

Control of a medical activities – main characteristics

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Abstract. The main purpose of the of the paper is to analyze the infringement and the penalties imposed on inpatient and outpatient facilities for the period 2013-2022 and to highlight the problem areas in the inspected facilities. Data from the Reports on the activities of the Executive Agency “Medical Audit” (2013-2018) and the Executive Agency “Medical Supervision” (2019-2022) were used. On the basis of the data, an analysis of the administrative violation acts issued has been carried out, the most significant violations for the period under study have been highlighted, the choice of facilities subject to inspection, the most frequently inspected medical institutions, etc. have been examined. The main conclusion is that the Agency should focus more on transparency in the selection of the establishments to be inspected and continue in the direction of increasing its revenues and reducing the number of revoked penalty decrees.

1 Nature and features of the concepts of ‘supervision’ and ‘audit’

This paper deals with the activities of the Executive Agency "Medical Supervision", which is the legal successor of the Executive Agency "Medical Audit" and the Executive Agency on Transplantation. It is therefore necessary to clarify the terms 'supervision' and 'audit' as they have different characteristics and should not be used in the same context.

The common between these two concepts is that they are concrete forms of control, but as each has its own specific characteristics, it is necessary to draw out their essential features. Some researchers point out that supervision should be understood as "a form of observation aimed at influencing the observed object under certain conditions" [1]. Others consider it as "inspections and other procedures that are carried out by persons external to the organization in order to ascertain the legality of certain activities" [2]. "Supervision" as a concept can also be defined as "controlling and regulating the activities of banks in the country and maintaining the stability of the banking system. It ensures compliance with established rules and acts" [3]. Although banks are mentioned, the purpose is to clarify that supervision is an activity that has many dimensions and at the same time its main function is to observe whether the objects adhere to the established norms. It can be summarised from the above-mentioned essential characteristics that what they have in common is that they are actions carried out by persons external to the organisation subject to supervision. They must be independent and objective in the performance of their duties. The purpose of supervision is to influence in a certain way the improvement of the quality of the services provided, the effectiveness, efficiency and economy in the normal operation of the sites. What is special in

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this case is that the Executive Agency is part of the system of the Ministry of Health (MH), and although it appears as an external inspection body, it supervises the activities of establishments which are also included in the MH system. This is indicative of the dual nature of the activities carried out by the Agency and of the need for increased objectivity and independence with regard to the actions it undertakes.

The audit has its varieties - financial, compliance audit of financial management, performance audit, specific audits, internal audit, etc. The object of this paper is to characterise audit in a synthesised form. There are a number of studies and perspectives on what audit is, as there are written audit standards that serve as a starting point in distinguishing audit from other specific forms of control. An essential feature of auditing is that it takes place after phenomena and processes have been completed, i.e. it is clearly *ex post* in nature. Whereas monitoring can also take place on an ongoing basis, during the implementation of phenomena. Auditing, in general, should be understood as establishing the status of a particular entity at a given point in time and increasing the level of confidence of service users in the audited entity. Medical auditing is "an activity whose existence is necessitated by the public's increased expectation that adequate action be taken when poor medical outcomes occur" [4].

The **main purpose** of this paper is to analyze the infringement and the penalties imposed on inpatient and outpatient facilities for the period 2013-2022 and to highlight the problem areas in the inspected facilities.

The **object** of the study is the adaptation to the challenges faced by the subjects of control of the two agencies in the fulfilment of their authorities and responsibilities.

The **subject** of this paper is the study of the interrelationship between the legal framework, issued criminal decrees and imposed penalties and their impact on the objects of control.

This paper mainly uses the **analysis** of the reports on the activities of the medical audit and medical supervision agencies and the regulations, as well as **synthesizing** the main infringement and penalties imposed. The observation of the problem areas and the formulation of certain conclusions has been realized through **the inductive and deductive methods**.

2 Infringement detected and penalties imposed by the Executive Agency 'Medical Supervision' (EA MS) for the period 2013-2022

The study used data from the Reports on the activities of the Executive Agency "Medical Audit" (EA MA) for the period 2013-2018 and the EA MS for the period 2019-2022, inclusive. This paragraph presents the inspections carried out by the agencies, focusing on the violations found and penalties imposed on medical institutions and individuals, as well as the reasons that led to this.

The implementation of inspection activities is regulated in Art. 13 of the Structural regulation act of the Executive Agency "Medical Inspectorate" (ex.), which regulates the scope and objects of inspection. Art. 13 of the current Structural regulation act of the Executive Agency for Medical Supervision states that these activities are carried out by the Directorate for the Control of Medical Activities and Quality Assessment and the Directorate for the Administration of Registration Regimes and Licensing of Medical Activities. The latter carries out checks on compliance with medical standards, health requirements and the like.

In the first place, the data on the acts to establish an administrative violation (AEAV) were analysed. In the course of its activities, the Agency has the right to draw up such acts when some of the established norms and rules are not complied with by the inspected structures (see Figure 1).

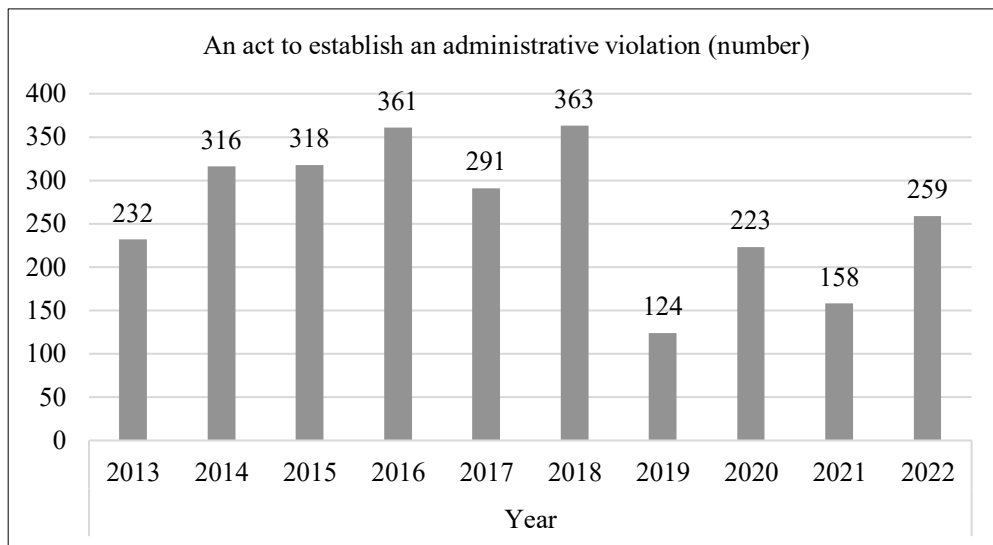


Fig. 1. Numbers of composed acts to establish an administrative violation (2013-2022)

It is evident from the figure that the highest number of AEAJs were issued in 2018 - 363, which were related to 1 230 detected Infringement. The most frequent of which as follows:

- non-compliance with Art. 81, paragraph 2, item 1 of the Health Act (HA) "the right to accessible medical care shall be implemented in application of the following principles: ... timeliness, sufficiency and quality of medical care".
- non-compliance with Art. 86, paragraph 2, item 2 of the HA "the patient shall have the right to have the medical devices necessary for his/her treatment provided by the hospital, when they are not paid for by the NHIF or the state budget" - 349 pc.
- non-compliance with Art. 86, paragraph 1, item 1 of the HA "as a patient, everyone has the right to respect for his civil, political, economic, social, cultural and religious rights" - 28 pcs.
- non-compliance with Art. 29, item 1 of the Regulation on the implementation of the right of access to medical care (RIRAMC) "it shall not be allowed to make a choice of the doctor/team to treat and monitor the patient for the entire duration of his stay in the medical institution, including the patient's official attending physician appointed by the medical institution" - 360 pcs., etc. [5].

During the periods studied, there was no significant change in the violations found, but those found in 2022 are of interest:

1. Violations related to non-compliance with the HA - 131 pcs, the most frequent of which as follows:

- violations of Art. 86, paragraph 1 on the economic rights of the patient.
- violations of Art. 89, paragraph 1 on the obligation of written informed consent of the patient in case of surgical interventions, general anesthesia, invasive and other diagnostic and therapeutic methods that lead to an increased risk to the patient's life and health or to a temporary change in the patient's consciousness.

2. Violations related to non-compliance with the RIRAMC - 74 pcs, the most frequent of which as follows:

- violations of Art. 29, item 1 for the selection of the doctor/team with the participation of the attending physician.
- violations of Art. 24a, paragraph 1 for additional requested services not allowed in the Regulation.

3. Violations related to non-compliance with the Medical Establishment Act (MIE) - 63 pcs, the most frequent of which as follows:

- violations of Art. 68, paragraph 7 on the obligation to appoint the heads of clinics/departments and head nurse after a competition.
- violations of Article 98, paragraph 3 on the obligation of medical establishments to display in public places in their building information on the type and price of all medical and other services provided and on the method of payment for them, etc.

4. Violations related to non-compliance with Ordinance No. 49 - 31 items, the most frequent of which as follows:

- violations of Article 20, paragraphs 2 and 3 for lack of documentation when admitting patients.
- violations of Art. 3, paragraph 1, item 4 on the obligation to ensure continuous 24-hour performance of medical treatment.
- violations of Art. 24, paragraph 1 on the obligation to issue an epicrisis on the day of discharge.

5. Violations of medical standards (MS) - 108 pcs, the most frequent of which are:

- violations of the MS 'Emergency care'.
- breaches of the MS 'Diagnostic Imaging'.
- violations of the MS 'Neonatology'.
- violations of the MS 'Surgery'.
- violations of the MS 'Internal Diseases', etc [6].

As a consequence of the outlined violations, it is necessary to clarify that these are common deficiencies in medical institutions and control over them should be strengthened. The need for more frequent, and in certain cases timely, inspections is the best option the Agency can use. The latter works both on signals and on an operational plan, with tasks set for a certain period. Of interest is the way in which a particular establishment or individual is selected and chosen for inspection. The explanatory memorandum to Section II 'Proceedings on proposals' of the Structural regulation act of the Executive Agency for Medical Supervision that the alerts received are examined by a specially appointed committee by the Executive Director. In case they do not fall within the competence of the Agency, the signals shall be forwarded to the competent authority. The lack of data on the more specific choice of exactly which sites will be inspected is also due to insufficient and comprehensive knowledge of the internal acts that the Agency may have developed and implemented.

In relation to the selection of hospitals and medical centres, the most frequently inspected ones for **2021** are [7]:

- Pirogov Hospital - 34 inspections.
- Emergency centre medical assistance, Sofia-city - 28 inspections.
- Multi-profile hospital for active treatment (MPHAT) 'Sveta Anna', Sofia - 25 inspections.
- MPHAT 'Sveti Georgi' - 23 inspections.
- Acibadem City Clinic Tokuda – 27 inspections.
- Aleksandrovska Hospital - 21 inspections, etc.

The following sites were inspected in **2022** [6]:

- Alexandrovska Hospital - 28 inspections.
- Acibadem City Clinic Tokuda - 27 inspections.
- Emergency centre medical assistance, Sofia-city - 26 inspections.
- Military Medical Academy - 26 inspections.
- Pirogov Hospital- 26 inspections.
- Tsaritsa Ioana Hospital - ISUL - 21 inspections, etc.

The increase in the number of inspections carried out in certain hospitals may be due to increased media interest in their activities and/or more reports submitted. Nonetheless, the number of violations detected in 2022 was 367 and for the same period "954 inspection reports were drawn up, 9 of which were on inspections from 2021" [6]. Compared to the previous year, 2021, there were 170 more.

The Executive Agency, through the Executive Director, imposes "compulsory administrative measures and issues penalty decrees (PD) in the cases provided for by law" [8]. This power derives from the provisions of Article 7b of the Medical Establishment Act, in relation to which the EA MS has the power to impose this type of decree, and Section 19 of the same Act states that the Agency 'shall make proposals to the Minister of Health for the imposition of administrative penalties and the application of compulsory administrative measures' [9]. The implementation of this type of action requires in-depth analyses and inspections of the establishments, since in order to impose a fine or sanction, the competent persons have to track a large amount of data and assess to what extent, and whether the information, services or subject of activity of the inspected establishments comply with the statutory requirements. It is possible that the penalty orders may be appealed in court and set aside. This is why it is imperative that the inspection entities are aware of the many requirements not only at the level of the individual entity, the internal acts, but also at the national and international level, including the regulations related to the type of liability that is sought.

The following figure presents data related to the criminal rulings issued by the Executive Agency Medical Supervision (see Figure 2).

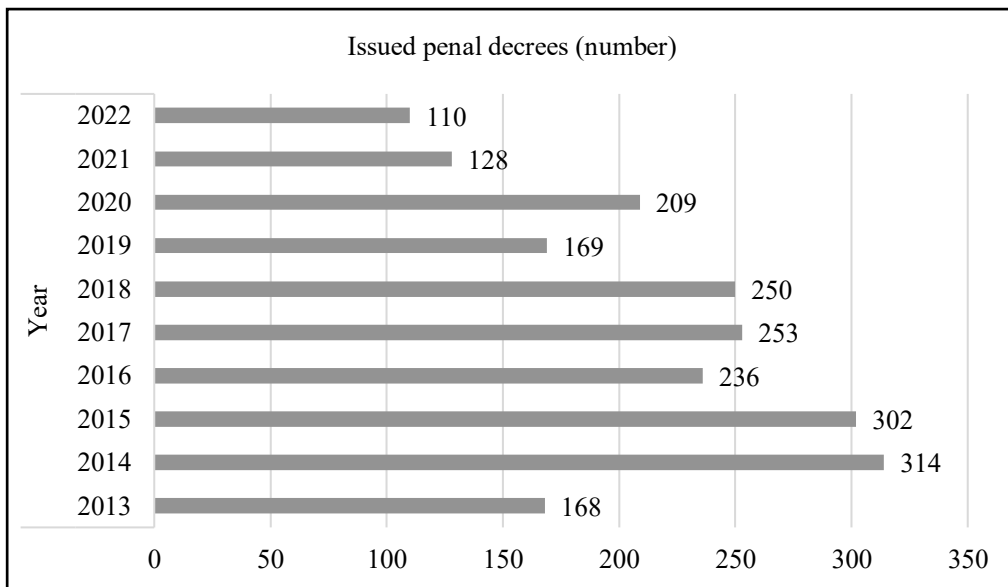


Fig. 2. Numbers of penal decrees issued by Executive Agency ‘Medical Supervision’ (2013-2022)

In 2014, the highest number of penalty decrees was issued - 314, "of which as follows:
- 191 pcs. ND, which imposed fines on persons.
- 123 pcs. ND, which imposed financial penalties on legal persons" [10].

The value of the decrees amounts to BGN 537 600, which shows that the benefits of the Agency's control activities are high and have a positive impact on the establishments. Irrespective of the number and value of the ND, 39 of them were annulled by the court competent to rule on the proceedings, 26 were confirmed and one was amended in the 'penalty' part. Some of the reasons for annulment of administrative penalty proceedings are:
- the norms of the Health Act, the Medical Establishment Act and the implementing regulations are bland [10]. The Court accepts that the blandness of these acts is tantamount to the non-existence of such a norm. It follows that a penalty cannot be imposed.

- the period of the offences, the description of the offence, the date and place, etc., as set out in Art. 42, item 3 and Art. 57, paragraph 1, item 5 of the Law on Administrative Offences and Penalties does not correspond unequivocally to the date indicated as the period of the offence. The Court therefore refers to the provisions of the Criminal Code, which defines the date differently.

The trend is one of a gradual reduction in the number of rulings issued by the Agency. The number in 2022 - 110 - is indicative of this. During this period, two of them are yet to be served, 13 have entered into force, 53 have been paid, 30 are pending in the relevant regional court, seven are pending in the administrative court and five have been annulled by final court decisions. The following figure (see Fig. 3) shows the revoked penal decrees.¹

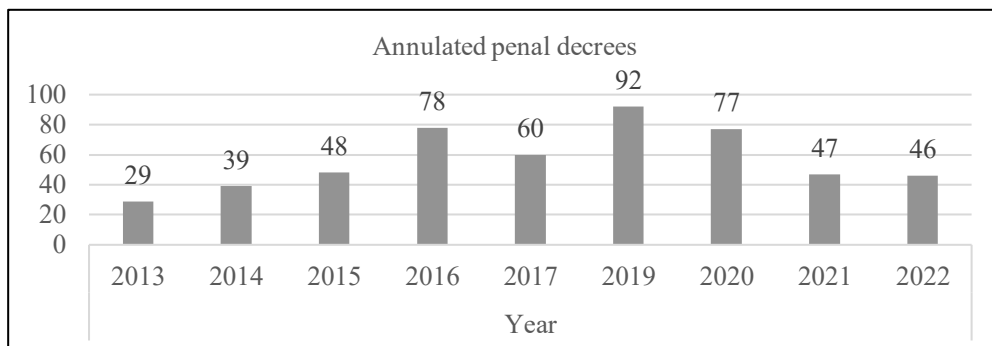


Fig. 3. Total number of annulated penal decrees (PD) by qualified courts (2013-2022)

It is necessary to clarify that the annulled penal decrees are final judgments. Although the data for the period under examination vary, the trend is towards an increase in revoked judgments (until 2020, except for 2017) and a gradual decrease in the number of revoked penal decrees until 2022. The main infringements are of the following regulations:

- Health Act.
- Medical Establishment Act.
- Medical standards.
- Regulation on the implementation of the right of access to medical care.
- Ordinance No. 2 of 01 July 2015 on the conditions and procedure for the provision of medical assistance to foreigners who do not enjoy the rights of Bulgarian citizens, etc. [11].

Some of the reasons for the revocation of the decrees are the revocation of the regulations which have established part of the medical standards, subjective non-constitutionality of the act, lack of a normatively prescribed obligation to act or not to act which could implement a specific component of the administrative offence. Therefore, the control subjects must be precise and accurate in ascertaining violations. They are required to have gathered sufficient and relevant evidence to support what they have found.

With the introduction of the epidemic situation in Bulgaria in 2020, the Executive Agency for Medical Supervision is monitoring compliance with the pandemic-related regulatory requirements. One part of the inspections focuses on:

- requirement for PCR test upon admission to a hospital - as a result of the control activities carried out, the Agency has not identified "categorical substantive prerequisites for initiating administrative criminal proceedings" [12].
- violation of access to in-patient and out-patient medical care facilities - three administrative criminal proceedings were initiated, and the heads of the medical facilities were instructed to take immediate action to prevent violation of patients' rights.

¹ There is no specific information on revoked penalty decrees in the Agency's activity report in 2018, therefore no data have been derived

In 2020 there were 120 alerts related to COVID-19, in 2021 there were "over 233 inspections of 192 complaints". In 2022, due to the pandemic situation related to SARS-CoV-2, some hospitals were restructured and most of the wards were organized and segregated so that they could be used to treat COVID-19 patients. This has resulted in a reduction in: the number of beds; the number of operations; operational activity, volume of activity, etc. The following facilities were the subject of scrutiny in 2020:

- Acibadem City Clinic Tokuda. The following company, Sofia.
- Tsaritsa Ioanna-ISUL, Sofia, Bulgaria.
- Uni Hospital, Panagyurishte.
- Hospital – Pazardzhik.
- Hospital – Velingrad.

The aim is to determine whether there is a discrepancy in Remdesivir² therapy of patients with COVID-19. No significant disorders or deficiencies were found. In the Pazardzhik Hospital it was found that "medicinal products are prescribed on the medication lists which do not contain all the requisites according to Annex 5a of the Regulation No 4/04.03.2009" [12]. In Velingrad Hospital it was found that "the temperature sheet did not reflect all vials dispensed by the pharmacy, and another one reflected a greater number than dispensed by the hospital pharmacy" [12]. An inspection of Acibadem City Clinic Tokuda found that "in two of the patients treated with Remdesivir, no evidence of a proven RT-PCR test for COVID-19 was provided, as treatment was conducted on the basis of clinical, paraclinical and imaging evidence of COVID-19 infection" [12].

From the 233 inspections conducted in 2021, 24 acts to establish an administrative violation and 17 mandatory prescriptions were issued. Some of the most frequent violations are as follows:

- violations of the medical standard "Emergency Medicine".
- violations of Art. 86, par. 1 - right to quality and accessible medical care.
- violations of Ordinance No. 49, Art. 23, paragraph 1 - failure to take action to implement inter-hospital transport.
- other violations related to lack of informed consent, release from autopsy without request from the relatives of the deceased, lack of the Examination List, violation of economic rights of the patient, denial of access to a medical facility, etc. [7]

Both in 2020 and 2021 the Agency has inspected 21 medical institutions in connection with therapy conducted with Remdesivir. The results of the inspections have been submitted to the Ministry of Health and the Bulgarian Drug Agency. In this connection, the Agency, together with the National Health Insurance Fund (NHIF), has supervised several laboratories that perform the medical diagnostic test 'Polymerase Chain Reaction for the Demonstration of COVID-19'. Some of them as follows:

- Medical laboratory 'Zdrave 99'.
- Medical centre 'Treta poliklinika'.
- Hospital 'Sveta Marina'.
- National Reference Laboratory 'Influenza and ARD', Nacional Center of Infectious and Parasitic Disease.
- Multi-profile Hospital for Active Treatment of Pulmonary Diseases (MPHATPD) 'Sveta Sofia'.
- Diagnostic consultancy center 'Sofiamed'.
- Hospital 'Georgy Stranski', Pleven, etc. [12]

² Remdesivir is the active substance in Veklury, which is an antiviral drug used to treat COVID-19. Veklury stops the formation of viral particles in cells and this stops the spread of the virus in the body [15].

The purpose of the examination is to establish whether these entities register, report and keep records of COVID-19 according to the requirements of Regulation 21/2005 on Registration, Reporting and Keeping records of Communicable Diseases to the Regional Health Inspectorate (RHI), including the provision of personnel and equipment, training and rules and algorithms in place for the performance of the "Polymerase Chain Reaction for the Demonstration of COVID-19". No violations were found, only at MPHATPD 'Sveta Sofia', Hospital Georgi Stranski, Pleven were found that such activities were not carried out.

In addition to medical institutions, the Executive Agency controls insurance funds, outpatient facilities, dental structures, etc. Regarding the inspection of insurance companies, the results of the Executive Agency are of interest:

1. **In 2013**, the following companies were subject to supervision:

- 'Dall Bogg Zhivot i Zdrave', Sofia, Bulgaria.
- Euroins - Health Insurance, Sofia, Bulgaria.
- 'European Health Insurance Fund', Sofia.
- 'Tokuda Health Insurance Fund', Sofia.

It has been established that: "the requirements for concluding contracts with the medical care providers and with the insured persons have been complied with; the contracts comply with the issued license and the general conditions for health insurance funds; there is a lack of timely and accurate information to the insured persons about changes in the legislation concerning their health insurance rights and the related reimbursement" [13].

2. **In 2014**, the following companies were subject to supervision:

- 'Dall Bogg Zhivot i Zdrave', Sofia, Bulgaria.
- 'Generali Insurance'.
- Insurance Company 'Saglasie'.

No inconsistencies were found.

3. **In 2015**, the following companies were subject to supervision:

- Insurance Company 'Medico-21', Sofia, Bulgaria.
- Euroins - Health Insurance.
- European Health Insurance Fund.

No inconsistencies were found.

4. **In 2016**, the following companies were subject to supervision:

- 'Dall Bogg Zhivot i Zdrave', Sofia, Bulgaria.
- 'Bulgaria' - 2 inspections.
- 'DZI - Life Insurance'.
- Insurance Company 'Saglasie'.

There were no violations of the terms and conditions for the provision of health activities to the insured persons. No deficiencies were found in the conditions of conclusion of contracts between the health insurance companies and the medical care providers [14].

5. **In 2020**, the following companies were subject to supervision:

- 'Grave Bulgaria Life Insurance'.
- 'Unica' Life Insurance Company.
- Life Insurance Institute.
- Insurance company 'CCB Zhivot'.
- Insurance company 'Allianz'.
- Insurance company 'Armeec'.

No deficiencies were found in the terms and conditions for the provision of health activities. No deficiencies were found in the conditions of conclusion of contracts between health insurance companies and medical care providers [12].

6. **In 2021**, the following companies were subject to supervision:

- Insurance company 'Saglasie'.
- Insurance company 'Medic-21'.

- United Health Insurance Fund (UHF) ‘Doverie’.
- DZI Life Insurance.

No inconsistencies in the terms and conditions for the provision of health care activities were found. No deficiencies were found in the conditions of conclusion of contracts between health insurance companies and medical care providers [7].

7. In 2022, the following companies were subject to supervision:

- Insurance company ‘Saglasie’.
- Generali Insurance.
- Dall Bogg Zhivot I Zdrave.
- Phi Health Insurance.
- Axiom Insurance Company.

No inconsistencies were found in the terms and conditions for the provision of health activities. No deficiencies were found in the conditions of conclusion of contracts between health insurance companies and medical care providers [6].

The reason why all years are not mentioned is that the Annual Activity Reports of the agencies lack further information on how the inspections were completed and what was found. There has been an increased interest in the activities of several of the insurance companies, Dall Bogg Zhivot I Zdrave and Insurance Company ‘Saglasie’, which are inspected almost every year by the Agency or appeared four times during the period surveyed. Despite the fact that it is stated in the activity reports that the inspections are carried out not at the request of customers but at the request of the companies themselves, account must be taken of the fact that the inspection of the same insurers suggests that there may still be shortcomings in their activities, either in their subjective attitude towards the insured persons or, conversely, in the subjective attitude of the persons insured towards the insurers. The increased interest in these companies is also conditioned by the sums which the insured expect to receive in the event of a negative event.

3 Main conclusions and implications

Based on the analysis of the activity reports of the two agencies, the following conclusions can be drawn:

First. The agencies shall carry out their activities in accordance with the regulatory requirements. Nevertheless, the need to enhance transparency in the selection of the subject of scrutiny, including the criteria by which it is assessed that a particular natural or legal person is 'appropriate' to be subject to scrutiny, is essential, as through it users of information can be assured that the principles of objectivity and independence are respected.

Second. Most violations, in the period 2013-2022, were observed of the following normative acts - the Medical Establishment Act, the Health Act, Regulations related to the provision of health services to patients, Medical Standards, etc. The relatively persistent nature of these violations needs to be taken into account by the facilities and/or more serious sanctions/fines imposed by the Agency. By correcting their behavior, the facilities being inspected can provide better patient care and better performance of their duties.

Third. The Executive Agency for Medical Supervision may impose Acts to establish an administrative violation, including the issuance of penalty decrees. This right and responsibility of the Agency obliges it to use comprehensive methods and approaches that can gather reliable, relevant and sufficient evidence to support or refute the facts and circumstances.

On the basis of the conclusions formulated and the analysis made of the activities of the two agencies, it can be **concluded** that the Executive Agency ‘Medical Supervision’ functions and performs its delegated powers in a lawful manner. However, the challenges it faces are numerous, ranging from the resolution of specific cases to reaching decisions and

imposing sanctions and/or fines on the establishments subject to control. Improving transparency, clarity and timely response at certain moments is essential, as the publicity of the activities carried out should benefit society as a whole. Should any of the ethical or legal norms relating to giving 'publicity' to the results of the Agency's activities be breached, this could jeopardise and undermine the credibility that control entities should have.

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