

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 federal 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 around 40 health insurance companies in Switzerland. The catalogue of benefits of these insurers is defined by law, but the insurers offer different insurance models and services. As mentioned above, individuals can also contract private health insurance to cover additional or supplementary benefits to those provided under the mandatory health insurance. In addition, other types of social insurance – such as accident or invalidity insurance – also exist.

Mandatory and private health insurance pay or reimburse 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.

Law stated - 30 September 2024

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 HIA, the Federal Council and the responsible department have issued the Health Insurance Ordinance and the [Healthcare Services Ordinance](#) (HSO). In addition, the cantonal health acts and the federal [Therapeutic Products Act](#) are also important to the provision of healthcare services. With regard to the individual requirements that healthcare providers must fulfil in order to be allowed to offer services independently, various federal acts governing the different healthcare professions need to be observed. Worthy of mention are the [Medical Professions Act](#), the [Psychology Professions Act](#) and the [Health Professions Act](#).

Law stated - 30 September 2024

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), provided under the mandatory health insurance is mainly financed through flat-rate payments per case. The costs are borne by the cantons (at least 55 per cent) and mandatory health insurance (maximum 45 per cent). Outpatient treatment under the mandatory health insurance is financed by mandatory health insurance. Subject to a vote which at the time of writing was due to take place on 24 November 2024, financing of healthcare services in the outpatient and inpatient sectors shall be uniform in future with the same percentage of cost-coverage by the health insurance companies and the cantons. 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.

Law stated - 30 September 2024

| **Delivery structures**

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

Mandatory health insurance provides for quite a broad, though limited, catalogue of reimbursed healthcare services delivered 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, patients may have to bear part of the costs if they choose a hospital that is not on a list issued by their canton of residence and they do not have private health insurance to cover these costs. Private health insurance covers certain additional healthcare services to those covered by the mandatory health insurance, 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.

Law stated - 30 September 2024

| **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 extensive. 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 feature on the 'list of specialties'; unlisted drugs or use (off-licence, off-list, off-limitation and off-label use) may also be reimbursed in individual cases.

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 that the mandatory health insurance does not cover or covers only in certain circumstances. Such services are usually services that the responsible federal department considers to be ineffective, inappropriate or inefficient.

Law stated - 30 September 2024

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 mandatory health insurance is obligatory for all persons residing in Switzerland. 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. There are exceptions to the insurance obligation for various groups of persons. EU, European Free Trade Association (EFTA) or UK nationals or Swiss nationals who reside in Switzerland and, for example, are employed in an EU or EFTA state or the United Kingdom, or receive a pension exclusively from an EU or EFTA member state or the United Kingdom, do not have to obtain Swiss 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.

Law stated - 30 September 2024

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 sum 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, in principle, 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 covered in only a few exceptional cases.

Law stated - 30 September 2024

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 called TARMED. TARMED is 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. TARMED will be replaced from 1 January 2026 by TARDOC, a single service tariff structure and a tariff structure for flat rates. 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 and medical devices) 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 healthcare 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 relevant 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*).

Law stated - 30 September 2024

Reimbursement

How is reimbursement for healthcare services structured?

There are two general reimbursement modes under the mandatory health insurance: the *tiers garant* and the *tiers payant* mode (see above). For inpatient services, the *tiers payant* is always used (article 42, paragraph 2 of the 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} of the HIA). However, subject to a vote due to take place in November 2024, this difference in cost coverage between outpatient and inpatient services will be eliminated.

Law stated - 30 September 2024

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 primarily on whether the service is covered by mandatory health insurance. Healthcare 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 efficacy, appropriateness and cost-efficiency criteria (article 25, paragraph 2(a) of the HIA). However, health insurers may refuse to pay for services that they believe do not meet these criteria. Health insurers may also reclaim costs from healthcare providers for services that were wrongfully reimbursed (article 56, paragraph 2 of the 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 of the HIA). In principle, prices are to be agreed in tariff contracts between insurers and healthcare providers (article 43, paragraph 4 of the HIA). This applies to outpatient and inpatient services. The tariff partners are not completely free in setting the tariffs: they must be guided by the tariff principles (article 43, paragraph 4 of the HIA and articles 59c et seq of the Health Insurance Ordinance). For instance, tariffs must be calculated in an economical manner and be cost-efficient (article 43, paragraph 4 of the HIA).

Only in the cases provided for by law can the competent authority directly determine tariffs or prices (article 43, paragraph 4 of the HIA). Such an authority price fixing is foreseen in particular for medicinal products (specialty list) (article 52, paragraph 1(b) of the HIA). In addition, tariffs are set by the authorities, for instance, if the tariff partners cannot reach an agreement (article 47 of the 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.

Law stated - 30 September 2024

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 usually regulated by the applicable cantonal health act. Various conditions apply relating to

education and experience, among other things. The requirements regarding education and experience are regulated in various legal texts at the federal and cantonal levels.

Only certain categories of healthcare providers are recognised as such under the Federal Health Insurance Act so that their services are reimbursed under the mandatory health insurance system. The recognised categories include hospitals, physicians and pharmacists. The recognition of healthcare service providers is regulated in articles 35 to 40 of the Health Insurance Act. The cantons are competent to recognise the healthcare 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 service 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 mandatory health insurance for one or more specialties in the outpatient sector. As of 1 July 2025 at the latest, the cantons must implement the maximum numbers in accordance with federal requirements.

Law stated - 30 September 2024

Legal structures

What types of legal entities can offer healthcare services?

Healthcare services can be provided under different legal structures. Physicians' practices 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.

Law stated - 30 September 2024

Foreign companies

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

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

Law stated - 30 September 2024

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 relation to healthcare arrangements vary greatly depending on the specific arrangement. They may concern administrative licences, 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 (that is considered highly sensitive data under the Swiss Data Protection Act). Switzerland's data protection laws are in line with the European Union's General Data Protection Regulation and need to be adhered to in healthcare settings.

In the case of extraterritorial participation, it is important to know that mandatory health insurance covers therapeutic services only if they are provided in Switzerland. Services provided abroad for insured persons residing in Switzerland are covered only if they are necessary for medical reasons or part of cross-border cooperation (article 34, paragraph 2(a) of the 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 of the 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.

Law stated - 30 September 2024

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 healthcare undertakings may potentially be affected by antitrust proceedings. For example, in August 2022 the Competition Commission opened an investigation against Fresenius Kabi, which had refused to allow the Swiss pharmaceutical wholesaler Galexis to purchase special food products sold abroad at the more favourable conditions offered abroad. In July 2024, the Swiss Competition Commission concluded that Fresenius Kabi does not hold relative market power in relation to Galexis for these products and that even if it existed, there was likely no abusive behaviour, as foreign pricing conditions were only slightly better. This marks the closure of the first investigation under the new legal provision.

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.

Law stated - 30 September 2024

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.

Law stated - 30 September 2024

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

Law stated - 30 September 2024

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. Healthcare providers require a cantonal health police licence (also known as a professional practice licence) to carry out their activities. 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.

Law stated - 30 September 2024

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). With regard to the professional practice licence, health professionals with a place of business in one Swiss canton 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 (article 35, paragraph 2 of the MPA or article 15, paragraph 2 of the HPA). Where a healthcare provider provides services outside the canton for which it holds a licence, each canton in which it also operates must check whether the licensing requirements are met in order to charge the services rendered to the mandatory health insurance.

Foreign healthcare providers must obtain the same licences as Swiss providers. 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 healthcare providers must take into account that the cantons, based on article 55a of the Health Insurance Act (HIA), limit the number of physicians in one or more medical specialities or in certain regions (admission ban).

Law stated - 30 September 2024

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 healthcare providers hold the necessary licences. In many instances, in particular in cases of regular or in-depth cooperation, a contractual arrangement concerning the duties and responsibilities of the cooperation partners is advisable. The exact arrangement of the agreement depends on the goals and results pursued in each case. If any direct or indirect benefits are granted between the healthcare providers, or between healthcare 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 of the HIA).

Law stated - 30 September 2024

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 healthcare providers, a contractual arrangement concerning the cooperation is often recommended. If any direct or indirect benefits are granted between the healthcare providers, or between healthcare 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 of the HIA).

Law stated - 30 September 2024

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 MPA, the Psychology Professions Act or the HPA is applicable. The laws regulate the content of initial and continuing education and training. Thus, the federal legislator sets minimum substantive requirements concerning the education and training of the professions. A minimum duration is also often specified for continuing education or training titles (eg, in article 18 of the MPA).

The general requirements that physicians and healthcare professionals must fulfil in order to obtain the right to practise are that they have a federal diploma that is sufficient according to the law governing the profession. In the case of persons holding 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. Lastly, they must have the necessary language skills in one official language of the canton in which they apply for a licence. Licences to practise are issued by the cantons.

Law stated - 30 September 2024

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 MPA, 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 mandatory 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 HIA 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 mandatory 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.

Law stated - 30 September 2024

Patient complaints

How are patient complaints processed and adjudicated?

For patient complaints against healthcare providers, there are 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;
- 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); and
- 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.

Law stated - 30 September 2024

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.

Law stated - 30 September 2024

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-authorised third parties. There is no regular need for a qualified data protection officer.

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

Law stated - 30 September 2024

Regulatory guidance

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

The Swiss Federal Data Protection Commissioner 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](#).

Law stated - 30 September 2024

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 failing to provide 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.

Law stated - 30 September 2024

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, various laws apply. One main principle is that based on their mandate contract with the patient, physicians 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(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.

Law stated - 30 September 2024

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?

The consultation process for the partial revision of the Ordinance on Integrity and Transparency in the Field of Therapeutic Products, which is necessary because of the extension of article 55 of the Law on Therapeutic Products to undue benefits related to medical devices, has been scheduled for 2025. The extension of the integrity rules of the Law on Therapeutic Products to medical devices will therefore take longer.

In the area of mandatory health insurance, numerous legislative revisions are in the pipeline. A revision of the provisions for determining the prices of medicinal products and of the regulation regarding the reimbursement for products that do not feature on the specialty

list, or are used off-label or off-limitation, came into effect on 1 January 2024. Furthermore, the Swiss parliament discusses the introduction of cost targets or cost limits in the area of mandatory health insurance. On 22 December 2023, the parliament passed an amendment to the Health Insurance Act regarding uniform financing of services in the outpatient and inpatient sectors by the health insurance companies and the cantons. As a referendum was requested against this, the Swiss people will vote on this amendment on 24 November 2024.

One important revision of the Health Insurance Act has already been adopted: the amended article 55a 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. From 1 July 2025 at the latest, the cantons must implement the maximum numbers in accordance with federal requirements.

Law stated - 30 September 2024