HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

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LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT

1. Please provide a bird's-eye view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).

Powers and responsibilities within the Swiss healthcare system are divided among the federal, cantonal and municipal levels. The federal government is responsible for regulating the financing of the system, ensuring the quality and safety of pharmaceuticals and medical devices, and overseeing public health initiatives. Each canton operates under its own constitution and is in charge of coordinating and financing the hospital infrastructure and licensing service providers. Municipalities primarily organise and deliver long-term care, such as nursing homes and home care services, along with other social support services for vulnerable groups. While regulation is primarily on the federal government, the cantons and municipalities are responsible for the provision and funding of healthcare services.

Basic health insurance is mandatory for all residents. Residents get coverage from one of the licensed private insurers (around 50 providers), which run the standardised plan of the mandatory health insurance (OKP) on a not-for-profits basis. Insurers can also provide supplementary, non-mandatory insurance plans which may be for profit but which are also heavily regulated. For their OKP leg, insurers are supervised by the Federal Office of Public Health (FOPH). Supplementary plans are supervised by the Federal Swiss Financial Market Supervisory Authority (FINMA).

Besides the (cantonal and municipal) government and insurers, patients have to pay a part of their treatment costs themselves (apart from the premiums they pay for mandatory and supplementary insurances). Treatments outside insurance schemes are fully self-paid. Foundations and patient organisations contribute to the funding of certain institutions but generally do not play a prominent role regarding the financing of healthcare.

2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.

Financing and reimbursement are mainly governed by the Federal Health Insurance Act (KVG). It specifies which medical services and therapeutic products must be covered by the mandatory insurance (OKP), defines the conditions for and level of their reimbursement (tariffs and prices) as well as the conditions for service providers to be allowed to provide services covered by the OKP. The Ordinance on Health Insurance (KVV) specifies these provisions and regulates, among other things, the structure of premiums, risk equalisation and the authorisation of service providers. The Health Care Benefits Ordinance (KLV) specifies the types of medical, chiropractic, complementary and pharmaceutical services covered by the

OKP and the conditions for their reimbursement. It also defines the conditions for reimbursement of pharmaceutical products and the reviews of their cost-effectiveness.

The Federal Act on the Supervision of the Mandatory Health Insurance (KVAG) governs the supervision of healthcare insurers by the FOPH. The respective regulations are aimed at ensuring high-quality and economically efficient healthcare, and at the same time limiting the financial burden on insured persons. Supplementary insurance is governed by the Federal Act on the Supervision of Private Insurances (VAG) and its related ordinances, ensuring transparency and accountability in their operations. FINMA monitors the adequacy of insurers' financial reserves and the fairness of their contractual terms and tariffs, ensuring consumer protection and market stability.

Typically, healthcare providers and insurers (or their respective industry organisations) negotiate their tariffs without involvement of the government. However, depending on the geographic scope of the tariff, the federal or respective cantonal government must approve the tariff, once an agreement is reached. If there is no agreement, the competent authority determines the tariff. In some areas, such as pricing of pharmaceuticals and tariffs for laboratories, the federal government determines the level of reimbursement unilaterally.

3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?

The FOPH is the supervisory authority in the area of mandatory health insurance. It is responsible for safeguarding compliance with the requirements of the KVG and KVAG, monitoring the solvency of the insurers, approving the premiums to be paid by the insured and supervising administration costs of the insurers, which must not be excessive. For the private health insurance, FINMA executes similar supervisory functions, and the FOPH and FINMA coordinate their responsibilities. On a national level, prices and tariffs are approved or set either by the Federal Council (ie, the federal government), the Department of the Interior (EDI), or the FOPH. The cantonal health departments and governments are responsible for approving tariffs on the local level. The cantonal authorities also decide on the budgets for the financing of hospitals and nursing homes in the respective canton.

Separately from the Competition Commission, the Price Monitoring Authority is responsible, on a federal level, to monitor prices which are not the result of effective competition. In the healthcare sector, the authority has the formal right to submit recommendations towards the authorities setting prices or approving premiums and/or tariffs. In the past, the Price Monitoring Authority has successfully promoted various price reductions and improvements in tariff negotiations, although it ultimately cannot enforce its recommendations.

Cantonal and federal courts play an important role in price and tariff matters when health insurers or service providers appeal decisions by the competent authorities. Administrative courts review compliance with legal requirements and may confirm or refer decisions back for re-evaluation, rarely taking a final decision themselves. In the context of reimbursement decisions by health insurers, courts can also assess the legality of coverage denials. In these instances, courts frequently issue orders that have an immediate effect, eg, that oblige the insurers to cover costs they previously denied paying for.

4. Has there been a change with healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?

The pandemic has not changed the general system of healthcare financing. During the pandemic, the federal government contributed around CHF5bn, while cantons paid between CHF2.3–2.9bn. In the area of inpatient treatment for Covid-19 patients, the share of costs borne by insurers under the mandatory health insurance was between CHF816–958m in the years 2020–2022. Insurers also covered CHF380m of the vaccination costs. These extraordinary costs led to an above average increase in premiums in 2023.

5. Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?

Healthcare insurance for basic medical services is mandatory for every resident and ensures equal access to the healthcare system in principle. All healthcare providers providing services on the expense of the OKP are obliged to treat every patient (principle of equal treatment), ie, they cannot refuse a patient as long as the institution has open capacity. Also, in the field of the OKP, every health insurer has to generally accept every resident as an insured at the same level of premium. An insurer may only differentiate premiums by municipality of residence, and for persons below 25 years.

In the area of voluntary additional private insurance, there is full contractual freedom, ie, the insurer may refuse to accept a person as an insured and it may also include reservations in the individual insurance policy. Supplementary insurance plans are exclusively financed by premiums paid by the respective insured persons (at the end of 2021, the premium volume in the supplementary setting was around CHF7bn). These insurance plans cover services and goods not covered by the mandatory health insurance. In the inpatient setting, they typically allow for free choice of hospital doctors, additional care and better amenities (single occupancy rooms, choices of meals, etc.). In case of a hospital stay, it must be determined which services fall under OKP expenses and which are to be charged to supplementary insurance (or need to be paid out-of-pocket). Mixing finances of the mandatory and the supplementary insurance that leads to cross-fundings are prohibited, as the OKP must be self-supporting.

In essence, health insurers are free to configure their supplementary insurance products. They negotiate and conclude contracts with the healthcare providers, mainly hospitals. FINMA reviews the tariffs before they may be implemented, checking if the insurance model is plausible and if terms and tariffs are fair. However, since supplementary insurance operates entirely under private law and on a voluntary basis, the rates and premiums can incorporate a profit margin.

Healthcare providers and professionals generally must be authorised by the cantons to operate respectively to practice in the healthcare sector. In addition, entities or individuals who want to provide services at the expense of the OKP must also be authorised to do so by the canton. While the authorisation to practise/run a healthcare institution intends to safeguard and protect public health and patient safety, the authorisation to provide services at the expense of the OKP intends to safeguard and protect the economics of the healthcare system.

For inpatient healthcare institutions to be able to work at the expense of the OKP, the planning criteria in the hospital sector must be fulfilled. Hospitals must be included in the cantonal hospital plans which distinguish between various areas of medical (inpatient) services, such as

paediatrics, gynaecology or psychiatry (for example). For the outpatient sector, healthcare professionals must have certain educational qualifications, a minimum of three years of work experience, local language proficiency and a good professional standing. However, to control costs more effectively, the KVG provides for a restriction (*Zulassungsstopp*) on the number of doctors licensed to charge the OKP for outpatient services in certain medical specialty areas and cantons.

For pharmaceuticals and other medical devices to be reimbursed by the OKP, they must be included in specific lists. Pharmaceuticals must first be authorised by Swissmedic, the federal authority responsible for granting marketing authorisations. Authorisation holders can then apply to the FOPH to have the respective pharmaceutical included in the list of specialties. If deemed effective, appropriate and economic by the FOPH, the pharmaceutical will be admitted to the list at the price determined by the FOPH (in agreement with the marketing authorisation holder).

Insured persons who do not pay their premiums may only receive emergency treatments to avert life-threatening conditions.

Swiss residents' mandatory health insurance also covers certain treatments abroad. Emergency treatments abroad are covered at least up to the extent that the same treatment would be covered in Switzerland. Planned treatments abroad are not covered by the OKP, unless a collaboration with foreign institution is medically indicated.

Tourists from the European Union/European Free Trade Area and United Kingdom can be treated in Switzerland for emergencies, if they are in possession of a European insurance card (ie, they have coverage from their home country). Tourists from other countries must have travel insurance that covers health costs.

HEALTH INSURANCE FINANCING AND COVERAGE

6. How are health insurance carriers financed? How are premiums determined?

The primary source of income of insurers are the premiums paid by the insured (at the end of 2021 the premium volume was CHF33bn) along with their cost-participation (out-of-pocket, deductible), followed by indirect government contributions (such as tax exemption for OKP-insurers, premium reductions through federal and cantonal subsidies, contributions to stationary treatments) and further revenues (such as contributions from risk equalisation, recourse income, or reimbursement claims).

The insurances must cover all current expenses by the total of their current income. Therefore, insurers must set the premiums annually in such a way that they can cover the services expected for the same period. Mandatory health insurances must be self-sustaining. Additionally, the insurers must build up (capped) reserves from their income.

Premiums for the basic plan are primarily determined by the insurer. Each year health insurers set their premiums for the following year based on the expected costs. The law allows premium differentiations based on place of residency, age, level of deductible, and insurance model (HMO, family doctor, telemedicine, etc). However, all premiums must be approved by the FOPH.

Courts can only assess whether the premiums were set in accordance with the law if an insurer challenges a non-approval by the FOPH. Conversely, the Price Monitoring Authority can

assess the calculations and numbers at the basis of the premiums and ultimately has the right to submit a recommendation to the FOPH in this respect.

7. How is coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in-person medical appointments and telemedicine appointments?

All health insurers that provide mandatory health insurance must cover the same set of services, pharmaceuticals and medical devices, all defined by law. The mandatory health insurance may not pay for any additional services or goods. Also, mandatory health insurance only covers services that are effective, appropriate and economical (EAE criteria). Services, both new and existing, which may not meet these criteria (anymore) are excluded from coverage.

The Federal Department of Home Affairs (FDHA) is responsible for defining the scope of services reimbursed by the OKP. For treatments and examinations carried out by doctors or physicians as well as chiropractors, the basic principle is that OKP reimburses all examinations and treatments unless they are excluded or restricted by law. Conversely, exhaustive positive lists are drawn up by the FDHA or the FOPH for ready-to-use pharmaceuticals (List of Specialties), medical devices, and laboratory analysis. Goods not included in these lists are not covered or reimbursed by mandatory health insurance.

The coverage for in-person visits and telemedical appointments is basically the same: ie, by law they are not billed differently. However, healthcare insurances can differentiate premiums for different insurance models. Specifically, if the insured accepts to be obliged to use telemedicine for first consultations, premiums are reduced by a certain amount.

If certain conditions are met, mandatory health insurance may reimburse the cost for pharmaceuticals in individual cases even if they are not (yet) included in the respective List of Specialties such as novel orphan drugs or pharmaceuticals used off-label (see Q12).

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?

In essence, a distinction is made between outpatient and inpatient treatment. Outpatient treatments are reimbursed based on the national TARMED tariff, which combines time-based and per-treatment tariffs. For inpatient treatments, in contrast, per case flat rates are mandatory (eg, daily flat rates or diagnosis-related flat rate). There are three national flat rate tariffs in the inpatient setting: 'SwissDRG' for hospital services (which is the most important one), 'TARPSY' for inpatient psychiatric treatments and 'ST REHA' for inpatient rehabilitation treatments.

Both systems face criticism. SwissDRG rates are inadequate at today's cost level, leading to important losses for hospitals and pushing even more treatments to the outpatient sector where services can be charged more freely. Conversely, TARMED can lead to unwarranted cost increases and may create inappropriate incentives due to outdated tariffs; some rates overcompensate while others do not cover costs. This leads to unnecessary treatments or neglect of necessary ones, causing resource misallocation with overspending in some areas and underfunding in others.

Currently, inpatient treatments are covered by the mandatory health insurance up to 45 per cent of total costs. The remaining 55 per cent must be borne by the canton (out of tax income) where the insured person resides. Outpatient treatments are fully covered by the mandatory health insurance, after deduction of a contribution by the insured.

9. How are the prices of such services determined? How is economic efficiency controlled?

In essence, the law allows for time tariffs, per-service tariffs and flat rate tariffs. Outside of the stationary area (where per case flat rates must be applied), the parties can decide what type(s) of tariff(s) they choose or combine. The KVG defines how all tariffs and prices must be calculated. The primary objective should always be to offer high-quality, suitable care at the most affordable cost. Tariffs need to be designed economically and appropriately. They must adhere to principles of economic efficiency and fairness. Regular reviews and adjustments of the tariffs are essential to ensure ongoing compliance.

Tariffs and prices are set in accordance with the principle of contractual freedom. The tariffs are primarily agreed in contracts between insurers and service providers. Mostly, associations representing a group of tariff partners lead the negotiations. If insurers and service providers agree on a tariff contract, it must be submitted to the competent authorities (cantonal or federal) for approval. If no agreement can be reached, the tariff is set autonomously by the competent authority. The tariffs are protected by law, which means that service providers must respect the prices and do not have the right to ask for higher compensation.

Flat rates per case in the stationary area include all services and associated diagnostics without additional reimbursement. Conversely, in the outpatient sector, every service and good used can be billed individually. Therefore, prices and tariffs for pharmaceuticals, laboratory analyses, aids and equipment as well as medical care are defined in exhaustive positive lists (see Q12). However, for these lists, the federal government sets the tariffs unilaterally after consultation, as the case may be, of the respective suppliers.

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?

Healthcare services provided by private practitioners are financed and reimbursed in the same way as for hospitals in the ambulatory/outpatient setting (see Q8 and Q9).

11. How are the prices of such services determined? How is economic efficiency controlled?

Again, prices of such services are set and their economic efficiency is being controlled in the same way as for hospitals in the ambulatory/outpatient setting (see Q8 and Q9).

PHARMACEUTICALS AND MEDICAL DEVICES

12. How are pharmaceuticals and medical devices financed and reimbursed?

Ready-to-use pharmaceuticals and medical devices are covered by the mandatory healthcare insurance if they are included in the List of Specialties (SL) respectively on the List for Aids and Devices (MiGeL). The same mechanism applies for laboratory analyses (AL) and

pharmaceuticals based on magistral formula (*Arzneimittelliste*). Only the SL includes specific (branded) products and their prices, the other lists merely define the prices for certain types of generic goods.

Pharmaceuticals can be included in the SL after having been granted marketing authorisation by Swissmedic. The authorisation holder must apply to the FOPH and suggest a price. For listing, the pharmaceutical must be effective and appropriate, and its price must be economical (EAE criteria). Importantly, the listing only allows reimbursement up to the list price if the pharmaceutical is used in-label, ie, according to its authorised indication, dosage etc. To list a type of medical devices on MiGeL, an application must also be submitted to the FOPH and the same criteria must be fulfilled. Once a pharmaceutical or a device group is on the respective list, it is re-evaluated based on the EAE criteria every three years.

The law stipulates a simplified fast-track authorisation process for orphan drugs to be included in the SL. In addition, pharmaceuticals which have no Swiss marketing authorisation (yet), have not been listed on the SL (yet), or are used off-label, can be reimbursed by the mandatory healthcare insurer on a case-by-case basis if they provide a high therapeutic benefit and there is no alternative treatment available. However, such reimbursement is often associated with excessive administrative effort and inconsistent assessments, ie,, comparable patient cases being assessed differently by different healthcare insurers.

13. How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?

The FOPH sets the prices respectively with the maximal rates of reimbursement for the pharmaceuticals or devices covered by the OKP. Moreover, the Price Monitoring Authority is actively checking prices and calculation methods and has a right to address the FOPH when it detects inconsistencies in the price determination.

The FOPH determines the price for pharmaceuticals based on (1) international reference pricing (APV) and (2) therapeutic cross-comparison with other pharmaceuticals listed in the SL for the same indication (TQV). For the APV, the price is compared with the prices in nine European reference countries. The results of APV and TQV are equally weighed 50/50. This process is repeated every three years for the respective pharmaceutical in order to lower the price over its lifetime. Generics have to respect a defined price difference to the respective original pharmaceutical.

The mechanisms of price determination are criticised on the one hand for not allowing enough cost savings, in particular for generics (which are relatively expensive in Switzerland compared to similar countries). On the other hand, pharmaceutical companies complain that the FOPH has too much discretion to fix prices (in particular when it comes to determining the TQV), and that legal challenges would not allow for immediate reimbursement of the respective pharmaceutical, even on a provisional basis.

The prices in the MiGel are set by the FOPH and define the maximum level of reimbursement, but patients (or their supplementary insurance carriers) may be asked and prepared to pay the excess price of a certain device (which is not allowed for pharmaceuticals).

So far, the law does not include explicit provisions for confidential rebates. Switzerland maintains one of the most transparent pricing systems globally. However, because confidential rebates have become frequent practice in other jurisdictions (in particular the reference countries for the APV), such rebates have also been introduced in Switzerland in order not to

disadvantage Swiss patients. The federal parliament is currently discussing whether this principle should be changed, so that rebates may be kept confidential on a regular basis.

LITIGATION INVOLVING HEALTHCARE FINANCING AND REIMBURSEMENT

14. Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.

BGE 136 V 395

The Federal Supreme Court's decision of 2010 concerns the reimbursement of Myozyme for treating the rare Pompe disease. The court ruled that the health insurer is not required to cover Myozyme costs beyond six months due to insufficient evidence of high therapeutic benefit and economic feasibility. Although approved by Swissmedic, the court found Myozyme's therapeutic benefit modest and not well-supported by clinical studies. It therefore did not meet the high threshold needed for reimbursement on a case-by-case basis. Even with proven high benefit, the court deemed the CHF500,000 annual cost disproportionate compared to the benefits. The ruling emphasised the need to balance costs and benefits to ensure adequate healthcare resource distribution. This leading case marks a milestone in Swiss healthcare jurisprudence by addressing economic feasibility in reimbursement decisions, promoting a balanced and equitable healthcare system.

BGE 144 V 138

The Federal Supreme Court ruled in 2018 that the Federal Council's adjustments to the national TARMED tariff for ambulatory treatments, including a linear reduction of technical service tariffs by 8.5 per cent, were lawful and within its competence. The court emphasised that the Federal Council could consider political objectives, such as promoting services provided by general practitioner (and not specialists), when making such adjustments. The decision underscores the Federal Council's broad discretion in ensuring the tariff structures' appropriateness and economic efficiency.

BGE 142 V 425

The Federal Supreme Court ruled in favour of A., requiring her healthcare insurance to cover the costs of special dietary foods for the treatment of her metabolic disorder. The court found that the dietary products, previously covered by the disability insurance until A. turned 20, are essential for her health and must be covered by the mandatory health insurance going forward. The decision emphasised the legislative intent to ensure a seamless transition of necessary therapeutic measures from disability to health insurance. The court rejected the insurance's argument that the products were not included in the relevant health insurance laws, stating that the legislative framework mandates their inclusion. Consequently, the healthcare insurance was *directly* ordered to reimburse A. for the costs of the dietary foods.

It is to be noted that disputes between insurers and healthcare providers regarding tariffs and prices often lead to court cases. However, the courts rarely decide on prices themselves but remit the cases to the previous instance to redo their calculations based on the court's arguments.

Several Swiss hospitals are currently in financial difficulties due to inadequate tariffs, cost increases and oversupply. Public hospitals owned by municipalities were traditionally 'saved' by way of extraordinary subsidies. However, governments have recently indicated that only

hospitals which are essential for medical supply will be considered for such subsidies in the future and that others will have to merge or close down.

RECENT DEVELOPMENTS AND TRENDS

15. What are the recent developments and trends for the next few years? Please outline any unresolved issues, proposed changes, or trends for healthcare financing and reimbursement and briefly indicate how these may foreseeably affect the medical sector in the near future.

Since January 2023, the federal government has launched two legislative programmes to reduce healthcare costs. The second one was launched in January 2024 and suggests four measures:

- obligation for tariff partners to agree on a mutual monitoring regarding the cost development under the respective tariff;
- introduction of the right to appeal for insurers against planning decisions of the cantons regarding hospital infrastructure;
- simplification of parallel imports of pharmaceuticals, and
- the right of pharmacist to dispense generics instead of original pharmaceuticals, if both pharmaceuticals have equal effect and are equally appropriate.

It remains to be seen how the current hospital crisis will shape the law and healthcare policy going forward. Obviously, cantonal and regional planning of stationary medical supply has proven to be inefficient and unable to ensure a healthy hospital sector. However, shifting the power to the federal government in this area even more would be very controversial politically.