

Overview of the national laws on electronic health records in the EU Member States and their interaction with the provision of cross-border eHealth services

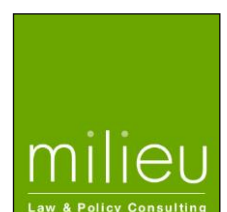
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Overview of the national laws on electronic health records in the EU Member States

National Report for Bulgaria



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Executive Summary

1. Stage of development of EHRs in Bulgaria

The Personalised Information System (PIS) is an electronic record system set in place by the National Health Insurance Fund (NHIF).

It is the only EHR initiative in Bulgaria that comprises the following elements: a framework present at national level, formalities on the data-hosting institution, modalities concerning the patient, and identification of health practitioners. The PIS was launched in 2009 and some of its modalities were extended in 2013 ensuring wider access and more services to its users.

Individual PIS records exist for every person covered under the Health Insurance Law in Bulgaria. They contain information on all their medical care performed during the last five years and covered by the NHIF. However, PIS records are created by the NHIF mainly with an informational and financial control purpose, and not as a tool to record and share electronic health data for medical purposes.

The Ministry of Health has launched a number of eHealth pilot projects but none of them led to the development of EHRs in Bulgaria.

2. Summary of legal requirements applying to EHRs

There are no specific legal provisions applicable to PIS records. Therefore, general rules on health information, data protection, liability and secondary use apply to PIS records.

The NHIF has the obligation to provide to persons covered under the Health Insurance Law (ZZOL) access to all information on medical care concerning them and performed during the last five years that enters in the ‘basic package’ covered by the NHIF. The basic package includes general and specialist care, home and hospital care, prescription of medicinal products and dental care. Information provided in PIS records reaches back to 2009 with regard to medical care provided by general practitioners, medical specialists, hospitals, medical laboratories and pharmacies. Dental care information contained in PIS records only reaches back to 2012.

Bulgaria has detailed requirements applying to institutions hosting personal data. Pursuant to Article 5 of the Personal Data Protection Law, health data can be processed only under the conditions and for purposes provided by law. The NHIF and health practitioners in Bulgaria fall in the legal definition of ‘administrator of personal data’ (Administrator) and as such are subject to the Personal Data Protection Law’s requirements. Administrators cannot begin collecting, hosting and processing personal data before being officially registered by the Commission for Personal Data Protection. The Commission controls Administrators’ compliance of personal data protection requirements and can impose mandatory instructions on them.

ZZOLs can access to their PIS records by using an electronic signature or a unique access code. They can also grant access to their PIS records to health practitioners on a case-by-case basis. However, only health practitioners contracted by the NHIF have the right to access PIS records by using their electronic signatures and ‘unique identification number’, both given only to health practitioners that are members of the Bulgarian Medical Association. Therefore, health practitioners of another Member State cannot access PIS records.

Both ZZOLs and NHIF Partners have access to all of the PIS record content. ZZOLs cannot update, modify or erase information in their PIS record. If PIS records of ZZOLs contain incorrect information, ZZOLs can send complaints to a Regional Health Insurance Fund.

If errors occur in PIS records, health practitioners can be held liable for violation of their contract with the NHIF, as well as of the Health Insurance Law or of the National Framework Contract between the NHIF and the Bulgarian Medical Association. Health practitioners' professional liability and criminal liability can be engaged for breach of professional secrecy. Finally, both the NHIF and health practitioners can be held liable under the Personal Data Protection Law.

The NHIF has to keep all information related to ZZOLs for 5 years after the end of their national health insurance coverage. However, there are no specific rules neither about the data from PIS records at the end of the archiving duration nor a specific obligation to destroy PIS records. The NHIF is only obliged to provide access to ZZOLs to information on medical care performed during the last five years. Pursuant to Article 25 of the Personal Data Protection Law, after the Administrator has achieved the purpose of personal data processing, the Administrator is obliged to destroy the data or to transfer it to another Administrator. If an Administrator wants to store data for historical, statistical or scientific purposes, the data has to be anonymised and the Administrator has to inform the Commission for Personal Data Protection.

There are no legal obligations to develop interoperability of PIS records with other systems in Bulgaria, as these records are an initiative of the NHIF. All systems related to the NHIF are interoperable by using the same file format ('xml').

ePrescriptions do not exist in Bulgaria yet. However, the NHIF is planning to develop an ePrescription system by the end of 2014. This would imply legal and regulatory amendments.

3. Good practices

PIS records exceeded their original purpose of finance control and became the first electronic record system in Bulgaria allowing patients to consult their medical history online, to grant access to their records to health practitioners and to receive notifications with preventive purposes (mandatory check-ups and vaccinations).

In its current architecture, the PIS could serve as foundation for the future development of EHRs in Bulgaria. Firstly, the Integrated Information System of the NHIF offers an already existing and extensive database as all the medical care reports of all health practitioners contracted by the NHIF – individual health practitioners, hospitals, laboratories, pharmacies – are centralised in it. Moreover, this database is regularly updated, on a daily or monthly basis, by NHIF Partners who are obliged to send their medical care reports in order to receive reimbursement. Secondly, individual PIS records already exist in Bulgaria for every ZZOL. Thirdly, the electronic format used by the NHIF (xml) is suited for future interoperability with other health systems in Bulgaria and possibly other EU Member States.

4. Legal barriers

The main obstacle for the development of EHRs in Bulgaria is the lack of legal framework. Every aspect of EHRs has yet to be regulated, as there are no specific provisions in place.

PIS records were not created with the purpose of being patients' official EHRs. As a NHIF initiative, their original purpose is financial control by the NHIF and by ZZOLs. For this reason, PIS records do not comply with health records standards and present a number of shortcomings.

eHealth and EHRs in Bulgaria have to be further developed by reorganising the existing system and by adopting new legal measures on the form, content, terms and conditions for the processing, use, access, sharing, transfer, storage and protection of electronic health information. A clear regulatory framework for standardisation and wider interoperability of information systems is a major component for EHRs development in Bulgaria and for cross-border transfers. In terms of cross-border healthcare, besides technical interoperability, the main barrier according to stakeholders is the language barrier.

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List of abbreviations

Administrator	Administrator of personal data under the Personal Data Protection Law
BAPD	Bulgarian Association for Patients' Defence
Commission	Commission for Personal Data Protection
EDES	Electronic Document and Electronic Signature Law
EHRs	Electronic Health Records
IIS	Integrated Information System
NHIF	National Health Insurance Fund
NHIF Partner	Health practitioner contracted by the National Health Insurance Fund
NSOPLB	National Association of General Practitioners in Bulgaria
PIS	Personalised Information System
UAC	Unique Access Code
ZZO	Health Insurance Law
ZZOL	Person covered under the Health Insurance Law

1. General context

1.1. EHR systems in place

The Personalised Information System (*Персонализирана информационна система*) (PIS) is an electronic record system set in place by the National Health Insurance Fund (*Национална здравноосигурителна каса*) (NHIF - see below for more information)¹.

It is the only EHR initiative in Bulgaria that comprises the following elements: a framework present at national level, formalities on the data-hosting institution, modalities concerning the patient and identification of health practitioners.

Other EHRs are being held in Bulgaria by health practitioners, hospitals and other institutions. They are, however, not designed to have a national scope nor a generalised shared access and are therefore not detailed in this study.

The Ministry of Health has launched a number of eHealth pilot projects² in Bulgaria but none of them led to the development of EHRs in Bulgaria.

PIS records

Under the Bulgarian Health Insurance Law (*Закон за здравното осигуряване*) (ZZO), the NHIF is responsible for implementing and providing mandatory health insurance. In this context, it is in charge of all persons subscribed to the national health insurance system i.e. 'all persons covered under the Health Insurance Law' (*Задължителна здравноосигурени лица*) (these persons are thereafter referred to as 'ZZOL'). Mandatory health insurance is provided to Bulgarian nationals since their date of birth, and to foreign citizens and individuals without nationality or refugees since their authorisation to reside in Bulgaria³.

The Ministry of Health has set a 'basic package' of medical care procedures and medicinal products covered entirely or partially by the NHIF budget⁴. This basic package is very wide and includes general and specialist care, home and hospital care, prescription of medicinal products and dental care. Health practitioners that provide medical care or prescribe medicinal products to ZZOLs are required to send monthly or daily medical care reports to the NHIF in order to receive reimbursement⁵. The reports are sent in an electronic format and are centralised in the Integrated Information System (*Интегрирана информационна система*) (IIS) of the NHIF⁶.

The NHIF has the obligation to provide access to every ZZOL to all information on medical care concerning them performed during the last five years⁷. In order to fulfil this obligation, the NHIF undertook the PIS initiative whereby it created an individual electronic record for every ZZOL in Bulgaria by using the medical care reports of health practitioners centralised in its IIS. The PIS was launched in 2009 and further extended (e.g. easier access, additional user services) in 2013.

¹ PIS official portal: <https://pis.nhif.bg/main> (last access March 2014).

² Pilot project for the introduction of eHealth cards (2007), National Health Portal (2008), electronic personal ambulatory books (eLak) involving 40.000 state employees (2008), pilot projects on telemedicine.

³ Articles 33 and 34 of the ZZO.

⁴ Ordinance n° 40 of 24 November 2004 determining the basic package of health services covered by the NHIF budget (*Наредба № 40 от 24.11.2004 г. за определяне на основния пакет от здравни дейности, гарантиран от бюджета на НЗОК*) (available at <http://www.nhif.bg/web/guest/67>) (last access February 2014)

⁵ Interview with the NHIF on 6 March 2014.

⁶ Interview with the NHIF on 6 March 2014.

⁷ Article 64 of the ZZO.

PIS records are automatically created for every ZZOL in Bulgaria and the NHIF is not required to obtain the ZZOL's consent for their creation.

PIS records are accessible through a specific web portal (<https://pis.nhif.bg/main>) protected with a security encryption system. ZZOLs can access their PIS record by using a Unique Identification Code (*Уникален код за достъп*) or a Qualified Electronic Signature (*Квалифициран електронен подпис*) (see [Section 2.4](#)).

PIS records contain the following information: general information about the ZZOL, allergies, vaccinations, risk groups, check-ups, dispensaries, prescribed medicinal products, history of medical check-ups, lab exams, medical procedures, implants, hospitalisations, and dentistry. PIS records are automatically updated with the daily or monthly medical care reports of the NHIF Partners. Information provided reaches back to 2009 with regard to medical care provided by general practitioners, medical specialists, hospitals, medical laboratories and pharmacies. Dental care information only reaches back to 2012.

ZZOLs have full access to their PIS records but cannot change or hide any health information. They can grant access to their PIS records to health practitioners on a case-by-case basis. The PIS allows ZZOLs to receive an e-mail or SMS notification whenever a health practitioner has accessed their PIS records and/or the record is being updated via the medical care report of health practitioners. ZZOLs can also choose to receive a notification when their next mandatory check-up or vaccination is due⁸.

The general rules on the content of medical health records detained by health practitioners are set in Articles 27 and 28 of the Health Law (*Закон за здравето*). These rules are however not applicable to the existing PIS records as they are not considered as the patients' official health record⁹. The NHIF explicitly states on the PIS portal that PIS records are not an official document¹⁰. Indeed, PIS records are created by the NHIF mainly with an informational and financial control purpose, and not as a tool to record and share electronic health data for medical purposes. In addition, PIS records include information only on medical care that is part of the NHIF 'basic package' when provided by a health practitioner contracted by the NHIF (thereafter referred to as 'NHIF Partner').

1.2. Institutional setting

The main competent authorities responsible for the development and functioning of PIS records in Bulgaria are:

The National Health Insurance Fund (NHIF)¹¹

The NHIF was founded in 1999 as an independent public institution when mandatory health insurance was introduced in Bulgaria. The NHIF is regulated by the Health Insurance Law.

The NHIF has a central structure and 28 regional structures entitled Regional Health Insurance Funds (*Районна здравно-осигурителна каса*) (RHIF).

The NHIF is responsible for implementing and providing mandatory health insurance to all ZZOLs in Bulgaria, and is both the creator and host of the existing PIS records. The NHIF enters directly in contracts with individual health practitioners, hospitals and pharmacies (NHIF Partners) that provide medical care to ZZOLs who are paying their contributions to the NHIF.

⁸ PIS description available at http://www.nhif.bg/c/document_library/get_file?uuid=092c7f4b-9bfc-4b18-b68b-03562fccb938&filename=pis3.pdf&groupId=10139 (last access March 2014).

⁹ Interview with the NSOPLB on 20 February 2014 and with the Bulgarian Association for Patients' Defence (*Българска Асоциация за Зашита на Пациентите*)(BAPD) on 21 February 2014.

¹⁰ 'Rights of Use of the PIS', available at https://pis.nhif.bg/pis-main_files/Rights_of_use.htm (last access February 2014).

¹¹ Official website : www.nhif.bg .

The Ministry of Health¹²

The Ministry of Health (*Министерство на здравеопазването*) is responsible for public health and the organisation of the healthcare system. As such, it is responsible for amending and adopting new regulations, proposing legal changes and implementing the National Healthcare Strategy (*Национална здравна стратегия*).

The Bulgarian Medical Association¹³

The Bulgarian Medical Association (*Български лекарски съюз*) is the professional union of health practitioners in Bulgaria. It holds the registry of health practitioners and is responsible for applying the Codes of professional ethics. The Bulgarian Medical Association participates in the elaboration of healthcare policies.

The NHIF and the Bulgarian Medical Association establish together a National Framework Contract on a yearly basis. The National Framework Contract sets the NHIF Partners' obligations as well as the requirements on medical care reports (e.g. the content of reports, or the periodicity of reporting). NHIF Partners' medical care reports are the main component of PIS records.

The Commission for Personal Data Protection¹⁴

The Commission for Personal Data Protection (*Комисия за защита на личните данни*) is the institution responsible for implementing the Personal Data Protection Law (*Закон за защита на личните данни*).

The NHIF and health practitioners in Bulgaria fall under the legal definition of 'Administrators of personal data' (*администратор на лични данни*) (thereafter referred to as 'Administrator') and are subject to the Personal Data Protection Law's requirements.

The Commission for Personal Data Protection holds the registry of Administrators and regularly controls the effective protection of personal data.

1.3. Legal setting and future legal development

There are no specific provisions with regard to the development and implementation of EHRs in the current Bulgarian regulatory framework.

The 2008 Electronic Governance Law (*Закон за електронното управление*) sets requirements for administrative authorities when working with electronic documents. It also regulates the electronic provision of public services and the exchange of electronic documents between administrative authorities. However, the PIS developed by the NHIF does not constitute an 'e-service' in the sense of this law and therefore falls outside of its scope¹⁵.

The PIS is the NHIF's initiative and is therefore not set up by any law. As a result, PIS records are regulated by the general health and data protection laws and regulations.

Article 63 of the ZZO provides that the NHIF is obliged to build an information system containing a registry of ZZOLs and NHIF Partners. As a result, in 2008, the NHIF created its Integrated

¹² Official website: www.mh.government.bg .

¹³ Official website: www.blsbg.com .

¹⁴ Official website: <https://www.cpdp.bg> .

¹⁵ Article 4 of the Internal NHIF rules of 7 June 2013 on the issuing of a UAC for the PIS (available at: http://www.nhif.bg/c/document_library/get_file?p_1_id=58538&folderId=11374&name=DLFE-7903.pdf) (last access February 2014).

Information System (IIS) containing all relevant registries, contracts with NHIF Partners and medical care reports sent by NHIF Partners.

The PIS was the next stage of development of the Integrated Information System¹⁶. Pursuant to Article 64 of the ZZO, every ZZOL must have access to all information on their medical care and performed during the last five years that enters in the NHIF basic package. In order to fulfil this obligation, in 2009, the NHIF decided to use the centralised medical care information in the IIS and create an individualised PIS record for every ZZOL. The system was largely extended in 2013 making it more easily accessible and including additional services for the users.

The NHIF hopes to further develop the PIS services by including an ePrescription system by the end of 2014¹⁷. This will however involve legal and regulatory amendments (see [Section 2.8](#)).

In terms of interoperability requirements, review of the relevant legislation is awaited¹⁸. This should widen the interoperability of health care systems in Bulgaria and further develop eHealth policies.

With regard to the future legal development on eHealth in Bulgaria, no specific developments seem to be planned¹⁹. Moreover, the Ministry of Health did not participate in the stakeholder interviews undertaken for this study, and as a result it was not possible to shed light on the stages of development of existing strategies and projects, nor on the Ministry's intentions to develop new specific legal or regulatory measures on eHealth.

In the 2007-2013 National Health Strategy, the creation of an integrated system for electronic data exchange was set as a priority²⁰. In 2011, the Ministry of Health launched the creation of a 'Base for health information system' (*База за здравно-информационна система – БаЗИС*) (BaZIS) that was due to be finalised in October 2013 (NB. finalisation of BaZIS has not occurred at the time of writing this study)²¹. BaZIS's purpose is to provide the conceptual framework for eHealth in Bulgaria and 'improve health services through the application of innovative technologies in order to optimise the process efficiency in the health system at all levels'.

The 2014-2020 National Health Strategy has not been officially adopted yet. The draft Strategy²² sets eHealth development as a priority and foresees the creation of a single integrated information system that will lay down the ground for EHRs and ePrescriptions. The Strategy project envisages the development of the following measures:

- mandatory standards for health information and statistics,
- policies and interoperability of healthcare information systems for all providers of health care, including in order to improve cross-border use of health records of patients,
- national health information system and providing public access to the system through electronic ID,
- electronic health cards,
- electronic health records,
- security measures for data protection.

¹⁶ Interview with the NHIF on 6 March 2014.

¹⁷ Interview with the NHIF on 6 March 2014.

¹⁸ Interview with the NHIF on 6 March 2014.

¹⁹ Interview n°1 with the Bulgarian Medical Association on 17 February 2014 and with the BAPD on 21 February 2014.

²⁰ National Health Strategy for 2007-2013 available at www.mh.government.bg.

²¹ Project available at:

<http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=468&categoryid=4662&articleid=4329> (last access March 2014).

²² Draft available at:

<http://www.mh.government.bg/Articles.aspx?lang=bg-BG&pageid=393&categoryid=6465> (last access March 2014).

List of relevant legislative and regulatory instruments

- Health Insurance Law (*Закон за здравното осигуряване*)²³

The Health Insurance Law regulates mandatory and voluntary health insurance in Bulgaria. It sets the NHIF's functioning and obligations.

- Health Law (*Закон за здравето*)

The Health Law²⁴ regulates the social relations associated with the health of citizens. It also sets the general rules on health information and documentation.

- Personal Data Protection Law (*Закон за защита на личните данни*)

The Personal Data Protection Law²⁵ regulates the hosting and processing of personal data. It sets legal requirements for the Administrators and provides control rights to the Commission for Personal Data Protection.

- Electronic Document and Electronic Signature Law (*Закон за електронния документ и електронния подпис*)

The Electronic Document and Electronic Signature Law²⁶ regulates the provision of electronic signature.

- National Framework Contracts (*Национален рамков договор за медицинските дейности между Националната здравноосигурителна каса и Българския лекарски съюз и Национален рамков договор за денталните дейности между Националната здравноосигурителна каса и Българският зъболекарски съюз*).

The National Framework Contract for medical activity and the National Framework Contract for dental activity are adopted on a yearly basis between the NHIF and the Bulgarian Medical Association and the Bulgarian Dental Association²⁷. They regulate the NHIF Partners obligations.

²³ Published in the State Gazette on 19 June 1998, last amended on 3 January 2014.

²⁴ Published in the State Gazette on 10 August 2004, last amended on 3 January 2014.

²⁵ Published in the State Gazette on 4 January 2002, last amended on 15 February 2013.

²⁶ Published in the State Gazette on 6 April 2001, last amended on 21 December 2010.

²⁷ National Framework Contracts for 2014 available at <http://www.nhif.bg/web/guest/65> (last access March 2014).

2. Legal requirements applying to EHRs in Bulgaria

2.1. Health data to be included in EHRs

2.1.1. Main findings

There are no specific rules defining the content of Personalised Information System (PIS) records.

The NHIF has the obligation to provide access to ZZOLs to all information on medical care concerning them and performed during the last five years that enters in the ‘basic package’ covered by the NHIF²⁸. The basic package includes general and specialist care, home and hospital care, prescription of medicinal products and dental care.

Information provided reaches back to 2009 with regard to medical care provided by general practitioners, medical specialists, hospitals, medical laboratories and pharmacies. Dental care information only reaches back to 2012²⁹.

Each PIS record is divided in the following 16 categories: general information about the ZZOL, allergies, vaccinations, risk groups, check-ups, dispensaries, registered general practitioners, medicinal products, prescription book, history of medical check-ups, lab exams, medical procedures, implants, hospitalisations, dentistry, protocols. PIS records are automatically updated with the daily or monthly medical care reports of the NHIF Partners. They however do not include thorough description of the actual diagnosis of doctors (e.g. patient summaries), which does not allow to record in details the patient individual’s medical history. PIS records use a coding system, based on the International Classification of Diseases, which provides diagnostic codes for diseases, including nuanced classifications depending on a variety of criteria, symptoms, complications, abnormal findings and others. Besides the classification codes, medical care reports of NHIF Partners also contain a brief description of patient’s health state, the prescribed exams and the imposed treatment. These descriptions, however, are not included in PIS records. In case of hospitalisation, PIS records contain nevertheless the epicrisis (*епикриза*) which is an analytical report of the medical case history.

In all administrative matters, including healthcare, citizens in Bulgaria are individually identified by a ‘uniform civil number’ (*единен граждански номер (ЕГН)*) generated from the person's date of birth. Foreigners in Bulgaria are identified by a ‘personal number of a foreigner’ (*личен номер на чужденец*) or a ‘service number of a foreigner’ (*служебен номер на чужденец*) depending on their residency status. The NHIF and PIS records both use these numbers of identification.

²⁸ Article 64 of the ZZO.

²⁹ PIS description available at http://www.nhif.bg/c/document_library/get_file?uuid=092c7f4b-9bfc-4b18-b68b-03562fccb938&filename=pis3.pdf&groupId=10139 (last access March 2014).

2.1.2. Table on health data

Questions	Legal reference	Detailed description
Are there specific rules on the content of EHRs? (or regional provisions, agreements, plans?)	ZZO, Articles 63 (last amended 18 December 2009) and 64 (last amended 17 December 1999)	<p>There are no specific rules defining the content of Personalised Information System (PIS) records.</p> <p>Pursuant to Article 64 of the Health Insurance Law (Закон за здравното осигуряване - 330) (ZZO) every Person covered under the ZZO (задължително здравно осигурено лице - 330Л) (ZZOL) must have access to all information on medical care concerning them performed during the last five years that enters in the ‘basic package’ covered by the NHIF³⁰.</p> <p>As a result, medical care information concerning every ZZOL is centralised by the NHIF in individualised PIS records³¹.</p> <p>A PIS record, therefore, contains information on all medical care provided and drugs prescribed by NHIF Partners to a ZZOL.</p> <p>The PIS was created in 2009, and following its extension in 2013, each PIS record contains the following information:</p> <ul style="list-style-type: none"> - Medical care provided by general practitioners, medical specialists, hospitals, medical laboratories and pharmacies since 2009; - Dental care provided since 2012. <p>Each PIS record is divided in the following 16 categories³²:</p> <ul style="list-style-type: none"> - general information about the ZZOL - allergies - vaccinations

³⁰ Ordinance n° 40 of 24 November 2004 determining the basic package of health services covered by the NHIF budget (*Наредба № 40 от 24.11.2004 г. за определяне на основния пакет от здравни дейности, гарантиран от бюджета на НЗОК*) (available at <http://www.nhif.bg/web/guest/67>) (last access February 2014).

³¹ Internal NHIF rules of 7 June 2013 on the issuing of a UAC for the PIS (*Вътрешни правила по издаване на уникален код за достъп до Персонализираната информационна система на НЗОК*) (available at: http://www.nhif.bg/c/document_library/get_file?p_l_id=58538&folderId=11374&name=DLFE-7903.pdf) (last access February 2014).

³² ‘Guidelines on the use of medical records by ZZOLs’ - <http://www.president.bg/docs/1352303612.pdf> and PIS record available at <https://pis.nhif.bg> (last access February 2014).

Questions	Legal reference	Detailed description
		<ul style="list-style-type: none"> - risk groups - check-ups - dispensaries - registered general practitioners - medicinal products - prescription book - history of medical check-ups - lab exams - medical procedures - implants - hospitalisations - dentistry - protocols.
<p><i>Are these data restricted to purely medical information (e.g. physical or mental health, well-being)?</i></p>		<p>PIS records are not strictly limited to purely medical information.</p> <p>As such, a PIS record also contains general information about the ZZOL:</p> <ul style="list-style-type: none"> - national identification number (<i>единен граждански номер ETH</i>) used for identifying Bulgarian citizens (or ‘personal number’ or ‘service number’ for foreigners (see table below)), - possession of a European health insurance card³³, - consent to organ donations, - contact information (address, phone numbers, e-mail, contact person). - <p>A PIS record also contains information about the ZZOL’s current general practitioner (identification number, contact information)³⁴.</p> <p>Moreover, PIS records have a section ‘Notifications’ where a ZZOL can choose to receive a notification by e-mail or by a phone text message when</p> <ul style="list-style-type: none"> - the PIS record has been consulted by an authorised NHIF

³³ European Health Insurance Card - <http://ec.europa.eu/social/main.jsp?catId=559> (last access February 2014).

³⁴ ‘Guidelines on the use of PIS records by ZZOLs’ - <http://www.president.bg/docs/1352303612.pdf> (last access February 2014).

Questions	Legal reference	Detailed description
		<p>Partner and when it has been updated (see Section 2.4.2).</p> <ul style="list-style-type: none"> - the next mandatory check-up or vaccination is due³⁵. <p>A ZZOL has the possibility to change general practitioner directly via the PIS record. For that purpose, as well as for the purpose of granting access to a NHIF Partner (see Section 2.4.2), PIS records contains the list of all NHIF Partners.</p>
<i>Is there a definition of EHR or patient's summary provided in the national legislation?</i>	ZZO, Article 64 (last amended 1 st January 2000)	<p>There is no legal definition of PIS records.</p> <p>Rather, PIS records are defined by which information ZZOLs should have access to. Pursuant to Article 64 of the ZZO, every ZZOL is entitled to receive information from the NHIF on 'all available information on the medical care used during the last five years, as well as its cost' (see above).</p>
<i>Are there any requirements on the content of EHRs (e.g. detailed requirements on specific health data or general reference to health data)?</i>		<p>As explained above, a PIS record is based on the obligation for the NHIF to provide information for all medical care provided to a ZZOL in the last five years³⁶.</p> <p>Ordinance n°40 of 24 November 2004³⁷ determines the basic package of health services covered by the NHIF budget. The basic package includes general and specialist care, home and hospital care, prescription of medicinal products and dental care. Information relevant to the listed services and drugs is provided in the PIS.</p>
<i>Are there any specific rules on the use of a common terminology or coding system to identify diseases,</i>	ZZO, Article 66 (last amended 15 November 2002)	Pursuant to article 66 of the ZZO, the NHIF information system must use established national codes and nomenclatures for registration and reporting activities in healthcare.

³⁵ Interview with the NHIF on 6 March 2014.

³⁶ Article 64 of the ZZO.

³⁷ Ordinance n° 40 of 24 November 2004 determining the basic package of health services covered by the NHIF budget (available at <http://www.nhif.bg/web/guest/67>) (last access February 2014).

Questions	Legal reference	Detailed description
<i>disorders, symptoms and others?</i>		<p>The coding system is provided on a yearly basis as an annex to the National Framework Contract³⁸ established between the NHIF, the Bulgarian Medical Association and the Bulgarian Dental Association.</p> <p>The NHIF uses the International Statistical Classification of Diseases set by the World Health Organisation³⁹.</p>
<i>Are EHRs divided into separate categories of health data with different levels of confidentiality (e.g. data related to blood type is less confidential than data related to sexual diseases)?</i>		<p>Information in PIS records is not divided into separate categories with different levels of confidentiality. This possibility is foreseen by the NHIF but there is no legal ground for implementing it⁴⁰.</p> <p>At the moment, therefore, the content of the entire record becomes available upon access irrespective of the individual that accesses the PIS record (see Section 2.4.2).</p>
<i>Are there any specific rules on identification of patients in EHRs?</i>		<p>In Bulgaria, every citizen is identified by a ‘uniform civil number’ (<i>единен граждански номер (ЕГН)</i>) generated from the person's date of birth. It is a unique 10-digit number that serves as national identification number.</p> <p>ZZOLs are also identified by their uniform civil number in all health-related matter⁴¹. For instance, health practitioners use this uniform civil number to identify patients whom they have provided medical care to. Health practitioners also use it in their medical care reports sent to the NHIF⁴².</p>

³⁸ Annex n°3 ‘Basic Medical Documents’ to the 2014 National Framework Contract (available at: <http://www.nhif.bg/web/guest/233>) (last access February 2014).

³⁹ Interview with the NHIF on 6 March 2014.

⁴⁰ Interview with the NHIF on 6 March 2014.

⁴¹ Interview with the NHIF on 6 February 2014.

⁴² Interview n°1 with the Bulgarian Medical Association on 17 February 2014.

Questions	Legal reference	Detailed description
		As a result, the NHIF centralises health information for every ZZOL by using the uniform civil number ⁴³ . Foreigners residing in Bulgaria are identified either by a ‘personal number of a foreigner’ (<i>личен номер на чужденец</i>), or by a ‘service number of a foreigner’ (<i>служебен номер на чужденец</i>) ⁴⁴ depending on their residency status.
<i>Is there is a specific identification number for eHealth purposes?</i>		No, there is no specific identification number for eHealth purposes.

⁴³ Interview n°1 with the Bulgarian Medical Association on 17 February 2014 and interview with the National Union of General Practitioners in Bulgaria (*Национално сдружение на общопрактикуващите лекари в България*)(NSOPLB) on 20 February 2014.

⁴⁴ Article 6 of the Internal NHIF rules of 7 June 2013 on the issuing of a UAC for the PIS (available at: http://www.nhif.bg/c/document_library/get_file?p_l_id=58538&folderId=11374&name=DLFE-7903.pdf) (last access February 2014).

2.2. Requirements on the institution hosting EHRs data

2.2.1. Main findings

Bulgaria has detailed requirements applying to institutions hosting personal data in its Personal Data Protection Law based on Directive 95/46/EC⁴⁵ on the protection of individuals with regard to the processing of personal data and on the free movement of such data⁴⁶.

Pursuant to Article 5(1) of the Personal Data Protection Law, health data cannot be processed unless it fulfils the conditions and purposes specified in Article 5(2).

The NHIF and health practitioners in Bulgaria fall in the legal definition of 'administrator of personal data' (thereafter referred to as 'Administrator') and as such are subject to the Personal Data Protection Law's requirements.

Administrators cannot begin collecting, hosting and processing personal data before being officially registered by the Commission for Personal Data Protection⁴⁷ (thereafter referred to as 'Commission'). Administrators have to prove compliance with the requirements of the Personal Data Protection Law in their application to the Commission. Moreover, the Commission considers that health data is 'sensitive data' and performs a prior control of Administrators before admitting them to the Administrators Registry.

Administrators must take appropriate technical and organisational measures to protect the data against accidental or unlawful destruction or accidental loss, unauthorised access, modification or disclosure, and against other unlawful forms of processing⁴⁸. As required by the Data Protection Law, the Commission adopted Ordinance n°1 of 30 January 2013 establishing the minimum level of technical and organisational measures for personal data protection which further details requirements applicable to Administrators.

Administrators are required to set deadlines for conducting periodic reviews on the need to continue processing personal data or to delete it⁴⁹. They also have to periodically review the level of protection of technical and organisational measures⁵⁰.

The Commission controls Administrators' compliance of personal data protection requirements⁵¹. The Commission can impose mandatory instructions to Administrators and temporarily forbid the processing of personal data. As part of its controlling duties, the Commission elaborates a yearly control action plan designating a number of Administrators that will be subject to controls⁵².

⁴⁵ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1995:281:0031:0050:EN:PDF>).

⁴⁶ Interview with the Commission for Personal Data Protection on 6 March 2014.

⁴⁷ Article 17 of the Personal Data Protection Law.

⁴⁸ Article 23 of the Personal Data Protection Law.

⁴⁹ Article 23 of the Personal Data Protection Law.

⁵⁰ Article 11 of Ordinance n°1 of 30 January 2013 of the Commission for Personal Data Protection on the minimum level of technical and organisational (available at <https://www.cdpd.bg/?p=element&aid=632>) (last access February 2014).

⁵¹ Articles 10 and 12 of the Personal Data Protection Law.

⁵² Interview with the Commission for Personal Data Protection on 6 March 2014.

2.2.2. Table on requirements on the institutions hosting EHRs data

Questions	Legal reference	Detailed description
<p>Are there specific national rules about the hosting and management of data from EHRs?</p>	<p>Personal Data Protection Law, Articles 2 (last amended 18 October 2011) and 5 (last amended 25 December 2005)</p> <p>ZZO, Articles 63 (last amended 18 December 2009) and 64 (last amended 17 December 1999)</p>	<p>There are no specific national rules on the hosting and management of data from PIS records. Therefore, the general rules for hosting and managing health data apply.</p> <p>According to Articles 63 and 64 of the ZZO, the NHIF has to keep information about all medical and dental care provided to a ZZOL. According to the Personal Data Protection Law⁵³ (<i>Закон за защита на личните данни (ЗЗЛД)</i>), the legal definition of personal data includes health information.</p> <p>As a result, the Personal Data Protection Law considers the NHIF as an administrator of personal data (<i>администратор на лични данни</i>) (Administrator) subject to the Law's requirements⁵⁴. Every health practitioner is also considered an Administrator⁵⁵.</p> <p>Under the Personal Data Protection Law, personal data can only be used and gathered for purposes defined by law⁵⁶. The Personal Data Protection Law further requires personal data to be precise, updated and to contain no errors⁵⁷.</p> <p>The identification of a person whose data is collected should be possible only for the period that is necessary for the purposes for which personal data is being processed⁵⁸.</p>

⁵³ Article 5 of the Personal Data Protection Law.

⁵⁴ Interview with the NHIF on 6 March 2014.

⁵⁵ Interview with the Commission for Personal Data Protection on 6 March 2014.

⁵⁶ Article 2(2)4° of the Personal Data Protection Law.

⁵⁷ Article 2(2)5° of the Personal Data Protection Law.

⁵⁸ Article 2(2)6° of the Personal Data Protection Law.

Questions	Legal reference	Detailed description
		Pursuant to Article 5(1) of the Personal Data Protection Law, health data cannot be processed unless it fulfils the conditions and purposes specified in Article 5(2).
<i>Is there a need for a specific authorisation or licence to host and process data from EHRs?</i>	Personal Data Protection Law, Articles 7 (last amended 10 November 2006) to 18 (last amended 10 November 2006)	<p>The general rules for hosting and managing personal data are provided in the Personal Data Protection Law.</p> <p>Administrators cannot begin collecting, hosting and processing personal data before being officially registered as Administrators⁵⁹.</p> <p>Therefore, before commencing the processing of personal data, the Administrator has to send an application to the Commission for Personal Data Protection (<i>Комисия за защита на личните данни</i>) (Commission) requesting registration on the Personal Data Administrators Register⁶⁰.</p> <p>The application contains:</p> <ol style="list-style-type: none"> 1. information identifying the Administrator and its representatives, if any; 2. the purposes of processing personal data; 3. the categories of individuals whose data are processed, and the categories of personal data related to them; 4. the recipients to whom the personal data may be disclosed; 5. the proposed provision of data in other countries; 6. general description of the data protection measures⁶¹. <p>The Commission is a collegial body consisting of a chairman and four members. The members of the Commission and its chairman are elected by the Bulgarian National Assembly (<i>Народното събрание</i>) upon a proposal by the Council of Ministers. They are elected for a period of five years and may be reappointed for another term⁶².</p>

⁵⁹ Interview with the Commission for Personal Data Protection on 6 March 2014.

⁶⁰ Article 17 of the Personal Data Protection Law.

⁶¹ Article 18 of the Personal Data Protection Law.

⁶² Article 7 of the Personal Data Protection Law.

Questions	Legal reference	Detailed description
		<p>In the application, the Administrator needs to prove compliance with the requirements of the Personal Data Protection Law⁶³. The Commission can ask for complementary proof and information⁶⁴.</p> <p>Moreover, the Commission considers that health data is ‘sensitive data’ and as such it performs a prior control of the Administrator before admitting them to the Administrators Registry⁶⁵. The Personal Data Protection Law explicitly states that the Commission has to perform a prior control of the Administrator within two months of the application when the personal data processing could disclose information on a person’s ethnic origin⁶⁶.</p> <p>14 days after the application is made, the Commission registers the Administrator in the Administrators Registry⁶⁷. The Administrator receives a certificate with a registry identification number.</p> <p>Pursuant to Articles 10 and 12 of the Personal Data Protection Law, the Commission has the right to perform controls on Administrators. After each control, the Commission drafts a report evaluating the Administrator’s compliance with the legal obligations.</p> <p>The Commission can give mandatory instructions related to personal data protection and has the right to temporarily forbid the processing of personal data if the provisions of the Personal Data Protection Law have not been complied with.</p> <p>The Commission establishes the minimum level of technical and</p>

⁶³ Article 17(3) and (5) of the Personal Data Protection Law.

⁶⁴ Interview with the Commission for Personal Data Protection on 6 March 2014.

⁶⁵ Interview with the Commission for Personal Data Protection on 6 March 2014.

⁶⁶ Article 17b of the Personal Data Protection Law.

⁶⁷ The NHIF Administrators Registry Application is N° 3 – 10115958; the number of certificate issued by the Commission is N°52412. The Administrators registry is public and is available at <https://www.cdpd.bg/?p=rubric&aid=12> upon registration on the web-site (registration formalities available at https://www.cdpd.bg/files_eRALD_new/ukazanija_eRALD_new.pdf).

Questions	Legal reference	Detailed description
<p><i>Are there specific obligations that apply to institutions hosting and managing data from EHRs (e.g. capacity, qualified staff, or technical tools/policies on security confidentiality)?</i></p>	<p>Personal Data Protection Law, Article 23 (last amended 18 October 2011)</p> <p>Ordinance n°1 of 30 January 2013</p>	<p>organisational measures. It also sets out admissible types of data protection measures⁶⁸.</p> <p>According to the general rules on personal data hosting and processing, provided in Article 23 of the Personal Data Protection Law, every Administrator must take appropriate technical and organisational measures to protect the data against accidental or unlawful destruction or accidental loss, unauthorised access, modification or disclosure, and against other unlawful forms of processing.</p> <p>The Administrator sets deadlines for conducting periodic reviews on the need to continue processing personal data or to delete personal data⁶⁹.</p> <p>The Administrator has to take special protection measures when the processing involves the electronic transmission of data⁷⁰.</p> <p>All data protection measures have to be consistent with modern technological progress and provide an appropriate level of security compared to the risks represented by the processing of data, as well as the nature of the data protected⁷¹. Administrators have to perform periodic reviews of the level of protection of the technical and organisational measures⁷².</p> <p>Pursuant to Article 23(5) of the Data Protection Law, the Commission establishes by ordinance the minimum level of technical and organisational measures and admissible type of data protection measures.</p> <p>As a result, the Commission adopted Ordinance n°1 of 30 January 2013</p>

⁶⁸ Articles 10 and 23 of the Personal Data Protection Law.

⁶⁹ Article 23(1) of the Personal Data Protection Law.

⁷⁰ Article 23(2) of the Personal Data Protection Law.

⁷¹ Article 23(3) of the Personal Data Protection Act.

⁷² Article 11 of Ordinance n°1 of 30 January 2013 of the Commission for Personal Data Protection on the minimum level of technical and organisational (*Наредба № 1 от 30 януари 2013 г. за минималното ниво на технически и организационни мерки и допустимия вид защита на личните данни*) (available at <https://www.cdpd.bg/?p=element&aid=632>) (last access February 2014).

Questions	Legal reference	Detailed description
		<p>on the minimum level of technical and organisational measures. The Ordinance describes the following type of protection measures⁷³:</p> <ul style="list-style-type: none"> - physical protection (e.g. access to the buildings, offices and desks of the Administrators), - personal protection (e.g. knowledge of data protection laws, training of staff, signing of confidentiality agreements), - document protection (e.g. determination of the paper registers containing the data protection, regulation of the access to the registers, the transfer and deletion of personal data), - automated information systems and networks protection (e.g. authentication, surveillance, remote control, archiving duration), - encrypted protection (e.g. standards for encrypted protection of operational systems and data registers).
<i>In particular, is there any obligation to have the information included in EHRs encrypted?</i>	Ordinance n°1 of 30 January 2013	<p>There is no specific obligation to have the information included in a PIS record encrypted.</p> <p>As mentioned above, encrypted information is one type of protection measure listed by Ordinance n°1 of 30 January 2013 of the Commission for Personal Data Protection on the minimum level of technical and organisational measures.</p> <p>At the time being, the connection between the PIS portal and the ZZOL's Internet browser is encrypted by using SSL⁷⁴. The online service is protected with WS Security (XML I Security XML Encryption)⁷⁵.</p>
<i>Are there any specific auditing requirements for institutions hosting and processing EHRs?</i>		<p>There are no specific auditing requirements for institutions hosting and processing EHRs.</p> <p>As mentioned above, pursuant to Articles 10 and 12 of the Personal Data Protection Law, the Commission controls Administrators' compliance</p>

⁷³ Ordinance n°1 of 30 January 2013 of the Commission for Personal Data Protection on the minimum level of technical and organisational measures (available at <https://www.cdpd.bg/?p=element&aid=632>) (last access February 2014).

⁷⁴ 'Rights of Use of the PIS', available at https://pis.nhif.bg/pis-main_files/Rights_of_use.htm (last access February 2014).

⁷⁵ Interview with the NHIF on 6 March 2014.

Questions	Legal reference	Detailed description
		<p>with personal data protection requirements. The Commission can also impose mandatory instructions on Administrators.</p> <p>The Commission performs controls in the following situations :</p> <ul style="list-style-type: none"> - before the Administrator is registered as such, the Commission performs a prior control if the Administrator wants to process sensitive data; - when the Commission receives a complaint from an individual; - when the Commission has issued mandatory instructions to particular Administrators⁷⁶. <p>As part of its controlling duties, the Commission elaborates a yearly control action plan designating a number of Administrators that will be subject to controls⁷⁷.</p> <p>Moreover, the Administrator is required to set deadlines for conducting periodic reviews on the need to continue processing personal data or to delete it⁷⁸. Administrators also have to perform periodic reviews of the level of protection of technical and organisational measures⁷⁹.</p>

⁷⁶ Interview with the Commission for Personal Data Protection on 6 March 2014.

⁷⁷ Interview with the Commission for Personal Data Protection on 6 March 2014.

⁷⁸ Article 23 of the Personal Data Protection Law.

⁷⁹ Article 11 of Ordinance n°1 of 30 January 2013 of the Commission for Personal Data Protection on the minimum level of technical and organisational (available at <https://www.cdpd.bg/?p=element&aid=632>) (last access February 2014).

2.3. Patient consent

2.3.1. Main findings

The NHIF automatically creates PIS records for every ZZOL. The NHIF is not required to inform ZZOLs of the existence and the purpose of PIS records. After the system's extension in 2013, the NHIF organised a number of media campaigns and conferences in order to inform the population of PIS records⁸⁰.

There are no specific national rules on consent from ZZOLs to create, share or process PIS records. ZZOLs have full access to their PIS records. In practice, ZZOLs can grant access to health practitioners on a case-by-case basis. This requirement (to grant access on a case-by-case basis) is not established in the law. Only NHIF Partners may have access to PIS records. NHIF Partners access PIS records by using their electronic signatures and their 'unique identification number', both given only to health practitioners that are members of the Bulgarian Medical Association⁸¹. Therefore, health practitioners of another Member State cannot access PIS records.

⁸⁰ Interview with the NHIF on 6 March 2014.

⁸¹ Interview with the NHIF on 6 March 2014.

2.3.2. Table on patient consent

Questions	Legal reference	Detailed description
<i>Are there specific national rules on consent from the patient to set-up EHRs?</i>		There is no specific rule in Bulgaria on consent from ZZOLs to set up a PIS record ⁸² . As the NHIF possess information on all medical care provided to ZZOLs, the NHIF automatically creates an individual PIS record for every ZZOL.
<i>Is a materialised consent needed?</i>		No consent is needed for the creation of PIS records.
<i>Are there requirements to inform the patient about the purpose of EHRs and the consequences of the consent or withholding consent to create EHRs?</i>		There are no requirements to inform the patient about the purpose of PIS records and the consequences of the consent or withholding consent to create PIS records ⁸³ .
<i>Are there specific national rules on consent from the patient to share EHRs data?</i>		There are no specific national rules on consent from the patient to share PIS record data. However, the PIS interface allows a ZZOL to grant access to her/his PIS record to a NHIF Partner on a case by case basis. A ZZOL can also remove this authorisation to access at any time ⁸⁴ (see Section 2.4.2).
<i>Are there any opt-in/opt-out rules for patient consent with regard to processing of EHRs?</i>		There are no opt-in/opt-out rules for ZZOL consent with regard to processing of her/his PIS record.
<i>Are there any opt-in/opt-out rules for patient consent with regard to sharing of EHRs?</i>		There are no opt-in/opt-out rules for ZZOL consent with regard to sharing PIS record. Once a ZZOL grants access to a NHIF Partner to her/his PIS record, all information updated on the record is available. The patient is only able to grant and remove access to her/his PIS record to a given health practitioner.
<i>Are there requirements to inform the patient about the purpose of EHRs?</i>		There are no requirements to inform the patient about the purpose of PIS records ⁸⁵ .

⁸² Interview with the NHIF on 6 March 2014.

⁸³ Interview with the NHIF on 6 March 2014.

⁸⁴ 'Guidelines on the use of medical records by ZZOLs' - <http://www.president.bg/docs/1352303612.pdf> and PIS record available at <https://pis.nhif.bg> (last access February 2014).

⁸⁵ Interview with the NHIF on 6 March 2014.

Questions	Legal reference	Detailed description
<i>and the consequences of consent or withholding consent on the sharing of EHRs?</i>		The PIS portal webpage describes the system's purpose as allowing ZZOLs to access information on all medical care provided to them by NHIF Partners ⁸⁶ .
<i>Can the patient consent to his/her EHRs being accessed by a health practitioner or health institution outside of the Member State (cross-border situations)?</i>		<p>The PIS is a NHIF initiative and contains only information about the medical care provided by a health practitioner contracted by the NHIF to a person covered under the ZZOL.</p> <p>Therefore, only ZZOLs and NHIF Partners have the right to access PIS records. NHIF Partners access PIS records by using their electronic signatures and 'unique identification number', both given only to health practitioners that are members of the Bulgarian Medical Association and⁸⁷ (see Section 2.4.2).</p> <p>Moreover, a ZZOL can grant access right to her/his PIS record only to health practitioners that are in the NHIF registry.</p> <p>However, as a ZZOL has access to her/his own PIS record, the ZZOL may provide access to a health practitioner by disclosing her/his details and access code or by logging in directly on the health practitioner's computer. The PIS portal introductory page specifies however that the information contained in the PIS is intended for ZZOL's personal use only, and that the NHIF bears no responsibility should a ZZOL provides information from her/his PIS record to another person⁸⁸.</p>
<i>Are there specific rules on patient consent to share EHRs data on a cross-border situation?</i>		<p>There are no specific rules on patient consent to share PIS records data on a cross-border situation.</p> <p>The PIS is a NHIF initiative and, therefore, a ZZOL can grant access right to her/his PIS record only to health practitioners that are in the NHIF</p>

⁸⁶ 'Rights of Use of the PIS', available at https://pis.nhif.bg/pis-main_files/Rights_of_use.htm (last access February 2014).

⁸⁷ Interview with the NHIF on 6 March 2014.

⁸⁸ 'Rights of Use of the PIS', available at https://pis.nhif.bg/pis-main_files/Rights_of_use.htm (last access February 2014).

Questions	Legal reference	Detailed description
		<p>registry. Moreover, every health practitioner is identified in the PIS with a ‘unique identification number’⁸⁹ that is given only to health practitioners that are members of the Bulgarian Medical Association (see Section 2.4.2).</p> <p>However, the ZZOL may provide access to a health practitioner by disclosing her/his details and access code or by logging in directly on the health practitioner’s computer.</p>

⁸⁹ Article 112 of the National Framework Agreement between the NHIF and the Bulgarian Medical Association for 2014.

2.4. Creation, access to and update of EHRs

2.4.1. Main findings

The NHIF automatically creates individual PIS records for every ZZOL.

ZZOLs can access their PIS records by using an electronic signature or a unique access code (UAC). The issuing of electronic signature is regulated by the Electronic Document and Electronic Signature Law. Only ‘providers of certification services’ registered at the Commission for Regulation of Communications can provide electronic signatures.

In 2013 the NHIF introduced the possibility of access by UAC in order to facilitate access to PIS records, ZZOLs can request their UAC at each Regional health insurance fund (RHIF). The RHIF can issue UACs only to ZZOLs in person or to a third party holding an official certified procurement. In their capacity of legal guardians, ZZOLs can use their own UAC to access the PIS record of children under 18 under their care.

The UAC can be deactivated when it has been compromised or when the ZZOL requests it⁹⁰. The PIS record, however, is not deleted.

Only ZZOLs that access their PIS record by using an electronic signature can grant access to their PIS record to a NHIF Partner. This possibility is not given to ZZOLs accessing their PIS record through UAC. ZZOLs can grant access either until a specific date or for a period of one, three, six or 12 months. ZZOLs can also remove the access right given to a NHIF Partner at any time. In terms of identification of health practitioners, every individual health practitioner is identified in the PIS with a ‘unique identification number’⁹¹. This number is given to all health practitioners members of the Bulgarian Medical Association.

NHIF Partners are however not entitled to update the PIS records directly. They are automatically updated with information from the medical care reports sent by NHIF Partners on a daily or monthly basis.

Both ZZOLs and NHIF Partners have access to all of the PIS record content. ZZOLs cannot update, modify or erase information in their PIS record. If PIS records contain incorrect information, ZZOLs can send complaints to a RHIF⁹².

ZZOLs can choose to receive a notification when their PIS record has been accessed and/or updated by an authorised health practitioner. They can also choose to receive a notification when their next mandatory check-up or vaccination is due.

⁹⁰ Article 13 of the Internal NHIF rules on the issues of a UAC.

⁹¹ Article 112 of the National Framework Agreement between the NHIF and the Bulgarian Medical Association for 2014.

⁹² Interview with the NHIF on 6 March 2014.

2.4.2. Table on creation, access to and update of EHRs

Questions	Legal reference	Detailed description
<p><i>Are there any specific national rules regarding who can create and where can EHRs be created?</i></p>		<p>Article 64 of the ZZO only states that ZZOLs have the right to access information on the medical care they received in the last 5 years.</p> <p>There is, however, no specific rule about creating a PIS record such as how and where it can be created.</p> <p>PIS records are part of the centralised information system of the NHIF. They are automatically generated and updated based on the electronic reports NHIF Partners are legally required to send to the NHIF. These records are stored in the IIS of the NHIF that also contains all relevant registries of ZZOLs and health practitioners.</p>
<p><i>Are there specific national rules on access and update to EHRs?</i></p>	<p>Electronic Document and Electronic Signature Law (last amended 21 December 2011)</p>	<p>There are specific rules on access to PIS records and their update.</p> <p>Access by the ZZOL</p> <p>There are two methods for a ZZOL to access her/his PIS record:</p> <ul style="list-style-type: none"> - Electronic signature <p>From 2009 until April 2013, a ZZOL could access her/his PIS record only by using a ‘qualified electronic signature’.</p> <p>The issuing of such an electronic signature is regulated by the Electronic Document and Electronic Signature Law (<i>Закон за електронния документ и електронния подпис</i>) (EDES Law).⁹³</p> <p>Only ‘providers of certification services’ registered at the Commission for Regulation of Communications (<i>Комисия за регулиране на съобщенията</i>) can create electronic signatures. The criteria (e.g. qualified personnel, secured systems, financial stability) that need to be</p>

⁹³ Electronic Document and Electronic Signature Law (*Закон за електронния документ и електронния подпис*) (available at <http://www.crc.bg/section.php?lang=bg&id=72>) (last access February 2014).

Questions	Legal reference	Detailed description
		<p>fulfilled by the providers, as well as their legal obligations are set in Articles 19 to 22 of the EDES Law.</p> <p>At the moment, only the five providers on the Register of Providers of Certification Services⁹⁴ are authorised to issue qualified electronic signatures.</p> <ul style="list-style-type: none"> - Unique access code <p>In order to facilitate and promote access to the PIS record, in April 2013 the NHIF introduced the possibility to access the PIS by the means of a unique access code (UAC).</p> <p>The Internal NHIF rules of 7 June 2013 on the issuing of a unique access code for the Personalised Information System⁹⁵ regulate the new access system.</p> <p>ZZOLs can request their UAC to each Regional Health Insurance Fund (RHIF)⁹⁶. The RHIF can issue UACs only to ZZOLs in person or to a third party holding an official certified procurement⁹⁷.</p> <p>In Bulgaria, every citizen is identified by a ‘uniform civil number’ (<i>единен граждански номер (ЕГН)</i>) generated from the person's date of birth. Each UAC, a combination of 10 letters and numbers, is associated to the citizen’s uniform civil number⁹⁸. Therefore, each access code is unique for every ZZOL.</p>

⁹⁴ Register of Providers of Certification Services: <http://crc.bg:8080/dpls/apex/f?p=923:310:5715425272544763> (last access February 2014).

⁹⁵ Internal NHIF rules of 7 June 2013 on the issuing of a UAC for the PIS (available at: http://www.nhif.bg/c/document_library/get_file?p_1_id=58538&folderId=11374&name=DLFE-7903.pdf) (last access February 2014).

⁹⁶ Article 5 of the Internal NHIF rules of 7 June 2013 on the issuing of a UAC for the PIS (available at: http://www.nhif.bg/c/document_library/get_file?p_1_id=58538&folderId=11374&name=DLFE-7903.pdf) (last access February 2014).

⁹⁷ Articles 10 and 11 of the Internal NHIF rules on the issues of a UAC.

⁹⁸ Article 6 of the Internal NHIF rules on the issues of a UAC.

Questions	Legal reference	Detailed description
		<p>The UAC can be deactivated when it has been compromised or when the ZZOL requests it⁹⁹. The PIS record, however, is not deleted.</p> <p>Access to a minor's PIS record</p> <p>The internal NHIF rules of 7 June 2013 on the issuing of a unique access code for the Personalised Information System set specific access rules regarding minors' PIS records.</p> <p>As explained above, every ZZOL can receive a UAC to access her/his PIS record. In their capacity of legal representatives, ZZOLs can use their personal UAC to access the PIS record of children under 18 under their care. Legal guardians can use their personal UAC to access the minor's PIS record only if they are the one that had chosen the minor's general practitioner and registered the minor under the practitioner's care¹⁰⁰.</p> <p>When the child reaches 18 years old, s/he can request her/his personal UAC. As a result, the legal representatives access to the child's PIS record is automatically removed.</p> <p>Access granted to health practitioners</p> <p>ZZOLs that access their PIS record by using an electronic signature can grant access to their PIS record to a NHIF Partner. Hence, at the moment, the large majority of ZZOLs who access their PIS record through UAC, do not have this possibility¹⁰¹.</p> <p>ZZOLs give the right to access on a case by case basis – the ZZOL has to enter each health practitioner's name and identification number.</p>

⁹⁹ Article 13 of the Internal NHIF rules on the issues of a UAC.

¹⁰⁰ Article 7 of the Internal NHIF rules on the issues of a UAC.

¹⁰¹ Interview with the NHIF on 6 March 2014.

Questions	Legal reference	Detailed description
		<p>For that purpose, PIS records contain a list of all NHIF Partners and ZZOLs can research a health practitioner by region, by name or by identification number¹⁰².</p> <p>ZZOLs can grant access either until a specific date or for a period of one, three, six or 12 months¹⁰³.</p> <p>ZZOLs are also allowed to remove the access right given to a NHIF Partner at any time. PIS records list all NHIF Partners that are granted access and ZZOLs have to simply click on “End Access” in order to end the sharing of their PIS record.</p> <p>Update of PIS records</p> <p>PIS records are automatically updated with information extracted from the medical care reports sent by NHIF partners.</p> <p>The NHIF Partners’ reporting obligations are set in the National Frame Agreements between the NHIF and the Bulgarian Medical Association and the Bulgarian Dental Association.</p> <p>NHIF Partners must send the reports to the RHIFs in an electronic form on a daily basis for hospitals and on a monthly basis for individual health practitioners¹⁰⁴.</p> <p>The reports describe all medical care and medicinal products that NHIF Partners have provided or prescribed to ZZOLs.</p>
<p><i>Are there different categories of access for different health</i></p>		<p>Consultation of a PIS record is possible, subject to the access authorisation of a ZZOL, by NHIF Partners¹⁰⁵.</p>

¹⁰² ‘Guidelines on the use of medical records by ZZOLs’ - <http://www.president.bg/docs/1352303612.pdf> (last access February 2014).

¹⁰³ Interview with the NHIF on 6 March 2014.

¹⁰⁴ Interview with the NHIF on 6 March 2014.

¹⁰⁵ ‘Guidelines on the use of medical records by ZZOLs’ - <http://www.president.bg/docs/1352303612.pdf> (last access February 2014).

Questions	Legal reference	Detailed description
<i>professionals?</i>		Once access has been granted, the health practitioner can access all information in a PIS record. ZZOLs cannot hide any of the information contained in their PIS record ¹⁰⁶ .
<i>Are patients entitled to access their EHRs?</i>		ZZOLs can access their PIS record via a portal created for that purpose on the NHIF website. As explained above, ZZOLs can access their PIS records by using an electronic signature or by introducing a UAC delivered by a RHIF.
<i>Can patient have access to all of EHR content?</i>		The patient has access to all information updated by the NHIF on her/his PIS record ¹⁰⁷ .
<i>Can patient download all or some of EHR content?</i>		The content of the PIS record cannot be downloaded, but the ZZOL can copy-paste the information from the screen.
<i>Can patient update their record, modify and erase EHR content?</i>		ZZOLs cannot update, modify or erase information in their PIS record ¹⁰⁸ . The information in PIS records is generated automatically from the medical care reports sent to the NHIF by NHIF Partners. ZZOLs can make the following changes directly in their PIS record : <ul style="list-style-type: none"> - Change her/his contact information (phone number, e-mail address) - Change her/his general practitioner - Choose to receive a notification for the next mandatory check-up or vaccination (by email or by a phone text message) - Choose to grant or remove access to the PIS record to a health practitioner - Choose to receive a notification when her/his PIS record has been accessed an authorised health practitioner by and/or

¹⁰⁶ Interview with the NSOPLB of 20 February 2014.

¹⁰⁷ Interview with the NHIF on 6 March 2014.

¹⁰⁸ Interview with the NHIF on 6 March 2014.

Questions	Legal reference	Detailed description
		<p>updated via medical care report of a NHIF Partner¹⁰⁹.</p> <p>If PIS records of ZZOLs contain incorrect information, ZZOLs can send complaints to a RHIF¹¹⁰.</p>
<p><i>Do different types of health professionals have the same rights to update EHRs?</i></p>		<p>As explained above, health practitioners do not directly update the PIS records.</p> <p>The information in a PIS record is automatically updated when health practitioners send their medical care reports to the NHIF.</p> <p>PIS records are also updated with pharmacists' reports when ZZOLs buy drugs fully or partially covered by the NHIF.</p>
<p><i>Are there explicit occupational prohibitions (e.g. insurance companies/occupational physicians...)?</i></p>		<p>There are no explicit occupational prohibitions¹¹¹.</p>
<p><i>Are there exceptions to the access requirements (e.g. in case of emergency)?</i></p>		<p>There are no exceptions to the access requirements¹¹².</p> <p>Health practitioners can access PIS records only upon authorisation by ZZOLs.</p> <p>It should be kept in mind that PIS records are mainly an informative tool allowing ZZOLs to view their medical care history and are created by NHIF with a reporting and financial purpose.</p>
<p><i>Are there any specific rules on identification and authentication for health professionals?</i></p>		<p>In terms of identification of health practitioners, every individual health practitioner is identified in the PIS with a 'unique identification number'¹¹³. This number is given to all health practitioners members of</p>

¹⁰⁹ Interview with the NHIF on 6 March 2014.

¹¹⁰ Interview with the NHIF on 6 March 2014.

¹¹¹ Interview n°1 with the Bulgarian Medical Association on 17 February 2014.

¹¹² Interview n°2 with the Bulgarian Medical Association on 17 February 2014.

¹¹³ Article 112 of the National Framework Agreement between the NHIF and the Bulgarian Medical Association for 2014.

Questions	Legal reference	Detailed description
<i>Or are they aggregated?</i>		<p>the Bulgarian Medical Association. Hospitals¹¹⁴ and pharmacies are identified in the PIS with their ‘registration number’.</p> <p>In order to access the PIS interface allowing access to authorised PIS records, the health practitioner has to be registered in the PIS portal as a ‘provider of medical care’¹¹⁵. The health practitioners must identify themselves by using an ‘advanced electronic signature’ integrating the practitioner’s unique identification number¹¹⁶.</p> <p>When health practitioners access the PIS, they can view¹¹⁷</p> <ul style="list-style-type: none"> - Their own PIS record (in their quality of ZZOL) - PIS records of minors (in their quality of legal representatives) - PIS records of patients that have granted them access (in their quality of health practitioners).
<i>Does the patient have the right to know who has accessed to his/her EHRs?</i>		<p>ZZOLs have the right to know who has accessed their PIS record.</p> <p>Every ZZOL can choose to receive an e-mail or phone text message notification when an authorised health practitioner is accessing her/his PIS record and when the PIS record is being updated via medical care report of a NHIF Partner¹¹⁸.</p>
<i>Is there an obligation on health professionals to update EHRs?</i>		<p>Health practitioners do not update directly the PIS record.</p> <p>However, pursuant to Article 55 of the ZZO and Chapter X of the 2014 National Framework Agreement, NHIF Partners are obliged to send daily or monthly reports to the NHIF with all medical activity provided to ZZOLs.</p> <p>Following those centralised reports, PIS records of ZZOLs are automatically updated.</p>

¹¹⁴ Article 170 of the National Framework Agreement between the NHIF and the Bulgarian Medical Association for 2014.

¹¹⁵ ‘Guidelines on the use of medical records by ZZOLs’, p.13 - <http://www.president.bg/docs/1352303612.pdf> (last access February 2014).

¹¹⁶ Interview with the NHIF on 6 March 2014.

¹¹⁷ ‘Guidelines on the use of medical records by ZZOLs’, p.13 - <http://www.president.bg/docs/1352303612.pdf> (last access February 2014).

¹¹⁸ Interview with the NHIF on 6 March 2014.

Questions	Legal reference	Detailed description
<i>Are there any provisions for accessing data on ‘behalf of’ and for request for second opinion?</i>		There are no provisions for accessing a PIS record on behalf of and for request for second opinion ¹¹⁹ . When ZZOLs grant access to their PIS records, their unique identification number identifies health practitioners.
<i>Is there in place an identification code system for cross-border healthcare purpose?</i>		There is no identification code system for cross-border healthcare purposes ¹²⁰ .
<i>Are there any measures that consider access to EHRs from health professionals in another Member State?</i>		There are no measures that consider access to PIS records from health practitioners in another Member State ¹²¹ . Only health practitioners members of the Bulgarian Medical Association and possessing a unique identification number and ‘advanced electronic signature’ can access PIS records upon authorisation by the ZZOL ¹²² .

¹¹⁹ Interview with the NSOPLB on 20 February 2014.

¹²⁰ Interview n°1 with the Bulgarian Medical Association on 17 February 2014.

¹²¹ Interview with the NSOPLB on 20 February 2014.

¹²² Interview with the NHIF on 6 March 2014.

2.5. Liability

2.5.1. Main findings

The national legislation does not set specific medical liability requirements related to the use of PIS records.

As explained above, PIS records are automatically updated with information from the reports that health practitioners send to the NHIF in order to get payment for their medical care. Errors in PIS records originate therefore from errors made in the health practitioners reports either by negligence or for financial benefit. Health practitioners can be held liable for violation of their contract with the NHIF, of the ZZO or of the National Framework Contract between the NHIF and the Bulgarian Medical Association.

In Bulgaria, different types of medical liability coexists that may be cumulated depending on circumstances. The general rules and legal principles on medical negligence and malpractice in Bulgaria can be summarised as follows.

Contractual Liability (*Договорна отговорност*)

Doctors bear civil contractual liability for misconduct or neglect of duties when providing medical care¹²³. The contractual liability covers the material damages suffered by the patient as a result of poor medical care. Moral damages are excluded.

Tort (*Деликтна отговорност*)

When a doctor's conduct violating legal medical obligations and best practices causes damage to a patient, the patient is entitled to damages in tort. This type of liability encompasses all material and moral damages caused to the patient and directly arising from the illegal actions of the doctor¹²⁴. The patient has the burden of proof of the fault causing harm, the causality and the type of damage suffered.

Criminal liability (*Наказателна отговорност*)

Health practitioners' criminal liability can be engaged for the most serious medical misconducts, e.g. ignorance or negligence causing a patient's death¹²⁵ or non-providence of medical care¹²⁶. Breach of professional secrecy can also engage health practitioners' criminal liability¹²⁷.

Administrative liability

Health Law

Patients can make complaints to Regional Health Centres in case of violation of their rights protected by the Health Law¹²⁸. The complaint is forwarded to the Bulgarian Medical Association or the RHIF. For instance, health practitioners are liable to fines when they violate the legal requirements regarding the form, content, conditions for use, processing, analysis, storage and delivery of medical records¹²⁹.

Personal Data Protection Law

In their quality of Administrators of personal data, health practitioners, have to comply with the Personal Data Protection Law. Every individual whose data rights have been violated can make a complaint to the Commission for Personal Data Protection¹³⁰ or go in front of the administrative

¹²³ Article 79 and Article 82 of the Law on Obligations and Contracts Act (*Закон за задълженията и договорите*).

¹²⁴ Articles 45 to 49 of the Law on Obligations and Contracts Act.

¹²⁵ Article 123 of the Penal Code (*Наказателен кодекс*).

¹²⁶ Article 141 of the Penal Code.

¹²⁷ Article 145 of the Penal Code.

¹²⁸ Article 93 of the Health Law (*Закон за здравето*).

¹²⁹ Article 228 of the Health Law.

¹³⁰ Article 38 of the Personal Data Protection Law.

courts¹³¹. Administrators of personal data violating their obligations are sanctioned with pecuniary sanctions or fines¹³².

Professional Liability

Health practitioners are liable for violating the Codes of professional ethics¹³³. The Bulgarian Medical Association can reprimand health practitioners, impose fines or erase them from the health practitioners register for a certain period¹³⁴.

¹³¹ Article 39 of the Personal Data Protection Law.

¹³² Article 42 of the Personal Data Protection Law.

¹³³ Code for professional ethics (*Кодекс на професионалната етика*), Code for professional ethics of dentists (*Кодекс за професионалната етика на лекарите по дентална медицина*).

¹³⁴ Article 38 of the Law on the Professional Associations of Doctors and Dentists (*Закон за съсловните организации на лекарите и лекарите по дентална медицина*) and Article 13 of the Law on Administrative Violations and Sanctions (*Закон за административните нарушения и наказания*).

2.5.2. Table on liability

Questions	Legal reference	Detailed description
<p><i>Does the national legislation set specific medical liability requirements related to the use of EHRs?</i></p>		<p>There are no specific medical liability requirements related to the use of PIS records in Bulgarian legislation.</p> <p>One should keep in mind that one of the PIS' main aims is financial control. Moreover, health practitioners can consult PIS records only if the patient has granted them access and, even if they have access, health practitioners are not obliged to consult PIS records when treating a patient¹³⁵. Therefore, the conditions of use and obligations regarding medical information and records, as defined by Article 27 the Health Law, are not applicable to PIS records.</p> <p>However, some of the general liability rules are applicable for the misuse of a PIS records.</p> <p>Personal Data Protection Law Every health practitioner is subject to obligations set in the Personal Data Protection Law in their capacity of Administrators (see Section 2.2).</p> <p>Every individual whose data rights were violated can make a complaint to the Commission¹³⁶ or go in front of the administrative courts¹³⁷. The Commission has the right to perform controls on the Administrators¹³⁸. Administrators violating their legal obligations are liable to pecuniary sanctions or fines¹³⁹.</p>

¹³⁵ Interview n°2 with the Bulgarian Medical Association of 17 February 2014.

¹³⁶ Article 38 of the Personal Data Protection Law.

¹³⁷ Article 39 of the Personal Data Protection Law.

¹³⁸ Articles 10 and 12 of the Personal Data Protection Law.

¹³⁹ Article 42 of the Personal Data Protection Law.

Questions	Legal reference	Detailed description
		<p>Criminal liability Breach of professional secrecy can also engage medical practitioners' criminal liability¹⁴⁰.</p> <p>Professional liability Pursuant to Article 52 of the Code of professional ethics, professional secrecy covers all information and documentation relevant to a patient. The Bulgarian Medical Association can reprimand health practitioners, impose fines or erase them from the health practitioners register for a certain period for any lack of compliance with the Code of professional ethics¹⁴¹.</p> <p>Liability towards the NHIF The NHIF can hold liable health practitioners for errors in their reports. Pursuant to Article 105c(1) of the ZZO, a health practitioner that violates the requirements regarding medical or financial documentation, except for cases of obvious factual errors, is liable to fines of BGN 50 to 150¹⁴².</p>
<i>Can patients be held liable for erasing key medical information in EHRs?</i>		Patients are not able to erase medical information from their PIS records.
<i>Can physicians be held liable because of input errors?</i>	ZZO, Article 105c (last amended 18 December 2009)	<p>As PIS records are automatically updated with information from the health practitioners' reports sent to the NHIF, input errors in PIS records originate from these reports.</p> <p>Health practitioners' reporting obligations are detailed in the National Framework Contract between the NHIF and the Bulgarian Medical Association.</p> <p>If a NHIF Partner has not filled in a report correctly, the NHIF will investigate if it was done by negligence or for the purpose of financial benefit¹⁴³.</p>

¹⁴⁰ Article 145 of the Penal Code.

¹⁴¹ Article 38 of the Law on the Professional Associations of Doctors and Dentists and Article 13 of the Law on Administrative Violations and Sanctions.

¹⁴² I.e. approximately EUR 25 to 75.

¹⁴³ Articles 72 to 79 of the ZZO.

Questions	Legal reference	Detailed description
		Pursuant to Article 105c of the ZZO, health practitioners that violate the requirements regarding medical or financial documentation are liable to fines of BGN 50 to 150 ¹⁴⁴ , except for cases of obvious factual errors.
<i>Can physicians be held liable because they have erased data from the EHRs?</i>	ZZO, Article 105c (last amended 18 December 2009)	Same as above.
<i>Are hosting institutions liable in case of defect of their security/software systems?</i>	Personal Data Protection Law, Article 42(9) (last amended 10 November 2006)	<p>According to the general rules for hosting and managing personal data, provided in Article 23 of the Personal Data Protection Law, every Administrator must take appropriate technical and organisational measures to protect the data against accidental or unlawful destruction or accidental loss, unauthorised access, modification or disclosure, and against other unlawful forms of processing.</p> <p>The Administrator has to take special protection measures when the processing involves the electronic transmission of data. These measures have to be consistent with modern technological advances and provide a level of security appropriate to the risks represented by the processing of data, as well as the nature of the protected data.</p> <p>Pursuant to Article 42(9) of the Personal Data Protection Law, Administrators are liable to fines of BGN 500 to 5,000¹⁴⁵ for all violation of their legal obligations.</p>
<i>Are there measures in place to limit the liability risks for health professionals (e.g. guidelines, awareness-raising)?</i>		<p>The national legislation does not set specific medical liability requirement related to the use of PIS records and, therefore, no measures are in place to limit the liability risk of health practitioners in relation to the PIS record.</p> <p>As explained above, if health practitioners' reports sent to the NHIF contain errors, they are liable to fines or pecuniary sanctions.</p> <p>In order to ensure the correct use of the NHIF software and electronic</p>

¹⁴⁴ I.e. approximately EUR 25 to 75.

¹⁴⁵ I.e. approximately EUR 250 to 2,500.

Questions	Legal reference	Detailed description
		<p>reporting system, the NHIF publishes guidelines on the official website¹⁴⁶. Whenever there is a change in the system, the NHIF has to publish the new instructions at least a month prior to the launch of the updated system¹⁴⁷.</p> <p>The Bulgarian Medical Association also organises regular trainings for health practitioners regarding the correct use of the reporting system¹⁴⁸.</p>
<p><i>Are there liability rules related to breach of access to EHRs (e.g. privacy breach)?</i></p>		<p>There are no specific liability rules to breach of access to PIS records.</p> <p>If the NHIF detects attempts of unauthorised information retrieval from the PIS, other unauthorised activities or system attacks, the NHIF may prohibit access to the system temporarily or permanently¹⁴⁹.</p> <p>Pursuant to Article 319a of the Penal Code, whoever copies, uses or accesses data in a computer system without authorisation, when such authorisation is needed, is punishable by a fine up to BGN 3,000¹⁵⁰.</p>
<p><i>Is there an obligation on health professionals to access EHRs prior to take a decision involving the patient?</i></p>		<p>There is no obligation for health practitioners to access PIS records before taking a decision involving the patient.</p> <p>It is important to note that the PIS record is not considered as the compulsory health record of a patient set by the Health Law. Even if a PIS record exists for every ZZOL in Bulgaria, first ZZOLs have to make the necessary steps to gain access to it by creating an electronic signature or obtaining a UAC. Afterwards, even if ZZOLs have access to their PIS record, they may not have granted access to their health practitioner.</p>
<p><i>Are there liability rules related to the misuse of secondary use of health data?</i></p>	<p>Personal Data Protection Law, Articles 2(2) (last amended 18 October 2011)</p>	<p>Pursuant to Article 2(2) of the Personal Data Protection Law, personal data must be :</p>

¹⁴⁶ Guidelines available at www.nhif.bg (last access February 2014).

¹⁴⁷ Interview with the NHIF on 6 March 2014.

¹⁴⁸ Interview n°1 with the Bulgarian Medical Association on 17 February 2014.

¹⁴⁹ 'Rights of Use of the PIS', available at https://pis.nhif.bg/pis-main_files/Rights_of_use.htm (last access February 2014).

¹⁵⁰ I.e. approximately EUR 1,500.

Questions	Legal reference	Detailed description
	and 42(1) (last amended 18 October 2011)	<ul style="list-style-type: none"> - processed lawfully and in good faith ; - collected for specified, concretely defined and legitimate purposes and not further processed in a way incompatible with those purposes. Further processing of personal data for historical, statistical or scientific purposes is permitted, provided that the Administrator provides appropriate protection by ensuring that the data is not processed for any other purposes except as expressly provided in the Personal Data Protection Law; - relevant and not exceeding the purposes for which they are processed; - kept in a form that allows the identification of the person whose data is collected only for the period that is necessary for the purposes for which personal data are processed. Personal data stored for longer periods for historical, statistical or scientific purposes must be kept in a form that prevents identification of individuals. <p>All use of personal data in a way or for a purpose other than the ones specified in the Personal Data Protection Law is punishable by pecuniary penalties and administrative fines. Pursuant to Article 42(1) of the Personal Data Protection Law, non-compliance with Article 2(2) is punishable by fines of BGN 10,000 to 100,000¹⁵¹.</p> <p>If health data is used in a way that allows identification of the individual, this use is considered as a misuse in infringement of the Code of professional ethics¹⁵².</p>

¹⁵¹ I.e. approximately EUR 5000 to 50,000.

¹⁵² Article 54 of the Code of professional ethics

2.6. Secondary uses and archiving durations

2.6.1. Main findings

There are no specific national rules on the archiving duration of PIS records. Moreover, pursuant to Article 67 of the ZZO, the NHIF is required to keep all information related to ZZOLs for 5 years after the end of their national health insurance coverage. However, there are no specific rules about the data from PIS records at the end of the archiving duration, nor a specific obligation to destroy PIS records¹⁵³. The NHIF is only obliged to provide access to ZZOLs to information on medical care performed during the last five years¹⁵⁴.

Pursuant to Article 25 of the Personal Data Protection Law, after the Administrator has achieved the purpose of personal data processing, the Administrator is obliged to destroy the data or to transfer it to another Administrator and notify in advance the Commission. When the purpose of processing personal data has been achieved, the Administrator can store data only in cases provided by law, e.g. for historical, statistical or scientific purposes.

Personal data stored for longer periods for historical, statistical or scientific purposes must be kept in a form that prevents identification of individuals. If an Administrator wants to store data for historical, statistical or scientific purposes, the data has to be anonymised and the Administrator has to inform the Commission¹⁵⁵. The Commission can prohibit such storing if the Administrator has not provided sufficient protection of the processed data in terms of their anonymity¹⁵⁶.

Pursuant to Article 27(3) of the Health Law, the form and content, as well as the terms and conditions for the processing, use and storage of medical information and the exchange of medical statistical information shall be determined by ordinance of the Minister of Health, coordinated with the National Statistical Institute. The ordinance will have to specify the general rules on archiving duration of health records, the destruction of records, the automatic transfer of health data for statistic purposes and the type of health data that can or cannot be used for such purposes. However, no such general ordinance has been adopted yet¹⁵⁷.

The Ministry of Health adopted Ordinance n°1 of 27 February 2013 on the provision of medical statistical information and information about medical activity of health institutions¹⁵⁸. Pursuant to Article 7 of this Ordinance, all health institutions have to keep medical statistical documentation. When providing information to the Ministry of Health, data identifying the patient must be deleted unless (i) there is a legal ground to use this data, (ii) patients' rights are protected and (iii) data are protected from unauthorised access. The National Centre for Public Health and Analysis (*Националният център по общественно здраве и анализи*), the Regional Health Inspectorates (*Регионални здравни инспекции*) and the National Institute of Statistics (*Националният статистически институт*) control compliance with data privacy and protection of health information.

¹⁵³ Interview with the NHIF on 6 March 2014.

¹⁵⁴ Article 64 of the ZZO.

¹⁵⁵ Article 25(3) of the Personal Data Protection Law.

¹⁵⁶ Article 25(3) of the Personal Data Protection Law.

¹⁵⁷ Interview n°1 with the Bulgarian Medical Association on 17 February 2014.

¹⁵⁸ Ordinance n°1 of 27 February 2013 on the provision of medical statistical information and information about medical activity of health institutions (*Наредба н°1 от 27 февруари 2013 за предоставяне на медико-статистическа информация и на информация за медицинската дейност на лечебните заведения*) (available at <http://www.mh.government.bg/Articles.aspx?pageid=391&categoryid=5722>) (last access March 2014).

2.6.2. Table on secondary uses and archiving durations

Questions	Legal reference	Detailed description
<i>Are there specific national rules on the archiving durations of EHRs?</i>	ZZO, Article 67 (last amended 18 December 2009)	<p>There are no specific national rules on the archiving duration of PIS records.</p> <p>Moreover, pursuant to Article 67 of the ZZO, the NHIF has to keep all information related to ZZOLs for 5 years after the end of their national health insurance coverage, which in the majority of cases corresponds to the ZZOL's death¹⁵⁹.</p> <p>However, the NHIF is only obliged to provide access to ZZOLs to information on medical care performed during the last five years¹⁶⁰ (see Section 2.1.2).</p>
<i>Are there different archiving rules for different providers and institutions?</i>		There are no different archiving rules for different providers because only the NHIF creates and keeps all existing PIS records.
<i>Is there an obligation to destroy (...) data at the end of the archiving duration or in case of closure of the EHR?</i>	<p>Personal Data Protection Law, Article 25 (last amended 23 December 2005)</p> <p>Health Law, Article 27 (last amended 10 August 2004)</p>	<p>There are no specific rules neither about the data from PIS records at the end of the archiving duration nor a specific obligation to destroy PIS records¹⁶¹.</p> <p>Pursuant to Article 25 of the Personal Data Protection Law, after the Administrator has achieved the purpose of personal data processing, the Administrator is obliged to:</p> <ol style="list-style-type: none"> 1. destroy the data <p>or</p> <ol style="list-style-type: none"> 2. transfer the data to another Administrator and notify in advance the Commission if the transfer is authorised by law and if the purposes of the processing are known. <p>When the purpose of processing personal data has been achieved, the Administrator can store data only in cases provided by law, e.g. for historical, statistical or scientific purposes.</p>

¹⁵⁹ Interview with the NSOPLB on 20 February 2014.

¹⁶⁰ Article 64 of the ZZO.

¹⁶¹ Interview with the NHIF on 6 March 2014.

Questions	Legal reference	Detailed description
		<p>When Administrators fill in their registration application, they have to specify the archiving duration and what happens to the data at the end of that period. When a law regulates these questions, the Administrator has to fill in what is set by law. When no law regulates the matter, the Administrator can decide on the archiving duration but cannot keep the data for a longer period than what is necessary for the purpose for which data is processed. In any case, if an Administrator has no longer a legal ground to keep personal data, s/he has to destroy it¹⁶².</p> <p>Pursuant to Article 27(3) of the Health Law, the form and content, as well as the terms and conditions for the processing, use and storage of medical information and the exchange of medical statistical information shall be determined by ordinance by the Minister of Health, coordinated with the National Statistical Institute. The ordinance will have to specify the general rules on archiving duration of health records, the destruction of records, the automatic transfer of health data for statistic purposes and the type of health data that can or cannot be used for such purposes. However, no such general ordinance has been adopted yet¹⁶³.</p>
<i>Are there any other rules about the use of data at the end of the archiving duration or in case of closure of the EHR?</i>		
<i>Can health data be used for secondary purpose (e.g. epidemiological studies, national statistics...)?</i>	<p>Personal Data Protection Law, Articles 2(2) (last amended 18 October 2011) and 25 (last amended 23 December 2005)</p> <p>Health Law, Article 27 (last amended 10 August</p>	<p>There are no specific rules on the secondary use of PIS records data.</p> <p>The general rules on secondary use of health data are set in the Personal Data Protection Law and the Health Law.</p> <p>Pursuant to Article 5 of the Personal Data Protection Law, data related to individual's health cannot be processed. However, health data can be processed if it is necessary for the purposes of preventive medicine,</p>

¹⁶² Interview with the Commission for Personal Data Protection on 6 March 2014.

¹⁶³ Interview n°1 with the Bulgarian Medical Association on 17 February 2014.

Questions	Legal reference	Detailed description
	2004)	<p>medical diagnosis, the provision or management of health services, provided that the data are processed by a health care professional who is bound by law to observe professional secrecy or by another person under a similar obligation of secrecy¹⁶⁴.</p> <p>Pursuant to Article 2(2) of the Personal Data Protection Law, personal data are :</p> <ul style="list-style-type: none"> - collected for specified, concretely defined and legitimate purposes. Further processing of personal data for historical, statistical or scientific purposes is permitted, provided that the Administrator provides appropriate protection; - kept in a form that allows the identification of the person whose data is collected only for the period that is necessary for the purposes for which personal data are processed. Personal data stored for longer periods for historical, statistical or scientific purposes must be kept in a form that prevents identification of individuals. <p>Article 25 of the Personal Data Protection Law states that when the purpose of processing personal data has been achieved, the Administrator can store data only in cases provided by law. If an administrator of personal data wants to store data for historical, statistical or scientific purposes, the data has to be anonymous and the Administrator has to inform the Commission.</p> <p>The Code of professional ethics allows the use of medical documentation for scientific and academic purposes¹⁶⁵.</p>
<i>Are there health data that cannot be used for secondary use?</i>		At the time being, all health data can be used for secondary use subject to requirements set under the Personal Data Protection Law.

¹⁶⁴ Article 5(2) of the Personal Data Protection Act.

¹⁶⁵ Article 54 of the Code of professional ethics.

Questions	Legal reference	Detailed description
		As explained above, the Minister of Health has to determine the conditions for the processing, storage and use of health data for medical statistical purposes through an ordinance. The ordinance will have to specify the transfer of health data for statistic purposes and the type of health data that can or cannot be used for such purposes. This ordinance has not been adopted yet ¹⁶⁶ .
<i>Are there specific rules for the secondary use of health data (e.g. no name mentioned, certain health data that cannot be used)?</i>	Personal Data Protection Law, Articles 2(2) (last amended 18 October 2011) and 25 (last amended 23 December 2005)	<p>Pursuant to Article 2(2) of the Personal Data Protection Law, personal data stored for longer periods for historical, statistical or scientific purposes must be kept in a form that prevents identification of individuals.</p> <p>Article 25(3) states that if an administrator of personal data wants to store data for historical, statistical or scientific purposes, the data has to be anonymous and the Administrator has to inform the Commission. The Commission can prohibit such storing if the Administrator has not provided sufficient protection of the processed data in terms of their anonymity¹⁶⁷.</p> <p>Pursuant to Article 54 of the Code of professional ethics, when medical documentation is used for scientific or academic purposes, health information covered by professional secrecy has to be anonymous. The identification of patients by third parties is not allowed.</p>
<i>Does the law say who will be entitled to use and access this data?</i>		No, this is subject to authorisation by the Commission on a case-by-case basis.
<i>Is there an opt-in/opt-out system for the secondary uses of health data included in EHRs?</i>	Personal data Protection Law, Article 34a (last amended 23 December 2005)	<p>There is no specific opt-in/opt-out system for the secondary use of health data included in PIS records¹⁶⁸.</p> <p>Pursuant to Article 34a(1) of the Personal data Protection Law, every individual has the right to protest to the administrator of personal data against the processing of her/his personal data if the individual has a legal basis for objecting to it. If the objection is grounded, personal data of this individual can no longer be processed.</p>

¹⁶⁶ Interview n°1 with the Bulgarian Medical Association on 17 February 2014.

¹⁶⁷ Article 25(4) of the Personal Data Protection Law.

¹⁶⁸ Interview with the NHIF on 6 March 2014.

2.7. Requirements on interoperability of EHRs

2.7.1. Main findings

PIS records are centralised in one database hosted by the NHIF. There are no legal obligations to develop interoperability of PIS records with other systems in Bulgaria, as these records are an initiative of the NHIF.

All systems related to the NHIF are interoperable by using the same file format ('xml'). The systems of all NHIF Partners (hospitals, individual health practitioners, pharmacies) are adapted to this format and the Partners also send their monthly or daily medical care reports to the NHIF in xml format¹⁶⁹. The entire information is centralised in the IIS of the NHIF and relevant information for ZZOLs is automatically extracted and updated in PIS records.

The connection between the PIS portal and the ZZOL's Internet browser is encrypted by using SSL and the online service is protected with WS Security (XML I Security XML Encryption). The technology used would allow successful cross-border interoperability¹⁷⁰.

¹⁶⁹ Interview with the NHIF on 6 March 2014.

¹⁷⁰ Interview with the NHIF on 6 March 2014.

2.7.2. Table on interoperability of data requirements

Questions	Legal reference	Detailed description
<i>Are there obligations in the law to develop interoperability of EHRs?</i>		<p>There are no legal obligations to develop interoperability of PIS records, as these records are an initiative of the NHIF.</p> <p>The NHIF systems are interoperable with each other. All NHIF Partners send their medical care reports in 'xml' format. The IIS of the NHIF, the PIS, the hospitals, pharmacies and health practitioners' systems are all adapted to the xml format making them interoperable¹⁷¹.</p>
<i>Are there any specific rules/standards on the interoperability of EHR?</i>		See above.
<i>Does the law consider or refer to interoperability issues with other Member States systems?</i>		See above.

¹⁷¹ Interview with the NHIF on 6 March 2014.

2.8. Links between EHRs and ePrescriptions

2.8.1. Main findings

ePrescriptions do not exist in Bulgaria yet. However, the NHIF is planning to develop an ePrescription system by the end of 2014¹⁷². This would imply amendments in the ZZO and the National Framework Contracts between the NHIF and the Bulgarian Medical Association and Bulgarian Dental Association. In order for ePrescriptions to work in the current NHIF system, all health practitioners will have to send their medical care reports on a daily basis. At the moment, this obligation exists only for hospitals but not for individual health practitioners and pharmacies.

The law should also explicitly allow health practitioners to prescribe all medical products in an electronic form and not only on a paper form¹⁷³.

¹⁷² Interview with the NHIF on 6 March 2014.

¹⁷³ Ordinance n°4 of 4 March 2009 on the conditions and orders for prescribing and issuing of medicinal products (*Наредба n°4 от 4 март 2009 за условията и реда за предписване и отпускане на лекарствени продукти*).

2.8.2. Table on the links between EHRs and ePrescriptions

- **Infrastructure**

Questions	Legal reference	Detailed description
<i>Is the existence of EHR a precondition for the ePrescription system?</i>		ePrescriptions do not exist in Bulgaria.
<i>Can an ePrescription be prescribed to a patient who does not have an EHR?</i>		ePrescriptions do not exist in Bulgaria.

- **Access**

Questions	Legal reference	Detailed description
<i>Do the doctors, hospital doctors, dentists and pharmacists writing the ePrescription have access to the EHR of the patient?</i>		ePrescriptions do not exist in Bulgaria.
<i>Can those health professionals write ePrescriptions without having access to EHRs?</i>		ePrescriptions do not exist in Bulgaria.

2.9. Other requirements

None identified.

3. Legal barriers and good practices for the deployment of EHRs in Bulgaria and for their cross-border transfer in the EU.

- *Good practices for the development of EHRs in Bulgaria*

As an initiative of the NHIF, the PIS was created with the main purpose of having a better control of healthcare expenditures¹⁷⁴. By having access to their individual PIS records, ZZOLs can easily detect when health practitioners have reported wrongly their medical activities and report it to the NHIF.

PIS records exceeded their original purpose and became the first electronic record system in Bulgaria allowing patients to consult their medical history online, to grant access to their records to health practitioners and to receive notifications with preventive purposes (mandatory check-ups and vaccinations). The system is actually not serving its original purpose because patients are rarely making complaints against their health practitioners¹⁷⁵.

In its current architecture, the PIS could serve as foundation for the future development of EHRs in Bulgaria.

Firstly, the IIS of the NHIF bears a strong potential because the medical care reports of all NHIF Partners – individual health practitioners, hospitals, laboratories, pharmacies – are centralised in it¹⁷⁶. Therefore, Bulgaria is already vested with an existing database. Moreover, this database is regularly updated, on a daily or monthly basis, by NHIF Partners who are obliged to send their medical care reports in order to receive reimbursement¹⁷⁷. The mandatory electronic reporting has also helped health practitioners to develop their IT skills which is an important element for the future development of EHRs¹⁷⁸.

Secondly, individual PIS records are automatically created for every ZZOL in Bulgaria. Therefore, individual PIS records already exist in Bulgaria. Moreover, ZZOLs can access their record upon receiving an electronic signature or a UAC, hence accessing modalities and issues have already been successfully dealt with.

Thirdly, the electronic format used by the NHIF (xml) is suited for future interoperability with other health systems in Bulgaria¹⁷⁹.

The representative of the NHIF in a written comment stressed that this project can be seen as a one of the major tools for ensuring effective functioning of the Bulgarian health system. One of the key measures specified in the draft 2014-2020 National Health Strategy is the integration and connectivity of the Bulgarian health system by developing a national health information system and providing access to citizens. This is the basis on which development of eHealth will step on with its main elements - electronic health record, electronic direction, ePrescriptions and more¹⁸⁰.

- *Potential legal barriers for the development of EHRs in Bulgaria*

According to all stakeholders, the main obstacle for development of EHRs in Bulgaria is the lack of legal framework. Every aspect of EHRs has to be regulated, as there are no specific provisions in place¹⁸¹.

¹⁷⁴ Interview n°1 with the Bulgarian Medical Association on 17 February 2014.

¹⁷⁵ Interview with the NHIF on 6 March 2014.

¹⁷⁶ Interview n°2 with the Bulgarian Medical Association on 17 February 2014.

¹⁷⁷ Interview with the NHIF on 6 March 2014.

¹⁷⁸ Interview with the NHIF on 6 March 2014.

¹⁷⁹ Interview with the NHIF on 6 March 2014.

¹⁸⁰ Interview with the NHIF on 6 March 2014 - quotation from the NHIF written answers.

¹⁸¹ Interview n°2 with the Bulgarian Medical Association on 17 February 2014.

PIS records were not created with the purpose of being patients' official EHRs. As a NHIF initiative, their original purpose is financial control by the NHIF and by ZZOLs¹⁸². For this reason, PIS records do not comply with health records standards¹⁸³ and present a number of shortcomings.

PIS records contain only information on medical care and medicinal products covered by the NHIF and it does not include the proper diagnosis of doctors. When patients consult private practitioners, this health information will not find its way to their PIS records. Therefore, the health information provided in PIS records is not comprehensive. Moreover, there are often delays with the records' update because of insufficient coordination between the different systems¹⁸⁴.

In addition, for the moment, medical results and other documents are not uploaded in the PIS records. The NHIF explained that it has no legal ground to require health practitioners to upload results, as they are not part of their reporting obligations which serves the purpose of getting reimbursement¹⁸⁵. Furthermore, the content of the medical care reports of the NHIF Partners can somewhat be biased as health practitioners fill in those reports in order to receive payment and not in the perspective of filling in a patient's health record¹⁸⁶.

Finally, in terms of PIS records access, health practitioners consider that access to patients' records should be possible when needed, such as in emergency cases, and not be subject to a prior consent from patients¹⁸⁷. Moreover, only ZZOLs who access their PIS record by using an electronic signature can grant access to their PIS record to a NHIF Partner while the majority of ZZOLs access their PIS records through UAC. The accessibility of the PIS from a technical point of view is also criticised from both patients and health practitioners – the current authentication measures (access codes and electronic signatures) are considered too complicated and restrictive and often there are technical problems to access the system¹⁸⁸.

eHealth and EHRs in Bulgaria have to be further developed by reorganising the existing system and by adopting new legal measures on the form, content, terms and conditions for the processing, use, access, sharing, transfer, storage and protection of electronic health information¹⁸⁹. A clear regulatory framework for standardisation and wider interoperability of information systems is a major component for EHRs development in Bulgaria¹⁹⁰ and for cross-border transfers¹⁹¹. In terms of cross-border healthcare, besides technical interoperability, the main barrier according to stakeholders is the language barrier¹⁹².

¹⁸² Interview with the NSOPLB on 20 February 2014.

¹⁸³ Interview with the Bulgarian Association for Patients' Defence on 21 February 2014.

¹⁸⁴ Interview with the NSOPLB on 20 February 2014 and with the BAPD on 21 February 2014.

¹⁸⁵ Interview with the NHIF on 6 March 2014.

¹⁸⁶ Interview with the BAPD on 21 February 2014.

¹⁸⁷ Interview with the NSOPLB on 20 February 2014 and with the BAPD on 21 February 2014.

¹⁸⁸ Interview with the NSOPLB on 20 February 2014 and with the BAPD on 21 February 2014.

¹⁸⁹ Interview with the NSOPLB on 20 February 2014, n°2 with the Bulgarian Medical Association on 17 February 2014 and with the NHIF on 6 March 2014.

¹⁹⁰ Interview n°1 and n°2 with the Bulgarian Medical Association on 17 February 2014.

¹⁹¹ Interview with the NHIF on 6 March 2014.

¹⁹² Interview with the NSOPLB on 20 February 2014 and with the NHIF on 6 March 2014.