

Home »Practice» Opinions of the CPDP for 2019 »Opinion of the CPDP on clarifying the relationship" administrator - processor "between the NHIF and pharmacies that have concluded contracts with it on the implementation of Regulation (EU) 2016/679 (General Regulation on Protection) Opinion of the CPDP on clarifying the "controller-processor" relationship between the NHIF and pharmacies that have concluded contracts with it regarding the implementation of Regulation (EU) 2016/679 (General Data Protection Regulation) OPINION OF THE COMMISSION ON PROTECTION OF PERSONAL DATA Reg. (EU) 2016/679 (General Data Protection Regulation). The Commission for Personal Data Protection (CPDP) composed of members: Tsanko Tsolov, Tsvetelin Sofroniev, Maria Mateva and Veselin Tselkov, at a meeting held on 30.01.2019, considered a request for opinion / ent. № NDMSPO-01-1180 / 11.12.2018 / by Ms. VVK, in her capacity of manager of "C." Ltd. The company is engaged in the retail sale of medicinal products. Mrs. V.V.K. informs that "C." Ltd. is the sole owner of the capital of 11 other companies with the same subject of activity. In the ordinary course of business, C. Ltd. and its subsidiaries have opened and maintain the operation of 31 pharmacies under the trade name "C." (Pharmacies). In view of the above, the management of "C." Ltd. aims to initiate correspondence between Pharmacies and the NHIF, to clarify the role of the NHIF in relation to Pharmacies in terms of personal data of patients and medical professionals contained in prescriptions that Pharmacies perform and whose personal data Pharmacies send to the NHIF by virtue of of the Contract for granting medicinal products, medical devices and dietary foods for special medical purposes for home treatment, paid in full or in part by the NHIF / RHIF (the Contract). Mrs. V.V.K. indicates the following facts and circumstances, which in her opinion should be taken into account: 1. Art. 7 of Ordinance № 4 of 4.03.2009 on the terms and conditions for prescribing and dispensing medicinal products (Ordinance 4) contains the regulatory requirements for the content of the prescription. These requirements include personal data such as the names of the doctor prescribing the prescription, names, age, address and other personal data of the patient. 2. When accepting the prescriptions, the master pharmacists working in the Pharmacies make different types of processing of these data - they check them, store them, send them to the NHIF. 3. The relations between the NHIF and the Pharmacies shall be regulated by a contract, as art. 20, para. 1, item 3 of the Agreement for 2018, for example, stipulates that Pharmacies must submit to the NHIF copies of the executed prescriptions. Pharmacies cannot negotiate the terms of this contract and it is signed in the text adopted under Art. 45, para. 15 of the Health Insurance Act. According to the current provisions of the General Regulation on Data Protection, NHIFs and Pharmacies are controllers of personal data, each acting on their own basis, for the different types of processing they perform. However, in the specific case of a signed Agreement

between a pharmacy and the NHIF, the pharmacy, by virtue of the Agreement, is obliged to send to the NHIF prescription forms and various reports containing personal data. Even the standard software used by pharmacies must comply with the requirements of the NHIF - Art. 14 of the Treaty. The understanding of the company is that in cases where a pharmacy processes personal data, which processing is assigned to it by the Contract, it acts as a processor of the NHIF, and the latter is the administrator. This is because the processing of personal data provided for in the contract is done by the pharmacy. The pharmacy would not have made them if they had not been assigned to it by the Treaty. The goals and means of processing (including software) are determined by the NHIF, and Pharmacies are simply a contractor. In view of the above and given the relationship that Pharmacies have with the NHIF, Ms. V.V.K. asks the CPDP to rule on the processing of personal data - sending prescriptions and reports containing personal data from Pharmacies to the NHIF and other processing under the Treaty. In addition, the request is to be informed whether, in view of the relations thus presented, Pharmacies should be processors of personal data in relation to the NHIF for these specific treatments arising from the Treaty. Legal analysis: Regulation (EU) 2016/679 (General Regulation on Data Protection), which has been in force since 25 May 2018, is the normative act defining the rules related to the protection of personal data of individuals during their processing. The General Regulation builds on the previous data protection regime introduced by Directive 95/46 / EC, transposed into the Bulgarian Personal Data Protection Act of 2002, while taking into account the dynamics of the development of new technologies and data processing activities. personal data. The concept of controller and processor has been introduced by Directive 95/46 / EC and has been further developed with the new European legal framework for the protection of personal data. According to the legal definition referred to in Art. 4, item 7 of Regulation (EU) 2016/679, controller "means a natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union law or the law of a Member State, the controller or the specific criteria for determining it may be laid down in Union law or in the law of a Member State. ' The quality of administrator is a direct consequence of the fact that a particular legal or natural person has chosen to process personal data for their own purposes or for purposes that are regulated by law. In this situation, except where legally required, the controller decides on the need to collect personal data, the categories of personal data, whether to change or modify it during processing, where and how to use this data and with what purpose, whether the data should be disclosed to third parties and what they should be, as well as for how long they will be stored, and when and how they will be destroyed. In

addition, the Regulation imposes a certain range of obligations on the administrator. It must take appropriate technical and organizational measures relating to data security, taking into account the nature, scope, context and objectives of the data processing, as well as the existing risks to the rights and freedoms of data subjects. In addition, according to the provision of Art. 30, § 1 of Regulation (EU) 2016/679, the administrator shall maintain a register of the processing activities for which he is responsible. This commitment stems from the principle of accountability and the need for the administrator to be able to demonstrate at all times that he complies with the requirements set out in the Regulation. On the other hand, the processor is "a natural or legal person, public authority, agency or body which processes personal data on behalf of the controller" (Article 4, point 8 of Regulation (EU) 2016/679). The main difference between the figures of the controller and the processor is that the latter does not act alone, but on behalf of the controller of personal data, ie. the legal consequences of the processing of personal data occur directly in the legal sphere of the controller. The controller-controller relationship is governed by a contract or other legal act under EU or Member State law governing the subject matter and duration, the nature and purpose of the processing, the type of personal data and the categories of data subjects and the rights and obligations of administrator, incl. to carry out inspections (audits). In principle, the controller may entrust the processor with personal data processing activities for which he or she has the legal possibility to carry out, but for various organizational, technical, financial or other reasons he / she has considered it more appropriate to carry out the figure of the processor. In this line of thought it should be borne in mind that the provision of services, which usually exchange personal data between the contracting authority and the contractor, does not automatically lead to a relationship between administrator and processor within the meaning of Art. 28 of the Regulation (thesis expressed in a number of opinions of the CPDP). The General Regulation also introduces specific obligations for the data processor, which are not limited to data security. For example, he is obliged to process personal data only on a documented order from the administrator / arg. Art. 28, § 3, b. "A" in conjunction with Art. 29 of the General Regulation. In cases where it is necessary to appoint another data processor, this is done only with the express written permission of the controller. Like the administrator, according to Art. 30, § 2 of the General Regulation, the processor also maintains a register of the processing activities for which he is responsible. In addition, for the sake of even greater clarity, the provision of Art. 28, § 10 of the General Regulation explicitly provides that if the processor begins to determine the purposes and means of processing himself, he automatically begins to be considered an administrator. The division of roles and responsibilities between the controller and the processor has one main purpose, namely to ensure that the processing of

personal data takes place in accordance with the requirements of Regulation (EU) 2016/679 and accordingly ensures the protection of data subjects' rights. The legal relationship between pharmacies and the National Health Insurance Fund is a strictly regulated activity regulated by the Health Insurance Act (HIA) and Ordinance № 4 of 4 March 2009 on the terms and conditions for prescribing and dispensing medicinal products issued by the Minister of Health. In this regard, the provision of Art. 46, para. 2 of Ordinance № 4 stipulates that the dispensing of medicinal products from pharmacies operating under a contract with the NHIF is carried out in accordance with this ordinance and with the terms and conditions for concluding individual contracts under Art. 45, para. 15 of the Health Insurance Act.

These contracts have a pre-defined and unilaterally set form and content, which is not subject to change by pharmacies. For the parties to the contract (Pharmacies and NHIF) are provided rights and obligations that are directly related to the implementation of the subject of the contract, namely the release of medicinal products.

There is no doubt that the fulfillment of the obligations for the parties to the contract is related to activities for processing personal data of patients, medical specialists and pharmacists, whose data should be provided in the form of various documents of the NHIF. The contract provides for obligations for pharmacies, which, however, should not be classified as "assignment", which is the main distinguishing feature of the relationship controller - processor / arg. Art. 4, item 8 of Regulation (EU) 2016/679 /. On the contrary, the obligations in question are of a public law nature for the pharmacy, even though it is a commercial company. In practice, regardless of its name, the contract between the NHIF and the respective pharmacy has the character of a normative administrative act, which complements the mandatory legal framework of this strictly regulated activity. The situation is similar with the National Framework Agreement, which by virtue of Art. 4a of the Health Insurance Act is also a normative administrative act, which is valid throughout the country for a certain period and is mandatory for the NHIF, health care providers, insured persons and insurers.

In addition, the special legislation in the field of healthcare (legal and regulatory) provides for a number of obligations, measures, mechanisms, terms and conditions for processing and protection of personal data, which cannot be derogated from by contract between controller and processor within the meaning of Art. 28 of the General Regulation.

In view of the above and on the grounds of Art. 58, § 3, b. "B" of Regulation (EU) 2016/679, the Commission for Personal Data Protection states the following

OPINION:

1. The contract between the NHIF and the pharmacies, which regulates the relations between them on the basis of the Health Insurance Act and Ordinance № 4 of 4 March 2009 on the terms and conditions for prescribing and dispensing medicinal products issued by the Minister of Health, does not lead to emergence of a legal relationship administrator - processor of personal data within the meaning of Art. 28 of Regulation (EU) 2016/679. The contract in question has the character of a normative administrative act, which complements the mandatory legal framework in this area.

2. In principle, companies providing services under strict and comprehensive legislation, on the basis of a license or similar individual authorization from the state and under the control of explicitly designated public authorities, could not be considered as processors of personal data but as independent administrators. In addition, the special legislation in the field of healthcare provides a number of obligations, measures, mechanisms, procedures and conditions for processing and protection of personal data, which cannot be derogated from by a contract within the meaning of Art. 28 of the General Regulation.

MEMBERS:

Tsanko Tsolov

Tsvetelin Sofroniev / p /

Maria Mateva / p /

Veselin Tselkov / p /

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