# COUNTRY PROFILE BULGARIA


- Mihaela Astinova, student at the University of Groningen/ International and European Law, LL.B; email: mihaela.astinova@gmail.com
- Dr Brigit Toebes , Associate Professor and Rosalind Franklin Fellow, Faculty of Law, University of Groningen, the Netherlands
- Prof dr Hans V. Hogerzeil, Professor of Global Health and the Right to Health, University of Groningen, the Netherlands



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## Legal System

Bulgaria is a parliamentary republic with a clear separation of powers where the supreme law is the Bulgarian Constitution adopted in 1991. Since its adoption, the Constitution of the Republic of Bulgaria has governed the path towards democratization where the basic principles of the new social order were underlined (e.g. respect for international agreements adopted by the national assembly, independent judiciary, separation of powers, respect for human rights, etc.).
Bulgaria is a civil law country based on the legal models of France, Germany, Italy and Belgium. Since the fall of the communist regime in 1989, when the democratization processes began, most of the laws governing the country, including those for healthcare, have been influenced by and harmonized with the law of the European Union.

## Health Care System

The national healthcare system shall include the medical establishments under the Medical Treatment Facilities Act, the healthcare establishments under this Act and the Human Medicinal Drugs and Pharmacies Act, as well as the central, local and non-governmental bodies and institutions for organisation, management and control of health-protection and building activities.[1]
The leading responsible institutions for the Bulgarian Healthcare are the National Assembly, the Ministry of Health, the National Health Insurance Fund (NHIF) and the Supreme Medical Council. The system itself has a three level structure and is characterized by limited statism:
• National - covers the territory and population within the whole country (Ministry of Health);
• Regional - covers the territory and population of an administrative area of the territorial division of the country (governed by the Head of the Regional Health Centre);
• Municipal - covers the territory and population within the different municipalities.[2]
**The National Assembly** as the main law making body of Bulgaria is responsible for voting the national policies, including such for health. Additionally, it approves the budget of the NHIF.
**The Minister of Health** shall guide the national healthcare system and exercise control over the activities related to the protection of the citizens' health and the state health control; the provision of urgent medical aid, transfusion haematology, psychiatric aid at specialised facilities, medical and social care for children aged up to three years, transplantations and health information; the provision and sustainable development of health activities at medical and healthcare establishments, and medical expert activities.[3]
**The Supreme Medical Council** shall be set up at the Minister of Health. It shall include five representatives designated by the Minister of Health, five representatives of the Bulgarian Doctors' Union, three representatives of the Union of Dentists in Bulgaria, three representatives of the National Health Insurance Fund (NHIF), one representative of the Bulgarian Association of Health Care Professionals and a representative of the National Association of Municipalities, each higher medical school and the Bulgarian Red Cross each. The Minister of Health shall serve as the Chairperson of the Council in a non-voting capacity.

[1] Bulgarian Health Act 2006, article 4, http://www.en.nhif.bg/web/guest/legal-framework
[2] Health Systems in Transition, Bulgaria Health system review 2012, http://www.euro.who.int/__data/assets/pdf_file/0006/169314/E96624.pdf?ua=1
[3] Bulgarian Health Act, 2006, article 5, http://www.en.nhif.bg/web/guest/legal-framework

The Supreme Medical Council shall be an advisory body, discussing and giving opinions on the priorities of the National Health Strategy, ethical issues of medicine and biomedicine; bills and drafts of secondary legislative acts of the Council of Ministers in the field of healthcare and within the purview of the Minister of Health. It shall also give opinions on the report of the Minister of Health and on the draft of the annual health budget.[4]
**National Health Insurance Fund** was established with the purpose of implementing the compulsory health insurance.[5] In the Republic of Bulgaria there is compulsory and voluntary health insurance which is regulated by the Health Act and the Health Insurance Act. The insured citizens take the principal position in the health insurance program, followed by national health care providers and the third party payers – the National Health Insurance Fund (NHIF) and the private health insurance companies (falling within the voluntary health insurance). The Health care is financed by compulsory payment contributions by the insured citizens. It is collected by the form of taxes, direct payments, voluntary health insurance premiums, donations, corporate payments, and external funding.[6]

Meanwhile, new reforms are being prepared to be voted; the main key points are discussed under section "Reforms".

## Treaty Ratifications

| | Signed | Ratified | Acceded |
|---|---|---|---|
| International Convention on Economic, Social and Cultural Rights (ICESCR) | 8 Oct 1968 | 21 Sep 1970 | - |
| Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)<br><br>Optional Protocol | 17 Jul 1980 | 8 Feb 1982<br><br>20 Sep 2006 | - |
| Convention of the Rights of the Child (CRC) | 31 May 1990 | 3 Jun 1991 | - |
| ILO Convention 169 (Indigenous and Tribal Peoples Convention) | - | - | - |

[4] Ibid, article 6
[5] Ibid.
[6] Health Systems in Transition, Bulgaria Health system review 2012, http://www.euro.who.int/__data/assets/pdf_file/0006/169314/E96624.pdf?ua=1, see also Health Insurance Act 2006, article 23, http://www.en.nhif.bg/web/guest/legal-framework

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| International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families | - | - | - |
| International Convention on the Elimination of All Forms of Racial Discrimination (ICERD) | 1 Jun 1966 | 8 Aug 1966 | - |
| International Covenant on Civil and Political Rights (ICCPR) | 8 Oct 1968 | 21 Sep 1970 | - |
| United Nation Convention on the Rights of Persons with Disabilities | 27.09.2007 | - | - |

## Constitution

The Constitution of the Republic of Bulgaria (1991) does not include the right to health as such. It however refers to the right to medical insurance and to the statutory obligation of the state to finance, protect, and exercise full control over the health-care facilities, manufacture, production, and trade of medicinal products and medical equipment.[7] Additionally, in relation to the right to work, the right to healthy and safe working conditions is acknowledged by the Constitution along with the right to healthy and favorable environment.[8] The latter is linked to the protection of the environment, and the Constitution imposes obligation to the citizens to protect it.

## Overview of Relevant Provisions

| Indicator | National Legislation | National Regulation |
|---|---|---|
| **Government Commitment** Mandatory language | The protection of the citizens' health as a condition of full physical, mental and social wellbeing is a national priority and it shall be guaranteed by the government through the application of the established | |

[7] Constitution of the Republic of Bulgaria 1991 (in English), article 52, http://www.vks.bg/english/vksen_p04_01.htm
[8] Id., article 48 and article 55

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| | principles laid down in the Bulgarian Health Act and the Health Insurance Act.[9] More precisely, the Bulgarian governmental and policy making authority shall protect the health of the people by respecting the principle of equality in the use of health services; ensuring accessible and high-quality healthcare, giving priority to children, pregnant women and mothers of children aged up to one year; giving priority to health promotion and the integrated disease prevention; to prevention and reduction of the health risk to citizens as a result of adverse effects of environmental factors; providing special health protection of children, pregnant women, mothers of children aged up to one year and people with physical and mental disabilities; and participation of the government in the financing of activities aimed at protecting the health of citizens. | |
| **Sustainable Financing**<br>State reimbursement scheme | The National Health Insurance Fund (NHIF) is the organization responsible for the governance and implementation of the compulsory health insurance within the country; it is a system of social protection of the population guaranteeing a package of health services for every insured citizen. Its responsibilities are to finance the healthcare and to secure the insured population a free access to it.[10] Precisely, it finances the healthcare institutions, which signed a contract with NHIF/RHIF. The Health Insurance Act regulates the procedure of signing the National Framework Agreements (NFA) between NHIF and the professional associations of the health care providers - doctors and dentists. The NFA define the order, the contents and the payment of the health care | Under the mandatory health insurance, the insured individual pays for each visit to the doctor/dentist or the hospital 2.90 lev. The patient is also required to pay for each day of hospital treatment, but not more than 10 days per year, an amount 5.40 lev per day.[15]<br><br>In the Ministry of Health Ordinance № 38 for determining the list of the diseases for home treatment for which NHIF pays, fully or in part, for drugs, medical devices and dietetic foods for special medical purposes 2005 (last amended on 4 February 2014, entry into force 1 January 2014). In *Ministry of Health Ordinance № 38 for determining the list of the* |

[9] Bulgarian Health Act 2006 and Health Insurance Act, English text is available at: http://www.en.nhif.bg/web/guest/legal-framework

[10] The management of health systems in the EU Member States - The role of local and regional authorities, European Union, http://cor.europa.eu/en/documentation/studies/Documents/health-systems/health-systems-en.pdf, accessed 13 Apr 2015

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| | activities and services to be provided to the insured population. NFA are valid for one year, until the signing of the next one.[11] More accurate, the NFA regulate the requirements to be met by the providers of medical care, as well as the procedure for concluding contracts with them. Similarly, the NFA specify the particular types of medical care, the conditions, quality, accessibility and the procedure criteria under which the care should be provided.[12] Additionally, article 45 under section VI of the Health Insurance Act draws the framework of the medical care which is paid by the NHIF.<br>Under the Minister of Health, a National Council on Prices and Reimbursement of medicinal products has the obligation to maintain the medicinal products included in the Positive Drug List (PDL). The Positive Drug List includes medicinal products dispensed on medical prescription, which are necessary to cover the healthcare needs of the population and are paid by money from the budget of the NHIF, from the state budget outside the scope of the obligatory health insurance, from the budget of the healthcare establishments according to article 5 of the Medical-Treatment Facilities Act (MTEA)[13], and from the budget of the therapeutic establishments with state and or/municipal participation according to article 9 and 10 of the MTEA with state participation. Apart from the finances for health from the NHIF, the health insured population is obligated to pay the physician, the dental doctor or the medical establishment certain amount of out-pocket money for each visit as well | *diseases for home treatment of which NHIF pays, fully or in part, for drugs, medical devices and dietetic foods for special medical purposes* the reader could learn what the diseases for home-treatment reimbursed by the NHIF are (in Bulgarian only).[16] |

[15] Council of Ministers Decree № 193 of August 28, 2012 to determine the amounts paid by insured persons to visit a doctor, dentist and hospital treatment and procedures for payment under Art. 37(6) of the Health Insurance Act (Постановление № 193 от 28 август 2012г. за определяне размера на сумите, заплащани от здравноосигурените лица за посещение при лекар, лекар по дентална медицина и за болнично лечение), available in Bulgarian at: http://dv.parliament.bg/DVWeb/showMaterialDV.jsp?idMat=68080

[11] National Health Insurance Fund website, http://www.en.nhif.bg/web/guest/welcome, accessed 23 Feb 2015, Health Insurance Act 2006, Article 53, http://www.en.nhif.bg/web/guest/legal-framework

[12] Health Insurance Act 2006 (English), article 55(2), http://www.ncpr.bg/images/bul_zakonodatelstvo/Health%20Insuarence%20Act.pdf

[13] Medical-Treatment Facilities Act 2006, http://www.en.nhif.bg/web/guest/legal-framework

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| | as for each day of hospitalization but not more than 10 days a year. The particular amount is regulated in a decree of the Council of Ministers.[14] | |
| **Sustainable Financing**<br>State subsidy | Ministry of Healthcare can provide subsidies to state and municipal healthcare institutions, medical establishments for hospital care, and government and community centers for psychological care. The Ministry of Health can also subsidize centers for emergency medical assistance, state and municipal healthcare centers that provide consultations care of emergency patients, municipal hospitals that are located in difficult to reach and/or remote areas to carry out activities outside the scope of mandatory health insurance. The amount and the share of the subsidies are regulated in the budgetary program and are paid from the budget of the Ministry of Health. | |
| **Rational Selection**<br>Essential medicines framework | Medicinal Products in Human Medicine Act (2007) gives the terms and procedure for, inter alia, the authorization for use or registration of medicinal products designated for the human medicine, follow-up of the safety of the medicinal products released on the market; classification of the method of prescribing and dispensing medicinal products; pricing of medicinal products and development of positive drug list.<br>Under the Minister of Health, a National Council on Prices and Reimbursement of medicinal products (the Council) was established. Its activities are financed by the budget of the Ministry of Health and its main functions are to regulate the prices of medicinal products included in the Positive Drug List[17], to regulate the limit | |

[16] Ministry of Health Ordinance № 38 for determining the list of the diseases for home treatment of which NHIF pays, fully or in part, for drugs, medical devices and dietetic foods for special medical purposes (Наредба № 38 за определяне на списъка на заболяванията, за чието домашно лечение Националната здравноосигурителна каса заплаща лекарства, медицински изделия и диетични храни за специални медицински цели напълно или частично), available in Bulgarian at: http://www.nhif.bg/web/guest/67

[14] Id., article 37

[17] The archive of the Positive Drug Lists and their amendments is available in Bulgarian at: http://www.ncpr.bg/en/registers/archive-of-registers/archive-of-registers-for-2015-%D0%B3 List of all pharmaceuticals without prescription, last amended on 23 January 2015, can be found at: http://www.bda.bg/images/stories/documents/med_inf/OTC.pdf

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| | prices of the medicinal products, which are sold after doctor's prescription, to register maximum selling prices for retail trade of the medicinal products sold without doctor's prescription, to confirm, refuse to confirm, change or delete a price, or to limit a price of medicinal products, to register, refuse to register, change or delete prices of medicinal products, sold without doctor' prescription; to include, maintain, update change or exclude medicinal products from the PDL. Additionally, the Council keeps public registers of the confirmed prices of the medicinal products included in the PDL.[18] | |
| **Affordable Prices**<br>Availability of generics | Under article 621a (5) Medicinal Products in Human Medicine Act, the Council of Ministers, upon proposal of the Minister of Health, shall determine by an ordinance the conditions and rules for regulation of prices of medicinal products as well as the conditions and procedure for registration for prices of medicinal products, which are sold without doctor's prescription.[19] | Ordinance on the terms, rules and procedures for regulation and registration of prices for medicinal products[20] (30 April 2013, last amended 8 August 2014). |

**Observations**

-The Bulgarian Constitution recognizes the right to medical insurance, the right to work, the right to healthy and safe working conditions, as well as the right to healthy and favorable environment;

-Bulgaria ratified the International Covenant on Economic, Social and Cultural Rights, the Convention on the Elimination of all Forms of Discrimination against Women, the Convention on the Rights of the Child, International Covenant on the Elimination of all Forms of Racial Discrimination and the International Covenant on Civil and Political Rights.

-The Government has a mandatory obligation to protect citizens' health and their mental and social wellbeing by respecting the principle of equality in the use of health services; ensuring accessible and high-quality healthcare.

- Priority should be given to children, pregnant women and mothers of children aged up to

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List of pharmaceuticals with marketing authorization in the Republic of Bulgaria: http://en.bda.bg/index.php?option=com_content&view=section&layout=blog&id=7&Itemid=7 and http://www.bda.bg/images/stories/documents/bdias/drugs2_list2_2.htm

[18] Medicinal Products in Human Medicine Act (last amended SG. 18/4 Mar 2014), article 259 available in English at: http://www.ncpr.bg/images/bul_zakonodatelstvo/MPHMA%20amend.18_3%202014.pdf

[19] Наредба за условията, правилата и реда за регулиране и регистриране на цените на лекарствените продукти (2013)/Ordinance on the terms, rules and procedures for regulation and registration of prices for medicinal products (30 April 2013, last amended 8 August 2014), available in English at: http://www.ncpr.bg/en/regulations/bulgarian-legislation/regulations

[20] Ibid.

one year.

- First concerns should also be given to people with physical and mental disabilities.

## Government Commitment Overview

**Bulgarian Health Act**

**Article 2**

The protection of the citizens' health as a condition of full physical, mental and social wellbeing is a national priority and it shall be guaranteed by the government through the application of the following principles:
1. equality in the use of health services;
2. ensuring accessible and high-quality healthcare, giving priority to children, pregnant women and mothers of children aged up to one year;
3. priority of health promotion and the integrated disease prevention;
4. prevention and reduction of the health risk to citizens as a result of adverse effects of environmental factors;
5. special health protection of children, pregnant women, mothers of children aged up to one year and people with physical and mental disabilities;
6. participation of the government in the financing of activities aimed at protecting the health of citizens.

**Original text**

**Закон за Здравето**

Чл. 2. Опазването на здравето на гражданите като състояние на пълно физическо, психическо и социално благополучие е национален приоритет и се гарантира от държавата чрез прилагане на следните принципи:
1. равнопоставеност при ползване на здравни услуги;
2. осигуряване на достъпна и качествена здравна помощ, с приоритет за деца, бременни и майки на деца до една година;
3. приоритет на промоцията на здраве и интегрираната профилактика на болестите;
4. предотвратяване и намаляване на риска за здравето на гражданите от неблагоприятното въздействие на факторите на жизнената среда;
5. особена здравна закрила на деца, бременни, майки на деца до една година и лица с физически увреждания и психически разстройства;
6. държавно участие при финансиране на дейности, насочени към опазване здравето на гражданите.

**Article 82**

(1) Beyond the scope of the mandatory health insurance of Bulgarian citizens, medical services shall be provided in relation to:
1. medical aid in emergency cases;
2. psychiatric hospital aid;
3. the provision of blood and blood products;
4. the transplantation of organs, tissues and cells;
5. the mandatory treatment and/or mandatory isolation;
6. expert opinions and reports on the degree of disability and long-term loss of the ability to

work;
7. the payment for the treatment of diseases under terms and conditions set out by the Minister of Health;
8. medical transport under terms and conditions set out by the Minister of Health.
(2) Each Bulgarian citizen shall use:
1. vaccines for mandatory immunization and re-immunization, vaccines for specific indications and in emergency situations, specific serums, immunoglobulins and other bioproducts related to the prevention of infectious diseases, as well as the technical means for their application;
2. the full range of anti-epidemic activities;
3. access to healthcare activities within the framework of national, regional and municipal health programmes.
(3) Children below the age of 16 shall be entitled to medical aid beyond the scope of the mandatory health insurance.
(4) Children accommodated at medical establishments under Article 5, Paragraph 1 of the Medical Treatment Facilities Act shall be entitled to medical and social care free of charge.
(5) The activities under Paragraphs 1, 2, 3 and 4 shall be financed from the central and local government budgets and used under terms and conditions set out in regulations issued by the Minister of Health.

**Original Text**

**Чл. 82.** (1) Извън обхвата на задължителното здравно осигуряване на българските граждани се предоставят медицински услуги, които са свързани със:
1. медицинска помощ при спешни състояния;
2. (нова - ДВ, бр. 59 от 2006 г., доп., бр. 41 от 2009 г., в сила от 1.07.2009 г.) профилактични прегледи и изследвания и акушерската помощ за всички здравно неосигурени жени, независимо от начина на родоразрешение, по обхват и по ред, определени с наредба на министъра на здравеопазването;
3. (предишна т. 2 - ДВ, бр. 59 от 2006 г.) стационарна психиатрична помощ;
4. (предишна т. 3 - ДВ, бр. 59 от 2006 г.) осигуряване на кръв и кръвни продукти;
5. (предишна т. 4 - ДВ, бр. 59 от 2006 г.) трансплантация на органи, тъкани и клетки;
6. (предишна т. 5 - ДВ, бр. 59 от 2006 г.) задължително лечение и/или задължителна изолация;
7. (предишна т. 6 - ДВ, бр. 59 от 2006 г., изм., бр. 41 от 2009 г., в сила от 1.07.2009 г.) експертизи за вид и степен на увреждане и трайна неработоспособност;
8. (предишна т. 7 - ДВ, бр. 59 от 2006 г.) заплащане на лечение за заболявания по ред, определен от министъра на здравеопазването;
9. (предишна т. 8 - ДВ, бр. 59 от 2006 г.) медицински транспорт по ред, определен от министъра на здравеопазването;
10. (нова – ДВ, бр. 106 от 2013 г., в сила от 1.01.2014 г.) асистирана репродукция.
(2) Всеки български гражданин ползва:
1. (изм. - ДВ, бр. 101 от 2012 г., в сила от 1.01.2013 г., бр. 106 от 2013 г., в сила от 1.01.2014 г.) ваксини за задължителни имунизации и реимунизации, ваксини по специални показания и при извънредни обстоятелства, специфични серуми, имуноглобулини и други биопродукти, свързани с профилактиката на заразните болести, както и техническите средства за прилагането им;
2. пълен обем от противоепидемични дейности;
3. достъп до здравни дейности, включени в национални, регионални и общински здравни програми.
(3) Децата до 16-годишна възраст имат право на медицинска помощ извън обхвата на задължителното здравно осигуряване.
(4) Децата, настанени в лечебни заведения по чл. 5, ал. 1 от Закона за лечебните

заведения, имат право на безплатни медико-социални грижи.
(5) (Изм. - ДВ, бр. 15 от 2013 г., в сила от 1.01.2014 г.) Дейностите по ал. 1, 2, 3 и 4 се финансират от държавния бюджет и от общинските бюджети и се ползват при условия и по ред, определени с наредба на министъра на здравеопазването.

**Sustainable Financing (State Reimbursement scheme) Overview**

**Health Insurance Act**

**Article 45**

(1) The National Health Insurance Fund shall pay for the following medical services:
1. medical and dental services for the prevention against diseases;
2. medical and dental services for early discovery of diseases;
3. outpatient and hospital medical care for diagnosis and treatment of a disease;
4. (amend. - SG. 101 of 2009, effective 1.01.2010) further treatment and medical rehabilitation;
5. emergency medical care;
6. medical care for pregnancy, labour and motherhood;
7. (new - SG. 59 of 2006) medical care under Art. 82, para. 1 item 2 of the Health Act;
8. (prev. 7 - SG. 59 of 2006) abortions for medical indications and for pregnancy as a result of rape;
9. (suppl. - SG. 110 of 1999 previous item. 8 pcs. 59 of 2006, amend., SG. 59 of 2010, effective 31.07.2010) dental services ;
10. (previous. 9 - SG. 59 of 2006) medical care in cases of home treatment;
11. (amend. - SG. 107 of 2002, the previous item. 10, No. 59 of 2006) prescribing and dispensing of authorized medicines for home treatment on the territory of the country;
12. (new - SG. 111 of 2004 previous item. 11, No. 59 of 2006, suppl., No. 101 of 2012, effective 1.01.2013) prescription and dispensing of medical products and dietetic foods for special medical purposes designated for home treatment throughout the country, as well as medical devices used in hospital care;
13. (previous. 11 - SG. 111 of 2004 previous item. 12, No. 59 of 2006) medical expertise of labour capacity;
14. (previous. 12 - SG. 111 of 2004 previous item. 13, No. 59 of 2006) transport services for medical indications;
15. (new - SG. 60 of 2012, effective 7.08.2012) Healthcare activities under Art. 82, para. 2 pt. 3 of the Health Act;
16. (new - SG. 101 of 2012, effective as of 1.01.2013, the revoked. No.. 106 of 2013, effective from 1.01.2014 onwards);
17. (new - SG. 101 of 2012, effective as of 1.01.2013, the revoked. No.. 106 of 2013, effective from 1.01.2014 years).
(2) (amend. - SG. 107 of 2002, SG. 41 of 2009, effective 2.06.2009, supplemented., No. 101 of 2009, effective 1:01. 2010, amend., SG. 60 of 2012, effective 7.08.2012) The medical care under par. 1, except item. 11, 12 and 15 is defined as a basic package guaranteed by the budget of the NHIF. The basic package is determined by the Minister of Health.
(3) (new - SG. 107 of 2002, as amended. No. 111 of 2004, SG. 60 of 2012, effective 7.08.2012) The Minister of Health shall determine by ordinance the list of diseases for the home-treatment of which NHIF pays fully or in part the medicinal products, medical devices and dietary foods for special medical purposes as well as the health activities under Art. 82, para. 2 pt. 3 of the Health Act.
(4) (new - SG. 107 of 2002, amend., SG. 28 of 2004 repealed. SG. 31 of 2007, in force from 14.04.2008).
(5) (new - SG. 107 of 2002, amend., SG. 28 of 2004 repealed. SG. 31 of 2007, in force from

14.04.2008).
(6) (new - SG. 28 of 2004 repealed. SG. 31 of 2007, in force from 14.04.2008).
(7) (new - SG. 111 of 2004, repealed. SG. 31 of 2007, in force from 14.04.2008).
(8) (new - SG. 99 of 2011, effective 1.01.2012) The inclusion in the list of diseases for which home-treatment NHIF pays for the medicinal products, medical devices and dietary foods for special medical purposes fully or in part, shall be carried out annually in the terms and conditions determined by an ordinance as regulated under para. 3.
(9) (New - SG. 111 of 2004, amend., SG. 31 of 2007, in force since 14.04.2008, No. 71 of 2008, effective 12.08.2008 SG. 101 of 2009, effective 1.01.2010, SG. 60 of 2011, effective as of 5.08.2011, the previous paragraph. 8, No. 99 of 2011, effective from 1.01.2012, suppl. SG. 60 of 2012, effective 7.08.2012, amended. No.. 102 of 2012, in force from 21.12.2012) The conditions and order of payment of the 22 medicinal products specified under Art. 262, para. 6 item 1 of the Law on Medicinal Products in Human Medicine, medical devices and dietary foods for special medical purposes, as well as medicines for health activities under Art. 82, para. 2 item 3 of the Health Act, shall be determined by an ordinance issued by the Minister of Health on the proposal of the supervisory board of the NHIF.
(10) (new - SG. 98 of 2010, effective 1.01.2011, amend., SG. 60 of 2011, effective as of 5.08.2011, the previous para. 9 amend., SG. 99 of 2011, effective 1.01.2012, SG. 60 of 2012, effective from 7.08.2012 SG. 102 of 2012, effective from 21.12. 2012) For medicinal products included in the Positive drug list under Art. 262, para. 6 pt. 1 of the Law on Medicinal Products in Human Medicine Act, NHIF negotiates with the holders of marketing authorization or their authorized representatives' discount on the cost of packing, calculated on the basis of the reference value of the medicinal product for which NHIF pays under the conditions and procedures determined by the ordinance under para. 9.
(11) (new - SG. 60 of 2012, effective 7.08.2012) The negotiated discount under par. 10 shall be apportioned in favor of NHIF and the insured person under the conditions and procedures specified by the ordinance under para. 9.
(12) (new - SG. 60 of 2012, effective 7.08.2012) The pharmacies which had signed a contract with the NHIF cannot calculate on the amount paid by the insured person under par. 10, which NHIF pays for.
(13) (new - SG. 60 of 2012, effective 7.08.2012) For medicinal products for health activities under Art. 82, para. 2 pt. 3 of the Health Act NHIF negotiates with the holders of marketing authorizations and / or their authorized representatives' discount on the price of medicinal products under the conditions, criteria and procedures determined by an ordinance under para. 9.
(14) (new - SG. 60 of 2012, effective 7.08.2012) For medical devices included in the list under Art. 30a of the Law on medical devices NHIF negotiates with manufacturers or wholesalers of medical devices and / or their authorized representatives' discounts on the price of the particular group medical devices under the conditions, criteria and procedures determined by the ordinance under para. 9.
(15) (new - SG. 101 of 2009, effective from 1.01.2010, previous para. 9, No. 98 of 2010, effective from 1.01.2011, amend. SG. 60 of 2011, effective as of 5.08.2011, the previous paragraph. 10, amend., SG. 99 of 2011, effective from 1.01.2012, previous para. 11, No. 60 from 2012, effective 7.08.2012, amended. No.. 102 of 2012, in force since 21.12.2012, supplemented. SG. 18 of 2014) The terms and conditions for conclusion of individual contracts for payment of medicinal products under Art. 262, para. 6 pt. 1 of the Medicinal Products in Human Medicine Act, medical devices and dietary foods for special medical purposes between the Director of the RHIF and marketing authorization for retail sale of medicinal products are coordinated by nine representatives from NHIF and 9 representatives of the Bulgarian Pharmaceutical Union as defined by the supervisory board of the NHIF and the Management Board of the Bulgarian Pharmaceutical Union, in accordance with the ordinance under para. 9.

(16) (new - SG. 18 of 2014) The terms and conditions under par. 15 are published in the "Official Gazette" by the Director of the NHIF.
(17) (new - SG. 62 of 2010, effective from 1.01.2011, previous para. 10, No. 98 of 2010, effective from 1.01.2011, previous paragraph. 11, No. 99 of 2011, effective from 1.01.2012, previous para. 12, amend., SG. 60 of 2012, effective as of 7.08.2012, the previous paragraph. 16, No. . 18 of 2014) For dental activities included in the basic package as defined in the ordinance under para. 2, allows for payment by the insured person under the terms and conditions of Art. 55e.
(18) (new - SG. 99 of 2011, effective from 1.01.2012, previous para. 13, No. 60 of 2012, in force 23 of 7.08.2012, the previous paragraph 17, No. 18 of 2014) The basic package determined by the ordinance under para. 2 may include medicinal products intended for treatment of malignancies in a hospital.
(19) (new - SG. 60 of 2012, effective as of 7.08.2012, the previous paragraph. 18, No. 18 of 2014) NHIF negotiates discount and pay the reduced value of the agreed discount for all medicinal products used in treatment of malignancies to the hospital as follows:
1. (amend. - SG. 102 of 2012, in force from 21.12.2012) The concessions negotiated by the value of the package, calculated on the basis of a reference value of medicinal products for the treatment of malignant diseases included in the Positive drug list under Art. 262, para. 6 pt. 2 of the Medicinal Products in Human Medicine Act;

**Original text**

Чл. 45. (1) Националната здравноосигурителна каса заплаща за оказването на следните видове медицинска помощ:
1. медицински и дентални дейности за предпазване от заболявания;
2. медицински и дентални дейности за ранно откриване на заболявания;
3. извънболнична и болнична медицинска помощ за диагностика и лечение по повод на заболяване;
4. (изм. - ДВ, бр. 101 от 2009 г. в сила от 1.01.2010 г.) долекуване, продължително лечение и медицинска рехабилитация;
5. неотложна медицинска помощ;
6. медицински грижи при бременност, раждане и майчинство;
7. (нова - ДВ, бр. 59 от 2006 г.) медицински грижи по чл. 82, ал. 1, т. 2 от Закона за здравето;
8. (предишна т. 7 - ДВ, бр. 59 от 2006 г.) аборти по медицински показания и при бременност от изнасилване;
9. (доп. - ДВ, бр. 110 от 1999 г. предишна т. 8, бр. 59 от 2006 г., изм., бр. 59 от 2010 г., в сила от 31.07.2010 г.) дентална помощ;
10. (предишна т. 9 - ДВ, бр. 59 от 2006 г.) медицински грижи при лечение в дома;
11. (изм. - ДВ, бр. 107 от 2002 г., предишна т. 10, бр. 59 от 2006 г.) предписване и отпускане на разрешени за употреба лекарства, предназначени за домашно лечение на територията на страната;
12. (нова - ДВ, бр. 111 от 2004 г., предишна т. 11, бр. 59 от 2006 г., доп., бр. 101 от 2012 г., в сила от 1.01.2013 г.) предписване и отпускане на медицински изделия и диетични храни за специални медицински цели, предназначени за домашно лечение на територията на страната, както и на медицински изделия, прилагани в болничната медицинска помощ;
13. (предишна т. 11 - ДВ, бр. 111 от 2004 г., предишна т. 12, бр. 59 от 2006 г.) медицинска експертиза на трудоспособността;
14. (предишна т. 12 - ДВ, бр. 111 от 2004 г., предишна т. 13, бр. 59 от 2006 г.) транспортни услуги по медицински показания;
15. (нова - ДВ, бр. 60 от 2012 г., в сила от 7.08.2012 г.) здравни дейности по чл. 82, ал. 2,

т. 3 от Закона за здравето;
16. (нова - ДВ, бр. 101 от 2012 г., в сила от 1.01.2013 г., отм., бр. 106 от 2013 г., в сила от 1.01.2014 г.);
17. (нова - ДВ, бр. 101 от 2012 г., в сила от 1.01.2013 г., отм., бр. 106 от 2013 г., в сила от 1.01.2014 г.).
(2) (Изм. - ДВ, бр. 107 от 2002 г., бр. 41 от 2009 г., в сила от 2.06.2009 г., доп., бр. 101 от 2009 г., в сила от 1.01.2010 г., изм., бр. 60 от 2012 г., в сила от 7.08.2012 г.) Медицинската помощ по ал. 1, с изключение на т. 11, 12 и 15, се определя като основен пакет, гарантиран от бюджета на НЗОК. Основният пакет се определя с наредба на министъра на здравеопазването.
(3) (Нова - ДВ, бр. 107 от 2002 г., изм., бр. 111 от 2004 г., бр. 60 от 2012 г., в сила от 7.08.2012 г.) Министърът на здравеопазването определя с наредба списък на заболяванията, за чието домашно лечение НЗОК заплаща напълно или частично лекарствени продукти, медицински изделия и диетични храни за специални медицински цели, както и здравните дейности по чл. 82, ал. 2, т. 3 от Закона за здравето.
(4) (Нова - ДВ, бр. 107 от 2002 г., изм., бр. 28 от 2004 г., отм., бр. 31 от 2007 г., в сила от 14.04.2008 г.).
(5) (Нова - ДВ, бр. 107 от 2002 г., изм., бр. 28 от 2004 г., отм., бр. 31 от 2007 г., в сила от 14.04.2008 г.).
(6) (Нова - ДВ, бр. 28 от 2004 г., отм., бр. 31 от 2007 г., в сила от 14.04.2008 г.).
(7) (Нова - ДВ, бр. 111 от 2004 г., отм., бр. 31 от 2007 г., в сила от 14.04.2008 г.).
(8) (Нова - ДВ, бр. 99 от 2011 г., в сила от 1.01.2012 г.) Включването в списъка на заболяванията, за чието домашно лечение НЗОК заплаща лекарствени продукти, медицински изделия и диетични храни за специални медицински цели напълно или частично, се извършва веднъж годишно при условия и по ред, определени с наредбата по ал. 3.
(9) (Нова - ДВ, бр. 111 от 2004 г., изм., бр. 31 от 2007 г., в сила от 14.04.2008 г., бр. 71 от 2008 г., в сила от 12.08.2008 г., бр. 101 от 2009 г., в сила от 1.01.2010 г., бр. 60 от 2011 г., в сила от 5.08.2011 г., предишна ал. 8, бр. 99 от 2011 г., в сила от 1.01.2012 г., доп., бр. 60 от 2012 г., в сила от 7.08.2012 г., изм., бр. 102 от 2012 г., в сила от 21.12.2012 г.) Условията и редът за заплащане на 22 лекарствени продукти по чл. 262, ал. 6, т. 1 от Закона за лекарствените продукти в хуманната медицина, на медицински изделия и на диетични храни за специални медицински цели, както и на лекарствени продукти за здравните дейности по чл. 82, ал. 2, т. 3 от Закона за здравето, се определят с наредба, издадена от министъра на здравеопазването, по предложение на надзорния съвет на НЗОК.
(10) (Нова - ДВ, бр. 98 от 2010 г., в сила от 1.01.2011 г., изм., бр. 60 от 2011 г., в сила от 5.08.2011 г., предишна ал. 9, изм., бр. 99 от 2011 г., в сила от 1.01.2012 г., бр. 60 от 2012 г., в сила от 7.08.2012 г., бр. 102 от 2012 г., в сила от 21.12.2012 г.) За лекарствените продукти, включени в Позитивния лекарствен списък по чл. 262, ал. 6, т. 1 от Закона за лекарствените продукти в хуманната медицина, НЗОК договаря с притежателите на разрешенията за употреба или с техни упълномощени представители отстъпки от стойността за опаковка, изчислена на база референтната стойност на съответния лекарствен продукт, за който НЗОК заплаща, при условия, по критерии и ред, определени с наредбата по ал. 9.
(11) (Нова - ДВ, бр. 60 от 2012 г., в сила от 7.08.2012 г.) Договорената отстъпка от стойността по ал. 10 се разпределя пропорционално в полза на НЗОК и здравноосигуреното лице при условия и по ред, определени с наредбата по ал. 9.
(12) (Нова - ДВ, бр. 60 от 2012 г., в сила от 7.08.2012 г.) Аптеките, сключили договор с НЗОК, не могат да начисляват върху сумата, заплащана от здравноосигуреното лице, размера на договорената отстъпка по ал. 10 от стойността, която НЗОК заплаща.
(13) (Нова - ДВ, бр. 60 от 2012 г., в сила от 7.08.2012 г.) За лекарствени продукти за

здравните дейности по чл. 82, ал. 2, т. 3 от Закона за здравето НЗОК договаря с притежателите на разрешенията за употреба и/или с техни упълномощени представители отстъпки от цената на лекарствения продукт при условия, по критерии и ред, определени с наредбата по ал. 9.
(14) (Нова - ДВ, бр. 60 от 2012 г., в сила от 7.08.2012 г.) За медицинските изделия, включени в списъка по чл. 30а от Закона за медицинските изделия, НЗОК договаря с производителите или търговците на едро с медицински изделия и/или с техните упълномощени представители отстъпки от стойността за съответната група медицински изделия при условия, по критерии и ред, определени с наредбата по ал. 9.
(15) (Нова - ДВ, бр. 101 от 2009 г., в сила от 1.01.2010 г., предишна ал. 9, бр. 98 от 2010 г., в сила от 1.01.2011 г., изм., бр. 60 от 2011 г., в сила от 5.08.2011 г., предишна ал. 10, изм., бр. 99 от 2011 г., в сила от 1.01.2012 г., предишна ал. 11, бр. 60 от 2012 г., в сила от 7.08.2012 г., изм., бр. 102 от 2012 г., в сила от 21.12.2012 г., доп., бр. 18 от 2014 г.) Условията и редът за сключване на индивидуални договори за заплащане на лекарствени продукти по чл. 262, ал. 6, т. 1 от Закона за лекарствените продукти в хуманната медицина, на медицински изделия и на диетични храни за специални медицински цели между директора на РЗОК и притежателите на разрешение за търговия на дребно с лекарствени продукти се съгласуват от 9 представители на НЗОК и 9 представители на Българския фармацевтичен съюз, определени съответно от надзорния съвет на НЗОК и управителния съвет на Българския фармацевтичен съюз, в съответствие с наредбата по ал. 9.
(16) (Нова - ДВ, бр. 18 от 2014 г.) Условията и редът по ал. 15 се обнародват в "Държавен вестник" от управителя на НЗОК.
(17) (Нова - ДВ, бр. 62 от 2010 г., в сила от 1.01.2011 г., предишна ал. 10, бр. 98 от 2010 г., в сила от 1.01.2011 г., предишна ал. 11, бр. 99 от 2011 г., в сила от 1.01.2012 г., предишна ал. 12, изм., бр. 60 от 2012 г., в сила от 7.08.2012 г., предишна ал. 16, бр. 18 от 2014 г.) За денталните дейности, включени в основния пакет, определен в наредбата по ал. 2, се допуска заплащане и/или доплащане от задължително здравноосигурените лица при условията и по реда на чл. 55е.
(18) (Нова - ДВ, бр. 99 от 2011 г., в сила от 1.01.2012 г., предишна ал. 13, бр. 60 от 2012 г., в 23 сила от 7.08.2012 г., предишна ал. 17, бр. 18 от 2014 г.) В основния пакет, определен с наредбата по ал. 2, могат да бъдат включени лекарствени продукти, предназначени за лечение на злокачествени заболявания в условията на болнична медицинска помощ.
(19) (Нова - ДВ, бр. 60 от 2012 г., в сила от 7.08.2012 г., предишна ал. 18, бр. 18 от 2014 г.) Националната здравноосигурителна каса договаря отстъпки и заплаща намалената с договорените отстъпки стойност за всички лекарствени продукти, приложими при лечението на злокачествените заболявания, на изпълнителите на медицинска помощ, както следва:
1. (изм. - ДВ, бр. 102 от 2012 г., в сила от 21.12.2012 г.) отстъпките се договарят от стойността на опаковка, изчислена на база референтна стойност на лекарствени продукти за лечението на злокачествени заболявания, включени в Позитивния лекарствен списък по чл. 262, ал. 6, т. 2 от Закона за лекарствените продукти в хуманната медицина;

**Rational Selection Overview**

- The authorization for use or registration of medicinal products designated for human medicine is regulated in the Medicinal Products in Human Medicine Act (2007);

- The development of the PDL as well as the pricing, method of prescribing and dispensing of medicinal products is administered by the Medicinal Products in Human Medicine Act.

- The National Council on Prices and Reimbursement of medicinal products regulates the

(limit) prices of medicinal products included in the Positive Drug List or sold after a doctor's prescription;

- Additionally, the Council keeps public registers of the confirmed prices of the medicinal products included in the PDL and has the authority to include, maintain, update change or exclude medicinal products from the PDL.

## Affordable prices Overview

**Medicinal Products in Human Medicine Act**

**Article 261a**
(1) The National Council on Prices and Reimbursement of medicinal products shall regulate the prices of medicinal products, included in the Positive Drug List under Art. 262, Para. 1 and paid by public means in compliance with the lowest reference prices in the Member States.
(2) The Council shall regulate the limit prices of the medicinal products, which are sold after doctor's prescription apart from those under Para. 1 in compliance with the lowest reference prices of the Member States.
(3) The Council shall register maximum selling prices for retail trade of the medicinal products, which are sold without doctor's prescription.
(4) The price, defined under Para. 1 shall also be the limit price of the medicinal products at their retail trade.
(5) The Council of Ministers upon proposal of the Minister of Health shall determine by an ordinance the conditions and rules for regulation of prices of medicinal products under Para. 1 for regulation of the limit prices of medicines, sold after doctor's prescription under Para. 2 at their retail trade, as well as the conditions and procedure for registration for prices of medicinal products, which are sold without doctor's prescription.

**Original text**

Чл. 261а. (Нов - ДВ, бр. 60 от 2011 г., в сила от 5.08.2011 г., изм., бр. 102 от 2012 г., в сила от 21.12.2012 г.) (1) Съветът регулира цените на лекарствените продукти, включвани в Позитивния лекарствен списък по чл. 262, ал. 1 и заплащани с публични средства, в съответствие с най-ниските референтни цени от държави членки.
(2) Съветът регулира пределните цени на лекарствените продукти, които се отпускат по лекарско предписание, извън тези по ал. 1 в съответствие с най-ниските референтни цени от държави членки.
(3) Съветът регистрира максимални продажни цени на дребно на лекарствените продукти, които се отпускат без лекарско предписание.
(4) Цената, определена по реда на ал. 1, е и пределна цена на лекарствените продукти при продажбата им на дребно.
(5) Министерският съвет по предложение на министъра на здравеопазването определя с наредба условията и правилата за регулиране на цените на лекарствените продукти по ал. 1, за регулиране на пределните цени на отпусканите по лекарско предписание лекарствени продукти по ал. 2 при продажбата им на дребно, както и условията и реда за регистриране на цените на лекарствените продукти, които се отпускат без лекарско предписание.

**Ordinance on the terms, rules and procedures for regulation and registration of prices for medicinal products (2013)**

**Article 2.**
(1) “Price for a medicinal product included in the PDL and paid for by public funds” shall be the price in Bulgarian lev terms as endorsed by the Council.
(2) The price referred to in Paragraph (1) shall furthermore be a ceiling price for the medicinal products upon the retail sale of the said products.
(3) The ceiling price for a medicinal product dispensed on medical prescription, which is not included in the PDL, shall be the price in Bulgarian lev terms, as endorsed by the Council, which is the highest permissible one upon the retail sale of the said product.
(4) The price for an over-the-counter medicinal product shall be the maximum retail selling price in Bulgarian lev terms, as declared by the marketing authorisation holder and as registered by the Council.
(5) In respect of the medicinal products for which a parallel import authorisation has been obtained, a price shall be endorsed/registered according to the procedure established by the Ordinance.

**Original text**:

**Чл. 2.**
(1) Цена на лекарствен продукт, включван в ПЛС изаплащан с публични средства, е цената в български левове, утвърдена от Съвета.
(2) Цената по ал. 1 е и пределна цена на лекарствените продукти при продажбата им на дребно.
(3) Пределната цена на лекарствен продукт, отпускан по лекарско предписание, който не е включен в ПЛС, е цената в български левове, утвърдена от Съвета, която е максимално допустима при продажбата му на дребно.
(4) Цената на лекарствен продукт, отпускан без лекарско предписание, е максималната продажна цена на дребно в български левове, заявена от притежателя на разрешението за употреба и регистрирана от Съвета.
(5) За лекарствените продукти, за които е получено разрешение за паралелен внос, се утвърждава/регистрира цена по реда на наредбата.

**Article 6.**
(1) Medicinal products authorised for marketing according to the procedure established by the MPHUA, classified by pharmacological group according to the Anatomical Therapeutic Chemical Classification (ATC), shall be included in the Positive Drug List.
(2) The Positive Drug List shall consist of four annexes and shall include:
1. medicinal products intended for treatment of diseases which are paid for according to the procedure established by the Health Insurance Act (HIA);
2. medicinal products paid for from the budget of the medical-treatment facilities covered under Article 5 of the Medical-Treatment Facilities Act and from the budget of the medical-treatment facilities wherein the State and/or a municipality holds a participating interest under Articles 9 and 10 of the Medical-Treatment Facilities Act;
3. medicinal products intended for treatment of AIDS, of infectious diseases, of diseases beyond the scope of the HIA which are paid for according to the procedure established by Item 8 of Article 82 (1) of the Health Act, as well as vaccines for compulsory immunisations and boosters, vaccines on special indications and in an emergency, specific sera, immunoglobulins, designated by the ordinance referred to in Article 58 (2) of the Health Act;
4. ceiling price for medicinal products, referred to in Article 2 (2), disaggregated by element.
(3) The annexes to the PDL referred to in Items 1 to 3 of Paragraph (2) shall state: ATC code,

international non-proprietary name (INN), name of the medicinal product, pharmaceutical form and quantity of the active ingredient, final packaging, marketing authorisation holder, defined daily dose (DDD) for a treatment course, the price under Article 261a (1) of the MPHUA, reference value for DDD for a treatment course, level of reimbursement of the medicinal product, diseases according to International Classification of Diseases (ICD) code, information on the restrictions in the prescribing method varying by indication and additional information.

**Original text**

**Чл. 6.** (1) В позитивния лекарствен списък се включват разрешени за употреба поредана ЗЛПХМ лекарствени продукти, класифицирани по фармакологични групи съгласно кода по анатомо-терапевтично-химичната класификация (АТС).
(2) Позитивният лекарствен списък се състои от четири приложения и включва:
1. лекарствени продукти, предназначени за лечение на заболявания, които се заплащат по реда на Закона за здравното осигуряване (ЗЗО);
2. лекарствени продукти, заплащани от бюджета на лечебните заведения по чл. 5 от Закона за лечебните заведения и от бюджета на лечебните заведения с държавно и/или общинско участие по чл. 9 и 10 от Закона за лечебните заведения;
3. лекарствени продукти,предназначени за лечение на СПИН,на инфекциозни заболявания, назаболявания извън обхвата на ЗЗО, заплащани по реда на чл. 82, ал.1, т. 8 от Закона за здравето, както и ваксини за задължителни имунизации и реимунизации, ваксини по специални показания и при извънредни обстоятелства, специфични серуми, имуноглобулини, определени с наредбата по чл. 58, ал. 2 от Закона за здравето;
4. пределна цена на лекарствените продукти по чл. 2, ал. 2 по елементи.
(3) В приложенията на ПЛС по ал. 2, т. 1 - 3 се посочват: АТС код, международно непатентно наименование (INN), наименование на лекарствения продукт, лекарствената форма и количеството на активното лекарствено вещество, окончателна опаковка, притежател на разрешението за употреба, дефинирана дневна доза (ДДД)/терапевтичен курс, цената по чл. 261а, ал.1 ЗЛПХМ, референтна стойност за ДДД/терапевтичен курс, стойност за опаковка, изчислена на базата на референтна стойностза ДДД/терапевтичен курс, ниво на заплащане на лекарствения продукт, заболявания по международен код на заболяванията (МКБ), информация за ограниченията в начина на предписване при различни индикации и допълнителна информация.
(4) За лекарствените продукти, за които няма определена ДДД, референтната стойност се определя на база терапевтичен курс, концентрация или обем.

**Article 8.**
(1) The price for a medicinal product included in the PDL and paid for by public funds shall be formed of the following elements:
1. ex-factory price, which may not be higher than the lev equivalent of the lowest exfactory price for the same medicinal product in the countries specified in the information referred to in Article 33 (2) herein;
2. wholesale mark-up at the rate of 7, 6 and 4 per cent of the price declared under Item 1 according to the criterion established in Article 9 herein;
3. pharmacy mark-up at the rate of 20, 18 and 16 per cent of the price declared under Item 1 according to the criterion established in Article 9 herein.
(2) The price for a medicinal product included in the PDL shall be calculated as a sum total of the elements referred to in Items 1, 2 and 3 of Paragraph (1) and value added tax.
(3) Where there is no ex-factory price in the countries specified in Article 33 (2) herein, the ex-

factory price may not be higher than the lowest price for the same medicinal product paid for by the public health insurance funds of Belgium, the Czech Republic, Poland, Latvia and Hungary.
(4) Where an ex-factory price for the same medicinal product cannot be found in the countries specified in Article 33 (2) and in the countries referred to in Paragraph (3), the exfactory price may not be higher than the lowest price of a manufacturer/manufacturers entered in the marketing authorisation/the decision of the European Commission issued according to the procedure established by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136 of 30 April 2004) for a medicinal product of the same pharmaceutical and dosage form and in a final packaging nearest to the declared one, paid for by the public health insurance funds of the countries referred to in Article 33 (2) herein.

**Original text**

**Чл.8**. (1) Цената на лекарствен продукт, включван в ПЛС и заплащан спублични средства, се образува от следните елементи:
1. цена на производител, която не може да бъде по-висока от левовата равностойност на най-ниската цена на производител за същия лекарствен продукт в страните, посочени в справката по чл. 33, ал. 2;
2. надценка за търговец на едро в размер 7, 6 и 4 на сто от заявената по т. 1 цена съобразно критерия, определен в чл. 9;
3. надценка за търговец на дребно в размер 20, 18 и 16 на сто от заявената по т. 1 цена съобразно критерия, определен в чл. 9.
(2) Цената на лекарствен продукт, включван в ПЛС, се изчислява като сбор от елементите по ал. 1, т. 1, 2 и 3 и данък върху добавена тастойност.
(3) (Изм. И доп. - ДВ, бр. 92 от 2014г., в сила от 07.11.2014г.) Когато няма цена на производител в страните, посочени в чл. 33, ал. 2, цената на производител не може да бъде по-висока от най-ниската цена за същия лекарствен продукт в Белгия, Чехия, Полша, Унгария, Дания, Финландия и Естония.
(4) (Изм. - ДВ, бр. 92 от 2014г., в силаот 07.11.2014г.) Когато за лекарствен продукт не може да бъде намерена цена на производител за същия лекарствен продукт в страните, посочени в чл. 33, ал. 2, и в страните по ал. 3, цената на производител не може да бъде по-висока от най-ниската цена на производител/производители, вписан/вписани в разрешението за употреба/решението на Европейската комисия, издадено по реда на Регламент (ЕО) №726/2004 на Европейския парламент и на Съветаот 31 март 2004г. За установяване на процедури на Общността за разрешаване и контрол на лекарствени продукти за хуманна и ветеринарна употреба и за създаване на Европейска агенция по лекарствата (ОВ, L 136 от 30 април 2004г.), на лекарствен продукт в същата лекарствена и дозова форма и в окончателна опаковка, най-близка до заявената, заплащан в страните по ал. 3 и страните по чл. 33, ал.2.

**Article 9.**
(1) In case the declared ex-factory price does not exceed BGN 10.00, the rate of the wholesale mark-ups and pharmacy mark-ups which are added on to the said price shall be 7 and 20 per cent, respectively.
(2) In case the declared ex-factory price is within the range from BGN 10.01 to BGN 30.00, the rate of the wholesale mark-ups and pharmacy mark-ups which are added on to the said price shall be 6 and 18 per cent, respectively.
(3) In case the declared ex-factory price exceeds BGN 30.00, the rate of the wholesale mark-ups and pharmacy mark-ups which are added on to the said price shall be 4 per cent but not

more than BGN 10 and, respectively, 16 per cent but not more than BGN 25.

**Original text**

**Чл.9.** (1) В случай че заявената цена на производител е до 10,00 лв.,размерът на надценките за търговец на едро и за търговец на дребно, които се добавят към нея, есъответно 7 и 20 на сто.
(2) В случай че заявената цена на производител е в границите от 10,01 лв. до 30,00 лв., размерът на надценките за търговец на едро и за търговец на дребно, които се добавят към нея, е съответно 6 и 18 на сто.
(3) В случай че заявената цена на производител е над 30,00 лв., размерът на надценките за търговец на едро и за търговец на дребно, които се добавят към нея, есъответно 4 на сто, но не повече от 10 лв., и 16 на сто, но не повече от 25 лв.

**Article 10**
(1) The ceiling price for a medicinal product dispensed on medical prescription, which is not included in the PDL, shall be formed of the following elements:
1. ex-factory price, which may not be higher than the lev equivalent of the lowest exfactory price for the same medicinal product in the countries specified in the information referred to in Item 5 of Article 14 (1) herein;
2. wholesale mark-up at the rate of 7, 6 or 4 per cent of the price declared under Item 1 according to the criterion established in Article 11 herein;
3. pharmacy mark-up at the rate of 20, 18 or 16 per cent of the price declared under Item 1 according to the criterion established in Article 11 herein.
(2) The ceiling price for a medicinal product shall be calculated as a sum total of the elements referred to in Items 1, 2 and 3 of Paragraph (1) and value added tax.
(3) Where there is no ex-factory price in the countries specified in Item 5 of Article 14 (1) herein, the ex-factory price may not be higher than the lowest price in Belgium, the Czech Republic, Poland, Latvia and Hungary.

**Original text**

Образуване на пределна цена на лекарствен продукт, отпускан по лекарско предписание по чл. 2, ал. 3

Чл. 10. (1) Пределната цена на лекарствен продукт, отпускан по лекарско предписание, който не е включен в ПЛС, се образува от следните елементи:
1. цена на производител, която не може да бъде по-висока от левовата равностойност на най-ниската цена на производител за същия лекарствен продукт в страните, посочени в справката по чл. 14, ал. 1, т. 5;
2. надценка за търговец наедро в размер 7, 6 или 4 на сто от заявената по т. 1 цена съобразно критерия, определен в чл. 11;
3. надценка за търговец надребно в размер 20, 18 или 16 на сто от заявената по т. 1 цена съобразно критерия, определен в чл. 11.
(2) Пределната цена на лекарствен продукт се изчислява като сбор от елементите по ал. 1, т. 1, 2 и 3 и данък върху добавената стойност.
(3) (Изм.- ДВ,бр.92 от2014 г.,всилаот07.11.2014 г.) Когато няма цена на производител в страните, посочени в чл. 14, ал. 1, т. 5, цената на производител не може да бъде по-висока от най-ниската цена в Белгия, Чехия, Полша, Унгария, Дания, Финландия и Естония.

**Provincial Legislation**

On a national level, the management and healthcare system coordination is governed by the Minister of Health, who is the sole public authority responsible for the health care in the country. On a regional level, the management and coordination is carried out by the Director of Regional Health Centre (RHC), which is the territorial body of the Ministry of Health, and on a municipal level, the Head of municipal government in health care is responsible for the implementation of the national policies of health.

**Overview of Relevant Provisions**

| Indicator | Provincial Legislation | Provincial Regulation |
|---|---|---|
| **Provincial Government Commitment** Mandatory language | | |
| **Sustainable Financing** State reimbursement scheme | | |
| **Sustainable Financing** State subsidy | | |
| **Rational Selection** Essential medicines framework | | |
| **Affordable Prices** Availability of generics | | |

## Observations

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**Sustainable Financing (State Reimbursement Scheme) Overview**

- The National Health Insurance Fund is the organization responsible for the governance of the compulsory health insurance within the country;

- The National Framework Agreements define the order, the contents and the payment of the health care activities and services provided to the insured population;

- Under the Minister of Health, a National Council on Prices and Reimbursement of medicinal products has the obligation to maintain the medicinal products included in the Positive Drug List;

- The insured population is obligated to pay the physician, the dental doctor or the medical establishment certain amount of out-pocket money for each visit as well as for each day of hospitalization;

| **Sustainable Financing (State Subsidy) Overview** |
| --- |
| Decree № 8 of 16 January 2015 for the execution of the state budget of the Republic of Bulgaria for 2015<br><br>Author's translation:<br><br>**Article 58**.<br><br>Ministry of Health could provide subsidies to hospitals turned into companies with 50 and more than 50 percent state participation, to high-technology activities of national importance according to criteria and procedures determined by the Minister of Health and within the resources stipulated in the Law on State Budget of the Republic of Bulgaria for 2015 for this activity and in compliance with the legislation on state aid.<br><br>**Original text**<br><br>**Чл. 58.**<br><br>Министерството на здравеопазване - то може да предоставя субсидии на болници, преобразувани в търговски дружества с 50 и над 50 на сто държавно участие, за високотехнологични дейности с национално значение по критерии и по ред, определени от министъра на здравеопазването, в рамките на средствата, предвидени в Закона за държавния бюджет на Република България за 2015 г. за тази дейност и при съобразяване със законодателството в областта на държавните помощи.<br><br>**Article 59.**<br><br>**(1)** Ministry of Health subsidizes state and municipal health care institutions for the following activities:<br>1. provision of medicinal products in life-threatening bleeding and urgent surgical and invasive interventions in patients with congenital coagulopathies and medicines and consumables for money parenteral nutrition for patients with short bowel syndrome;<br>2. ambulatory monitoring and treatment of patients with active tuberculosis;<br>3. continuing treatment and rehabilitation of patients with tuberculosis and non-specific lung diseases;<br>4. ambulatory monitoring and treatment of HIV patients and AIDS patients;<br>5. diagnosis and treatment of patients with infectious diseases for the prevention of epidemic risk;<br>6. maintain medical records;<br>7. providing diagnostics, therapy and<br>specialized care for children with high medical risk outside the compulsory<br>health insurance;<br>8. therapeutic apheresis.<br>**(2)** The Ministry of Health subsidizes state and municipal medical establishments for hospital care and government and community centers for psychological care for the following needs:<br>1. Hospital treatment of patients with mental illness, and substitution methadone maintenance programs and daily psycho-rehabilitation programs;<br>2. The medical examination carried out by National Expert Medical Commission (NEMC).<br>**(3)** Outside the cases under par. 1, the Ministry of Health subsidizes the following activities:<br>1. Hospital care for emergency medical assistance to patients with pressing conditions who undergone emergency wards, and who are not hospitalized at the same hospital;<br>2. The state and municipal healthcare centers that provide consultations care of emergency patients at the request of the rescue teams in the emergency medical assistance in cases of art. 11, para. 2 of Ordinance № 25 of 1999 for emergency medical assistance (Prom. SG. 98 of 1999. amend. and suppl., SG. 69 of 2001 and SG. 18 of 2014). |

**(4)** The Ministry of Health subsidizes municipal hospitals that are located in difficult to reach and/or remote areas to carry out activities outside the scope of mandatory health insurance.[21]

**Original text**:

**Чл. 59.**

(1) Министерството на здравеопазването субсидира държавни и общински лечебни заведения за болнична помощ за
следните дейности:
1. осигуряване на лекарствени продукти при животозастрашаващи кръвоизливи и спешни оперативни и инвазивни интервенции при пациенти с вродени коагулопатии и
лекарствени продукти и консумативи за парентерално хранене за пациенти със „синдром
на късото черво“;
2. амбулаторно проследяване (диспансеризация) и активно лечение на пациенти с активна туберкулоза;
3. продължаващо лечение и рехабилитация на пациенти с туберкулоза и с неспецифични белодробни заболявания;
4. амбулаторно проследяване и лечение на пациенти с ХИВ и стационарно лечение на пациенти със СПИН;
5. диагностика и стационарно лечение на пациенти с инфекциозни заболявания за
предотвратяване на епидемиологичен риск;
6. поддържане на медицински регистри;
7. осигуряване на диагностика, лечение и специализирани грижи за деца с висок медицински риск, извън обхвата на задължителното
здравно осигуряване;
8. терапевтична афереза;
9. бъбречнозаместителна терапия.
(2) Министерството на здравеопазването субсидира държавни и общински лечебни заведения за болнична помощ и държавни и общински центрове за психично здраве за следните дейности:
1. стационарно лечение на пациенти с психични заболявания, субституиращи и
поддържащи програми с метадон и дневни психорехабилитационни програми;
2. медицинска експертиза, осъществявана от ТЕЛК.
(3) Извън случаите по ал. 1, Министерството на здравеопазването субсидира:
1. лечебни заведения за болнична помощ
за оказване на спешна медицинска помощ на пациенти със спешни състояния, преминали през спешни отделения, които пациенти не са хоспитализирани в същото лечебно заведение;
2. държавни и общински лечебни заведения за болнична помощ, за оказване на консултативна медицинска помощ на спешни пациенти по искане на дежурните екипи в центровете за спешна медицинска помощ в случаите по чл. 11, ал. 2 от Наредба № 25 от 1999 г. за оказване на спешна медицинска помощ (обн., ДВ, бр. 98 от 1999 г.; изм. и доп., бр. 69 от 2001 г. и бр. 18 от 2014 г.).
(4) Министерството на здравеопазването субсидира общински лечебни заведения, които се намират в труднодостъпни и/или отдалечени райони на страната, за осъществяване на дейности извън обхвата на задължителното здравно осигуряване.

[21] Decree № 8 of 16 January 2015 for the execution of the state budget of the Republic of Bulgaria for 2015, available in Bulgarian on the website of the Ministry of Finance: http://www.minfin.bg/bg/page/940

## Affordable prices Overview

The price for a medicinal product included in the PDL and paid for by public funds is calculated as a sum of the following elements and the value added tax:
- an ex-factory price not higher than the lev equivalent of the lowest exfactory price for the same medicinal product in the countries specified in the information referred to in Article 33;
- the wholesale mark-up at the rate of 7, 6 and 4 per cent of the price declared under Item 1;
- pharmacy mark-up at the rate of 20, 18 and 16 per cent of the price declared under Item 1;

In case there is not an ex-factory price from Romania, France, Estonia, Greece, Slovakia, Lithuania, Portugal, Italy, Finland, Denmark, Slovenia and Spain, the ex-factory price may not be higher than the lowest price for the same medicinal product paid for by the public health insurance funds of Belgium, the Czech Republic, Poland, Latvia and Hungary.

Provided that the exfactory price for a specific medicinal produc cannot be found in the above mentioned countries, the exfactory price may not be higher than the lowest price of a manufacturer/manufacturers entered in the marketing authorisation/the decision of the European Commission in Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March.

## Reforms

**Seven priority areas in the National reform in the Healthcare sector (part of the National Healthcare strategy 2014-2020)**[22]

– Improving the effectiveness of hospital care by creating conditions for guaranteeing basic medical care for the population in inaccessible and remote regions. This step will be supported by subsidizing 51 municipal hospitals. Additionally, the statutory mechanism for establishing and updating the National Health Map were developed. The infrastructure and equipment of the medical treatment establishments is also underlined in this program.
– Optimizing emergency medical care by strengthening the relationship between the centers for emergency care and the other medical institutions (improve the relationships between the National System for Emergency Calls to the Single European Emergency Number 112 and the emergency medical care). Enhanced training and specialization of the people working in the emergency care is also provided for in document.
– Optimized expenditure on medicinal products - Concept Paper on Drug Policy has been produced and its primary aim is to better regulate the role of the actors in the pharmaceutical market. The access of the Bulgarian population to medicinal products will be analyzed and the governments will seek for a more flexible manner for contracting medicinal products, and rationalization in the method of medicine prescription.
– Strategic planning in the financing of hospital activities - the methodology shall reinstate the negotiations principle with regard to health services on the grounds of strategic planning based on objective criteria and available financial resources and will replace the passive reimbursement model. The next steps will include negotiations with medical care establishments and payments based on the methodology.
– Improved control of the activities of medical treatment establishments for hospital care through the implementation of joint checks for abiding the rules of good medical practices.
– The government will develop a new medical standard for general medicine for the purpose of improving the quality of primary care. This initiative has the goal to improve the access to out-patient medical care and will be achieved through the creation of a standard in general medicine. A positive continuation of this step will be the increase of the quality of health services and optimized efficiency in fund spending.
– Reviewing the medical standards for hospital and out-patient care – the government wants to introduce statutory regulation of the principle of implementing hospital care only where the therapeutic purpose cannot be achieved by outpatient treatment. Thus, the number of

[22] Available in English at: http://www.minfin.bg/en/page/867

unnecessary hospitalizations will reduced along with the expenditure of hospital care. Additionally, the statutory instruments regulating the activities of the NHIF will be amended and the main focus of the changes will be related to the transfer of activities from the hospital to the out-patient care, the improved complex monitoring of patients with chronic diseases needing regular care, and the care for pregnant women and children.
- The new reform will also include amendment of the Bulgarian Health Act which will regulate merger of hospitals and dispensaries, and will introduce a new method of payment of the NHIF. The changed legislation will lead to the possibility patients to be treated in one and the same medical facility, where a complete algorithm of treatment will be created. The new method should save more time and money of the patients;

**In the National Program for Sustainable development 2014-2018 the following main alteration in the healthcare system are envisaged:**

- Improving the quality and access to health by advancement of human resources in the healthcare system, technological development and innovation in the health care system, introduction of e-health, optimizing the outpatient care.
- Priority over reconstruction of the emergency care through investments in resources, technical, logistical and personnel development, ensuring efficient organization, coordination and management of the single emergency medical care system.
- Implementation of the National Health Card and accreditation of the health institutions as a tool for effective resource management system in the healthcare.
- Reconstruction of NHIF and its expenditure and making it an active financing and controlling organ representing the insured population – a policy making instrument for providing easier access to a high quality health care.
- Increasing the effectiveness of drug treatment in order to improve quality of life of patients and reduce treatment costs.
- Developing a new model of labor remuneration of workers in the healthcare system.
- Establishing obligatory rules for the NHIF to purchase medicines through transparent and competitive procedures. Mechanisms for transparency and fair competition in the payment of medicinal products and medical devices by the NHIF is introduced. This will be secured by establishing of e-commerce platform in medicinal products in the medical institutions and by creating a registry of medical devices.[23]

[23] Програма на правителството за стабилно развитие на Р. България за периода 2014-2018 г./ Program for sustainable development of the Republic of Bulgaria for the period 2014-2018, available in Bulgarian at: http://www.government.bg/fce/001/0211/files/Government%20programme%202014-2018_.pdf