THE HEALTHCARE LAW REVIEW

SECOND EDITION

Editor
Sarah Ellson

THE LAWREVIEWS

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EDITOR'S PREFACE

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

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

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

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

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

Sarah Ellson
Fieldfisher
Manchester
July 2018

Chapter 2

BRAZIL

Renata Fialho de Oliveira, Priscila David Sansone Tutikian, Fábio Luiz Barboza Pereira, Mauro Hiane de Moura, Denise Figueira Louzano and Vanessa Bertonha Felício[1]

I OVERVIEW

Pursuant to the 1988 Brazilian Constitution, health is a fundamental social right of every person (Article 6) and a duty of the state (Article 196). In Brazil, the constituent power has melded health with social security[2] and afforded universal, gratuitous[3] and equal access to the public health system to all, with no distinction whatsoever.[4] It is correct to state, thus, that in Brazil, individuals have the subjective right to demand free access to the public healthcare structure, and it is an obligation of the state to provide it.[5]

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

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

Under the Federal Constitution and the Organic Health Law, all entities of the federation (union, state, federal district and municipalities) are bound to the SUS and must cooperate with actions and resources to render health services. Also, they are joint and severally liable with respect to healthcare.[6]

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1 Renata Fialho de Oliveira, Priscila David Sansone Tutikian, Fábio Luiz Barboza Pereira, Mauro Hiane de Moura, Denise Figueira Louzano and Vanessa Bertonha Felício are members of Veirano Advogados' healthcare practice. The authors thank Amanda Celli Cascaes, Amanda Mattos Rudzit and Vitória Ayer de Azevedo Velho for their relevant contribution to the second edition of this article.

2 In fact, the specific Section of the Constitution dealing with health is part of the Chapter dedicated to social security.

3 In view of the SUS's gratuity principle, users of the public healthcare system may not be charged for services, equipment or other health-related actions; namely, healthcare must be funded on taxes collected by the different government entities (union, the state and municipalities).

4 Differently from the period that preceded the promulgation of the 1988 Constitution, when Health was conceived as a social security contribution and only those who contributed to the social security fund were entitled to treatment. See Dallari, Sueli Gandolfi et al., Direito Sanitário, São Paulo, p. 72.

5 Brazilian Supreme Court, Extraordinary Appeal No. 393175 RS, published in the Official Gazette on 16 February 2006, p. 54.

6 See free translation of part of a Brazilian Supreme Court decision in Extraordinary Appeal No. 195,192-3/RS of 22 February 2000, in a matter involving the supply of medicine to a bearer of a rare disease: 'Health

Notwithstanding the above, among the three of the SUS's constitutional directives, the first of them is the directive of 'decentralisation in a sole direction in each governmental level' (Article 198, I). Such directive mandates the municipalisation of treatment, meaning that services to the population shall be taken care of by the municipalities.[7] Pursuant to this directive, not only federal and state hospitals shall be managed by municipalities, but also the relationship between the SUS and private healthcare providers shall be implemented through the municipalities.

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

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

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

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

The direction of the SUS is incumbent to each level of the government: at a national level, to the Ministry of Health, at the state, federal district and municipality levels to the State Health Secretary, Federal District Health Secretary, and Municipal Health Secretary or equivalent, respectively. In view of the decentralisation directive provided for by the Brazilian Constitution, in each of the union's, state's, federal district's and municipal's administrative sphere, entities of their direct and indirect administration have authority to deliver, commission, license and regulate healthcare services in consonance with the guidelines of the Organic Health Law, Law No. 8,142/1990 and the SUS Basic Operational Norm (NOB 1/96), among others.

– Acquisition and Supply of Medicine – Rare Disease. It is incumbent on the State to provide for means to achieve health, especially when involving a child or teenager. The Unified Health System makes linear the liability achieving the Union, States, the Federal District and the Municipalities.'

7 This obligation is further detailed in Law No. 8,080/90, Article 17, I and in the SUS Basic Operational Norm (NOB 1/96).

At a national level, the Brazilian Ministry of Health is the highest sanitary authority, responsible for ultimately resolving health issues in Brazil.[8] The Ministry of Health counts in its organisational structure with authorities, foundations and state-controlled companies responsible, at the federal level, for public health actions and services. The most relevant institutions bound to the Ministry of Health are the National Health Committee (CNS), the National Sanitary Surveillance Agency (ANVISA) and the National Supplementary Health Agency (ANS).

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

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

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

II THE HEALTHCARE ECONOMY

i General

Free access to the public health system is ensured by the 1988 Federal Constitution and the Organic Health Law. Within the SUS, public services are rendered directly (i.e., by public hospitals) or indirectly by means of the execution of a public contract between the SUS manager, usually a municipality, and private parties (Article 199 of the Constitution and Articles 24 to 26 of the Organic Health Law), free of charge. The Brazilian government is still not prepared to fulfil its duties as regards healthcare, and does not own the necessary infrastructure to do so, lacking hospitals, laboratories and clinics. Thus, the partnership with private parties is a relevant means of pursuit of its constitutional goals.[9]

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

According to the CNS's data, in January 2018, the total number of hospitals in Brazil amounted to 6,805, among which, 70 per cent are private hospitals, 1 per cent belong to the union, 8 per cent to the states and 21 per cent to the municipalities.[10]

As reported by the ANS, in April 2018, the rate of the Brazilian population covered by private insurance plans (with and without dentistry coverage) was 22.7 per cent,[11] meaning that almost one-quarter of the Brazilian population uses private healthcare services, relying on private health insurance or a plan.

8 Law No. 10,683 of 2003, which regulates the organisation of the Presidency of Brazil and Ministries, sets forth in its Article 27 the topics within the Ministry of Health's authority.

9 Fernando Aith, Curso de Direito Sanitário, São Paulo, 2007, p. 351.

10 www.cns.org.br/links/DADOS_DO_SETOR.htm.

11 www.ans.gov.br/perfil-do-setor/dados-gerais.

ii The role of health insurance

Private health insurance plays an important role in Brazil, representing a relevant alternative to the much-demanded and sometimes inefficient public healthcare system. Recently, owing to the increase of life expectancy,[12] healthcare has become a major concern of Brazilian citizens, and has incremented the search for this type of service, in which the insured has freedom of choice. Despite its importance, in Brazil, the purchase of health insurance is absolutely voluntary. Labour laws in general do not oblige an employer to contract health insurance for its employees, however, this may be obligatory to certain categories of employees depending on the provisions of the applicable collective bargaining agreement executed with the relevant union.

iii Funding and payment for specific services

Every two years, the SUS issues a list of medical products available to citizens free of charge,[13] provided that each municipality has its own list prepared according to demand. Each municipality also has a high-cost medicine list that may be supplied free of charge upon receipt of a special clinical report and, in some states, a proper form. Another governmental programme, by means of which one may access basic free of charge or discounted medicine, is the Brazilian Popular Drugstore Programme.

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

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

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

Article 198 of the Federal Constitution sets forth that the SUS comprehends a regionalised and hierarchical net. By referring to a regionalised system, the Constitution points out to territorial organisation (Decree No. 7,508 of 28 June 2011, which regulates the Organic Health Law, governs the setting up of Health Region and Health Attention Nets). The term 'hierarchical' indicates the need to organise treatment according to the different levels of complexity and a net of references and counter-references to optimise the use of the resources in primary, secondary and tertiary treatment units.[14]

The universal and equal access to public healthcare is ordered by the primary care and must be based on the severity of the individual and collective risks, with due regard to

12 From 1940 to 2015, life expectancy in Brazil increased by 30 years. See www.brasil.gov.br/governo/2016/12/expectativa-de-vida-no-brasil-sobe-para-75-5-anos-em-2015.

13 Decree No. 7,508, of 28 June 2011, which regulates the Organic Health Law.

14 See Dallari, Sueli Gandolfi et al., *Direito Sanitário*, São Paulo, p. 83-84.

specifics for people with special protection pursuant to the legislation. Hospital and special ambulatory services, as well as others of higher complexity or technological density, shall be refereed by the 'entry doors' to the Health Attention Nets, which are primary care, urgent and emergency care, psychosocial care and specific healthcare for those who need special care as a result of labour hardship (open access) (Articles 9 to 11 of Decree No. 7,508 of 28 June 2011).

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

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

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

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

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

The Organic Health Law and Law No. 9,782/1999, which instituted the National Sanitary Surveillance System, set forth that regulation, standardisation, control and sanitary surveillance are incumbent to institutions of direct and indirect public administration of the union, the states, federal district and municipalities. The Ministry of Health's Consolidation Resolution No. 04/2017 organised the distribution of authority among such governmental entities. Sanitary surveillance at all such levels is exercised through the issuance of regulations, execution of actions and services and political and administrative inter-sectorial articulation (Article 10). In general, municipalities have more executory roles.

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

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

ii Institutional healthcare providers

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

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

The National Healthcare Facility Enrolment is a general registry to which all healthcare facilities must register.[16]

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

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

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

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

iii Healthcare professionals

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

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

When it comes to nursing, Federal Law No. 2,604 and the Federal Nursing Council's Resolution No. 564/2017 set the main legal framework with respect to the compulsory registration of nurses.

16 Ministry of Health Ruling No. 511 of 2000.

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

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

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

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

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

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

V NEGLIGENCE LIABILITY

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

From a physician's liability standpoint, the obligation is to provide attentive care and employ his or her knowledge in the best possible way to improve a patient's health condition – without being bound to any promise of healing or achievement of a certain result (except for physicians who specialise in aesthetic surgery).[18] This general obligation related to the provision of medical services, thus, is an obligation of means, and not an obligation of results. Therefore, for a physician to be held liable for damages to a patient, fault must be proven (negligence, recklessness or malpractice) – that is, the general standard of fault-based liability applies. However, legal doctrine advises for a cautious interpretation of these concepts, as it is also important to assess the conditions in which the physician is providing medical care. For instance, in the public health system, often the professional is confronted with lack of adequate equipment, structure and support staff, among other adverse conditions, which may impair the provision of the service – so the services performed by the physician should be assessed in light of these circumstances.[19]

17 Dias, José de Aguiar. *Da responsabilidade civil*. 11. ed. Rio de Janeiro: Renovar, 2006.

18 Stoco, Rui. Responsabilidade civil dos hospitais, sanatórios, clínicas, casas de saúde e similares em face do Código de Defesa do Consumidor. *Revista dos Tribunais*, São Paulo, v. 84, No. 712, p. 71-77, fev. 1995.

19 See Dias, José de Aguiar. *Da responsabilidade civil*. 11. ed. Rio de Janeiro: Renovar, 2006. p. 333.

Hospitals, laboratories, clinics and other healthcare providers (including those operated by the state directly or indirectly)[20] are subject to strict liability standard (Article 14 of the Consumer Defence Code (CDC) and Article 927, sole paragraph, of the Civil Code), which disregards the existence of fault.[21] However, when it comes to liability owing to the actions of members of a hospital's staff, their fault must be proved, which means that the hospital will be held accountable (strict liability, based on Article 932 of the Civil Code) if its employees or agents acted with fault.[22] In this scenario, because the patient can be qualified as a consumer according to the CDC, healthcare providers (e.g., physicians and the hospital) will be jointly liable for the damages. However, the corresponding healthcare provider has recourse against those responsible for the damage, and may succeed if able to prove that the damage was caused by such professional acting with fault.

From a procedural perspective, there are two important highlights. Firstly, the burden of proof regarding the physician's fault can be switched by the court – so the consumer (patient), deemed technically vulnerable, does not have to produce this evidence. If that happens, the physician will have to demonstrate his or her regular and legal conduct, and that he or she has acted with all the due care, not constituting a negligent or reckless practice. According to the Superior Court of Justice, the fault-based liability of the physician does not prevent the reversal of the burden of proof.[23] Secondly, if a patient files a lawsuit solely against the hospital because of an alleged fault committed by a member of the staff, it will not be able to call this member to the proceeding, even though the latter could be the one to blame for the occurrence of the damage. This understanding arises from a CDC provision[24] that prohibits possible co-defendants from being called to the lawsuit, so that the patient can be more easily compensated, avoiding a discussion of fault (as the hospital's liability is strict).

VI OWNERSHIP OF HEALTHCARE BUSINESSES

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

20 'The State is a legitimate defendant to join the passive action of an indemnity claim based on medical malpractice supposedly occurred in care provided within the SUS by a private hospital with whom the State signed a management contract' (São Paulo Court of Appeals, lawsuit No. 2069342-16.2013.8.26.0000, ruled in February 2014).

21 For instance, a hospital was held liable for damages caused to a patient because of the absence of a specialised physician and lack of a vacancy in the intensive care unit, which aggravated the patient's health condition (Superior Court of Justice, lawsuit No. 1.145.728/MG, ruled in June 2011).

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

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

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

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

VII COMMISSIONING AND PROCUREMENT

As a default rule, the Brazilian Constitution establishes that all purchases and sales made and all services and works hired by the Public Administration, including health services, shall be preceded by a public bid. Law No. 8,666/1993 is, currently, the main federal public bids and contracts statute. The requirements to participate in a public bid or to execute a public contract are usually set forth in each 'request for proposal' presented by the Administration; they include legal, tax and labour regularity, as well as proper technical and financial requirements. As the bill of law has recently made significant progress in the National Congress, the federal system of public bids and contracts is likely to be substantially remodelled in the near future.

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

VIII MARKETING AND PROMOTION OF SERVICES

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

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

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

Also, healthcare professionals shall not promote:

a the exercise of more than two specialisations; or

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

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

a it must be in accordance with the rules of the professional and governmental bodies applicable to the matter;
b it shall mention the medical management in charge;
c it shall contain a clear and adequate description of the type of treatment or diet;
d it shall not contain testimonials given by laymen; and
e it shall not contain promise of cure or reward to those who have no success after the use of the treatment or diet.

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

Claims can be brought before CONAR by competitors affiliated with CONAR, groups of consumers or even members of CONAR's board; which puts advertisements under heavy surveillance. For instance, CONAR's Superior Committee started an investigatory procedure – based on concerns raised by the São Paulo State Health Council to the general public – to scrutinise advertisements of paracetamol-based medicines that led consumers to believe that those products could treat the symptoms of dengue and other diseases caused by the *aedes aegypti* mosquito. Even though pharmaceutical companies – who had long been exploiting this topic in Brazil – tried to present scientific studies and demonstrate that the advertisements show proper disclaimers, CONAR recommended[25] in a decision of December 2017 the modification of the advertisement.

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

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

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

One pressing issue in Brazil regards the further regulation and permission for private healthcare providers to exploit the various facets of telemedicine. Currently, the Medical

25 CONAR's decision are not mandatory, but tend to be followed by the companies to demonstrate good marketing practices.

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

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

In a scenario of constant modernisation of the health sector in Brazil – as seen by the implementation of digital systems and massive databases, such as the public DATASUS (the SUS Informatics Department) – it is also important to rethink how to reconcile technological innovation with the rights and guarantees of patients concerning privacy, such as the confidentiality of their information and the protection of their data. For instance, the Brazilian jurisdiction supports the use of electronic or digital medical records and the Brazilian Federal Medical Council issued Resolution No. 1,821/2007, which regulates the replacement of physical files of patients' medical charts for a digital medical record. However, it is a challenge to implement easily accessible universal records and still efficiently secure sensitive data and 'protected health information' contained in patient records.

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

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

X CONCLUSIONS

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

In view of the advancement of technology and several market players and institutional investors' interest in novelty, it is reasonable to expect that further regulation for telemedicine, e-health, telecare, e-care and mobile health will be issued, and if not, at least that the competent authorities will possibly have their views on such matters tested, hopefully aiding in the construction of a coherent case law and the advancement of healthcare in Brazil through technology.[26]

In addition to a certain level of legal uncertainty, excessive regulation tends to lead to illegal practices. Brazil is going through a particular time in its history, and contemporary developments indicate a trend toward intolerance with regard to harmful acts.[27] The enactment of Law No. 12,846/2013 (the Brazilian Anticorruption Law) was another signal of the commitment of the countries' authorities in this matter. Private practices have also been enhancing their internal policies concerning, among others, compensation models and ethical supply chains.[28]

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

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

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

28 The topic of the 2016 three-day Congress of ANAHP was 'Ethics: Sustainability of Healthcare in Brazil'.

Appendix 1

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