



# Program Information Document (PID)

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Concept Stage | Date Prepared/Updated: 15-Apr-2019 | Report No: PIDC179111



**BASIC INFORMATION**

**A. Basic Program Data**

Country Romania	Project ID P169927	Parent Project ID (if any)	Program Name Romania Health Program for Results
Region EUROPE AND CENTRAL ASIA	Estimated Appraisal Date 06-May-2019	Estimated Board Date 19-Nov-2019	Does this operation have an IPF component? No
Financing Instrument Program-for-Results Financing	Borrower(s) Romania	Implementing Agency Ministry of Health	Practice Area (Lead) Health, Nutrition & Population

**Proposed Program Development Objective(s)**

The Program Development Objective (PDO) is to increase the coverage of primary health care for underserved populations and improve the efficiency of health spending by addressing underlying institutional constraints.

**COST & FINANCING**

**SUMMARY (USD Millions)**

<b>Government program Cost</b>	55,473.00
<b>Total Operation Cost</b>	4,601.00
Total Program Cost	4,601.00
<b>Total Financing</b>	4,601.00
<b>Financing Gap</b>	0.00

**FINANCING (USD Millions)**

<b>Total World Bank Group Financing</b>	570.00
World Bank Lending	570.00
<b>Total Government Contribution</b>	4031.00



## B. Introduction and Context

### Country Context

- Romania is an upper-middle income country with a GNI per capita of USD 9,970 and a population of approximately 19.7 million in 2017.** The population has been declining at an average annual rate of 0.6 percent since 1990 due to low fertility and high premature mortality, as well as high levels of migration. This has resulted in a relatively older demographic structure of the population. The old age dependency ratio – or the number of people aged 65 and over as a share of the working age population – is 27 percent.
- Romania's membership to the European Union (EU) has triggered important positive socio-economic and political transformation in the country.** Since Romania joined the EU in 2007, the country has benefitted substantially from the free movement of capital and labor and from access to grants associated with membership. Entry into the EU opened the door for fundamental societal changes and has enabled modernization linked to the EU economic markets and institutions. The EU has become an anchor for Romania's prosperity and has spurred the process of income convergence with the other members. The country's gross domestic product (GDP) per capita (at purchasing power standard) increased from 30 percent of the EU-28 average in 1995 to around 61 percent in 2017. Over 70 percent of Romanian exports go to the EU, which is also the main source of investment into the country. Social and political progress has accompanied these gains.
- Following parliamentary elections in December 2016, Romania is governed by a coalition.** The governing coalition consists of the Social Democratic Party and the Liberal-Democratic Alliance. In January 2018, the coalition appointed a Cabinet led by Prime Minister Viorica Dăncilă, the first woman to lead the Romanian Government. The Government's priorities for 2017 –2020 include investments in infrastructure, health care, education, agriculture, job creation, and small and medium enterprise development, and tax and pension reforms. The first two years of the coalition have been marked by a high turnover of ministers – three prime ministers and over 70 ministers took office since the December 2016 elections –which has impacted the predictability of policy-making and affected the investment climate.
- Despite political volatility, Romania enjoys high rates of economic growth, but macroeconomic imbalances are widening.** Romania's economy grew by 7 percent in 2017 and 4.1 percent in 2018, driven by consumption, investment and exports. Information and communication technology sector is one of the most dynamic in Europe, but foreign direct investment inflows of around 2 percent of GDP per year remain below potential. High economic growth and external migration have triggered increased labor shortages for both skilled and unskilled jobs. A series of pro-cyclical fiscal measures was promoted in 2017, consisting mainly of tax cuts (value-added, income, profit) and pensions and public sector wage increases. These measures boosted private consumption, leading to a peak in inflation in May 2018, at 5.4 percent, and the widening of the current account deficit, which reached 4.7 percent of GDP at end-2018. Although recurrent public spending expanded by 16.5 percent in 2018, the fiscal deficit was contained at 2.9 percent of GDP, but at the expense of the investment budget. Public debt, at 42.1 percent of GDP<sup>1</sup> as of November 2018, remains one of the lowest in the EU. A slowdown in Romania's export markets in the EU, mainly Germany and Italy, could generate important domestic adverse effects on growth and investment. These could be exacerbated by the uncertainty in fiscal policy, coupled with a tightening labor market. The partial decoupling of real wage growth and productivity could also affect Romania's competitiveness, putting supplementary upward pressures on the current account deficit.

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<sup>1</sup> Source: Ministry of Public Finance.

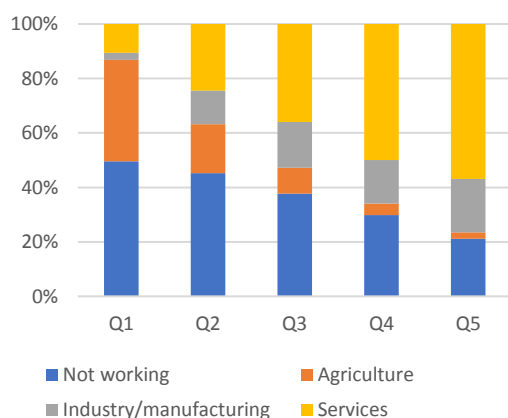


5. **Economic growth has positively impacted poverty.** In line with robust economic growth, a boost in private consumption and labor market improvements, the poverty rate corresponding to upper middle-income countries (using the USD 5.50/day 2011 purchasing power parity poverty line) is forecast to have declined to 22.3 percent in 2018, from 25.6 percent in 2015, after peaking at nearly 32 percent in 2012. The incomes of the bottom 40 of the population were boosted by employment gains in sectors with a large share of low-skilled workers. The impact has been stronger for those in the bottom 80 percent of the income distribution, who have seen an increasing share of total income over this period. This has contributed to a reduction in inequality, reversing the rise in the Gini index seen between 2010 and 2016. Since 2014, poverty declined in both rural and urban areas, but in 2016 poverty rates in rural areas remained six times higher than in cities and just over twice as high as in towns and suburbs.

6. **Despite progress, Romania continues to face large social and spatial disparities in inclusion, presenting a significant development challenge.** The incomplete structural transformation is associated with an uneven spatial distribution of opportunities – 45 percent of the population still resides in rural areas, where poverty is substantially higher. Disparities in living standards between urban and rural areas are striking: the urban-rural gap in mean equivalized net income is the second-highest in the EU, with mean urban income almost 50 percent higher than mean rural income. Poverty rates also vary significantly across regions, with poverty in some counties in the North-East region being more than ten times higher than that of Bucharest (Map 1). Consequently, the poor are concentrated in regions with high rates of poverty (Map 1).

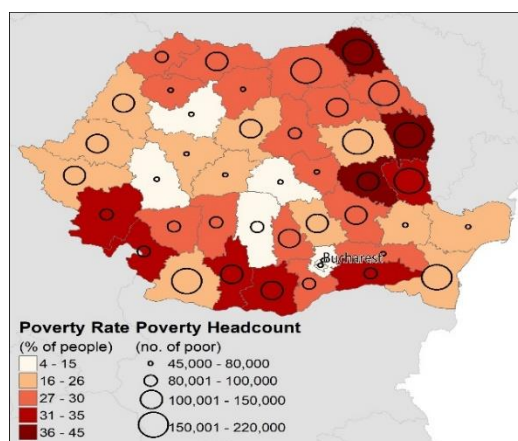
7. **This strong duality is a manifestation of unequal opportunities and unequal access to markets that has no parallel in any other EU country.** Disparities in endowments (notably human capital) and various factors that influence the returns to endowments combine to shape the high levels of social and regional disparities, and fiscal policies have failed to counter high levels of inequality. To counter the consequences of a shrinking and aging population, driven mainly by external migration of its working-age population, Romania faces an imperative to enhance equality of opportunities, -between groups and across regions-, to foster broad-based improvements in living standards and allow those at the bottom to contribute more actively to economic growth, which could trigger a virtuous cycle of inclusive growth and development.

**Figure 1: A large share of the bottom 40 percent has limited access to work or relies on subsistence agriculture**



Source: Romania SCD -staff calculation using EU-SILC 2016.

**Map 1: The poor are concentrated in regions with high rates of poverty**



Source: Romania SCD based on World Bank (2016).



8. **The need for tailored and integrated social services targeting vulnerable groups is acknowledged in the 2015-2020 Government Strategy on Social Inclusion and Poverty Reduction.** In the Government's strategy, vulnerable groups are defined irrespective of poverty levels, as they face other barriers to social service access. Vulnerable groups thus require targeted and integrated interventions to increase their social and economic participation. The main categories of vulnerable groups identified in the Government's strategy are poor people, children, youth deprived of parental care and support, lone or dependent elderly, Roma, persons with disabilities, people living in marginalized communities, and other vulnerable groups.<sup>2</sup> In 2013, vulnerable groups in Romania included an estimated 1.85 million Roma, 1.4 million poor children aged between 0 and 17 years, over 725,000 people aged above 80 years, 687,000 children and adults with disabilities living in households, 16,800 children and adults with disabilities living in institutions, 62,000 children living in placement centers or family-type care, and 1,500 children abandoned in medical units.

9. **Human capital is a central driver of sustainable growth and poverty reduction, and Romania has made substantial progress in improving health outcomes and educational attainment over the last two decades, but challenges remain.** Between 1990 and 2016, life expectancy increased from 69.7 to 75.0 years, while under-five mortality declined from 31.1 to 8.5 deaths per 1,000 live births. Expected years of schooling stand at 12.2 years in 2017, but factoring in what children actually learn, expected years of school is only 8.8 years. This translates into Romania's relatively low human capital index of 0.60, which is significantly below the predicted values for its income level and puts Romania in the 67<sup>th</sup> place out of 157 countries surveyed. This indicates that a child born in Romania today will only be 60 percent as productive when the child grows up as he/she could be if he/she enjoyed complete education and full health.

#### Sectoral and Institutional Context of the Program

10. **While health outcomes have improved in Romania over the past two decades, they remain below the EU average, with significant geographic disparities.** Healthy life expectancies in Romania at 57.9 years for women and 58.6 years for men are lower than the EU average of 61.5 years for women and 61.4 years for men, respectively. Furthermore, national averages hide significant gaps in health outcomes: for instance, the mortality rate in rural areas is 15.4 deaths per 1,000 population compared to 11.7 deaths per 1,000 population in urban areas.<sup>3</sup> Breast and cervical cancers are the top two causes of death among women ages 15-49, and Romania has the highest cervical cancer mortality rate in the region.<sup>4</sup> The rate of amenable mortality in Romania is the highest in the EU for women and the third highest for men, which signal that there are opportunities to improve health outcomes through provision of essential services and public health interventions.

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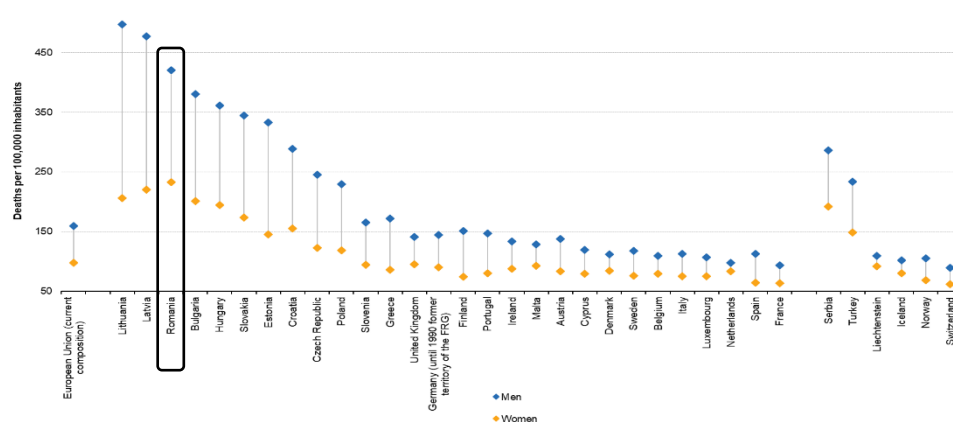
<sup>2</sup> This category includes persons suffering from addiction, persons deprived of freedom or on probation, homeless people, victims of domestic violence, victims of human trafficking, refugees, and immigrants.

<sup>3</sup> National Institute of Statistics. Romania. 2015.

<sup>4</sup> Institute for Health Metrics and Evaluation.



Figure 2: Amenable mortality rates in EU countries in 2015



Source: Eurostat.

11. **Romania has relatively low levels of utilization of the essential services required for an effective health system response to the high burden of chronic diseases.** The proportion of women aged 20 to 69 years who are screened for cervical cancer within the recommended three-year interval is 25 percent in Romania, relative to an average of 60 percent in the EU.<sup>5</sup> In 2017, while 94 percent of children across the EU received at least one dose of the measles vaccine before age one, in Romania the vaccination rate was 87 percent, and coverage has declined by ten percentage points from 97 percent in 2000.<sup>6</sup> In 2013, the number of primary health care (PHC) contacts per person per year in Romania was 4.8, which was lower than the EU average of 6.9.<sup>7</sup>

12. **The uninsured, 14 percent of the population, are reported to have lower rates of utilization of essential health care in Romania.** While the insured population is entitled to a basic benefits package that covers a wide range of preventive, curative, and rehabilitative services (Table 1), the uninsured are entitled to a minimum benefits package that covers only life-threatening emergencies, infectious diseases, and birth, and there are volume caps for reimbursement for these services and services provided to the insured. The uninsured include the Roma population who lacks identity cards, the unemployed or self-employed persons who are not registered for benefits, and informal workers. While 18 percent of urban residents are uninsured, the proportion of rural residents who lack insurance is 21 percent. Only 50 percent of all Roma aged 16 years or older in Romania are covered by health insurance compared to 80 percent of the general population.<sup>8</sup> In 2017, the average number of reimbursed health services per uninsured person was 0.03 compared to 3.11 services per insured person, which is a result of both under-utilization and under-reporting.

<sup>5</sup> OECD/EU (2018), Health at a Glance: Europe 2018: State of Health in the EU Cycle.

<sup>6</sup> OECD/EU (2018), Health at a Glance: Europe 2018: State of Health in the EU Cycle.

<sup>7</sup> World Health Organization. European Health Information Gateway. January 2018.

<sup>8</sup> Romania Systematic Country Diagnostic Background Note: Roma Inclusion. June 2018.



**Table 1: Minimum and basic benefits packages for PHC**

<b>Minimum benefits package</b>	<b>Basic benefits package</b>
<i>Reimbursed by fee-for-service</i>	<i>Reimbursed by fee-for-service</i>
<ul style="list-style-type: none"> <li>• medical-surgical emergencies;</li> <li>• surveillance and identification of diseases with epidemic potential;</li> <li>• pregnancy registration and monitoring consultations;</li> <li>• consultations for family planning;</li> <li>• preventive consultations for asymptomatic adults;</li> <li>• other activities (death ascertainment and certificates etc.).</li> </ul>	<ul style="list-style-type: none"> <li>• consultations for acute and sub-acute conditions or acute manifestations of chronic conditions;</li> <li>• periodic consultations for chronic patients;</li> <li>• case management consultations based on integrated management plans (hypertension, dyslipidemia, type 2 diabetes mellitus, chronic obstructive pulmonary disease, asthma, chronic kidney disease);</li> <li>• preventive consultations (0 to 18 years);</li> <li>• pregnancy registration and monitoring consultations;</li> <li>• preventive consultations for asymptomatic adults;</li> <li>• home consultation for patients unable to travel;</li> <li>• home consultation for death ascertainment;</li> <li>• drug administration services (tuberculosis patients);</li> <li>• additional services - abdominal and pelvic ultrasound.</li> </ul>
	<i>Reimbursed by capitation</i>
	<ul style="list-style-type: none"> <li>• medical-surgical emergencies;</li> <li>• surveillance and identification of diseases with epidemic potential (infectious diseases);</li> <li>• consultations for family planning;</li> <li>• support activities (sick leave, referrals, prescriptions, medical certificates, death certificates etc.);</li> <li>• drug administration services (other).</li> </ul>

Source: Framework Contract 2017-2018.

13. **Significant gains in efficiency and effectiveness could be made by recalibrating expenditures toward prevention and primary care.** The Romanian health sector, which is largely public financed (80 percent), is characterized by low levels of spending, including underfunding of PHC, and inefficient resource allocation. Romania allocates less than 6 percent of GDP to health care compared to an average of about 10 percent in the rest of the EU. Government spending is the main source of funding, representing 78 percent of current health spending and consisting largely of social health insurance contributions and general government transfers for the exempt categories. While government health expenditures grew between 2013 and 2017 in Romania, per capita spending, at EUR 983, was far below the EU28 average of EUR 2,773 in 2017, and five times less than the weighted health spending per capita in the EU15 countries.<sup>9</sup> The National Health Insurance House (NHIH) – the purchasing agency for health services – accounts for 67 percent of total health spending. Almost half of National Health Insurance Fund (NHIF) annual expenditures are spent on hospital care, with only 6 percent being spent on family medicine, which is the most important delivery modality for both primary and secondary prevention activities. In contrast to the low spending on primary care and low coverage of preventive programs, such as cancer screening, the three National Health Program, which cover treatment costs (mostly medication) for oncology, diabetes, and dialysis, account for 13 percent of total NHIF expenditure.

14. **Medicines and therapeutic devices are a significant cost driver, which has prompted the Government to implement pharmaceutical regulation focused on containing costs and curbing increased demand.** Between 2006 and 2017, medicines and therapeutic devices accounted for 37.5 percent of health spending, which is more than double the EU average. Five positive lists of pharmaceuticals are published by the National Agency for Medicines and Medical Devices,

<sup>9</sup> EU15 are the 15-member countries in the EU prior to the accession of ten candidate countries on May 1, 2004; the EU13 are the countries that have acceded to the EU since 2004; and the EU28 are all member states of the EU.



with input from the Health Technology Assessment (HTA) Department. A reference price system is used for all drugs on the lists, taking into account a basket of 12 EU countries.<sup>10</sup> Drugs that are reimbursed by NHIH are included in positive lists defined by the Ministry of Health (MoH) following a simple scorecard-based HTA process undertaken by the HTA Department. A reference pricing system is also applied for reimbursed medicines to determine patient co-payments. Reference prices (covered by the NHIH) are based on the lowest-priced product within a cluster of medicines. Clusters are mostly molecule-based (i.e., international non-proprietary denomination), with some exceptions when different molecules of similar therapeutic effect are grouped together. Expenditures on medicines are also controlled through the claw-back tax<sup>11</sup> (introduced in 2011) and a system of managed entry agreements (cost–volume and cost–volume outcome agreements) for innovative medicines that are granted conditional reimbursement recommendations by the HTA process, implemented as of 2015.

15. **Implementation of various pharmaceutical policies needs to be adjusted for greater impact.** The price referencing is not regularly implemented. The HTA assessment does not take into account the cost-effectiveness of medicines in the Romanian context; instead it awards points based on therapeutic benefit, reimbursement status in other countries, treatment costs, and evidence published in other countries.<sup>12</sup> The clawback tax represents almost 6.6 percent of NHIH revenues. There is concern, however, that the combined effect of regulatory measures impacting prices has disproportionately affected some of the old and very cheap generics that have as a result been withdrawn from the market by pharmaceutical companies due to unprofitability. There are also concerns that the lower prices of some medicines in Romania compared to other EU countries may lead to parallel exports, which may threaten access to certain innovative medicines. The number of medicines under managed entry agreements (approximately 30 in 2018) is much lower than in other countries in the region.

16. **Decentralized procurement of medical supplies and devices leads to substantial inefficiencies in public spending.** Hospital procurement in Romania is highly fragmented: over 350 public hospitals individually procure almost all medicines, medical supplies, and medical devices. While the NHIH-administered clawback tax and managed entry agreements effectively control expenditure on hospital medicines through financial ceilings imposed on the pharmaceutical industry, decentralized procurement of medical devices done at the level of health care facilities presents missed opportunities for economies of scale. In addition, it leads to a lack of standardization and multiplication of administrative procurement activities. Information on the numerous procurement processes, including tendered prices, is not routinely shared through formal channels between hospitals or with the MoH to inform procurement practice. Scarce analyses point to substantial differences between unit prices of identical goods in individual hospitals, which provides ample opportunities for savings.

17. **Limited use of information for decision making is a lost opportunity.** Although a lot of data is collected, there is a high degree of data fragmentation and duplication of data collection. The NHIH manages the Integrated Unique Informatics System (SIUI), which collects information, including patient medical information, from contracted providers. Aggregate data are published on the National School of Public Health Management and Professional Development (NSPH)

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<sup>10</sup> Czech Republic, Bulgaria, Hungary, Poland, Slovakia, Austria, Belgium, Italy, Lithuania, Spain, Greece, and Germany.

<sup>11</sup> Under the clawback tax, every quarter, each producer must return to the state budget a percentage of the profits (the clawback point) according to a formula that depends on the difference between the sales value in that quarter and the reference sales value set annually by the government. Medicines under the managed entry agreements are not subject to the claw back tax.

<sup>12</sup> The French National Authority for Health, the Institute for Quality and Efficiency in Health Care in Germany, the National Institute of Health and Care Excellence in England, and the Scottish Medicines Consortium, among others.





and on the website of the NHIH. The NHIH electronic health record (EHR), however, is not integrated with the community care information system. The MoH does not have access to the NHIH database, and due to a lack of standardization, communication between and within systems is minimal. Due to a lack of a centralized data exchange platform, there is limited analysis of the collected data and poor use of information for decision-making.

**18. Recognizing the inefficient system of service delivery that is heavily skewed towards inpatient care, the government of Romania has identified primary care as a central component of the National Health Strategy 2014-2020.**

As outlined in the Strategy, the goal is to restructure the inefficient pyramid of services and to gradually ensure a wider coverage of the population health needs through the services at the foundation of the system (community care services, health care services provided by the family doctor, and specialized ambulatory). In addition, the Strategy identifies cross-cutting solutions that would improve the sustainability and predictability of the health system to ensure financial protection and quality and access to care.

**19. The vision of enhanced primary care for 2014-2020, however, is yet to materialize.** Access to effective primary care is still limited by constraints in financing and service delivery:

- Overall suboptimal supply of family physicians limits PHC provision in Romania. The absolute density of family physicians in Romania was 0.60 per 1,000 population in 2013, below the EU15 average of 0.87 per 1,000 population, and above the EU13 average of 0.45 per 1,000 population.<sup>13</sup>
- Underpopulated and rural areas have a significantly lower supply of family physicians than urban areas, contributing to geographic disparities in access to care. In 211 local public administration authorities, over 90 percent of which are rural, there is no family physician – these authorities are considered underserved. The Roma are less likely to be enrolled with a family medicine practice; up to 9 percent of Roma are not registered with a family physician, which is double the rate in the general population.<sup>14</sup>
- Conditions in family medicine practice are not up to modern standards for providing effective primary care, particularly in rural areas.
- Effectiveness of PHC is limited by existing clinical guidelines and provisions of the framework contract between the NHIH and providers, which does not allow for performance-based payments that reward the attainment of targets related to service outputs and health outcomes. The framework contract also includes cost-containment caps on fee-for-service reimbursements that lead to undersupply of preventive and case management services, as well as under-reporting of services above the cap.
- Primary care physicians have a gatekeeping role in Romania, but bypassing is allowed for acute or emergency conditions. With limited triage, patients continue to opt for emergency services for care that can be provided in family medicine settings.
- Technical and managerial capacity gaps prevent community health care from linking underserved communities to PHC. Only 20 percent of family physicians report regular meetings with community health personnel.<sup>15</sup> There are no official protocols for community health care nor guidance on coordination with PHC physicians and nurses.

<sup>13</sup> WHO Europe. 2017. European Health Information Gateway: General Practitioners per 100,000.

<sup>14</sup> European Commission. Roma Health Report: Report on the health status of the Roma population in the EU and monitoring data collection in Roma health in the Member States. August 2014.

<sup>15</sup> WHO. Evaluation of the structure and provision of primary care in Romania: a survey-based project. 2012.



20. Overall fragmentation of the health information system, as well as the NHIH information system's narrow focus on insurance reimbursement transactions, limits the system's ability to accurately report and analyze performance of the health system, including primary care, and to take action based on data analytics.

#### Relationship to CPF

21. **The Country Partnership Framework (CPF) for Romania covers a five-year period from July 2018 to June 2023, and it is aligned with the objectives of the country's development strategy.** The overarching goal of the CPF is to build institutions fit for a prosperous and inclusive Romania. The CPF is rooted in the findings and recommendations of the World Bank Group Systematic Country Diagnostic (SCD) for Romania, which contains an analysis of key challenges and institutional constraints for inclusive and sustainable growth. The SCD identifies the functioning of the institutions and the quality of governance as key factors limiting Romania's ability to make sustainable progress towards reducing poverty and promoting shared prosperity. Growth is constrained by weak commitment to policy implementation and an adverse environment for investment, unequal opportunities and uneven service delivery, including in health. Building on past experiences, the CPF envisages a combination of instruments, lending and technical assistance, to maximize the impact of Bank's support. The Bank and International Finance Corporation will pursue focused interventions, with clear indicators to show progress and mobilize support for further reform.

22. **The proposed operation is highly relevant for the ongoing CPF.** The first area of focus for Bank's support under the CPF is to ensure equal opportunities for all. Within this area, the second objective of the CPF is to improve access to modern health care, particularly for the poor and vulnerable. Most premature deaths in Romania are from chronic diseases that can be prevented or slowed down with modern healthcare, and particularly through primary care. Early deaths from preventable diseases are concentrated in the bottom 40 percent of the population and rob them of peak productivity years, as well as the opportunity to realize investments in human capital. The Bank can help Romania to transition to a more balanced and integrated health system that will improve the quality of care delivered to all social groups. Stronger institutions are indispensable for moving towards that direction. Thus, the proposed operation is in full alignment with the stated objective of the CPF to build institutional capacity and consolidate governance for inclusive development in Romania.

#### Rationale for Bank Engagement and Choice of Financing Instrument

23. **The World Bank has established twin goals to anchor its overarching mission, and to galvanize international and national efforts in this endeavor** to: (i) end extreme poverty at the global level within a generation, and (ii) promote shared prosperity which is defined as a sustainable increase in the wellbeing of the poorer segments of the society. The proposed operation will contribute to the achievement of both goals, as it aims to improve access to effective PHC, which will bring about the best value for public financing. It also emphasizes support for the expansion of access to PHC to underserved areas and the uninsured segment of the population, particularly the Roma population.

24. **In recognition of the urgent need for additional investments in human capital globally, the World Bank Group launched the Human Capital Project in 2017.** The Human Capital Project leverages advocacy, measurement and analytical work to inform strategic policies to build human capital through investments in health, education, social protection, and labor. Through the Human Capital Project, the World Bank introduced the Human Capital Index which measures the amount of human capital that a child born today can expect to attain by the end of secondary school given the education and health risks that prevail in the country in which she was born. One of the proxies of the health component of the



Human Capital Index measures adult survival rates which captures the range of fatal and non-fatal health outcomes that a child born today would experience as an adult if current conditions prevail into the future. As the current operation strengthens the effectiveness of PHC it will reduce mortality and morbidity from non-communicable diseases in Romania and contribute to human capital improvement.

25. **The World Bank's involvement in the proposed Program-for-Results (PforR) builds on the Government's existing capacity and expertise developed in recent years.** Since 1991, the World Bank has been a key partner in Romania, working on reforms and strengthening the health sector. The Bank's recent health sector support has included: (a) a Health Services Rehabilitation Project (1991); (b) a Health Sector Reform Project – APL1 (2000); (c) a Health Sector Reform Project – APL2 that increased access to, and improved the quality of, maternal, rural, and emergency health care services; (d) the DPL-DDO; and (e) the ongoing Health Sector Reform Project, which aims at improving access to and quality of selected public health services, including (i) strengthening health service delivery; and (ii) improving public health sector governance and stewardship. The World Bank also supported the sector through several technical assistances and is currently leading the health sector dialogue between the Government and the International Financing Institutions.

26. **Lessons from past projects in Romania and experience from other countries with PforRs have shaped the focus of this proposed operation and the choice of instrument.** Moving forward, this concept note is proposing several major changes compared to the ongoing and preceding operations, most importantly: (i) a shift to a small number of carefully selected areas in support of the government's program to allow for a focused approach and assure best chance for success. Specifically, the PforR aims at improving equity and efficiency by focusing on PHC. Without access to effective primary care, the population would otherwise resort to specialized care and hospital care that are less efficient and equitably distributed, as it is currently the case; and (ii) use of the PforR instrument to encourage the client to adopt a results orientation. In parallel, it is envisaged that implementation support and capacity building will be provided, through the ongoing Health Sector Reform operation (closing date December 15, 2020) and potentially with EU support.

27. **The PforR instrument is appropriate for the proposed operation because it focuses on results while addressing the main constraints to their achievement.** The operation will support a defined Program within the Ministry of Health's National Health Strategy 2014–2020 and accompanying Action Plan 2014–2020, which provide a framework for improving the health of the population in Romania. The instrument focuses on results rather than inputs, which allows flexibility to innovate. It also responds to the Government of Romania's demand for using a results-based approach to its investments. The uses of country systems with attention to system strengthening and institutional capacity building will enhance development impact and sustainability with a view to support efficiency gains in the government's program over time. The PforR instrument will allow for improvements, as necessary, in the implementation of the government's own technical, fiduciary and environment and social systems. Lastly, the PforR instrument encourages collaboration with potential development partners (e.g., the EU) around a common results framework.

### C. Program Development Objective(s) (PDO) and PDO Level Results Indicators

28. The Program development objective is to improve access to effective primary health care in Romania.

#### PDO Level Results Indicators



29. **There are five PDO indicators identified within the Program**, which aim to capture improvements in two results areas: 1) improving access and effectiveness of PHC; and 2) increasing fiscal space for health care (including PHC) through efficiency gains. Tentative PDO indicators are as follows:

- PDO 1. Increase in the percentage of family medicine practices receiving funding from the state aid scheme for improving service standards;
- PDO 2. Increase in the percentage of women 25 to 64 years old reported to have received cervical cancer screening in the past five years;
- PDO 3. Increase in the percentage of pregnant women in underserved local public administration authorities who have at least one antenatal care visit attended by a physician;
- PDO 4. Increase in the percentage of reimbursements by volume for metformin initiation that are prescribed by primary care physicians; and
- PDO 5. Increase in the share of NHIH funding allocated to PHC.

#### D. Program Description

##### Program Boundary

30. **The proposed PforR operation is anchored in the National Health Strategy 2014-2020<sup>16</sup> and the Government program<sup>17</sup> for the period 2018-2020, which endorses the Strategy.** The recently published Fiscal-Budgetary Strategy of the Government for the period 2019-2021<sup>18</sup> reconfirms the strategic directions of the Health Strategy.

##### The National Health Strategy 2014-2020

31. **National Health Strategy 2014-2020 and accompanying Action Plan 2014-2020 provide a framework for improving population health in Romania.** The Strategy aligns with the Health 2020 Strategy of the World Health Organization Regional Office for Europe, recommendations developed by the European Commission for the health sector, and the proposed reforms in the World Bank Functional Review of the Romanian Health Sector. Three Strategic Areas have been identified each of which includes priority actions and strategic objectives. Strategic Area 1 focuses on improving public health, including reproductive, maternal, and child health; reducing the burden of communicable diseases including tuberculosis, HIV/AIDS, vaccine-preventable diseases, and hepatitis; and reducing the burden of non-communicable diseases via local, regional, and national preventive programs. Strategic Area 2 focuses on ensuring access to quality and cost-effective health services, especially for vulnerable groups, including community-based, primary and ambulatory services. Strategic Area 3 includes cost-cutting policies and programs in the health system relating to information and communication technology, human resource for health, service infrastructure, health financing, quality of care, research and innovation, and evidence-based drug policy.

32. **The proposed Program is a well-defined subset of the Government program.** The Program is defined by strategic objectives (SO) 3.2, 4.1, 4.2, 5.3, 5.5, and 6.1 in Strategic Areas 1, 2, and 3 of the National Health Strategy 2014-2020 (Table 2). These objectives focus on reducing the cancer burden by early detection through organized screening interventions

<sup>16</sup> <http://www.ms.ro/strategia-nationala-de-sanatate-2014-2020/>

<sup>17</sup> <http://gov.ro/ro/obiective/programul-de-guvernare-2018-2020>

<sup>18</sup> [http://cdep.ro/pdfs/buget/2019/strategie/SFB\\_2019-2021](http://cdep.ro/pdfs/buget/2019/strategie/SFB_2019-2021); February 2019.



(SO 3.2), strengthening community-based health services for vulnerable groups (SO 4.1), increasing the effectiveness and diversification of PHC (SO 4.2), sustainable policy ensuring financial resources for health, cost control, and financial protection (SO 5.3), developing and implementing an evidence-based drug policy (SO 5.5), and developing an integrated health information system by implementing sustainable e-Health solutions (SO 6.1)

**Table 2: Overview of National Health Strategy 2014-2020**

<u>Vision:</u>	
A nation with healthy and productive people through access to quality preventive, emergency, curative and rehabilitation services, efficient and effective use of available resources, and promotion of higher standards and good practices.	
<u>Strategic Area 1:</u> Improving public health	<u>Strategic Area 2:</u> Ensuring access to quality and cost-effective health services, especially for vulnerable groups
a) Improve maternal and child health	a) Strengthen community-based health services for vulnerable groups (SO 4.1)
b) Reduce the burden of communicable diseases	b) Increase effectiveness and diversification of PHC (SO 4.2)
c) Reduce the burden of non-communicable diseases (SO 3.2)	c) Consolidate specialized ambulatory care to reduce hospitalization
	d) Improve access to emergency services
	e) Regionalization of hospital care to improve performance and quality
	f) Increase access to quality rehabilitation, palliative, and long-term care
	g) Create local, country, and regional provider networks
<u>Strategic Area 3:</u> Cross-cutting measures for a sustainable and predictable health system	
a) Implement priority cross-cutting policies and programs related to administration, human resource for health, financial protection, cost control, quality of care, access to medicines, research and innovation, and better health for vulnerable groups (SO 5.3, SO 5.5)	
b) Accelerate the use of modern information and communication technologies (SO 6.1)	
c) Develop health infrastructure at the local, regional, and national levels to reduce inequality in health care access	

Source: Adapted from Ministry of Health, Romania. National Health Strategy 2014-2020. November 2014.

Note: Blue shading represents areas that cover the proposed Program.

### Strategy for Integrated and Comprehensive Community Care

33. **Integrated and comprehensive community health care are identified in the National Health Strategy 2014-2020 as a cost-effective means of providing access to basic medical services in rural areas and among vulnerable groups.** SO 4.1 focuses on the development of community centers to promote healthy lifestyles and to supply primary, secondary and tertiary preventive services, home care, and palliative services. This model of community care will involve integration with PHC, specialized medical care, school care, and social services. Following decentralization of the health system in 2009, the day-to-day organization of community health care has become the responsibility of local authorities, with strategic direction provided by the MoH. The national strategy for community health care contributes to national efforts to reduce poverty and promote social inclusion, through the targeting of vulnerable groups and rural areas. Hence, as part of the EU Human Capital Operational Program (POCU) Priority Axis 4 on social inclusion and combatting poverty, the MoH is developing and piloting integrated community health services in 139 rural and small urban marginalized communities, in partnership with the Ministry of Labor and Social Justice and the Ministry of National Education. Emergency Ordinance no. 18/2017 on community health care provides the legislative framework for implementation of the National Strategy.



34. **The Strategy identifies key measures to improve efficiency, including the development of an evidence-based drug policy (SO 5.5) and implementation of an integrated health information system (SO 6.1).** The Strategy outlines several key interventions needed to ensure equal and sustainable access to medication for the population. Among these are the revision of the HTA methodology, use of risk-sharing mechanisms and cost-volume regulations for all new high-cost drugs, and revision of the positive drug lists to ensure cost-effectiveness. These measures are expected to address the current shortcomings in the system contributing to increasing costs and improve the sustainability and predictability of public funding in the long-run. An advanced information system is envisioned that would ensure integration, standardization, and interoperability of the existing subsystems, including the introduction of national EHRs. Such measures will improve access to data and information and enable evidence-based decision making.

### **Strategy for the Development of Primary Health Care in Romania**

35. **With support from the Health Sector Reform Project II (Loan IBRD 47600), the MoH developed and approved a comprehensive strategy for PHC development in Romania.** The strategy and a related action plan were developed on February 27, 2012. The strategy was revised to observe the provision of Government Decision No. 870/2006 for the development, coordination, and planning of public policies at the national government level. The SO 4.2 of the National Health Strategy 2012 aims to implement the recommendations of the Strategy for the Development of Primary Health Care in Romania 2012-2020. The government intends to make PHC comprehensive, widely accessible, and responsible for ensuring continuity of care with other providers. The SO 4.2 also includes a commitment to adapting the legal and normative framework to support a stronger PHC system through new funding mechanisms, strategies to attract human resources, improving coordination and monitoring, and adequately equipping facilities.

### **The Program Results Areas and Theory of Change**

36. **The Program focuses on two result areas:** (i) increasing access and effectiveness of PHC; and (ii) increasing fiscal space for health care (including primary care) through efficiency gains.

#### **Result area 1: Increasing access and effectiveness of PHC**

37. This result area aims to support the government's efforts to improve access to primary and community care. The PforR will support the following actions: (i) strengthening the coordination function of PHC; (ii) promoting preventive care and case management services in PHC; (iii) improving access to primary care, particularly in underserved areas and for the uninsured; and (iv) improving service delivery conditions of primary care through the state aid scheme.

38. To strengthen the coordination function of PHC, the MoH will revise clinical guidelines and patient pathways to expand the role of the primary care provider in initiating care, treating ambulatory-sensitive conditions, and coordinating service provision. Patient pathways will identify the roles of community health workers and specialists in support of the primary care provider in service provision, and specify coordinating mechanisms including e-referrals and discharge notes. The revision of the framework contract to include performance-based payments, modification of the fee-for service mechanism, and expansion of the scope of services will incentivize better PHC performance. These changes are expected to increase the utilization of PHC services and ultimately lead to better prevention, early detection, and coordinated management of chronic diseases at the PHC level. The expansion of the basic benefits package for primary care for the uninsured is expected to improve access to preventive care and in the long run may lead to overall savings for the health





system on expensive emergency services for the uninsured. The government also envisions a state aid scheme which will provide financial support for primary care providers (family medicine practice) to improve service delivery conditions.

## **Result area 2: Increasing fiscal space for health care (including primary care) through efficiency gains**

39. This result area aims to target inefficiencies in the system to generate additional fiscal space for primary care. Primary care spending represents only six percent of NHIH's expenditures compared to an average of 27 percent in other upper-middle income countries. Efficiency gains in the health sector can be an important source of fiscal space for health given the difficult macroeconomic environment. Under this result area, the Program will support interventions targeted at improving efficiency, while promoting cost-effectiveness and evidence-based policymaking, through the (i) introduction of centralized procurement for the health sector by National Office of the Centralized Procurement (ONAC); (ii) introduction of an integrated health information management framework, including national EHRs; and (iii) revision of pricing and reimbursement mechanisms for pharmaceuticals. Undertaking reforms to improve health system efficiency may increase budgetary space to support the scale-up of primary and community care in Romania.

**A preliminary list of DLIs by result area is described below (see also Annex 1):**

### **Result Area 1: Increasing access and effectiveness of PHC<sup>19</sup>**

40. **DLI 1: Access of the uninsured population to the basic benefits package for family medicine.** The MoH proposes to include the uninsured population in the basic benefits package for family medicine, eliminating the need for verification of insurance coverage for services received at this level. This will require changes to the Law 95/2006 on Health Care Reform to remove the minimum benefits package which the uninsured population is entitled to and to allow inclusion of the uninsured people in the more generous basic benefits package. The MoH and Ministry of Public Finance (MoPF) will jointly redefine the scope of the basic benefits package for PHC, and if the service scope will be uniform for the insured and uninsured population. The funds to cover 100 percent of the additional cost of service provision under the basic benefits package for PHC for the uninsured population will be transferred to the NHIH.

41. **DLI 2: Modification of the framework contract to incentivize effective PHC.** The MoH will modify clinical pathways for selected non-communicable diseases to expand the scope of services the family physician can provide, including pharmaceutical prescriptions and laboratory services. These changes will include prescription of oral medication for Type 2 Diabetes Mellitus. The framework contract will be modified to increase the provision of primary care overall and the focus on results as follows: modification of the fee-for-service mechanism, improvement of the risk-adjustment mechanism for capitation (currently only adjusted for age), introduction of performance-based payments in health services, and expansion of the scope of services a family physician can provide, as discussed earlier. Because of the increase in service provision at the PHC level which will result from the Program's support, the share of the NHIH budget allocated to family medicine may increase from six percent in 2018 to 10 percent in Year 4 of the Program.

42. **DLI 3: The number of family medicine practices or group practices that receive support through the de minimis state aid scheme.** The MoPF and MoH will set up a de minimis state aid scheme that will provide financial aid to family physicians. This aid will support expenditures on facility rehabilitation, equipment, and training, as decided by the family physician, within limits defined by regulation developed and approved by the MoH and MoPF. The state aid scheme will

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<sup>19</sup> Also referred to as family medicine.



come into force following a government decision that also specifies regulation for the sale, concession, or lease of family medicine practices from local public administration authorities. The government decision and other regulation will specify a required minimum of five years for concession or lease of facilities. The threshold for the aid amount for underserved areas and group practices may be higher to incentivize family doctors to practice in underserved and/or establish group practices.

43. **DLI 4: Proportion of pregnant women in underserved local public administration authorities who have at least one antenatal care visit attended by a physician.** This DLI will act as a tracer indicator to monitor access to PHC in underserved communities, or local public administration authorities that lack a family medicine practice in March 2019 and have a population below 800, the minimum threshold for contracts with the NHIH. The clinical protocols to be developed for community health care will stipulate the need for pregnant women to be referred by community health nurses in underserved areas to family physicians. Where there is no family physician, the community health nurses will refer pregnant women to a specialist physician.

44. **DLI 5: Integrated community and primary care implemented in underserved local public administration authorities.** The MoH proposes to implement integrated and community care in underserved local public administration authorities, as defined under DLI 4. Under this intervention, the MoH will develop and implement health promotion and care protocols for community health services and for coordination with PHC; hire and train at least one community health nurse for each local public administration authority; establish and staff a primary and community health unit in the MoH; and undertake a community needs assessment to inform the targeted roll-out of community health services nationally.

45. **DLI 6: Increase in the number of women 25 to 64 years old reported to have received cervical cancer screening in the past five years.** The National Program for Cervical Cancer, which currently does not report screenings undertaken outside the National Program, will host a unified database to monitor cervical screening coverage nationally, including data from the NHIH on the insured population. To facilitate reporting, the NHIH will link their database for cervical cancer screening to this unified database. Given that lags in analysis of pap smears dissuade family physicians from performing this test, the MoH will finance the training in cytotechnology to staff in all regional cytology and pathology laboratories.

46. **DLI 7: Increase in the percentage of reimbursements by volume for metformin initiation that are prescribed by primary care physicians.** This DLI will act as a tracer indicator to monitor the extended scope of services provided at the PHC level. Currently, PHC providers are only able to refill prescriptions by specialists. The framework contract will be modified to enable PHC providers to initiate prescriptions, which could lead to better continuity of care. See DLI 2 for associated activities.

## **Result Area 2: Increasing fiscal space for health care (including primary care) through efficiency gains**

47. **DLI 8: Centralized procurement for health sector developed and implemented by ONAC.** This DLI supports the development and implementation of centralized procurement for the health sector by ONAC. This will require legislative amendments to Emergency Ordinance 46 of 2018. ONAC will implement centralized procurement of standardized products for all publicly-owned hospitals and conclude multi-year contracts for medical supplies and devices for Emergency Medical Services and hospitals. Procurement of standardized products will include commodities and utilities (e.g., electricity, fuel, and telecommunications). Medical supplies and devices will include emergency medical service kits, needles, syringes, bandages, etc. The MoH will design technical specifications for hospital medical supplies and devices,





and the Ministry of Interior will provide technical specifications for medical supplies and devices for emergency medical services.

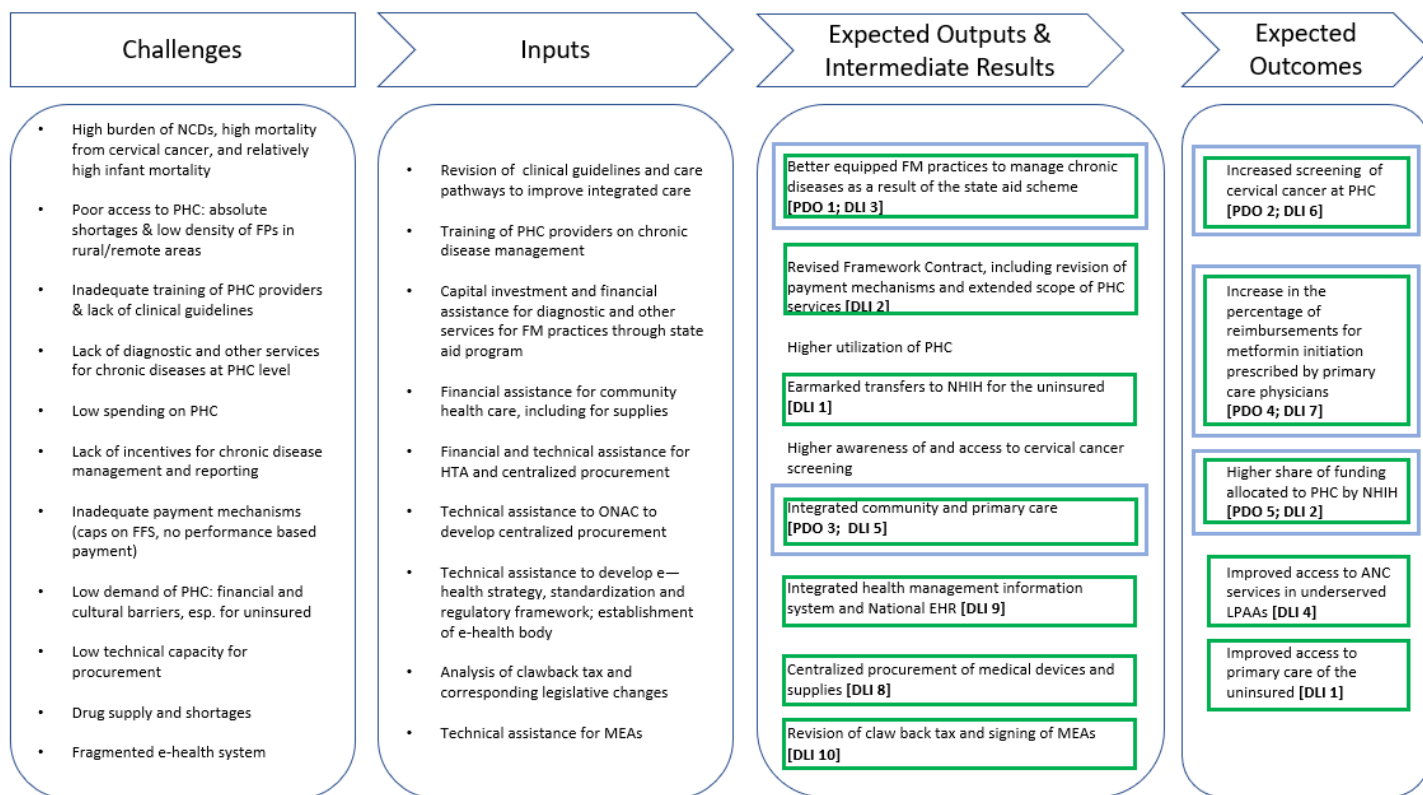
48. **DLI 9: Health information integration framework defined and launched.** To improve data and its use, the Program will strengthen the health information system and promote integration of data across community care, primary care, and hospital care. The MoH and NHIH propose to develop and implement e-health solutions to modernize PHC service delivery and improve integration between NHIH and other providers (e.g., laboratories, pharmacies), including an upgrade of the e-prescription system and the introduction of central e-referrals. The MoH will develop and adopt an e-Health Strategy for strengthened health management information system covering all data sources, data users, and data channels, including integration with EHR. The NHIH systems will be upgraded to support a wider range of services and healthcare institutions. The NHIH EHR will be re-designed to become National EHR, at a minimum allowing: (i) data exchange with any system, (ii) a master patient index for data consolidation, (iii) a clinical data repository, including data on prescriptions and referrals, (iv) a document repository, (v) a digital imaging repository, (vi) a document repository, and (vii) a patient self-managed data repository. Community health providers, family doctors, and hospitals will share records and will have the ability to access online patient records in the National EHR. The MoH will establish a National Health Data Observatory, which will be integrated with EHR and the NHIH systems (data statistics and business analytics) to ensure availability and facilitate analysis of key health indicators that will enable evidence-based decision and policy making.

49. **DLI 10: Revised medicine pricing and reimbursement mechanisms implemented.** This DLI supports the implementation of revised pricing and reimbursement mechanisms for medicines. A revision of the claw-back tax regulation will be required to remedy the negative side effects of the tax on accessibility of medicines. The National Agency for Medicines and Medical Devices will revise the HTA methodology. The positive lists of medicines will be revised based on the new HTA methodology. To improve transparency and accountability, the MoH and NHIH pricing process for medicines will be completed and published on the NHIH website annually. The NHIH will gradually increase the use of MEA to improve risk sharing arrangements between the NHIH and pharmaceutical companies in the reimbursement of patented medicines.

50. The theory of change for the Program is illustrated in Figure 3, starting with challenges identified and followed by the inputs, expected outputs and intermediate results, and expected outcomes. As indicated, a subset of intermediate results and expected outcomes have been selected as DLIs.



Figure 3: Theory of change



DLI PDO

### E. Initial Environmental and Social Screening

51. The proposed Program is likely to have positive environmental impacts to the health sector. Benefits include improved overall access to quality and efficient PHC services, including in underserved areas. However, there might be potential negative impacts associated with the Program as a result of an increase in medical waste generation and point source pollution due to the potential increase in the number of PHC facilities delivering primary care services. The country has a comprehensive legislation on environmental protection, which is fully aligned with the EU legislation and, therefore, the Borrower’s systems can handle the activities proposed under the two Program result areas. The results areas identified under the Program and the corresponding DLIs do not recommend activities/actions that will have significant adverse impacts on the environment that are sensitive, diverse or unprecedented. The screening will confirm that there are no category A and B-type activities included in the Program and only Category C investments would be financed.

52. An environmental and social systems assessment (ESSA) will be conducted during preparation to identify the adequacy of the environment and social systems, of institutional and legal framework for medical waste management at the PHC level, as well as the role of PHC in preparing for and responding to climate change related threats to human health. Public consultation on the draft ESSA report will take place during appraisal.



### *Climate Screening*

53. Climate and disaster risk screening conducted for the Program has confirmed that the risk of exposure to climate change or geophysical hazards for this Program is moderate. There is a moderate chance that Program activities may get affected by possible river floods and earthquakes. These risks will be mitigated by the improvement of health services delivery in the selected rural communities, which will help improve preparedness to potential disaster events.

### *Social System*

54. The Program is expected to produce a wide range of social benefits for communities and groups that currently have no access to primary and community care in Romania. However, a number of social risks have been identified in relation to the capacity of the Program to address the specific needs of vulnerable groups and to assure social sustainability for the future. While vulnerable groups are defined at the level of the Program (the poor, children, youth deprived of parental care and support, lone or dependent elderly, Roma, persons with disabilities, people living in marginalized communities) and are the main beneficiaries of a number of actions, there is limited capacity to collect and produce relevant social data to inform decision making on extending and improving primary care and community care in a manner the benefits these target groups.

55. From an institutional perspective, the Social Inclusion Unit in the MoH is currently coordinating the health mediation and community nurses networks and is responsible for the extension and improvement of the network in the country. The unit is understaffed (only one person at the moment) and has limited resources for monitoring and evaluating the social performance and effects of community health care. At the local level, public authorities and public health districts at the county level have limited capacity and knowledge for planning the activities of community health workers and for providing medical guidance. Integration with primary care is limited and does not follow a specific guideline or protocol. The main barrier to improving the effectiveness of community health care is the pending by-laws of a 2017 law that regulates the sector, which is expected to be approved in March 2019.

56. In relation to consultations with key stakeholders, the Program and the normative act supporting the implementation have undergone standard disclosure and consultation procedures as per national legislation. There is no grievance mechanism at the level of the Program, but petitions and recommendations can be received by the MoH or local authorities, through their standardized and public procedures, under national legislation. Given that the Roma community is among the most vulnerable population groups in Romania, the role of health mediation has proven successful in the past two decades in facilitating access to primary and specialized care. However, the involvement of Roma institutions and non-governmental organizations in the design and implementation of the Program is very limited. A Roma filter will be applied to the Program to identify the specific shortfalls and proposed mitigation measures. A consultation with the Roma Sounding Board will be part of the process (the board was formed by the World Bank in 2017 and consists of eight civil society organizations active at the national level and eight Roma-organizations active at the local or regional level, with one non-governmental organization representing each region of Romania).

57. *Gender Dimension.* Cultural gender norms in many communities where Roma live make Roma women a particularly vulnerable group. They often marry young and are expected to stay at home and take care of children. Reproductive health risks are related to early marriage, with approximately 10 percent of girls giving birth when they are 12-15 years old and 48 percent at the age of 16-18 years. Although 89 percent of Roma mothers gave birth in a hospital, more than half the adolescent mothers (aged 15-19) lack counseling during pregnancy. They are registered as the highest



prevalence of non-users (10 percent) and under-users (51.4 percent) of prenatal care services. Lack of financial resources, health insurance, and knowledge, as well as cultural norms that make reproductive related conditions a taboo in traditional communities, are some of the barriers experienced by Roma women when seeking to access health care. However, the role of health mediators and community nurses has proven to have a significant role in improving the health of Roma women. Because the vast majority of community health workers are women, the positive impact of their actions is likely to be more prominent with Roma women than men. Although financial barriers and the lack of health insurance remain important barriers, community health workers can provide counseling and support the access to healthcare (even if it is sometimes to emergency units, where healthcare is free of charge).

58. Another gender dimension is that close to 70 percent of physicians in Romania are women, thus allowing for provider choice in cases where traditional norms are barriers for Roma women to seek care from a male physician. Gender aspects in accessing healthcare for Roma women will be further discussed as part of the Roma Filter consultations that will be carried out within the World Bank’s Roma Sounding Board.

59. *Citizen engagement.* Citizen engagement is carried by the MoH through a number of processes and actions that are regulated by national legislation. These include a petitioning system, public debates, one-to-one meetings based on request, consultation of normative acts, and consultations with civil society. However, the engagement is rather centralized, institutionally-oriented and involves little community-driven approaches in designing and implementing health policies and actions. A petitioning system is established at the level of the Ministry, with an online platform that can be used to forward a petition and monitor its evolution. In 2017, a total number of 6,700 petitions have been recorded at the level of the Ministry, with 4,854 being addressed within the institution, 1,572 forwarded to other competent bodies, and 274 recorded as non-compliant. Twenty public debates have been organized on different topics and 326 persons have registered for an audience with staff from the Ministry. A total number of 624 requests for accessing public information have been submitted in the same year.

60. At the level of primary care, the Physician’s College usually collects grievances from citizens related to a medical act. Given that family practices are mostly private entities, there is no centralized grievance system. As part of the proposed Program, community health workers will directly interact with beneficiaries, which can then constitute a basis for designing community-driven approaches, based on the data they will collect on health status and needs at the community level.

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