Decision No 498 of 17 July 2018
concerning the exception of unconstitutionality against the provisions of Article 30 (2) and (3) and the words "patient's electronic health record system" contained in Article 280 (2) of Law No 95/2006 on healthcare reform
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Summary

I. As grounds for the referral of unconstitutionality, the author of the exception of unconstitutionality focuses mainly on the criticism that the contested legal texts do not contain guarantees regarding the protection of personal data, of a medical nature, contained in the electronic health records, the regulation of which is left to secondary legislation. It is further argued that, in the field of health care insurance, the legal framework must be regulated in a way which does not collide with the fundamental rights laid down in Article 26 of the Constitution, which lay down the obligation of public authorities to respect and protect the personal, family and private life. In matters relating to personal rights, the unanimous rule is that of guaranteeing and complying with those rights, that is to say, confidentiality, with the State having, in that sense, mainly negative obligations, of abstention, avoiding, as far as possible, its interference with the exercise of the right or freedom.

II. Having examined the exception of unconstitutionality, the Court finds that the establishment of the electronic health file was achieved by law without it providing for the data to be included in the file. It is true that from its name and from the reference in Article 30 (2) to "mobility of medical information", it can be inferred that it contains medical data, but only Article 1 of the Implementing Rules states that the electronic health file "shall mean nationally consolidated electronic records, including data and medical information relevant to doctors and patients" and that it "contains clinical, biological, diagnostic and therapeutic data and information that are personalised throughout the life of the patient, who are also the rightful owners of that information/data". Consequently, as the law does not provide for the subject matter of the electronic health file, only from a combined reading of the legal text with that of the methodological norms in the interpretation of the rule, it can be concluded that the electronic health records contain personal data of a medical nature.

The option of the State to create a modern/flexible mechanism by means of which the medical units can record the patient's medical history and make it available, in the form of the electronic health record, does not call into question in itself a limitation of the right to personal, family or private life; on the contrary, it may be an appropriate measure, given in the application of the right to health protection. On the other hand, the data entered in this electronic file fall within the scope of protection of the provisions of Article 26 of the Constitution, since they are medical data, which in turn are personal data.

Thus, the obligation for medical units which provide prophylactic and curative health care to document/update/consult the patient's medical information within the patient's medical records is a measure which supports the achievement of the State's positive obligation to ensure public health, but also a processing of medical data. However, the State's positive obligation to create the best possible conditions for public health must be carried out in compliance with the safeguards attached to the right to personal, family and private life of the patient. Thus, if the State is active, in the sense that it exercises its discretion in the context of its positive obligation to defend the right to protection of health, it must also be active in its positive obligations with regard to the right to personal, family and private life. In other words, if the State has put in place, by law, a measure in the application of the right to protection of the

health of the person, it is also the responsibility of the State to protect and guarantee the confidentiality of the medical information processed, by a regulatory act of the same level or by law.

In the light of the situation at hand, it follows from the examination of Article 30 (2) and (3) and Article 280 (2) of Law No 95/2006 on healthcare reform that *de lege lata* it has been considered to be sufficient for the law to cover the following aspects: the establishment of the electronic health record; the establishment of the manager of the health insurance information platform, namely the National Health Insurance Agency, including also the patient's electronic health record system; determination of the aforementioned obligation holders; the assumption that another IT system is used which should be compatible with the system in the health insurance IT platform, in which case suppliers are obliged to ensure security and privacy conditions in the data transmission process.

The Court finds that the abovementioned provisions are far from constituting in themselves guarantees of respect for the right to personal, family and private life. In reality, they are the basic elements for organising and ensuring the functioning of the new electronic system designed by the legislator. However, the organisation of such a system in the light of the State's positive obligation to take measures to protect the right to health protection necessarily implies a positive obligation on that State to protect and safeguard the right enshrined in Article 26 of the Constitution. In this respect, it is noted that the law does not provide for any measure that can be described as a guarantee of the right to personal, family or private life. As a result, in the light of the foregoing, the State did not pay any attention to those guarantees and these are therefore disregarded in the body of law.

The regulation of the electronic health file thus appears as an intrusion by the State into the personal, family and private life of the person. Even though it is a means by which the State fulfils its constitutional obligation to safeguard the health of the individual, the measure should appear to be an authorising, mandatory for person, for the purposes of the storage of the person's medical data on a given electronic platform, without it being possible for that person to resist in any way it.

In this case, the Court finds that, while the legal interference with the right provided for in Article 26 of the Constitution may have a legitimate purpose (protection of the health of the person by putting in order his or her medical history and ensuring that it is kept by a State authority), it is appropriate and necessary for the intended purpose, it does not strike a fair balance between competing interests, namely: the State's interest in relation to public health, the interest of the person that his health be protected, but also the interest of the individual to benefit of protection of his or her personal, family and private life.

It is not enough for the protection of health data to be carried out by an infralegal legislation, as the Court, in many cases, warned that secondary regulatory acts, exempli gratia, Government decisions, are anyway characterised by increased degree of instability or inaccessibility. It should be noted that safeguards to ensure the constitutional right provided for in Article 26 are contained in a Government Decision, but that such regulation is totally inadequate, undermining the constitutional protection of personal, family and private life. In practice, the administrative authority may at any time modify the guarantee standards associated with this right, by issuing regulatory administrative acts, and the citizen/patient is thus at the mercy of the administrative authority. An appropriate protection of that right is that established by law, which is not the case in the present case. Consequently, the contested texts are in breach of Article 26 of the Constitution.

It is also a matter of principle that primary legislation is that enjoying the legal force of the law and, therefore, stability, so that it seems even inappropriate that a measure of the nature of the law, given in the application of Article 34 of the Constitution, be subject to limitations by means of a Government decision, which is considered to be sufficient to comply with Article

26 of the Constitution. In such a way, a restructuring/reshaping of the law is achieved through the administrative act, which is unthinkable. It follows that the limits of a State's interference laid down by law are established by an administrative act, issued under the same law, which infringes Article 1 (5) of the Constitution.

It is therefore for the legislator to regulate the guarantees associated with the right to personal, family and private life. This obligation must be materialised by law in the sense of the instrumentum. To the centre of these statutory guarantees must be the consent of the patient. In the light of Article 26, the legislator has a constitutional obligation not to make the medical act as such subject to the application of entries in the electronic health file, as there is no direct correspondence between them. Consent must also be a free consent, which cannot be stimulated by providing possible medical or other (economic) advantages, because in this case it would be indirectly flawed. The individual, particularly in the case of his health, is particularly vulnerable and tempted to accept, completely and unconditionally, the legislative measures promoted by the State which are proposed to him for acceptance, without considering the right balance that must exist between the right to protection of health and the right to personal, family and private life. Moreover, the person is even more vulnerable as he is in a physical/emotional state that no longer enables him to objectively appreciate his consent. Therefore, the legislative framework must not disregard him and place him on a secondary position in relation to the desire of the State to keep an electronic health file and/or to centralise various medical data (as an objective public health protection measure). The same considerations apply to the way in which the person who does not consent to the processing of his medical data under the electronic health file is treated.

The processing of data of a medical nature must be regulated in such a way as to ensure their confidentiality At this point, the Court is not in a position to examine whether the safeguards contained in the secondary regulatory acts are sufficient or not, or whether they should be supplemented by other guarantees, such a task and jurisdiction can only be exercised once they are transposed into law. It should be recalled that the guarantees associated with the protection of such data, even if legally regulated, must have a high standard of safeguarding the confidentiality of the patient's medical data. The law must also expressly provide for both the nature of the liability and the penalties — which in themselves must be the corresponding in degree of the high standard of protection of medical data — applicable to persons involved in the management of the electronic health file in the event of a breach of obligations and safeguards that are to be regulated by law.

Social relationships are regulated primarily by law/emergency ordinances/ordinances, while regulatory administrative acts can organise their implementation or enforcement , as appropriate, without being a primary source of law. The regulation of primary rules in the body of secondary regulation is a contradiction in terms. The latter act must be strictly confined to the organisation of the implementation or enforcement of the primary provisions, and not itself regulate such provisions. Therefore, administrative acts of a normative nature, whether they are decisions of the Government or orders of Ministers, cannot, through their normative content, exceed the scope of the organisation of the implementation of primary law [Article 108 (2) of the Constitution], respectively enforcement thereof or o Government's decisions (Article 77 of Law No 24/2000 on the legislative technical rules for drawing up legislative acts, republished in the Official Gazette of Romania, Part I, No 260 of 21 April 2010), as the case may be, because it would lead to amendment/completion of the law itself by means of such a process. Consequently, given that the legal texts complained of not only allow for such an approach, but also unequivocally regulate it — by the extensive reference they make to secondary regulatory acts — the Court is to find an infringement of Article 1 (5) of the Constitution.

In view of the unconstitutionality declared with reference to Article 1 (5) and Article 26 of the Constitution, the Court finds that — in the absence of guarantees established by law in relation to the right to personal, family and private life, having regard to the content of the electronic health file — the existing legal provisions concerning the electronic health file are no longer able to form part of the positive law.

III. For all these reasons, the Court unanimously upheld the exception of unconstitutionality raised directly by the Advocate of the People and found unconstitutional the provisions of Article 30 (2) and (3), a well as the words "patient's electronic health record system" in Article 280 (2) of Law No 95/2006 on healthcare reform.