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Regulatory Impact Assessment of cross-border healthcare in Poland

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The relationship between economics and law was noticed by economists and lawyers, but it was not until the second half of the twentieth century that the scientific movement using the term "Law and Economics" to describe its activities became widely recognized. The relationship between law and economy has also been noticed by business entities and state authorities, resulting in the dissemination of analyses in the field of socio-economic effects and taking them into account in the law-making process. On the basis of the theory of economic analysis of law, within the framework of the institutional economic analysis of law, the Regulatory Impact Assessment (RIA) has been developed.

RIA is a process aimed at improving the law. The legal basis for carrying out the RIA is the Regulation on Proceedings of the Council of Ministers, while the individual stages of the RIA process are described in the *Guidelines for the Impact Assessment and Public Consultations* under the Government's Legislative Process. Pursuant to § 25 of the Regulation, the scope of the impact assessment is determined depending on the type of document and the subject and scope of impact of the planned interventions. In turn, § 28 of the Regulation stipulates that RIA includes in particular: a list of stakeholders; information on pre-consultations, consultations and issuing opinions on the project; presentation of the impact on: the public finance sector (with an indication of the source of expenditure financing and the methodology of their estimation), the labour market and enterprises. The current shape of RIA in Poland is the result of many years of changes in the approach to economic analyses and their use in the legislative process. The use of this tool also reflects international standards in this area, resulting from documents adopted by the European Commission and by the Member States of the Organization for Economic Cooperation and Development (OECD).

The main assumption of the regulation of cross-border healthcare is to ensure the implementation of the principle of the free movement of services within the territory of the EU in the field of healthcare in accordance with the achievements of the European Court of Justice, i.e. creating a transparent legal framework for the use of health services in other EU Member States, with the possibility of obtaining by everyone reimbursement of such benefits by the patient's public health insurance scheme to which the person is subject.

The use of benefits under cross-border healthcare financed from public funds is provided in Poland and in other Member States of the European Union on the basis of the provisions on the coordination of social security systems and on the basis of the provisions of the Directive on the application of patients' rights in cross-border healthcare. Directive 2011/24 / EU of the

European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (the so-called "cross-border directive") was implemented into the Polish legal system in 2014 in the provisions of the Act of August 27, 2004 on health care services financed from public funds ("the Act on benefits"). The recipient is entitled to reimbursement of costs incurred for healthcare services provided in the territory of an EU Member State other than Poland. The basis for determining the amount of reimbursement is the amount of financing a given benefit in the country, not higher than the value resulting from the bills submitted.

The market of cross-border services is of interest to healthcare entities throughout the European Union, including Poland, the more so as it is commonly believed that Polish healthcare entities do not obtain sufficient funds for the provision of services purchased by the National Health Fund. As shown in the literature on the subject, changes in EU law, expanding the scope of using cross-border healthcare, affect the functioning of service providers through, inter alia, obtaining additional funding streams and improving the quality of care, changing the allocation of resources and attracting new patient groups. The literature also raises the need to shape the strategy of a medical entity that would allow not only to attract a new, foreign patient, but also to detain a Polish patient, so that he would not migrate abroad in search of services. The premise for the creation of the dissertation is the existence of a research gap regarding the economic impact of patient migration on the health systems.

Economic analysis is used more and more in the study of law, but the scientific status of Law and Economics remains controversial due to the terminology used in the history of economic theory. One of the fundamental assumptions of economic analysis of law is the pursuit of economic effectiveness through regulations. Contemporary trends in this analysis point out that government interventions in the form of a regulation should be based on a cost-benefit analysis, and government institutions have an important role to play in mitigating or preventing from the market failure.

Similarly to the approaches proposed by individual schools of economic analysis of law, the practices of RIA application also change over time. These changes are noticeable in periodic revisions of methods at the EU level, e.g. the last one in 2014, as a result of which the guidelines on the methods and scope of analyses prepared for the purposes of RIA were updated. Changes in practices are also visible at the national level through the formalization of the process, e.g. the amendment to the rules of procedure of the Council of Ministers in the scope of empowering the assessment of the impact of regulations in the government legislative process. The methods

used so far as basic, incl. cost-benefit analysis and cost-effectiveness analysis are supplemented, e.g. with a sensitivity analysis, or new methods and tools are introduced into practice, e.g. standard cost model or quality of life measurement (*Quality-adjusted life-years*, QALY) to estimating the cost of disease and the benefits of treatment.

More than seven years have passed since the entry into force of the provisions of the act implementing the cross-border directive, and no analysis of the functioning of the regulation has been carried out yet, nor has its impact on access to healthcare services, the NHF budget and the activity of healthcare entities been assessed. Many service providers are interested in developing solutions enabling the acquisition of new groups of patients. As part of the work on the draft cross-border directive, research was carried out in 2007, which showed that approximately 54% of EU citizens are ready to receive healthcare services in another EU country. In the regulatory impact assessment attached to the legislative proposal - the draft directive on cross-border healthcare, the European Commission indicated that expenditure on cross-border healthcare will amount to EUR 9.7 billion annually in the EU, which is approx. health. The literature review shows that researchers focus on signalling changes in legal regulations, without examining the impact on the health care system and stakeholders (addressees of legal acts). Pursuant to Art. 118 sec. 2 point 1 letter d of the Act on benefits, funds to cover the costs of performing tasks under Art. 42b above. the acts have been secured in the Fund Headquarters Financial Plan. In connection with the above, the costs incurred in connection with the reimbursements made on the basis of the provisions implementing the directive are settled by the provincial branches of the National Health Fund with the Head Office of the Fund, in which the Financial Plan includes a provision for this purpose. The limit of the Fund's costs for benefits provided under cross-border healthcare for 2014-2023 is indicated in Art. 11 sec. 1-4 of the act. In 2014, approximately PLN 940 million was guaranteed for the provision of services based on cross-border healthcare, and in subsequent years - approximately PLN 1 billion. According to the information included in the reports on the activities of the National Health Fund, in 2014 no funds were spent, in 2015 - approx. PLN 9.2 million (funds due from November 14, 2014 to December 31, 2015), in 2016 - approx. PLN 17.6 million, in 2017 - approx. PLN 36.2 million; in 2018 - approx. PLN 33.6 million; in 2019, approximately PLN 32 million. In the light of such a large discrepancy in the prognosis of the effects and implementation of the provisions of the Act on benefits, it is justified to examine the methodology of estimating the impact of regulations and to try to explain the reasons for these discrepancies.

The theoretical and practical aspects of the functioning of the provisions on the basis of which it is possible to provide cross-border care services remain relatively poorly described. Thus, there is a clear need for a comprehensive study of the theoretical foundations and methods used to assess the impact of regulations and the systematization of information on the latest practices and theories on RIA, including a case study of estimating the impact of cross-border healthcare and factors influencing the demand and supply of these services. This will enrich the economic debate on the system of functioning of the regulatory impact assessment in Poland, in particular in the area of health protection and the implementation of health policy based on the economic analysis of the law.

The discussion on regulatory impact assessment in Poland has been going on for two decades and during this time there has been a visible evolution in the preparation and use of economic analyses in the law-making process. In the face of the currently observed attempts to evaluate the cross-border directive and assess the functioning of national regulations, examining the methodologies and assumptions adopted for estimating the effects also has a high cognitive value. The observation of this relatively new and still little explored legal basis for cross-border care allows for drawing preliminary conclusions on the forecasting of consequences for the state budget, healthcare providers (clinics and hospitals) and patients. In addition, it will allow to study the phenomena that have arisen in connection with the introduction and functioning of the regulations, and in the long term - to consider monitoring these phenomena and measuring the results obtained. The analysis of the regulatory impact assessment process, the scope of analyses and the methodology for carrying them out is also important from the point of view of the ongoing debate on the shaping of regulatory impact assessment in Poland, including the specificity of the health care sector.

The subject of the dissertation are the theoretical foundations of RIA and methods used in estimating the effects of regulations, with particular emphasis on the methods used to assess the impact of cross-border healthcare implemented on the basis of the cross-border directive. Both the legislative proposal and the bill implementing EU law were preceded by economic analyses of the socio-economic effects of the regulation of cross-border healthcare. The scope of the research includes a comparative analysis of the existing methodologies and tools used to estimate the socio-economic effects of regulations arising from the theory of economic analysis of law. The scope of methods used in Poland as part of the government's legislative process was also analysed, including by the Ministry of Health to prepare RIA for the draft act implementing

the cross-border directive, as well as the selection of methods for RIA preparation made by the European Commission, namely the Directorate General for Health (DG SANTE).

The main aim of the dissertation is to examine the assessment of the effects of regulations and methods of their estimation on the example of cross-border healthcare. Another goal is to review the methods used, which is a set of tools for analysing the cause-and-effect relationships between economic phenomena and the legal instruments that are being created, such as the cross-border directive and the law implementing it. Thanks to the analysis of the methods used to quantify the effects, including the specificity of health protection, it is possible to learn and understand the effects of cross-border healthcare, and thus to deepen the knowledge about the relatively new phenomenon of cross-border healthcare. The dissertation also aims to present the most comprehensive overview of patient migration, in which market phenomena are presented in the context of a politically created framework (regulation) for economic interactions.

There are two assumptions at the heart of the dissertation. On the one hand, economic analyses of law are presented in the form of the regulatory impact assessment process at the European Union level and in Poland, along with the RIA methodology. This is done through a review of the literature on the subject and a comparative analysis of legal acts and guidelines in the field of regulatory impact assessment and the presentation of methods for their quantification. On the other hand, the study includes an assessment of the effectiveness of the created instruments on the example of cross-border health care (resulting from the directive and the amendment to the Act on Benefits) and its impact on the health care system in terms of its effects on the public finance sector (the payer's budget, i.e. the National Health Fund), service providers providing benefits on the basis of cross-border healthcare, and final beneficiaries, i.e. patients.

The thesis of the dissertation is expressed in the following statement: the methods used in the regulatory impact assessment allow for the estimation of the projected impact and the assessment of the achieved regulatory effects. The thesis is discussed on the example of cross-border healthcare provided to patients covered by health insurance in Poland. The following hypothesis is put forward: the introduction of provisions enabling the use of services under the cross-border directive has a positive impact on the financing of care and the functioning of the National Health Fund, healthcare providers and patients' access to healthcare services. In order to reject or prove it, an analysis of available data and methods of RIA are used to estimate the planned effects and obtained effects of the cross-border directive.

The dissertation provides answers to the following research questions:

1) what is RIA and what is its genesis;

2) what methods are used in RIA, what are their theoretical foundations and what practice of applying particular methods;

3) which of the methods correspond to the specificity of the health care sector in estimating the effects of *ex ante* regulation,

4) what was the course of the *ex ante* RIA and how the effects of the implementation of the cross-border directive were estimated with reference to the applied methods of estimating the effects

5) what are the effects of the implementation of the cross-border directive in Poland;

6) what methods, other than those used by the Ministry of Health, can be used to estimate the effects of the directive and what are their advantages and disadvantages.

The research objectives required an interdisciplinary theoretical approach and various research tools that can help in understanding and explaining both political and economic aspects of the functioning of the regulatory impact assessment.

The main source of data used in the dissertation are:

a) Polish and foreign monographs and scientific articles on the theory of health economics and economic analysis of law as well as the issues of regulatory impact assessment;

b) published government documents specifying the principles of conducting regulatory impact assessment, with particular emphasis on the area of health protection (problem guidelines);

c) Regulatory Impact Assessment documents prepared at the level of international organizations (European Union, Organization for Economic Co-operation and Development, World Health Organization);

d) the LEX legal information system, enabling the analysis of changes in the procedures for regulatory impact assessment in Poland;

e) the website of the Parliament of the Republic of Poland and the Government Legislation Centre, where government bills are published with attached RIA forms;

f) website of the Government Legislation Centre, where government draft laws and regulations are published along with the attached Regulatory Impact Assessment forms and guidelines;

g) websites of: the Chancellery of the Prime Minister and the Ministry of Health, where, inter alia, information on bills and assumptions;

h) website of the Ministry of Development and websites of regional cross-border cooperation projects (Poland-Czech Republic; Poland-Lithuania, Poland-Mecklenburg, Poland-Saxony, Poland-Brandenburg);

i) replies to requests for access to public information, referring to the Ministry of Health, the National Health Fund and other institutions.

j) results of a survey conducted among service providers, as well as interviews (individual in-depth interviews) with administration employees, including medical statisticians and medical directors;

k) interviews with people involved in the construction and implementation of the RIA system in Poland (both government administration employees and academic teachers); as well as in the field of health economics, migration and medical tourism.

The dissertation is divided into five chapters.

The first one presents the result of a literature review dealing with the relationship between economics and law. This part discusses the scientific achievements of thinkers and researchers of economic analysis of law. The chapter begins with a historical introduction describing the precursors of ancient times, then Niccolo Machiavelli, Thomas Hobbes, Adam Smith and David Hume, until the systematization of information and the emergence of the "first wave of economic analysis of law" in the nineteenth century. The "second wave of economic analysis of law", which began in the 1930s, was the result of the research conducted by Guido Calabresi and Ronald Coase, who undertook the first modern attempt to systematically apply economic analysis of law to those areas of law that directly they did not concern economics. In the 1960s, it also began to cover other thematic areas. The movement was applied to the analysis of government acts, the issues of the rule of law, the theory and practice of criminal, administrative and enforcement proceedings as well as constitutional law, consequently extending economic analysis to almost all branches of law. The first chapter will also provide a review of economic theories regarding the role of the state in shaping medical activity. The

chapter will close with a discussion of the institutional school of economic analysis of law, within which the Regulatory Impact Assessment (RIA) was developed.

The second chapter presents the rationale for RIA and evolution of the RIA process, both internationally and nationally, along with the process of law-making with the use of this tool, as well as elements of RIA. The scope of analyses and the selection of methods used for the purposes of regulatory impact assessment are presented. In addition, the results of the review of theoretical perspectives in the field of international political economy and health economics were taken into account in terms of their usefulness in the RIA process, and then the achievements in the field of economic analyses in health care were discussed. This chapter also discusses the methods used in RIA: cost-benefit analysis; cost-effectiveness analysis; cost and benefit estimation; risk assessment; direct and indirect cost-benefit analysis; sensitivity analysis; standard cost model; *Willingness to pay* (WTP) analysis; and *measuring the quality of life* (Quality-adjusted life-years, QALY). The second chapter also presents the directions of RIA development, including a proposal to extend the application of RIA throughout the legislative process, i.e. both at the stage of governmental and parliamentary proceedings.

The third chapter discusses theoretical issues related to the emergence of cross-border healthcare, the process of its shaping, definition and implementation. First, the historical context of the adoption of Directive 2011/24 / EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare is presented. The idea of the common market and the four main freedoms (including the freedom of services), which is at the basis of European integration, forces EU member states to take action in many areas traditionally treated as domestic, including health protection. The process of developing and adopting the final text of the directive on the application of patients' rights in cross-border healthcare was preceded by extensive social and intergovernmental consultations, and the jurisprudence of the Court of Justice of the EU. The directive, as a tool of EU health policy, is intended to substantially facilitate the receipt of healthcare services by residents of the European Union, regardless of where they are located. However, only certain benefits will be fully and always reimbursed, and only those that the patient would have received in their own country of affiliation (up to the amount of reimbursement applicable in that country). In this part of the dissertation, together with the genesis of cross-border care, the definitions adopted in EU law and in national regulations are discussed. Also included are the results of the literature review on cross-border healthcare and patient migration.

In the fourth chapter, based on the available statistical data on the implementation of healthcare services under the cross-border directive, the assumptions and methods used to estimate the potential effects of the directive were validated in order to examine the actual effects of the directive on the healthcare system in Poland. In addition to the results of the historical comparative analysis and statistical analysis, this chapter also includes the results of the survey of service providers and national contact points in countries neighbouring Poland. In addition, the results of the analysis of cross-border cooperation programs in the field of health protection and data obtained from national contact points for cross-border care were presented, and the forecasting of the effects in the next period of the functioning of the provisions, i.e. 2020-2029, was also proposed.

The fifth chapter contains a discussion on the results of the literature review and the results of own research. Due to the length of the arguments, they were structured into three parts. The first subchapter refers to the existing models for assessing the impact of cross-border healthcare and the legitimacy of their application. The second subchapter is the most extensive as it relates to research results along with a qualitative and quantitative evaluation of the collected data, possibilities and limitations in estimations, as well as approaches used in *ex ante* impact estimation. Comprehensive examination of methods and tools is to lead to conclusions and recommendations for forecasting the effects of regulation, which are included in the third section.

Many changes have been made in Poland that contribute to the improvement of the quality of RIA in Poland. RIA is not only being treated as a legal instrument (a formal requirement under the Regulation of the Council of Ministers), but as a tool for economic analysis of the law. However, the RIA process still requires improvement and therefore it is recommended to:

- increase the importance of public consultations in the RIA process;

- use the data collected by individual ministries at the stage of RIA preparation for estimating the effects;

- strengthen analytical competences in the public administration; and

- the standardization of the RIA process throughout the law-making process.

Without continuous efforts on improving the quality of RIA, valuable initiatives that have been implemented in the last two decades in Poland may regress and be lost.

In addition, in the scope of RIA for cross-border healthcare, it is recommended to:

- use of information systems in health care for detailed analyses of the use of services in individual areas of care;

- establish cooperation with countries bordering Poland, in particular with regard to understanding the health needs of residents of countries neighbouring Poland;

- forecast the impact of the cross-border directive in the long term in order to create a health policy in this area.