

# Information system in health care and the problems of planning and evaluation of health policies in Poland<sup>2</sup>

## 1. Introduction

In the era of the information society, without a well-functioning information system in health care, it is impossible to achieve an adequate level of not only efficiency, but above all effectiveness of the state's health policies <sup>implemented</sup><sup>3</sup>. Without an up-to-date and complete set of data on various aspects of the functioning of the sector in question, it is not possible to make optimal decisions on the deployment and use of health care resources, nor is it possible to assess the results of such measures on the basis of precise, measurable indicators. In the literature on the subject, the important role of information components for ensuring the effective functioning of health care in Poland was pointed out as early as 1983.<sup>4</sup> However, it should be remembered that the resources processed in information systems should be properly organized and meet the characteristics of usability, so that they can become a valuable source of knowledge in the processes of managing the undertaken <sup>undertakings</sup><sup>5</sup>. The experience of Australia, the United Kingdom and Canada indicates that collections of information collected in the sector

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<sup>3</sup> Effectiveness is understood as the degree to which planned activities are carried out and planned results are achieved, while efficiency refers to the relationship between the results achieved and the resources used and the resulting added value (T. Żylicz, *Sku- teczność a efektywność*, "Aura" 2006, No. 10, p. 8).

<sup>4</sup> L. Frąckiewicz, *Health care policy. Synteza*, Wydawnictwo Akademii Ekonomicznej im. K. Adamieckiego, Katowice 1991, p. 109.

<sup>5</sup> R. Griffin, *Fundamentals of organizational management*, PWN Scientific Publishers, Warszawa 2007, pp. 723-726.

health care are a useful instrument to help shape public policies in this area<sup>6</sup>. Comprehensive evaluation, on the basis of aggregated empirical data, of the effects of such public health undertakings, allowing them to be improved in the future, is becoming increasingly important today<sup>7</sup>.

Taking into account the importance of these issues for the formulation of health policies, it should be mentioned that in the Third Programme of Union Action in the Field of Health (2014-2020), introduced by Regulation No. 282/2014 of the European Parliament and of the Council of March 11, 2014. (Official Journal of the EU L of 2014, No. 86, p. 1), recital 18 indicates that the project in question should contribute to evidence-based decision-making by supporting the health information and knowledge system, taking into account relevant activities carried out by international organizations. These should include, among other things, initiatives to make more effective use of existing technical and organizational instruments, as well as the further development of standardized collections of health information and tools for capturing, monitoring and analyzing health data. The implementation of these demands at the EU level is also supported by the e-Health Action Plan 2012-2020 - Innovative Healthcare for the 21st Century (COM(2012) 736). It points out that the use of ICT in health and healthcare systems can increase their efficiency, improve quality of life and spur innovation in health-related markets<sup>8</sup>.

This article will attempt to analyze the legal basis for the functioning of the elements of the state's information infrastructure linked to the health sector and constituting the primary source of data that are important from the point of view of the formation of state health policies.

The considerations carried out will also address the role of normative instruments, which are a guarantee of ensuring an adequate level of security.

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<sup>6</sup> L. Roos, V. Menec, R. Currie, "Policy analysis in an information-rich environment," *Social Science & Medicine* 2004, no. 58, pp. 2238-2239.

<sup>7</sup> C. Stokes, *The Electronic Health Revolution: How Health. Information Technology Is Changing Medicine - And the Obstacles in Its Way*, "Health Law & Policy Brief," 2013, vol. 7, no. 1, s. 23-24.

<sup>8</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century (COM(2012) 736), Brussels 2012, p. 4.

of collected information, from the point of view of maintaining a satisfactory level of trust in ICT systems operating in the health sector and using such resources. Of particular importance in this context are the issues of the due realization of patients' rights to privacy and the protection of personal data processed electronically in medical records and electronic medical records systems.

## 2. The role of the health care information system in the process of implementing health policies

The health care information system is one of the most essential parts of the state's information infrastructure, which is a complex of institutions, organizational units, information resources and systems, as well as information and communication technologies that determine the optimal functioning of certain social, economic and political systems<sup>9</sup>. This infrastructure serves to collect, store and provide access to information that meets quality standards and is necessary for the proper functioning of such systems<sup>10</sup>. This category undoubtedly includes the health care system, the observed organizational and economic problems of which are to some extent due to the insufficient coherence and efficiency of the related information system<sup>11</sup>. It has therefore become necessary to take measures to organize its functioning and support the processes occurring in it with solutions based on information and communication technologies. The information system in health care occurs at the local, regional, national and international levels, including the EU area.

The most important legal act regulating the functioning of the health care information system in Poland is the Act of April 28, 2011 on the health care information system (u.s.i.o.z.) (consolidated text: Journal of Laws 2018, item 1845). As stated in Article 1(1), it defines the organization and principles of operation of this system, in which data necessary for the conduct of the

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<sup>9</sup> J. Oleński, *Infrastruktura informacyjna państwa w globalnej gospodarce (Information Infrastructure of the State in the Global Economy)*, University of Warsaw Publishing House, Warsaw 2006, pp. 270-271.

<sup>10</sup> Ibid, p. 270.

<sup>11</sup> B. Goryński, P. Wojtyniak, *Description of the information system in health care in Poland. Elements of assessment*, State Institute of Hygiene, Warsaw 2006, pp. 5-7.

state health policy, raising the quality and availability of health care services and financing health care tasks. The previously observed fragmentation and incompleteness of the scope of normative regulations in this area was criticized in the <sup>literature</sup><sup>12</sup>. The health care information model in operation before the entry into force of the legal solutions in question was characterized by "considerable dispersion, both territorially and institutionally. The technological level of the infrastructure and software used was heterogeneous." <sup>13</sup> This state of affairs called for measures to increase the efficiency of information processes in this area.

It is worth pointing out the significant problems associated with running an undertaking of this complexity. The implementation of successive functionalities of the health care information system is facing serious difficulties, manifested by delays in the implementation of key functionalities compared to the original schedule, as well as insufficient coordination between the Center for Health Information Systems (CSIOZ) and the National Health <sup>Fund</sup><sup>14</sup>. In 2016. The Supreme Audit Office (NIK), in a report on the creation and sharing of medical records, drew attention to the insufficient level of computerization of medical data processing by healthcare providers, and the consequent low level of their preparation for optimal use of the system's functionalities, which poses a significant risk to the realization of the goals set for this <sup>project</sup><sup>15</sup>. This element of the state's information infrastructure will not function properly if unstructured and fragmented data on medical events is transferred to it.

The system operates on a decentralized model and includes databases containing data on health care services provided, delivered and planned, providers and medical workers, as well as recipients.

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<sup>12</sup> Ibid, pp. 42-43.

<sup>13</sup> M. Kedzierski, *Information governance in health care*, "Information Time" 2011, no. 3(8), s. 66.

<sup>14</sup> M. Boni (ed.), *Państwo 2.0. Nowy start dla e-administracji*, Ministry of Administration and Digitization, Warsaw 2012, [https://mc.gov.pl/files/wp-content/uploads/2012/04/MAC-Panstwo-2-0-Nowy-start-dla-e-administracji-4-2012\\_raport\\_web.pdf](https://mc.gov.pl/files/wp-content/uploads/2012/04/MAC-Panstwo-2-0-Nowy-start-dla-e-administracji-4-2012_raport_web.pdf), pp. 36-37 (date of reading: 19.06.2017).

<sup>15</sup> Information on the results of the audit of the Supreme Audit Office (NIK) - creation and sharing of medical records, case no: KZD.430.002.2015, pp. 33-34.

The said information resources, according to the wording of Article 5 (1) of the s.i.o.z., are processed under the following solutions:

- The Medical Information System (SIM) - is a tele-information system for processing data related to the provided, administered and planned health care services, made available by the tele-information systems of service providers (Art. 10 (1) of the Act). The solution in question is a basic element of the health care information system, the main purpose of which is to aggregate data related to the health care services <sup>provided</sup><sup>16</sup>.
- Domain information systems - information and communication systems that support a specific area of the health care system's operation (Art. 2 pt. 5 of the Act). Their integration with the health care information system is intended to enable more efficient and effective exchange of medical data in areas relevant to public health, as well as to ensure compliance with semantic and technical standards that are generally accepted and common to all elements of this <sup>environment</sup><sup>17</sup>. This group of systems includes:
  - RUM system of the National Health Fund - Register of Medical Services of the National Health Fund,
  - Health Statistics System,
  - Health Care Resource Inventory System,
  - Threat Monitoring System,
  - Health Care Availability Monitoring System,
  - Treatment Cost Monitoring System,
  - Integrated System for Monitoring the Circulation of Medicinal Products,
  - Medical Staff Training Monitoring System,
  - Refund List Maintenance System,
  - Health Sector Investment Proposal Evaluation Facility.
- Medical registers - legally created registers, records, lists, inventories or other structured collections of personal data, individual medical data or data that are not personal data, used for the implementation of public tasks, maintained by the

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<sup>16</sup> M. Ferdzyn, M. Gerwatowski, P. Gumiela, A. Kostusiak, M. Rasielewska, *Informatization of health care in Poland. Assumptions of the program and its implementation* [in:] A. Jaron (ed.), *Management of information and tools for implementation of selected public policies*, Krajowa Szkoła Administracji Publicznej, Warsaw 2014, p. 57.

<sup>17</sup> D. Wąsik, *Law on the information system in health care. Commentary*, Wolters Kluwer, Warsaw 2015, pp. 32-33.

an entity functioning in the health care system (Article 2, item 12 of the s.s.i.o.z.). These resources are collected on the basis of subject criterion (concerning the entities occurring in health care) or object criterion (data are collected in this case according to the criterion of disease groups or type of health care service).<sup>18</sup> Medical registers are, next to electronic medical records, the primary source of data on the functioning of the various areas of the health care sector in Poland. The architecture of the health care information system also assumes the existence of-

tion and coordination layer, which organizes the processes of data exchange in the solutions in question. This information environment will be supported by two specialized IT solutions:

- Platform for On-Line Sharing of Services and Digital Resources of Medical Registries (P2) - this solution allows the Medical Information System to communicate with medical registries in order to obtain data processed in them, integrate them, update them and share information resources with service providers and payers, within the scope of the powers held by these entities (Article 6(1) of the s.i.o.z.).
- Electronic Platform for Collection, Analysis and Sharing of Digital Resources on Medical Events (P1) - this tool, via the *Universal Service Bus (Enterprise Service Bus)*, will enable service recipients and other authorized entities to access information provided by service providers and collected in the SIM about planned and already provided health care services. The realization of this functionality will be possible thanks to mechanisms of exchange between service providers of data contained in electronic medical records and related electronic documents, if this is necessary to ensure continuity of treatment. In addition, the solution in question will allow access of the entities keeping medical records, within the scope of their tasks and authorizations, to the data processed in the SIM through the P2 platform (Article 7(1) of the Act).

In addition to increasing the efficiency of the functioning of treatment processes, which are based on the concept of *evidence-based medicine* (*-based medicine*), as well as improving access to medical information for patients, the solutions being introduced as part of the health care information system will allow the acquisition of up-to-date and reliable data necessary for optimal formation of assumptions, goals and indicators

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<sup>18</sup> Ibid, p. 37.

implementation of health policies. As W. Włodarczyk rightly notes, the higher the level of quality of the data used in these processes, the greater the chances of achieving the positive effects of their implementation assumed for such instruments<sup>19</sup>. In addition, obtaining up-to-date, time-oriented information on the living conditions of the population can undoubtedly facilitate the verification of the ongoing effects of public policies, positively influencing their effectiveness<sup>20</sup>.

Pursuant to Article 11(1)(3) of the Act of August 27, 2004 on health care services financed from public funds (u.ś.o.z.f.ś.p.) (unified text: Journal of Laws of 2017, item 1938), the competence of the minister responsible for health includes the development, financing and evaluation of the effects of health policy programs, as well as supervision of their implementation. Given the normative context of the issues at hand, it is important to note the scope of the tasks of this body in the area of coordination of public health activities, imposed on this entity by the Law of September 11, 2015 on public health (consolidated text: Journal of Laws of 2017, item 2237). According to the wording of Article 4(2) of this act, the minister's duties include: preparing a draft of the National Health Program, monitoring the implementation of the tasks under the law in question, collecting and analyzing information on the health situation of the population and the prevalence of risk factors and making this information available in a manner that does not allow identification of the persons to whom it applies, as well as preparing information on public health tasks implemented or undertaken in a given year, together with their evaluation.

In the context of using the resources of the health care information system in the processes of shaping health policies, attention should be drawn to Article 95a of the Law on the National Institute of Public Health - National Institute of Hygiene, which obliges the National Institute of Public Health - National Institute of Hygiene to prepare draft Regional Health Needs Maps, taking into account epidemiological, demographic data and data from the register of entities performing medical activities (paragraph 4). On their basis, a Nationwide Map of Health Needs is created (para. 6). All of these studies are published on the subject pages of the Public Information Bulletin of the minister in charge of health and the offices serving governors (para. 9).

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<sup>19</sup> W. Włodarczyk, *Health policy in a democratic society*, University Medical Publishing House "Vesalius", Cracow 1996, p. 139.

<sup>20</sup> V. Korporowicz, *Health policy in the system of public policy sciences*, "Studies in Public Policy," 2015, no. 1(5), p. 51.

It is widely recognized in the literature that the basis for the proper implementation of the decision-making process is the possession of adequate information on related factual <sup>circumstances</sup><sup>21</sup>. Certainly, the effective execution of the above-mentioned competencies of the minister in charge of health will be relatively difficult to implement and not very effective without a well-functioning health care information system that feeds this sub-committee with data on the current level of public health indicators and the state of processes occurring in health care in Poland. This conclusion was confirmed by the NIK, in one of its post-audit reports, indicating that the Health Needs Maps should be based on reliable data, so that they can form the basis for planning the financing of <sup>services</sup>.<sup>22</sup> It seems that only the optimal state of information processes in the field in question will allow fully rational decisions to be made about the shaping of national health policies in subsequent years.

### 3. Electronic medical records as a primary source of information in health care

In Polish law, we will not find a uniform and comprehensive legal definition of the concept of medical records. The current regulations are limited to indicating the minimum scope of data processed in it or the types of documents that are part of <sup>it</sup><sup>23</sup>. In the literature, medical records are defined as "a collection of documents that are carriers of information of a medical nature."<sup>24</sup> It is a basic institution that stabilizes information processes in health care by ensuring accountability and transparency in the functioning of health care. Within the framework of EU law, a normative definition of medical records was introduced in Article 3(m) of Directive 2011/24/EU of the European Parliament and of the Council of March 9, 2011 on the application of patients' rights in cross-border healthcare

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<sup>21</sup> W. Włodarczyk, *Contemporary Health Policy. Selected issues*, Wolters Kluwer, Warsaw 2014, p. 221.

<sup>22</sup> Information on the results of the audit of the Supreme Audit Office (NIK) - Creation of Health Needs Maps, case mark: KZD.430.008.2017, p. 13.

<sup>23</sup> M. Dercz, T. Rek, *The Law on Medical Activity. Commentary*, Wolters Kluwer, Warsaw 2014, p. 27; D. Wąsik, *Law on the Information System...*, p. 20.

<sup>24</sup> U. Drozdowska (ed.), *Dokumentacja medyczna*, Cegedim, Warsaw 2012, p. 22.

(Official Journal of the EU L of 2011, No. 88, p. 45), indicating that it includes all documents containing all kinds of data, assessments and information concerning a patient's condition and course of illness during the period of health care provision. The concept of electronic medical records is defined in Article 29 of the Working Group document as "comprehensive medical records or similar documentation about a person's past and current physical and mental health, in electronic form and providing access to such data for the purpose of treatment or for other closely related purposes."<sup>25</sup> According to Article 2(6) of the s.s.i.o.z. electronic medical records include documents produced in electronic form, bearing a qualified electronic signature or a signature confirmed by the ePUAP trusted profile, or using a method of confirming the origin and integrity of data available in the tele-information system made available free of charge by the Social Insurance Institution, enabling the recipient to obtain a specific type of health care service from the service provider, excluding orders for medical devices, as well as other documents defined by the minister responsible for health in a regulation issued on the basis of Article 13a of the a.s.i.o.z.

The content of § 1 of the Ordinance of the Minister of Health of November 9, 2015, on types, scope and specimens of medical records and the manner of their processing (Journal of Laws of 2015, item 2069) indicates the possibility of keeping medical records in electronic form or in traditional paper form, the use of which, however, will be allowed only until December 31, 2018, in accordance with the disposition contained in Article 56 of the s.s.i.o.z. The current wording of Article 11

The u.s.i.o.z. obliges service providers to maintain, as of that date, an electronic form of medical records, based on data formats consistent with the Polish implementation of the HL7 CDA standard, published by CSIOZ<sup>26</sup>.

Reliable medical record-keeping facilitates the goals of providing appropriately profiled personalized health care for patients, duly respecting their autonomy.<sup>27</sup> Access to the

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<sup>25</sup> Working Document on the Processing of Personal Health Data in Electronic Health Records (EHR) (00323/07/PL WP 131), Brussels 2007, [http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2007/wp131\\_pl.pdf](http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/2007/wp131_pl.pdf), p. 4 (accessed June 19, 2017).

<sup>26</sup> A description of the Polish HL7 CDA National Implementation can be found at: <https://www.csioz.gov.pl/HL7POL/pl-cda-html-pl-PL/> (read date: 21.06.2017).

<sup>27</sup> M. Rothstein, "Autonomy and Paternalism in Health Policy," *The Journal of Law, Medicine & Ethics* 2014, vol. 42, iss. 4, s. 591.

These information resources also support the performance of administrative duties in health care, the processes of managing the quality of health services, as well as health education and research in the area of health sciences<sup>28</sup>. Undoubtedly, aggregated data extracted from medical records through the health care information system can provide very useful analytical material from the point of view of evaluating implemented health policies. However, in the case of such use of the information resources in question, it is necessary, at the same time, to ensure adequate guarantees of the realization of the right to privacy of the data subjects.<sup>29</sup> The acquired data, which do not have to be linked to a specific person from the point of view of the purposes of their processing, should be subjected to anonymization or at least pseudonymization, thus reducing the risk of potential misuse of these resources.

#### 4. The importance of interoperability of data sets in health care

In the case of modern information systems, ensuring mechanisms for effective cooperation between such solutions becomes an important issue for assessing their usability<sup>30</sup>. EU policy documents point out that interoperability of ICT-based solutions and ensuring the ability to exchange data effectively is a prerequisite for better coordination and integration across the entire chain of healthcare delivery and health data exchange.

In the content of Article 3(18) of the Act of February 17, 2005 on informatization of the activities of entities performing public tasks (unified text: Journal of Laws 2017, item 570), the concept of interoperability is defined as the ability of various entities and the information and communication systems and public registries they use to work together to achieve mutually beneficial and agreed objectives, taking into account the sharing of information and knowledge

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<sup>28</sup> F. Leiner, W. Gaus, R. Haux, P. Knaup-Gregori, *Medical Data Management. A Practical Guide*, Springer, New York 1993, pp. 3-6.

<sup>29</sup> C. Di Iorio, F. Carinci, *Privacy and Health Care Information Systems: Where Is the Balance?* [in:] G. Carlisle, D. Whitehouse, P. Duquenoy (eds.), *eHealth: Legal, Ethical and Governance Challenges*, Springer, Berlin Heidelberg 2013, p. 101.

<sup>30</sup> C. Stokes, op.cit., p. 29.

by the business processes they support, carried out by means of data exchange through the tele- information systems used by these entities. In the literature, interoperability is considered as the ability of components or systems to distribute information to each other, understand it uniformly and use it effectively to realize the intended effects of the actions taken.<sup>31</sup> When discussing this issue, attention is also paid to such important related issues as compatibility, cooperation or interoperability of distributed autonomous IT solutions<sup>32</sup>. Specific standards for the public sector in this area of issues are regulated in the content of the Regulation of the Council of Ministers of April 12, 2012 on the National Interoperability Framework, minimum requirements for public registers and information exchange in electronic form, and minimum requirements for ICT systems (Journal of Laws 2012, item 526).

EU institutions are supporting processes to agree on standards for cooperation and data exchange between ICT systems and public registries in the health sectors of EU member states. At the European level, there are pilot projects, such as *epSOS*<sup>33</sup>, whose main goal is to build models of open and intelligent electronic health services for patients and medical personnel, enabling efficient cross-border data exchange. The basic legal framework for such interoperability is established in Article 14(1) of Directive 2011/24/EU, which indicates that the EU shall promote and facilitate cooperation and exchange of information between Member States operating within a voluntary network bringing together national authorities designated by Member States as responsible for eHealth. One of the primary goals of the existence of this organizational structure is to strive for interoperability of national e-Health solutions, by issuing guidelines on the architecture used and standards for data exchange by these tools, as well as supporting standardization and certification procedures in this area. Attention is also drawn to the fact that any projects undertaken in this area should duly take into account the basic principles of privacy and data protection

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<sup>31</sup> B. Szafrński (ed.), *Interoperability and Security of Information Systems of Public Administration*, Polskie Towarzystwo Informatyczne, Górnśląski Oddział, Katowice 2006, p. 13.

<sup>32</sup> B. Szafrński, *Interoperability of public registers* [in:] A. Gryszczyńska (ed.), *Public Registers. Openness and interoperability*, C.H. Beck, Warsaw 2016, pp. 61-62.

<sup>33</sup> <http://www.epsos.eu/home/about-epsos.html> (read date: 20.06.2017).

personal data. In this aspect, it seems particularly important to prevent situations where unauthorized profiling of a person may occur by combining data about him from different sources. The indicated events should be prevented by the use of appropriate technical and organizational standards, linked to user authentication and authorization of access to resources at various stages of data processing, which will ensure accountability. Thanks to such an approach, on the one hand it will be possible to properly use the potential of aggregated medical data, while on the other hand the risk of their misuse and violation of the rights and freedoms of data subjects will be effectively minimized.

## 5. Information security and data protection in ICT-based solutions -communications in health care

The issue of protecting medical data and preserving patient privacy seems to be a particularly topical issue in an era of widespread use of information and communication technologies in health <sup>care</sup><sup>34</sup>, manifested by the use of electronic medical records in entities performing medical activities and the implementation of comprehensive eHealth IT solutions at the regional and national level, serving the health care information system. Ensuring the confidentiality, integrity and availability of such information resources requires taking into account adequate physical, technical, organizational and legal safeguards to the current state of security threats. This issue assumes particular importance for the proper functioning of business processes in health care, given the challenges of adapting entities belonging to this sector to the new requirements for ensuring the security of processed information resources, established under the reform of legal instruments guaranteeing data protection in the EU.

The content of Article 47 of the Polish Constitution indicates that everyone has the right to legal protection of private life. Complementing this regulation is the norm expressed

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<sup>34</sup> M. Safjan, *Law and Medicine. Protection of individual rights and the dilemmas of modern medicine*, Institute of Justice, Warsaw 1998, p. 124.

in Article 51(1) of the Constitution, indicating that no one may be obliged other than by law to disclose information concerning his person<sup>35</sup>. A detailed normative basis for the right to the protection of personal data can be found in Article 8(1) of the EU Charter of Fundamental Rights.

In addition, as of May 25, 2018, a single Regulation of the European Parliament and of the Council (EU) 2016/679 of April 27, 2016 on the protection of natural persons with regard to the processing of personal data and on the free flow of such data and repealing Directive 95/46/EC (RODO) (Official Journal of the EU L of 2016, No. 119, p. 1) has been applied throughout the EU, replacing the regulations of the member states relating to this scope. The principle of accountability, arising from Article 5(2) of this act, obliges data administrators to take proactive measures that are appropriate to the circumstances, which they will comprehensively document and, if necessary, demonstrate their implementation, in order to ensure a level of security appropriate to the nature and value of the information resources processed and the risks involved<sup>36</sup>. As part of the new regulations, new obligations related to the processing of special categories of personal data, which include health data, have been introduced. A data controller under Article 25 of the RODO should take into account issues related to the protection of these information resources already in the design phase of their processing (*Privacy by Design*). An extension of this concept is the instrument of *Pri- vacy Impact Assessment*, provided for in Article 35 of the RODO, which is carried out by the controller when such information processes, due to their nature, scope, context and purposes, are highly likely to cause a high risk of violation of the rights or freedoms of individuals. Such a procedure is carried out in particular in cases:

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<sup>35</sup> As the Constitutional Court pointed out in its judgment of November 12, 2002 (ref. SK 40/01, OTK 2002, no. 6, item 81), the right to the protection of personal data arising from Article 51 of the Constitution "undoubtedly constitutes a special instrument for the protection of those interests of the subject that are related to the protection of private life. Thus, this right is a specialized means of protecting the same values that are protected through Article 47 of the Constitution."

<sup>36</sup> R. Thomas, *Accountability - a modern approach to regulating the 21st century data environment* [in:] H. Hijmans, H. Krankenberg (eds.), *Data Protection Anno 2014: How to Restore Trust*, Intersentia, Cambridge 2014, p. 146.

- systematic, comprehensive assessment of personal factors relating to individuals that is based on automated processing of information resources, including profiling,
- large-scale use of special categories of personal <sup>data37</sup>. Entities performing such activities will also be required to designate-  
to appoint data protection officers (Article 37(1) of the RODO).

As part of the reform of data protection regulation in the EU, the scope of information obligations (regarding the intention to transfer personal data to a recipient in a third country or an international organization, automated decision-making, as well as the data protection officer's contact details) of entities processing such resources towards data subjects has been significantly expanded. In addition, from the wording of Articles 33 and 34 of the RODO derive the notification obligations imposed on the controller to the supervisory authority and data subjects regarding data protection violations. Under Article 83 of the RODO, failure to comply with the discussed rules for securing these information resources may result in the imposition of an administrative fine by the supervisory authority.

Any patient-specific medical data processed in electronic medical records and the health care information system is personal <sup>data38</sup>. The use of these resources for the implementation of health policies, therefore, undoubtedly involves a potential high risk of violation of the rights or freedoms of individuals, which must be adequately managed by applying adequate organizational and technical safeguards arising from the established security policy. It should take into account not only the minimum obligations of data controllers under the law, but also the requirements and guidelines of the ISO 27000 family of technical standards on information security. It is also necessary to use effective cryptographic techniques and pseudonymization of collected information resources to ensure their confidentiality. In a situation where, in the analyses conducted on the health situation of the population, it is not required to determine the identity of the

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<sup>37</sup> A document issued by the GIODO in 2018 titled *Proposed list of types of processing for which an impact assessment is required* (<https://giodo.gov.pl/pl/file/13366>, pp. 3-5) indicated that a data protection impact assessment should be carried out by hospitals for the storage and sharing of medical records, as well as in situations of telemedicine consultations with non-EU centers or cross-border transfer of personal medical data.

<sup>38</sup> M. Jackowski, *Medical Data Protection*, Wolters Kluwer, Warsaw 2011, p. 28.

individual participants in such a study, anonymized data should be used. Taking adequate security measures by data controllers in the area of health care, according to the level of threats, will duly guarantee the protection of the privacy sphere of participants in this system.

## 6. Summary

Health policy is widely recognized as an important area of social policy<sup>39</sup>. The data collected in the health care information system have great potential from the point of view of the possibility of their use in the planning and evaluation processes of this category of public policies implemented in Poland. However, when considering ways to exploit these resources, one should not forget about the issues of ensuring their appropriate level of security, since any incidents in this area may carry irreversible consequences for individuals in the form of permanent restriction of their spheres of intimacy and privacy, by violating the confidentiality of sensitive data concerning them. Guaranteeing the transparency of the functioning of information processes within the framework of the introduced IT solutions and building users' trust in them should be the most important task of entities operating such systems. Thanks to the application of such an approach, it will be possible to systematically increase the benefits of safe use of information and communication technology capabilities in the health sector, while preserving the essence of patients' rights, linked to the informational autonomy of the individual.

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<sup>39</sup> M. Sokolowska, J. Holowka (eds.), *Social Policy and Health*, Książka i Wiedza Publishing House, Warsaw 1978, p. 7.

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## The Healthcare Information System in the Context of Planning and Evaluating Healthcare Policies in Poland

### Abstract

Achieving adequate efficiency of the healthcare information system, which is a part of the information infrastructure in the state, is an important prerequisite to achieve the desired level of efficiency and effectiveness of activities undertaken within the life cycle of healthcare policies and their planning and evaluation phases. An insufficient information base could create obstacles for optimal decision-making processes related to resources usage in the healthcare. This paper presents the legal issues related to managing of the healthcare information system, use of this data source to conduct health policies, as well as the issues of ensuring security of information in this area. Guarantees of transparency of data processing operations within

information systems and building trust for those solutions will allow increasing the benefits of using ICT in the processes of creation and management of healthcare policies, where an essence of the patient's rights related to information autonomy should remain intact.

**Keywords:** healthcare policy, healthcare information system, interoperability, information security