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Message from the President



Dear members, dear colleagues,

Summer is over and for many of you, the past few months may have given you more time to spend with family and friends. Hopefully it was also an opportunity to take a break and reflect on what was and refuel energy and inspiration for what is to come.

At the same time, it was a period that once again confronted us with our own vulnerability and that of our planet. The extreme weather in several places in Europe may have affected several of you. The aggressive Russian invasion of Ukraine still strikes us daily with shock and horror. The courage shown daily by our friends and colleagues from Ukraine commands tons of respect.

These circumstances underline the importance of a strong and reliable network and warm, human contacts. An association like ours can contribute to good relations and strengthen mutual trust. A newly composed board is ready to further develop our association and initiate and support activities in European health law. Unfortunately, on the board we also had to say goodbye to chair Karl Sovig and vice-chair Verena Stühlinger, both of whom were at the end of their term of office. It is in large part due to their tireless efforts that we can get off to a flying start today and build on all the efforts of previous years.

We can recently look back on the successful PhD seminar at the University of Göttingen in May, a report of which you will find in this newsletter. The seminar was the perfect platform to allow young researchers to present their research and meet each other. It also provided an opportunity to increase the visibility of the Young Scholars Interest Group. The high turnout and rich substantive discussions make us believe in the future.

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The icing on the cake is our biennial conference taking place next September in Warsaw. Together with the board, the organizers do whatever they can to make the program attractive to all. We hope to meet you all there again.

Those who have certainly not been idle this summer are our national contact points. Thanks to their efforts, in this newsletter you will again find a nice overview of recent national legislative reforms in the field of health law.

I would like to close this foreword with a warm appeal to all of you. The success of our association relies on your involvement and participation. Therefore, please do not hesitate to bring to our attention any initiative that contributes to the development of European health law. Whether it is a research project, a seminar or scientific publication, it concerns us all. The European association is there for you!

Steven Lierman
Chair EAHL

Minor survey amongst scholars writing a PhD in health law - Some reflections

The EAHL PhD seminar in Göttingen in May gathered around 40 doctoral students from across Europe. At the start of the seminar, we had a plenary session where we talked in general about writing a dissertation within health law. As a part of this, we used an interactive survey tool («Mentimeter»), in order to have direct feedback from the audience. The participants can view the questions on the screen, while they respond with their own devices, normally a cell phone. The results of the survey are not in any way representative and scientific. Still, they may be of interests for EAHL members. It should be noted that the responses are anonymous, and the organizer can not track back answers to individuals.

In many other academic disciplines, most dissertations are article based, and monographs are rare exceptions. Of the 36 respondents at the seminar, around 2/3 (25 out of 34) wrote monographs, while 2 had not yet decided. I guess this reflects law in general; more than health law as a sub-discipline. It could be claimed that lawyers are more conservative than other academic fields, but it could also be due to the fact that legal writing has some particularities. The text of the dissertation is the “core” and there are often no datasets or research in a laboratory.

When it comes to the topic – within health law – we asked the participants which would best describe their project. The 39 respondents answered in the following way:

- Health data: 6
- Artificial intelligence: 4
- Eternal issues (informed consent, liability, etc): 12
- Biotechnology: 6
- None of these: 7

This indicates that both “contemporary” topics and “eternal” issues are covered. However, it should be noted that the categorization is rather dichotomic, which leads it difficult to classify a dissertation addressing e.g. “liability and artificial intelligence when handling big data in the health care sector”.

When it comes to the legal approach, the participants were asked which of the legal sources that played a major role in their work. The 39 respondents answered in the following way:

- Domestic law 12
- International law (EU/EEA) 17
- International law (Human rights) 4
- Comparison with other jurisdictions 3

Even though health law tends to be more oriented towards international sources during the last decades, we see that domestic law still holds a solid position. Of course, there will be few dissertations that are solely drawing on national legal sources, since they are to be interpreted in the light of international sources, which in part also are supranational.

As a starting point for a discussion of academic expectations for a PhD thesis, we cited the following requirement (from the Regulations for the degree of Philosophiae Doctor (PhD) at the University of Bergen) as an example:

“The thesis must be an independent, academic work that meets international standards, and must be at an advanced academic level in respect of the formulation of the research topic, conceptual clarification and methodical, theoretical and empirical rationale, documentation and formal presentation. The thesis must be capable of developing new academic knowledge in the chosen field and must be of such quality as to qualify for publication as a part of the academic literature in the field.”

The participants were asked whether they agreed that this requirement was similar to those at their home institutions. The scale was from 1 to 5, where 5 was articulated as “strongly agree”. The average score of 39 respondents, were 4,3. This indicates that there is a kind of “common expectations” to a PhD dissertation across Europe. On this background, it is perhaps a bit surprising that the time available to writing is so different. We asked the participants how much time they had for their thesis (regardless of any teaching obligations and with time deducted for ph.d.-courses/doctoral training). Of 36 respondents, 2 had less than 2 years, 18 had between 2 and 3 years, and 16 had more than 4 years. This should also be noted by those assessing dissertations. It cannot be taken for granted that the time allocated for research is the same as in your home country.

Karl Harald Søvig

News about the Young Scholars Interest Group and the seminar for young scholars and PhD students on current challenges in medical law

After its initial foundation in 2022, the EAHL Young Scholars Interest Group had its official kick-off last May at the PhD Seminar on Current Challenges in Medical Law in Göttingen. During the last two years, we have witnessed a rise in the number of students enrolling in programs dedicated to legal issues in health, healthcare, biomedicine, technology, bioethics, and public policy who are also taking part in the EAHL activities.

This increase of students in EAHL's field of interest was testified by the large attendance at the conference in Göttingen last May 2023. The conference was an enriching and stimulating two-day event where - as well as attending high-level PhD presentations - we were able to present the Young Scholar Interest Group and gather feedback on the goals to be pursued.

Accordingly, the aim of this group is to support the work of the EAHL as well as to develop and organize young scholars in the field of health law, medical law, pharmaceutical, and biolaw. Knowing the importance of professional associations such as the EAHL in the academic growth of young scholars our vision is to act as a support mechanism for the Association to connect with young researchers (those who are in the early stage career after obtaining their Ph.D. as well as those undertaking their Ph.D. studies).

After an initial networking period to include new members and to refine shared goals, the EAHL Young Scholars Interest Group wishes to offer training and career support in collaboration with the EAHL, enhance scientific performances, and provide networking opportunities in line with EAHL's interests.

Our first activity, which will hopefully take place in early 2024, is the realization of a writing school for young researchers. With the help of EAHL board members, we aim to offer early-stage researchers high-level lessons with eminent speakers on writing techniques, advice on how and where to publish, and much more.

We also take the opportunity of this newsletter to sincerely thank the organisers of the PhD Seminar on Current Challenges in Medical Law in Göttingen. The PhD workshop was an excellent exchange between young researchers and more experienced health law researchers. The relaxed and convivial atmosphere made the event even more enjoyable, allowing new members of the association to feel at ease and promoting the relaxed and fruitful exchange of ideas.

In conclusion, we thank the organisers for giving us the time to promote our ideas, which were consolidated at the first General Assembly of the Young Scholars Interest Group. The attention and kindness we were afforded certainly did not go unnoticed and further enriched the overall care given to young researchers.

Sofia Palmieri

Mirko Dukovic

Announcement

Venue and theme

9th Conference of the European Association of Health Law is going to take place in Warsaw, Poland on 18-20 September 2024.

The Conference venue is the University of Warsaw.

The theme of the conference is *Health and Fundamental Rights*.

Topics

The aim of the 9th EAHL Conference is to focus upon the current challenges to health provision in Europe, with a special attention upon the impact upon fundamental rights.

The conference themes will be divided into five panels:

1. Health provision during emergency situations (pandemics, environment and climate crisis, medical services during armed conflicts)
2. Health law and collective rights (organization of healthcare system; financial, geographical and generational distribution of medical services)
3. Health law and personal rights (patients' rights, diverse patients groups – minors, persons with disabilities, quality of life, healthcare services and care, services connected to beginning and end of life – prenatal medicine, hospices and wake-up clinics)
4. Provision of healthcare (standardization of health services, communication between physicians and patients; medical errors and negligence, personal data protection)
5. Healthcare and modern technologies (artificial intelligence, genetics and biomedical law, advanced therapies)

Dates:

- **October 2023** – launch of the registration for the conference
- **31st March 2024** – deadline for abstract submissions
- **15 May 2024** – final decisions about acceptance of abstract proposals
- **15 June 2024** – end of early bird registration
- **1st September 2024** – end of registration for the conference.

Special invitation to young scholars and Ph.D. students (separate conference panel, conference fee discounts).

Austria: Introduction of new apprenticeships for professional care and nursing and Amendments of the mental health act

Caroline Voithofer and Alexander Mitter

Department of Theory and the Future of Law, University of Innsbruck

1. Introduction of new apprenticeships for professional care and nursing

The training and education in the professional care sector (“Pflegeassistentenberufe”) has been offered in Austria in a specific certified form, including theoretical and compulsory training parts in professional care facilities. In autumn 2023 a three-year and a four-year model of professional care and nursing apprenticeships will be added to these well-established educational courses. The trainees will receive a fixed apprenticeship pay from the first day of their apprenticeship. Furthermore, there will be a high level of practical training which serves to gain initial professional experience in the care sector.

For this reform amendments in the Vocational Training Act (“Berufsausbildungsgesetz”) as well as in the Health Care Act (“Gesundheits- und Krankenpflegegesetz”) were required. However, it was highly criticized that the necessary legal amendments were not submitted as a whole for a joint expert opinion in advance: The general pedagogical statutes were submitted before and the specific health care and medical acts followed afterwards. Therefore, it was difficult to assess the entire reform package.

Along with other measures, the newly introduced apprenticeship models shall contribute to close the existing care gap.

2. Amendment of the mental health act (“Unterbringungsgesetz; UbG”)

The Austrian UbG deals with the hospitalization of persons in psychiatric institutions. The hospitalization may be conducted with or without consent of the patients. In case of a hospitalization without consent, the patients must be at a very high risk of a severe self-harm or a severe danger to someone else’s health in the moment of the hospitalization. The hospitalization against the will of the patient is considered a last resort, therefore the further requirements in the UbG are strict, given that the “forced” hospitalization is a major interference with the fundamental rights of freedom of the patients. The UbG was amended by 1.7.2023. These latest amendments do not bring a fundamental change of the established hospitalization system in psychiatric institutions within Austria.

The main amendments affect the regulations on hospitalization without consent. § 8 UbG deals with the medical examination by the admitting physician. The admitting physician can now be either a public health

officer (“Amtsarzt”) or a physician authorized by the local governor. His or her contact details as well as the considered reasons for the hospitalization must be stated readably on the hospitalization letter so that the admitting physician can be contacted easily and the reasons for the hospitalization can be checked by the staff of the psychiatric institution. Before arranging the hospitalization, the admitting physician must conduct a mandatory examination whether other means are available that interfere less with the patients’ fundamental rights. This needs to be documented.

Further amendments affect the restriction of competencies of the public security organs involved. They now are only allowed to check whether the requirements of § 3 para 1 UbG are fulfilled. All other requirements for the hospitalization are checked by the admitting physician or the head of the department of the psychiatric institution. In case, the consultation of those physicians is unreasonable due to the waiting time or the acute dangerous situation (§ 9 para 3 UbG) a consulted specialized physician or an emergency physician present may decide if the requirements for the hospitalization are met.

According to § 10 UbG the head of the department of the psychiatric institution must as well check if means which are less interfering with fundamental rights are available for this patient and if the requirements for the hospitalization are met. If the hospitalization is considered not appropriate after these checks, the head of the department must make demonstrable efforts to provide appropriate alternative care if this is considered necessary instead of the hospitalization. In case of the hospitalization after those checks, the patient must be informed of the reasons for the hospitalization and of his*her right to name a person of trust and of who is the patient’s rights officer in charge. The head of the department must inform the legal representative of the patient, the patient’s rights officer, the person of trust of the patient, a relative living with or caring for the patient or the institution caring for him*her. The legal representative as well as the patient’s rights officer have to get the hospitalization letter.

Further amendments of the UbG affect the hospitalization with the consent of the patient, the simplified communication – with due respect payed to data protection – between all involved actors, the dismissal of the patient and the termination of the hospitalization, the treatment schedules, the hospitalization of minors and some procedural rules.

Anyway, the shortage of mental health care and mental health support instruments in Austria still waits to be eliminated. But that’s another issue.

Date of submission: 9 September 2023

Financial Consolidation of Public Healthcare Institutions in Federation of Bosnia and Herzegovina

Ervin Mujkic

NCP for Bosnia & Herzegovina

In Bosnia and Herzegovina there is no unified law on health care or law on health insurance. Health care is under the jurisdiction of the two entities (Federation of Bosnia and Herzegovina and Republika Srpska) and Brčko District of BiH, which have regulated this area with their laws and special regulations. Republika Srpska have a centralized health care system, while it's decentralized in the Federation of BiH where health care is in the joint jurisdiction of the Federal government and ten cantons.

Weak and fragmented public sector institutions, devolved responsibilities and poor financial management have led to financial deficits among health care providers in the last decades. In order to address the significant debts of public healthcare institutions, especially university clinical hospitals, and to meet established financial losses, the Federation of Bosnia and Herzegovina has enacted the Law on Financial Consolidation and Restructuring of Public Healthcare Institutions. Financial consolidation of healthcare institutions involves addressing the debts of healthcare institutions that have been identified as illiquid according to the provisions of the Law on Financial Operations and/or have accumulated losses. The estimates at the time of enacting the law were that this amounted to approximately 250 million EUR, with over 100 million EUR attributed to accumulated losses of healthcare institutions.

The Law on Financial Consolidation and Restructuring of Public Healthcare Institutions implies the allocation of 115 million EUR from the federal budget in the next three years (since the law came into force) to university-clinical and public cantonal and general hospitals. Based on the above, it is evident that the allocated funds from the federal budget will not be sufficient to fully resolve the entire amount of debt or cover the accumulated losses. However, the law has left open the possibility of exploring other sources, in accordance with the commitment of the founders of public healthcare institutions.

Towards the end of the previous year and throughout the current year, the majority of public healthcare institutions have adopted financial consolidation programs and commenced their implementation. It is important to note that these financial consolidation programs are designed based on the principles of preventing further debt and losses while defining spending priorities. However, it should be highlighted that there are circumstances that can significantly impact the revenues from health insurance contributions. Specifically, the challenge of financial consolidation in the healthcare sector is related to the planned reduction of mandatory health insurance contribution rates (aimed at enhancing economic competitiveness), which could

lead to a decrease in overall revenues for health insurance funds and seriously jeopardize the operations of most public healthcare institutions.

It is evident that financial consolidation is a lengthy process, and ensuring the financial sustainability of public healthcare institutions during the implementation of this law, including the execution of financial consolidation procedures, will require efforts and dedication not only from the managerial structures of healthcare institutions but also from the relevant ministries of health, finance ministries, and health insurance funds in the Federation of Bosnia & Herzegovina. In addition, there is a need for continuous strengthening of internal financial controls and internal auditing within public healthcare institutions, as well as other participants in the healthcare sector. This includes ongoing and long-term efforts to address the root causes that have led to multi-year operational losses in public healthcare institutions because, otherwise, the results of the financial consolidation of public healthcare institutions will not be sustainable in the long term.

It is interesting to note that, even though the law provides healthcare institutions with the opportunity to create a restructuring plan, defined as a series of actions, procedures, and activities that a healthcare institution should undertake in terms of financial, organizational, and human resource management, with the aim of improving overall performance, introducing new healthcare technologies, modernizing, expanding capacity, and ensuring the safety and quality of healthcare services, not a single healthcare institution has taken advantage of this opportunity.

This can be interpreted as a sign that any structural changes within public healthcare institutions in this context will ultimately need to be created through amendments to the existing systemic healthcare laws. In that regard, the Federal Ministry of Health has recently initiated the process of drafting new systemic healthcare laws, specifically the Law on Health Care and the Law on Health Insurance, and published a public call on their website inviting all interested parties to submit proposals, suggestions, and opinions related to these laws, along with explanations and analysis.

Dare of submission: 11 September 2023

Leave no one behind: how France palliates inequities of access to healthcare professionals

Éloïse Gennet

NCP for France

After heated debates between the French Senate and National Assembly in a joint negotiating committee, a new text was adopted, the law 2023-379 of 19 May 2023 on improving access to healthcare through trust in healthcare professionals.

As a background, the law 2016-41 of 26 January 2016 modernizing our healthcare system, implemented since 2018, has created the degree of “advanced practice nurses” (APNs) as well as territorial professional health communities (TPHCs). The degree of APN enables nurses to assume more advanced roles and skills that were traditionally exclusive to physicians, thus creating a hybrid role with expanded responsibilities. TPHCs have been created to facilitate the collaboration of professionals within a region who voluntarily wish to unite around a healthcare project, addressing shared concerns through self-organization.

The 2023 law focuses on combating medical deserts and improving access to care in three main ways.

First, patients will be granted direct access to APNs, physiotherapists and speech therapists without having to go through their general physician first. APNs will be able to take direct charge of patients in health establishments, medical establishments and services and in the most integrated coordinated practice structures. Patients will also have direct access to physiotherapists for up to eight sessions, as well as to speech therapists when established on a coordinated care structure, including a TPHC. A report will systematically be sent to the general physician and added to the patient’s shared medical file.

Second, several paramedical professions will acquire expanded competencies. For instance, it enables APNs to prescribe certain products and services subject to compulsory medical prescription. It also creates a higher level of qualified dental assistances who will support dental surgeon in a wider range of procedures. Pharmacists can now renew prescriptions for chronic diseases up to three times within a month. Due to the pandemic, pharmacy assistants will have the authority to administer specific vaccines, and a broader range of professionals will be authorized to conduct rapid diagnostic tests.

Third, the law establishes collective responsibility of healthcare professionals regarding permanence of care. This ensures access to urgent care during closing hours by sharing responsibilities among facilities and doctors in a given area.

This law has been adopted in a controversial context as medical deserts are a growing issue in France triggering a lot of political debate. A proposal for a law to restore territorial equity in the face of medical deserts and guarantee access to healthcare for all had been submitted by the National Assembly to the Senate in October 2022 but rejected in December of that same year. Besides, the law of 23 December 2022 on the funding of social security for 2023 has been adopted using article 49.3 of the French Constitution, *ie* without a vote at the National Assembly. Inequities of access to healthcare are an ever-continuing hot topic and in fact, on 15 June 2023, the National Assembly adopted a new legislative proposal aimed at “improving access to care through the territorial commitment of professionals”. The proposal includes measures to enhance healthcare accessibility and tackle health disparities in different regions, both urban centers and rural regions. For instance, it allows territorial civil servants to be placed at the disposal of health centers in under-dense areas, and authorizes contract health professionals to work up to the age of 72 in medical deserts. It also fights medical nomadism by banning temporary employment at the start of a career and imposing a six-month notice period for doctors (as well as midwives, dentists, etc.) leaving a medical desert. This proposal for a law is yet to be debated and adopted by the Senate.

Acknowledgments: This work has been supported by the French government under the France 2030 program as part of the Aix-Marseille University - A*MIDEX Excellence Initiative (AMX-22-CPJ-03) and by the ANR (N°ANR-22-CPJ2-0021-01).

Resources:

LOI n° 2016-41 du 26 janvier 2016 de modernisation de notre système de santé, *JORF*, n°0022, 27 janvier 2016.

Proposition de LOI n° 68 visant à rétablir l'équité territoriale face aux déserts médicaux et accès à la santé pour tous, Texte déposé au Sénat le 24 octobre 2022.

LOI n° 2023-379 du 19 mai 2023 portant amélioration de l'accès aux soins par la confiance aux professionnels de santé, *JORF*, n°0116, 20 mai 2023.

Proposition de LOI n°137 visant à améliorer l'accès aux soins par l'engagement territorial des professionnels, Texte adopté par l'Assemblée nationale en première lecture le 15 juin 2023.

de Montecler MC, « La loi Accès aux soins est adoptée », *AJDA*, 2023, n°17, 15 mai 2023, p. 862.

Mariller P, « L'infirmier en pratique avancée, nouveau pansement aux déserts médicaux ? », *RGDM*, n°67, p. 183-185.

Maupin E, « Améliorer l'accès aux soins par l'engagement territorial des professionnels », *AJDA*, 2023, n°22, 26 juin 2023, p. 1149.

Date of submission: 3 August 2023

Current health law issues in Germany

(by Ottilia Voigt and Jula Kruse)

Abolishing the ban on advertising abortions according to § 219a StGB

In 2022, § 219a of the Criminal Code (StGB) was abolished, which previously had prohibited the advertising of abortion, including detailed information on various methods of abortion and the risks associated with each. In Germany, abortion is generally possible within the first twelve weeks after counselling.

Assisted Suicide

According to Section 217 of the Criminal Code (Strafgesetzbuch, StGB), it is a criminal offence to grant or procure the opportunity for another to commit suicide on a businesslike basis. This regulation has been declared null and void by the Federal Constitutional Court. The legislature has not yet been able to agree on a new regulation; of several proposals, none has yet received a majority vote

New right of emergency representation for spouses

There has been a comprehensive reform of the law on guardianship. Amongst others a new right of spouses to represent each other in emergency situations has been introduced.

Triage

On the occasion of the Corona pandemic, the Federal Constitutional Court called on the legislature to ensure that, should triage become necessary, no criteria may be applied that disadvantage people with disabilities. The legislature then amended the Infection Protection Act accordingly. An allocation decision may only be made on the basis of the current and short-term survival probability of the patients concerned. Comorbidities may only be taken into account in the assessment of the current and short-term probability of survival insofar as they significantly reduce the short-term probability of survival related to the current disease due to their severity or combination. Criteria that do not affect the current and short-term probability of survival, such as in particular disability, age, remaining medium or long-term life expectancy, degree of frailty and quality of life, shall not be taken into account in the assessment of the current and short-term probability of survival. Survival intensive care capacities already allocated shall be excluded from the allocation decision.

Introduction of an electronic patient file

Since 2021, all statutorily insured persons can receive an electronic patient file from their health insurers. The decision and control over the electronic patient file and the health data stored in it are solely in the hands of the patients. They can decide what is stored and to whom they make it available.

A digitalisation strategy presented in March 2023 aims at ensuring that at least 80% of those with statutory health insurance have an electronic patient record by the end of 2025. The strategy is to be implemented with

the help of two bills, the Digital Act and the Health Data Usage Act. Among other things, the Digital Act stipulates that the electronic patient file is to be set up for all statutorily insured persons by the end of 2024 and that the e-prescription is to be used as a mandatory standard by 1 January 2024. The Health Data Usage Act in turn simplifies data release from electronic patient records, which are to be controlled in a user-friendly way via an app. Furthermore, research data will be made more easily accessible in order to promote the research industry.

Care reform

With the Care Support and Relief Act, the financial basis of social long-term care insurance has been stabilised since 1 July 2023. This enables the implementation of an urgently needed improvement in benefits.

One difference to the previous payment of the contribution rate is that the contribution payments now depend on the number of children under the age of 26 of the persons liable to insurance. The more children this person has, the lower the contribution that it must pay.

The improved benefits include the increase and subsequent dynamization of care allowances and outpatient benefits in kind by 5% to strengthen home care. Furthermore, the supplement paid by the health insurance funds for stays in fully inpatient care facilities will be significantly increased. In addition, there is a funding programme for digital and technical acquisitions in care facilities in the amount of € 300 million, as part of an intensified digitisation effort in Germany.

Reform of the hospital system

In October 2023, the federal and the state governments agreed on key points for a hospital reform. A corresponding law is to come into force on 1 January 2024. The aims are to de-economise, ensure and increase the quality of the treatment, reduce bureaucracy and ensure security of care. This is to be achieved in particular by switching from flat rates per case to a retention fee in order to counteract the problem that hospitals also perform unnecessary operations to have enough cases. Hospitals will thus receive a guarantee of existence, even if they perform comparatively few treatments. In addition, from 1 January 2024 there is to be a transparency offensive so that patients can see which hospitals offer which services in which quality.

Legalization of cannabis

A partial legalization of cannabis is currently in the legislative process. According to the draft, adults will be allowed to cultivate cannabis in limited quantities privately (up to three plants) or in non-commercial associations. Through these cultivation associations, cannabis may be passed on to adults for personal consumption in a controlled manner. The possession of up to 25 grammes of cannabis will be exempt from punishment. For minors, the possession of cannabis remains prohibited, and there will be special regulations for young adults - with lower dispensing quantities and reduced THC contents. Cannabis may not be consumed within a distance of 200 metres from schools, children's and youth facilities, children's playgrounds as well as

in publicly accessible sports facilities. Education and prevention of cannabis use are planned to be strengthened, among other things through expanded early intervention programmes for minors.

Date of submission: 12 September 2023

Health Policy updates in Hungary

Varga Orsolya

NCP for Hungary

From primary care to specialist clinics and hospitals, centralization is a common feature of recent change in health policies in Hungary. There were fundamental changes in primary care. Government Decree 53/2021 (9 February 2021) was published in the Hungarian Official Gazette on 9 February 2021, detailing the rules of the practice of family doctors. Family doctors can work together in different types of professional groups, which can have a significant impact on their operational funding.

On 21 December 2022, Law LXXIII of 2022 amending certain health-related laws was promulgated, introducing new rules on the disposal of practices, the definition of practice areas for state involvement, the use of software meeting the conditions for on-call duty and primary care, from 1 January 2023.

In line with the change in the law, according to a Decree (630/2022. (XII. 30.) Government Decree), the National Directorate General for Hospitals (NDGH) takes into account in the establishment of family doctors districts that the population served by a practice of family doctors must reach at least 600 in the case of a general pediatric practice and at least 1200 in the case of an adult and mixed practice of family doctors. Therefore, no districts can be created below these numbers, or the practice will be closed if the number of patients is less than this.

The decree modifies the centralized on-call system: it is organized by the National Emergency Medical Service outside Budapest. According to the decree, the National Emergency Medical Service provides on-call services involving general practitioners and general pediatricians from 16:00 to 22:00 on weekdays and from 08:00 to 14:00 on weekends and public holidays. A family doctor or a general pediatrician working in a family doctor's or general pediatrician's service with a territorial duty of care must be on call no more than twice a month. The on-call time for family doctors provided by the National Emergency Medical Service is from 22:00 to 08:00 on weekdays and from 14:00 to 08:00 on weekends and public holidays.

In February, Parliament amended the law (2006. XCVII.) abolishing compulsory membership of the Medical Chamber. The decision followed allegations that the Medical Chamber had proposed some of its members to stop working in the changing on-call service. Following the Parliament's decision, the Chamber asked its existing members to confirm their voluntary membership. 80 percent of doctors have confirmed their membership. Under this legislation, ongoing and future ethics procedures was transferred to the Medical Research Council, with the new Code of Ethics, which is be drafted by this body and approved by the Minister responsible for health. In the future, the Chamber will only have the right to give an opinion on the Code of Ethics. The body appointed by the minister responsible for health and higher education will be responsible for

assessing and giving an opinion on continuing training in health. The Chamber will only formulate an opinion on the appointment of directors over its members.

On 14 October 2020, Act C of 2020 on the Health Care Service was promulgated, which has sparked considerable debate as the rights granted by Act XXXIII of 1992 on the Status of Public Servants have shrunk. The background legislation for the Act C of 2020 is the Labor Code. From 2020, health workers' wages have increased significantly. Under the Act, there are three stages of pay increases for doctors, with the final stage in 2023. This means that the salary of a junior doctor has risen from HUF 619,000 to HUF 687,000. The pay scale is based on the pay scales drawn up by the Hungarian Medical Chamber. Under the law, doctors who receive gratuities (was common in Hungary) may be imprisoned and second jobs are subject to authorization. In 2023, the basic salary of healthcare professionals is increased by 18%, while the salaries of health workers are also increased by a lump sum of 57 600 HUF (256/2013. (VII. 5.) Gov decree).

Date of submission: 29 August 2023

Current issues in the field of health law in Latvia

Ph.D. Assist. Prof. **Karina Palkova**,

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Developing Patient-Centered Palliative Care

Palliative care is explicitly acknowledged as an integral part of the fundamental right to healthcare. In general, it should be delivered through healthcare services that prioritize individual needs and preferences, emphasizing integration and person-centered care.

Palliative care not only improves the quality of life for patients but also safeguards their fundamental rights. These rights to health are protected both at the international and national levels. To enhance this protection, the Latvian healthcare system takes a significant step forward in ensuring the protection of patients' rights in palliative care and in preserving patient dignity at the end of life by creating a peaceful atmosphere during their final hours.

The Latvian government, in cooperation with patient organizations, has initiated efforts to enhance the regulation of palliative care. As a result, the Latvian Saeima has conceptually supported amendments to the Law on Medical Treatment and the Law on Social Services and Social Assistance. These amendments aim to improve access to palliative care and establish that hospice services will be funded from state budget resources. The amendments to the law will come into the force on October 1, 2023.

The amendments clarify that palliative care is intended to be provided to individuals with a predicted limited survival period of no more than six months. The Social Services and Social Assistance Law stipulates that the State offers social care and psychosocial rehabilitation to adults who, as determined by medical professionals, require palliative care and have an expected survival period of up to six months.

According to the amendments in the Law on Medical Treatment, the Cabinet of Ministers shall determine the conditions and procedures related to the type, volume, content, receipt, granting, financing, termination, and cessation of the service

Protecting Patients' rights to a dignified death.

Amendments to the Law on the Rights of Patients have been submitted for public consultation and will soon be presented to the Saeima. The purpose of these amendments is to clarify existing norms in the law and supplement them with new rights and obligations to strengthen the protection and oversight of patients' rights. This includes the rights of minor patients, the establishment of new obligations for both medical institutions and healthcare professionals, the specification of the rights of the legal representatives of the patient's and the provision for the patient's representatives (support person) to participate in the patient's treatment.

Description of the problem: The Article 6 (4) of the Law on the Rights of Patients defines that the patient has the right to refuse from medical treatment prior to its commencement, from any method used in

the medical treatment without refusing from the medical treatment at large, or to refuse from medical treatment during it. At the same time Section 6 (5) states that the attending physician shall inform the patient of the possible consequences of the decision. After receipt of the information provided by the attending physician, the patient shall, with his or her signature, confirm his or her decision to refuse from medical treatment or to suspend it, or to refuse from any method used in the medical treatment, indicating that he or she has received the relevant information. If the patient does not change his or her decision, it is the duty of the medical practitioner to encourage him or her to have the consultations from another medical practitioner.

The mentioned before does not fully apply to the patient's ability to express his will, with which the patient has the right to refuse resuscitation treatment methods or life-sustaining treatment under certain conditions.

Active discussions about the new regulation of patients' rights to a dignified death have taken place within the medical law community and among patient organizations in Latvia.

The patient's right to a dignified death at the end of the life process, occurring over a certain period of time, and the right to choose not to start or stop futile treatment are important human rights issues that have not been previously addressed within the framework of regulatory acts in Latvia

The essence of the amendments to the Law of Patients' Rights is to ensure a person's right to make a conscious choice to refuse futile treatment, receive pain and suffering-relieving therapy, access psychological support appropriate to their state of health, and ensure humane treatment of the patient at the end of life. The rights of patients in cases of futile treatment will be improved.

The new legal norms provide a simplified and accessible opportunity for the patient to express their will regarding not starting or stopping futile treatment for anticipated future situations. They also establish a mechanism for the implementation and protection of the patient's right to autonomy at the end of life, particularly in situations when the patient is no longer able to express their will.

In order to ensure a person's right to make an informed choice to refuse futile treatment and die with dignity, receiving appropriate pain and suffering-relieving therapy, psychological and spiritual support, as well as to ensure humane treatment of the patient at the end of life, it is necessary to provide a mechanism for ensuring patients' right to autonomy and for the protection of patients at the end of life.

To solve the problem, the new amendments are provided, including the definition of "Patient will", which defines the criteria for who has the right to issue a patient will, under what conditions the patient will is intended to exist or arise, as well as the patient can determine wishes and values at the end of life and authorize another person to issue the will of the patient. The right of the patient to agree on to start or stop futile treatment will be provided in the law now. The amendments will provide the right to choose to refuse futile treatment at the end of life or not. And the decision will be made based on the information provided by the General practitioner or attending physician. As well as other mechanisms is provided in the amendments of the Law on the Rights of Patients to ensure the patients' rights to a dignified death.

The development of new policy papers regarding AI in healthcare.

In order to promote the use of safe and evidence-based artificial intelligence solutions in healthcare, the Ministry of Health has established a working group on the use of artificial intelligence in healthcare. The task of the working group is to create the guidelines/road map for the safe use of artificial intelligence solutions in medical treatment should be prepared; to develop legal regulations to ensure the safe use of artificial intelligence in medical treatment provide proposals to the Minister of Health on current issues in order to ensure high-quality and modern health care that is in line with the Latvian Public Health Guidelines 2021-2027.

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Malta: Criminal law in relation to Abortion

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The Criminal Code in Malta was amended in 2023 adding Article 243B to the Title ‘Of Crimes against the Person’ in its subtitle ‘Of Abortion, of the Administration or Supplying of Substances Poisonous or Injurious to Health, and of the Spreading of Disease’. Article 243B relates to two offences. First, the offence under Article 241 of the Criminal Code of procuring a miscarriage but only in relation to Article 241 (2) that refers to the punishment being ‘awarded against any woman who shall procure her own miscarriage, or who shall have consented to the use of the means by which the miscarriage is procured’. As such, any other person procuring the miscarriage falling within the remit of Article 241 (1) is not affected by the new Article 243B of the Criminal Code. However, the second offence to which Article 243B relates arises from Article 243, which stipulates that any ‘physician, surgeon, obstetrician, or apothecary, who shall have knowingly prescribed or administered the means whereby the miscarriage is procured, shall, on conviction, be liable to imprisonment for a term from eighteen months to four years, and to perpetual interdiction from the exercise of his profession’. In relation to the offences arising from Articles 241 (2) and 243 of the Criminal Code alone, Article 243B now provides that no offence shall be committed ‘when the cessation of a pregnancy or damage to the foetus results from a medical intervention carried out for the purpose of saving the life and protecting the health of a pregnant woman suffering from a medical complication which may put her life at immediate risk or her health in grave jeopardy which may lead to death’.

Requirements for the exemption from criminal responsibility arising consequent to Article 243B to apply vary depending on the condition of the pregnant woman at hand. First, in the case where ‘a pregnant woman is suffering from a medical complication which may put her life at immediate risk’,¹ the exemption from criminal responsibility in Article 243B shall only be tenable when, after having considered the medical practices current in Malta, circumstances of necessity still subsist which dictate that the medical intervention be carried out and the medical intervention is in fact done when, in the reasonable opinion of the medical practitioner carrying out that intervention, the foetus has not reached the period of viability, which is defined as meaning ‘the point in a pregnancy at which the foetus is capable of living outside the uterus according to current medical practices’.² If that period of viability has been reached, based upon the latter definition at law as interpreted by the reasonable opinion of the medical practitioner carrying out the intervention, then the exemption from criminal responsibility arising from Article 243B will not be an option.

¹ Criminal Code, Chapter 9 of the Laws of Malta, Art 243B (a).

² *Ibid.*, Art 243B (c).

Second, in the case where ‘a medical intervention is carried out due to a medical complication which places the health of a pregnant woman in grave jeopardy which may lead to death’³ but her life is not then at immediate risk, in addition to the requirement to consider the medical practices current in Malta so as to determine whether circumstances of necessity still subsist which dictate that the medical intervention be carried out, it is in this case also a requisite so that the Article 243B exemption from criminal responsibility apply that ‘the medical intervention be carried out in a licensed hospital having the facilities required for the necessary medical intervention to be carried out’.⁴ Additionally, a further two requirements must subsist in relation to this second scenario for Article 243B to apply and these requirements refer to decisions to be taken by a medical team. This three-person team must consist of medical practitioners registered as specialists with the Maltese Medical Council involving the obstetrician who carries out the intervention, a second obstetrician or gynaecologist, and a third medical practitioner who is a specialist in the condition from which the pregnant woman is suffering.⁵ In order for the Article 243B exemption from criminal responsibility to apply in this second scenario, the medical intervention must then only be carried out after that medical team ‘has confirmed the necessity of the intervention’⁶ and it must furthermore be the reasonable opinion of that same medical team that ‘the foetus has not reached the period of viability and cannot be delivered according to standards of the medical profession’.⁷

The process leading to the addition of Article 243B to the Criminal Code began soon after Ms Andrea Prudente was admitted to hospital for treatment in Malta in 2022 due to complications in her pregnancy during her vacation from the USA. Ms Prudente’s pregnancy was not terminated in Malta but was later terminated after she was transferred to a jurisdiction where Maltese law did not apply. An application was then made to the Maltese courts on behalf of Ms Prudente *inter alia* claiming that the Criminal Code’s provisions in relation to abortion violated her human rights arising from the Constitution of Malta and the European Convention of Human Rights.⁸ That case is still ongoing at the time of writing but, following advice from the State Advocate, a Bill was tabled before the House of Representatives in November 2022 by the Minister for Health on behalf of the Minister for Justice proposing the addition of Article 243B to the Criminal Code. That Bill stipulated that ‘[n]o offence under article 241 (2) or article 243 shall be committed when the termination of a pregnancy results from a medical intervention aimed at protecting the health of a pregnant woman suffering from a medical complication which may put her life at risk or her health in grave jeopardy’.⁹ Although the objects and reasons of the latter Bill were ‘*to provide clarification* of the parameters that shall apply in the Criminal Code to circumstances of necessity in which a medical intervention is required in order to protect the life and

³ *Ibid.*, Art 243B (b).

⁴ *Ibid.*, Art 243B (b)(iii).

⁵ *Ibid.*, Art 243B (c).

⁶ *Ibid.*, Art 243B (b)(ii).

⁷ *Ibid.*, Art 243B (b)(i).

⁸ *Dimitrijevic Avukat Dr Lara v. L-Avukat Tal-Istat et.*, Civil Court First Hall (Constitutional Jurisdiction) [Ref: 499/2022] Registered 20/09/2022.

⁹ Bill No 28, Criminal Code (Amendment No. 3) Bill, 14th Legislature [Government Gazette of Malta No 20,962 – 21/11/2022].

health of a pregnant woman suffering from a medical complication’,¹⁰ months of debate and protest ensued particularly due to the words ‘her health in grave jeopardy’ in the Bill that were, it was objected, considered to be unclear.¹¹ An amended version of the Bill was then presented in late June 2023, which was approved and adopted into law in the form detailed above.¹²

There are however differing accounts of the significance or otherwise to the domestic legal order of the addition of Article 243B to Malta’s Criminal Code. On one account, for example, Article 243B furnishes the first instance when there is, it is contended by exponents of this account, no blanket ban on the intentional procurement of miscarriage in Malta.¹³ This is based on the assumption that, inasmuch as there were no offence-specific exceptions in relation to the criminal law on abortion until the addition of Article 243B, this meant that, at least on this account, ‘the law contemplate[d] no exceptions that would allow a woman or any other person to terminate a pregnancy under any circumstance’.¹⁴ The second account of Article 243B however postulates that this new law does no more than consolidate in statutory law what used to occur in practice, meaning that Article 243B would be no novelty to abortion in Malta at all since it only serves to ‘codify the existing life-saving practices currently being applied in Malta’¹⁵ even before the addition of Article 243B to the Criminal Code entailing that there never was in practice, at least on this account, a blanket ban in Malta on the intentional procurement of miscarriage. Consequently, on this second account, Article 243B provides ‘further safeguards for mothers, unborn babies, and doctors [medical practitioners]’¹⁶ but does not per se introduce or otherwise add to permissible abortion practices in Malta that existed prior to its addition to the Criminal Code. As such, the consequences of the addition of Article 243B to Malta’s Criminal Code arguably have yet to settle debate on the topic.

Date of submission: 11 September 2023.

¹⁰ *Ibid.*, emphasis added.

¹¹ See for instance: Emmanuel Agius, Kevin Aquilina, et al, ‘An Act to further amend the Criminal Code, Cap. 9. Bill No. 28 – A Position Paper’ (November 2022) [6].

¹² Act XXII of 2023 – Criminal Code (Amendment No. 3) Act, 2023 [Government Gazette of Malta No 21,078 – 30/06/2023].

¹³ See for instance: Doctors for Choice Malta, ‘Malta’s Abortion Law’ <<https://www.doctorsforchoice.mt/abortion-law>> (Last accessed: 8 September 2023).

¹⁴ Doctors for Choice Malta, *Position Paper on Abortion and the implications of Malta’s complete ban on abortion on women, children, and their doctors* (Version 1.0 – February 2020) 4. See, however: Daniel Bianchi, *Medical Law in Malta* (Alphen aan den Rijn: Kluwer Law International – 2023) 184 – 193.

¹⁵ Life Network Malta, ‘The Coalition in favour of Life accomplishes its objective: No to Abortion Wins’ (23 June 2023) <<https://lifenetnetwork.eu/press-release/the-coalition-in-favour-of-life-accomplishes-its-objective-no-to-abortion-wins/>> (Last accessed: 8 September 2023).

¹⁶ *Ibid.*

Outline of developments in health legislation in the Slovak Republic in 2023

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1/ Palliative Care.

In 2022, a number of new legal documents and standards were adopted, which came into force during 2022 and 2023. New legislation and amendments to earlier legislation aim to better integrate palliative medicine into the health care system, improve the availability of palliative care for patients, as well as increase their awareness by enacting a duty of attending physician to provide an extended instruction to the patient before obtaining an informed consent, including identification of available providers of palliative care and the attending physician is obliged to further provide specific identification data of another doctor specializing in another specialized field, depending on the disease of the person. Also, reimbursement mechanisms are reformed. The document "The Concept of the Medical Specialty of Palliative and Hospice Care" was adopted by the Ministry of Health of the Slovak Republic in 2006 already and amended later. In the conditions of the Slovak Republic, palliative health care is defined as "health care provided to a person with an incurable and progressive disease, which usually leads to his death, with the aim of alleviating suffering and preserving the quality of life of this person". (§2, paragraph 39 of the Act No. 576/2004 Coll. on health care). Recent legislation (after amendments came into force) distinguishes a/ general palliative care and b/ specialist palliative care. However, general practitioners are not adequately trained to provide palliative care and also they face limitations in prescribing painkillers and other medication needed to decrease suffering of the dying person and helplessness of the caring family members. Besides existing financial barriers, lack of specialised healthcare workforce, increasing shortage of primary care physicians and lack of hospices and mobile hospices, modern palliative care is not really available for many in need, still.

2/ Ethic committees.

The system of ethic committees in Slovak Republic has developed continuously since 1990, with a big share of prof. Jozef Glasa, MD, PhD. Various ethical dilemmas can relate to health care delivery and to biomedical research, especially. Recently, there is a comprehensive legislative framework for creation and operation of ethical committees on various levels. Fundamental laws are:

a/ Act on Health Care No. 576/2004 collection of laws of the Slovak Republic, as amended - Especially article 5 (§5) Available from: <https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2004/576/20230801.html>

b/ Act on Medicines and Medicinal Products No. 362/2011 collection of laws of the Slovak Republic, as amended Available from: <https://www.slov-lex.sk/pravne-predpisy/SK/ZZ/2011/362/>

The last amendment to both acts came into force on August 1, 2023 and amended the definition of the concept of biomedical research. Ethical issues arising specifically during clinical trials of human drugs within the framework of the centralized procedure of clinical trials of human drugs, clinical trials of medical devices according to the revised regulatory framework or studies of the performance of diagnostic medical devices in vitro under the revised regulatory framework are assessed by the ethics committee for clinical trials of human drugs, for clinical trials of medical devices and for studying the performance of diagnostic medical devices in vitro, under provisions of Act No 362/2011 coll., as amended (and not under provisions of Act on Health Care No. 576/2004 Coll.).

3/ Psychiatric care.

In-patient psychiatric care and strict limitation of restrictive measures (physical, pharmaceutical) imposed to patients had been subject of regulation in 2022 and affects provision of in-patient psychiatric care to adults and children. The tasks of the national preventive mechanism according to the international treaties to which the Slovak Republic is bound, required amendments of control system over health care and social care facilities, providing care to patient suffering of mental disorders. Specific duties and competences were imposed to the Public Defender of Rights (Ombudsman) by the Act No.110/2023 Coll., amending Act No. 564/2001 Coll. the Public Defender of Rights. Decree of the Ministry of Health of the Slovak Republic No č. 143/2023 Coll. is focusing internal mechanisms regulating operation of in-patient psychiatric wards.

4/ Act No. 54/2023 Coll. Z. z. amending act No. 129/2002 Coll. On integrated national rescue system, improves conditions for better coordination and collaboration of particular divisions within an integrated national rescue system. Act came into force since on September 1, 2023.

5/ An important change to prevent secondary victimization of victims of crimes and offenses during medical examination of a victim had been introduced by Act No. 49/2023 Coll., amending the act No. 301/2005 the Criminal Procedure Act and also Act No. 274/2017 Coll. on Victims of Crimes. The amendment came into force on April 1, 2023.

6/ Health promotion also had been addressed in 2023, by amended regulation of alcohol by taxation changes and support to access fruits, vegetables and dairy products to children and pupils.

7/ Access to novel drugs and therapies for rare diseases (such as Zolgensma) is limited by financial condition of health system in Slovakia and dependent upon former approval by a public health insurance fund, where a patient is insured. New case law is in progress. Also the Slovak National Centre for Human Rights is engaged in recent cases. Price regulation and distribution of medicines covered by public health insurance is subject of continuous adjustments by legislation, also in 2023.

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Legislative developments and latest updates in Spanish health law.

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During 2023, Spanish authorities have been developing a progressive reduction of restrictive health measures associated with COVID-19 until the official declaration of the end of the pandemic. Meanwhile, new legislative developments in health law have come into force. Consequently, this report includes a part for the study of new regulations and a second section to stand out new case law by the Spanish Constitutional Court on the following issues: voluntary termination of pregnancy, euthanasia and vaccination of people with disabilities.

1. Regulatory developments.

Talking about regulatory developments, Order SND/726/2023 of 4 July must be highlighted, including the Agreement of the Council of Ministers, which declared the end of the health crisis caused by COVID-19.

Thus, after 5 July 2023, the health crisis is officially declared over, and prevention measures in workplaces must be concluded (e.g. the mandatory use of masks). However, these kinds of measures are recommended when respiratory infection symptoms occur and when necessary in nursing homes and homes for older people.

Secondly, Organic Law 1/2023, of 28 February, has come into force and has amended the following laws regarding voluntary termination of pregnancy:

- (a) Organic Law 2/2010, of 3 March, on sexual and reproductive health and voluntary termination of pregnancy.
- b) Law 41/2002, of 14 November, on patient autonomy and rights and obligations regarding clinical information and documentation.
- c) Organic Law 10/1995, of 10 November, on the Penal Code.

Thus, taking into account the new regulation, following I will summarise some parts, among other measures:

- The age of 16 is established to access voluntary pregnancy termination without their legal representatives' consent. Moreover, if minors under 16 years of age do not understand the scope of the surgical intervention, approval will be granted by parents or legal representatives.
- The scope of application of voluntary pregnancy termination is expressly extended to all persons in Spain, regardless of their nationality or legal residence status.

- There are changes in the information to be provided to the pregnant woman during the first 14 weeks of gestation: Health personnel must provide information regarding different pregnancy termination methods, surgical and pharmacological, health centres, conditions and procedures.
- The three-day reflection period is abolished.
- After the indicated 14 weeks of gestation, professionals must provide information on possible procedures to choose the most appropriate option. The rest of another kind of data is additional and only if the pregnant woman requests it.
- Regarding guarantees, if the procedure cannot be carried out, the health service must manage a referral to another local health centre, including compensation for expenses and judicial protection.
- Conscientious objection is a legal option recognised for health professionals directly involved in the voluntary termination of pregnancy. Health professionals must make their decisions in writing and in advance. The purpose of registers of objectors will be the accurate planning of health care activities.
- The free provision of emergency contraception will be set in health centres of the National Health System.
- The respect for women's autonomy and capacity to make informed decisions on their reproductive health, under the terms of Law 41/2002 of 14 November, on patient autonomy, rights and obligations regarding clinical information and documentation.
- Concerning violence in the area of sexual and reproductive health, the regulatory framework is completed with measures to prevent cases of forced abortions or sterilisations, with particular attention to women with disabilities.

Thirdly, Law 4/2023, of 28 February, for the effective equality of trans people and to guarantee LGBTBI people's rights.

This law includes health measures for both intersex people and trans people and highlights the principle of autonomy and non-pathologisation.

In the case of minors under 12 years of age, genital modification is forbidden unless medically indicated. However, for patients between 12 and 16 years old, professionals must analyse their maturity and informed consent.

Fourthly, Royal Decree-Law 5/2023, of 28 June, regulates some measures of health interest:

- The right to be forgotten when contracting insurance and banking products for patients who have had cancer.

- The possibility of dispensing medicines and health products in a non-face-to-face modality is maintained. This measure is envisaged for exceptional health situations and those who need it due to clinical reasons or distance from the health centre.

Fifthly, another state regulation of interest is the Royal Decree 192/2023, of 21 March, which regulates medical devices.

Its new features include the national regulation of the manufacture of medical devices in hospitals, the conditions of the reprocessing and reusing of single-use medical devices and the creation of a national register for the marketing of medical devices.

And finally, from the point of view of people with disabilities, we must stand out the Royal Decree 193/2023, of 21 March, which regulates conditions of accessibility and non-discrimination for people with disabilities to access and use goods and services available to the public.

According to the new regulation, universal accessibility is extended to health emergencies. And for this purpose, it compels health centres and establishments to have mechanical and electronic elements, assistive technology and qualified support staff.

2. Case law of the Spanish Constitutional Court.

a) Firstly, a doctrine has been established about vaccinating people with disabilities under the Law on patient autonomy (Law 41/2002).

Thus, public vaccination policies are linked to the constitutional duty of public authorities to protect collective health through preventive measures (Article 43 of the Spanish Constitution).

At the same time, the Court considers that the legal rule enabling interference with the right to personal integrity (art. 9.6 of the Law on Patient Autonomy) has the exclusive purpose of protecting the person concerned who is unable to give valid consent on their own.

The Court also considers that the vaccinated person could not express their wishes because of illness, and vaccination offered more significant benefits than harm in protecting their health.

b) Secondly, the Constitutional Court has declared constitutional the Organic Law 3/2021, of 24 March, regulating euthanasia (STC 19/2023 of 22 March).

Thus, the Constitutional Court declares that the Spanish Constitution protects a right of self-determination that allows a person to decide freely, informed and consciously the manner and moment of death in medically proven situations of terminal or seriously incapacitating illnesses.

This possibility is based on the fundamental right to physical and moral integrity, human dignity, and the free development of the personality (Articles 15 and 10.1 of the Constitution). To reach this conclusion, the

Constitutional Court considers that the interpretation of the Constitution must consider the historical context. Furthermore, it states that it is impossible to attribute an absolute value to the right to life, nor is a duty of individual protection imposed on the State implying a paradoxical commitment to live.

We must also remark that the Constitutional Court considers that this organic law establishes a system of guarantees and controls that fulfils the constitutional standard of protecting life from interference by third parties.

c) Thirdly, the Constitutional Court has ruled on the voluntary termination of pregnancy regulated in Organic Law 2/2010 of 3 March. This ruling recognises that the right to decide on the continuation of pregnancy within the first fourteen weeks of gestation is under the Spanish Constitution (STC 44/2023 of 9 May).

The Constitutional Court also declared that the system of time limits guarantees the State's duty to protect prenatal life, as it regulates a gradual limitation of the woman's constitutional rights according to the progress of the pregnancy and the vital development of the foetus.

Likewise, the Constitutional Court determines that the person's dignity protects a woman's decision to conclude her pregnancy, the free development of the personality and the fundamental right to physical and moral integrity (articles 10.1 and 15 of the Spanish Constitution).

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Health law-related legislative changes in Sweden 2023

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A possibility for caregivers to use coherent health and social care documentation

New law: Law (2022:913) on coherent health and care documentation.

Summary: A new law on coherent health and care documentation is introduced, replacing the provisions of the Patient Data Act (2008:355) on coherent record keeping. The Act also contains provisions concerning those parts of the social services' activities that relate to the care of older people and people with disabilities. This means that healthcare providers and care providers, through direct access or other electronic disclosure, have access to personal data held by other healthcare providers and social care providers. The law introduces privacy-enhancing measures and explicit provisions on children's consent to the processing of personal data.

SFS 2022:913 https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/lag-2022913-om-sammanhallen-var-d-och_sfs-2022-913/

Expanding and clarifying the regulation of biobanks

New law: The biobank act (2023:38)

New regulation: Biobank regulation (2023:38)

Summary: The biobank act provides for the collection, storage and use of human biological material for certain purposes, while respecting the integrity of the individual.

SFS 2023:38-44 https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/biobankslag-202338_sfs-2023-38/

- <https://svenskforsamling.se/sites/default/files/sfs/2023-05/SFS2023-285.pdf>
- <https://svenskforsamling.se/sites/default/files/sfs/2023-02/SFS2023-39.pdf>
- <https://svenskforsamling.se/sites/default/files/sfs/2023-02/SFS2023-40.pdf>
- <https://svenskforsamling.se/sites/default/files/sfs/2023-02/SFS2023-41.pdf>
- <https://svenskforsamling.se/sites/default/files/sfs/2023-02/SFS2023-42.pdf>
- https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/biobanksforordning-202343_sfs-2023-43/
- <https://svenskforsamling.se/sites/default/files/sfs/2023-02/SFS2023-44.pdf>

Measures to strengthen the security of supply of healthcare products

Legal changes: Act (2009:366) on trade in medicinal products, the Public Access to Information and Secrecy Act (2009:400), the Medicines Act (2015:315) and the Health and Health Care Act (2017:30).

Summary: The Health Care Act defines what is meant by the term "health care product". medical product and clarifies the equipment that must be available where health health care is conducted in an added section of the Act. Furthermore, a certain stockholding obligation is introduced for pharmacies and a delivery obligation for wholesalers to hospital pharmacies. The Medical Products Agency is authorized to charge a penalty fee from pharmaceutical companies that are late in notifying that the sale of a medicine ceases temporarily or permanently. A new amendment to the Freedom of Information and Secrecy Act makes it possible for, among other things, a region with retained secrecy to access information from the Swedish Medical Products Agency about shortages of medicines or medical devices. The state-owned company Apotek Produktion & Laboratories AB is given an expanded public service mission to maintain its operations even during peacetime crises, high alert and ultimately war.

SFS 2023:188-191

- <https://svenskfattningssamling.se/sites/default/files/sfs/2023-04/SFS2023-188.pdf>
- <https://svenskfattningssamling.se/sites/default/files/sfs/2023-04/SFS2023-189.pdf>
- <https://svenskfattningssamling.se/sites/default/files/sfs/2023-04/SFS2023-190.pdf>
- <https://svenskfattningssamling.se/sites/default/files/sfs/2023-04/SFS2023-191.pdf>

The regulation on digital COVID certificates expires

Summary: Regulation (EU) 2021/953 and the Swedish Regulation (2021:708) on digital COVID certificates will be repealed after June 2023, but the repealed Regulation will continue to apply to cases started before this date. This means that as of July 1, 2023, new Swedish digital COVID certificates will not be issued under these regulations, and only a few countries currently require digital COVID certificates for entry.

SFS 2022:1103 <https://svenskfattningssamling.se/sites/default/files/sfs/2022-06/SFS2022-1103.pdf>

Date of submission: 11 August 2023

Updates on UK health-related legislation

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For the purpose of this newsletter, it is not possible to highlight every legislative change in the past year or so that impacts the provision of healthcare or health research. Nor is it particularly sensible to discuss bills that may or may not become law; this includes, in the UK Parliament, the Mental Health Bill 2022 and the Data Protection and Digital Information (No 2) Bill 2022; and in the Scottish Parliament the Abortion Services Safe Access Zones (Scotland) Bill. Instead, I focus on the changes that are in my view ‘significant’, meaning they have direct impact on the organisation of healthcare or health research in the UK or the provision of health care and health research.

There have been several significant changes in the UK legislatively (from both the UK Government and the Devolved Administrations) in the past two years, which I proceed to summarise below:

Health and Social Care Act 2022

Undoubtedly the most significant piece of health legislation in a number of years is the Health and Social Care Act 2022, which received Royal Assent in April 2022. As NHS Providers [puts it](#): ‘The Health and Care Act 2022 contains the biggest reforms to the NHS in nearly a decade, laying the foundations to improve health outcomes by joining up NHS, social care and public health services at a local level and tackling growing health inequalities.’ The Act establishes a legislative framework in England that supports collaboration and partnership-working to integrate services for patients. The Act also includes targeted changes to public health, social care, and the oversight of quality and safety.

Most importantly, the Act formalises *Integrated Care Systems* (ICSs); this means that in England, formerly existing Clinical Commissioning Groups will be absorbed into their local ICSs. ICSs are partnerships that bring providers and commissioners of NHS services across a geographical area together with local authorities and other local partners to collectively plan health and care services to meet the needs of their local population. Each ICS is made up of two parts: an *Integrated Care Board* (ICB) and an *Integrated Care Partnership* (ICP). ICBs will be tasked with the commissioning and oversight of most NHS services and will be accountable to NHS England for NHS spending and performance. ICPs will bring together a wider range of partners (not just the NHS), to develop a plan to address the broader health, public health, and social care needs of the population. ICSs are expected to go beyond the NHS and work alongside local authorities and other partners to address the wider determinants of health in local communities.

The Act also formalises the merger of NHS England and NHS Improvement and gives the Secretary of State a range of powers of direction over the national NHS bodies and local systems and trusts. The Act also

introduces targeted changes to public health (e.g. limiting the advertisement of junk food), and formalises the role of the Health Services Safety Investigations Body, which is an independent body to investigate patient safety issues in England.

Health and Social Care Act (Northern Ireland) 2022

The health service in Northern Ireland is known as Health and Social Care (HSC). Northern Ireland's Department of Health has overall responsibility for the allocation of funding for health and social care. The Strategic Planning and Performance Group (SPPG) in the Department is responsible for commissioning services, resource management, performance management, and service improvement for the HSC. It deploys and manages funds allocated by the Department and oversees the work of the six HSC trusts. It also works to identify and meet the needs of the local population through five Local Commissioning Groups (LCGs), which cover the same geographical areas as the HSC Trusts. The Health and Social Care Act (Northern Ireland) 2022 provides for the dissolution of Regional Health and Social Care Board (also known as the HSC Board), which had previously been the statutory organisation which commissioned health and social care services for the population of Northern Ireland, while retaining LCGs, and place a duty on Northern Ireland's Department of Health to make regulations to establish bodies for local areas. In addition, it provides for the transfer of the HSC Board functions and requires the Department to make transfer schemes for assets and staff. It also makes the necessary transitional provision.

Health and Social Care Information Centre (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023

The Health and Social Care Information Centre, also known as NHS Digital, was established by Part 9 of the Health and Social Care Act 2012. Section 103(1) of the Health and Care Act 2022 introduced a power for the Secretary of State to make regulations transferring the functions of certain non-departmental public bodies to others. Section 102 lists the bodies to which section 103 applies; the list includes NHS Digital and NHS England. Under these Regulations (secondary legislation), the Health and Social Care Information Centre (NHS Digital) is abolished and its statutory functions transfers are to NHS England. It does this by making amendments to various items of primary and secondary legislation. The transfer of NHS Digital's functions follows a recommendation in Laura Wade-Gery's review *Putting data, digital and tech at the heart of transforming the NHS*, which called for a realignment of the organisational responsibilities for digital transformation of the NHS to ensure delivery of a new operating model. The Secretary of State for Health and Social Care announced on publication of the review that NHS Digital's functions would be transferred to NHS England as soon as legislation allowed.

Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022

Under this legislation, from 1 June 2023, all adults in Northern Ireland will be considered potential organ donors unless they choose to opt out or are in an excluded group. Those excluded from deemed consent legislation are: children under 18; people who lack the mental capacity to understand the change in law; and visitors to Northern Ireland and temporary residents. With this statute coming into force, Northern Ireland joins the UK's other nations in moving from opt-in to opt-out (deemed consent) regimes for deceased organ donation. (Wales was the first jurisdiction in the UK to shift from an opt-in to an opt-out system for organ donation, having initially passed legislation to this effect in 2013, followed by England and Scotland both in 2019.)

Medicines and Medical Devices Act 2021

This UK Government statute enables six fundamental changes to medicines and medical devices in the post-Brexit regulatory environment. It: (1) establishes a Patient Safety Commissioner, with the core duties of promoting patient safety and the importance of the patient voice in relation to the regulation of human medicines and medical devices; (2) introduces targeted delegated powers in the fields of human medicines, veterinary medicines, and medical devices to enable the existing regulatory frameworks to be updated following the UK's departure from the European Union; (3) provides information sharing gateways to enabling sharing of information with relevant persons (such as regulators and regulatory networks) outside of the UK in order to give effect to international agreements and arrangements concerning the regulation of human medicines, veterinary medicines, and medical devices; (4) provides a delegated power to establish one or more information systems in relation to medical devices; (5) provides a delegated power to establish on a legislative basis a medical device expert advisory committee; and (6) consolidates the enforcement provisions for medical devices and introduces civil sanctions.

Medical Devices (Northern Ireland Protocol) Regulations 2021

As many readers know, from 1 January 2021 Northern Ireland has continued to be aligned to EU legislation and regulations in respect of medicines and medical devices as a requisite of the Ireland/Ni Protocol and Great Britain (England, Wales, and Scotland) has not. Under the terms of the Northern Ireland Protocol, the rules for placing medical devices on the Northern Ireland market differ from those applicable to Great Britain. The Medical Devices (Northern Ireland Protocol) Regulations 2021 relate to the implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, (EU MDR), which fully applies in Northern Ireland since 26 May 2021. The Regulations update existing legislation, make provision for fees, and ensure that enforcement provisions can operate properly in Northern Ireland. The instrument also implements areas of national decision allowed for within the EU MDR which will allow the regulatory framework in Northern Ireland to align with that of the rest of the UK where possible. Specifically, these areas of national decision allow for: the continued practice of allowing the reprocessing of single-use

devices if re-processors adhere to the requirements of an original manufacturer; and maintaining the requirement to register custom-made devices; maintaining the UK medical devices regulator's (MHRA) ability to authorise clinical investigations for all device risk classes before they can start and to continue requiring all clinical investigations for custom-made devices to be subject to MHRA assessment. The instrument will also give the MHRA powers to serve enforcement notices for breaches of the EU MDR. The territorial extent of this instrument varies between provisions; some parts apply UK-wide, other parts only to Northern Ireland.

Health and Social Care (Quality and Engagement) (Wales) Act 2020

The Health and Social Care (Quality and Engagement) (Wales) Act 2020 came into force on 1 April 2023. The act aims to: strengthen the existing *Duty of Quality* on NHS bodies in Wales and extend it to the Welsh ministers for their health service functions; create a *Duty of Candour* on NHS service providers in Wales for openness and honesty with patients and service users harmed during care; amplify voices by replacing community health councils with Llais, an all-Wales *citizen voice body* for health and social care; and enable the appointment of *Vice Chairs for NHS Trusts*, bringing them in line with health boards.

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Some laws of Ukraine that were adopted in the field of health care for the first half of 2023

Khrystyna Tereshko,
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On August 9, 2023, the Verkhovna Rada of Ukraine adopted the Law of Ukraine "On Amendments to Certain Legislative Acts of Ukraine Regarding the Functioning of Telemedicine".

The Law of Ukraine "On Amendments to Certain Legislative Acts of Ukraine Regarding the Functioning of Telemedicine" was developed with the aim of introducing a comprehensive and systematic approach to the formation and implementation of state policy in terms of the development of telemedicine to preserve and strengthen the nation's health by improving the quality and availability of medical services, increasing opportunities for patients, increasing the efficiency of management and use of health care resources.

✦ More details at the link:

<https://itd.rada.gov.ua/billInfo/Bills/Card/42121>

On July 14, 2023, the Verkhovna Rada of Ukraine adopted the Law of Ukraine "On Overcoming Tuberculosis in Ukraine"

The law was developed with the aim of updating and updating the provisions of the legislation in the field of combating tuberculosis, synchronizing it with the current legislation in the field of health care and regulating the application of modern achievements of medical science and practice in accordance with WHO guidelines. This is a new comprehensive version of the Law, which will ensure proper diagnosis, prevention and treatment of TB.

✦ More details at the link:

<https://itd.rada.gov.ua/billInfo/Bills/Card/41634>

On July 14, 2023, the Verkhovna Rada of Ukraine adopted the Law of Ukraine "On Amendments to Certain Laws of Ukraine Regarding the Definition of Categories of Persons Recognized as Persons with Disabilities as a Result of the War and Family Members of Fallen Defenders of Ukraine, as well as Providing Social Guarantees to Them".

The law provides for the possibility of classifying servicemen who were injured, contused, maimed, or diseased during military service or training in military educational institutions, training units (centers), military units that were hit by rocket, artillery, or air strikes, to the category of persons with disability due to war. In addition, the right to provide social guarantees to the above-mentioned servicemen, who belong to persons with disabilities as a result of the war, and to the families of fallen (deceased) Defenders of Ukraine has been enshrined.

✦ More details at the link:

<https://itd.rada.gov.ua/billInfo/Bills/Card/41544>

On June 29, 2023, the Verkhovna Rada adopted the Law of Ukraine "On Amendments to Certain Legislative Acts of Ukraine Regarding the Verification of Patient Information."

The Law of Ukraine "On Amendments to Certain Laws of Ukraine Regarding the Verification of Patient Information" was developed with the aim of creating conditions for the performance of tasks and functions assigned to the electronic health care system in order to ensure the possibility of patients using electronic services to exercise their rights in terms of updating information and verification of patient data between the electronic health care system and the Unified State Demographic Register, the State Register of Civil Status Acts of Citizens and/or the State Register of Individuals - Taxpayers.

✦ More details at the link:

<https://itd.rada.gov.ua/billInfo/Bills/Card/41890>

On May 02, 2023, the Verkhovna Rada of Ukraine adopted the Law of Ukraine "On Amendments to the Statute of the Internal Service of the Armed Forces of Ukraine regarding the improvement of documents and treatment of servicemen during martial law".

The purpose of the law is to improve the issue of issuing a certificate to military personnel about the circumstances of an injury (injury, contusion, mutilation) both as a result of an appropriate investigation (official or special) and without it, as well as to improve the issue of issuing and sending medical and other documents between military units and healthcare institutions.


Also, the task of this normative act is to simplify the procedure for implementing the conclusions of the military medical commission on granting leave for treatment due to illness and on unfitness for military service.

✦ More details at the link:

<https://itd.rada.gov.ua/billInfo/Bills/Card/41665>

On January 12, 2023, the Verkhovna Rada of Ukraine adopted the Law of Ukraine "On Amendments to the Law of Ukraine "On Combating the Spread of Diseases Caused by Human Immunodeficiency Virus (HIV) and Legal and Social Protection of People Living with HIV"

The law was developed with the aim of updating and updating the Law of Ukraine "On Combating the Spread of Diseases Caused by the Human Immunodeficiency Virus (HIV) and Legal and Social Protection of People Living with HIV", synchronizing it with current legislation in the field of health care and regulating it in it is the application of modern achievements of medical science and practice in accordance with WHO guidelines. The presented changes will ensure proper diagnosis, prevention and treatment of HIV infection.

 More details at the link:

<https://itd.rada.gov.ua/billInfo/Bills/Card/28417>

Draft laws of Ukraine

On July 13, 2023, the Verkhovna Rada of Ukraine adopted as a basis the Law of Ukraine "On Regulation of the Circulation of Cannabis Plants for Medical, Industrial Purposes, Scientific and Scientific-Technical Activities to Create Conditions for Expanding Patients' Access to the Necessary Treatment of Oncological Diseases and Post-Traumatic Stress Disorders as a result of the war".

The project of the Law of Ukraine "On regulation of the circulation of plants of the genus hemp (Cannabis) for medical, industrial purposes, scientific and scientific and technical activities to create conditions for expanding access of patients to the necessary treatment of oncological diseases and post-traumatic stress disorders obtained as a result of war" was developed with the aim of implementing a better experience in the field of regulating the limited circulation of cannabis, cannabis resin, cannabis extracts and tinctures, as well as tetrahydrocannabinol (its isomers and their stereochemical variants), by making changes to the laws of Ukraine that regulate the handling of narcotic drugs, in order to create conditions for expanding patient access to the necessary treatment, conducting scientific research on the effectiveness of cannabis.

 More details at the link:

<https://itd.rada.gov.ua/billInfo/Bills/Card/39783>

On April 11, 2023, the draft Law of Ukraine "On the use of assisted reproductive technologies and surrogate motherhood" was registered in the Verkhovna Rada of Ukraine.

The draft Law was developed with the aim of regulating the organizational and legal principles in the field of the use of assisted reproductive technologies and surrogate motherhood, namely: conditions and procedures for the use of assisted reproductive technologies, including surrogate motherhood services; the rights and obligations of persons to whom assisted reproductive technologies are applied; conditions and procedure for donation of reproductive cells, their storage and use; protection of the rights and legitimate interests of citizens of Ukraine and foreigners during surrogacy.

 More details at the link:

<https://itd.rada.gov.ua/billInfo/Bills/Card/41737>

On March 21, 2023, the Verkhovna Rada of Ukraine adopted as a basis the project of the Law of Ukraine "On Amendments and Supplements to Certain Laws of Ukraine in order to ensure the rights of war participants to biological post-traumatic paternity/maternity"

The purpose of the draft law is to create state guarantees regarding the preservation of the possibility of biological paternity/maternity for the defenders of Ukraine, in case they receive injuries that affect reproductive functions. Also, one of the tasks of the draft law is to extend part of the guarantees in the field of medical care and rehabilitation measures provided to military personnel to police officers who perform official duties in areas of military operations.

✦ More details at the link:

<https://itd.rada.gov.ua/billInfo/Bills/Card/40292>

On January 10, 2023, the project of the Law of Ukraine "On Amendments to the Law of Ukraine "On the Status of War Veterans, Guarantees of Their Social Protection" on Medical Care and Social Protection of War Veterans" No. 8318-1 was registered.

The purpose of the draft law is to improve the system of medical care for war veterans, Defenders of Ukraine and increase the level of their social protection, which they earned by defending the independence of Ukraine. The draft law provides for emergency treatment of war veterans, defenders of Ukraine abroad, in cases where medical assistance cannot be provided in health care institutions of Ukraine, as well as free preventive medical examinations at least once a year, which meet today's requirements.

✦ More details at the link:

<https://itd.rada.gov.ua/billInfo/Bills/Card/41144>

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