THE HEALTHCARE LAW REVIEW

Seventh Edition

Editor
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URÍA MENÉNDEZ

PREFACE

The seventh edition of *The Healthcare Law Review* covers three new jurisdictions (India, Mexico and Nigeria), summing up to a total of fifteen jurisdictions from countries in Europe, North and South America Asia and – for the first time – Africa. All reports have been provided by leading experts in the field of healthcare law in their countries. The reviews have been prepared by the authors as a practical, business-focused analysis of recent changes and developments, their effects, and a look forward at expected trends. The reviews are intended to provide an overview of legal issues which are of interest for healthcare providers and related businesses.

The global covid-19 pandemic has come to an end this spring. The WHO chief Tedros Ghebreyesus declared the end to covid-19 as a global health emergency on 5 May 2023. According to the reviews from the individual countries, most of the exceptional measures, which had been implemented by the countries to fight the pandemic, have largely been scaled back or totally withdrawn. Therefore, the authors report back to normal in their reviews.

As a major result of the pandemic, many countries have geared their healthcare systems to ensure safe access to healthcare for citizens, even in extraordinary situations, through more digitisation and telemedicine. This is not just about supplementing or replacing face-to-face doctor visits with communication options via telephone or video consultation. Many countries, not only in Europe, have also introduced electronic patient files, regulations for the exchange of health data and other digital communication channels. It seems that it is still a long way to go to implement these innovations successfully in a healthcare reality that is no longer solely determined by a pandemic. A particular challenge in the future will also be to utilise the new digital tools not only within a national healthcare system in a single country, but also across borders.

The European Union is already well on the way with the implementation of a European Health Data Space. Furthermore, the European Commission has published a proposal of a new pharma package, which may have major impact on the healthcare systems in the member states of the European Union in particular.

Germany however, the largest healthcare system in the European Union, still faces many hurdles before implementing electronic prescriptions, electronic patient records or statutes for the secondary use of health data. The authors report from South Korea that the strict measures for telemedicine services are back in force. These examples show that healthcare systems in the individual countries tend to defend the status quo rather than to implement digital and electronic tools with fast speed.

Even if the individual countries solve the problems differently, we all can only benefit from knowing the different approaches to solving the problems and how successful

the respective countries have been with their solutions in each case. I truly hope that the publication of the new edition of *The Healthcare Law Review* will particularly be helpful in that respect.

Like in past years, it has been an extraordinary pleasure to work with this group of exceptional authors of *The Healthcare Law Review* in this edition and in the years to come to provide a practical overview of the healthcare systems of the countries covered. We will continue our efforts to include more countries to be able to give a comprehensive worldwide approach to health issues by each country.

Ulrich Grau
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Chapter 13

SWITZERLAND

Michael Reinle and Daniel Donauer[1]

I OVERVIEW

The Swiss healthcare ecosystem consists of different hierarchical layers of regulatory requirements and democratic processes that can influence the healthcare regulation framework, such as mandatory and reimbursable services in the event of illness (including their characteristics in individual cases), the admissibility of therapeutic products and medical devices, the accreditation and requirements for healthcare professionals (HCPs) and healthcare organisations (HCOs) as well as the requirements for the protection of the public health.

At a state organisational level, there are relevant legal requirements at the federal level, in the 26 different cantons and in each of the total of 2,136 municipalities in Switzerland (as of 1 January 2023). In addition to the above-mentioned political bodies, there are numerous state-recognised (licensed) HCOs that perform legally outsourced tasks in the area of mandatory health insurance (MHI). Furthermore, as a result of the structural organisation of Swiss direct democracy, the Swiss electorate (the Swiss citizens) may influence the legal framework of the Swiss healthcare ecosystem (at any time) using various democratic instruments, such as public referenda and plebiscite.

In terms of federal legislative competences, the Swiss Confederation is 'only' authorised to issue regulatory requirements and provisions – including in the area of healthcare – within the framework of explicitly granted competences within the Federal Constitution of the Swiss Confederation of 18 April 1999 (FC). In the area of health and healthcare, the Swiss Confederation has the competence to issue regulations:

a on MHI and accident insurance;[2]

b on professional requirements for HCPs and other (non-university) health professions;[3]

c for the protection of public health, inter alia, in the areas of product regulation (i.e., foodstuffs, medicinal products, medical devices, narcotics, chemicals and utility articles) and epidemic control;[4] and

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2 Article 117 FC.

3 Article 117a FC.

4 Article 118 FC.

d concerning (medical) research on humans, reproductive medicine, gene technology in the human sector, as well as gene technology in the non-human sector, and transplantation medicine.[5]

Regarding disease-related healthcare, the federal provisions under health insurance law on the compulsory provision of services and compulsory reimbursement of such services within the MHI are particularly noteworthy. In this context, the Federal Act on Health Insurance of 18 March 1994 (HIA) is the most relevant and most notable piece of legislation. The HIA regulates the basic principles of the MHI (i.e., the social and basic health insurance) that applies nationwide and grants benefits in the event of illness, accident (as far as no accident insurance is responsible for this) and maternity. A special focus within the HIA is on the provisions on compulsory remuneration and reimbursability by the MHI insurers for medical services as well as medicinal products and medical devices.

Based on various delegation provisions within the HIA, the Federal Council (i.e., the Swiss national government) is authorised or mandated to issue implementing provisions on ordinance law (e.g., the Federal Ordinance on the Health Insurance (HIO)). Both the provisions within the HIA and provisions based on the ordinance law must subsequently be implemented by the cantons.

Finally, the provisions of the Federal Act concerning the Supervision of Social Health Insurances of 26 September 2014 (HISA) are of great importance with regard to the supervision as well as the authorisation of health insurance companies in the area of MHI. The purpose of the HISA is to protect the interests of insured persons under the HIA by ensuring transparency within the MHI and the solvency of health insurance funds.

II THE HEALTHCARE ECONOMY

i General

As briefly indicated at the beginning of this chapter, the Swiss health insurance system is divided into the MHI (in the sense of a basic and mandatory health insurance system) and the voluntary supplementary health insurance. While the requirements for the MHI are anchored in the HIA, the principles of any supplementary health insurance mainly follow private Swiss contract law. These principles are largely regulated in the Federal Act on the Insurance Contract of 2 April 1908. The actual core of the Swiss health insurance system is thus a compulsory insurance coverage in the form of the MHI, regulated via the HIA.

The MHI covers all benefits in the event of illness, accident (insofar as not covered by another insurance) and maternity. The MHI is, in principle, mandatory for all persons residing in Switzerland. However, the HIA contains a complex catalogue of exceptions for certain groups of persons (for example, persons who are subject to the legislation of another state under a relevant Annex of the Agreement on the Free Movement of Persons due to their gainful employment in that state) who – by way of exception – might be exempt from the MHI or, in certain constellations, may voluntarily subject themselves to a foreign health insurance scheme and can accordingly exempt themselves from the Swiss MHI (see, for example, the provisions concerning the cross-border commuter exception).

5 Articles 118b, 119 and 120 FC.

According to the basic principles of the HIA, each person residing in Switzerland has guaranteed access to basic healthcare and medical treatment. Costs for services under the MHI are generally covered by the health insurance (i.e., the insurer), although rules on cost-sharing and annual deductibles must be considered in terms of rationing and cost-efficiency in the context of providing healthcare services.[6]

Temporary non-resident visitors must pay for any healthcare-related treatment costs up front and may reclaim potential reimbursement under insurance coverage they might have in their home country.

Furthermore and in parallel with the MHI, there is a legal obligation for all persons employed in Switzerland to take out accident insurance in accordance with the Federal Act on Accident Insurance of 20 March 1981 (AIA). The mandatory accident insurance provides insurance benefits for occupational accidents, non-occupational accidents and occupational diseases (i.e., diseases that are caused during occupational activity solely or principally by harmful substances or certain types of work according to Annex 1 of the Federal Ordinance on Accident Insurance).[7] The mandatory accident insurance does not cover non-employed persons, such as children, students, and pensioners.[8] However, from a legal point of view, there is no insurance gap for these persons, as these persons are subsidiarily covered via the MHI in corresponding constellations.[9]

ii The role of health insurance

It is mandatory for every person residing in Switzerland to have insurance coverage for MHI services according to the HIA. Persons who transfer their place of residence from abroad to Switzerland must take out an MHI coverage within three months of taking up residence. Similarly, an MHI coverage for children must be taken out by their legal representative within three months of their birth.[10] The Federal Council may extend or restrict the compulsory character of MHI coverage for certain residents in certain constellations.[11]

The MHI was introduced in 1996. Since its introduction, the number of insurers available in Switzerland has steadily decreased. While in 1996 MHI coverage was offered by 145 insurers, as of 2022 there were only 45 different insurers offering the MHI.[12]

Health insurers in the area of the MHI are legal entities under private or public law that pursue a non-profit purpose and provide the MHI in accordance with the requirements of the HIA. However, these insurance companies are free to offer supplementary insurance products in addition to the MHI in accordance with the HIA. Likewise, they may operate

6 Article 64 HIA.

7 Article 6 Paragraph 1 AIA.

8 Article 1a AIA.

9 Article 1a Paragraph 2 lit. b HIA.

10 Article 3 Paragraph 1 HIA; see general information, provided by the Federal Office of Public Health (FOPH), accessible online under the URL: https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung/krankenversicherung-versicherte-mit-wohnsitz-in-der-schweiz/versicherungspflicht.html (accessed on 5 July 2023).

11 Article 3 Paragraphs 2 and 3 HIA.

12 See Primeinfo, 'Kennzahlen Krankenversicherer – Anzahl Versicherer', accessible online under the URL: https://www.priminfo.admin.ch/de/zahlen-und-fakten/kennzahlen (accessed on 5 July 2023).

other types of insurance to a certain extent.[13] All insurance undertakings operating in the field of MHI are authorised and supervised by the competent supervisory authority in the form of the Federal Office of Public Health (FOPH).

The insured person may freely choose among the insurers authorised to provide the MHI.[14] In addition, the insured person may change their insurer at the end of a calendar semester subject to a three-month notice period.[15] Due to the 'dual system' in the Swiss health insurance system (i.e., the MHI and the supplementary insurance), there is an important difference between these two insurance compartments in terms of the obligation to contract. Health insurers are obliged to accept every applicant for basic insurance without reservation, regardless of age, gender and state of health. In the case of supplementary insurance, on the other hand, health insurance companies may reject applications or make reservations based on the health status.

iii Funding and payment for specific services

The MHI itself is financed by various sources of 'income'. On the one hand, each insured person is obliged to contribute annually in form of a premium. The premiums are not linked to employment and must therefore be paid by the insured persons themselves (even if unemployed). Exceptionally, if poor financial circumstances of the insured person allow it, premium reductions (i.e., partial, or full reductions regarding health insurance premiums) may be granted. These premium reductions are subsidised by the Swiss Confederation and by the cantons. The premiums as such are independent of the income of an insured person[16] and may vary according to the insurer, the place of residence (geographical regions) of the insured person, and the selected form of insurance (deductible level, insurance model). In addition, premiums may vary for three different age categories: reduced premiums are offered for children and young people (up to 18 years) and young adults (19 to 25 years). To keep the premiums low, the insurers usually offer specific insurance models, such as health maintenance organisation (HMO) models, which may be selected by the insured person. In addition, as has been mentioned above, the insured person may lower or increase the premium by choosing a higher or lower franchise (beginning at 300 Swiss francs, up to a maximum of 2,500 Swiss francs). Specific health insurance conditions may be changed on an annual basis.

Another source of funding for the MHI – in addition to premiums – consists of direct cost-sharing by the insured persons themselves.[17] In addition, the costs for the MHI are covered by direct (tax-based) contributions at all levels (i.e., the Swiss Confederation, the cantons and the municipalities) whereby the most important cost contribution by far is made by the cantons via tax revenue to the hospitals operating in their respective cantonal territory.[18]

13 Article 2 Paragraphs 1 and 2 HISA.

14 Article 4 HIA.

15 Article 7 Paragraph 1 HIA.

16 Article 61 HIA.

17 Article 64 HIA.

18 For concrete numbers regarding the financing of Swiss hospitals, see overview of H+, accessible online under the URL: https://www.hplus.ch/de/zahlen-statistiken/h-spital-und-klinik-monitor/gesamtbranche/finanzierung (accessed on 5 July 2023).

With regard to the provision of healthcare related benefits by the MHI, the Swiss health insurance law system – based on the HIA – follows a strict listing principle (i.e., negative and positive lists), according to which the MHI covers benefits for healthcare services and therapeutic products (i.e., medicinal products and medical devices) that are explicitly described in the HIA.[19] Thematically, the benefits subject to and eligible for remuneration are divided into the following sections:

a general sickness benefits;
b sickness care benefits;
c medical prevention;
d birth defects;
e accidents;
f maternity;
g termination of pregnancy; and
h dental treatment (to a limited extent).

Accordingly, under the given conditions, the MHI covers the costs of general medical treatment (by general practitioners) as well as the costs of treatment by specialists, hospital costs, the costs of nursing services at home (so-called Spitex, which is limited by the MHI to concrete amounts), the costs of physiotherapy (if prescribed by a physician), as well as the costs of certain preventive measures such as vaccinations, general health assessments and disease-related early detection measures. In addition to the 'traditional' medical services, the costs of psychotherapy are also partially covered by the MHI. The Federal Council decided on 19 March 2021 that psychological psychotherapists will be able to work independently and on their own account at the expense of the MHI. The prerequisite for this is a physician's order. The changes entered into force on 1 July 2022.[20]

All services for which the MHI must cover the costs must meet the general criteria of effectiveness, expediency, and economic efficiency.[21] If the medical service in question does not meet one of these criteria, the competent insurer may refuse to pay the costs for the provided healthcare service. Hence, if the healthcare provider has not adequately informed the patient about the absence of one of the criteria and, accordingly, the patient has not agreed to treatment that is not covered by the MHI, such costs must generally be borne by the respective healthcare provider. As a result, this mechanism should ensure that there is no 'overmedicalisation' on the part of the healthcare provider and, consequently, that no medical services are provided that are not necessary.

Furthermore, only costs for medical services provided by approved healthcare providers can be covered under the MHI. These healthcare providers include physicians; pharmacists; chiropractors; midwives; persons providing services on the order of or on behalf of a physician and organisations employing such persons; laboratories; dispensaries of therapeutic products used for examination or treatment; hospitals; maternity hospitals; nursing homes;

19 Articles 25–31 HIA.

20 See FOPH information with regard to the recent legislative change, accessible online under the URL: https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Nicht-aerztliche-Leistungen/neuregelung-der-psychologischen-psychotherapie-ab-1-juli-2022.html (accessed on 5 July 2023).

21 Article 32 Paragraph 1 HIA.

spas; transport and ambulance companies; and establishments providing ambulatory care by physicians.[22] In this context, the designated service providers must fulfil the applicable (licensing) requirements in the cantons in which they are active.

Finally, the insured persons may have their insurance coverage extended by means of voluntary supplementary insurance models within the framework of the principles described above. This insurance coverage is voluntary and goes beyond the basic coverage of the MHI (e.g., contribution to rescue costs and transport costs, free choice of hospital in the general ward and cost sharing for dental treatment, glasses and contact lenses).

III PRIMARY/FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

For outpatient treatment, insured persons are in principle free to choose among the authorised healthcare providers who are suitable for the treatment of their illness (i.e., 'free choice of doctor').[23] Different rules may apply if the insured person has chosen a special insurance model, such as Managed Care or HMO (e.g., Hausarztmodell). Most patients in Switzerland contact their general practitioner or family doctor when they face a health issue. If the general practitioner is not able to solve the health problem (immediately) due to his or her general expertise, a referral to a medical specialist or a (specialised) hospital facility, including specialised private practices, usually takes place.

For inpatient treatment, the insured person is free to choose from the existing or approved hospitals (i.e., 'listed hospitals') within the cantonal territory at their place of residence. The canton of residence and the competent insurer proportionally bear the costs incurred for the treatment of the insured person.[24]

Medicinal products can – depending on applicable (cantonal) regulations – be dispensed to patients either directly via HCPs or HCOs respectively, or indirectly (through a HCPs prescription) via local pharmacies.

The Federal Act on the Electronic Patient Dossier (EPDA) regulates the framework conditions for the introduction and dissemination of the electronic patient dossier. It entered into force on 15 April 2017. The electronic patient dossier is intended to strengthen the quality of medical treatment, improve treatment processes, enhance patient safety, and increase the efficiency of the healthcare system, as well as promote the health literacy of patients. Due to the complexity in terms of logistical implementation, the various service providers (such as hospitals and nursing homes) were granted transition periods of varying durations for the respective implementation. Since 2020, the 'Electronic Patient Dossier' (EPD) has been gradually introduced in Switzerland by the legislator. The handling is supposed to be simple and secure, since it involves sensitive medical information that is to be made available by doctors via a decentralised filing system.[25] The written consent of the patient is required for the creation of an EPD. Consent shall only be valid if the data subject gives it voluntarily after having been adequately informed about the way the data will be processed and about

22 Article 32 Paragraph 2 HIA.

23 Article 41 Paragraph 1 HIA.

24 Article 41 Paragraph 1 *bis* HIA.

25 See FOPH information regarding the EPD, accessible online under the URL: https://www.bag.admin.ch/bag/de/home/gesetze-und-bewilligungen/gesetzgebung/gesetzgebung-mensch-gesundheit/gesetzgebung-elektronisches-patientendossier.html (accessed on 5 July 2023).

its effects.[26] If consent has been given, it shall be assumed in the case of treatment that the person concerned consents to the health professionals recording data in the electronic patient file. In this case, HCPs of institutions under public law and of institutions which have been entrusted by a canton or a municipality with the fulfilment of a public task are entitled to record and process data in the electronic patient record.[27] In order to enable handling of EPD data, patients and HCPs must have secure electronic identities for processing data in the EPD.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

In the Swiss healthcare sector, the supervisory and licensing regime is largely dualistic, including administrative bodies of the Swiss Confederation as well as cantonal authorities. Certain selective competences exist only on the part of the Swiss Confederation, such as the licensing and supervision of healthcare insurance in MHI. Health insurers must be approved and supervised by the FOPH based on the provisions of the HISA.

The licensing of healthcare service providers, such as HCPs and HCOs, on the other hand, is partially based on federal requirements and cantonal requirements, whereby authorisation is granted in individual cases by the responsible cantons (e.g., HCP professional authorisation, authorisation for a pharmacy etc.). The most important rules for HCPs, for example, derive from the Federal Act on University Medical Professions (UMPA). In this context, the UMPA sets out the basic quality and training requirements for doctors, dentists, chiropractors, pharmacists, and veterinarians. However, if an HCP wishes to exercise his/her activity in a specific canton, he/she must, in addition to the UMPA requirements, be licensed by the respective canton.

ii Institutional healthcare providers and healthcare professionals

HCOs

Facilities in which medical or health care services are provided require a cantonal operating licence if they are run by private individuals or belong to a private sponsorship. This concerns all private healthcare providers (as establishments), such as hospitals, medical practices (like doctors' offices, physiotherapy centres, psychiatric clinics) pharmacies, drugstores, emergency services and day care centres. The purpose of such a permit is to ensure the quality of healthcare providers in the canton is only granted if the requirements are fulfilled in terms of medical supervision, hygiene, structure and quality management.

Further requirements are added if the hospitals and other healthcare providers exercise services within the scope of the mandatory health insurance. As recognised service providers, they may only offer services that are covered by the HIA if they meet the applicable federal

26 Article 3 Paragraph 1 EPDA.

27 Article 3 Paragraph 2 EPDA.

requirements (according to the HIA)[28] and, in addition, if they are authorised as such (on a cantonal level). For example, they must guarantee corresponding premises regarding sufficient medical care and the necessary specialist staff.[29]

HCPs

There are three categories of healthcare professionals in Switzerland. Different requirements apply to all three categories regarding licensing and authorisation.

Medical professions requiring a university degree and playing a key role in providing medical care to the population are listed in the first category. This category includes doctors, dentists, pharmacists, chiropractors and veterinary surgeons. They are subject to strict legal regulation ranging from training to professional practice. The FOPH works closely with the stakeholders involved, including universities, professional associations and cantonal authorities. All university medical professionals are listed in a register and require a cantonal licence if they wish to practise the university medical profession in their own professional capacity on the territory of the corresponding canton.[30]

Even though the cantons are responsible for issuing the licences, the essential provisions for admission and recognition as a medical professional are regulated at the national level in the UMPA, which sets out uniform requirements for university education, continuing professional development, further training and the practice of university medical professions. Provided that the conditions of the UMPA are fulfilled,[31] such as having the necessary professional diplomas, sufficient language skills to exercise the profession and a good standing, the applicant is entitled to obtain the cantonal licence.[32] The UMPA also regulates the recognition of foreign diplomas and continuing education titles.[33]

A special case in Switzerland needs to be highlighted in terms of doctors. *In concreto*, the HIA[34] requires the cantons to limit the number of doctors working in the ambulatory sector and providing services at the expense of the MHI. Hence, new licences may only be granted if the correspondingly stipulated maximum number has not been reached.[35]

Psychology professions are listed in the second category. This includes psychotherapists, child and adolescent psychologists, clinical psychologists, neuropsychologists and health psychologists. The psychology professions are another important cornerstone of the Swiss healthcare system and are anchored in a separate Act, the Federal Act on Psychology Professions (PPA), analogously to the other categories.

A cantonal licence is required to practise a psychology profession in Switzerland.[36] Such a licence is granted if the applicant is in possession of a federal or a (similarly) recognised foreign continuing education title, is trustworthy and physically and mentally capable of practising the profession properly and speaks one of the official languages of the canton in

28 Article 39 HIA.

29 Article 39 Paragraph 1 lit. a-f HIA.

30 Article 34 UMPA.

31 Article 36 UMPA.

32 Article 34 UMPA.

33 FOPH information regarding regulation of psychology professions, accessible online under the URL: https://www.bag.admin.ch/bag/de/home/berufe-im-gesundheitswesen/psychologieberufe.html (accessed on 5 July 2023).

34 Article 55a HIA.

35 Article 55a HIA.

36 Article 22 PPA.

which the practice is to be operated.[37] However, these requirements only apply to the practice of psychotherapy; other psychology professions listed in the PPA are not affected. In this sense, there are corresponding exceptions.

For the third category – the 'other healthcare professions' – there has also been separate law since 2020: the Federal Act on Health Professions (HPA). Seven subcategories of health professions fall under the scope of the HPA and include the professions of nursing specialists, physiotherapists, occupational therapists, midwives, nutritionists, optometrists and osteopaths.

Members of this category require a cantonal licence to practise their profession if they work under their 'own professional responsibility'. That means, if they are already under the (professional) supervision of a member of the same profession, they do not need their own licence to practise (e.g., in the case of a physiotherapy centre, only the head physiotherapist needs to have a licence, but employees do not if they are under the supervision of the head physiotherapist).

Also, for health professions, the HPA regulates the licensing requirements and the corresponding necessary competences, which, however, barely differ from the second category (i.e., psychology professions).[38]

V OWNERSHIP OF HEALTHCARE BUSINESSES

In the past, the 'traditional' working model for privately active HCPs was the model of an independent (i.e., self-employed) or private medical practice (with unlimited personal liability). Over time, this traditional model has constantly evolved; in practice, the group practice model has increasingly prevailed, according to which different HCPs started organising themselves and were then able to provide their medical services in a synergetic manner within an organised practice (with unlimited personal liability).

The aforementioned development was further supported by a revision and the implementation of new law entering into force as of 1 January 2001 according to which HPCs were able to practice not only in an independent manner (i.e., self-employed, but also in an employment relationship).[39] This, in essence, finally allowed HCPs to organise their practice model through a legal entity in form of a limited liability company structure (e.g., a company limited by shares (Ltd or AG) or a partnership limited by shares (Ltd or GmbH). Due to these developments, certain cantons have introduced additional licensing requirements for such company structures operated by HCPs, so that in these cases an operating licence must first be obtained from the competent canton.

In the area of hospitals,[40] a fundamental distinction can be made between public and privately operated hospitals. As a rule, the public hospitals are wholly or at least majority owned by the respective cantons or municipalities and are, accordingly, operated as public institutions. These hospitals appear on the cantonal hospital lists and must fulfil the prescribed service catalogues according to the HIA (as well as cantonal law). However, hospitals controlled by private individuals can also be included in the cantonal hospital lists

37 Article 24 PPA.

38 Article 12 Paragraph 1 lit. a-c HPA.

39 Article 35 Paragraph 2 lit. n HIA.

40 Article 35 Paragraph 2 lit. h HIA.

(without qualifying as public hospitals). Hence, in these cases, such private hospitals – like public hospitals – are also allowed to provide and bill their services (within the scope of the HIA) via the MHI.

VI MARKETING AND PROMOTION OF SERVICES

Swiss marketing and promotion law in the area of healthcare services (and corresponding products, such as medicinal products and medical devices) is divided into two layers. This includes, on the one hand, the specifications for the permissible advertising of therapeutic products (specifically medicinal products), and, on the other hand, specifications for advertising measures in accordance with professional duties.

Advertising of medicinal products is based on strict regulations according to the Federal Act on Medicinal Products and Medical Devices of 14 December 2000 (TPA) and, in more detail, the Federal Ordinance on Medicinal Products Advertising of 17 October 2001 (MPAO). In brief, prescription medicines may not be advertised to a general audience (i.e., publicly); advertising is only possible within closed circles of appropriately trained medical professionals.[41]

Regarding the advertising of healthcare services, reference is made to the applicable professional duties (according to the UMPA and the PPA respectively). Professionals with a university education within the meaning of the UMPA may only make advertising that is objective, meets the public need, and is neither misleading nor intrusive.[42] The same rule applies to advertising measures carried out by persons in the psychological professions.[43]

The TPA and the associated Federal Ordinance on the Integrity and Transparency in the Therapeutic Products Sector of 10 April 2019 (ITO) contain provisions on integrity and transparency as well as on the admissibility of kickbacks.[44] In addition, there are specific regulations concerning the obligation to pass on benefits in the case of remuneration in the area of MHI in accordance with the HIA and the associated HIO.[45] For example, persons who prescribe, dispense, use, or purchase for this purpose prescription medicinal products, and organisations employing such persons shall not claim, be promised, or accept any undue advantage for themselves or for the benefit of a third party. Similarly, it is forbidden to offer, promise or grant an undue advantage to any such person or organisation for their benefit or for the benefit of a third party.[46]

Similarly, in the context of the HIA (and therefore the benefits under the MHI), the healthcare service provider must pass on to the debtor of the remuneration (i.e., either the patient or the health insurance) the direct or indirect benefits granted to them by: (1) another service provider acting on their behalf; or (2) persons or institutions supplying medicinal products or means or objects for examination or treatment.[47]

41 Article 14 MPAO.

42 Article 40 lit. d UMPA.

43 Article 27 lit. d PPA.

44 Article 55 Paragraph 1 TPA and Articles 33 ff. ITO.

45 Article 56 Paragraph 3 HIA in connection with Articles 76a ff. HIO.

46 Article 55 Paragraph 1 TPA.

47 Article 56 Paragraph 3 HIA.

VII PROCUREMENT OF SERVICES AND GOODS

The procurement of health care services is – to a primary extent – the responsibility of the cantons. For inpatient care, cantonal hospital planning and the 'hospital list' are the most relevant tools for steering sufficient and cost-effective institutional health care. The hospital lists must be periodically reviewed and updated by the cantons.

Based on the provisions of the HIA, the cantons are obliged to coordinate their planning regarding the provision of health care services geographically and quantitatively.[48] In terms of the requirements for hospitals and comparable institutions, only institutions or their departments that serve the inpatient treatment of acute illnesses or the inpatient implementation of medical rehabilitation measures (i.e., hospitals), are licensed if they:

a guarantee adequate medical care; have the necessary specialist staff;
b have adequate medical facilities and ensure adequate pharmaceutical care;
c comply with the planning jointly drawn up by one or more cantons for needs-based hospital care, whereby private sponsors are to be appropriately included in the planning;
d comply with the planning jointly drawn up by one or more cantons for needs-based hospital care, whereby private sponsors are to be appropriately included in the planning; and
e are included in the canton's list of hospitals, which is divided into categories according to service mandates.

Concerning the tariff structure (i.e., the pricing of various medical services that can be reimbursed via the MHI), different lists apply in Switzerland.[49] Accordingly, there is the list of analyses with tariff for medical analyses; a list for the preparations, active substances and excipients used in a prescription, which also includes services of pharmacists; a list for the MHI remuneration of means and objects (i.e., medical devices); and list for pharmaceutical specialities.

VIII REIMBURSEMENT OF SERVICES AND GOODS

In the Swiss health insurance system (i.e., the MHI), healthcare costs are reimbursed after the services have been provided (the cost-reimbursement-principle). The healthcare service providers can be reimbursed for their services in two ways: (1) by the insured person itself (the 'tiers garant system') – in this case, the insured person may subsequently be reimbursed by the insurer for the costs incurred; or, alternatively; and (2) by the insurers directly, if they have agreed with the healthcare service providers that their services will directly be compensated (the 'tiers payant system').

Which services and therapeutic products are covered by the MHI is regulated within the HIA and corresponding ordinance law, such as the HIO and the particularly relevant Ordinance on Healthcare Services of 29 September 1995. In the MHI system under the HIA, certain services and therapeutic products (in the event of illness, accident, and maternity) are covered. However, for the services and therapeutic products to be considered as payable by the MHI, the services must be effective, appropriate, and economically efficient (as mentioned above in this chapter in Section II.iii).

48 Article 39 HIA.
49 Article 52 Paragraph 1 HIA.

For example, in the case of digital health applications, new developments have led to an increase in the reimbursement of digital health applications within the framework of the MHI. For the MHI to reimburse or cover the services for such digital health applications, the digital applications must fulfil the requirements for approval on the Swiss market in accordance with the Ordinance on Medical Devices of 1 July 2020. In addition and in accordance with the HIA,[50] they must serve to diagnose or treat a disease and its consequences within the framework of the aforementioned mandatory requirements of effectiveness, appropriateness and economic efficiency.

IX DIGITAL HEALTH DEVELOPMENTS

Although Switzerland has an excellent healthcare system, it lags behind other countries in the area of digitalisation.

Because numerous international examples have shown the advantages of meaningful digitisation, the Federal Council has launched a joint strategy, 'Strategy eHealth Switzerland 2.0',[51] together with the cantons. This strategy defines the goals and measures of the Swiss Confederation and the cantons for the dissemination of the EPD as well as for the coordination of digitisation around the EPD. The strategy is based on three pillars, namely (1) promoting digitisation; (2) aligning and coordinating digitisation; and (3) enabling digitisation.[52]

In parallel, there is an additional funding programme in the area of digitisation, which is managed and coordinated by the Federal Department of Home Affairs (FDHA). The programme is named 'DigiSanté' and has the purpose of promoting the digital transformation in the healthcare sector. It is being developed on behalf of the Federal Council and will be jointly developed by the FOPH and the FSO until the end of 2023. Concrete implementation will take place from 2025.[53] DigiSanté has four main strategic objectives: (1) laying the foundations and supporting projects; (2) coordinating activities and involving stakeholders; (3) ensuring secure and compatible data exchange; and (4) creating adequate legal foundations.[54]

X CORONAVIRUS

The aftereffects of the coronavirus still reverberate. The coronavirus has exposed the weaknesses and strengths of the country's own health system and has shown where it needs to be improved in the future and where it was already well positioned. The post-processing is still in full operation in Switzerland, which is why not all conclusive findings can yet

50 Article 25 HIA.

51 See FOPH information regarding 'Strategie eHealth Schweiz 2.0', accessible online under the URL: https://www.bag.admin.ch/bag/de/home/strategie-und-politik/nationale-gesundheitsstrategien/strategie-ehealth-schweiz.html (accessed on 5 July 2023).

52 id.

53 See FDHA information regarding DigiSanté, accessible online under the URL: https://www.bag.admin.ch/bag/de/home/strategie-und-politik/nationale-gesundheitsstrategien/digisante.html (accessed on 5 July 2023).

54 id.

be presented. However, an important priority for Switzerland, even after the pandemic management, is to continue to work actively with scientific experts to review the events of the covid-19 pandemic.[55]

On 18 June 2023, the Swiss population voted on the topic of a further extension of the Federal Act on Covid-19 of 25 September 2020 (the Covid-19 Act). As a result the extension was accepted by the electorate on 18 June 2023 with 61.9 per cent of the vote. The extension will now have the consequence, among other things, that medicines for severe covid-19-diseases can continue to be imported without being licensed in Switzerland.

Already before the corona pandemic had started, the Federal Council adopted the 'Health Policy Strategy 2020–2030'. The covid-19 pandemic has delayed the implementation of this strategy, which is now to be addressed after the pandemic has been mostly overcome. However, as mentioned at the beginning, the pandemic has also provided further insights, which need to be implemented now. In particular, the pandemic has shown the urgency of taking measures in the context of rising health costs, the lack of structures and the shortage of skilled (medical) professionals. The need for new digitalisation options was also ruthlessly highlighted by the pandemic.[56]

Future will show how the findings will be implemented in the follow-up to the pandemic within the framework of the Swiss Health Policy Strategy 2020–2030. It will be interesting to see how the covid-19 may also have significant effects on the future direction of the healthcare system in Switzerland.

XI FUTURE OUTLOOK AND NEW OPPORTUNITIES

i Organ donation

On 15 May 2022, the Swiss people decided to introduce the extended objection solution (opt-out system) in Switzerland. The new regulation will enter into force in 2025 at the earliest. Until then, the extended consent solution (opt-in system) will continue to apply. Under the previously applicable (extended) consent solution, organs, tissues, or cells could only be removed from a deceased person if explicit consent has been obtained. Under the newly introduced (extended) objection solution, organs, tissues, and cells can now – in simplified terms – be removed after consultation with the next of kin based on the presumed will of the deceased person. By changing the current donor model, the legislator clearly hopes to increase the amount of available human donation material.

ii Electronic patient dossier

See Sections III and IX.

55 See FOPH information regarding scientific cooperation in connection with covid-19, accessible online under the URL: https://www.bag.admin.ch/bag/de/home/das-bag/aktuell/medienmitteilungen.msg-id-91826.html (accessed on 5 July 2023).

56 FOPH information regarding the Federal Council's health policy strategy 2020-2030, accessible online under the URL: https://www.bag.admin.ch/bag/en/home/strategie-und-politik/gesundheit-2030/gesundheitspolitische-strategie-2030.html (accessed on 5 July 2023).

iii Revised Law on Human Genetic Testing

On 1 December 2022, the revised provisions of the Federal Act on Human Genetic Testing of 8 October 2004 and the Ordinance on Human Genetic Testing of 23 September 2022 entered into force. The new regulations expand the group of persons who may order genetic tests in their medical field. The background for this change is that until the entry into force of the new rules, genetic tests could only be ordered by doctors. However, after the revision, dentists, pharmacists, and chiropractors (in each of their respective field of expertise) may also order selected medical genetic tests. In addition, genetic laboratories in the medical field are now subject to an additional accreditation requirement. The revised law also regulates the area of prenatal diagnostics, namely the examination of the unborn child. These genetic tests may now only be conducted if they concern health.

XII CONCLUSIONS

As has been highlighted in this chapter, the Swiss healthcare system is based on a dualistic model consisting, on the one hand, of legally prescribed 'basic insurance' in the form of the MHI and, on the other hand, of supplementary insurance organised under private law, (i.e., based on principles of contract law).

Targeted government restrictions in the area of the MHI, such as the abolition of freedom of contract or – from an opposite perspective – the guarantee of compulsory contracting can ensure that the basic health needs of all insured persons in Switzerland are met at a very high standard. Thanks to the MHI, it can therefore be summarised that the Swiss healthcare system presents itself at a very good level in an international comparison.

At the same time, the high quality of the healthcare system is in a strong area of tension with regard to financing. Not only are the Swiss legislators and the cantons and municipalities struggling with constantly rising costs, but the insured are also increasingly confronted with rising premiums. Cost containment is therefore regularly the subject of political and legislative discussions and will continue to be of particular concern to the Swiss population in the coming years.

Finally, it should be noted that the current healthcare system in Switzerland has not been satisfactorily successful in initiating the digital transformation in a timely manner. In an international comparison, Switzerland thus seems to be lagging behind – despite its high qualitative standards in healthcare. In the future, these problems should be remedied as efficiently as possible through targeted support measures, particularly at the federal level, and digitisation should also be adequately implemented in the Swiss healthcare system.