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Message from the President

Dear Members and Colleagues,

It is a true pleasure to welcome you to the first 2026 issue of our EAHL Newsletter, which covers the latest health law developments across 12 European countries.

As our Association continues to grow, I am thrilled to report that we are actively expanding both our membership base and our portfolio of activities across Europe and beyond. This ongoing vitality is a testament to the dedication of our community and the increasing relevance of health law in addressing contemporary global challenges.

A particularly inspiring development in our flourishing landscape is the renewed energy of our Young Scholars Interest Group. Investing in the next generation of health lawyers is vital for the future of our field. With the support of the Board of Directors, the Interest Group is currently organising a series of dynamic initiatives designed to help early-career researchers and practitioners establish their position, showcase their scholarship, and actively contribute to the development of European health law. Crucially, our young scholars will not be walking this path alone. I am deeply grateful that they will be nurtured by the wise, dedicated support and guidance of Vice-President Santa Slokenberga and Secretary Magdalena Flatscher-Thöni, whose mentorship will provide an invaluable foundation for their growth.

Looking ahead, we are all eagerly anticipating our landmark 10th EAHL Conference in Uppsala. A major event of this scale requires extraordinary dedication, and I want to express my profound gratitude to our Vice-President and the local organising committee at the University of Uppsala for the immense work and effort they have poured into making this conference a success. It promises to be an exceptional gathering for our community, paving the way for fruitful outcomes that will meaningfully contribute to the further development of our field.

Last but not least, a warm welcome to our new members and the newly appointed National Contact Point for Georgia.

Thank you for your continued commitment to the EAHL, and I look forward to seeing many of you in Uppsala!

Warm regards

Salerno, 31 July 2026

Stefania Negri

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Latest Developments in Austrian Legislation and Case Law

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1. Introduction of the Healthcare Reform Fund by Federal Law 2025/104[1]

Under the Budget Consolidation Measures Act 2025 Part II (BSMG 2025 II), the health insurance contribution payable by recipients of old-age pensions and comparable benefits (e.g. retirement pensions) was uniformly increased to 6%. As the health insurance contributions to be transferred by the pension insurance funds are linked to the total contributions of pensioners, these contributions also increased. The lawmaker decided that the extra amounts resulting from the increase in health insurance contributions payable by pension insurance funds should be made available to a health reform fund. This provision is implemented by the Federal Law I 2025/104 with effect from 1 January 2026.

Each statutory health insurance provider will establish a health reform fund, which will be funded between 2026 and 2030 according to a ratio laid down by law, using the amounts transferred by the pension insurance providers to the federal government.

Each year, approximately 80% to 90% of the fund's resources will initially be transferred to the health insurance providers' ordinary accounts. The remaining amount will only be transferred to the ordinary accounts retrospectively once the health insurance provider has demonstrated that it has achieved certain targets laid down by regulation.

The Federal Minister for Labour, Social Affairs, Health, Care and Consumer Protection must determine each year the specific purposes for which the fund's resources are to be used and the targets to be achieved. The regulations are preceded by recommendations from an advisory board appointed by the Federal Government, which are not, however, legally binding on the Federal Minister. Pursuant to § 1 of the Health Reform Fund Act, eligible measures include, for example, measures to improve community-based healthcare, including telemedicine services and services offered during daytime hours and at weekends; the optimisation of patient pathways; the strengthening of age-specific healthcare and prevention; the promotion of mental health; measures within the framework of health target management; and efficiency improvements within the health insurance funds.

An evaluation of the use of funds will be carried out in 2028.

[1] Cf Schöll, Sozialversicherungsrecht, ASoK 2026, 38-39.

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2. Supreme Court ruling on the duty of care of ambulance paramedics

In a ruling dated 22 October 2025 (7 Ob 114/25b), the Supreme Civil Court clarified that, whilst ambulance paramedics are not subject to a physician's duty to provide information, and therefore have no duty to provide information regarding medical diagnoses or medical treatment. However, on the basis of the patient's right to self-determination, the ambulance paramedic is also under a duty to provide information insofar as the patient's physical integrity is affected. In addition, they are required to provide information within the scope of the general duty under § 4 (1) of the Paramedics Act. Accordingly, the patient's welfare must be safeguarded in accordance with professional and scientific knowledge and experience. In doing so, an ambulance paramedic must inform the patient in general terms of the circumstances and considerations on which they have based their assessment that the proposed (emergency) measure appears necessary in the specific case. S*He must therefore explain to a patient who refuses a proposed or recommended (emergency) measure, in general terms, the reasons why, from his*her professional point of view, carrying out the measure is advisable. Only in doing so can the patient be given a clearer understanding of the proposed measure and be enabled to make an informed decision regarding it.

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Recent Updates and Strengthening Digitalization in the Healthcare System of the Azerbaijan Republic

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Ongoing reforms in the compulsory health insurance system are directed primarily toward broadening the scope of services covered under the insurance package and advancing the digital transformation of the healthcare provision. Some news of 2026 (January - 20th of June) are summarised below:

- A cornerstone initiative in the establishment of a digital healthcare ecosystem has been the development of the *Unified Healthcare Information System*. This project facilitated the integration of diverse information systems and governmental registries, thereby achieving substantial progress in consolidating and managing medical data within a unified platform.
- Another news is that the nationwide implementation of the electronic sick leave system has been successfully completed, thereby eliminating the use of paper-based forms in this domain. In parallel, a unified registry of electronic medical records has been established, and their application has commenced in processes related to social payments and health insurance.
- Created recently Medical Digital Twin System (*az. Tibbi Rəqəmsal Əkiz Sistemi,* or *TRƏS*) became a centralized digital healthcare platform launched by the Azerbaijan Ministry of Health. It creates a lifelong, secure, and unified digital health profile for every citizen, consolidating their complete medical history into one accessible location. Built on international FHIR standards, the system integrates over 20 digital solutions into a single environment, ensuring the secure and continuous exchange of data on citizens' health.
- The powers of the public legal entity State Agency for Compulsory Medical Insurance in the field of compulsory medical insurance of the population were assigned to the Ministry of Labor and Social Protection of the Population of the Republic of Azerbaijan. By reorganizing in the form of a merger of the public law legal entity "State Agency for Compulsory Medical Insurance" and the public law legal entity "State Agency for Medical and Social Expertise and Rehabilitation" under the Ministry of Labor and Social Protection of Population of the Republic of Azerbaijan, the public law legal entity "State Agency for Medical Insurance and Expertise" was created under the Ministry of Labor and Social Protection of Population of the Republic of Azerbaijan.

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- In May 2026, the process of integrating digital services provided through the "e-Tabib" mobile application into the "Mygov" platform has already been completed. By that, the "e-Tabib" application has completely ceased its activities and healthcare-related services will now be provided through the "mygov" platform. "Mygov" is Azerbaijan's official digital government platform. It functions as a centralized bridge between the government and citizens, allowing users to access hundreds of state services and official documents digitally without visiting physical offices or dealing with paperwork.
- In June 2026, the opening ceremony of the Data Analytics and Artificial Intelligence Laboratory was held at the Azerbaijan Medical University. This was one of the important steps towards building a unified digital healthcare ecosystem, digitizing processes, and improving management within the framework of the "National Strategy on Digital Healthcare for 2024–2028".

Sources:

1. *The Official Website of the President of the Republic of Azerbaijan. URL: https://president.az/az/articles/view/71960*
2. *Ministry of Health of the Azerbaijan Republic. URL: https://sehiyye.gov.az/en/media/xeberler-ve-yenilikler/s-hiyy-nazirliyi-v-t-ndas-saglamligina-r-q-msal-qaygi-tibbi-r-q-msal-kiz-sisteminin-t-qdimatini-kecirib/*
3. *The Azerbaijan State News Agency. URL: https://azertag.az/en*

Date of submission: 20 June 2026

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Country Report: Czechia

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The period from the late 2025 to the first half of 2026 brought an unusually dense set of changes to Czech health law. A large package of amendments took effect on 1 January 2026 and reshaped the rules on health services, public health insurance, medical devices, and the electronization of prescriptions. In parallel, the higher courts decided several disputes that clarified long debated questions on liability and on the rights of patients. This report summarises the developments that appear most significant.

1. Legislative developments

1.1. Amendment to the Act on Health Services

Act No. 290/2025 Coll., which amends Act No. 372/2011 Coll. on health services and about ten related statutes, including the Act on Specific Health Services, took effect on 1 January 2026. With more than three hundred individual changes, it is the most extensive revision of the Act since it entered into force in 2012.

The amended Act gives statutory definitions and a clearer place in the system to several types of care: the hospice (Section 44a), the mental health centre (Section 44b), the centre of complex care for children (Section 44f), and emergency admission (Section 44g). It puts the provision of spiritual care, volunteer activity, and the function of the hospital chaplain on an express legal footing, which reflects a wider move towards to patient centred care. Other parts of the amendment address, among other things, complaints against providers, screening programmes, and patient organisations.

Through the same Act, the system of external clinical audits at workplaces that use medical exposure to ionising radiation, governed by the Act on Specific Health Services, was reformed. The previous uniform five-year audit cycle was replaced by intervals differentiated according to the level of radiation risk, with the highest risk workplaces audited most frequently.

1.2. Public health insurance, medical devices, and electronization

Act No. 289/2025 Coll. substantially amended the Act on Public Health Insurance (Act No. 48/1997 Coll.). The Act raised the limits for the prevention funds of the health insurers, broadened reimbursement in some areas, for example white dental fillings in adulthood and home postpartum care.

A separate new statute, Act No. 288/2025 Coll. on the categorization of medical devices prescribed on a voucher, carved the categorization rules out of the Act on Public Health Insurance so that they can respond

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more quickly to technological change. It improved the availability of compensatory aids for persons with physical disabilities, including the restoration of reimbursement for certain hygienic aids from 1 May 2026 and clearer rules on the replacement of batteries for electric wheelchairs.

In the field of prescribing, the electronic voucher (ePoukaz) became fully mandatory on 1 January 2026. With narrow exceptions defined by law for emergency situations, paper vouchers for medical devices can no longer be issued, and the duty applies to all healthcare establishments regardless of their size or founder.

1.3. A specific legal regime for psychomodulatory substances

A distinctive Czech development reached full application during the reporting period. Act No. 321/2024 Coll., which amends the Act on Addictive Substances (Act No. 167/1998 Coll.), took effect on 1 January 2025, but the implementing regulations, the listing of substances, and the licensing procedures became fully operational only during 2025 and at the beginning of 2026. The Act created two new categories of substances. The first, listed psychoactive substances, works as a rapid quarantine list for newly appearing substances with an unclear risk profile; such substances may be used only for scientific and research purposes and may not be sold commercially, although possession of a small amount for personal use is not a criminal offence. The second category, psychomodulatory substances, covers substances assessed as carrying a low social and health risk, such as kratom, which are removed from the unregulated market and made subject to strict rules on sale.

The implementing regulations took effect in November 2025, namely the government regulation listing kratom and kratom extract as psychomodulatory substances and the decree setting out detailed rules on labelling, records, and good manufacturing practice. Dealing with these substances requires a permit from the Ministry of Health, and the administrative and annual fees were deliberately set at a high level in order to prevent an uncontrolled market. Sale to minors is prohibited, as is sale through vending machines and at schools, healthcare establishments, and sporting events. Internet sale is conditional on strict age verification of the buyer and on delivery into the buyer's own hands. Municipalities were empowered to regulate the use and sale of these substances through generally binding ordinances near schools. Permits for internet sale began to be issued at the end of January 2026.

1.4. Medicinal psilocybin and the partial decriminalisation of cannabis

Act No. 270/2025 Coll., which amends the Criminal Code and related statutes, including the Act on Addictive Substances and the Act on Pharmaceuticals, took effect on 1 January 2026. From that date, therapeutic psilocybin may be administered as an individually prepared medicinal product for defined therapeutic purposes in healthcare establishments, strictly in accordance with a clinical guideline issued for this purpose, while an implementing government regulation (No. 552/2025 Coll.) sets the conditions of use. The Czech Republic is among the first European countries to bring medicinal psilocybin into clinical practice, primarily for treatment resistant depression and selected serious psychiatric conditions. The same Act also introduced a

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partial decriminalisation of cannabis for personal use, allowing limited home cultivation and possession within defined limits, while sale and distribution remain prohibited.

2. Case law

2.1. Compensation for harm caused by vaccination

The most prominent judicial development was the judgment of the Supreme Court of 27 May 2026, file no. 25 Cdo 946/2024, which changed the previous restrictive practice in compensating non-pecuniary harm to health caused by mandatory vaccination and by vaccination against COVID-19. The two compensation statutes, Act No. 116/2020 Coll. on compensation for harm caused by mandatory vaccination and Act No. 569/2020 Coll. on compensation for harm caused by COVID-19 vaccination, make compensation conditional on particularly serious harm to health. The lower courts and the Ministry of Health had read this term as narrowly as the equivalent term used for secondary victims under Section 2959 of the Civil Code, which in practice required consequences comparable to death and left most claimants without compensation. In the case before the Court, a man who developed myocarditis after a third dose claimed vompensation; his claim had been rejected by the Ministry and by the courts of first and second instance, among other reasons because his hospitalisation had been short and he had been discharged in a stabilised condition.

The Supreme Court rejected this mechanical equation. The State, by introducing mandatory vaccination or by strongly promoting voluntary vaccination during the pandemic, pursues a benefit for society as a whole; where an individual bears that risk in the public interest and suffers serious harm, it is contrary to justice and to the Convention on Human Rights and Biomedicine for the State to minimise its responsibility by pointing out that the injured person is not in a coma or fully dependent. According to the Court, compensation is due where vaccination causes a medically diagnosable condition with more serious permanent consequences in the form of impairment of social life, longer incapacity for work, or quality of life.

2.2. The presence of a parent with a hospitalised child

In its resolution of 18 February 2026, file no. IV. ÚS 3773/25, the Constitutional Court clarified the relationship between the rights of patients and the operational reality of healthcare establishments. The complainant, the mother of an infant hospitalised in intensive care, sought compensation because the hospital had not allowed her to sleep at her child's bedside at night. The Court rejected the complaint and set out several interpretative rules. The right to the continuous presence of a legal representative under Section 28(3)(e) of the Act on Health Services cannot be equated with a right to stay, that is, to sleep or be accommodated, directly on a specialised ward; such a stay is always limited by the technical and material capacity of the workplace. On highly specialised wards such as intensive care units, the interest in the parent's continuous presence must yield to other legitimate interests, namely the undisturbed provision of intensive care, the hygiene and

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epidemiological regime, the safety of staff during urgent resuscitation, and the rights of the other child patients in the same room.

2.3. Protection of life during birth

Two decisions addressed the tension between the autonomy of the woman giving birth and the protection of the life and health of the child being born.

In its resolution of 15 January 2026, file no. II. ÚS 2517/23, the Constitutional Court dealt with the complaint of a woman on whom an urgent caesarean section had been performed under general anaesthesia, without her informed consent, because of acute distress of the foetus. She sought an apology and compensation for non-pecuniary harm. The Court rejected the complaint, but it emphasised that childbirth is a sensitive moment touching a woman's bodily and mental integrity, her autonomy, and her reproductive rights, and that these interests fall within the protection of private life. It acknowledged that a caesarean section without informed consent, combined with coercion or with inappropriate conduct by staff, could in some circumstances amount to an impermissible interference or to obstetric violence, although the threshold of unavoidable humiliation was not crossed in this particular case. It also indicated that a mere finding that the medical staff had acted in accordance with the rules of the profession (*lege artis*) is not by itself sufficient to exclude an unlawful interference with personality rights, and that the ordinary courts must strictly examine proportionality and the existence of an immediate danger to life.

Shortly afterwards, the Supreme Court, in a decision made public in the spring of 2026, file no. 4 Tdo 120/2026, confirmed the criminal liability of a defendant, a midwife by profession, for negligent homicide in connection with a planned home birth in the breech position, in which the newborn suffered severe brain damage and died several weeks later. The Court held that the decisive moment for the beginning of criminal law protection of human life is the start of birth, that is, the moment when the child begins to leave the mother's body. The right of parents to a free choice of the place and manner of birth is limited by the interest in a safe birth and in the protection of the life of the child being born, and where there is an immediate danger, necessary medical interventions may be carried out even against the will of the parents.

3. Concluding remarks

Taken together, the developments of this period show two consistent directions in Czech health law. The legislator has pursued the electronization of clinical processes and a reduction of administrative burden, while at the same time creating new duties for providers, distributors, and payers. The courts, for their part, have strengthened the protection of patients, both by widening access to compensation for harm caused by vaccination and by giving more precise content to the rights of parents and of the child being born, while also confirming that those rights are not without limits. The coming period will show how these changes are applied

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in practice, in particular in the still unsettled questions of the financing of new therapies and the balance between patient autonomy and the protection of life and health.

Date of submission: 22 June 2026

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A New Stage in the Development of Health Law in Georgia: Reforms in Blood Safety, Organ Transplantation, and Medical Liability

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Introduction

In recent years, Georgian health law has entered a new phase of development, particularly through substantial legislative reforms in the fields of blood safety and organ transplantation, as well as through the evolving judicial approach toward patient rights and medical liability. These developments represent far more than technical legal amendments; they reflect Georgia's broader effort to align its healthcare governance system with contemporary European standards, strengthen the protection of human dignity and patient autonomy, and establish a more transparent, accountable, and ethically oriented healthcare framework.

Within this context, particular significance attaches to the adoption of the Law of Georgia on the Quality and Safety of Blood and Blood Components and the new Law of Georgia on Human Organ Transplantation. Although both laws were adopted several years ago as part of Georgia's broader healthcare modernization agenda, their full practical implementation and entry into force are scheduled for the autumn of 2026, reflecting the extensive institutional and administrative preparations required for the functioning of the new regulatory frameworks.

Both legislative acts form part of a broader process of systemic modernization within Georgian health law and substantially transform the fragmented and outdated regulatory framework that had long failed to meet the demands of modern biomedicine, patient rights protection, and institutional healthcare governance.

1. Reform of blood safety regulation in Georgia

1.1. Fragmented regulatory framework prior to reform

Prior to the adoption of the new blood safety legislation, the regulation of blood donation and transfusion activities largely relied upon scattered administrative regulations and sector-specific rules addressing only isolated aspects of transfusion medicine. There was no integrated legal framework capable of ensuring effective supervision and safety control throughout the entire lifecycle of blood and blood components.

Particularly problematic were deficiencies concerning:

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- traceability systems;
- quality assurance mechanisms;
- haemovigilance procedures;
- donor protection standards;
- storage and transportation requirements;
- institutional oversight and supervision.

As transfusion medicine evolved and international safety standards became increasingly sophisticated, the Georgian regulatory system gradually became outdated and insufficiently coordinated. Existing legislation failed to establish unified obligations for healthcare institutions and did not adequately incorporate modern European approaches concerning patient safety, documentation standards, and institutional accountability.

In practice, this fragmented framework created inconsistencies between healthcare providers and weakened the effectiveness of state supervision.

1.2. The new legislative model

The Law of Georgia on the Quality and Safety of Blood and Blood Components fundamentally restructures the legal regulation of blood safety in Georgia by introducing a comprehensive "whole-chain" model of governance. Under this approach, safety monitoring extends throughout every stage of the transfusion process — from donation and laboratory testing to storage, transportation, distribution, and clinical use.

This model closely reflects contemporary European transfusion standards and significantly strengthens guarantees for both donor and recipient safety.

The legislation introduces detailed legal definitions concerning:

- autologous donation;
- blood components;
- plasma-derived medicinal products;
- donor assessment procedures;
- quality management obligations.

At the same time, healthcare institutions are subjected to stricter obligations regarding:

- documentation and reporting;
- infection prevention mechanisms;
- laboratory control;
- traceability systems;
- quality assurance procedures.

One of the most significant innovations of the reform is the strengthening of traceability requirements. Blood and blood components must now remain identifiable throughout the entire transfusion chain, thereby enabling rapid institutional responses in cases involving contamination, adverse reactions, or procedural irregularities.

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The law also significantly expands the supervisory role of competent authorities and imposes more rigorous compliance obligations upon blood establishments operating within Georgia.

1.3. Europeanization of blood safety governance

Of particular importance is the fact that the legislation expressly refers to harmonization with relevant European Union directives. This reflects the broader Europeanization of Georgian health law, within which patient safety and protection of human dignity increasingly occupy a central normative position.
The reform therefore represents not only a technical modernization of transfusion medicine regulation but also part of Georgia's broader legal approximation process in the context of European integration.

2. Reform of organ transplantation law in Georgia

2.1. Limitations of the previous framework

The reform of organ transplantation law likewise constitutes a transformative stage in the development of Georgian healthcare regulation.
The previous legal framework provided only a general basis for transplantation activities and failed to establish the legal, ethical, and administrative mechanisms required by modern transplantation medicine. Important issues remained insufficiently regulated, including:

- organ procurement procedures;
- organ allocation mechanisms;
- transportation logistics;
- donor and organ characterization;
- informed consent requirements;
- centralized coordination and state supervision.

As a result, the transplantation system lacked institutional coherence and did not fully correspond to contemporary European standards concerning transparency, patient protection, and ethical governance.

2.2. Establishment of a Centralized and Ethical Regulatory Framework

The new Law on Human Organ Transplantation establishes a significantly more centralized and detailed regulatory system governing both living and deceased donation.
The legislation regulates:

- organ procurement;
- transplantation procedures;
- organ transportation and allocation;
- donor and recipient protection mechanisms;

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- institutional supervision and coordination.

A particularly important aspect of the reform is its strong emphasis on ethical safeguards and the protection of human dignity.

The legislation substantially strengthens:

- informed consent procedures;
- donor autonomy protections;
- confidentiality guarantees;
- transparency in organ allocation;
- safeguards against exploitation and abuse.

These provisions reflect internationally recognized bioethical principles and align Georgian transplantation governance more closely with European legal standards.

The reform also increases the role of the state in coordinating and supervising transplantation activities. Competent authorities are granted broader powers concerning monitoring, oversight, institutional coordination, and allocation procedures.

This centralized governance model represents a substantial departure from the earlier fragmented system and aims to improve institutional accountability, transparency, and patient safety.

2.3. European integration and healthcare governance

As in the field of blood safety regulation, the transplantation reform forms part of Georgia's broader effort to harmonize domestic healthcare legislation with European Union standards.

The incorporation of principles such as traceability, centralized oversight, ethical governance, and enhanced patient rights protections demonstrates the growing influence of European healthcare governance models within Georgian law.

3. Judicial practice and the transformation of medical liability in Georgia

Alongside legislative reform, Georgian judicial practice has undergone significant transformation in recent years, particularly regarding patient rights, informed consent, and medical liability. Increasingly, Georgian courts have begun to approach healthcare disputes not merely through the lens of clinical outcomes, but through a broader assessment of procedural fairness, professional ethics, and institutional accountability.

A particularly important development in this regard is the emerging practice of the Supreme Court of Georgia concerning cases involving patient death allegedly resulting from medical negligence.

In its developing jurisprudence, the Supreme Court has emphasized that healthcare providers are under a heightened professional duty to ensure lawful, diligent, and medically appropriate treatment. Importantly, the Court has clarified that medical institutions and physicians bear responsibility not only for the technical quality

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of medical intervention but also for compliance with procedural obligations arising from patient rights legislation, including informed consent requirements and proper medical documentation.

The Court's reasoning reflects a broader transformation in Georgian medical liability law. Traditionally, medical disputes were assessed primarily through the narrow question of whether a physician's actions directly caused physical harm or death. However, recent judicial practice demonstrates a gradual expansion of the analytical framework toward evaluating whether healthcare providers fulfilled their broader professional and ethical obligations.

In cases involving patient death, the Supreme Court has attached particular significance to:

- the completeness and accuracy of medical documentation;
- compliance with professional standards of care;
- proper communication with patients and family members;
- observance of informed consent procedures;
- timely diagnosis and monitoring obligations;
- institutional transparency and accountability.

The Court has repeatedly emphasized that medical documentation constitutes not merely an administrative formality but an essential safeguard for patient rights and legal certainty. Deficiencies in documentation may therefore become highly relevant when assessing whether healthcare providers complied with professional standards and statutory obligations.

Equally important is the Court's developing approach toward the burden of proof in medical negligence disputes. Georgian judicial practice increasingly recognizes the structural imbalance between patients and healthcare providers in access to medical information and technical expertise. Courts have acknowledged that physicians and medical institutions bear a professional obligation to demonstrate that medical services were provided lawfully, properly, and in accordance with professional standards.

This jurisprudential development is particularly significant in cases involving patient death, where evidentiary difficulties often arise due to informational asymmetry between medical institutions and claimants.

The Supreme Court's approach also demonstrates the increasing ethicalization of medical liability within Georgian law. Judicial review now extends beyond purely clinical considerations and increasingly incorporates broader principles of:

- patient autonomy;
- human dignity;
- transparency;
- procedural fairness;
- ethical medical governance.

Consequently, modern medical liability disputes in Georgia are no longer assessed exclusively through the existence of adverse clinical outcomes. Rather, courts increasingly examine whether healthcare institutions respected the procedural and ethical dimensions of patient care throughout the treatment process.

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This emerging jurisprudence reflects the broader Europeanization of Georgian health law and demonstrates the judiciary's growing role in strengthening patient rights protections and institutional accountability within the healthcare system.

Conclusion

Taken together, these legislative and judicial developments demonstrate that Georgian health law is currently undergoing a profound systemic transformation.

The reforms concerning blood safety and organ transplantation significantly modernize the legal framework governing healthcare regulation and align Georgian law more closely with contemporary European standards. At the same time, evolving judicial practice reflects the growing importance of patient rights, informed consent, ethical governance, and institutional accountability within Georgian healthcare law.

This transformation is grounded in the strengthening of human dignity, patient autonomy, procedural fairness, and state oversight mechanisms. It also reflects Georgia's broader aspiration toward integration with the European legal and healthcare space.

Ultimately, the ongoing modernization of Georgian health law represents not only a legal reform process but also a broader shift toward a more transparent, patient-centered, and ethically grounded healthcare governance model.

Date of Submission: 22 May 2026

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Country Report: Ireland

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1. Access to termination of pregnancy

Within the past two months, two different legislative bills proposing to amend the existing legislation regarding access to termination of pregnancy in Ireland have been introduced in An Dáil Éireann. Both are private member's bills.[1]

2. Reproductive Rights (Amendment) Bill 2026

The first bill, the Reproductive Rights (Amendment) Bill 2026, was introduced on 28th April 2026. The purpose of this Bill was to "enact recommendations of the Marie O'Shea report into the operation of legislation on the termination of pregnancy, providing clarity on terminations for medical reasons, removal of the 3 day waiting period, and ending the criminalisation of doctors."[2]

The proposed amendment regarding clarity on termination for medical reasons,[3] namely for fatal foetal abnormalities, sought to remove the current requirement under section 11(1) of the Health (Regulation of Termination of Pregnancy) Act 2018 that two medical practitioners must confirm that there is "…present a condition affecting the foetus that is likely to lead to the death of the foetus either before, or within 28 days of, birth."[4] The rationale for removing the 28 day criteria is to prevent the difficulties arising from this requirement of certainty which has meant that women who have received a fatal foetal abnormality diagnosis have had to travel outside the jurisdiction to access termination of the pregnancy.[5]

During the Dáil debate of the Reproductive Rights (Amendment) Bill, the Minister for Health noted "significant legal and operational concerns" regarding removal of the requirement for two clinicians to be involved in decisions regarding a termination where the life or health of a mother is at risk,[6] and reducing the number of doctors required to examine a pregnant women in relation to termination of pregnancy involving a

[1] For further information on private member's bills, please refer to https://www.oireachtas.ie/en/procedure-guide-dail/legislation/private-members-bill/ and https://www.citizensinformation.ie/en/government-in-ireland/houses-of-the-oireachtas/legislation/
[2] Reproductive Rights (Amendment) Bill 2026 – available at https://www.oireachtas.ie/en/bills/bill/2026/40/
[3] Section 3(a) Reproductive Rights (Amendment) Bill 2026
[4] Section 11(1) of the Health (Regulation of Termination of Pregnancy) Act 2018 – available at https://www.irishstatutebook.ie/eli/2018/act/31/section/11/enacted/en/html#sec11
[5] Deputy Holly Cairns, Dáil Éireann debate – Tuesday 28th April 2026 - Reproductive Rights (Amendment) Bill 2026: First Stage – available at https://www.oireachtas.ie/en/debates/debate/dail/2026-04-28/10/ and https://www.socialdemocrats.ie/holly-cairns-introduces-legislation-to-amend-our-abortion-law/
[6] Section 2 – Clarity in regards to risk to life or health, Reproductive Rights (Amendment) Bill 2026

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fatal foetal abnormality.[1] The Minister for Health also noted concerns regarding the proposed decriminalisation of medical professionals.[2] The Reproductive Rights (Amendment) Bill 2026 was defeated in An Dáil Éireann by 85 votes against, 30 in favour, at the second stage on the 13th May 2026.[3]

3. Health (Abolition of Three Day Wait Rule) (Amendment) Bill 2026

A second private member's bill, the Health (Abolition of Three Day Wait Rule) (Amendment) Bill 2026 was introduced on 7th May 2026. The purpose of this Bill is to amend section 12 of the Health (Regulation of Termination of Pregnancy) Act 2018 and abolish the mandatory three day wait rule for access to a termination of pregnancy. A free vote on the Health (Abolition of Three Day Wait Rule) (Amendment) Bill 2026 was held on Wednesday 17th June 2026 with 86 ministers voting in favour (70 ministers voted against) of removing the mandatory three day waiting rule for access to termination of early pregnancy.[4] This bill will now progress to the Committee Stage (Third stage in An Dáil Éireann).

Date of submission: 19 June 2026

[1] Section 3 – Terminations for medical reasons, Reproductive Rights (Amendment) Bill 2026.
[2] Section 6 – Ending criminalisation of medical professionals, Reproductive Rights (Amendment) Bill 2026.
[3] Reproductive Rights (Amendment) Bill 2026: Second Stage (Resumed) [Private Members].
Dáil Éireann - 13 May 2026 - https://www.oireachtas.ie/en/debates/vote/dail/34/2026-05-13/110/ .
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DATA SUMMIT on the Implementation of the EHDS Regulation in Italy

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Italy aims to have the European Health Data Space (EHDS) fully operational by 2029, enabling the large-scale use of data and artificial intelligence in healthcare. During the DATA SUMMIT 2026, hosted by the Senate of the Italian Republic last March, participants took stock of the DATA PACT adopted in June 2025 to facilitate the full and proper implementation of Regulation 2025/327.

The DATA PACT serves as a compass to guide innovation with operational proposals for the collection, sharing, and use of health data for primary and secondary purposes. It represents a voluntary and participatory forum that brings together all interested stakeholders: public institutions (Ministry of Health, European Commission, parliamentary committees, and regions); healthcare facilities (hospitals, research centers); businesses and industry (pharmaceutical companies, developers of health products and services, ICT companies); citizens and patients (patient associations and individual citizens); academia (universities and experts). The goal is to share experiences and knowledge, promote a better understanding of the regulations, and support, at both the national and European levels, the transition to the EHDS.

The DATA PACT is structured around five main points:

1) facilitate and promote the implementation of the pertinent parts of the EHDS Regulation by June 2026 and Italy's accession to the MyHealth@EU and HealthData@EU platforms;[1]

2) build trust and collaboration within the healthcare ecosystem through a community of practice among various stakeholders;

3) promote responsible innovation by incentivizing the early adoption of technical standards (privacy by design, privacy by default), governance procedures, and control tools;

4) establish Health Data Access Bodies by defining roles, responsibilities, and common workflows, as well as by training personnel and developing expertise dedicated to health data access;

5) foster public-private partnerships through agreements between hospitals, research institutes, startups, and institutions to share anonymized data, accelerating the development of predictive and personalized tools

[1] Art. 105 of the EHDS Regulation foresees the following implementation phases: 1) March 26, 2027 for Digital Health Authorities, National Contact Points (NCPs), and the EHDS Board; 2) March 26, 2029 for the rules on primary use, EHR systems, and secondary use regarding certain types of data; 3) March 26, 2031 for the rules on primary use, EHR systems, and secondary use regarding the remaining types of data; 4) March 26, 2034 for the participation of third countries in HealthData@EU.

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within the prevention campaigns based on heterogeneous datasets (medical records, environmental data, lifestyle data) and their secure integration.

The DATA SUMMIT recognizes institutional clarity, data quality, process efficiency, and trust as priorities. Compared to other Member States such as Belgium and Finland, however, Italy is still in a transitional phase. The progress made in this area with the Electronic Health Record and the Health Data Ecosystem is significant,[1] but the system remains highly fragmented, primarily due to the regional organization of healthcare. In this regard, there is an evident, yet physiological difficulty in reconciling the Italian constitutional framework with the creation of a fully interoperable national infrastructure. On the other hand, while the centralization of processes brings significant benefits in terms of efficiency, it also true that the creation of a single authority responsible for managing and regulating data use entails considerable risks for the effective protection of personal data.

Moreover, the DATA SUMMIT highlighted that the digital transition in healthcare is not solely linked to technological development. Secure digital infrastructure, adequate professional expertise and clear and transparent authorization procedures are also required to foster public trust and the secondary use of data. At the same time, the ongoing systemic transformation of the healthcare sector implies profound institutional and social adjustments. It is not merely a matter of adopting new technologies, but of redefining how the healthcare system produces, shares, and utilizes knowledge.

The topics addressed by the DATA SUMMIT and the DATA PACT are at the core of the European Health Union. The ability to collect and process data is essential for supporting and promoting research, innovation, and the quality of care, but is invariably tied to the constitutional structure of each Member State. Ensuring a viable effective digital governance for the primary and secondary use of health data is indeed one of the most prominent challenges linked to the creation of the EHDS and the correct and uniform application of Regulation 2025/327. The necessary institutional reforms at the domestic level require attentive scrutiny and ample discussion, with the involvement of all potential stakeholders.

In this sense, initiatives like the DATA SUMMIT and the DATA PACT are certainly welcome and should be promoted (and advertised) in all Member States.

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[1] The Health Data Ecosystem (EDS) is the national infrastructure that, based on the Electronic Health Record 2.0, will transform clinical documents into structured, searchable data for 59 million citizens. It adopts a federated architectural model: data remains in the regional systems where it is generated, but becomes interoperable through a secure national infrastructure.

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Health Law in Lithuania: Recent Legal and Policy Developments

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This is a concise overview of recent legal and policy developments influencing health law and health governance in Lithuania:

- On 5 May 2026, Lithuania, Latvia and Estonia signed a joint Baltic declaration in Vilnius, Lithuania, on strengthening regional health system resilience. The declaration was adopted during the first international strategic conference "Resilient Medicine 2026" and focuses on preparedness for large-scale crises, hybrid threats and armed conflict. The Baltic States committed to closer cooperation in joint planning of civilian health protection systems, regional medical training programmes, and a coordinated approach to medical stockpiles and reserves. The declaration also highlights the need to strengthen secure information exchange, cybersecurity and resilience against disinformation in crisis management. Particular attention is given to resilient supply chains for pharmaceuticals, blood components and critical medical equipment. Overall, the initiative aims to integrate civilian healthcare more closely into the broader defence and crisis-response architecture of the Baltic region.
- From 1 May 2026, Lithuania introduced new rules aimed at eliminating unjustified patient co-payments for healthcare services covered by public funds. Healthcare institutions that have contracts with the health insurance funds must ensure that insured patients with a valid referral receive specialist services without additional charges. The reform seeks to improve transparency and prevent misleading practices concerning whether services are publicly funded or privately paid. Institutions are required to publish clear information, both on-site and online, about publicly covered services and the prices of medical devices. Patients may still voluntarily pay for non-medical comfort services or choose more expensive medical devices, but only after being properly informed about publicly covered alternatives. May 2026 is a transitional period, so some uncertainty may arise as healthcare institutions adjust to the new requirements.
- On 15 April 2026, the Lithuanian Government broadly endorsed a proposal prepared by the Ministry of Health to restrict the sale or transfer to minors of non-alcoholic beverages whose names refer to types of alcoholic drinks. The initiative is intended to protect children and adolescents from products that imitate alcohol culture and may contribute to early normalisation of alcohol consumption. The proposed amendments would introduce administrative liability for non-compliance. The measure would extend Lithuania's existing restrictions, in force since 2019, on products for children and adolescents whose design imitates alcoholic drinks or their packaging. The proposed regulation is aimed only at protecting minors and would not limit

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adults' ability to buy or consume such non-alcoholic beverages. Since the amendments may qualify as a technical regulation, the Government proposes notifying the European Commission and postponing adoption for three months.

- On 9 April 2026, the Lithuanian Parliament was presented with a new draft version of the Law on Assisted Reproduction. The proposal would liberalise access to assisted reproduction services by opening infertility treatment to unmarried heterosexual couples and women who are not in a couple. It would also expand public funding for fertility preservation services and embryo storage, and simplify the rules on the import and transit of gametes and embryos. The draft introduces a new possibility to bury or cremate embryos, which the Ministry presents as a measure respecting human dignity and personal convictions. The Ministry emphasises that the proposal does not introduce commercial trade in gametes; surrogacy would remain categorically prohibited. After presentation, the draft was approved for further consideration, with the Health Affairs Committee appointed as the lead committee.
- On 24 March 2026, the Lithuanian Ministry of Health approved funding conditions for a project introducing an innovative mental health case management model for children and adolescents. The new model will be developed, tested and evaluated within primary outpatient mental health care, with the aim of ensuring more continuous and coordinated support. Around 500 children and adolescents are expected to receive services, particularly those facing suicide risk or severe mental and behavioural disorders. A central role will be given to mental health case managers, who will coordinate care, maintain contact with the child and family, support treatment continuity and respond to changes in the child's condition. The project will also include specialist training, supervision and practical implementation in healthcare institutions across Lithuania. Funded under the Child Guarantee initiative with EUR 1.7 million from EU and national co-financing, the project is expected to lead to a methodological document enabling wider national application of the model.

Main sources: The Ministry of Health of Lithuania: https://sam.lrv.lt/
The Parliament of Lithuania: https://www.lrs.lt/

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Poland: Selected recent developments in health law

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1. Lex Charlatan – protection against pseudo-treatment and medical misinformation

A few years ago, news spread across Poland of the death of a six-year-old boy suffering from acute lymphoblastic leukaemia – a cancer that is curable in 90% of children. The child was taken to a quack somewhere in southern Poland. The quack treated him with non-existent vitamins (e.g. B16). Although 'pseudo-treatment' does not always end as tragically for the patient as in this case, fraudsters are increasingly using modern technologies, AI and social media, employing highly aggressive pseudo-medical manipulation and promoting alleged cures that are inconsistent with current medical knowledge.

To counter this, on **12 May 2026, the Polish government adopted a draft amendment to the Act on Patients' Rights and the Patients' Rights Ombudsman (the so-called Lex Charlatan).** The draft is currently being debated in the Sejm. The amendment strengthens the powers of the Patient Ombudsman, who will be able to respond more swiftly to illegal and dangerous practices, including those of entities operating without the required registration. The Ombudsman will gain the power to issue public warnings about practices that may endanger patients' health or lives, and to issue interim orders requiring the immediate cessation of harmful activities even before the conclusion of formal proceedings. The Ombudsman's role in civil proceedings concerning breaches of patients' rights, including cases involving a patient's death, is also strengthened. The draft also provides for higher penalties – up to PLN 1 million for violating patients' collective rights and up to PLN 100,000 for failing to cooperate with the Ombudsman. Penalties may also be imposed if the activity is terminated just before a decision is issued.

The provisions of the amendment define what constitutes so-called pseudo-medical practice, i.e. activities involving, amongst other things:

- offering 'treatment' by persons without medical qualifications;
- promoting methods that lack scientific validation;
- discouraging patients from seeking treatment in accordance with current medical knowledge.

When the law enters into force, it will be prohibited to attribute healing properties to methods that are not healthcare services, e.g. unproven therapies advertised as effective treatments for diseases. The new regulations will also cover cases of so-called medical misinformation, provided they are linked to the pursuit of financial or personal gain. This includes, amongst other things, the public dissemination of false information about treatment or discouraging therapies based on medical knowledge. The draft does not restrict activities

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such as herbalism, cosmetology, podiatry, yoga or massage. The aim of the bill is to ensure safety and prevent situations where unproven methods are unjustifiably attributed with therapeutic effects, or where their promotion encourages patients to forego diagnosis and conventional therapies.

2. Electronic health records (EDM) and the development of e-health services

Significant changes in Polish healthcare law are linked to the digitisation of the healthcare system, the use of AI tools, and the increasing complexity of medical records. Although the development of e-health services is generally beneficial for patients, it must be borne in mind that e-health services require appropriate safeguards for the processing and storage of medical data, as well as for the verification and control of AI-powered tools, in accordance with EU law and Council of Europe standards.

Electronic medical records currently constitute (though often still in theory) the primary, standard form of medical record-keeping in Poland. For several years, healthcare facilities have had a legal obligation to make documents available in this form, yet many still fail to do so. The reasons cited include technological and financial barriers, as well as the lack of legislative consequences that would incentivise healthcare providers to introduce EDM.

On **15 May 2026, the Polish Sejm passed a bill amending certain acts in connection with the development of e-health services.** The bill currently awaits the President's signature. The new regulations significantly expand the national system, introducing several solutions, of which only a selection is discussed below:

- Amendments aimed at introducing a new type of electronic medical record (EDM), namely the patient card. The structure of the Polish patient card is based on the eHealth Network guidelines on the electronic exchange of health data, drawn up pursuant to Directive 2011/ 24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, pp. 45–65), compiled in the Patient Summary and described in the eHDSI Requirements Catalogue. The aim, therefore, of introducing a document in Poland known as the patient card, the equivalent of the EU Patient Summary, is not only to enable Polish healthcare professionals to access their patients' basic data, but also to facilitate the transfer of this data to recipient countries, so as to make it easier for patients to seek medical consultations or undergo treatment in those countries.
- One of the tools being implemented is the e-Patient Profile, which is intended to enable primary care doctors to provide more comprehensive and coordinated healthcare and to intuitively access a patient's medical history. This is intended to eliminate the need to manually search through the resources of various systems. The system is to contain data aggregated from various ICT systems within the healthcare information system and preliminarily analysed by AI-powered tools.
- The Intelligent Services Platform is intended to be a tool supporting doctors' decision-making based on certified AI tools for medical diagnosis in several specific areas.

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Current Legal Issues in the Field of Health Law in the Republic of Latvia

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The Biobanks Law enters into force, opening new opportunities for research development and the implementation of precision medicine in the Republic of Latvia

At present, the most significant development in the Republic of Latvia's health sector is the adoption of the Biobanks Law, which strengthens a human-rights-based regulatory framework and reinforces patient rights.

On June 9th 2026, the Biobanks Law entered into force in the Republic of Latvia, establishing for the first time a comprehensive legal framework for the collection, storage, processing, and use of human biological samples and related data for scientific and medical purposes. The new regulation is intended to promote biomedical research and facilitate the implementation of precision medicine in the healthcare system.

Biobanks are organized collections of human biological material, such as blood, tissue, or cell samples, together with associated health and genetic information. These resources are essential for advancing scientific knowledge, developing innovative therapies, and improving disease prevention and diagnosis. Prior to the adoption of the Biobanks Law, the Republic of Latvia lacked a unified legal framework governing these activities, creating challenges for research institutions and international cooperation.

The Biobanks Law sets out the principles for the establishment and operation of biobanks, as well as provides for strict requirements for data protection, compliance with ethics, and the safeguarding of donors' rights. It particularly emphasizes the importance of informed and dynamic consent, ensuring that individuals have control over the use of their biological samples in research.

See here for more information:

- https://likumi.lv/ta/id/368558-biobanku-likums
- https://lvportals.lv/skaidrojumi/390827-stajas-speka-biobanku-likums-tas-paver-iespejas-petniecibas-attistibai-un-precizijas-medicinas-ieviesanai-2026

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Report from Spain.
A Mid-Year Review of Health Law Developments in Spain

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This report provides an overview of the principal health law developments that have taken place in Spain during the first half of 2026. It examines recently enacted legislation and regulatory measures that have entered into force.

1. Legislative developments

In this first section, mention should be made of Royal Decree-Law 11/2026 of 12 May, amending the contribution payable by users and their beneficiaries in respect of outpatient pharmaceutical provision, which amends Article 102 of the consolidated text of the Law on Guarantees and Rational Use of Medicines and Medical Devices (Royal Legislative Decree 1/2015), governing outpatient pharmaceutical co-payment.

Its purpose is to strengthen the equity of the system and to prevent economic circumstances from constituting an effective barrier to access to necessary medicines, particularly for persons with chronic conditions — in other words, to ensure that no patient discontinues treatment for financial reasons.

Furthermore, as the preamble expressly indicates, the system of contribution bands is widened from three to six levels for persons holding the status of active insured person and their beneficiaries. And from three to four levels for Social Security pensioners and their beneficiaries. For pensioners, the general 10% structure is retained (save for those whose income exceeds €100,000, who are subject to 60%), and a 40% rate is added for foreign nationals neither registered nor authorised as residents in Spain, as referred to in Article 3 ter of Law 16/2003. The reform also introduces a substantial change to the exemption regime for the lowest-income pensioners. Thus, in place of the previous fixed income threshold, the exemption is now linked to entitlement to the supplements for pensions below the minimum level under Article 59 of the consolidated text of the General Social Security Act (Royal Legislative Decree 8/2015).

2. Government regulatory developments

First of all, particular attention should be paid to Royal Decree 180/2026 of 11 March, regulating recognition of the right to health protection and healthcare funded from public funds for foreign nationals who, while present in Spain, do not hold legal residence in Spanish territory.

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The instrument, implementing Article 3 ter of Law 16/2003 on cohesion and quality of the National Health System, regulates the procedure for recognising the right to health protection and healthcare funded from public funds for foreign nationals who, while present in Spain, lack legal residence.

Royal Decree 180/2026 implements by regulation Article 3 ter of Law 16/2003 on cohesion and quality of the National Health System, establishing a single, uniform administrative procedure for recognising the right to healthcare funded from public funds for foreign nationals without legal residence in Spain. Its most significant procedural features are as follows:

a) No requirement of a minimum prior period of residence (without prejudice to the special two-year transitional regime applicable to transplant waiting lists).
b) Flexible proof of identity and habitual residence through a broad range of documents alternative to municipal registration.
c) Issuance of a provisional document enabling immediate access to healthcare from the moment the application is lodged.
d) A three-month decision period, with positive administrative silence where the procedure is initiated at the applicant's request, and negative silence where initiated ex officio.
e) No invoicing of healthcare already provided where the substantive requirements are subsequently shown to have been met.
f) Indefinite validity of the accreditation document and portability of the right between Autonomous Communities without the need for fresh proceedings.
g) Article 26 of Royal Decree 8/2008 is also amended to extend the right to healthcare to Spanish nationals by origin residing abroad during temporary stays in Spain (and to certain family members), under a regime of three months renewable for a further three months, subject to a maximum of six months per year.

Furthermore, the article 4 lists groups warranting special protection — minors, pregnant women, applicants for international protection, victims of gender-based violence and of trafficking, cases of notifiable diseases, and voluntary termination of pregnancy — whose right is recognised in accordance with their specific governing rules.

Lastly, Royal Decree 180/2026 introduces two further elements of practical significance for healthcare management:

1º.- Allocation of a single, common personal identification code (CIP-SNS), permanently linked to the clinical information of unregistered foreign nationals and of the groups listed in Article 4 (seventh additional provision).

2º.- Strengthened safeguards for persons with disabilities, both as regards the signing of the responsible declaration (support in the exercise of legal capacity, accessible formats) and under the sixth additional provision, which refers to the specific rules on disability (Royal Legislative Decree 1/2013 of 29 November,

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and Royal Decree 383/1984 of 1 February establishing and regulating the special system of social and economic benefits) without altering their substantive content.

Finally, regarding this instrument, it should be noted that the special healthcare agreement remains in force, and that Royal Decree 1192/2012 of 3 August, governing the status of insured person and beneficiary for the purposes of healthcare in Spain funded from public funds through the National Health System, is partially repealed.

Secondly, it is worth noting Royal Decree 239/2026 of 25 March, amending Royal Decree 1277/2003 of 10 October, laying down the general framework for the authorisation of healthcare centres, services and establishments.

Under this instrument, which implements article 27.3 of Law 16/2003 of 28 May on cohesion and quality of the National Health System, patient safety ceases to be a merely recommended quality criterion and becomes a legally binding requirement. It is established as a standard applicable to all healthcare centres as a condition of authorisation. And, for the first time, Royal Decree 1277/2003 expressly regulates a guarantee of professional qualification and competence as a substantive condition of operation — not merely of initial authorisation — of healthcare centres.

In addition, the following key aspects of the instrument should be examined:

a) A new Article 7 is inserted, requiring centres to ensure that care is provided by professionals holding the official qualification and the competences appropriate to each care unit.

b) A minimum standard of a basic state-wide character is established, which may be supplemented but not reduced by the Autonomous Communities.

c) A documentary obligation to keep up-to-date information on all healthcare staff — regardless of their legal relationship or the manner in which services are provided, which expressly extends to externally engaged personnel, third-party contractors and service providers — together with a personal file recording the qualification and specialty of each professional, without prejudice to the notification owed to the State Register of Healthcare Professionals (Royal Decree 640/2014).

d) An obligation to provide training and information to newly appointed professionals on the centre's safe-practice arrangements.

e) As regards its temporal application and transitional regime, the Royal Decree enters into force on 1 July 2026 and establishes two further staggered deadlines: six months from entry into force (i.e. until 1 January 2027) for centres, services and establishments themselves to hold up-to-date information on their staff in accordance with the new Article 7.2, and one year from entry into force (until 1 July 2027) for the Autonomous Communities to adapt their range of services to the new definitions set out in Annexes I and II.

Thirdly, Royal Decree 415/2026 of 27 May, regulating the assessment of health technologies, establishes the System for the Assessment of Health Technologies, structured around a Governance Council and two functionally independent Offices: one for medicines, integrated within the Spanish Agency for Medicines and

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Health Products (AEMPS), and another for non-pharmacological health technologies. It constitutes the instrument by which Spain implements Regulation (EU) 2021/2282 as regards the institutional architecture of the national system.

The substantive contributions are as follows:

- Formal separation between the assessment function and the decision-making function — the Offices produce technical reports without taking part in financing or pricing decisions.
- The widening of the scope of assessment to encompass both clinical and non-clinical aspects.
- The establishment of statutory deadlines (70+70 days for medicines; 140 days, or 50 days for re-assessments, for non-pharmacological technologies).
- The promotion of the use of real-world data through the National Health Data Space, processed on a preferentially anonymised basis and, only where this would not allow the purpose of the assessment to be achieved (temporal traceability or the attribution of data from different sources to the same individual), on a pseudonymised basis.

Finally, mention should be made of Royal Decree 467/2026 of 10 June, regulating the return and destruction of narcotic and psychotropic substances and of narcotic medicines by pharmacies and pharmacy services, which constitutes the first unified regulation governing the management of narcotics in community and hospital pharmacies.

It is the first instrument to regulate, in a unified manner, the return and destruction of narcotic and psychotropic substances and of narcotic medicines for human use by pharmacies and pharmacy services. The instrument repeals the Resolution of 2 December 1983 of the Directorate-General for Pharmacy and Medicines, fixes a five-year document retention period, and strengthens traceability by means of three annexes (a responsible declaration by the pharmacy proprietor, a certificate from the Official College of Pharmacists, and a declaration from the collection point).

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Country Report: United Kingdom

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The first part of 2026 has seen various significant reforms and case law developments with potential for long-reaching effects. A selection is discussed here.

1. Abortion

In England and Wales, sections 241 and 242 of the Crime and Policing Act 2026 now make provision, respectively, to remove women from the criminal law related to abortion, and for pardons and criminal records of women prosecuted under abortion law.

In March 2026, the Scottish Government reached out to stakeholders to seek views on the recommendations of the Expert Group on Abortion Law Reform in Scotland, which had published its report in November 2025 (see December 2025 UK report).

For new commentary on abortion law across the UK, see Stephanie Palmer, *Women's Bodies, Abortion Law in the UK and the Right to Abortion in Emergencies*.

2. Assisted Dying

In England and Wales, the Terminally Ill Adults (End of Life) Bill 2024–25, introduced by Kim Leadbeater MP, made provision for adults who are terminally ill and reasonably expected to die within 6 months to request, and lawfully be provided with, assistance to end their own life. Having successfully passed from the House of Commons to the House of Lords in summer 2025, the Bill ran out of parliamentary time at committee stage in the House of Lords prior to prorogation (April-May 2026) due to a record number of amendments. For commentary, see Chay M. Burt, *Terminally Ill Adults (End of Life) Bill 2024–25: A Commons milestone and a Lords reckoning*.

In the current parliamentary session, Lauren Edwards MP has indicated that she intends to bring back the aforementioned Bill as a Private Member's Bill. It has been considered that supporters of the Bill may use the Parliament Act for enactment – this would be a novel approach. For commentary, see Matthew England (Hansard Society), *Must MPs choose between improving the assisted dying bill and using the Parliament Act?*

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The Assisted Dying for Terminally Ill Adults (Scotland) Bill fell on 17 March 2026 at Stage 3, the final stage of parliamentary scrutiny in the Scottish Parliament. Following an emotional debate, a small majority of Members of the Scottish Parliament (MSPs) voted against the Bill. Following prorogation of the Scottish Parliament for elections in May 2026, a new bill could be put forward. For commentary, see Richard Brant, *The End of the Assisted Dying (Scotland) Bill.*

3. Best interests

In *Lesley Barnor Townsend v Epsom and St Helier University Hospitals NHS Trust*, the Court of Appeal provided authoritative clarification of a distinction drawn between "clinical decisions" and "best interests decisions", thus when disputes involving life-sustaining treatments for adults who lack capacity must be brought before the Court of Protection. For practitioner comment, see here. Permission to appeal to the UK Supreme Court was lodged in April 2026.

4. Deprivation of Liberty / Devolution

In a landmark ruling, *A Reference by the Attorney General for Northern Ireland of a devolution issue under para 34 of Sch 10 to the Northern Ireland Act 1998*, the UK Supreme Court unanimously provided a new meaning of "deprivation of liberty" which has implications across the UK.

The UKSC considered the question of whether the Minister of Health for Northern Ireland has the power to revise the Deprivation of Liberty Safeguards Code of Practice, and whether such revision would be compatible with Article 5 ECHR, and therefore within the Minister's powers. The Minister intends to revise the Code so that these persons can give valid consent to their confinement, even though they lack capacity, through the expression of their wishes and feelings. The proposed revision would be in conflict with the UKSC's 2014 judgment in *Cheshire West*, which adopted the approach of an "acid test" for defining a deprivation of liberty. With *A Reference*, the UKSC has overruled *Cheshire West*.

5. Loss of earnings for a negligently-injured young child

In *CCC v Sheffield Teaching Hospitals NHS Foundation Trust*, the UKSC considered the question of whether a young child with a shortened life expectancy from a negligently inflicted injury can recover damages for the loss of earnings in the 'lost years'. This is the period between the date at which the child is now expected to die, and the date at which the child would probably have died had their injury not happened. THE UKSC overruled an earlier Court of Appeal judgment, which had considered that loss of earnings would not be available for young children. For UKSC summary see here, and academic commentary here.

6. Mental Health

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The Mental Health Act 2025 received Royal Assent on 18 December 2025. It amends and significantly modernises the Mental Health Act 1983, but does not replace it. (For practitioner commentary, see here).

7. NHS ministers

There are recent changes in government-level oversight of the NHS in England, Wales, and Scotland.

In England, the Health Bill was presented to the UK Parliament in May 2026. This makes provision for abolishing NHS England, and restoring significant power to the Secretary of State for Health and Social Care. As such, it is the largest "top-down reorganisation" of the NHS since the Health and Social Care Act 2012, which established NHS England as an arms'-length body designed to insulate the NHS from day-to-day ministerial intervention. Wes Streeting MP was the Secretary of State who introduced this, but he resigned with its introduction – James Murray MP, as the new Secretary of State, now has responsibility for steering the Bill through parliament. For consideration of some of the implications, see here.

Elections to the Welsh Parliament (Senedd) in May 2026 have resulted in an historic political shift from Labour to a minority government comprising Plaid Cymru and the Greens. The Minister for Health and Care in Wales is now Mabon ap Gwynfor MS, who has previously indicated that reforming governance of the NHS in Wales will be a priority. There are now two Deputy Ministers as well – for Public and Preventative Health, and for Social Care, Mental Health and Women's Health.

Elections to the Scottish Parliament in May 2026 resulted in a Scottish National Party-led government. Following the elections, the Scottish Cabinet Secretary for Health and Social Care is supported by two ministers with portfolios for Community Care, and Mental Wellbeing, Public Health, Sport, Alcohol & Drugs.

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Recent Developments in Ukrainian Health and Pharmaceutical Law in 2026

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Introduction

In 2026, Ukrainian health and pharmaceutical law continued to develop in several key directions: the institutionalization of mental health policy, annual updating of the public healthcare financing framework, more detailed pharmaceutical licensing rules, further digitalization of prescriptions, and the gradual introduction of a national medicines verification system. These developments reflect the continuing transformation of the Ukrainian healthcare system, including its regulatory, institutional and digital components.

1. Mental health as a separate field of health governance

One of the most systemic developments is the implementation of the Law of Ukraine "On the Mental Health Care System in Ukraine" No. 4223-IX of 15 January 2025. Although adopted in 2025, the law is directly relevant for 2026 because it enters into practical operation after a transitional period: the law provides that it enters into force on the day following its publication and is put into effect one year after publication.

The law defines the legal, organizational, economic and social foundations of the mental health care system in Ukraine. Its stated aims include accessibility and quality of services, protection of the rights of people with mental disorders or other mental-health-related problems, prevention of mental disorders, promotion of psychological well-being and removal of factors that negatively affect mental health.

The act shifts the legal framework from a narrow psychiatric-care model to a broader mental health system. It provides for the establishment of a National Commission on Mental Health as a permanent collegial public-law body and assigns it functions such as participation in regulatory drafting, policy monitoring, coordination, international cooperation, certification of mental health professionals, and maintenance of registers of service providers and self-regulatory organizations. The law also introduces electronic registers in the field of mental health, with reference to legislation on personal data protection, information security and public electronic registers.

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2. The 2026 Programme of Medical Guarantees

The annual Programme of Medical Guarantees remains the key legal and financial instrument through which Ukraine purchases publicly funded healthcare services. For 2026, the Cabinet of Ministers approved the relevant procedure by Resolution No. 1808 of 31 December 2025, which entered into force in January 2026.

According to the National Health Service of Ukraine, the 2026 Programme of Medical Guarantees consists of 46 service packages, covering areas such as primary care, emergency medical care, maternity and childbirth care, specialized medical services and other priority areas. The 2026 Programme of Medical Guarantees reflects the continued functioning of Ukraine's purchaser-provider model of public healthcare financing, while the annual revision of service packages allows the system to respond to demographic, clinical and wartime challenges.

The 2026 framework also confirms the continuing role of the National Health Service of Ukraine as the central purchaser of services under the state-guaranteed benefits package. In legal terms, the Programme of Medical Guarantees is not merely a budgetary mechanism. It also defines access to publicly funded healthcare, contractual conditions for providers, tariff logic and the scope of state-guaranteed medical services.

3. Pharmaceutical licensing and access to medicines

Several changes in pharmaceutical licensing became relevant in 2026. The Cabinet of Ministers amended the Licensing Conditions for manufacturing, wholesale and retail trade, and import of medicinal products, including by Resolutions No. 1802 and No. 1803 of 26 December 2025, both of which were designed to enter into force after a two-month period.

Resolution No. 1802 introduced specific rules for pharmacies located in the premises of state or municipal healthcare institutions. In particular, such pharmacies are limited to medicines included in the National Price Catalogue and meeting certain price-related criteria. This connects pharmaceutical licensing with price transparency and affordability of medicines.

Resolution No. 1803 created a licensing framework for retail trade in over-the-counter medicines at petrol stations. It introduced requirements concerning the person responsible for the quality system of medicinal products and required specific information on material, technical and personnel capacity for this type of retail activity.

The Cabinet of Ministers further amended the Licensing Conditions by Resolution No. 275 of 2 March 2026. These amendments updated several licensing forms and introduced additional documentation requirements, including accessibility information for places of pharmaceutical activity. They also further detailed the regulatory conditions for the sale of over-the-counter medicines in the premises of petrol stations.

4. Electronic prescriptions, reimbursement and price information

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Digital prescription rules also changed in 2026. Amendments introduced by Ministry of Health Order No. 1924 of 19 December 2025 to Section IV of the Rules for prescribing medicinal products became applicable from 2 January 2026. Further amendments introduced by Ministry of Health Order No. 1969 of 30 December 2025, which entered into force on 26 January 2026, strengthened the information component of electronic prescribing. When an electronic prescription is issued for a medicine purchased at the patient's own expense or from other non-budget sources, the patient or representative must be provided with additional information on medicines corresponding to the three most economically favorable, that is, lowest, prices per unit in the National Price Catalogue, provided that such medicines have the same composition, dosage of active substances and pharmaceutical form, and that the number of units in the package does not exceed the number of units specified in the electronic prescription.

This change connects e-prescription infrastructure with price transparency and patient choice. The electronic prescription is therefore used not only as a digital substitute for a paper prescription, but also as a mechanism for informing the patient about price alternatives and potentially reducing out-of-pocket expenditure.

6. Voluntary launch of 2D coding and medicines verification

A major pharmaceutical-law development is the gradual introduction of a national medicines verification system based on safety features and 2D coding. The legal framework was adopted by Cabinet of Ministers Resolution No. 1121 of 26 September 2024, but the key operational stage began in 2026. The resolution provides that most provisions of the verification system and the procedure for applying safety features to medicine packaging apply voluntarily from 1 January 2026, subject to technical readiness of the national system, and become mandatory from 1 January 2028.

The resolution defines the national medicines verification system as an information and communication system ensuring identification and authentication of medicinal products through verification of medicines bearing safety features. Its purpose is to support control over the circulation of medicinal products exclusively to prevent and counteract falsified medicines.

The reform is built around a national verification organization, a central data repository, unique identifiers and deactivation mechanisms. In practical terms, it prepares the Ukrainian pharmaceutical supply chain for stronger traceability, improved anti-falsification safeguards and future technical compatibility with verification mechanisms used in highly regulated pharmaceutical markets.

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