# THE RIGHT TO MEDICAL CARE IN ROMANIA. ACCESS TO PREVENTIVE MEDICINE

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**Abstract**

*The right to health protection is a fundamental right of the person. But one of the most frequently diagnosed cancers worldwide, breast cancer, is detected in Romania, in 85% of cases, in the advanced stage of the disease, in the context where mammography as a screening method would reduce mortality by 20%. Is there a national prevention program in Romania that transposes the regulations on the European Union level? Romania has created new legal measures in order to improve the right to health protection for its own citizens, but the achieving of this goals implies more attention to the preventive medicine, including screening for breast cancer.*

**Keywords:** right to health protection; preventive medicine; screening; discrimination; oncological disease; COVID-19

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## 1. The Right to Health Protection

The right to health protection is a fundamental right of the person, closely related to his physical and mental, individual and social existence, being defined as such in several international documents, such as the Preamble of the Constitution of the World Health Organization (1946), the Universal Declaration of Rights of Man (1948), the European Social Charter, Revised (1996), the International Covenant on Economic, Social and Cultural Rights and the Charter of Fundamental Rights of the European Union (Pop, 2013, p. 500).

The Romanian Constitution regulates in article 34, through its three paragraphs that:

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"(1) The right to health protection is guaranteed.

(2) The state is obliged to take measures to ensure hygiene and public health.

(3) The organization of medical assistance and the social insurance system for illness, accidents, maternity and recovery, the control of the exercise of medical professions and paramedical activities, as well as other measures to protect the physical and mental health of the person are established according to the law".

The right to health is closely related to public health. Ensuring public health is a general obligation of the state. This obligation is also imposed at the level of the European Union, so ensuring public health at the national level must follow the objectives set at the level of the European Union, taking into consideration the principles of good administration (Slabu, 2018, p. 59). Thus, the three strategic objectives of the EU health policy are the following: promoting good health – preventing diseases and promoting healthy lifestyles by addressing aspects related to nutrition, physical activity, alcohol consumption, smoking and drugs, environmental risks and injuries. Given the aging of the population, the specific health needs of older people also demand more attention, and in recent years greater importance has been given to mental health; protecting citizens from health threats – improving monitoring and emergency preparedness in cases of epidemics or bioterrorism, to increase responsiveness to new health challenges such as climate change.

However, the main responsibility for the protection of health and, in particular, of health systems, still rests with the Member States.

The normative act at the national level that regulates the field of public health is Law no. 95 of April 14, 2006 regarding health reform. According to this law, the field of public health is an objective of major social interest and represents the organized effort of society in order to protect and promote the health of the population. By public health is understood the state of health of the population in relation to the determinants of the state of health: socio-economic, biological, environmental, lifestyle, insurance with health services, the quality and accessibility of health services.

A component of the public health system is public health assistance, which:

- aims at promoting health, *prevent diseases* and improve the quality of life and
- is achieved through the set of political-legislative measures, programs and strategies addressed to the determinants of the state of health, as well as

through the organization of institutions for the provision of all the necessary services.

The importance of the state's obligation to ensure the health of the population and therefore of the correlative right of the citizen to benefit from all the methods and instruments that ensure a good state of his health, is also found in the practice of the High Court of Cassation and Justice. Thus, in a case (Decision no. 1837/2017 of the Romanian High Court of Cassation and Justice) it was shown that: by constitutional norms, art. 16 of the Romanian Constitution, but also international art. 7 of the Universal Declaration of Human Rights, art. 14 of the European Convention on Human Rights, the equality of citizens before the law is recognized and *discrimination is prohibited in whatever form it manifests itself*. Under this aspect, the insured citizen has the right to health care benefits regardless of when this need arises at the beginning of the year, quarter or month and regardless of whether or not a value threshold established by the Romanian State with the distributor of medical services is exceeded. Thus, to accept the fulfillment of the citizen's right until reaching a value threshold in order to exercise his right to health, clearly constitutes discrimination against the citizen who did not have the "chance" to get sick during the period accepted for settlement.

## 2. Prevention of Oncological Diseases during COVID-19 Pandemics

In the past, Romania lost the start several times in the promotion and implementation of medical policies focused on prevention and ensuring access to medical services for early diagnosis but also for adequate treatment (for example, the issue of oncological conditions should be carried out on the following levels: early detection; prevention; recovery; treatment; palliative care. Romania focused only on recovery and treatment, leading to a very large financial effort for curative cancer treatment).

With the COVID-19 pandemic, this situation has worsened, and now, through a retrospective analysis, we can identify a series of deficiencies in the medical system that prevented it from functioning properly (Dinu, 2021, p.109). Only by determining the causes that led to the lack or a restricted access to medical services, we will be able to establish what objectives can be envisioned in order to improve this access and prevent the repetition of borderline situations such as those with which both patients/patients and staff medical they faced.

The resource effort is twofold, as Romania must implement preventive medicine, but at the same time, it must repair the deficiencies identified especially during the COVID-19 pandemic, in order to be able to prepare in the event of a new virological "attack".

Patient access to medical services and treatments has become difficult during the COVID-19 pandemic, among the determining factors being the transformation of specialized medical units into COVID-19 units or the temporary abolition of some wards (for example, palliative care departments within hospitals of pneumophthisiology).

Patients diagnosed with oncological conditions, but also persons suspected of such conditions, must have access to diagnosis and treatment. The COVID-19 pandemic led to certain difficulties that these categories of people faced, despite the fact that chronic patients who required diagnostic or therapeutic interventions, the timing of which could lead to a reduction in the chances of survival, were exempted from the restrictions regulated.

The Romanian National Health Strategy 2022-2030 provides as a strategic objective the creation of clinical care networks, with the role of ensuring the continuity of diagnostic and treatment services for patients, including for oncological pathology - an objective aligned with the European Cancer Plan. For this objective, the Health Operational Program 2021-2027, which is in the negotiation stage to be approved by the European Commission, provides important financial allocations, both in terms of investments in the infrastructure of oncology services, and in terms of the development of protocols , guidelines and standards of care for cancer patients.

We find that these objectives regarding the prevention and control of cancer are found in the European Plan to fight cancer, which aims to support the member states of the European Union in the implementation of the necessary measures for prevention, early diagnosis, treatment, quality of life of cancer patients - presented plan to the general public on February 3, 2021.

Also, according to the Annex to the Communication of the European Commission on the Plan to fight cancer, one of the closest objectives is "Updating the European Cancer Information System for monitoring and evaluating cancer screening programs" (2021-2022) - Section on diagnosis early stage of cancer. From the statistics provided by the European Cancer Information System (ECIS), in 2020, Romania ranks last in terms of detected cancer cases.

## 3. Access to Screening for Breast Cancer

Regarding the situation of early diagnosis of oncological diseases, the Romanian medical website Raportul de Gardă.ro mentions that, according to Eurostat, Romania remains in last place in the EU in terms of screening for breast cancer, even if the percentage has increased from 0.2% to 9% in recent years.

According to the information published on the same website, "according to the latest Eurostat survey, only 9% of Romanian women between the ages of 50 and 69 reported in 2019 that they had a mammogram in the last 2 years. Once again, Romania ranks last in the EU. For Bulgaria, in penultimate place, the percentage is 36% - 4 times more than in Romania. In Sweden, the percentage is 95%, about 11 times more".

Thus, it is estimated that, in 2020, almost 4000 women died in Romania from breast cancer.

Starting from 2014, the National Romanian Health Strategy explicitly mentioned the introduction of organized population screening procedures for breast cancer, followed by actions to access non-reimbursable funding, with the ultimate goal of creating a National Screening Program for Breast Cancer, whose objective generally expected was to decrease breast cancer mortality in Romania by 5% until 2030.

Within the screening for breast cancer, two screening tools are provided - mammography and breast ultrasound, currently with two types of funding - the European Social Fund and the Unique National Fund of Social Health Insurance.

1. The financing of the National Breast Cancer Screening Program is ensured through the European Social Fund within the project "Increasing the institutional capacity and professional skills of specialists in the health system for the purpose of implementing the National Breast Cancer Screening Program" - implemented by the Institute Oncologist "Prof. dr. Ion Chiricuță" Cluj Napoca, Romania, in partnership with the National Institute of Public Health. The project contains the following:

a) a national project to prepare and plan the implementation of screening in safe and quality conditions according to European recommendations;

b) two North West – West regional pilot projects; North East – South East.

Beneficiaries in the project would be 60,000 women, of whom at least 50% are people from vulnerable groups, aged between 50 and 69, who are going to be provided with mammography testing.

2. Through the Unique National Fund of Social Health Insurance (FNUASS), funding is ensured within the basic package, according to the common *Order of the health minister and the president of the National House of Health Social Ensurance no. 1068/627/2021 regarding the approval of the methodological norms for the application in 2021 of the Government Decision no. 696/2021 for the approval of the service packages and the framework contract regulating the conditions for the provision of medical assistance, medicines and medical devices within the social health insurance system for the years 2021-2022, with subsequent amendments and additions*, for several types of medical services for the purpose of diagnosis-case and paraclinical investigations of medical imaging radiology and nuclear medicine.

Thus, women between the ages of 50 and 69 who meet the following criteria are eligible for the program for the early detection of precancerous lesions of the breast:

1. do not have a confirmed diagnosis of breast cancer;
2. are asymptomatic;
3. have no history suggestive of breast cancer pathology.

The mentioned medical services (general surgery/obstetrics-gynecology consultation/mammography performance/result communication) are performed once every 2 years by presentation to the obstetrics-gynecology or general surgery specialist, in order to detect dysplastic breast lesions early. In case of a negative result, the investigation is repeated after 2 years.

Also, beneficiaries are the asymptomatic women aged 50-69, with positive mammography results, who:

1. do not have a confirmed diagnosis of breast cancer;
2. are asymptomatic;
3. have no history suggestive of breast cancer pathology.

Medical services (general surgery/obstetrics-gynecology consultation, mammography, breast ultrasound, result communication) are performed once every 2 years by presentation to the obstetrician, gynecology or general surgery specialist, in order to detect dysplastic lesions of the breast early. In case of a negative result, the investigation is repeated after 2 years.

We undeline that by point VII (2) b) Chapter 1, Annex 1 of *Government Decision no. 423/2022 on the approval of national health programs*, the Screening Subprogram organized on a population basis for breast cancer was introduced, within the National Screening Program organized for chronic diseases with an impact on public health and this program is financed from the budget of the Ministry of Health.

This approach was motivated by the need to ensure the legislative framework necessary for the implementation of the priority objectives of the European Cancer Plan, transposed in Romania through the National Cancer Plan.

In conclusion, there is a regulated legal framework that allows the implementation of the breast screening program, the aforementioned government decision entering into force on April 1, 2022.

However, we believe that the implementation of this program for the early detection of precancerous/cancerous lesions of the breast requires a certain strategy to bring the necessary information to the public's attention, but also to facilitate access to this program for people who belong to certain vulnerable categories, such as, for example, people from rural areas or those with low incomes, or certain age categories.

Access to preventive medical care implies the following:

**1. In primary healthcare:**

1.1. Within the minimum package of medical services in primary healthcare, preventive consultations for people over 18 include:

a) Anamnesis, objective examination, diagnosis;

b) Recommendation for paraclinical examinations for inclusion in a risk group; medical advice, hygienic-dietary regimen recommendations.

The consultation can be carried out once every 3 years, for the prevention of diseases with major consequences in terms of morbidity and mortality, at the request of the person receiving a minimum package of medical services or at the request of the family doctor, and for people who do not have a family doctor, it is settled a consultation once every 3 calendar years.

1.2. As part of the basic package of medical services in primary health care, preventive consultations for individual risk assessment are given to asymptomatic adults, at the family doctor's office, to the following categories of beneficiaries:

a) all asymptomatic persons aged between 18 and 39 years – 1 (one) consultation every 3 calendar years/insured/prevention package; for people aged between 18 and 39 identified as high risk, preventive evaluation consultations are granted annually and a maximum of two consultations/insured/year are settled.

The prevention package also includes paraclinical investigations - laboratory analyzes (complete blood count, ESR, blood sugar, total serum cholesterol, LDL cholesterol, serum creatinine, VDRL/RPR - for women planning a pregnancy).

b) all asymptomatic persons aged > 40 years – 1-3 consultations/insured/prevention package, annually.

The prevention package includes a maximum of 3 consultations and consists of the assessment of exposure to risk factors and the completion of the riskogram, plus paraclinical investigations - laboratory analyzes (complete blood count, ESR, blood sugar, total serum cholesterol, LDL cholesterol, serum creatinine, PSA in men and TSH and FT4 in women).

The preventive services for asymptomatic adults contained in letter B of Annex 2 B to the Order of the Minister of Health and the President of CNAS no. 1068/627/2021, with subsequent amendments and additions, the individual risk assessment consultation for asymptomatic adults aims to identify and intervene on modifiable risks associated with conditions with a high burden of disease: cardiovascular and metabolic diseases, cancer, mental health, reproductive health.

As part of the preventive consultations to assess the individual risk of asymptomatic adults aged between 18 and 39 years, respectively aged > 40 years, a riskogram is made that also includes the oncological risk assessment, and high-risk persons are sent for assessment and monitoring by specialty, based on the referral ticket issued by the family doctor.

Also, according to art. 2 para. (4) of Annex 18 to the Order of the Minister of Health and the President of CNAS no. 1068/627/2021, with subsequent amendments and additions, for medical laboratory tests recommended by family doctors to asymptomatic people aged > 40 years, as part of the preventive consultations from the basic package, the amounts contracted with the health insurance companies can be supplemented by additional documents, after the end of the month in which they were granted, within the limits of the funds allocated to medical assistance in the specialized outpatient clinic for specialties paraclinical.

2. Within the specialized ambulatory medical care for clinical specialties

- medical services for diagnostic purposes - day hospitalization services.

a) early detection of precancerous lesions of the breast, is settled only if all mandatory services have been performed: general surgery/obstetrics-gynecology consultation/mammography.

Beneficiaries: asymptomatic women in the age group of 50-69 years who do not have a confirmed diagnosis of breast cancer, are asymptomatic, have no history suggestive of breast cancer pathology. It is performed once every 2 years.

b) early detection of precancerous lesions of the breast with suspicion identified mammographically.

### 3. In Hospital Medical Care

In the social health insurance system in Romania, the sanitary unit with beds in a contractual relationship with the health insurance company, regardless of the form of ownership (public or private), is obliged to provide medical services and support for the insured hospitalized in the hospital regime , all expenses necessary to solve the respective cases, including necessary paraclinical investigations.

According to art. 248 para. (1) of Law no. 95/2006 on health reform, republished, with subsequent amendments and additions, the services that are not settled from the fund, their consideration being borne by the insured, are:

- some high performance medical services;
- hotel services with a high level of comfort;
- aesthetic corrections made to people over 18 years of age (as an exception, the FNUASS budget covers the cost of breast reconstruction by endoprosthesis and its subsequent symmetrization in the case of oncological surgeries), etc.

Regarding the strategy of bringing to the public's attention the information necessary to ensure access to prevention services, on the CNAS website, in the "Insured information" section, the document "Guide to the Insured" can be found.

The project "Increasing the institutional capacity and professional skills of specialists in the health system for the purpose of implementing the National Screening Program for breast cancer", in addition to the main activities (developing the methodology for implementing the screening program that adapts to national circumstances the European Insurance Guidelines of Quality; the development of the IT application for the record of women tested in the program; the development of an information and awareness campaign regarding breast cancer prevention and participation in screening), prepared the implementation of two regional pilot projects:

1. "Be responsible for your health - regional programs for prevention, early detection, diagnosis and early treatment of breast cancer" for the North-West-West

region, implemented by the Oncological Institute "prof. dr. U. Chiricută" in partnership with Timisoara Municipal Hospital;

2. "Be responsible for your health - regional programs for prevention, early detection, diagnosis and early treatment of breast cancer" for the Northeast-East region, implemented by the Regional Institute of Oncology Iași in partnership with the "Enable" Foundation.

The two regional projects are based on the methodology developed in the phase I project and all will produce at the end of the implementation period, November 2023, the results that will substantiate the expansion of the pilot projects at the regional and national level.

Consequently, it can be deduced that this project did not currently lead to the mammography testing of the 60,000 beneficiary women (according to the response of the Ministry of Health), and the notified public authorities did not provide details about the implementation stage of the two regional projects.

We underline the fact that, according to the Profile on the status of public health in Romania (2021) developed by the European Commission, it follows that the preventable mortality rate is the third highest in the European Union, and the mortality from treatable causes is more than double the average European Union and includes deaths from prostate and breast cancers that are amenable to treatment.

Considering the inclusion of the Population-Based Screening Subprogram for breast cancer, within the National Screening Program organized for chronic diseases with an impact on public health, by Government Decision No. 423/2022 on the approval of national health programs, which entered into force on April 1, 2022, we believe that the new legal framework will have the long-term objective of reducing the differences in health status between Romania and the EU and between disadvantaged groups and the national average situation, but in short-term creates limitations and discrimination.

According to art. 51 para. (1) and para. (5) of the Law on health reform, republished, with subsequent amendments and additions, national health programs are developed by the Ministry of Health, with the participation of CNAS, and their development is carried out by the Ministry of Health for the national public health programs, and in this sense, the Technical Norms for the implementation of the national health programs are approved by order of the Minister of Health for the national public health programs.

Also, according to art. 15 para. (1) of the 2022 Technical Norms for the realization of national public health programs, approved by Order of the Minister of Health no. 964/2022:

d) "within the Oncological Institute "Prof. Dr. I. Chiricuță" UATM of the Oncological Institute "Prof. Dr. I. Chiricuță", which provides technical assistance and management for:

2. The national screening program organized for chronic diseases with an impact on public health - The screening subprogram organized on a population basis for breast cancer, implemented in the North-West region that groups the counties of Bihor, Bistrița-Năsăud, Cluj, Sălaj, Satu Mare and Maramureş and the West region which groups the counties of Arad, Caraş-Severin, Hunedoara and Timiş";

e) within the Regional Institute of Oncology Iasi, the UATM of the Regional Institute of Oncology Iasi is organized and operates, which provides technical assistance and management for:

2. The national screening program organized for chronic diseases with an impact on public health - The screening sub-programme organized on a population basis for breast cancer, implemented in the North-East region that groups the counties of Bacau, Botoşani, Iaşi, Neamț, Suceava and Vaslui and the region South-East which groups the counties of Brăila, Buzău, Constanța, Galati, Tulcea and Vrancea.

According to the same Technical Norms, "The population-based screening subprogram for breast cancer is implemented in a pilot regime, financed by non-reimbursable external funds and which, in accordance with the recommendation of the Council of Europe REC [2003] regarding the introduction of population screenings for cancer, with the guidelines European quality assurance in cancer screening programs and with the roadmap for the implementation of the European Cancer Plan published by C.E. in October 2021, it will be expanded at the regional and national level based on the uniform implementation, monitoring and evaluation methodologies (s.n.)".

According to Annex 14 to the Technical Regulations, no state budget allocated to this subprogram was mentioned.

Considering the information communicated by the notified authorities, as well as the stated legal provisions, we note that we have not been provided with concrete data regarding the stage of implementation of the breast cancer screening subprogram in the East, North-East, West regions, North-West, as well as the fact

that for the rest of the regions of the country *no budget is allocated to ensure access to breast cancer screening for women in the age group 50 - 69.*

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