

2<sup>ND</sup> EDITION

INNOVATION & COMPETITIVENESS



# HOW TO UNDERSTAND HEALTHCARE SYSTEM AND ITS TECHNOLOGY IN BRAZIL

Sponsor:

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*Brasil*

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American Chamber of Commerce for Brazil - AMCHAM  
International Affairs Department  
Brazil, 2016/2017

\*This guide is part of the project 

# ACKNOWLEDGMENTS



The American Chamber of Commerce for Brazil, being the largest Amcham outside the United States is serving its members building bridges for Brazilian businesses worldwide. Our foreign investment attraction efforts are a key mission for Amcham. The “How To” guides published by Amcham Brasil are part of this initiative. With the support of some of our members and Brazilian states and cities, we are putting together strategic information on the most various aspects of doing business in Brazil and its opportunities. As part of BRICS (Brazil, Russia, India, China and South Africa) and representing the 9<sup>th</sup> largest economy of the world, and the 8<sup>th</sup> largest destination for foreign investment, Brazil has an intrinsic importance for the global market. More than ever it is a strategic time for businesses opportunities in Brazil. We welcome you and hope that the information you are about to read will contribute to your commercial and investment decisions linked to Brazil.

A handwritten signature in dark ink, reading "Deborah Vieitas".

**Deborah Vieitas** - CEO, Amcham Brasil



Brazil’s social and health indicators have significantly improved in the past two decades. Public policies combined with economic growth have improved quality of life indicators in Brazil. As a result, medical products and services have become increasingly more accessible to the population. Health is considered a basic right of the citizens: the Federal Constitution requires the government to fund the healthcare system and allows the private sector to help provide such services. In many places across Brazil, public healthcare – despite the constitutional provisions – does not meet the needs of the population, given the insufficient number of doctors, outdated equipment, and long waiting lines for appointments and treatments. This difficulty in accessing the healthcare system makes room for health insurance providers that offer programs for people with different incomes.

A handwritten signature in dark ink, reading "Suzi Hong Tiba".

**Suzi Hong Tiba** - Partner, Pinhão & Koiffman Advogados

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# INTRODUCTION TO BRAZILIAN HEALTHCARE

## CHILD MORTALITY AND LIFE EXPECTANCY

Brazil has been reducing its child mortality rate. Today, according to the Brazilian Institute of Geography and Statistics (*Instituto Brasileiro de Geografia e Estatística* - IBGE) there are 13.82 deaths per 1,000 live births. This rate drops even more in major cities such as São Paulo, whose rate is 10.72 out of every 1,000 children born, according to a study conducted by the city hall in 2015.

Life expectancy for Brazilians is also on the rise: the national average is 75 years of age, as reported by the World Health Organization.

These positive numbers prove that the population is living longer, which demands more hospitals and healthcare services, creating opportunities for various branches of medicine.

## NUMBER OF HOSPITALS

Until May 2015, there were approximately 77,000 public hospitals in Brazil. At the same time, there were over 200,000 private hospitals, which is nearly three times the number offered by the government.

This scenario shows the great demand for private services, which most of the time are provided under healthcare plans.

The management of these private hospitals follow different models: many are family-run and need to transition to a more professional management. On the other hand, there is an increasing number of well-managed hospitals operating under a robust plan. Large hospital groups are growing, and relevant mergers and acquisitions have been drawing the market's attention. Early in 2015, a legislative change has allowed the access of foreign investments to be made in the field of healthcare. This innovation, which will be detailed in chapter 2, promises to give hospitals more incentives by bringing new business, partnership, and growth possibilities.

## NUMBER OF PHYSICIANS

There are 461,655 doctors working in Brazil today. Most of them are in the Southeast (54.6%), while the North accounts for only 4.5% of them<sup>1</sup>.

This discrepancy is in line with the social and economic differences between these two regions. The country's richest states, such as São Paulo and Rio de Janeiro, are located in the Southeast. On the other hand, the North – home to the Amazon rainforest – has a smaller number of large urban centers, but many remote villages and places of difficult access. While these factors may not be very appealing to the healthcare community at large, at the same time they represent great business opportunities.

1- **Source:** Conselho Federal de Medicina, 2016. Available at [http://portal.cfm.org.br/index.php?option=com\\_estatistica](http://portal.cfm.org.br/index.php?option=com_estatistica)



## PUBLIC AGENCIES AND ENTITIES INVOLVED

### THE NATIONAL HEALTHCARE SYSTEM

Brazil's national healthcare system is called Unified Health System (*Sistema Único de Saúde - SUS*). It is meant to provide the entire population with universal and free healthcare, as required by the Federal Constitution.

Public funds are concentrated in the National Healthcare Fund (*Fundo Nacional de Saúde - FNS*), which transfers public investments to State Healthcare Funds, in order to use them in the fields of pharmaceutical assistance, primary healthcare, SUS management, investments, medium and high complexity outpatient and hospital services, as well as health control. In 2015, over BRL 73 billion were transferred to the states. Given taxpayers' money is involved, information about the transfers and amounts invested in each field and State Fund is available at the FNS website: [www.fns.saude.gov.br](http://www.fns.saude.gov.br).

These public funds can also be used to contract private hospitals and clinics by means of public-private partnerships. This measure exempts the federal government for using the physical structure of private hospitals to provide healthcare to the population.

Public-private partnership (PPP) agreements follow specific legislation and must fulfill certain requirements,

such as remaining in force between 5 to 35 years, and include investments of at least BRL 20 million in construction or services.

The law only allows public-private partnerships to be created as sponsored concessions or administrative concessions. Under sponsored concessions, the private company's compensation is split between the service user, who pays a fee, and the government. In the case of administrative concessions, the private company is paid exclusively by the government, which is the case of hospital services. In the latter case, the federal government only pays a monthly amount to the partner hospital, whose performance is evaluated by public authorities.

Public-private partnerships are not the same as regular concessions given how private partners are compensated. Under regular concessions, which are regulated by a specific law, private companies are paid exclusively by service users, unlike PPPs, as seen above.

Private non-profit hospitals can also contract with the government and obtain tax benefits in return for allocating some of its beds to SUS.

Non-profit healthcare providers wishing to be accredited as charities must sign agreements or similar instruments

with SUS, ensuring that at least 60% of their service capability will be allocated to it (subject to verification by the Ministry of Health), in return for the exemption from paying social security taxes. In order to be granted this tax exemption, some healthcare providers renowned for their excellence are allowed to carry out projects supporting the institutional development of SUS instead of setting aside 60% of their capability.

## ANVISA

The National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária - ANVISA*) is under the purview of the Ministry of Health and is a part of SUS. It controls and regulates all sectors that are related to products and services that may affect the population's health. Therefore, it is not restricted to one single sector.

## NATIONAL AGENCY FOR SUPPLEMENTARY HEALTHCARE

Like ANVISA, the National Agency for Supplementary Healthcare (*Agência Nacional de Saúde Suplementar - ANS*) is related to the Ministry of Health. It is tasked with controlling and regulating healthcare carriers to ensure the interest of the population.

## TAX CONTROLLING ENTITIES

Taxes are managed and collected by the Federal Revenue Service (*Receita Federal do Brasil - RFB*) and State and City Offices of Finance.

The Federal Revenue Service regulates and controls domestic taxes levied by the federal government – Income

Tax (*Imposto de Renda - IR*), Tax on Manufactured Products (*Imposto sobre Produtos Industrializados - IPI*), Social Contribution on Net Profits (*Contribuição Social sobre o Lucro Líquido - CSLL*), and social security dues, as well as taxes levied on foreign trade activities - Import Tax (*Imposto de Importação - II*), Contribution to the Employees' Profit Participation Program (*Programa de Integração Social - PIS*), Contribution for the Financing of Social Security (*Contribuição para o Financiamento da Seguridade Social - COFINS*) and Contributions for Intervention in the Economy Domain (*Contribuições de Intervenção no Domínio Econômico - CIDE*).

In this scenario, the Federal Revenue Service controls medical and hospital machinery and equipment coming into or leaving Brazil, as well as medications and medicinal compounds, whether or not these are registered in Brazil. The Service controls ports, airports, borders, and bonded warehouses to enforce the payment of import and export taxes. The Federal Revenue Service also manages, conducts, and controls the collection of federal taxes levied on medical and hospital activities and the fulfillment of tax requirements related to those activities by doctors, clinics, hospitals, and laboratories, such as the issuance of bills and invoices and the filing of tax returns.

Similar control is also performed by State and City Treasury Departments. They control the payment of taxes levied by states and cities, especially the Tax on the Circulation of Goods and Services (*Imposto sobre Circulação de Mercadorias e Serviços - ICMS*) collected on the trade of healthcare goods, and review and collect the Tax on Services (*Imposto sobre Serviços de Qualquer Natureza - ISS*) applicable to medical and hospital services.



## FOREIGN INVESTMENTS IN HEALTHCARE

Until the end of 2014, the participation of foreign companies or capitals in the country's healthcare system was limited. They were only allowed to participate in healthcare plan providers that had their own healthcare service networks or in health insurance companies. However, since January 2015 foreign companies and investors have more options. Generically, Law 13,097, which was enacted on January 19, 2015, allows foreign companies to directly or indirectly provide complementary healthcare services. International companies are now allowed to take part in the following activities:

- General hospitals, including philanthropic ones; specialized hospitals; multi-specialized clinics; general practice; and specialized practice;
- Family planning initiatives and studies;
- Non-profit healthcare services run by companies to cater to employees and their dependents, exempt from social security taxes; and
- Activities supporting healthcare services, such as those carried out by human genetics labs, manufacturing and supply of medications and health products, medical laboratories, pathologic anatomy, and image-based diagnosis.

Since the healthcare industry is regulated by the government, public authorities are responsible for its legal frameworks and oversight. While this specific legislation on foreign investments is not enacted, foreign entities are subject to the same terms and regulations applicable to national entities providing healthcare services, especially the rules issued by the ANS, which will be addressed in greater detail below. Therefore, foreign investors may either set up a new business in Brazil, buy shares in another business already in operation, or bring part of an already established business to operate in Brazil.

Since the Law 13,097/15 entered into force, hospital operators and healthcare providers have been organizing in order to attract and receive foreign direct investments, either by the admission of a new partner, selling their assets or shares or by obtaining financing from foreign investors. These efforts include creating or revising governance policies in order to make them more clear and robust, reformulating management and operational practices, as well as creating business and investment strategies that place a greater focus on medium and long term goals.

Few noteworthy transactions involving foreign investment have been made in the two years since

the enforcement of the Law 13,097/15. This could be explained by Brazil's economic and political challenges, along with the fact that investors have focused their attention on more developed projects, with a higher number of hospital beds, patients and revenues.

The industry is currently undergoing a movement of domestic consolidation, without losing sight of its goal of attracting foreign investment to hospitals and healthcare services. These efforts are translated into expectations of renovated technology parks, expanded

infrastructure, more training programs, and the incorporation of successful internationally-adopted efficient management practices.

The healthcare demand, which still exceeds the availability of these services, and the forecast for the sector and for the Brazilian economy as a whole, are strong indicators that foreign investments in the health industry are still likely to go through some changes, with an increase in capitalization and transactions in the next few years.

# 04.

## IT IN THE FIELD OF HEALTHCARE

### SOFTWARE APPLICATION

Brazilian laws divide healthcare-related software into three categories:

- **Health products:** those meant for prevention, diagnosis, treatment, rehabilitation, or birth control, and which do not require hardware that must be registered with ANVISA for its operation;
- **Health product accessories:** software embedded in a hardware registered with ANVISA, and which is meant to ensure the proper operation of the hardware; and
- **Non-healthcare related software.**

According to a more conservative analysis, the Software in the first two categories must be registered with ANVISA and must comply with the same import requirements as hardware.

However, the law is still unclear about the matter, and ANVISA has already disclosed contradictory information regarding the need to register apps that can be used for purposes other than medical diagnostics.

During an unofficial announcement in July 2016, ANVISA stated that only apps created specifically for

medical diagnostics need to be registered according to the current rules.

Incidentally, the same procedures for the import of hardware apply to this type of software.

In other words, the documentation required by ANVISA must be filled, indicating the software's classification according to the agency's definitions, in order to ensure the safety and efficiency of the equipment. Specific registration with ANVISA is not required for the import of software in the third category.

For those software, ANVISA published a computer system validation handbook in 2010, which addresses the systems' lifecycle and their validation; software-related risk management; general guidelines for the development of healthcare-oriented software; and the main recommendations related to confidentiality and system protection.

In addition, some appointment-scheduling apps have been created recently, some of which even allow the user to request a doctor's visit at a specific location. Although these apps are not classified under the software category that needs to be registered with ANVISA, they have nonetheless been met with some resistance from medical councils.

The Regional Medicine Council of São Paulo (*Conselho Regional de Medicina de São Paulo - CRM/SP*) has already issued a position statement against companies

charging any fees from doctors for mediating these requests, which is how these apps are usually monetized. However, there is no clear sanction on this business model, and this type of apps are not only growing, but also attracting investments.

Another feature of healthcare apps is the storage of patients' records. In these cases, an effort must be made to remain in compliance with the specific legislation of the Federal Medicine Council (*Conselho Federal de Medicina - CFM*). According to CFM regulations, the software is only considered an electronic medical record if it meets the Council's requirements. Otherwise, the doctors must keep a physical patient record in order to avoid any penalty, which is explained below.

## PATIENT INFORMATION STORAGE AND EXCHANGE

Electronic medical records digitally store patient information. They are a groundbreaking tool that delivers great results, and require special care in order to be implemented correctly to protect patients' rights.

Electronic records facilitate the retrieval and access of patients' records and contain updated information that is easy to understand given the absence of poor handwriting or erasures. They also allow faster and more thorough medical care by eliminating physical files. The requirements for the use of electronic medical records have been established by the CFM and the Brazilian Society of Healthcare Information Technology (*Sociedade Brasileira de Informática em Saúde - SBIS*), and are compiled in the Certification Manual for Healthcare Electronic Recordkeeping Systems (*Manual de Certificação para Sistemas de Registro Eletrônico em Saúde - S-RES*). They also define the audit and certification procedures for all

establishments interested in using electronic medical recordkeeping.

The requirements are split into three categories:

**Security requirements:** all characteristics necessary for technical examiners to decide whether or not the stored information is valid, such as: requiring people who have access to the data to previously identify themselves and be authenticated; having mechanisms to block a user account in case of 10 failed attempts to access the system; and telling users the date and time of the latest successful authentication and the failed authentication attempts after the latest successful authentication.

**Structure, content, and functionality requirements:** systems dedicated to other types of healthcare services, emergency medicine, and outpatient occupational healthcare. The following system requirements are included: organizing RES information and data into different sections; searching (for text and numbers) in all fields (structured and freely written); univocally identifying the healthcare location; and being able to electronically send data.

**EDM (Electronic Document Management) requirements:** an indexing method that facilitates the creation of an organized filing system; enabling the organization of documents into folders and sub-folders; allowing the storage of various documents formats; and enabling integration with outside information systems and other requirements.

Even if the electronic medical recordkeeping requirements defined in the S-RES are not fulfilled, patient information can still be stored on digital media. However, in this case, physical records must be kept. Consequently,

keeping duplicate files will represent additional costs for healthcare providers.

Regardless of the system adopted (electronic medical records or other digital filing media), the entire system must be backed up since the information cannot be lost under any circumstances. This type of information is considered sensitive and confidential, and is therefore protected by the Criminal Code and other specific medical regulations.

To keep the information confidential, it is paramount that only identifiable and authorized people have access to these records. That is why personal digital certificates are seen as the essential tool for protecting confidentiality. These certificates may be a single and personal access key (such as a SIM card, for instance) that identifies the user when connecting to the system.

Today, remote access to the information storage system and the exchange of information among healthcare professionals are accomplished via Supplementary Healthcare Information Exchange (*Troca de Informação em Saúde Suplementar - TISS*), a system implemented by the ANS. This is the main system used given it is regulated by the ANS and supposed to be safe.

All information exchanges must be safely conducted in a way that prevents unauthorized access to the data or the information from being seized by any third parties. Therefore, data transferred between devices must be encrypted. Ensuring anonymity of data is also a useful tool for healthcare professionals in protecting patient information.

Currently, Brazil does not have any legislation to define which information should be considered personal, or the level of protection that must be adopted. Recently, a personal information protection bill was proposed to

finally define personal data and provide specific protection for sensitive information. Health-related information is sensitive, and its operator must obtain authorization from patients before collecting their information. Additionally, only data related to the intended purpose disclosed to patients may be collected. Furthermore, individuals to whom the information refers must have the right to access it and request to be corrected or even erased.

## REMOTE MONITORING AND VIDEO TECHNOLOGIES

Telemedicine involves the use of technology to provide medical services and information when distance is a critical factor. It allows for procedures, diagnoses, recommendations, or treatments based on data, documents, or other information to be obtained and/or sent via telecommunications technology.

The World Medical Association (WMA) has established telemedicine guidelines that have been incorporated by the Brazilian legislation to create general principles such as the preservation of mutual respect, the freedom of opinion for the physician seeing the patient, the patient's autonomy, and the doctor-patient confidentiality.

Healthcare services using telemedicine must be equipped with the proper structure, including a support system for technical emergencies related to equipment; thoroughness and precision of the information collected and sent; and be pertinent and abide by the regulations issued by the Federal Council of Medicine. In any case, patients must be informed and agree to the use of technology resources.

Telemedicine providers must be registered with the Legal Entity Registry of CRM in the state where they are located, operate under the technical responsibility of a

physician registered with the council, and produce a list of the doctors in their staff.

## DIAGNOSIS APPS AND RELATED

In Brazil, only physicians can diagnose health conditions and diseases, or determine any possible after-effects. In addition, the medical ethics code bars treatments or other procedures from being prescribed without direct patient examination, and remote medical assistance is subject to regulations by the CFM. Even though the databases used by diagnostics apps to reach a given conclusion are developed by certified healthcare professionals, the information collected by the apps is reviewed by a machine without any medical training. Therefore, CFM presents constraints regarding the diagnostics apps.

Nevertheless, diagnostics apps should not be rejected according to the CFM's interpretation. In fact, these apps may be used in Brazil if registered in ANVISA. By definition, a diagnostics app is a tool that determines a disease, which can be classified as an interruption, cessation or disorder of an individual's body, system or organ.

Other health-related user apps are also legal in Brazil. Those apps that store the users' medical information and history are allowed, as well as those that monitor the users' physical activity, as long as they merely store such information without providing any recommendations or assessing such information. Additionally, apps meant to prevent or help with the treatment of diseases (reminding users that it is time to take their medicine, helping schedule an appointment, among others) can be developed and made available to the public, as long as they are registered in ANVISA before being released.

## ELECTRONIC DATA STORAGE

Brazil has specific data protection legislation, and establishes obligations to providers of web-based apps, including the protection of users' personal data. The main obligation is transparency: users must be aware that the data is being collected, and for what purposes, as well as any important detail about the use and sharing of such information. Once informed, users must consent to its practices before it can be performed regularly. With this consent, the application provider is protected from any questions concerning the collection and processing of such data.

While this legislation is very specific, there is a fierce debate about personal data protection as a whole, whether online or offline. Among other things, this debate involves the establishment of stricter obligations for the protection of sensitive data such as medical information. There are three very similar bills on this matter under consideration in Congress, but they are not expected to be voted soon.

Regardless of whether this specific and more comprehensive legislation passes, the CFM already requires that all patient information be treated as confidential, and this requirement is reinforced by other applicable legal provisions. Therefore, there should already be a concern with protecting information related to patients, understood as healthcare apps users.

Thus, anyone interested in developing a healthcare app must be aware of these standards and future requirements, in order to create a secure system that protects the information entered into it. Ideally, healthcare apps must be protected by encryption, and clearly communicate these protective measures to patients and third parties apps.



# 05.

## BUYING AND SELLING MEDICATION: LOCAL MARKET, IMPORTS AND EXPORTS

It is under the purview of ANVISA to allow the commerce in the domestic market of imported and exported medication, as well as issuing specific licenses authorizing the operation of companies that conduct such activities. These licenses are issued by ANVISA on average within sixty days after the application documents have been filed, which can be done online on ANVISA's website. In order to be sold, imported or exported for commercial purposes, or used in hospitals, the medications must have had their efficacy and safety attested by ANVISA (via registration) and not be listed as controlled substances, otherwise their import may not be authorized or be considered contraband or drug trafficking.

Brazil has been granting medication patents since 1996 and protection timeframes range from ten to twenty years counted from the date of issuance. In the case of medications considered highly relevant for public health – such as HIV drug cocktails – the country reserves the right to break the patents in return for compensation to the pharmaceutical companies. However, such prerogative is rarely exercised in Brazil, as the country usually waits for patents to expire.

Once a patent expires, other companies are allowed to manufacture and sell these drugs as generics, which are

regulated by Law no. 9,787/1999. These drugs have the same active ingredient, pharmaceutical form, and dosage as the original medication but cannot use brand names or trademarks. On average, generics cost 35% less than branded drugs. Generic drugs are cheaper because they use medication formulas whose patents have expired, that is, their manufacturers are not required to pay any royalties to the owner of the original medication. As a result, they have become quite popular among the medical community and the population.

Medications and equipment are sorted into classes that must fulfill specific registration, sale, import, and export requirements. Simpler products, such as OTC (Over-the-counter) medication, go through a simpler process considering they pose lower risks for the population. On the other hand, drugs that are capable of causing more severe side effects, such as most psychiatric medications, must undergo a lengthier process. Currently, sale and export licenses can be obtained online through ANVISA's online filing page. The timeframe for getting a license may vary a great deal, but on average it takes about sixty days, as already mentioned.

The same rule applies to medical and hospital equipment, such as computer tomography (CT) scan or radiotherapy

machinery, which must also be registered with ANVISA before being sold or even used in clinics or hospitals. Like medications, simpler equipment follows a simplified process, while the process for more complex or invasive devices is longer.

To sell medications remotely (over the internet or telephone, for instance), companies are required to be a drugstore holding all of the necessary licenses to operate in the market and found in compliance with ANVISA's regulations. As a rule, controlled medication cannot be sold remotely, since buyers are required to provide identification and a prescription. In 2016, ANVISA issued a standard listing the drugs that can be sold without any prescription, including vitamins, propolis and products to prevent dehydration. Specific drugs with standardized leaflets are also included on this list, as long as the insert

submitted for registration or renewal purposes complies with the standardized insert provided by ANVISA.

The authorization granted by ANVISA is just one of the requirements for selling, exporting, and importing medications. Companies must comply with all of the rules in force and applicable to each case, including customs regulations in the case of imports and exports. ANVISA also regulates medicine prices, providing annually a list with the maximum price that may be charged for each medicine. If a violation is detected, the punishment for the infringing company may range from a warning to the cancellation of the company's operating license. In case a company fails to comply with an order or decision issued by an authority as the result of a violation, its directors may ultimately be held personally liable for the infringement of the order and even be sentenced to prison.

# 06.

## HEALTHCARE PLANS AND HEALTH INSURANCE

Healthcare plan providers and health insurance companies are directly overseen by the ANS, which is a government agency. Since 1998, these providers and insurance companies must fulfill minimum coverage requirements and follow criteria that restrict prices and price increases. Users can choose from several plans, coverage packages, and prices to suit their needs and financial conditions.

In Brazil, healthcare plans are basically classified as follows:

- **Individual plans:** offer coverage packages that can be purchased at the beneficiaries' discretion;
- **Corporate:** purchased by a company for its employees; and
- **Voluntary group plans:** offer coverage to a group of people connected to a union, trade association, professional board, cooperatives, and similar.

Individual plans in Brazil tend to be more closely monitored by the ANS, since individuals are more vulnerable when dealing with companies operating in this industry. That is why there have been signs of

a drop in the number of healthcare providers offering individual plans.

High litigation rates are a major challenge in this industry, which faces a wide variety of lawsuits, including actions for damages, review of price increases, and requests for treatments not covered by contracts. However, this increase is not owed to the industry's decline but as a result of the growing demand for this service. A survey conducted by Institute of Supplemental Health Studies (*Instituto de Estudos em Saúde Suplementar - IESS*) in May 2014 showed that healthcare plans had become the second most desired consumer good among Brazilians, which creates opportunities for new initiatives.

However, the demand for healthcare plans is still greater than the investments in public and private health, which is a challenge in terms of portfolio management. It is also a great investment opportunity considering the number of people moving up from lower income classes and wishing to escape the long waiting queues they face in the public healthcare system.

Foreign capital had already been allowed to invest in the healthcare plan industry since 2001. However,

the authorization for it to operate across the entire supplementary healthcare system may be a solution for many problems currently overloading the Brazilian courts, given the bottlenecks that still exist in the supply of these services. Incoming capital, increased investments, and greater diversity and number of service providers tend to benefit consumers directly by giving healthcare plan providers and insurance companies the ability to branch out in order to offer a different range to their beneficiaries.

In numbers, the IESS registered 48,487,129 people with medical and hospital insurance plans in Brazil in June 2016, a lot of opportunities since Brazil has a population of more than 200 million inhabitants. Compared with the same period of the past year, there was an increase of 0.5% (82,418) in the number of contracts with group medicine operators. On the other hand, in the same period, dental plans and insurance increased 1.9%, which represents 410,195 newly covered individuals.

# 07.

## HEALTHCARE TAX INCENTIVES

Healthcare investors wishing to cut their tax load can take advantage of tax incentives. With that, companies choose to allocate a portion of the taxes they pay to the development of outreach initiatives in the fields of health, sports, education, among others.

An example of tax incentive that can be used by the healthcare industry is the reduction of the tax burden for companies investing in research, development, and innovation. Some of the tax incentives are listed below:

- 50% of reduction in the IPI when purchasing goods meant for research and technology development;
- Accelerated full depreciation of the calculation base for corporate income tax and the social contribution on net profits CSLL on new products bought to be used in research, development, and innovation activities;
- 0% withholding income tax on foreign

remittances of amounts paid to register and keep trademarks, patents, and cultivars; and

- Up to 100% of disbursements on research, development and innovation excluded from the net profits to assess the taxable income and the CSLL calculation base.

Tax reduction can also be granted to companies that invest in organizations working to prevent and fight cancer, or to promote the rehabilitation of people with a disability. From the amounts companies allocated to these programs, they are allowed to deduct up to 1% from the income tax owed in every assessment period.

Brazilian taxes are not unified and can be levied by federal, state, and city authorities, depending on the taxable event. Therefore, there are several other incentives that may be granted in Brazil. Also, companies wishing to invest in healthcare must consider not only the federal legislation but also states' and cities' regulations to determine which benefits are more suitable and advantageous to decrease their tax burden.

## MAIN PROGRAMS

The access to healthcare secured under the Federal Constitution also includes pharmaceutical assistance. For that reason, the Brazilian government runs programs that subsidize a portion or the entirety of the price of some medications:

- **Saúde Não Tem Preço:** offers free medication for high blood pressure and diabetes since 2011. This program is carried out via private drugstores accredited under the Farmácia Popular program, created in 2004;
- **Saúde da Família:** offers prevention and health promotion initiatives, disease rehabilitation, and emergency services. Implemented in Brazil in 1994, its main focus is to promote the health of families outside the hospital environment; and
- **Farmácia Popular:** operates as a partnership between the federal government and local administrations and philanthropic hospitals, along with accredited privately-owned drugstores. Its goal is to ensure that people are able to buy essential medications at low prices, thereby expanding access to it for a larger number of people.

The Federal Government's partnership with the private pharmaceutical supply chain (manufacturing, distribution, and retailers) ensures the low prices. The program offers several medications at prices up to 90% lower. The list of drugs sold at a discount includes contraceptives and medications used to treat Parkinson's, osteoporosis, and

glaucoma. High blood pressure, diabetes, and asthma medications are provided free of charge.

SUS also offers medications free of charge for the population after patients are seen and evaluated by a physician. Through SUS, people can also have free access to expensive medications after proving they need it via medical prescriptions and specific reports.

- **Programa de Genéricos no Brasil:** created in 1999 to facilitate the access to medication treatments by allowing the manufacturing of generic drugs. By law, these medications may replace branded ones and even be recommended by pharmacists and doctors. There are currently 522 active ingredients registered with ANVISA and meant for more frequent and prevalent diseases.

Recently, the Brazilian government launched the National Plan for Fighting the Microcephaly, engaging 19 agencies and entities to counter new cases of diseases related to Zika virus. The plan is divided into three parts: mobilization and fight against the mosquito; assistance to population; and technological development. This plan will be put into practice to increase actions to counter the mosquito and is a result from the creation of the Strategic Interministerial Group of Emergency in Public Health of National and International Importance (*Grupo Estratégico Interministerial de Emergência em Saúde Pública de Importância Nacional e Internacional - GEI-ESPII*).



## HEALTHCARE OUTSOURCING

Companies are currently allowed to outsource some of their activities, as long as it is not related to the core business of the corporation. In other words, if an institution provides healthcare to patients, its doctors cannot be outsourced, given that they carry out exactly the core activity. Professionals who are not involved in this type of direct service can be outsourced, such as receptionists and cleaning personnel. Outsourcing can benefit companies by reducing payroll costs, considering labor charges are paid by the company providing the workers.

However, if the third party fails to duly pay such labor liabilities, the company benefitting from the outsourced personnel ends up being responsible for paying these rights. Therefore, in order to prevent losses, clients must constantly check and demand guarantees that all liabilities are being fulfilled.

A bill has been discussed for several years, which, if approved, will allow all activities to be outsourced. That means outsourced personnel will be allowed to perform

core activities as well. Deliberations on this bill have been suspended, and are expected to resume in 2017.

With the expected changes in the rules of hiring outsourced workforce, hospitals, clinics, and labs will have other ways to hire doctors, nurses, and other personnel associated with companies or institutions willing to supply labor to provide medical and hospital services.

If the bill passes, the same efforts currently employed by healthcare providers must remain a priority: contractors must be constantly checked up on to ensure that all legal obligations are being fulfilled, otherwise clients may be held jointly or severally liable for such obligations.

In this context, provided the proper precautions are taken, outsourcing healthcare professionals by hospitals, physicians, and labs may in fact result in advantages for the entity, especially with respect to social security charges levied on the employment of such labor.

## COMPLIANCE EFFORTS IN HEALTHCARE

Driven by the need for an effective management of resources, mitigation of risks, the possibility of attracting a foreign investor concerned with compliance, and also by the authorities' efforts to fight corruption, there has been a substantial increase in professionals specialized in comprehensive compliance (anti-corruption, ethics and risks). The Law 12,846, enacted on January 8, 2013 (known as the Brazilian Anti-Corruption Law) incorporated several concepts from the American FCPA (Federal Corrupt Practices Act) and has been applied since its publication, followed by its regulation in March 2015. Recently, compliance has become a major topic of discussion in Brazil due to the notoriety received

by investigations and actions based on accusations of corruption, bribery and money laundering.

The health private sector often works in partnership with public agencies providing services and supplying medications, equipment and other goods. The industry is becoming increasingly aware that it must review its practices and adopt a comprehensive and effective compliance program, with a focus not only on anti-corruption practices but also on internal governance practices, hiring employees, suppliers, training of physicians and other health professionals, risk mapping, transparency with the patient and the rational use of resources.

## ABOUT OUR SPONSOR

### OVER A DECADE OF DECISIVE WORK IN THE TECHNOLOGY AND HEALTHCARE

For over 15 years PINHÃO E KOIFFMAN ADVOGADOS has been providing fast, customized, and comprehensive legal solutions to Brazilian and foreign companies operating in a wide variety of industries.

Occupying three floors in the Vila Olímpia district in São Paulo, the firm is currently staffed by over 100 professionals dedicated to the complex issues of Business Law, especially in the firm's expertise areas of healthcare, innovation and IT.

With highly renowned Brazilian and foreign companies in the client portfolio, PINHÃO E KOIFFMAN ADVOGADOS team is composed of experts trained in several technical and scientific fields, and who are capable of providing clear and uncomplicated legal solutions for contract, tax, labor, and civil issues related to healthcare and IT. The PINHÃO E KOIFFMAN ADVOGADOS team has great expertise in a wide range of legal issues faced by companies operating in the electronic equipment business, such as software companies, hospitals, clinics, manufacturers and providers of technology and

telecommunication services, internet, e-commerce, cloud computing and new technologies at large.

In its operations, the firm interacts closely and dynamically with its clients and uses creativity to foster knowledge. This enables the teams to master complex issues and provide answers that streamline processes and boost business. With renowned specialization in legal matters related to technology and healthcare, the firm keeps permanently up to date with new, state-of-the-art technologies and their legal implications to help clients to set up, create and develop innovative business.

The firm provides Brazilian and foreign companies with both consulting and litigation services. PINHÃO E KOIFFMAN ADVOGADOS has taken active part in its clients' growth process and always seeks to add value to their activities through the expertise of its partners and staff.

In the past few years, the firm has been assisting companies in their main routine needs by supporting their strategies to decrease liabilities and prevent contingencies. This integrated work allows companies to reach their goals while following generally accepted compliance and corporate governance rules.

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