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Digitalisation and data exchange in healthcare in Poland[1]

Cyfryzacja infrastruktury ochrony zdrowia w Polsce

The study presents (a) the legal basis for creating digital infrastructure in health care, (b) currently used elements of this infrastructure and (c) solutions waiting to be implemented.

Keywords: health care, digitization

W opracowaniu przedstawiono (a) podstawy prawne tworzenia infrastruktury cyfrowej w ochronie zdrowia, (b) aktualnie wykorzystywane elementy tej infrastruktury oraz (c) rozwiązania oczekujące na wdrożenie.

Słowa kluczowe: ochrona zdrowia, cyfryzacja

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In response to ECPRD Request No. 5317 regarding digitalisation and data exchange in healthcare, the Bureau of Research provides the following information:

Question 1. How is the digital infrastructure for healthcare data organised in your Member State?

a) **Are there norms for the digital infrastructure? If so, can you describe the most important norms?**
b) **Can you give an indication of the number of providers there are for the digital healthcare infrastructure?**

The following components operate within the digital healthcare data infrastructure in Poland:

[1] *Digitalisation and data exchange in health care (ECPRD Request No. 5317)* prepared on February 7, 2023 as part of cooperation in The European Centre for Parliamentary Research and Documentation (Europejskie Centrum Badań Parlamentarnych i Dokumentacji); BAS-WASiE-115/23.

A. The Electronic Platform for Collecting, Analyzing and Sharing Digital Resources on Medical Events (P1)[2] enables the collection, processing and sharing of digital resources on patients' medical events and indexes of electronic medical records (EDM). The legal basis for the operation of the Platform is Article 7 of the Act of 28 April 2011 on the information system in health care (hereinafter: the Act on SIOZ)[3].

The system covers all medical entities, regardless of the source of financing the services provided by them.

The e-health ICT system (P1) consists of digital services: e-prescription, e-referral, electronic medical documentation, medical events and applications (Internetowe Konto Pacjenta, MojeIKP, gabinet.gov.pl), and solutions improving the processes of planning and implementing health protection services. It supports the work of healthcare entities, medical staff, and public administration responsible for the functioning of the healthcare sector in Poland, provide patients with digital tools to help manage their health.

The P1 platform is an ICT system that enables in particular:

1. access of service recipients to information on provided and planned healthcare services collected in the medical information system (hereinafter: SIM[4]) and reports on the provision of data concerning them.

2. submission by service recipients or their representatives of statutory statements, declarations and applications.

3. providing information by the Social Insurance Institution.

4. providing by the payer information on the amount of health insurance premiums paid by service recipients.

5. transfer by service providers and the payer to the SIM of information on provided, provided and planned healthcare services.

6. exchange of data contained in electronic medical records between service providers, if it is necessary to ensure the continuity of treatment.

7. exchange of electronic documents between service providers in order to conduct diagnostics, ensure the continuity of treatment and supply recipients with medicinal products and medical devices.

8. access by entities keeping medical records, within the scope of tasks performed and authorizations held, to data processed in the SIM, via the Online Platform for Sharing Services and Digital Resources of Medical Records.

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[2] More information: https://www.cez.gov.pl/pl/nasze-produkty/e-zdrowie-p1, accessed February 3, 2023, this date applies to all links in the study.

[3] Journal of Laws of 2022, item 1555 with later changes, https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20111130657; hereinafter: the SIOZ Act.

[4] SIM is an ICT system used to process data on provided, provided and planned healthcare services made available by ICT systems of service providers (Article 10 of the Act on SIOZ).

9. access of local government units to data processed in the SIM, enabling the implementation of tasks related to ensuring equal access to healthcare services for residents.

10. access of provincial governors (voivodes) to aggregate data necessary to perform the tasks set out in the Act on healthcare services financed from public funds.

11. access of the minister responsible for health to the data necessary to perform the tasks specified in the Act on healthcare services financed from public funds.

12. providing statistical data referred to in the Act on Civil Status Records and in the Act on Cemeteries and Burial of the Dead (for the purposes of official statistics).

13. transferring and receiving personal data and individual medical data of service recipients in the field of cross-border prescription exchange.

14. obtaining by doctors, dentists, nurses, midwives, feldshers, senior feldshers, physiotherapists, pharmacists, pharmaceutical technicians, and persons performing auxiliary activities in the provision of healthcare services the information about the additional rights of service recipients and information about their disability certificates or about the degree of disability.

The following operate within the system: Central List of Service Recipients – the register operates on the basis of Article 15 of the SIOZ Act; Central List of Service Providers – the register operates on the basis of Article 16 of the SIOZ Act; Central List of Medical Employees – the register operates on the basis of Article 17 of the SIOZ Act; Central List of Medicinal Products – the register operates on the basis of Article 17a of the SIOZ Act.

B. On-line Platform for Providing Entrepreneurs with Online Services and Resources of Digital Medical Registers (P2)[5] – enables access to information contained in the medical registers maintained as part of the system (https://rejestrymedyczne.ezdrowie.gov.pl):

The legal basis for the operation of the On-Line Sharing Platform for Digital Medical Records Services and Resources is Article 6 of the SIOZ Act. According to this article, the platform is an ICT system that enables, in particular:

1. communication of the SIM with medical registers in order to obtain data processed therein;

2. updating data in medical registers;

3. integration of medical records; providing service providers and payers, within the scope of their authorizations, with data from medical registers.

Medical records kept under P2:

[5] Https://ezdrowie.gov.pl/portal/home/rejestry-medyczne/.

The National Register of Permits to Operate Public Pharmacies, Pharmacy Outlets and the Register of Consents Granted to Operate Hospital and Company Pharmacies[6] (register of pharmacies) is kept by the Voivodeship (Provincial) Pharmaceutical Inspectorates with jurisdiction over the place. (https://rejestrymedyczne.ezdrowie.gov.pl/ra/search/public).

The Register of Permits to Operate a Pharmaceutical Wholesale Store[7] (register of pharmaceutical wholesalers) is kept by the Main Pharmaceutical Inspectorate in accordance with Article 83 of the Pharmaceutical Law Act (Journal of Laws of 2008 No. 45, item 271, as amended) and the Regulation of the Minister of Health of October 3, 2012 on the description of the ICT system in which the Register of Permits for Running a Pharmaceutical Wholesale Store is kept (Journal of Laws of 2012, No. 0, item 1118). The register contains the address data of the wholesaler and its owner as well as the permit number. (https://rejestrymedyczne.ezdrowie.gov.pl/rhf/search/public).

The Register of Entities Performing Medical Activity (RPWDL)[8] contains information on all entities authorized to conduct medical activity. It is kept by the locally competent registration authority, in accordance with the Act of 15 April 2011 on medical activity (Journal of Laws of 2013, item 217). (https://rpwdl.ezdrowie.gov.pl/).

The Register of Medicinal Products[9] contains information on all medicinal products intended for humans and veterinary products authorized for trading in the territory of the Republic of Poland. (https://rejestrymedyczne.ezdrowie.gov.pl/rpl/search/public).

The List of Pharmaceutical Raw Materials contains information on all pharmaceutical raw materials admitted to trading in the territory of the Republic of Poland based on the decision of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. (https://rejestrymedyczne.ezdrowie.gov.pl/rpl/lsf).

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[6] The register operates on the basis of Article 107 of the Pharmaceutical Law (Journal of Laws of 2008 No. 45, item 271, as amended) and the executive regulation of the Minister of Health, https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20011261381.

[7] The register operates on the basis of Article 83 sec. 5 of the Act of September 6, 2001 – Pharmaceutical Law and the executive regulation of the Minister of Health, https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20011261381.

[8] The register operates on the basis of the Act of 15 April 2011 on medical activity (Journal of Laws of 2013, item 217) and the executive regulation of the Minister of Health.

[9] The register operates on the basis of the Act of September 6, 2001 – Pharmaceutical Law and the executive regulation of the Minister of Health, https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20011261381.

The Central Register of Pharmacists of the Republic of Poland[10] is kept by the Supreme Pharmaceutical Council pursuant to Article 39 sec. 1 of the Act of 19 April 1991 on Pharmaceutical Chambers (i.e. Journal of Laws of 2014, item 1429). The Central Register of Pharmacists of the Republic of Poland includes data obtained from the district pharmacy councils referred to in Article 8 sec. 2 and Article 8a sec. 2 of the Act on Chambers of Pharmacists. (https://crf.ezdrowie.gov.pl/).

The register of decisions issued by the Main Pharmaceutical Inspector[11] collects the decisions of the Main Pharmaceutical Inspector in the field of withdrawal from the market, suspension of trade, re-admission to trade, ban on marketing and suspension of advertising issued on the basis of the Pharmaceutical Law Act (Journal of Laws of 2001 No. 126 item 1381). The register contains data on decisions, medicinal products contained in decisions and responsible entities. (https://rdg.ezdrowie.gov.pl/).

The Register of Laboratory Diagnosticians[12] registered in the territory of the Republic of Poland is kept by the National Council of Laboratory Diagnosticians pursuant to Article 8 of the Act of 27 July 2001 on laboratory diagnostics (Journal of Laws of 2014, item 174). The Register of Laboratory Diagnosticians is used to search for laboratory diagnosticians in the territory of the Republic of Poland. (https://rdl.ezdrowie.gov.pl/).

The Register of Medically Assisted Reproduction Centres and Reproductive Cells and Embryo Banks[13] is kept by the Minister of Health, pursuant to Article 56 sec. 1 of the Act of 25 June 2015 on infertility treatment (Journal of Laws of 2015, item 1087). (https://roib.ezdrowie.gov.pl/).

The Register of Medical Assistants – the system operates on the basis of Article 31c. the SIOZ Act. (https://ram.ezdrowie.gov.pl).

The Register of Medical Dictionaries – a collection of medical dictionaries. It is to eliminate misunderstandings resulting from the use of medical terms. (https://rsk3.ezdrowie.gov.pl/).

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[10] The register operates on the basis of the Article 39 par. 1 points 15 and 39a of the Act of 19 April 1991 on chambers of pharmacies (Journal of Laws of 2014, item 1429), https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu19910410179.

[11] The register operates on the basis of the Pharmaceutical Law (Journal of Laws 2001 No. 126 item 1381), https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20011261381.

[12] The register operates on the basis of Article 8 of the Act of 27 July 2001 on laboratory diagnostics (Journal of Laws of 2014, item 174), https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20011001083.

[13] The register operates on the basis of Article 56 sec. 1 of the Act of 25 June 2015 on infertility treatment (Journal of Laws of 2015, item 1087), https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20150001087.

C. Other ICT information systems in health care (P4)[14] – enable access to information contained in the medical registers kept by the Minister within the system. The legal basis for creating these registers is Article 19 of the SIOZ Act. The Minister of Health Matters may create and maintain or create and commission the maintenance of medical registers, constituting an ordered set of personal data, including individual medical data, in order to: monitor the demand for healthcare services, monitor the health of service recipients, conduct preventive health care or implement health programs or health policy programmes, monitoring and evaluation of the safety, effectiveness, quality and cost-effectiveness of diagnostic tests or medical procedures.

Currently operating:

Reimbursement Letters Handling System (SOLR), which collects and processes data necessary to make a decision on the reimbursement of medicines, foodstuffs for particular nutritional uses and medical devices. Electronic applications can be submitted via SOLR in matters related to reimbursement and determination of the official selling price, price increase or reduction and shortening of the period of validity of the reimbursement decision (https://solr.ezdrowie.gov.pl/). The system operates on the basis of Article 30a of the SIOZ Act

Destination Import Service System (SOID) The system collects and processes data necessary for the minister responsible for health issues to take a decision on importing a medicinal product or a foodstuff for particular nutritional uses from abroad and on marketing a medicinal product that does not have an authorization. The system enables the electronic issuing and processing of requests for importing medicinal products from abroad, necessary to save a patient's life or health (https://soid.ezdrowie.gov.pl/). The system operates on the basis of Article 31c of the SIOZ Act.

Instrument for the Assessment of Investment Applications in the Health Sector (IOWISZ) The Instrument for Assessment of Investment Applications in the Health Sector is a tool used by provincial governors and the Ministry of Health when issuing opinions on the advisability of investments planned for implementation in health care. The system provides a transparent and rational investment evaluation process (https://iowisz.ezdrowie.gov.pl/). The system operates on the basis of Article 31a of the SIOZ Act

Electronic Healthcare Logging Platform (EPLOZ) – the technical solution of Electronic Healthcare Services (EUOZ) consists of Systems and Registers maintained by the e-Health Centre and the Electronic Healthcare Logging Platform (e-PLOZ). Thanks to e-PLOZ, you can log in using the same login and password to the e-Health Centre systems. From the level of e-PLOZ, the user can also log in using identity identification services on the Internet. These services

[14] Www.cez.gov.pl/pl/page/dziedzinowe-systemy-teleinformatyczne.

are made available by the National Electronic Identification Node – by logging in at login.gov.pl (https://eploz.ezdrowie.gov.pl/)

Healthcare Resources Recording System (SEZOZ) The system enables healthcare entities to report their resources in the form of medical equipment and medical devices electronically. The collected data allow for their analysis and are helpful in the decision-making process regarding the purchase of medical equipment and its optimal distribution throughout the country. The main task of the system is to streamline business processes related to access to information on the state of healthcare resources (https://sezoz.ezdrowie.gov.pl/). The system operates on the basis of Article 24 of the SIOZ Act.

Resident IT System (SIR) The system enables electronic handling of financing residencies. In particular, it enables the registration and updating of the entity's data, managing the list of employed residents from all proceedings and the parameters of residencies, and submitting applications for financing residencies to the Ministry of Health (https://sir2.ezdrowie.gov.pl/). The system operates on the basis of Article 30 of the SIOZ Act.

Education of Medical Workers Monitoring System (SMK) The system collects and processes data on the organization, planning and course of postgraduate training of medical personnel. It enables the submission and assessment of applications for specialization and supports the process of conducting exams (https://smk.ezdrowie.gov.pl/). The system operates on the basis of Article 30 of the SIOZ Act.

Threat Monitoring System (SMZ) The task of the Threat Monitoring System is to collect information on events whose occurrence or scale may pose a threat to human health and life. These include epidemiological risks and those resulting from the use of a defective medicinal product. The system registers reports of suspected or diagnosed infections and contagious diseases, positive laboratory test results, adverse post-vaccination reactions and suspected influenza cases, adverse reactions to medicinal products and veterinary medicinal products. The system also includes the Departmental Early Warning System (RSWO) module (https://smz.ezdrowie.gov.pl/view-smz/login). The system operates on the basis of Article 26 of the SIOZ Act.

Integrated System for Monitoring Trade in Medicinal Products (ZSMOPL) The system collects and processes data on trade in monitored products from entities conducting wholesale and retail trade. Data on the volume of planned deliveries are provided by the responsible entities (MAH Marketing Authorization Holder), and information on shortages of medicinal products by pharmacies. Data to ZSMOPL are transferred via electronic messages or are entered via the ZSMOPL Portal (https://zsmopl.ezdrowie.gov.pl/). The system operates on the basis of Article 29 of the SIOZ Act.

Healthcare Statistics System (SSOZ) The main task of the Healthcare Statistics System (SSOZ) is to support the minister responsible for health and the

president of the Central Statistical Office in collecting and processing statistical data related to the healthcare sector in Poland. (https://ssoz.ezdrowie.gov.pl/). The system operates on the basis of Article 23 of the SIOZ Act.

System of the Medical Services Register of the National Health Fund – an ICT system whose purpose is to process data on provided and planned healthcare services financed from public funds and to settle these benefits. The system operates on the basis of Article 22 of the Act on SIOZ, **System for Monitoring Access to Health Care Services** – the system operates on the basis of Article 27 of the Act on SIOZ, **Treatment Costs Monitoring System** – the system operates on the basis of Article 28 of the SIOZ Act.

According to the Strategy of the e-Health Centre for 2023–2027[15], it is planned to expand the register system by: 1/ The e-Krew (e-blood) system, 2/ The e-Transplant system, 3/ The e-Haemophilia system, 4/ A system for collecting and analyzing genetic data, which in conjunction with the data from the e-health system (P1) will enable the conduct of analysis in order to implement actions aimed at optimizing the diagnostic and therapeutic process, 5/ The support system, which will consist in building a central repository for selected healthcare entities. The need for this solution was confirmed by the results of a survey conducted in 2022 on the degree of computerization of PWDL6. Such studies are periodically conducted by the e-Health Centre, 6/ Implementation of electronic registration functionality and teleconsultation service, 7/ Implementation of the functionality related to the creation and storage of the Electronic Death Card (e-KZ) and the Electronic Birth Card (e-KU) in the system, along with the annotation of stillbirth, 9/ digitization of documentation produced in the field of preventive health care for students, conducted by nurses of the teaching and upbringing environment or school hygienists.

D. Electronic medical records On the basis of Article 11 of the SIOZ Act, all service providers are obliged to keep and exchange electronic medical records, as specified in the Regulation of the Minister of Health of May 8, 2018 on the types of electronic medical records (Journal of Laws of 2021, item 1153).[16] Currently, this obligation covers certain types of medical documentation, while the list of types of documentation is successively expanded. The obligation currently covers:

1. information about the diagnosis of the disease, health problem or injury, the results of the tests carried out, the reason for refusing admission to the hospital, the health services provided and any recommendations – in the event of refusal to admit the patient to the hospital,

[15] CEZ Strategy of the e-Health Centre for 2023–2027, cez.gov.pl/sites/default/files/paragraph.attachments.field_attachments/2023-01/strategia_centrum_e-zdrowia.pdf.

[16] Https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210001153.

2. information for the doctor referring the beneficiary to a specialist clinic or hospital treatment about the diagnosis, method of treatment, prognosis, prescribed drugs, foodstuffs for particular nutritional uses and medical devices, including the period of their use and method of dosing and scheduled follow-up visits,

3. hospital treatment information card,

4. results of laboratory tests with a description,

5. description of diagnostic tests.

In addition, on July 1, 2021, the obligation to exchange data contained in the abovementioned electronic medical records via the Medical Information System.

The rules for creating medical documentation as well as the formats and standards for its exchange are available at the link: https://ezdrowie.gov.pl/portal/home/dla-dostawcow/interfejsy.

Question 1a. Are there norms for the digital infrastructure? If so, can you describe the most important norms?

The basic legal act is the Act of 28 April 2011 on the information system in health care (SIOZ Act) – it regulates the components of digital infrastructure, establishes the division of tasks between individual institutions, ensures coordination and control of activities. The legal basis for running digital infrastructure components is indicated in the previous answer about individual components of the healthcare information system (P1, P2, P4).

The provisions of the Act on the information system in health care shall apply to entities obliged to process data in the field of health care, in particular to the minister responsible for health, the provincial governor, the National Health Fund, the Supreme Medical Council, the Supreme Council of Nurses and Midwives, the provincial pharmaceutical inspector, regional pharmacy chambers, the Supreme Pharmaceutical Council, the National Council of Laboratory Diagnosticians, the Postgraduate Medical Education Centre, as well as public and private healthcare facilities (see Article 3 of the SIOZ Act).

The provisions of the Act on the information system in health care also apply to entities authorized to access data covered by the information system, i.a. to persons performing control activities of the information system and databases (Article 39(5) of the Act on SIOZ), to patients, their statutory representatives and persons authorized by patients (Article 26(1) Act on Patient's Rights[17]), entities providing health services to the extent necessary to ensure the continuity of services (Article 26(3)(1) of the Act on Patient's Rights), public authorities, national

[17] Act on patients' rights and the Ombudsman for Patients' Rights of November 6, 2008 (Journal of Laws of 2022, item 1876), https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=wdu20090520417; hereinafter: Act on Patient's Rights.

and provincial consultants and self-government bodies of medical professions to the extent necessary to perform their tasks, in particular supervision and control (Article 26 section 3 item 2 Act on Patient's Rights), disciplinary courts, prosecutors, forensic doctors and ombudsmen for professional liability (Article 26 section 3 item 4 Act on patient's rights), pension authorities (Article 26 section 3 item 5 patient's rights) and insurance institutions (Article 26(3)(7) Act on of Patient's Rights).

Other acts that are important for the digital healthcare infrastructure are: the Act of 19 July 2019 amending certain acts in connection with the implementation of solutions in the area of e-health (Journal of Laws 2019, item 1590[18]) and the Act of 17 February 2005 on computerization of the activities of entities performing public tasks (Journal of Laws of 2023, item 57).[19]

Question 1b. Can you give an indication of the number of providers there are for the digital healthcare infrastructure?

The development of e-health in Poland is the responsibility of the Ministry of Health, which is supported by a subordinate unit – the e-Health Centre (CeZ). The e-Health Centre (hereinafter: CeZ) is a state budget unit established by the Minister of Health, which has been operating since 2000. CeZ manages over 50 central IT systems, including the e-health system (P1), medical registers (e.g.: RPWDL, RHF, RA, RPL, RAM), systems supporting prevention and treatment (e.g.: EWP, e-Krew, e-Transplant) and field ICT systems (e.g.: SOLR, SOID, EPLOZ, SMZ, ZSMOPL).[20]

There are also companies on the market that provide software and services to entities performing medical activities and to pharmaceutical entities, local systems, enabling, among others, patient service, keeping medical records in electronic form and creating EDM. The available statistics do not distinguish this particular business.[21]

Question 2. To what extent is healthcare data digitalised in your Member State?

a) **Does legislation make it mandatory to digitalise healthcare data? If so, does legislation prescribe which data has to be digitalised?**
b) **How is the digital exchange of healthcare data organised?**
c) **How is ensured that data is shared in a safe way and with respect for data protection and privacy?**

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18 Https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20190001590.

19 Https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20050640565.

20 Detailed information on the projects implemented by CeZ can be found on the CeZ website: www.cez.gov.pl.

21 "Activities related to software and consulting in the field of IT and related activities in the data of the Central Statistical Office – do not reflect the number of providers specialized in e-health solutions.

Healthcare data is digitized in accordance with the above-mentioned regulations, their exchange takes place in the information system operated by ICT systems created by CeZ (Articles 5, 6 and 7 of the Act on SIOZ and related articles). ICT systems are built in accordance with the principles of ensuring security and data protection, including personal data. The scope of digitization also depends on the activities of entities providing healthcare services.

The Act on SIOZ – by creating an information system and legal basis for the operation of registers and ICT systems supporting the healthcare information system – is to lead to the full digitization of healthcare data. The Act defines the organization and operation of the healthcare information system (see Articles 3, 4, 5, 6, 7 of the Act). 2) Electronic Platform for Collecting, Analyzing and Sharing Digital Resources on Medical Events.3. ICT systems that support the information system within the scope of the tasks assigned to them use the services provided by the Electronic Platform of Public Administration Services. Numerous executive regulations enforce the digitization of data in specific scopes, in the executive regulations this obligation is imposed by using the words "Register X is kept using an ICT system" or "System X is an ICT system".

In accordance with the Regulation of the Minister of Health of 8 May 2018 on types of electronic medical records[22] pursuant to Article 13a of the Act of 28 April 2011 on the information system in health care (Journal of Laws of 2021, item 666), it was imposed on entities providing healthcare services to keep medical records in electronic form.

Electronic medical records include:

1) information about the diagnosis of a disease, health problem or injury, the results of tests carried out, the reason for refusing admission to hospital, the health services provided and any recommendations – in the case of refusal to admit a patient to hospital, referred to in the regulations issued on the basis of Article 30 of the Act on Patient Rights;

2) information for the doctor directing the beneficiary to a specialist clinic or hospital treatment about the diagnosis, treatment, prognosis, prescribed drugs, foodstuffs for particular nutritional uses and medical devices, including the period of their use and the method of dosing and scheduled follow-up visits referred to in regulations issued on the basis of Article 137 sec. 2 of the Act of August 27, 2004 on healthcare services financed from public funds (Journal of Laws of 2020, item 1398, as amended);

3) the hospital treatment information card referred to in the provisions issued on the basis of Article 30 of the Act of November 6, 2008 on patient rights and the Ombudsman for Patients' Rights;

4) results of laboratory tests with a description;

5) description of diagnostic tests other than those indicated in point 4;

[22] Https://isap.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WDU20210001153.

6) a card of the preventive examination of the student referred to in the regulations issued on the basis of Article 30 of the Act of November 6, 2008 on patient rights and the Ombudsman for Patients' Rights.

The rules for creating medical documentation as well as the formats and standards for its exchange are available at the link: https://ezdrowie.gov.pl/portal/home/dla-dostawcow/interfejsy.

11,580 completed and positively verified survey forms were received as part of the 6th edition of the "Research on the degree of computerization of entities performing medical activities". Based on the data, the actual degree of digitization of data in health care was determined.[23]

Question 3. Does your State have a legislative framework for quality standards and norms for the digital exchange of healthcare data?

In accordance with the Article 8b of the Act on the Information System in Healthcare, the document "Minimum technical and functional requirements for service providers' systems"[24] was published. Service providers and entities keeping medical records are obliged to comply with the ICT systems of their ICT systems with the requirements contained in the document within 9 months from the date of their publication.

The purpose of the document is to describe the minimum requirements for Service Provider Systems pursuant to Article 8b of the Act on SIOZ. The basic model of data exchange between the Service Provider's System and the P1 System are network interfaces. In order to issue an e-prescription, e-referral, handle electronic POZ declarations, generate medical event messages or index or exchange EDM, the service provider must connect its office, hospital or pharmacy system to the P1 System. The Service Provider's system must be able to create an XML document in accordance with the nationally accepted standard of the Polish National Implementation HL7 CDA, and then, respectively, send or index it to the P1 System. All network services of the P1 System are secured with the use of WS-Security mechanisms. In communication with the P1 System, it is required to use the Web Services Security extension and the Web Services Security X.509 Certificate Token Profile.

Authentication of the External System calling the P1 System service takes place in the transport layer of the connection using the TLS protocol with mutual

[23] 6th Edition "Research on the degree of computerization entities performing medical activity", https://cez.gov.pl/sites/default/files/2022-09/Raport%20CeZ_2022.pdf.

[24] Www.gov.pl/web/zdrowie/minimalne-wymagania-dla-systemow-uslugodawcow and www.gov.pl/attachment/931736c6-d44c-4499-9b87-d05c9982b121.

authentication – in addition to server authentication by the external system, the client (External System) is authenticated by the server. To establish a TLS connection, the external system is obliged to use a system authentication certificate issued by the P1 Certification Centre. Authentication of the origin of the message is required for the correct performance of the service. The external system is obliged to sign the SOAP message using a data authentication certificate used to verify the digital signature. Messages sent to the P1 System must meet the validation rules specified in the integration documentation for the services provided. In Project P1, the use of OID (Object Identifier, ISO 9834 standard) was adopted for all types of identifiers. The method of notation and the details of the application of the standard are included in the document "Instructions for the use of the Polish National Implementation HL7 CDA", and the list of OID nodes used for communication with P1 is included in the OID register, available on the website of the Polish National Implementation HL7 CDA.

Technical details for the above operations are described in the P1 integration documentation published on the e-health information portal and on a dedicated website for integrators (access after submitting the application and issuing the certificate). Running EDM Pursuant to Article 13a of the Act on SIOZ. The list of electronic medical records is specified in the Regulation of the Minister of Health of 8 May 2018 on types of electronic medical records (Journal of Laws of 2018, item 941, as amended). These documents must be maintained in accordance with PIK HL7 CDA.

Question 4. How does your parliament view the proposal for a European Health Data Space regulation?

a) **Has your parliament and/or government made a scrutiny reservation on the proposed regulation?**
b) **Are the objectives of the regulation supported?**
c) **What is the position on the system of self-certification for electronic patient record-systems?**
d) **How does your national parliament view the opt-in versus opt-out system for sharing electronic health data across borders?**

According to the opinion of the Sejm Research Bureau[25], the draft regulation on the European health data space requires significant changes, taking into account the specificity of the treaty regulation of health services in the European Union. The provisions concerning the specification of what data has to be contained in the electronic documentation and the rules of access to this documen-

[25] BAS, Opinion on the proposal for a regulation of the European Parliament and of the Council on a European health data space (COM(2022) 197 final). Grzegorz Ciura (points I and III) Tomasz Jaroszyński (point II).

tation by various entities should be eliminated from the draft regulation. The rules for creating and accessing medical records are part of the organization of health care and as such belong to the powers of the Member States. The current draft interferes too much in the powers of the Member States regarding the organization of health care.

Currently, only the document draft of the Government of the Republic of Poland is available[26]. According to this document, the Government positively assesses the draft regulation of the European Commission and the direction of the proposed solutions. At the same time, the Government indicates the need for significant adjustments in the process of further work on the draft. According to the Government, the area of health protection remains a national competence, as are healthcare systems, so the regulations that make up the draft regulation require further discussions, which will result in a more flexible approach, different periods of entry into force and adaptation of the proposed solutions to the organizational and financial capabilities of the Member States.

Government of the Republic of Poland:

- accepts the objectives of the regulation and the solutions contained in the draft regulation: discussed in Article 10 par. 1, and Article 64,
- indicates that the support for some solutions (contained in over 20 articles) will require changes, explanations and clarifications,
- evaluates negatively and applies for deletion of the following from the draft regulation or for their significant modification: Article 8, Article 12 par. 7, Article 51, Article 52 and Article 33, Article 44 and Article 72.

The Government submits a general remark that in the light of the wording of Article 168 TFEU, which in principle leaves issues related to health policy, including the organization and provision of health services, to the discretion of the Member States, the regulation of issues regarding the primary processing of health data at the level of EU legal acts raises significant doubts. E-health, including keeping medical records in electronic form, is one of the aspects of providing health services, which implies its assignment to regulations for national legislators, as long as there are no cross-border elements. In addition, in the Government's opinion, the issue of electronic data security should be more strongly emphasized in the pending draft regulation (application of the security-

[26] Document Draft of the Government of the Republic of Poland prepared in connection with Article 7 of the Act of 8 October 2010 on the cooperation of the Council of Ministers with the Sejm and the Senate in matters related to the membership of the Republic of Poland in the European Union (Journal of Laws No. 213, item 1395) concerning the proposal for a regulation of the European Parliament and of the Council on the European health data space. Date of submission of the document to Poland by the EU institutions 2 June 2022. Reference number of the document European Commission COM(2022)197.

first principle). All designed IT solutions should guarantee data security, in particular in the context of cross-border data exchange.

Question 4d. How does your national parliament view the opt-in versus opt--out system for sharing electronic health data across borders?

In the document draft[27], in the opinion of the Government the minimum catalogue of data (Article 33) that should be made available by data holders for the purpose of their secondary processing has been proposed too broadly, and the accompanying provisions do not provide optimal rules guaranteeing the protection of an individual's privacy and allowing for appropriate shaping of the state's health policy. It is necessary to ensure that the provisions of the draft regulation guarantee appropriate rules of security and protection of privacy of natural persons in connection with the processing of such a wide range of data. In the Government's opinion, at this stage an indirect approach should be chosen based on a narrowed catalogue of data intended for secondary processing, equipping Member States with tools to manage the process of sharing data for secondary processing, including limiting access to them, if justified by important public interests and taking into account the autonomy of the patient, e.g. by giving him the opportunity to object to the secondary processing of his data. In the Government's opinion, data generated by applications supporting well-being or other applications in the field of e-health should not be reused. Thus, from Article 33 sec. 1 lit. f of the draft regulation, welfare and other digital applications should be excluded accordingly. If the draft provision is maintained in this shape, the processing for secondary use of personal data from supporting applications and other digital applications should be subject to the prior consent of the person. It is crucial to introduce a regulation that will allow Member States to define in their national law the scope of data that cannot be subject to secondary processing and public disclosure. At the same time, in the government's opinion, the premise of Article 33 sec. 7 in terms of adapting the directory to the development of available electronic health data is not sufficient for the adoption of delegated Acts. The catalogue of electronic data for secondary data processing is not an area where dynamic changes can be made, therefore its definition in the regulation seems more justified and should be done with the active participation of State Members, also in the context of different data sets that are in their disposal.

[27] *Ibid.*

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