

PANORAMIC
**HEALTHCARE
REGULATION**

Switzerland



LEXOLOGY

Healthcare Regulation

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ORGANISATION, FINANCING AND STRUCTURE OF THE HEALTHCARE SYSTEM

Organisation

How is healthcare in your jurisdiction organised? What is the role of government?

The Swiss healthcare system has a federalist structure. Different areas are governed by federal law (eg, the reimbursement criteria for the mandatory health insurance or the regulations for the supervision of health insurers). Many competences and tasks are under the control of the 26 cantons such as the running of public hospitals.

The Swiss healthcare system is based to a great extent on mandatory health insurance. Mandatory health insurance must be contracted with a health insurance company of one's choice and there is the possibility of contracting additional private insurance. Health insurance companies can be public or private legal entities. There are currently just over 50 health insurance companies. The catalogue of benefits of these insurers is defined by law, but the insurers offer different insurance models and services. Persons can be insured for additional or supplementary benefits to mandatory health insurance by means of private health insurance. Apart from health insurance, there are other types of social insurance such as accident insurance.

Mandatory and private health insurance pays or reimburses the costs of healthcare providers (hospitals, physicians, pharmacists, etc). The healthcare providers can be of private or public nature. Hospitals in particular are often public institutions. The legal nature of the healthcare providers is irrelevant for the reimbursement of the services provided; the requirements are the same for private and public healthcare providers. The healthcare sector, which is not financed by social insurance, is also important.

Key legislation

What key legislation governs the provision of healthcare services in your jurisdiction?

One of the most important pieces of legislation for the provision of healthcare services is the [Health Insurance Act \(HIA\)](#). This federal law regulates all benefit requirements for mandatory health insurance. To specify and enforce the provisions of the Health Insurance Act, the Federal Council and the responsible department have issued the Health Insurance Ordinance and the [Healthcare Services Ordinance](#) (HSO). In addition, when dealing with the provision of healthcare services, the cantonal Health Acts and the federal [Therapeutic Products Act](#) are often particularly important. With regard to the individual requirements that healthcare providers must fulfil in order to be allowed to offer services independently, there are various federal Acts on the different healthcare professions. Worth mentioning is the [Medical Professions Act](#), the [Psychology Professions Act](#) and the [Health Professions Act](#).

Financing

How is the healthcare system financed in the various patient care sectors?

The healthcare system is mainly financed by social health insurance, private insurance, the Swiss Confederation, the cantons, the communities and the direct payments of patients. Inpatient treatment at a hospital, listed by a canton (performance mandate), provides is mainly financed by mandatory health insurance and the cantons through flat-rate payments per case. Outpatient treatment is financed mainly by mandatory health insurance. The mandatory health insurance provides for a patient co-payment of, at present (in principle), 10 per cent to a maximum of 700 Swiss francs and a deductible of between 300 and 2,500 Swiss francs (the amount can be chosen by the insured person) per year for adults. For both the outpatient and the inpatient sectors, private additional health insurance and direct payment of healthcare services are possible.

Delivery structures

What are the basic structures for the delivery of care to patients in your jurisdiction?

Mandatory health insurance provides for a quite extensive, though limited catalogue of reimbursed healthcare services. They are provided by public or private hospitals, physicians, pharmacists or other recognised healthcare providers. The mandatory health insurance system generally allows a free choice of healthcare providers. However, in the case of inpatient treatment, it is possible that the patient will have to bear part of the costs if they choose a hospital that is not on a list issued by the canton of residence and they do not have private care to cover these costs. Private health insurance offers certain additional healthcare services, such as alternative medicine or a different hospital accommodation. There are many types of private health insurance policies. Public hospitals also provide services for privately insured patients.

Access and coverage

What rules govern access to treatment and emergency services? Which items and services are covered and which are not covered?

The provisions of the HIA and the cantonal Health Acts govern the access and coverage of treatment and emergency services. Particularly important are articles 25 to 31 of the HIA, which define the catalogue of services that the mandatory health insurance covers. The mandatory health insurance only has to pay for these services if the conditions set out in articles 32 to 34 of the HIA are met. Article 32 of the HIA requires healthcare services to be effective, appropriate and cost-efficient.

The catalogue of services covered by mandatory health insurance is comprehensive. It includes, in particular, outpatient or inpatient examinations and treatments performed by physicians or by healthcare professionals acting on the orders of a physician. Drugs are reimbursed if they are listed on the so-called list of specialties, whereby reimbursement of unlisted drugs is also possible in individual cases (off-licence, off-list, off-limitation and off-label use).

Generally, dental services and preventive medical services are not covered, although there are exceptions in both areas. Furthermore, there are various medical services listed in Annex 1 of the HSO, which the mandatory health insurance does not cover or only covers under

certain circumstances. These listed services are usually services that the responsible federal department considers to be ineffective, inappropriate or inefficient.

Exclusions from statutory coverage

Are any groups excluded from statutory coverage? Are any groups covered under alternative schemes?

The conclusion of an insurance contract in the area of statutory coverage is mandatory for all persons residing in Switzerland ('mandatory health insurance'). In some cases, the insurance obligation is extended to persons who work or reside in Switzerland or who are employed abroad by an employer with a registered office in Switzerland. In addition, there are exceptions to the insurance obligation for various groups of persons. FEU, EFTA or UK nationals or Swiss nationals who reside in Switzerland and, for example, are employed in an EU or EFTA state or the UK or receive a pension exclusively from the EU or European Free Trade Association or the UK do not have to obtain mandatory health insurance.

If the competent cantonal authority discovers that a person has not complied with their insurance obligation, the authority will forcibly assign the person to an insurer.

Gaps in cost coverage

Are there any gaps in cost coverage?

There are certain co-payment obligations of patients: adult insured persons must each pay a deductible of between 300 and 2,500 Swiss francs (the amount can be chosen by the insured person) and above that a co-payment of 10 per cent up to a maximum of 700 Swiss francs per year themselves. In the case of hospitalisation, a small contribution must also be made to the cost of the stay, which is currently 15 Swiss francs per day in the hospital.

From a substantive perspective certain medical services or service areas are not covered by mandatory health insurance. For instance, dental treatment is only covered in a few exceptional cases.

HEALTHCARE PRICING AND REIMBURSEMENT

Pricing

How are prices for healthcare services set and paid for in your jurisdiction? To what extent is the cost of healthcare services governed by law or regulation?

The prices for healthcare services depend on the type of service, the setting in which they are provided, the healthcare provider and, above all, whether they are covered by the mandatory health insurance. Services that are reimbursed by mandatory health insurance are determined by tariffs or flat rates per case. For services that are paid for by patients themselves or covered by private insurance, there are no legal requirements regarding the price.

In the outpatient sector, medical services are billed via a tariff, the TARMED. TARMED is a tariff negotiated by the tariff partners (the Association of Swiss Doctors, the Swiss health insurers (santésuisse), the hospitals of Switzerland (H+) and the federal social insurers represented in the Medical Tariff Commission of Suva (Accident Insurance UV, Military Insurance MV, Disability Insurance IV) and approved by the Swiss Federal Council. Any medicinal products used or dispensed in an outpatient treatment or medical devices dispensed for the patient's own use are charged separately according to the prices of the speciality list (for medicinal products) and MiGeL (for medical devices). Services of laboratories are also charged separately according to the analysis list. The prices of the lists mentioned are set by the Federal Office of Public Health (speciality list) and the Federal Department of Home Affairs (MiGeL and analysis list).

In the inpatient sector, all medical services (including medicinal products) are covered by a flat rate called SwissDRG. The development and annual revision of the nationwide tariff structure is one of the central tasks of SwissDRG AG, a joint organisation of service providers, insurers and cantons. The rate structure must be approved by the Federal Council.

For services covered by the mandatory health insurance, there are two billing options. Payment of the healthcare provider's invoice can either be made directly by the respective health insurance company (*tiers payant*), in which case the insured person only receives a copy of the invoice, or invoicing can be made to the patient, in which case the patient pays the invoice and applies for reimbursement from the health insurance company (*tiers garant*).

Reimbursement

How is reimbursement for healthcare services structured?

There are two general reimbursement modes in mandatory health insurance: the *tiers garant* and the '*tiers payant*' mode. For inpatient services, the *tiers payant* is always used (article 42 paragraph 2 Health Insurance Act (HIA)). For outpatient treatment, the insurer and the healthcare provider decide which mode applies.

The financing of outpatient and inpatient services is currently regulated differently. For outpatient services, the insurances bear the costs in full – apart from the out-of-pocket contributions by the patients. For inpatient services, the cantons must cover at least 55 per cent of the costs and the insurers the rest (article 49a paragraph 2-ter HIA).

Adjudication

If applicable, what is the competent body for decisions regarding the pricing and reimbursement of healthcare services?

Whether a service is reimbursed or not depends first of all on whether the service is covered by mandatory health insurance. Service providers play an important role in assessing this question, as they are the first point of contact for patients and know the patient's medical situation best. In the case of physicians, it is also presumed that their services generally meet the EAE criteria (efficacy, appropriateness and cost-efficiency) (article 25 paragraph 2 lit. a HIA). However, health insurers may refuse to pay for services that they believe do not

meet these criteria. Health insurers may also reclaim costs for services that were wrongfully reimbursed (article 56 paragraph 2 HIA).

As far as the pricing of services is concerned, different stakeholders are responsible. In mandatory health insurance, providers charge for their services according to tariffs or prices (article 43 paragraph 1 HIA). In principle, prices are to be agreed in so-called tariff contracts between insurers and service providers (article 43 paragraph 4 HIA). This applies to outpatient and inpatient services. The tariff partners are not completely free in setting the tariffs, but must be guided by the tariff principles (cf. article 43 paragraph 4 HIA and articles 59c et seqq Health Insurance Ordinance). For instance, tariffs must be calculated in an economical manner and be cost-efficient (article 43 paragraph 4 HIA).

Only in the cases provided for by law the competent authority must determine tariffs or prices (article 43 paragraph 4 HIA). Such an authority price fixing is foreseen in particular for medicinal products (specialty list) (article 52 paragraph 1 lit. b HIA). In addition, tariffs are set by the authorities, for instance, if the tariff partners cannot reach an agreement (see article 47 HIA). Depending on the area of responsibility, prices are set by the cantonal governments, the Swiss Federal Council or the Federal Office of Public Health.

HEALTHCARE ORGANISATIONS AND BUSINESS STRUCTURES

Legal authorisation

What steps are necessary to authorise the provision of healthcare services, and what laws govern this?

The provision of most health services requires a licence from the canton that is mostly regulated in the respective cantonal Health Act. There are various conditions relating, among others, to education and experience. The requirements regarding education and experience are regulated in various legal texts at the federal and cantonal levels.

Only certain categories of health service providers are recognised as healthcare service providers under the Federal Health Insurance Act so that their services are reimbursed under the statutory health insurance system. Among others, these are hospitals, physicians and pharmacists. The recognition of healthcare services providers is regulated in articles 35 to 40 of the Health Insurance Act. The cantons are competent to recognise the service providers and to grant them a licence to provide services at the expense of the mandatory health insurance, which is in addition to the above-mentioned licence for the provision of health services. Some cantons have adopted additional provisions restricting the recognition of healthcare services providers for a certain period. Since 30 June 2023, all cantons are required to enact regulations to limit the number of physicians providing services at the expense of the statutory health insurance for one or more specialties in the outpatient sector.

Legal structures

What types of legal entities can offer healthcare services?

Healthcare services can be provided under different legal structures. Physicians' cabinets and pharmacies are often run as sole proprietorships or partnerships. Like hospitals, they can also be run as legal entities such as in the form of a corporation or limited liability

company. Hospitals are often entities governed by public law, sometimes also foundations or associations. The personal regulatory obligations of the medicinal persons managing the establishment are independent of the type of legal entity.

Foreign companies

What further steps are necessary for foreign companies to offer healthcare services?

Foreign companies wishing to offer health services in Switzerland need the same licences as Swiss companies if they are offering health services on Swiss territory. In addition, some cantons impose further requirements. In the canton of Zurich, for example, foreign companies need to have at least a registered branch office in the canton.

Healthcare arrangements

What regulatory and legal issues commonly arise in relation to healthcare arrangements? What are the main rules and principles that apply to extraterritorial participation in these arrangements?

The regulatory and legal issues that arise in healthcare arrangements vary greatly depending on the specific arrangement. They may concern administrative licences, questions regarding reimbursement, general contractual questions of cooperation, quality aspects or legal requirements regarding research. In addition, healthcare arrangements often involve the processing and storage of personal patient data (highly sensitive data according to the Swiss Data Protection Act). Switzerland has data protection laws in line with the European Union's General Data Protection Regulation, which need to be adhered to in healthcare settings.

In the case of extraterritorial participation, it is important to know that mandatory health insurance only covers therapeutic services if they are provided in Switzerland. Services provided abroad for insured persons residing in Switzerland are only covered if they are necessary for medical reasons or part of cross-border cooperation (article 34 paragraph 2 lit. a Health Insurance Act). One example that will be covered is emergency treatment abroad for which a repatriation to Switzerland is inappropriate (article 36 paragraph 2 Health Insurance Ordinance). Furthermore, in the case of extraterritorial participation, licensing issues often play an important role; whether they concern licences to practise independently or the reimbursement by mandatory health insurance.

COMPETITION, ANTI-CORRUPTION AND TRANSPARENCY RULES

Authority enforcement

Are infringements of competition law by healthcare providers pursued by national authorities?

The Swiss Competition Commission can pursue infringements of cartel law by healthcare providers. Civil actions in court are also possible. To date, there have been few cartel cases involving healthcare providers. This may be related to the fact that the [Cartel Act](#), according to

article 3, does not apply if the legislator wanted to exclude certain markets, goods or services from competition, for example, by granting special rights for executing public tasks. There are a number of such rules in the healthcare sector.

With the introduction of relative market power into the Swiss Cartel Act, more pharmaceutical companies may potentially be affected by antitrust proceedings. For example, in August 2022, the Competition Commission opened a new investigation against a pharmaceutical company that refuses to allow the Swiss pharmaceutical wholesaler Galexis to purchase special food products sold abroad at the more favourable conditions offered abroad. If this pharmaceutical company is found to have relative market power over Galexis, the refusal could violate the Cartel Act.

Additionally, healthcare providers are bound by the [Act on Unfair Competition](#). Infringements are usually brought forward in a civil court procedure; only in very limited circumstances will the authorities act ex officio.

Private enforcement

Is follow-on private antitrust litigation against healthcare providers possible?

The Swiss Cartel Act contains provisions on private enforcement in the case of breaches of antitrust law. However, private antitrust litigation plays only a very modest role in antitrust enforcement in Switzerland.

Anti-corruption and transparency

What are the main anti-corruption and transparency rules applicable to healthcare providers?

The main anti-corruption rules applicable to healthcare providers are article 55 of the Therapeutic Products Act and the Ordinance on Integrity and Transparency in the Field of Therapeutic Products as well as the anti-bribery provisions of the [Swiss Criminal Code](#) (articles 322-ter to 322-decies). The anti-bribery provisions are in line with the [Criminal Law Convention on Corruption of the Council of Europe](#) and, therefore, very similar to other current anti-corruption laws. From 1 July 2016, the provisions against bribery in the private sector (article 4a of the Act against Unfair Competition) were strengthened and became offences that are prosecuted ex officio.

The main mandatory transparency rule is article 56 of the Therapeutic Products Act, which requires that rebates granted in selling therapeutic products (ie, medicinal products and medical devices) be transparently displayed on the invoice and in the books of the selling and purchasing entity or person. Another important transparency rule is article 322-decies of the Swiss Criminal Code, which requires that certain advantages need to be approved by the organisation of the recipient to be legal. There are many other transparency rules in various acts and ordinances at the federal, cantonal and municipal levels.

The Code of Conduct of the Pharmaceutical Industry in Switzerland on cooperation with Healthcare Professional Circles and Patient Organisations issued by scienceindustries

obliges pharmaceutical companies adhering to it to disclose transfers of value to healthcare providers, healthcare organisations and patient organisations.

REGULATION OF HEALTHCARE SERVICES

Licensing authority and process

Which authorities are charged with licensing and regulating patient care facilities and healthcare professionals? What licensing processes apply?

The cantonal authorities are responsible for licensing and regulating patient care facilities and healthcare professionals. The responsible offices or persons are in each case attached to the cantonal health department. Service providers require a cantonal health police licence to carry out their activities (professional practice licence). The provisions to be complied with can be found in the cantonal Health Acts and, at federal level, in various Acts on individual professions, such as the Medical Professions Act (MPA) or Health Professions Act (HPA). In addition, for invoicing healthcare services to mandatory health insurance service providers must also have a licence under health insurance law, the requirements of which are based on the Health Insurance Act and the Health Insurance Ordinance. This authorisation is also granted by the cantons.

Cross-border regulation

What requirements and restrictions govern the mobility of licensed health professionals across borders?

As already described, health professionals require two different licences (health police licence and health insurance licence). In the case of the professional practice licence, health professionals with a place of business in Switzerland who work in another canton must report to that canton in each case. They may work in the canton for a maximum of 90 days per calendar year without a separate licence from that canton (cf. article 35 paragraph 2 MPA or article 15 paragraph 2 HPA). For licences to provide services at the charge of mandatory health insurance, each canton must fully check the licensing requirements if the service provider provides services outside the canton in which it holds a corresponding licence.

Foreign service providers must have the same licences. The Federal Office of Public Health determines whether foreign university degrees and continuing education titles in the medical and psychology professions are recognised in Switzerland. In addition, foreign service providers must take into account that the cantons, based on article 55a Health Insurance Act (HIA), may limit the number of physicians in one or more medical specialities or in certain regions (admission ban).

Collaboration between healthcare professionals

What authorisations are required for collaboration between healthcare professionals? How is this regulated?

No special authorisations are required for cooperation between different healthcare professionals. However, it is important that the individual service providers have the necessary licences. In many cases, in particular in cases of regular or in-depth cooperation, a contractual arrangement concerning the duties and responsibilities of the cooperation partners seems recommendable. The exact arrangement of the agreement depends on the goals and results pursued in the individual case. If any direct or indirect benefits are granted between the service providers or between service providers and third persons or institutions, these must be passed on to the insured persons or the health insurance scheme respectively (article 56 paragraph 3 HIA).

Collaboration between patient care facilities and healthcare professionals

What authorisations are required for collaboration between patient care facilities and healthcare professionals? How is this regulated?

No special authorisations are required for cooperation between patient care facilities and healthcare professionals. Similar to the cooperation between service providers, a contractual arrangement concerning the cooperation is often recommended. If any direct or indirect benefits are granted between the service providers or between service providers and third persons or institutions, these must be passed on to the insured persons or the health insurance scheme respectively (article 56 paragraph 3 HIA).

Training of healthcare professionals

What educational and training requirements must physicians and healthcare professionals satisfy to obtain the right to practise in your jurisdiction?

The educational and training requirements for physicians and other healthcare professionals are laid down in different federal laws. Depending on the profession, the Medical Professions Act, the Psychology Professions Act or the Health Professions Act are applicable. The laws regulate the content of initial and continuing education and training. Thus, the federal legislator set minimum substantive requirements concerning the education and training of the professions. A minimum duration is also often specified for continuing education or training titles (see, for example, article 18 MPA).

The general requirements that physicians and healthcare professionals must fulfil in order to obtain the right to practise are that they must have a federal diploma that is sufficient according to the respective law of the profession. In the case of persons with a foreign diploma, such diploma must be recognised in Switzerland. In addition, physicians and healthcare professionals must be trustworthy and offer physical and mental guarantees for the proper practice of their profession. Finally, they must have the necessary language skills in one official language of the canton for which the licence is applied. Licences to practise are issued by the cantons.

Discipline and enforcement

What civil, administrative or criminal sanctions, penalties, corrective measures and related tools may be imposed on patient care facilities and healthcare professionals for regulatory non-compliance?

The competent cantonal authority can withdraw a doctor's licence to practise if he or she does not (or no longer) meet the requirements for such a licence. The licence may also be subject to restrictions or conditions. In the event of a breach of professional duties or other breaches of the Medical Profession Act, the cantonal supervisory authority may order disciplinary measures such as a warning, a reprimand, a fine of up to 20,000 Swiss francs, a ban on practising the profession under one's own professional responsibility for a maximum of six years (temporary ban) or a definitive ban on practising the profession under own professional responsibility for all or part of the range of activities. In the case of certain breaches of duty or violations of medical professional law, criminal sanctions are also possible (eg, employment of assistant doctors without having the necessary authorisation).

For healthcare providers providing services at the expense of the statutory healthcare insurance, there are various requirements regarding the cost-efficiency and quality of the services. If a healthcare provider provides uneconomical (ie, unnecessary) services or violates other efficiency and quality requirements stipulated in the Health Insurance Act or contractual agreements such as the provisions on invoicing, sanctions are imposed. In addition to the sanctions provided for in the contracts with insurance companies, such sanctions also include warnings, full or partial reimbursement of fees received for inappropriate services, fines of up to 20,000 Swiss francs or, in repeated cases, temporary or definitive exclusion from practice at the expense of the statutory healthcare insurance.

Violation of the prohibition to accept or require undue financial benefits can be prosecuted and punished with a prison sentence of up to three years or a fine. Other violations of the Therapeutic Products Act can also be prosecuted (eg, if a physician dispenses medicinal products in breach of the duty of care). If the unlawful dispensing of medicinal products leads to a bodily injury, criminal sanctions based on the Criminal Code may also apply. Furthermore, depending on the institution in which the healthcare professional practices, there may be civil liability on the part of the physician or public liability on the part of the public hospital.

Patient complaints

How are patient complaints processed and adjudicated?

For patient complaints against healthcare providers, there are basically three possible avenues: In the case of unjustified interference with the physical integrity or other facts relevant to criminal law, a criminal charge can be filed with the criminal authorities. At the same time, violations of the duty of care or other duties under private or private professional law can be asserted by means of private law (legal claims or proceedings under the applicable professional association rules). Finally, under administrative law, a complaint can be filed with the supervisory authorities for violation of the professional duties laid down in the law.

The individual instruments available can also be combined or used in a layered manner. It must be decided in each individual case which instrument makes the most sense from a legal point of view and at what point in time.

If the patient's complaint is directed against a health insurer, the primary instrument for reimbursement disputes is the possibility of an objection and subsequent appeal procedure.

DATA PROTECTION, PRIVACY AND DIGITAL HEALTH

Responsible authorities and applicable legislation

Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation?

The authorities responsible for compliance with data protection and privacy are mainly the federal and cantonal data protection officers. Their tasks are laid down in the federal or cantonal data protection acts. The authorities have published several guidance documents for data protection in healthcare.

Requirements

What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

Health data is personal data that is particularly worthy of protection. Therefore, there are elevated requirements regarding the information of the data subjects on the collection and processing of this data. In general, explicit consent of the data subjects is required. Patient–doctor confidentiality also requires that patient data is safely stored and protected against access by non-authorized third parties. There is no regular need for a qualified data protection officer.

The revision of the [Data Protection Act](#) (DPA), which came into force on 1 September 2023, establishes the requirement of a data protection impact assessment for likely high-risk activities (article 22 DPA), which will often be relevant when personal data requiring special protection (such as health data) is processed on a large scale.

Regulatory guidance

Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The federal data protection officer has published several guidance documents on data protection in the healthcare sector (eg, on the [inspection, storage and deletion of patient data](#) or on the [disclosure of patient data](#)). Cantonal data protection officers can publish guidance documents too. For example, the data protection commissioner of the Canton of Zurich has published [various factsheets on data processing in the healthcare sector](#)

Common infringements

What are the most common data protection and privacy infringements committed by healthcare providers?

The most common data protection and privacy infringements committed by healthcare providers are a lack of up-to-date protection of electronic patient data against unauthorised access. In addition, there is often a lack of sufficient informed consent for further use of patient data.

Digital health services

Which authorities regulate the provision of digital health services and what is the applicable legislation? What basic requirements are placed on healthcare providers when it comes to digital health services?

There are no specific laws governing digital health services such as telemedicine. Instead, digital health services need to be assessed based on various laws. One main principle is that physicians based on their mandate contract with the patient must apply the diligence that can be expected from them based on their education and experience. This rule is also laid down in article 40 letter a of the Medical Professions Act. Some cantonal health laws require that healthcare providers treat patients personally and in principle through immediate contact (eg, section 12 paragraph 3 of the [Health Act of the Canton of Zurich](#)). The [professional rules of the Swiss physician's association FMH](#) merely prohibit regular treatment based solely on a digital contact. Furthermore, the provisions on patient-doctor confidentiality must be respected.

Consequently, as long as the medical obligations concerning diligence, data protection and confidentiality are guaranteed and there are no cantonal regulations to the contrary, digital health services are permitted.

UPDATE AND TRENDS

Key developments

Are there any current or foreseeable legislative initiatives, court cases, laws or other rules that affect the regulation of healthcare? What has recently changed (or will likely change), and what steps need to be taken in preparation?

Due to the extension of article 55 of the Law on Therapeutic Products to undue benefits related to medical devices, an amendment of the Ordinance on Integrity and Transparency in the Field of Therapeutic Products needs to be drafted by the administration. The partially amended ordinance is not expected to enter into force before 2025.

In the area of mandatory health insurance, there are many ongoing legislative revisions. A revision of the provisions for determining the prices of medicinal products and of the regulation regarding the reimbursement for products that are not listed in the SL or used off-label or off-limitation will come into effect on 1 January 2024. Furthermore, Parliament

discusses the introduction of cost targets or cost limits in the area of mandatory health insurance. Uniform financing of services in the outpatient and inpatient sectors (by the health insurance companies) is also being considered.

One important revision of the Health Insurance Act has already been adopted: The amended article 55a Health Insurance Act obliges the cantons to limit the number of doctors providing outpatient services at the expense of mandatory health insurance in one or more medical specialities or in certain regions. Some cantons have already enacted corresponding provisions. Other cantons are waiting for the legal basis at the federal ordinance level, which should follow in 2024.

The revised Data Protection Act, which further aligns data protection with EU data protection law, entered into force on 1 September 2023.