



CONTENTS

Executive Summary	3
Overview	4
The Struggle for Medical Self- Governance in Ukraine so far	4
The German System of Medical Self-Governance	4
Introduction of Medical Self-Governance as Part of Ukraine's Integration in the EU	7
Progress and Challenges in Ukraine's Legislative Procress	7
Conclusions and Recommendations for Further Advocacy of the Draft Law on Medical Self-Governance in Ukraine	8
General Recommendations	8
Next Steps	8
About the Authors	9

EXECUTIVE SUMMARY

Ukraine continues its path to European integration by reforming and harmonizing national legislation with the regulatory framework of the European Union (EU). Introducing a system of medical self-governance is a key part of this integration. It would entail professional self-governance for doctors and other medical and pharmaceutical professions with the authority to regulate professional activities, control the quality of services and protect patients' rights.

Crucially the organization of medical self-governance would issue certificates that confirm the professional qualifications of a doctor and his or her compliance with the established medical practice.

Harmonizing the Ukrainian healthcare legislation with European standards and practices will help international recognition of Ukrainian medical qualifications in the EU. This, in turn, will help Ukrainian doctors to practice in the EU, in particular in Germany.

The Verkhovna Rada adopted the relevant draft law (No. 10372) in the first reading in June 2024, which was prepared with support of international partners. This marked an important step towards medical self-governance. However, the draft law still needs to be finalized and contains a number of shortcomings that may hamstring an effective system of medical self-governance, an independent medical community or trust in medical self-governance.

As the Verkhovna Rada has already successfully worked together with international partners, their input for the draft law's final version could help make the bill compliant with European legislation and established practices in the EU member states. Such cooperation will help integrate Ukrainian doctors into the European medical community and increase confidence in the Ukrainian healthcare system.





OVERVIEW

Ukraine's Constitution guarantees everyone the right to health care and medical assistance. These basic rights can only be ensured in a society where doctors are not barred from entering the profession by red tape, where they are encouraged to constantly improve their skills, where they receive fair wages and where they have a strong lobby that furthers their professional interests and monitors the quality of their services.

Medical self-governance is an integral feature of all healthcare systems in the EU, where medical self-government bodies manage the healthcare system as equal partners alongside state authorities. Some of the world's most esteemed medical bodies have long called for medical self-governance, including the World Medical Association, which unites doctors from 94 countries. The 1987 Madrid Declaration adopted by the 39th World Medical Assembly emphasized the need for self-governance of the medical profession and professional autonomy. The basic principles of medical self-governance formulated in the document aim at covering patients' needs and protecting the rights of medical professionals, while delegating some core requlatory functions of the healthcare system to medical self-government bodies.

The Struggle for Medical Self-Governance in Ukraine so far

Ukraine curtails the professional freedom for doctors with excessive red tape for new doctors. Most doctors work long hours for small wages with little say over their employment conditions and are unable to realize their full potential. Currently, a Ukrainian doctor can practice medicine independently only as an individual entrepreneur.

Ukraine has already attempted to license doctors and create a system of medical self-governance. Bills that would have created self-governing organizations in the healthcare system have been submitted to Parliament since 2006,

but none of them has ever been adopted by the Verkhovna Rada.¹

Now the opportunity for real transformation has ripened. Recent healthcare reforms as well as international cooperation, including with European countries, have laid a solid foundation for medical self-governance. Bilateral cooperation and discussions between representatives of Ukrainian civil society, Parliament, the medical community, and the Health Committee of the German Bundestag made it clear that medical self-governance is impossible without a radical reform of Ukraine's medical sector.

The German System of Medical Self-Governance

In contrast to countries like the UK, Sweden or Italy, where the state regulates medical care and maintains a publicly funded network of doctors' surgeries and hospitals, Germany allows for greater medical self-administration.

Although the state provides the legal framework, health care providers and professionals organise themselves. The contemporary system of medical self-governance in Germany emerged after the end of the Second World War and is highly decentralized as the federal states are responsible for the medical sector.

The chambers of physicians and the Association of Statutory Health Insurance Physicians share the organisation and representation of the medical profession. Besides the Association of Statutory Health Insurance Physicians, the National Association of Health Insurance Funds, the German Hospital Federation and the Federal Joint Committee are the central organs of medical self-governance in Germany and are influential in overall health policy.

Germany holds elections to these bodies every six years. Elected representatives sit on the boards of these self-governing bodies and administer budgets, contribution rates and

¹ No. 3539 of 23 December 2008; No. 5124 of 1 October 2014; No. 5617 of 28 December 2016 and No. 5617-1 of 13 January 2017; No. 8250 of 6 April 2018; No. 2445 of 14 November 2019, No. 2445-1 of 26 November, 2019, No. 2445-2 of 26 November, 2019 and No. 2445-3 of 2 December 2019; No. 2445-d of 3 July, 2020.



benefits. The boards also oversee contracts with doctors and hospitals, giving them great influence over day-to-day medical practice. Candidates usually come from trade unions, social organisations and employers' associations.

Chambers of physicians (Ärztekammern) are the public representation of the profession in Germany. The 17 state chambers of physicians (Landesärztekammern; there are 17 state chambers of physicians in 16 federal states because North Rhine-Westphalia is organised in two chambers) are corporations under public law and subject to self-governance. State chambers of physicians and physicians' mandatory membership in them are regulated by law: on the basis of the Heilberufekammergesetz (federal state law) they are responsible for safeguarding the interests of the medical profession and represent the professional interests of their members. Their core task is to monitor compliance with professional duties and standards and to ensure specialist medical training and continued medical education of its members.

There is no standard structure for chambers of physicians, but they are usually organised around an executive board and an assembly elected by the members. In some cases, there are also district chambers of physicians (Bezirks-oder Kreisärztekammern) in the federal states, which operate at a sub-state level. Although these are separate public bodies, they are dependent on their respective state chambers of physicians.

In addition, Germany has a federal umbrella organization (Bundesärztekammer), a joint association of the 17 state chambers of physicians. It is not constituted as a corporation under public law but as a registered association. The German Medical Association is primarily responsible for communication between the state chambers of physicians and ensures that medical care is provided and maintained nationwide. It promotes the exchange of experience and opinions between the state chambers of physicians and the harmonisation and standardisation of the structures and regulations adopted by the state chambers of physicians. Furthermore, the German Medical Association represents the interests of the German medical

profession at federal level and plays an active role in agenda-setting and opinion-forming processes relating to health and social policy in legislative procedures and public opinion.

Like the chambers of physicians, the 17 associations of statutory health insurance physicians (Kassenärztlichen Vereinigungen - KVs) are corporations under public law and subject to the (legal but not professional) supervision of the health or social ministry of their respective federal states. The KVs are also organised around an executive board and an assembly elected by the members. Every psychotherapist and doctor who is authorised to participate in Statutory Health Insurance (SHI) accredited medical care is automatically a member of the KV in their region. At federal level, the KVs form the National Association of Statutory Health Insurance Physicians (KBV) which is also a corporation under public law and subject to the (legal but not professional) supervision of the Federal Ministry of Health.

The KVs and the KBV are responsible for nationwide outpatient medical and psychotherapeutic care for those with statutory health insurance. As an interface between the medical profession, patients and health insurance funds, the KVs are primarily responsible for financial matters. With the state associations of health insurance funds, the KVs negotiate the remuneration of services provided by SHI-accredited physicians and distribute the remuneration paid by the health insurance funds among the individual doctors and psychotherapists according to the services provided. At federal level, the KBV concludes agreements with the National Association of Statutory Health Insurance Funds, on the organisation of care provided by SHI-accredited physicians.

The National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) is the central representative body for all statutory health insurance funds at federal level. It coordinates overarching tasks that are relevant to the entire statutory health insurance system. These include negotiating framework agreements with doctors, hospitals and pharmacies, setting quality standards and helping to define the SHI benefit catalogue. It is also responsible

for long-term care insurance and develops measures to improve the quality of health and long-term care services. Its tasks include representing the statutory health insurance funds in political and public health discussions, negotiating contracts and reimbursement agreements with service providers, and defining the medical services covered based on the recommendations of the Federal Joint Committee. As a corporation under public law, the GKV-Spitzenverband is supervised by the Federal Ministry of Health and has an executive board made up of representatives of the insured and employers.

The state associations of health insurance funds represent the interests of the statutory health insurance funds at state level and play a key role in regional health care management. They negotiate contracts with doctors, hospitals and care facilities, implement national regulations and adapt them to regional conditions. They also work with the state health authorities, influence hospital planning and support public health initiatives. While the GKV-Spitzenverband takes on overarching strategic and political responsibilities at federal level, the regional associations focus on the implementation and adaptation of healthcare services at the regional level.

The German Hospital Federation (Deutsche Krankenhausgesellschaft, DKG) is the umbrella organisation of the central and regional associations of hospital operators in Germany. It represents the economic, legal and political interests of hospitals at federal level and negotiates with politicians, health insurers and other stakeholders to influence hospital financing, healthcare regulations and quality standards.

The DKG helps to define the services covered by statutory health insurance and contributes to hospital financing and quality assurance. The DKG also provides information, training and legal support to its members, which include regional hospital associations, public and private hospital operators and university hospitals.

The Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) is the highest self-governing body in the German healthcare system and decides which medical services and treatments are covered by statutory health insurance (SHI). Its main task is to set the framework for the content of health care services and to decide which treatments, drugs and diagnostic procedures will be reimbursed by the SHI system. Its legal mandate is to ensure comprehensive and efficient medical care that keeps pace with medical progress.

In addition to defining the catalogue of services provided by the SHI system, the G-BA also sets quality standards for health care providers to ensure that treatments meet the latest scientific and medical standards. It plays a key role in evaluating new medical procedures and innovations, assessing their effectiveness and cost-effectiveness before they are included in the SHI benefit catalogue.

The G-BA consists of three impartial members and representatives of SHI-accredited doctors (KBV), health insurance funds (GKV-Spitzenverband) and hospitals (DKG). Representatives of patient organisations attend the meetings with the right to co-advise and submit motions, but without the right to vote. In addition, representatives of the federal states are involved in issues of demand planning and quality assurance to ensure that regional health care needs are taken into account in decision-making.



Introduction of Medical Self-Governance as Part of Ukraine's Integration in the EU

The adoption of the Law on Self-Governance in the Healthcare Sector in Ukraine (No. 10372) is an important step towards Ukraine's integration into both the European legal and professional medical environment. Although the provisions of the draft law are regulated by national legislations of each EU member state and are not part of Ukraine's international legal obligations in the field of European integration, the Association Agreement between Ukraine and the EU² mentions medical self-governance as an integral feature of all EU healthcare systems that should be established in Ukraine in the process of preparing for European integration.³

Pursuant to Article 427(1)(a) of Chapter 22, Section V "Economic and Sectoral Cooperation" of the Association Agreement, cooperation covers, inter alia, such areas as strengthening the healthcare system of Ukraine and its capacity, in particular through the implementation of reforms, further development of primary healthcare and staff training.

What is more, the European Union also allows doctors who obtained their qualification in one member state to practice it in another member state.⁴ This is the basis for the development of medical self-governance in the EU.

As of August 2024, 1.674 Ukrainian doctors are trying to obtain the right to practice medicine in Germany.⁵

2 https://eur-lex.europa.eu/EN/legal-content/summary/ association-agreement-with-ukraine.html Given the above, to create conditions for Ukrainian healthcare professionals to access the EU labor market on an equal footing with representatives of other European countries, in accordance with EU rules, to the Verkhovna Rada should adopt this draft law and finalize it in cooperation with international partners to take into account the practice of EU member states.

Progress and Challenges in Ukraine's Legislative Procress

On June 6, 2024, the Verkhovna Rada of Ukraine adopted the Law of Ukraine "On Self-Governance in the Field of Healthcare in Ukraine" in the first reading.

Work on the draft law in the first reading demonstrated that if state officials, the medical community and international experts collaborate, legislative initiatives become better and take better account of potential risks.

This collaboration for example led the Verkhovna Rada to amend the draft law and include an individual licensing system that works through a digital register of medical professionals. The Rada also simplified regulation of medical practice by switching from licensing to declaration of medical practice, which s reduces the administrative burden and makes the process more transparent. The draft law also regulated the concept of medical errors in a novel way that helps to protect the interests of both medical professionals and patients.

If adopted, the law will unite the self-governing organizations of family doctors and specialists into a single structure, bringing thus far fragmented representative bodies together. The proposed implementation strategy would come in stages: first a register of doctors and then, after the end of martial law, creation of self-governing organizations.

To be sure, the draft law still has flaws that the Rada should address. For instance, it lacks a clearly regulated electoral mechanisms for the governing and disciplinary bodies of professional self-governance. That comes with the risk that the "old elite" of doctors and administrators will cling to their powers in a newly created self-governance system. The way qualification and disciplinary bodies monitor doctor's continuous training and professional development can also be improved.

³ Chapter 22, Article 426 of the Association Agreement between Ukraine and the EU: "The Parties shall develop their cooperation in the public health field, to raise the level of public health safety and protection of human health as a precondition for sustainable development and economic growth."

⁴ Article 1 of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications stipulates that the Directive establishes rules according to which a Member State which makes specific professional qualifications a condition for access to or exercise of a regulated profession in its territory shall recognize professional qualifications obtained in one or more other Member States which enable the holder of those qualifications to exercise the profession in question.

⁵ https://www.welt.de/politik/deutschland/article252822286/ Bilanz-verheerend-Deutsche-Buerokratie-bremstgefluechtete-ukrainische-Aerzte-aus.html



CONCLUSIONS AND RECOMMENDATIONS FOR FURTHER ADVOCACY OF THE DRAFT LAW ON MEDICAL SELF-GOVERNANCE IN UKRAINE

General Recommendations

Introducing medical self-governance in Ukraine is an important step towards a better healthcare system more closely aligned with international partners, including from Germany, could be instrumental in pushing the draft law. Dialogue with German medical associations and parliamentary committees would be very useful as Ukrainian practitioners could obtain technical expertise and knowledge about funding opportunities for pilot projects. This may include consultations on harmonizing legislation with European standards and digitalizing the individual licensing process.

Remaining legal and technical issues in the licensing procedure also require lawmakers' attention. The introduction of a digital registry to automate the certificates will reduce bureaucracy, tackle corruption, and ensure transparency. Such a system will be able to integrate data on the qualifications of medical professionals, their continuous professional development, and other important information, increasing the efficiency of medical practice management.

Lawmakers must also continue to demonstrate that the reform is feasible and worthwhile. This will help to attract investors and international partners. It will also build trust on the part of the medical community and the public. If Parliament engages civil society, trade unions and professional associations more actively, it could broaden support for the draft law.

Next Steps

We suggest focusing on the following practical steps for the Verkhovna Rada:

- Deepening cooperation with Germany:
 Initiate additional meetings with representatives of the German Bundestag, medical associations and experts to discuss technical and advisory assistance.
- 2. Develop a roadmap: Create a joint working group with the participation of international partners to develop a detailed plan for implementing the reform in accordance with European standards.
- **3. Financial justification:** Conduct a detailed cost analysis of the implementation of the individual licensing system and develop recommendations on sources of funding.
- **4. Information campaign:** Organize a public discussion with the participation of healthcare professionals, NGOs, and trade unions to support the transparency of the process.
- 5. Digitalization pilot project: Launch a pilot project to create a digital registry that will serve as the basis for automating the licensing process.

These steps will help to create an effective, transparent and modern system of medical self-governance that will meet European standards and facilitate the integration of Ukrainian doctors into the international medical community.



About the Authors

Tetyana Gavrysh is a lawyer, co-founder of the Charitable Foundation Health Solutions for Open Society, and founder and managing partner of the law firm ILF. She also serves as the Honorary Consul of Germany in Kharkiv. Tetyana has over 10 years of experience in health sector reform, health and human rights, and systems transformation.

As part of the Kharkiv Expert Group, she and her colleagues provided extensive support to the Government of Ukraine in implementing health reforms, transforming healthcare facilities, and building the capacity of central and local government bodies. Tetyana led a team of experts that developed recommendations for what is now the monitoring system of contractual obligations of healthcare facilities by the National Health Service of Ukraine.

Her recent professional interests and achievements include designing and advocating for professional medical self-governance, reforming medical practice, introducing individual medical licensing, and driving deregulation. Another key area of her work focuses on advancing integrated care and the healthy community model as central elements in the transformation of communities to meet both current and post-war recovery needs.

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He has served as a member of several working groups under the Ministry of Health, focusing on human capital development and the electronic health system. He has also been part of an expert group on monitoring contractual obligations between the National Health Service of Ukraine and healthcare facilities.

Oleksii's professional interests include human rights in patient care and the patient-doctor relationship. In 2024, he was elected Head of the Public Control Council at the National Health Service of Ukraine.

Viktoriia Tymoshevska is a doctor, public health specialist, and co-founder of the Charitable Foundation Health Solutions for Open Society. She has 16 years of experience in managing public health programs at the International Renaissance Foundation, where she facilitated initiatives aimed at improving access to medicines and care for marginalized groups and communities, expanding access to palliative care, and supporting the implementation of health reforms in Ukraine.

Viktoriia was closely involved in the development and approval of Ukraine's National Drug Strategy (2015–2020), advocating for more balanced and human rights-oriented policies and practices. She also played a key role in establishing Ukraine's health technology assessment body and the national essential medicines list—now the foundational instrument for the country's reimbursement system and the Program of Medical Guarantees.

Her recent professional interests include organizing and delivering medical services to communities near the front line and reforming the military medicine system. She focuses on protecting human rights and dignity through policymaking support and capacity building for key stakeholders.

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