Introduction

The crisis triggered by the SARS-CoV-2 virus epidemic demonstrated how much of a challenge it is for each Member State of the European Union to ensure the implementation of health policy in accordance with the provisions of Article 168 of the Treaty on the Functioning of the European Union and in the spirit of European solidarity. The objective of the EU health policy includes ensuring that its population has access to high quality health care, preventive health care, promoting healthy lifestyles, protecting its citizens from health hazards and ensuring the availability of health services. The responsibility for shaping the health policy and providing medical services and organising the healthcare service lies primarily with the Member States. The role of the European Union, on the other hand, is to support actions and to complement them through coordination and cooperation, the exchange of good practice and the use of appropriate legal and financial instruments.

The above activities result in a significant organisational and financial commitment on the part of the state, e.g. Poland’s current expenditure on health protection in 2022 (according to the estimates of the Central Statistical Office), amounted to PLN 205.6 billion, representing 6.7 per cent of GDP (increased by PLN 36.1 billion compared to 2021). It should be noted that the increase in health expenditure over the last three years was due, amongst
others, to the prevention and eradication of COVID-19. This required a modification of the existing state health policy. In addition, the risk of irregularities in the area of health protection has increased, especially in the area of spending and accounting for the funds allocated to combating the above-mentioned epidemic⁴.

Therefore, the implementation of health policy requires an effective, efficient and cost-effective system of supervision and control, an integral part of which are public authorities responsible for supervision and management of health protection, entities with ownership rights, e.g. regional or local authorities. This system also includes external evaluating bodies, e.g. the Supreme Audit Office [Najwyższa Izba Kontroli], the Ombudsman [Rzecznik Praw Obywatelskich], or the Patients’ Ombudsman [Rzecznik Praw Pacjenta]. An important role is also played by institutions monitoring and evaluating the quality of medical services, i.e. the Accreditation Council [Rada Akredytacyjna] and the Health Care Quality Monitoring Centre [Centrum Monitorowania Jakości w Ochronie Zdrowia]. The Organisation for Economic Co-operation and Development (OECD) and the European Observatory on Health Systems and Policies are also involved in evaluating the implementation of health policy and prepare cyclical reports, including an assessment of the Polish health system⁵.

The aim of this article is to present the legal determinants of supervision and control of the functioning of the health system in Poland in subjective and objective terms, and their analysis in terms of effectiveness and efficiency. The subject of this article includes the systematisation in legal terms of the competences and tasks of the entities responsible for the implementation of the state health policy, an indication of the criteria for supervision and control in health protection, and the presentation of the principles and techniques of control carried out in this area of the state activity. The research hypothesis is the view whereby in methodological terms, the system of control and supervision, the supervisory and controlling competences and the evaluation criteria should enable effective and efficient monitoring of the implementation of the state’s health policy, both in terms of the quality of the services provided and the organisational efficiency of the treatment providers.

Due to the limited framework of this study, the above issue will be presented around the example of the Minister of Health, the National Health Fund [NHF], provincial governors [wojewoda] and regional or local authorities.

⁴ W. Robaczyński, Dyscyplina finansów publicznych a stan epidemii, „Kontrola Państwowa” 2021, No. 5, pp. 16–18; see also the Act of 2 March 2023 on special solutions related to the prevention and combating of COVID-19, other infectious diseases and crisis situations caused by them (Journal of Laws of 2023, item 1327).
Legal determinants of the implementation of the health policy in Poland

The health system is defined as a set of elements (governmental administration, local authorities, medical potential, external sphere, e.g. patients), the purpose of which is to protect the health of citizens. The participants in such a system are the service recipients, the service providers (healthcare institutions) and the payer – the insurer who finances the service. Instruments used to shape the health policy depend on a country’s systemic assumptions and the effectiveness of their implementation by public authorities. The Constitution of the Republic of Poland states in Article 68 that every citizen has the right to health care. It is therefore the duty of public authorities to ensure that citizens, irrespective of their material situation, have equal access to publicly funded healthcare services. The healthcare system in force in Poland is classified as a so-called mixed model. It consists of:

- an insurance model, which results from the method of financing services and the requirement for service providers to ensure equal access to services;
- a budget model, which provides for the monopolistic position of the insurer setting the conditions for contracting services.

Bearing in mind the objectives of the EU health policy and the healthcare system adopted in Poland (the obligation of public authorities to guarantee equal access to medical services), it can be stated that ensuring effective and reliable assessment of the implementation of the health policy is determined mainly by legal factors. This is because a legal formalization is a necessary condition that consolidates the organization and reduces uncertainty of the operation.

In light of the current constitutional regulations, the entities responsible for ensuring the implementation of the health policy in Poland include the Minister of Health along with the provincial governors, the Social Insurance Institution, the National Health Fund and the regional or local authorities, and also other institutions undertaking activities in the field of organising, financing and providing health care services financed from public funds.

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8 M. Kolwitz, op. cit., pp. 140–141.

The tasks of the aforementioned authorities in terms of ensuring equal access to health care services (Article 6 of the Act of 27 August 2004 on healthcare services financed from public funds) include amongst others:

- creating the conditions for a functioning health system;
- analysis and assessment of health needs and the factors driving change;
- health promotion and prevention, aimed at creating conditions conducive to health;
- financing health care services in a manner and in accordance with the rules laid down by law\textsuperscript{10}.

**Legal determinants of control and supervision carried out in the area of health protection**

The guarantee for the realisation of the state’s interests in the area of health protection is a well-functioning system of supervision and control over the provision of proper health care, which ensures accountability for the implementation of public tasks in the area of health protection\textsuperscript{11}. This system includes the supervision and control exercised by the Minister of Health, inspections carried out by provincial governors, the National Health Fund, the Social Insurance Institution and the Social Security Fund for Farmers \([\textit{Kasa Rolniczego Ubezpieczenia Społecznego}]\). In addition, the system includes an external audit by the Supreme Audit Office, and assessments formulated by the Ombudsman and the Patients’ Ombudsman. An important element of the system also includes inspections carried out by regional or local authorities and other entities acting as the founding entities \([\textit{podmiot tworzący}]\) of independent public healthcare institutions, e.g. universities\textsuperscript{12}. Conducting inspections in treatment providers requires the use of inspection methods and techniques adapted to the specifics of the provision and settling of health services, taking into account the requirements and expectations of patients, the legal requirements for the services provided, the internal organisation and processes in treatment providers and the financial management of these entities.

The basic competences related to the evaluation of the implementation of health policy in Poland have been assigned by the legislator to the Minister of Health. Their tasks include developing, financing and assessing the effects


\textsuperscript{12} More on the system of control bodies: J. Jagielski, \textit{Kontrola administracji publicznej}, Warsaw 2018, pp. 133–159.
of health programs, supervising their implementation, assessing the suitability of health services as guaranteed services, cooperating with non-governmental regional or national organizations working for health protection, approving the financial plan of the National Health Fund in consultation with the minister in charge of public finances and giving opinions on the financial statements of the Fund, and submitting to the Sejm of the Republic of Poland [the lower house of the Polish Parliament] an annual report on the activities of the Fund, and also tasks in the area of assessing the suitability of health care services as guaranteed services and tasks related to the financing of highly specialized services and developing, determining and updating maps of health needs.

The supervisory competencies of the Minister of Health also include supervision over health insurance, the activities of the National Health Fund, the activities of service providers, the implementation of contracts with the Fund, the activities of entities entrusted by the Fund with the performance of certain activities, the activities of pharmacies in the area of drug reimbursement, supervision over the activities of the Agency for Health Technology Assessment and Tariff System [Agencja Oceny Technologii Medycznych i Tartyfikacji], and issuing opinions on the expediency of investments worth more than PLN 2 million, consisting in the establishment of a new treatment provider, new units or organizational units of a medical facility or other investments related to the performance of medical activities.

The supervision of the Minister of Health in the above scope is performed in accordance with the criteria of legality, reliability and purposefulness (Article 163 of the Act).

The Minister in charge of health within the supervision powers also has the power to annul the resolutions of the Council of the Fund or the decision of the President of the National Health Fund, where it violates the law or leads to improper security of health care services, or leads to the unbalancing of revenues and costs of the Fund.

It should be noted that the legislator has granted a number of powers enabling effective supervision, in particular, the right to:
- demand that the Fund provide them with documents related to the Fund’s activities or their copies in order to review their content;
- request any information and explanations regarding the Fund’s activities from the Fund’s Council, the President and the Deputy Presidents of the Fund, councils of the Fund’s provincial branches, directors of the Fund’s provincial branches, employees of the Fund and other persons performing work for the Fund based on a contract of mandate, contract for specific work

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or another contract to which the provisions on mandate apply in accordance with the Civil Code;

– demand that the service provider provide all information, documents and explanations regarding the implementation of the contract for the provision of health care services;

– demand that the inspected entity provide all information, documents and explanations regarding activities performed for the Fund;

– request access to all information, documents and explanations regarding drug reimbursement\(^\text{14}\).

The Act on medical activity in Art. 118 sections 1 and 2 also grants the Minister the right to inspect treatment providers in accordance with the criteria of compliance with the law and medical criteria. The controlling powers of the Minister entitle him to, amongst others, assess the implementation of tasks by the treatment provider in terms of the availability and quality of health services provided, assess medical documentation, and assess the management of property and public funds\(^\text{15}\).

In light of the aforementioned findings, it can be concluded that the Minister of Health has a full range of supervisory and controlling powers, enabling the assessment of the implementation of the state’s health policy. This is because supervision can be exercised based on the criteria of legality, purposefulness and reliability, whereas control is exercised in accordance with the criteria of compliance with the law, medicine and cost-effectiveness. The Minister can also assess the quality and availability of health services provided.

Another entity with extensive control powers in the area of proper implementation of the health policy is the National Health Fund, which is a state organizational unit with legal personality. As an entity established to manage public funds used to cover healthcare costs, it has a number of competences in the area of controlling service providers (treatment providers, doctors and others) implementing contracts for the provision of health care services concluded with the National Health Fund. The legal basis for these powers is the Act of 27 August 2004 on healthcare services financed from public funds (Article 61a–za). It should also be noted that contracts concluded by the NHF provide for the obligation to submit to inspections by the NHF as to the implementation of the contract.

In accordance with these provisions, the Fund can conduct an inspection of the provision of services to service recipients, and in particular, it can inspect the organization, manner and quality of the provision of healthcare services and their availability (including the inspection of the implementation of financial tasks in this respect), the provision of healthcare services in terms of

\(^{14}\) Journal of Laws of 2022, item 2561.

\(^{15}\) Act of 15 April 2011 on medical activity (Journal of Laws of 2023, item 991).
compliance with the requirements set out in the contract for the provision of healthcare services, the legitimacy of the choice of drugs and medical devices, compliance with the rules for issuing prescriptions, and medical documentation regarding healthcare services financed from public funds.

Another government administrative body responsible for the proper functioning of the healthcare system and equipped with audit rights is the provincial governor. The role of provincial governors as local government administration bodies, is primarily to secure the proper functioning of health care by assessing the provision of health care within the province, evaluation of the implementation of government administration tasks carried out by regional or local authorities, and issuing opinions on the purposefulness of investments worth more than PLN2 million with respect to the performance of treatment activities (including the establishment of a treatment provider)\textsuperscript{16}. The Minister of Health may also order provincial governors to carry out the aforementioned inspections of treatment providers within the scope set out in the aforementioned Article 118 of the Act on medical activity\textsuperscript{17}.

**Principles and techniques for carrying out inspections in treatment providers**

Pursuant to Article 122 sec. 1 of the Act on medical activity, an inspection is carried out on the basis of an authorisation granted respectively by the Minister in charge of health or a founding entity. In particular, the provisions of law permit the right to enter the premises of treatment provider, to review documents and other materials related to the activities of the treatment provider taking into account the provisions on the protection of statutorily protected information, to carry out visual inspections, to check the course of certain activities, to request oral and written explanations from the manager and employees of the treatment provider, and to secure evidence. The above-mentioned powers derive from Article 122 sec. 1 of the Act on medical activity.

Detailed rules for carrying out inspections are set out in the Regulation of the Minister of Health of 20 December 2012 on the manner and procedure for carrying out inspections of treatment providers. Pursuant to Article 3 of this Regulation, an inspection is ordered by the entity entitled to inspect. In light of the facts discussed, the entities entitled to inspect are primarily employees of the commune [gmina] authorised by the commune executive body to carry out the inspection. In accordance with Article 6 sec. 1 of the above-mentioned Regulation, as far as possible, inspections are carried out in teams

\textsuperscript{16} Journal of Laws of 2022, item 2561.
\textsuperscript{17} Journal of Laws of 2023, item 991.
of at least two inspectors, of whom a team leader is appointed. The Regulation requires that the findings and assessments are documented in the post-inspection report, which should include an assessment of the inspected activity, the causes, scope and effects of the irregularities found and the identification of persons responsible for the irregularities. At this point, it should be noted that neither the Act on medical activity nor the Regulation of 20 December 2012 specifies who exactly is to be part of such an inspection team\textsuperscript{18}.

In the case of inspections carried out by the National Health Fund, the provisions of Article 61a–za of the Act on healthcare services financed from public funds is applicable\textsuperscript{19}.

In theory and practice, in addition to assessing the legality of an action, extra-legal measures of the performance of treatment providers are used to assess the efficiency, cost-effectiveness and rationality of their activities. In the case of hospitals, yardsticks such as average hospitalisation time, waiting times for treatment services, operating theatre utilisation rate, number of procedures, bed occupancy rate, the rate of implementation of the contract with the National Health Fund, or the rate of utilisation of medical equipment are used. The determinants of such assessments are included, for example, in the ISO quality management systems that are often implemented in treatment providers, or in the CAF self-assessment system\textsuperscript{20}.

**Supervisory powers of the regional or local authorities**

The system adopted in Poland provides for the transfer of some tasks to regional or local authorities as their own tasks, which reflects the constitutional principle of decentralization and subsidiarity. The Act on healthcare services financed from public funds in Article 7 sec. 1 provides that the commune’s own tasks in ensuring equal access to health care services include:

– developing, implementing and assessing the effects of health programs resulting from the identified health needs and the state of health of the commune population;
– initiating and participating in setting directions for local projects aimed at familiarizing the population with factors harmful to health and their effects;
– taking other actions resulting from the identified health needs and state of health of the commune population.

\textsuperscript{18} Regulation of the Minister of Health of 20 December 2012 on the manner and procedure for carrying out inspections of treatment providers (Journal of Laws of 2015, item 1331).

\textsuperscript{19} Journal of Laws of 2022, item 2561.

The own tasks of the county [powiat] and provincial [województwo] local authorities in the area of ensuring equal access have been regulated in a similar way, with additional tasks assigned to the county in the area of assessing the effects of health programs resulting from the identified health needs and state of health of the county population – after consulting territorially competent communes, and initiating, supporting and monitoring the activities of local authorities in the field of health promotion and health education carried out in the county, while the province authorities are tasked to inspire and promote solutions in the area of efficiency increase, including restructuring in health protection\textsuperscript{21}.

A number of the inspection and supervisory powers of the regional or local authorities derive from the ownership rights of the commune, district and provincial government units in relation to healthcare institutions. In fact, one of the own tasks of regional or local authorities are matters related to health protection (Art. 7.1.5 of the Act on commune authorities\textsuperscript{22}, Art. 4 sec. 1 point 2 the Act on county authorities\textsuperscript{23}, Art. 14 sec. 1 point 2 the Act on province authorities\textsuperscript{24}). Public healthcare institutions established by bodies of regional or local authorities are – as a rule – run in the form of a company or a budgetary unit. The basis for the management of independent public healthcare institutions [SP ZOZs] are financial plans established by the head of the institution\textsuperscript{25}.

Supervision on the part of regional or local authorities that are founding entities consists, amongst others, in the possibility of changing the form and subject matter of the activity of the treatment provider by granting or amending the Articles of Association/Statute pursuant to Article 42 sec. 4 of the Act on medical activity. In addition, it follows from Article 121 of the Act on medical activity and the provisions of the Regulation of the Minister of Health of 20 December 2012 on the manner and procedure for carrying out inspections of treatment providers that these entities may exercise management by exercising supervision over the compliance of activities with the law, the articles of association/statute and the organisational regulations. As part of the supervision, the founding entity may request information, explanations and documents from the bodies of a treatment provider that is not an entrepreneur, and it performs inspections and assessments of the activity of this entity. The inspection and assessment may include, in particular, the implementation of the tasks specified in the organizational regulations and the articles of association/statute, the availability and quality of health services provided, the correctness

\textsuperscript{21} Journal of Laws of 2022, item 2561.
\textsuperscript{22} Act of 8 March 1990 on commune authorities (Journal of Laws of 2023, item 40).
\textsuperscript{23} Act of 5 June 1998 on county authorities (Journal of Laws of 2022, item 1526).
\textsuperscript{24} Act of 5 June 1998 on province authorities (Journal of Laws of 2022, item 2094).
\textsuperscript{25} Journal of Laws of 2023, item 991.
of the management of property and public funds, and the financial management. If any unlawful actions of the manager are established, the founding entity suspends their execution and imposes on the manager the obligation to change or withdraw them. In the event of failure to change or withdraw these actions within the prescribed period, the founding entity may terminate the employment relationship or civil law contract with the manager.

In addition, the supervisory powers of regional or local authorities in the area of health protection include the possibility of establishing, transforming and liquidating a public healthcare institution, the right to grant the articles of association/statute and the literally understood supervision over healthcare institutions. Regional or local authorities may also, within the ownership rights, grant healthcare institutions run in the form of an independent public healthcare institution, public funds for the implementation of tasks in the area of health programs and health promotion, including the purchase of medical devices and equipment and the implementation of other investments necessary to implement these tasks, repairs, or other investments, including the purchase of medical devices and equipment, and for the implementation of projects co-financed with funds from, amongst others, the budget of the European Union. Due to the material nature of the above-mentioned co-financing, regional or local authorities retain the right to inspect the correctness of spending the funds allocated for the above purposes.

Regional or local authorities, as part of their supervisory and control powers, may also check the proper functioning of treatment providers by: a) assessing the legitimacy of granting a suretyship or guarantee by a regional or local authority to a treatment provider or granting a loan from the budget to such a provider; b) checking the compliance with the rules laid down by the regional or local authority for making purchases or accepting donations of medical devices and equipment, and for determining their intended use and standard; c) checking the compliance with the rules laid down by the regional or local authority for the disposal of the fixed assets of the independent public healthcare institution, their lease, rental, usage and lending for use; d) requesting detailed explanations from treatment providers for the purpose of a potential approval by the regional or local authority to the contribution of assets or its rights thereto in the form of an in-kind contribution to companies, its transfer to a foundation or an association; e) assessing the legitimacy of granting subsidies from the budget of the local government to independent public healthcare institutions (SP ZOZ); f) financial analysis prior to taking over the assets of SP ZOZ including liabilities and receivables, following its liquidation.

A problem signalled in the local government environment, however, is the fact that the executive body of a commune, county or province does not have the power to order inspections in local government treatment providers. It
follows from Article 2 sec. 6, Article 6 sec. 2, Article 121 sec. 3 and Article 122 sec. 2 of the Act on medical activity that the entity entitled to carry out an inspection is the founding entity, which, in the matter of taking the decision to carry out an inspection in a local government treatment provider acts through the law-making body. Indeed, in order to legally carry out an inspection in a treatment provider, a resolution of the commune council, county council or province assembly is required, which will define the scope of the inspection, the deadline for its implementation and the entity directly performing the inspection activities in the treatment provider. The above interpretation is confirmed by judicial decisions, e.g. the Supreme Administrative Court in its judgment of 30 March 2017 in case ref. no. II OSK 1906/15, stated that: “The founding entity is the county, which acts through the county council – the law-making and controlling body.”

In addition, it is a well-established view amongst local government supervisory bodies (provincial governors) that “it is the law-making and controlling body that has the power to undertake inspection in the Independent Commune Healthcare Institution”.

The exercise of effective corporate governance may be difficult owing to the multi-person structure of the body, its political nature (clubs of councillors) and the cyclical regularity of meetings.

It should also be noted that the Act on medical activity does not literally refer to the “internal audit” as a form of supervisory and control activities in treatment providers. The internal audit regulated by the legislator in Art. 272–296 of the Act of 27 August 2009 on public finances is within the meaning of this Act, as a rule, carried out only in the entities of the sector of public finances entities. On the other hand, the Act on medical activity provides only for supervision (in cases specified in the provisions thereof) or control of an independent public healthcare institution.

Summary

To sum up, it is possible to formulate the conclusion that legal provisions (systemic and material), regulating the functioning of the system of control and supervision in the area of health protection, were formulated in accordance with the principles of legislative technique, including the principle of comprehensiveness, clarity of provisions, the principle of the actual impact of pro-

26 Journal of Laws of 2023, item 991.
28 Annulment of an unlawful resolution or order [Rozstrzygnięcie Nadzworcze] of the Provincial Governor of the Province of Warmia i Mazury of 2 May 2023, case ref. No. PN.4131.191.2023.
visions, and the application of measures to implement the provisions. Supervisory and control powers and assessment criteria make it possible to monitor the implementation of the state’s health policy, including the assessment of the quality of medical services for service recipients and the legality of the operation and financial efficiency of treatment providers. The inspection and supervision criteria adopted by the legislator enable the executive authorities and the founding entity to check the correctness of the functioning of treatment providers in accordance with the criteria of legality, cost-effectiveness, reliability, purposefulness, in medical terms and in terms of the quality and availability of medical services.

On the other hand, legal factors hindering the evaluation of treatment providers may include the dispersion of supervision and control competences vested with public authorities and the absence of provisions enabling the coordination of inspection tasks performed by government authorities. Another problem is the deprivation of the executive body of regional or local authorities of the right to order an inspection or internal audit in local government treatment providers. Indeed, in order to legally carry out an inspection in a treatment provider, a resolution of the commune council, county council or province assembly is required, which will define the scope of the inspection, the deadline for its implementation and the entity directly performing the inspection activities in the treatment provider. The execution of effective corporate governance may be difficult owing to the multi-person structure of the body, its political nature (clubs of councillors) and the cyclical regularity of meetings.

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Robaczyński W., Dyscyplina finansów publicznych a stan epidemii, „Kontrola Państwowa” 2021, No. 5.
Summary

Legal determinants of control and supervision in the health system in Poland

Keywords: law, health, supervision, control.

The crisis triggered by the SARS-CoV-2 virus epidemic has demonstrated how much of a challenge it is for each Member State of the European Union to ensure the implementation of its health policy in accordance with the provisions of Article 168 of the Treaty on the Functioning of the European Union and in a spirit of European solidarity. The aim of this article is to present the legal determinants of supervision and control of the implementation of health policy in Poland in terms of its subjective and objective scopes, and their analysis in terms of effectiveness and efficiency. The subject of this article includes the systematisation in legal terms of the competencies and tasks of the entities responsible for the implementation of the state health policy, an indication of the criteria for supervision and control in health protection, and the presentation of the principles and techniques of control carried out in this area of the state activity. The result of the analysis is the conclusion that the provisions of law ensure the proper functioning of the system of control and supervision in the area of health protection.

Streszczenie

Prawne determinanty kontroli i nadzoru w systemie ochrony zdrowia w Polsce

Słowa kluczowe: prawo, zdrowie, nadzór, kontrola.

Kryzys wywołany epidemią wirusa SARS-CoV-2 pokazał, jak dużym wyzwaniem dla każdego państwa członkowskiego Unii Europejskiej jest zapew-
nienie realizacji polityki zdrowotnej zgodnie z postanowieniami w art. 168 traktatu o utworzeniu Unii Europejskiej oraz w duchu europejskiej solidarności. Celem artykułu jest przedstawienie prawnych wyznaczników nadzoru i kontroli realizacji polityki zdrowotnej w Polsce w ujęciu podmiotowym i przedmiotowym, a także ich analiza pod względem skuteczności i wydajności. Przedmiot artykułu obejmuje systematykę w ujęciu prawnym kompetencji i zadań podmiotów odpowiedzialnych za realizację polityki zdrowotnej państwa, wskazanie kryteriów nadzoru i kontroli w ochronie zdrowia, a także przedstawienie zasad i technik kontroli przeprowadzanych w tej sferze działalności państwa. Efektem rozważań jest wniosek, że przepisy prawa zapewniają prawidłowe funkcjonowanie systemu kontroli i nadzoru w sferze ochrony zdrowia.