



LEGAL REGULATION OF THE PRIMARY HEALTH CARE CONTROL

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Abstract

The legal framework regulating the control of the reimbursement of the contracted and delivered medical services of the primary health care providers is exercised by the National Health Insurance Fund (NHIF) and includes the relevant laws and bylaws, as well as internal policies issued by the governor of the NHIF.

We present an analysis of the control of the implementation of the contracts regulating the delivery of the primary health care services which is carried out in accordance with the second chapter, section X of the Health Insurance Act and the twelfth chapter of the National framework contract on medical services 2017.

Keywords: control, service, primary health care.

INTRODUCTION

In the settings of increasing healthcare costs worldwide, the healthcare systems are facing the challenge of finding an answer to the question: „How to achieve effective disbursement of the scarce financial resources to improve the nation’s health in general?“. This effectiveness depends mostly on the accurate distribution of the financial resources allocated for healthcare and their reasonable disbursement (National Health Strategy 2020). It also emphasises the importance of the control of the reimbursement of the delivered health care services.

In the Republic of Bulgaria, this control is exercised by the National Health Insurance Fund (NHIF) – the public institution established with the Health Insurance Act since 1998 (HIA). NHIF protects the rights of the insured individuals. As an institution it acts as a mediator in funding primary healthcare services. NHIF reimburses the primary care providers for the delivered medical services.

The financial relations with the medical care providers are arranged on two levels: national and individual.

Nationally, the rights and obligations of the participants providing medical care are regulated with the signed National framework contract on medical services (NFC). It is an agreement between NHIF and the Bulgarian Medical Association (a professional organization, protecting the interests of the physicians). The statutory effective term of the NFC is one year.

Individually, the financial relations with the providers of medical care are arranged with individual contracts signed with the NHIF. These should be signed by the particular Regional Health Insurance Fund (RHIF) and the provider of medical care. The latter are effective until approval of a new NFC.

The NHIF Budget Act approved for the particular year defines the annual amount of the resources allocated for health insurance payments, distributed as follows: primary health care (PHC), specialized outpatient medical care (SOMC), medical-diagnostic activity (MDA) and hospital medical care (HMC). The worldwide trend of increasing healthcare costs could be seen in our country as well. For the period from 2005 to 2017, the increase of the health insurance payments in PHC is 86,6 %, in SOMC - 96,8 %, in MDA - 53,3 % and in HMC – five times (NHIF Budget Act for 2005 and 2017).

The contemporary model of the healthcare system in the Republic of Bulgaria ranks the PHC as one of the most important. It is the most widespread form for delivery of medical care, the most accessible, closest and with the greatest contribution for solving the healthcare problems of the individual citizens, families and the society in general. PHC is greatly the first patient's contact with the doctor (Zlatanova&Zlatanova-Velikova, 2008). Because of that the PHC creates the general notion of the comprehensive healthcare system.

The financial relations with the PHC providers are arranged with template contract for delivery of PHC services.

The utilization of the limited financial resources for reimbursement of the delivered PHC services is subject to control by the NHIF. The NHIF monitors the lawful and effective disbursement of the financial resources on the first level of medical care delivery. This is achieved by inspecting the enforcement of the established legal norms as well as the executed contacts with the PHC providers.

OBJECTIVE AND TASKS

The objective of the present article is to review and analyse the legal framework for the control of the execution of the contracts regulating the delivery of PHC services.

The following main tasks were outlined:

1. To establish the legislative requirements regulating the control over the delivery of the PHC services;
2. To present and analyse the types of control exercised by the NHIF;
3. To outline the stages and participants in the process of exercising control by the NHIF;
4. To present the sanctioning character of the control in the case of violations committed by the providers of medical care, including the PHC;
5. To clarify the cases of unreasonably received sums by the providers of medical care, including PHC providers and the respective consequences.

MATERIAL AND METHODS

To achieve the assigned objective and tasks we have analysed the norms of the HIA and the NFC on medical services for 2017.

The defined regulations were made public in the „State Gazette” issued by the legislative body of the Republic of Bulgaria – the National Assembly. The access via a webpage (www.dv.parliament.bg) is free and unlimited.

The above are publicly accessible via the Bulgarian legal portal (www.lex.bg), as well as at the webpage of the NHIF (www.nhif.bg).

Attached hereto you will find the documentary method.

For graphic processing of the presented data, Microsoft Office products were used.

DISCUSSION

As of 31.03.2018 the control over the PHC services is established in the HIA since 1998 and the NFC on medical services for 2017. The analysis of the defined regulation acts showed the following:

Health Insurance Act

The HIA is the main regulation which establishes the healthcare insurance in the Republic of Bulgaria and the related public relations. The implementation of the mandatory health care insurance in the country is assigned to the NHIF. Under article 2, paragraph 1 of the HIA, the mandatory healthcare insurance is an activity for control and disbursement of the funds collected through mandatory healthcare insurance contributions and subsequently used for the delivery of medical services. The good financial management of the accumulated public resources (health insurance contributions) is based on strict control of the established financial relations with the healthcare providers contracted by the NHIF. The control is exercised by the NHIF and is of key importance to the Bulgarian healthcare system.

The law is structured in four chapters, Supplementary provisions as well as Transitory and final provisions. The control over the implementation of the contracts with the medical care providers, including PHC, is outlined in the second chapter „Mandatory health insurance”, section X „Control, expertise and disputes” of the HIA. Of note is a separate chapter (fourth) in the Act outlining another type of control – „Medical control”. In the first case, the control over the implementation of the contracts regulating the delivery of medical care is exercised by the NHIF and covers the reimbursement of the agreed and delivered medical services by the health care providers. In the second case, the regulatory functions for exercising medical control are performed by the Executive Agency „Medical Audit” (EAMA) established to the minister of health.

The subject matter of the present analysis is the control of the implementation of the contracts for delivering PHC services, which is part of the comprehensive regulatory functions of the NHIF. In that respect the legislations regulating the control of the implementation of the contracts with the NHIF for the delivery of medical care are applicable to the control of the PHC services.

The term „control” originates from the French word „controle” which literally means „check”. In the Bulgarian dictionary of definitions, the word „control” means observation, supervision and inspection of someone or something (Andreychin, Georgiev, Ilchev, Kostov, Lekov, Stoykov & Todorov, 2005).

The text of article 72, paragraph 2 of the law originates from the etymology of the term, and defines that the control of the implementation of the contracts with the NHIF for medical care delivery, is exercised with inspections performed by officials – employees of the NHIF and officials of the RHIF - controllers, referred to as „control bodies” in the law. The NHIF performs its controlling function with scheduled and sudden inspections and on the account of filed complaints. Depending on the character (nature) of the inspections, the NHIF performs four types of control (Figure 1).

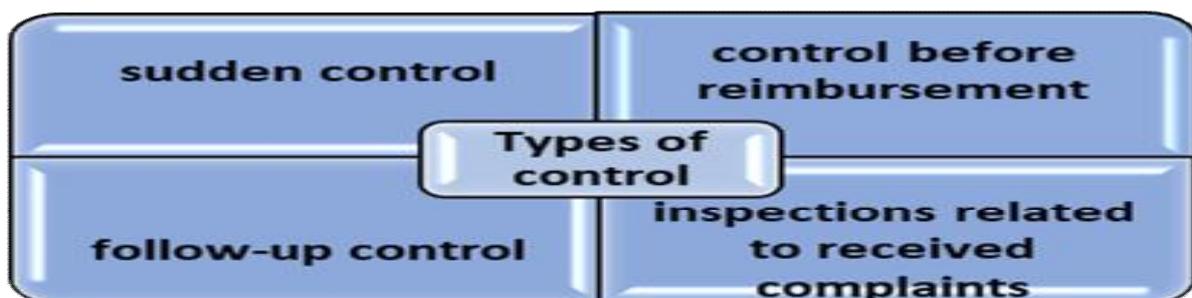


Fig. 1: Types of control being exercised by the NHIF

Under paragraph 1, point 25 of the Supplementary provisions of the HIA, **sudden control** is the control related to the payment for medical care services delivered in accordance with the contract with the NHIF. In addition, this type of control is used to confirm that the provided healthcare services adhere to the medical care accessibility and quality criteria, outlined in the NFC and takes place at the time of the actual medical care provision. In that respect the control functions of the NHIF approximate the medical control exercised by EAMA. The HIA contains no legal definition of the term „medical control“. Under article 3, paragraph 1 of the Arrangement rules of the EAMA passed in 2015 by the Council of Ministers of the Republic of Bulgaria, the agency exercises continuous control of the medical services provided to the citizens, the adherence to the established medical standards and patients' rights. In this light, exercising control on the implementation of the contracts for delivering of medical care is within the powers of the EAMA as well. Nevertheless, unlike the agency, the NHIF exercises control that is directly related to the financial part of the contracts with the providers of medical care, including the PHC providers.

Under paragraph 1, point 26 of the Supplementary provisions of the HIA, **the control before reimbursement** of the delivered medical care is carried out by inspection of the healthcare institution or by use of documents outlining medical service reported to the RHIF before its reimbursement.

Under paragraph 1, point 27 of the Supplementary provisions of the law, **follow-up control** is the inspection carried out at the healthcare institution or by the use of documents outlining medical service reported to the RHIF after its reimbursement.

The control exercised by **inspections triggered by received complaints** from medically insured individuals is carried out as per the legislation terms within one month of their receipt.

The legal rights of the control bodies inspecting the PHC providers are defined in article 73, paragraph 1 of the HIA (Figure 2). In case of obstruction, administrative sanctions are imposed as delineated in the Administrative Violations and Sanctions Act (a fine for the health care provider– physical person or material sanction for provider – sole trader or legal entity).

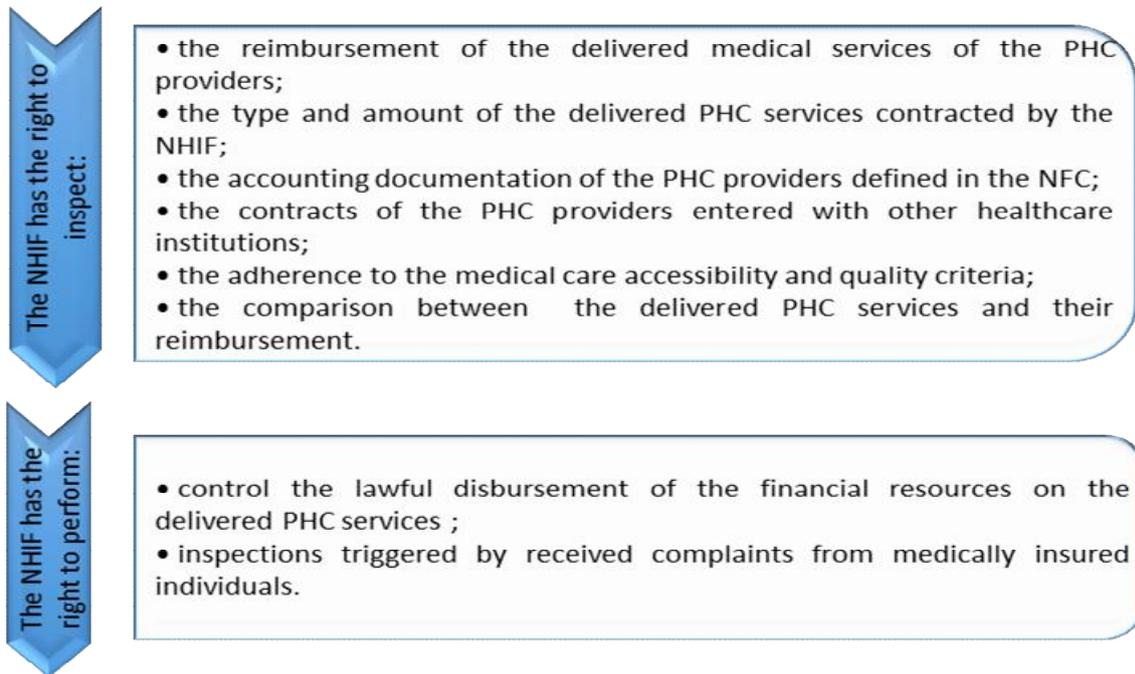


Fig. 2: Legal rights of the NHIF related to controlling the implementation of the contracts for delivery of the PHC services

The inspections carried out in relation to the control of the implementation of the contracts for delivering PHC services are performed on the grounds of a legal order. The order is issued by the governor of the NHIF, the director of the particular RHIF or an official authorized by them, in conformity with article 72, paragraph 2 of the HIA.

In case of violations, the control bodies draw and sign protocol with the established facts, under article 74, paragraph 3 of the HIA. A copy of the protocol would be provided to the person – being subjected to inspection against a signature, and copies would be sent to the governor of the NHIF or the director of the RHIF, as well as the particular regional association of doctors' professional organization.

Under article 74, paragraph 4 of the law, the person – subjected to the inspection has the right to provide a written statement on the conclusions drawn within 7-days of the protocol submission. When the person – subjected to the inspection does not express an opinion or the opinion expressed by them does not contain objections to the conclusions of the submitted protocol, the governor of the NHIF or the director of the RHIF issues an order with which he/she levies sanction. If nevertheless the person – subjected to the inspection exercises their legal right to object and challenges the conclusions of the control bodies, the governor of the NHIF or the director of the RHIF would refer the dispute to be solved by an arbitration commission.

The procedure for solving the dispute is regulated in article 75, paragraph 6 and article 76, paragraph 1 and paragraph 2 of the HIA. The arbitration commission presents its verdict with resolution within one month of receiving the transcript. If the verdict supports the conclusions drawn by the control bodies, the sanctions delineated in the contract between NHIF and the health care provider are implemented. The sanctions are levied with legal order issued by the governor of the NHIF or the director of the RHIF within one-month of the notification made by the arbitration commission to the

governor of the NHIF, correspondingly to the director of the RHIF. The sanctions are subject to court appeal under the Administrative-Procedural Code.

In view of the above, we could schematically outline the stages of the control of the implementation of the contracts for delivery of medical care, including PHC, in the case of established violations (Figure 3).



Fig. 3: Stages of the control exercised by the NHIF in the case of established violations

The HIA delineates not only the procedure for establishing and sanctioning the violations committed by the providers of medical care, including PHC, but also the cases of „groundlessly received sums“. The law contains no legal definition of this notion. These cases are regulated in article 76a and article 76b of the HIA and in practice represent deviations from the established medical standards detected by the control bodies. In that case the healthcare providers are obligated to restore the received overpayment for the SOMC and the MDA. Nevertheless, the HIA contains no explicit norms regulating the control of the adherence to the regulatory standards of the PHC. What are the regulatory standards? The regulatory standards are a financial mechanism for distributing the limited budget resources for the SOMC and MDA (Radeva, 2010). The regulation of the financial resources in the PHC is delineated in article 3 of the NHIF Budget Act for 2017 and outlines the number of the specialised medical care services and the MDA value.

The HIA defines two possible hypotheses for groundlessly received sums.

In the case of the first hypothesis, outlined in article 76a of the law, the provider of medical care has received sums without legal grounds that are not considered as violation under the HIA or the NFC, and this was established as a result of the inspection performed by the control bodies. In these cases, the contractor should reimburse the sums.

Under article 76a, paragraph 2 of the HIA, the control bodies draw a protocol on the groundlessly received sums.

The person, subject to the inspection has the right to object in writing within 7-days of protocol submission. After the expiration of the term, the governor of the NHIF or the director of the RHIF correspondingly, issues a written invitation to the medical care provider to have the sums received without legal grounds returned. The invitation is subject to appeal under the Administrative-Procedural Code.

Schematically speaking, the first hypothesis could be presented in the following manner (Figure 4):



Fig. 4: Stages of the control exercised by the NHIF in the cases of „groundlessly received sums” without statutory violations

The second hypothesis regulated in article 76b of the HIA is present in the cases where the provider of medical care has received sums without legal grounds, as a result of direct violation under the law or the NFC. As a result of this, the governor of the NHIF or the director of the RHIF issues invitation in writing to have the sums received without legal grounds returned, after the penal decree and/or order for levying sanction become effective. Compared to the first hypothesis, the second one is formulated in general manner; hence it cannot be schematically presented. Was this rectified in the NFC on the medical services for 2017?

National framework contract on medical services for 2017

Under article 4a of the HIA, the NFC is an administrative regulation that is effective throughout the country for a particular period of time and is mandatory to the NHIF, RHIF, the providers of medical care, the insureds and insurers.

The NFC on medical services for 2017 entered between the NHIF and the Bulgarian Medical Association, is one of the two types of framework contracts that regulates the delivery of the medical services under the HIA. Its effective term is one year, from 01.04.2017 to 01.04.2018.

The content of the NFC is defined in article 55, paragraph 2 of the HIA. It explicitly delineates the terms and conditions of the control over the executed contracts.

The NFC on the medical services for 2017 highlights the control functions performed by the NHIF. Under article 9, paragraph 1, point 3 of the NFC, the NHIF ensures that the legal rights of the health insureds are honoured by the medical care providers. This is achieved through exercising control over the implementation of the contracts with the health care providers.

The terms and conditions regulating the implementation of the contracts for delivery of medical care are defined in the twentieth chapter of the NFC on the medical services for 2017. Within it, the provisions of the second chapter, section X of the HIA additionally regulate the following: the subject matter of control (article 382, paragraph 3); the obligations of the providers of medical care (article 385, paragraph 1 and article 390, paragraph 4); the content of the order for inspection (article 387, paragraph 1, article 388, paragraph 1 and paragraph 2) and of the protocol drawn as a result of the performed inspection and the established violations (article 392, paragraph 1); as well as the rules for initiating inspections (article 390, paragraphs 1, 2 and 3) and submitting protocols (article 392, paragraph 2).

Subject matter of the control carried out by the NHIF are all healthcare institutions or their associations that have entered contract with the NHIF, which under the HIA are nominated for providers of medical care. The providers of the PHC are defined in article 14, paragraph 1 of the NFC on medical services for 2017. These could be the healthcare institutions for PHC – individual or group practice, under article 8, paragraph 1, point 1 of the Healthcare Institutions Act, as well as the healthcare institutions for hospital care under article 5, paragraph 1 of the same act that provide PHC – the centres for emergency medical care, the centres for transfusion haematology, the homes for medical-social cares and others.

The obligations of the providers of medical care include cooperation with the control bodies as well as providing the necessary requested and accounting documentation.

As we already mentioned, the NHIF inspections are carried out on the grounds of the issued order. Depending on the employees participating in the inspection and the territorial scope of the inspection, the order is being issued by the governor of the NHIF or the director of the RHIF (Figure 5).

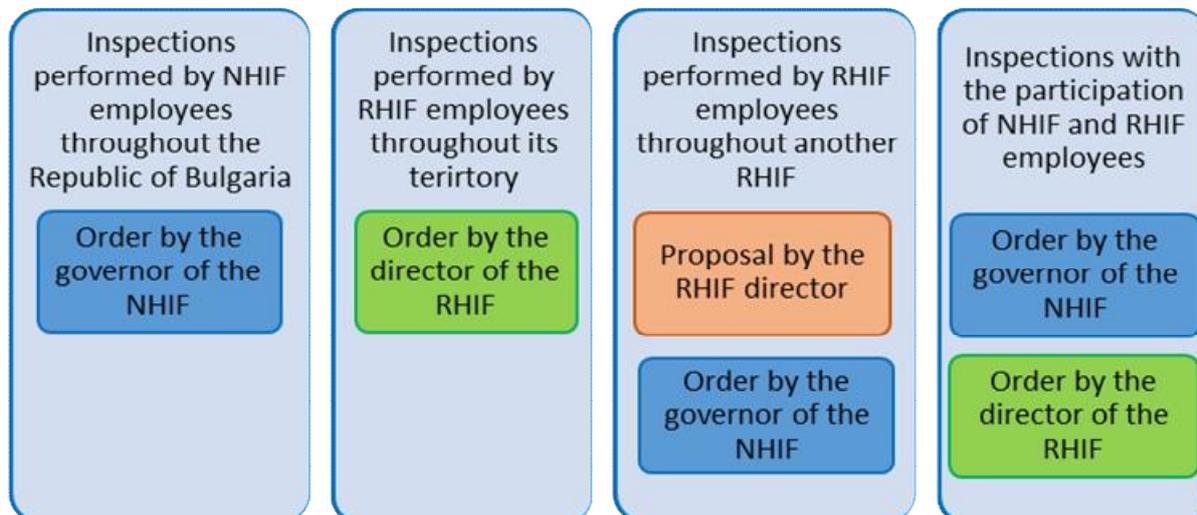


Fig. 5: Orders on inspection according to the participating employees and the territorial scope

Figure 5 shows that there are two stages in the process of issuing an order for individual inspections by the employees of the RHIF at the territory of another RHIF, as well as for joint inspections performed with the participation of employees of the NHIF and the RHI. In the first case, the governor of the NHIF issues order for the inspection, according to the proposal made by the director of the RHIF. In the second case, when the performance of joint inspection was ordered, the governor of the NHIF issues an order in which explicitly defines the RHIF at whose territory the inspection is to be performed, without specifying the subject matter of the inspection. On the grounds of the order issued by the governor of the NHIF, a second order is being issued, by the director of the RHIF,



supplemented with the controllers to take part in the inspection and the particular provider of the medical care – subjected to the inspection.

The content of the order for the inspection, issued by the governor of the NHIF is defined in the NFC on the medical services for 2017 and includes: the legal and factual grounds for its issuance, the person(s) who perform(s) the inspection, the subject matter of the inspection – appellation and location, term, type and task of the inspection.

The content of the order for inspection issued by the director of the RHIF is not explicitly defined in the NFC on medical services for 2017. This clarification is included in the guideline that has been effective since 2016 and was issued by the governor of the NHIF. The guideline is an internal policy that is not subject matter of the present research.

The NFC on the medical services for 2017 defines the rules for initiating the inspections. During the control process, initiating the inspection is the second stage after its assignation. It encompasses legitimisation of the person performing the inspection and submitting a copy of the order for inspection to the provider of the medical care – subjected to the inspection. It is possible to initiate the inspection without order submission (in case of refusal or inability to be accepted). This circumstance, as well as the date and time of submitting the order should be noted and certified with the signatures of all persons who participate in the inspection.

The NFC on the medical services for 2017 provides clarity on the protocol content that is to be drawn as a result of the performed inspection and the established violations. It should contain the following information: subject matter of the inspection – appellation and location; data about the inspection – date and location of drawing, grounds for performing the inspection, the person(s) that perform(s) the inspection; description of the established facts; the violations that were established in the implementation of the contract with the providers of medical care; the mandatory prescriptions and the time frame for resolving the established violations, recommendations on improving the services of the providers of medical care; the signature of the person(s) preparing the document; the legal time frame for raising objections established in the HIA; date of submission and signature of the person – subject matter of the inspection.

Levying sanctions as part of the control process related to non-implementation of the contracts for delivery of medical care is regulated in the twenty-first chapter of the NFC on the medical services for 2017. The goal of the sanctions is to discipline the violators of the HIA and the NFC.

The minor cases of violation are not subject of sanctioning by the control body but result in issuing of prescription for resolving the deviation within a particular time frame. After expiration of the defined term the control bodies could perform repeated inspection and request evidence for resolution.

In practice, levying sanctions and inspecting the completion of the issued prescriptions and recommendations for improvement of the services of the medical care providers, make the control effective.

The types of sanctions levied for established violation are defined in article 401, paragraph 1 of the NFC on the medical services for 2017. They are financial default payment and termination of the contract.

Levying sanction is performed in two manners: directly and indirectly.

Directly levying a sanction is the hypothesis where the person subjected to the inspection does not express an opinion in writing or the opinion, they express doesn't contain objections concerning the conclusions drawn by the control bodies. In this case, the inspection is finalized with an order for levying sanction issued by the governor of the NHIF or the director of the RHIF. In 14-days' term of

receiving the order, the provider of the medical care is obligated to transfer the payable sums. In the case of default under this obligation, the due sum should be deducted from the next payment under the contract. In the cases where the contract was terminated and/or no payments are due, the sum is collected via court order.

In the case of indirectly levying a sanction, the person subjected to the inspection is in disagreement with the conclusions drawn by the control bodies. In this case, the governor of the NHIF or the director of the RHIF issues an order for levying sanction after the disagreement is resolved with formal decision of the Arbitration commission confirming the conclusions of the control bodies.

The type and amount of the sanction are established by the governor of the NHIF or the director of the RHIF, depending on: the type and severity of the established violation, the number of the cases related to this violation, the sequence of its performance, as well as by the resolution of the arbitration commission if any (Figures 6 and 7). In the case of repeated violation, the sanction – financial default, would be levied at double the size of the initial one. The sanctions are subject to court appeal under the Administrative-Procedural Code.

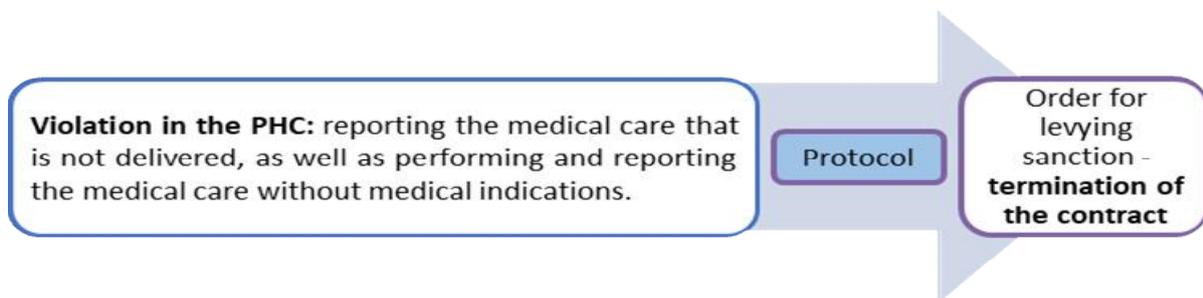


Fig. 6. Levying sanctions – termination of the contract in the PHC

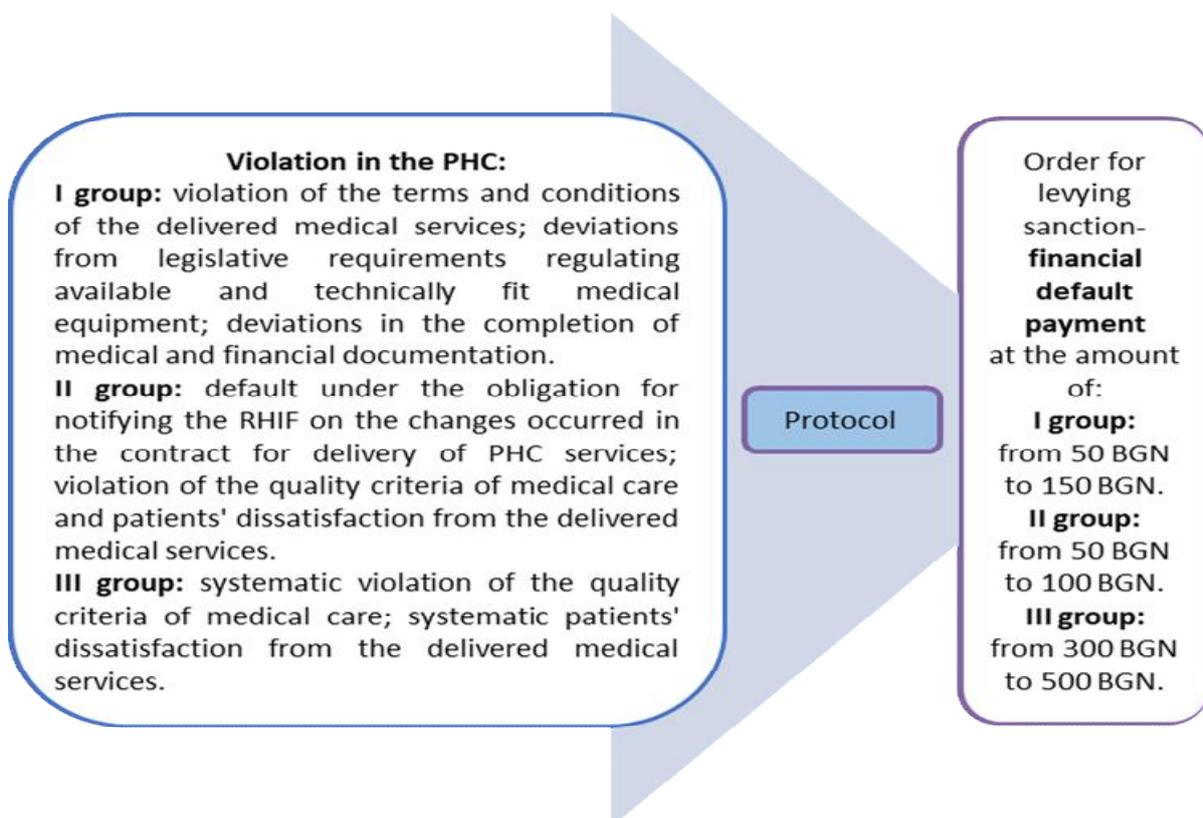


Fig. 7: Levying sanction – financial default payment in the PHC

The NFC on the medical services for 2017 also settles the cases of the groundlessly received sums, just like the HIA. Below we have considered both hypotheses of groundlessly received sums by the providers of medical care, including PHC, which could be both not related or related to the violations under the HIA or the NFC.

The first hypothesis is supplemented with the text of article 399, paragraph 3 of the NFC, which defines the content of the protocol for the groundlessly received sums. This should be drawn in established cases of received sums without legal grounds, not related to violation under HIA or the NFC. The protocol includes: subject matter of the inspection – appellation and location; data about the inspection – date and location of drawing, grounds for performing the inspection, the person(s) that perform(s) the inspection; description of the established facts; the establishment of the groundlessly received sums and their amount; the signature laid by the person(s) who drew the document; term for raising objections. Unlike the protocol content drawn as a result of performed inspection and established violations, the protocol on the groundlessly received sums doesn't not provide mandatory prescriptions and time frames for the established violations, as well as recommendations for improvement of the services of medical care providers.

The second hypothesis is also presented in general. It is not clear what document is to be drawn by the control bodies, as well as whether the person – subjected to the inspection has the right to challenge the conclusions just like in the cases of groundlessly received sums in the first hypothesis. These issues are clarified by the guideline from 2016, issued by the governor of the NHIF.

CONCLUSION

The main legislation that governs the healthcare insurance services in the Republic of Bulgaria – the HIA, regulates the following: the types of control exercised by the NHIF; the legal rights of the control bodies when exercising their functions; the process of inspections carried out by the NHIF and the establishment of violations, as well as the cases of groundlessly received sums by the providers of medical care.

In order to clearly understand the PHC control, the law should include explicit norms on exercising the control for adherence to the regulatory standards in the PHC and legal definition of the notion „groundlessly received sums“. The stages of control in established cases of „groundlessly received sums“ as a result of violation committed under the HIA or the NFC should be fully defined and not partially as it is currently under the HIA and the NFC on the medical services for 2017.

The legal rights of the NHIF and the EAMO should be clearly and precisely defined, bearing in mind their interweaving in respect to the sudden control exercised by the NHIF and inspecting the adherence of the services of the medical care providers to the medical care accessibility and quality criteria. The supplementation of the HIA with definition of the notion „medical control“ exercised by the EAMO would also contribute for clarifying the powers of both control institutions.

The NFC on the medical services for 2017 supplements the HIA in relation to the control of the implementation of the contracts for delivery of medical care, which is exercised by NHIF and has defined terms and conditions. There are omissions related to the content of the order for the initiation of inspection issued by the director of the RHIF. In the cases of established groundlessly received sums as a result of violation committed under the HIA or the NFC, it is not clear what document is to be drawn by the control bodies, as well as whether the person – subjected to the inspection has the right to challenge the conclusions as in the cases of groundlessly received sums not related to committing violation under the HIA or the NFC.



Based on the detailed review of the defined regulation acts, we could summarize that despite the outlined omissions and ambiguities, there are established legal regulations to govern the NHIF in exercising control of the implementation of the contracts for delivery of medical care, including PHC.

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