions that provide care while training healthcare professionals;
d information technology firms, construction companies and other infrastructure providers;
e insurance companies, self-insured employers and other third-party payors;
f labour unions representing the employees of healthcare organisations;
g medical entrepreneurs and investors (including private equity and venture capital) who finance the healthcare system;
h healthcare trade associations;
i patient advocates and special interest healthcare advocacy organisations; and
j patients and their families.

In addition, there is substantial governmental involvement in healthcare in the United States, with the government serving as a major payor, as well as a provider and regulator in various parts of the market.

ii The role of health insurance

Most medically necessary healthcare services in the United States are paid for by governmental or private third-party payors, including insurance companies, self-insured employer plans, 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 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. CMS decreased the outpatient hospital rates subject to Section 603 to 40 per cent per cent of the current OPPS rates, a major hardship for land-locked hospitals or those in communities with changing demographics and geographies, and further expanded ‘site neutrality’ rate cuts for all off-campus hospital departments. At the time of writing, litigation opposing a CMS regulatory expansion of site neutrality was pending, which, if successful, would limit the financial impact on hospitals. Site neutrality has also been embraced by private payors and state Medicaid programmes and is expected to be expanded to other services and payors.
Medicaid is a joint state and federal programme traditionally for certain indigent or impoverished individuals who are aged, blind or disabled, or members of indigent families with dependent children that meet income and resource standards set by the state Medicaid agency. Medicaid today covers more individuals than Medicare, making it the largest single payment system in the United States, in terms of persons served. The federal government contributes roughly half of the reimbursement for the Medicaid programmes, though some 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 preferred provider organisations**

Although there remain some ‘pure indemnity’ arrangements (wherein the beneficiary is reimbursed for all healthcare expenses he or she incurred regardless of the provider who rendered the care), most third-party payor arrangements involve some element of managed care, meaning that the healthcare services are provided subject to utilisation review procedures such as a primary care physician serving as a ‘gatekeeper’ for specialists, and typically create certain constraints on the beneficiary’s choice of provider, usually as a result of network or panel arrangements established by the payor.

There are two primary types of managed care arrangements: 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 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' (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 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’, namely an incentive to find and use cost-effective providers. To the extent that those providers include domestic or overseas providers, these consumer-driven plans may be a catalyst for the growth of overseas medicine in the United States. Patient advocates are concerned that high deductible plans, coupled with insufficiently funded HSAs, have caused a spike in consumer bankruptcy filings. Indeed, many view medical debt as one of the leading causes of personal bankruptcy in the United States.

### iii Funding and payment for specific services

Healthcare reform, including the ACA and any new healthcare legislation that may 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 (US$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 US$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 pans 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.5

The trend toward alternative payment models has strengthened in recent years, with recent data demonstrating that US healthcare payments associated with alternative payment models are steadily increasing.6 However, despite the appeal of certain alternative payment models (also known as value-based payment models), particularly those offering higher payments to providers who demonstrate a higher quality of care, providers have been reluctant to participate in programmes imposing full capitated risk. As a result, CMS has announced several new initiatives, including mandatory bundled payment models for certain clinical areas and a new direction for the Medicare Shared Savings Program, pushing accountable care organisations (the most popular type of alternative payment model, involving a group of providers that takes responsibility for the total cost and quality of care in exchange for a portion of the savings) into a two-sided risk model more quickly than before. Other laws passed in recent years, including the Medicare Access and CHIP Reauthorisation Act of 2015, have established new ways of paying for care that focus on value instead of volume.

Despite these requirements of the programme and other initiatives, changes to the ACA introduced under the Trump Administration have cut away at other features of the

6 Health Care Payment Learning & Action Network, Measuring Progress: Adoption of Alternative Payment Models in Commercial, Medicaid, Medicare Advantage, and Medicare Fee-for-Service Programs (22 October 2018).
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 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 these caps (typically around US$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 businesses 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 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. Capitalising on improvements in technology in this way can present opportunities 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. Most US healthcare providers (e.g., hospitals, physicians and skilled nursing facilities) determined that they are not subject to GDPR and have not voluntarily adopted a compliant position. A small minority of providers that advertise in the EU have complied with GDPR.

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 (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.

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 out 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, or 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 most recent 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, forego accreditation and rely on the surveys by the state survey agencies. The federal Medicare programme has contracted with the state healthcare agency in every state (usually the Department of Public Health) to be the official state survey agency for 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,7 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 practitionerers 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 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, ‘credentialling’ of individual professionals occurs at the facility level. Compliance with standards and requirements established by individual health facilities permits individual licentiates to perform services within those facilities. Health plans, professional associations and licensed outpatient facilities usually also impose such requirements.

---

7 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.’).
State and federal statutes applicable to physicians and certain other licentiates provide hearing and appeals rights when a state agency denies, or proposes to deny or revoke, licensure or certification. Similarly, hospitals, health plans and certain other providers or professional 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.8

VI OWNERSHIP OF HEALTHCARE BUSINESSES

i Types of ownership and management

The trend toward consolidation of the healthcare industry in the United States has created a number of different ownership and management models. Entities entering the healthcare market typically acquire a healthcare business through 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 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. These ‘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

---

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 US$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 practise of medicine' (CPOM), which is generally defined as the operation of a medical practice, or the employment of physicians (or other licensed practitioners of the healing arts), by lay corporations and entities that are not themselves licensed to practise medicine. The US states have wildly divergent degrees of CPOM regulation, with states 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 arrangements of this kind 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. Several US states have ‘all payor’ anti-kickback statutes, punishing similar activities when commercial payors are involved.

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 that individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under Medicare or Medicaid. Remuneration is defined to include (among other things) the waiver of co-payments and deductible amounts. Violation of the CMPL is punishable by a monetary penalty of US$10,000 per item or service, damages of up to three times the amount claimed for the item or service, and potential exclusion from Medicare. Similar to the Anti-Kickback Statute, there are several exceptions to the CMPL that, if met, protect the arrangement. Advertising and other promotional materials provided to patients present one example of potential risk under the CMPL’s patient inducement prohibition. Although these items or services can be structured to comply with an exception to the CMPL’s prohibition on patient inducements, arrangements of this kind 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 limited, less expensive
coverage of this kind. 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.

Healthcare finance is shaping up to be a major policy debate in the US 2020 elections,
with the Republican incumbent Trump facing an increasingly left-leaning field of dozens of
Democratic candidates, many of whom endorse a radical change to the US healthcare system.

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.

A number of initiatives have tried to address concerns about cost in different ways. Most notably, the expansion of alternative payment models that reward volume over value have proliferated and matured, with many payors – especially CMS – increasingly focused on getting providers to accept downside risk in addition to the opportunity for shared savings. Another result has been a focus on care settings and options to provide care in lower-cost settings, particularly through telehealth services. And in some cases, there has been increased scrutiny on the prices themselves, particularly for high-cost items such as expensive pharmaceuticals. There have been numerous efforts, including at the state level, to tamp down the cost of drugs, such as by establishing upper payment limits. Although relatively few changes have actually been made to date, drug pricing will certainly be an area to watch in the coming years.

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.
HOLLY BONTOFT
Fieldfisher LLP
Holly Bontoft is an associate in Fieldfisher’s regulatory group. She acts for a wide range of regulators, including the Human Fertilisation and Embryology Authority and the Human Tissue Authority, and also provides training on their regulatory systems. Holly has advised a number of international healthcare and life sciences companies. Holly also works with specific health and social care regulators, such as the Professional Standards Authority for Health and Social Care, the Nursing and Midwifery Council and the General Medical Council. Holly specialises primarily in healthcare and life sciences regulation, as well as the broader healthcare sector; in particular, advising on changes to regulatory schemes and regulation of innovative products and schemes and amendments to legislation.

JONAS BORNHAUSER
Bär & Karrer AG
Jonas Bornhauser has studied at the University of Zurich (lic iur, Dr iur) and at Nottingham Law School (LLM), and was admitted to the Bar in 2009. He is an associate and a member of Bär & Karrer’s intellectual property department, with a practice covering a wide range of contentious and non-contentious trademark, copyright, patent and other IP-related issues; in particular, matters related to the pharmaceutical and life sciences industry.

FRANCISCO BRITO E ABREU
Uría Menéndez – Proença de Carvalho
Francisco Brito e Abreu joined Uría Menéndez in 2001 after working as in-house counsel in the Portuguese subsidiary of a multinational corporation, a privately owned holding company and a listed Portuguese company, and as a lawyer in another prestigious Portuguese law firm. He was made partner of Uría Menéndez in January 2005.

He focuses his practice on commercial and corporate law issues and has extensive experience in corporate restructuring, M&A and private equity transactions. Francisco also has vast experience in the pharmaceutical sector, focusing on regulatory, distribution and advertising matters.

He is recognised by major publications (Chambers Global, IFLR1000, PLC Which lawyer?, etc.) for his work in M&A and private equity.
José Alberto Campos-Vargas heads the life sciences practice and the international trade and customs group at Sánchez Devanny.

He has experience in advising clients operating in regulated sectors on regulatory and operational matters, and on international trade matters. Alberto is skilled in health and hygiene law, and in the laws regulating food, non-alcoholic and alcoholic beverages, medicines and medical devices, cosmetics, perfume and beauty products, and tobacco and vaping products. He is also skilled in international trade and customs matters, particularly in connection with the importation and marketing of goods subject to sanitary control. He has advised clients on Mexican free trade agreements, import duties, export controls for regulated products, customs and non-customs requirements, and health, life sciences and trade issues in mergers and acquisitions, restructurings and privatisations, with a particular focus on the pharmaceutical industry, medical devices, food and beverages, tobacco and vaping, and other heavily regulated sectors. He has successfully represented national and foreign clients in administrative proceedings before the Mexican health authorities and in litigation before federal courts and the Mexican Supreme Court of Justice, as well as in negotiations with governmental authorities and in processes related to health issues.

Jonathan Coates is a health law and health-sector specialist. He is the managing partner of Claro, a specialist health sector law firm in New Zealand. He has practised and studied health law in New Zealand and the United Kingdom. He has a PhD in health law, which considered the regulation of health professionals in the New Zealand environment. He has a master’s in medical ethics and medical law (Distn) from King’s College London.

Théra van Swaay De Marchi specialises in private healthcare law. She has been recognised by Latin Lawyer 250 and was also named among the Most Admired Lawyers in Brazil by Análise Advocacia 500 in 2014 and 2018. Théra was elected as a member of Pinheiro Neto Advogados’ steering committee for two consecutive terms (2012–2014 and 2015–2017) and she has been head of the firm’s private healthcare and pension fund practice area since 2009. In the academic field, she has lectured on healthcare practice by invitation of Abramge, CONARH, Qualicorp, Willis Towers Watson, Mercer Marsh and the American Chamber of Commerce in Brazil (AmCham). Since 2010, she has taken part in the Annual Employee Health Care Conference in New York. In 2011, she was invited by the National Health Agency (ANS) to debate the private healthcare regulations, in particular matters related to post-employment healthcare benefits for former employees. Currently, she is a member of the ANS Working Party on Corporate Plans. Her regulatory practice includes mergers and acquisitions in the private health system, advising on redesigns of corporate health plans for domestic and international companies, advising on medical and dental healthcare contracts and on administrative and judicial proceedings (collective and individual claims), among other matters.
SARAH ELLSON  
*Fieldfisher LLP*

Sarah Ellson co-leads the firm’s regulatory group and specialises in healthcare regulation. She acts for numerous regulators, many of which cover disciplines at the frontiers of medical science, such as the Human Fertilisation and Embryology Authority, for whom Sarah has advised on new mitochondrial donation regulation and licensing and the authorisation of gene editing in research. With the Human Tissue Authority, Sarah has advised on aspects of living and postmortem organ donation and DNA preservation. She has worked with health and social care regulators, including the General Medical Council, the Nursing and Midwifery Council, the General Dental Council and the Northern Ireland and Scottish Social Care Councils, as well as those educating healthcare students. She has worked for numerous and diverse private providers in the pharmaceutical, optical, pharmacy and blood-banking sectors and supports new healthcare clients looking to enter the English market.

DANIEL FABIANO  
*Fasken Martineau DuMoulin LLP*

Daniel Fabiano is a partner at the Toronto office of the law firm of Fasken Martineau DuMoulin LLP. His business law practice emphasises public procurement, privacy/information protection and technology. In his procurement practice, Daniel advises organisations on documenting the bidding process, drafting and negotiating contracts, and mitigating procurement risks and bid disputes.

Daniel has certificates both in public procurement law and practice and in advanced procurement law and practice: major projects and tendering, from Osgoode. He also advises the Healthcare Supply Chain Network on common tendering and contracting templates and guidance documents for healthcare organisations, and regularly speaks on health sector procurement. In his privacy/information protection practice, Daniel regularly assists clients in complying with Canada’s privacy and freedom of information laws. Together with other members of Fasken, he co-authored a compliance manual on the Freedom of Information and Protection of Privacy Act for Ontario hospitals.

LYNNE GOLDING  
*Fasken Martineau DuMoulin LLP*

Lynne Golding leads the national health law group at the law firm of Fasken Martineau DuMoulin LLP. Out of their Toronto office, she has an active corporate-commercial practice principally in the health industry, which involves transactions dealing with public and private corporations in both regulated and unregulated industries. Her own practice focuses on corporate law, particularly structuring contractual arrangements between hospitals and private sector service providers and providing governance advice.

Together with other members of Fasken, she co-authored the Ontario Hospital Association’s Toolkit on the Freedom of Information and Protection of Privacy Act and advised the Healthcare Supply Chain Network on the Common Tendering and Contracting Templates for healthcare organisations, including by preparing guides and annotations for their use. She has led large teams involved in the merger or integration of large, medium-sized and small corporations involved in the delivery of healthcare.
STEFANIE GREIFENEDER

Fieldfisher (Germany) LLP

Dr Stefanie Greifeneder is a partner in the Munich office of Fieldfisher (Germany) LLP. She provides regulatory law, intellectual property and commercial law advice for national and international companies from a wide range of industry sectors, with a specific focus on the pharmaceutical, biotech, medical devices and food sectors. She represents these companies in administrative proceedings and before the courts. She also focuses on IP and commercial law issues in the framework of international corporate transactions. Stefanie has extensive experience in both court and out-of-court proceedings on patent infringement and trademark and unfair competition matters. She also advises clients in drafting and negotiating a broad range of agreements, such as licence agreements and R&D agreements, as well as distribution and supply agreements.

FUMIHARU HIROMOTO

Mori Hamada & Matsumoto

Fumiharu Hiromoto advises on an extensive range of finance transactions and regulatory matters, including asset management (including public offering and private placement of foreign domiciled investment funds) and real property investments (including inbound investments using a GK-TK or a TMK with leveraged debt financing). As a practitioner in real property investments in hospitals, he is fairly acquainted with healthcare laws and regularly advises funds investing in healthcare facilities. He received his LLB from the University of Tokyo in 1995 and his LLM from Columbia University School of Law in 2003. He also worked with Kirkland & Ellis in Chicago from September 2003 to August 2004. He is admitted in Japan (1997) and New York (2004) and is fluent in Japanese and English.

NABIL A ISSA

King & Spalding LLP in cooperation with the Law Office of Mohammed AlAmmar

Nabil Issa specialises in private equity, funds and investment structures in the GCC and Egypt. He is based in Dubai and in the affiliated Riyadh offices of King & Spalding LLP. Nabil regularly represents clients on healthcare transactional matters in Saudi Arabia and the United Arab Emirates. He is especially known for developing innovative shariah-compliant CMA funds and investment structures for real estate and private equity investments in Saudi Arabia and the United Arab Emirates. Proficient in Arabic and fluent in English, Nabil is a regular author and presenter on healthcare regulations and investments in the Middle East.

Nabil is ranked in Band 1 for his work on investment funds in the Middle East by Chambers Global (2014–2019) and Band 2 for his corporate work in the Middle East by Chambers Global (2017–2019), in addition to being highly ranked for his corporate work in the United Arab Emirates. He is also recognised as a leading individual for his corporate work in Saudi Arabia by The Legal 500: EMEA 2019.
MANDI KREBS
Hogan Lovells (South Africa) Inc

Mandi Krebs is a senior associate at Hogan Lovells and advises various multinational companies in the pharmaceutical and medical device industries on legal and regulatory matters, including marketing authorisations, licensing, product labelling, advertising and marketing activities, as well as pricing and reimbursement matters in South Africa.

In addition, Mandi advises multinational pharmaceutical companies regarding market entry into various jurisdictions across Africa.

Mandi has valuable experience in advising clients on matters related to interactions with healthcare professionals and patients, and reimbursement models, as well as experience in challenging competitors’ claims.

Mandi is very experienced in liaising with enforcement authorities and regulatory bodies in South Africa and across Africa.

SOON-YUB SAMUEL KWON
Lee & Ko

Soon-Yub Samuel Kwon is a senior partner with extensive experience over a broad range of regulatory and transactional matters under Korean law. He has advised several leading Korean hospitals and healthcare service providers on various regulatory issues under Korea’s healthcare laws, and also on the expansion of their services into overseas healthcare markets.

Mr Kwon’s recent work includes representing Seoul National University Hospital (SNUH) in connection with its operation of a UAE specialty hospital, advising a major Korean hospital on the establishment of check-up centres in Kazakhstan, the United Arab Emirates and China, advising SNUH on its operation of a UAE children’s specialty hospital, and advising a medical solutions provider on the exportation of its hospital information system.

Mr Kwon has also served as an adviser on the Ministry of Health and Welfare’s Committee for Reviewing Policies in Support of the Overseas Expansion of the Korean Healthcare System and Attraction of International Patients since 2016.

ANDREA LANE
Claro

Andrea Lane is a solicitor at Claro and has worked with a range of public and private health-sector clients in both an advisory capacity and in relation to litigious matters. She has practical health-sector experience, having gained a Bachelor of Medical Imaging and practised radiography for 10 years. She has an LLB from Canterbury University and is studying towards a master’s degree in medical law and ethics from the University of Edinburgh.
About the Authors

ZOHAR LEVY
Fasken Martineau DuMoulin LLP
Zohar Levy is a partner in the litigation department of the law firm of Fasken Martineau DuMoulin LLP. She works out of the Toronto office. Zohar has advised clients on the implications of Canadian healthcare legislation for companies interested in entering the Canadian markets. She is a member of a panel of litigators at Fasken who act as counsel to the Discipline and Fitness to Practise Committees of the College of Physicians and Surgeons of Ontario. She has represented numerous healthcare professionals both in civil and regulatory proceedings and has also represented clients who operate in the healthcare space in litigation matters.

SOPHIE MACRAE
Fasken Martineau DuMoulin LLP
Sophie MacRae is an associate in the business law group at the Toronto office of the law firm Fasken Martineau DuMoulin LLP and is engaged in a broad corporate/commercial practice. Sophie also focuses on legal and regulatory matters in the healthcare sector. Sophie advises both for-profit and not-for-profit clients (including charities) in the healthcare sector, including, for example, in respect of contractual arrangements, corporate governance, privacy and compliance matters.

Sophie is a graduate of Osgoode Hall Law School and, prior to law school, obtained a Bachelor of Arts (Honours) from Queen’s University, Ontario. Prior to joining Fasken, Sophie completed an internship in the legal department of a large teaching hospital in Toronto, Ontario (the Sinai Health System).

ABRIANNE MARAIS
Hogan Lovells (South Africa) Inc
Abrianne Marais was formerly an associate at Hogan Lovells. Abrianne has experience in advising companies in the pharmaceutical and medical device industries on legal and regulatory matters. In addition, he has general experience, including the drafting of commercial agreements, undertaking due diligence investigations and conducting regulatory and legal compliance audits.

MARIA SILVIA L DE ANDRADE MARQUES
Pinheiro Neto Advogados
Maria Silvia L de Andrade Marques specialises in private health law, focusing on counselling and litigation at administrative and judicial levels concerning the legislation and regulation of private healthcare plans and advising companies, associations, foundations, insurers and operators that offer or act in the area of healthcare. Her areas of practice also include customer service in civil matters (obligations, civil liability, contracts) and consumer law in the private health market. She obtained her Bachelor of Laws from the University of São Paulo (USP) in 2002 and a diploma in business administration from the Getúlio Vargas Foundation (CEAG-FGV) in 2007. She attended the intensive course on supplementary health law promoted by UNIDAS in 2008, as well as the Annual Employee Healthcare Conference.
in New York in 2012 and 2018 promoted by the Conference Board Inc. She is currently pursuing her master’s degree in civil law from USP, through research and studies into business and existing business contracts, and is also analysing collective health plan contracts.

JOANA MOTA
*Uría Menéndez – Proença de Carvalho*


Joana focuses her practice on the acquisition, protection and maintenance of national and international IP rights and has represented parties in related litigation proceedings. She has also advised companies on personal data protection issues.

Joana has a postgraduate qualification in IP law, awarded by the Portuguese Association of Intellectual Property Law in conjunction with the Faculty of Law of the University of Lisbon. She also has an advanced qualification in data protection law from the University of Lisbon.

VANESSA MUI
*Fasken Martineau DuMoulin LLP*

Vanessa Mui is an associate in the business law group at the Toronto office of the law firm Fasken Martineau DuMoulin LLP, practising in the areas of health law and life sciences. She advises clients on legal and regulatory compliance matters with respect to healthcare and the provision of health services, healthcare professionals, retail and the food industry, and other day-to-day business concerns.

Vanessa is also a registered dietitian in the province of Ontario with clinical, research and industry experience. Previously working in the areas of nutrition marketing and scientific and regulatory affairs, Vanessa’s work was focused on healthy food innovation, functional foods and natural health products. Vanessa was seconded to Cancer Care Ontario and the Centre for Commercialization of Regenerative Medicine, where she provided in-house legal support, drafted and reviewed funding, undertook research and consulting, and assisted with service and procurement agreements.

KIMBERLY POTTER
*Fasken Martineau DuMoulin LLP*

Kimberly Potter is a partner in the litigation department of the law firm of Fasken Martineau DuMoulin LLP. She works out of the Toronto office.

Kimberly has advised clients on the implications of recent changes to healthcare legislation, and assisted in drafting regulations for a professional college. She has also represented clients who operate in the healthcare space in litigation matters. She recently co-authored an article on proposed changes to Ontario’s healthcare regime, which was published in the *Canadian Health Facilities Law Guide and Risk Management in Canadian Health Care* by LexisNexis.
DAVID ROSENBAM

Fasken Martineau DuMoulin LLP

David Rosenbaum is a partner in the litigation department at the law firm of Fasken Martineau DuMoulin LLP. He works out of the Toronto office.

David has extensive experience in the health law area, which includes: acting for regulators of health professionals in discipline matters, prosecutions in the courts, drafting of regulations and advice on regulatory matters. He is a member of a panel of litigators at Fasken who act as counsel to the Discipline and Fitness to Practise Committees of the College of Physicians and Surgeons of Ontario. In addition to the work he has done for regulators, he has provided regulatory and liability advice to many institutions within the healthcare sector, including hospitals, long-term care homes and laboratories. He regularly advises clients on compliance with the statutes and regulations that govern the healthcare system in Canada. David has written and spoken extensively on topics in health law, including recently participating in a panel discussion at Ryerson University on the legal implications of the Cambie Surgery case in British Columbia.

ANNA S ROSS

Foley & Lardner LLP

Anna Ross is an associate and business lawyer in Foley & Lardner LLP’s Washington, DC office. She focuses her practice on healthcare, FDA regulatory and public policy matters. Ms Ross counsels clients in the healthcare and pharmaceutical and medical device industries with respect to a wide range of regulatory, compliance and corporate matters. In the scope of her healthcare practice, Ms Ross advises hospitals and health systems, post-acute care providers, physician groups, pharmacy benefit managers and health plans in all aspects of federal and state regulatory and compliance issues, including government and internal investigations and audits, self-disclosures, Medicare and Medicaid reimbursement compliance, state and federal fraud and abuse issues, state licensure issues, certificate of need requirements and change of ownership issues. She also provides clients with support related to their compliance programmes, including developing policies and procedures, creating training programmes and implementing compliance obligations in connection with a corporate integrity agreement. Ms Ross provides further assistance to clients with respect to preparing, reviewing and implementing hospital, physician and other provider contracts.

REBECCA RYAN

Matheson

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

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

LOLA SHAMIRZAYEVA

Herbert Smith Freehills CIS LLP

Lola Shamirzayeva is an associate at Herbert Smith Freehills CIS LLP. Lola specialises in advising clients on various infrastructure projects, in particular, in the healthcare sector.

Lola graduated from the National Research University Higher School of Economics (HSE) in 2012 with honours. Before joining the firm in 2013, Lola worked in the Moscow office of another international law firm.

EILEEN JAIYOUNG SHIN

Lee & Ko

Eileen Jaiyoung Shin is a partner in the healthcare team at Lee & Ko. Her practice focuses primarily on the health industry, including the pharmaceutical and biotechnology products, medical devices, food, nutritional supplements, cosmetics, tobacco and public healthcare sectors. Ms Shin has advised many multinational companies in the healthcare industry on a broad range of regulatory, corporate and competition law issues. In addition, with respect to the pharmaceutical industry in particular, Ms Shin regularly advises multinational clients on new drug pricing and after-launch life-cycle management with the firm’s active market access team.

NOBORU SUWA

Mori Hamada & Matsumoto

Noboru Suwa has been involved in a wide range of structured finance transactions, including cross-border real estate and financing transactions under TMK (specified purpose company for asset securitisation) or GK-TK (a collective investment scheme) structures for prominent foreign and domestic clients, including the securitisation of some of the largest hospital real estate in Japan. While representing J-REITs as well as Japanese financial institutions in Japan, his interest in the healthcare industry has increased through the securitisation and rehabilitation of healthcare facilities. To enrich his practice in this field, he has been participating in various activities in his capacity as a Healthcare Management Consultant registered with the Japan Association of Healthcare Management Consultants, which is a public interest incorporated association accredited by the Prime Minister. He received his LLB from the University of Tokyo in 1990 and his LLM from New York University School of Law in 1996. He also worked with Jenner & Block in Chicago from September 1996 to August 1997. He is admitted to practise law in Japan (1992) and New York (1997) and is fluent in Japanese and English.
ANDREA TITHECOTT

Al Tamimi & Company

Andrea Tithecott is a partner and head of the regulatory and healthcare practice groups at Al Tamimi & Company.

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, which is the largest healthcare legal practice in the Middle East region.

Andrea won the Middle East Legal Awards 2019 Regulatory and Investigations Team of the Year; was shortlisted for the Corporate Counsel Middle East awards consecutively in 2014 and 2015; and won In-House Community Firm of the Year 2016 for Compliance and Regulatory UAE awarded by Asian-mena Counsel. Andrea is also recognised by The Legal 500 for her regulatory expertise.

LAURIE TURNER

Fasken Martineau DuMoulin LLP

Laurie Turner is a partner 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

Foley & Lardner LLP

Lawrence Vernaglia is a partner and healthcare lawyer in Foley & Lardner LLP’s Boston office. He is department chair of the firm’s industry teams department and previously served as chair of the firm’s national healthcare industry team – named ‘Health Law Firm of the Year’ by US News–Best Lawyers on their ‘Best Law Firms’ list (2012–2014) three times during his tenure. 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

*Bär & Karrer AG*

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 in intellectual property law at the University of Fribourg.

AISLING WEIR

*Claro*

Aisling Weir is a senior commercial lawyer who specialises in health-sector business law, contracting and procurement. She has practised both in-house (including for 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

*Han Kun Law Offices*

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.
Appendix 2

CONTRIBUTORS’ CONTACT DETAILS

AL TAMIMI & COMPANY
26th Floor, Al Sila Tower
Abu Dhabi Global Market Square
Al Maryah Island, Abu Dhabi
United Arab Emirates
Tel: +971 2 813 0444
a.tithecott@tamimi.com
www.tamimi.com

BÄR & KARRER AG
Brandschenkstrasse 90
8002 Zurich
Switzerland
Tel: +41 58 261 5000
Fax: +41 58 261 5001
markus.wang@baerkarrer.ch
jonas.bornhauser@baerkarrer.ch
www.baerkarrer.ch

CLARO
PO Box 11-455
Wellington 6142
New Zealand
Tel: +64 3 550 0500
Fax: +64 4 974 7799
jonathan.coates@clarolaw.co.nz
aisling.weir@clarolaw.co.nz
andrea.lane@clarolaw.co.nz
www.clarolaw.co.nz

FASKEN MARTINEAU DUMOULIN LLP
Bay Adelaide Centre
Suite 2400, 333 Bay Street
Toronto, Ontario M5H 2T6
Canada
Tel: +1 416 366 8381 (general line) / +1 416 865 5166 (Lynne Golding)
Fax: +1 416 364 7813
lgolding@fasken.com
drosenbaum@fasken.com
dfabiano@fasken.com
kpotter@fasken.com
lturner@fasken.com
zlevy@fasken.com
vmui@fasken.com
smacrae@fasken.com
www.fasken.com

© 2019 Law Business Research Ltd
Contributors' Contact Details

FIELDFISHER LLP
Fieldfisher (Germany) LLP
Central Tower 18 OG
Landsberger Straße 110
80339 Munich
Germany
Tel: +49 89 620 30 6221
Fax: +49 89 620 30 6400
stefanie.greifeneder@fieldfisher.com

Free Trade Exchange
37 Peter Street
Manchester M2 5GB
United Kingdom
Tel: +44 161 835 8010
Fax: +44 161 835 8015
sarah.ellson@fieldfisher.com
holly.bontoft@fieldfisher.com

www.fieldfisher.com

HAN KUN LAW OFFICES
33/F, HKRI Centre Two
HKRI Taikoo Hui
288 Shimen Road (No. 1)
Shanghai 200041
China
Tel: +86 21 6080 0955
Fax: +86 21 6080 0999
min.zhu@hankunlaw.com
www.hankunlaw.com

FOLEY & LARDNER LLP
111 Huntington Avenue
Suite 2500
Boston, MA 02199-7610
United States
Tel: +1 617 342 4000
Fax: +1 617 342 4001
lvernaglia@foley.com

Washington Harbour
3000 K Street, NW
Suite 600
Washington, DC 20007-5109
United States
Tel: +1 202 672 5300
Fax: +1 202 672 5399
asross@foley.com

www.foley.com

HERBERT SMITH FREEHILLS CIS LLP
10 Ulitsa Nikolskaya
Moscow 109012
Russia
Tel: +7 495 363 6500
Fax: +7 495 363 6501
lola.shamirzayeva@hsf.com
www.herbertsmithfreehills.com

HOGAN LOVELLS (SOUTH AFRICA) INC
140 West Street
Sandton
Johannesburg 2196
South Africa
Tel: +27 11 286 6900
Fax: +27 11 286 6901
mandi.krebs@hoganlovells.com
www.hoganlovells.com

KING & SPALDING LLP IN COOPERATION WITH THE LAW OFFICE OF MOHAMMED ALAMMAR
20th Floor, Kingdom Centre
King Fahad Road
PO Box 14702
Riyadh 11434
Kingdom of Saudi Arabia
Tel: +966 11 466 9400
nissa@kslaw.com
www.kslaw.com

© 2019 Law Business Research Ltd
LEE & KO
Hanjin Building
63 Namdaemun-ro, Jung-gu
Seoul 04532
Korea
Tel: +82 2 772 4751 / 4831
Fax: +82 2 772 4001
samuel.kwon@leeko.com
eileen.shin@leeko.com
www.leeko.com

MATHESON
70 Sir John Rogerson’s Quay
Dublin 2
Ireland
Tel: +353 1 232 2460
rebecca.ryan@matheson.com
www.matheson.com

MORI HAMADA & MATSUMOTO
Marunouchi Park Building
2-6-1 Marunouchi, Chiyoda-ku
Tokyo 100-8222
Japan
Tel: +81 3 6212 8330
Fax: +81 3 5223 7632
noboru.suwa@mhm-global.com
fumiharu.hiromoto@mhm-global.com
www.mhmjapan.com

PINHEIRO NETO ADVOGADOS
Rua Hungria, 1100, 4th Floor
CEP 01455-906
Jardim Europa
São Paulo
Brazil
Tel: +55 11 3247 8602 / 8793
Fax: +55 11 3247 8600
tdemarchi@pn.com.br
msmarques@pn.com.br
www.pinheironeto.com.br

SÁNCHEZ DEVANNY
Av Paseo de las Palmas #525, Piso 6
Col Lomas de Chapultepec
Miguel Hidalgo
Mexico City
11000 Mexico
Tel: +52 55 5029 8500
Fax: +52 55 5029 8501
jacamp@sanchezdevanny.com
www.sanchezdevanny.com

URÍA MENÉNDEZ – PROENÇA DE CARVALHO
Edificio Rodrigo Uría
Praca Marquês de Pombal, 12
1250-162 Lisbon
Portugal
Tel: +351 21 030 8600
Fax: +351 21 030 8601
francisco.abreu@uria.com
joana.mota@uria.com
www.uria.com
For more information, please contact info@thelawreviews.co.uk

THE ACQUISITION AND LEVERAGED FINANCE REVIEW
Marc Hanrahan
Milbank Tweed Hadley & McCloy LLP

THE ANTI-BRIBERY AND ANTI-CORRUPTION REVIEW
Mark F Mendelsohn
Paul, Weiss, Rifkind, Wharton & Garrison LLP

THE ASSET MANAGEMENT REVIEW
Paul Dickson
Slaughter and May

THE ASSET TRACING AND RECOVERY REVIEW
Robert Hunter
Edmonds Marshall McMahon Ltd

THE AVIATION LAW REVIEW
Sean Gates
Gates Aviation LLP

THE BANKING LITIGATION LAW REVIEW
Christa Band
Linklaters LLP

THE BANKING REGULATION REVIEW
Jan Putnis
Slaughter and May

THE CARTELS AND LENIENCY REVIEW
John Buretta and John Terzaken
Cravath Swaine & Moore LLP and Simpson Thacher & Bartlett LLP

THE CLASS ACTIONS LAW REVIEW
Camilla Sanger
Slaughter and May

THE COMPLEX COMMERCIAL LITIGATION LAW REVIEW
Steven M Bierman
Sidley Austin LLP

THE CONSUMER FINANCE LAW REVIEW
Rick Fischer, Obrea Poindexter and Jeremy Mandell
Morrison & Foerster