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Report No: PCBASIC0177223

PROGRAM APPRAISAL DOCUMENT

ON A

PROPOSED LOAN

IN THE AMOUNT OF EUR 500 MILLION
(US$557.2 MILLION EQUIVALENT)

TO

ROMANIA

FOR A

ROMANIA HEALTH PROGRAM FOR RESULTS

August 15, 2019

Health, Nutrition & Population Global Practice
Europe and Central Asia Region

CURRENCY EQUIVALENTS

(Exchange Rate Effective: June 2019)

Currency unit =	Euro
EUR 1.00 =	US$ 1.11
US$ 1.00 =	EUR 0.897
EUR 1.00 =	RON 4.76

FISCAL YEAR
January 1–December 31

Regional Vice President:	Cyril E Muller
Practice Group Vice President:	Annette Dixon
Country Director:	Arup Banerji
Practice Manager:	Tania Dmytraczenko
Task Team Leader(s):	Huihui Wang, Ana Holt

ABBREVIATIONS AND ACRONYMS

ADCIA	Inter-Active Community Development Agency
ANAP	National Agency for Public Procurement
CHC	Community health care
CNSC	National Council for Solving Complaints
CPF	Country Partnership Framework
DALY	Disability-adjusted life-year
DHIH	District Health Insurance House
DLI	Disbursement-linked indicator
DLR	Disbursement-linked results
DNA	National Anticorruption Directorate
DPHA	District Public Health Authority
EC	European Commission
EHR	Electronic health record
ERP	External reference pricing
ESSA	Environmental and Social Systems Assessment
EU	European Union
GDP	Gross domestic product
GO	General objective
GoR	Government of Romania
HTA	Health technology assessment
ICT	Information and communication technology
IFC	International Finance Corporation
IMF	International Monetary Fund
INT	Integrity Vice Presidency
INTOSAI	International Organization of Supreme Audit Institutions
IT	Information technology
MEA	Managed entry agreement
MoPF	Ministry of Public Finance
MoH	Ministry of Health
MoU	Memorandum of understanding
NCD	Noncommunicable disease
NGO	Nongovernmental organization
NHIH	National Health Insurance House
NHIF	National Health Insurance Fund
NHS	National Health Strategy
ONAC	National Office for Centralized Procurement
PAP	Program Action Plan
PDO	Program development objective
PER	Public Expenditure Review
PHC	Primary health care
PforR	Program-for-Results
RAS	Reimbursable Advisory Services
RCoA	Romanian Court of Accounts
RHM	Roma Health Mediator

RON	Romanian Lei
SCD	Systematic Country Diagnostic
SIUI	Integrated Unique Informatics System
TA	Technical assistance
WBG	World Bank Group

BASIC INFORMATION

Is this a regionally tagged project?	Financing Instrument
No	Program-for-Results Financing

Bank/IFC Collaboration	Does this operation have an IPF component?
No	No

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 challenges.

Organizations

Borrower : Romania

Implementing Agency : Ministry of Health

COST & FINANCING

SUMMARY (USD Millions)

Government program Cost	55,473.00
Total Operation Cost	5,087.20
Total Program Cost	5,087.20
Total Financing	5,087.20
Financing Gap	0.00

Financing (USD Millions)

Counterpart Funding	**4,530.00**
Borrower/Recipient	4,530.00
International Bank for Reconstruction and Development (IBRD)	**557.20**

Expected Disbursements (USD Millions)

Fiscal Year	2020	2021	2022	2023	2024
Absolute	28.30	173.50	106.60	149.10	99.70
Cumulative	28.30	201.80	308.40	457.50	557.20

INSTITUTIONAL DATA

Practice Area (Lead)

Health, Nutrition & Population

Contributing Practice Areas

Climate Change and Disaster Screening

Yes

Private Capital Mobilized

No

Gender Tag

Does the program plan to undertake any of the following?

a. Analysis to identify Project-relevant gaps between males and females, especially in light of country gaps identified through SCD and CPF

Yes

b. Specific action(s) to address the gender gaps identified in (a) and/or to improve women or men's empowerment

Yes

c. Include Indicators in results framework to monitor outcomes from actions identified in (b)

Yes

SYSTEMATIC OPERATIONS RISK-RATING TOOL (SORT)

Risk Category	Rating
1. Political and Governance	Substantial
2. Macroeconomic	Substantial
3. Sector Strategies and Policies	Moderate
4. Technical Design of Project or Program	Substantial
5. Institutional Capacity for Implementation and Sustainability	High
6. Fiduciary	Substantial
7. Environment and Social	Substantial
8. Stakeholders	Moderate
9. Other	
10. Overall	Substantial

COMPLIANCE

Policy

Does the program depart from the CPF in content or in other significant respects?

[ ] Yes [✔] No

Does the program require any waivers of Bank policies?

[ ] Yes [✔] No

Safeguard Policies Triggered

Safeguard Policies	Yes	No
Projects on International Waterways OP/BP 7.50		✔
Projects in Disputed Areas OP/BP 7.60		✔

Legal Covenants

Sections and Description

Section I.A.1 (a): Establish, not later than three months after the Effective Date, and thereafter maintain throughout Program implementation, a strategic working group for the support of the implementation of the Program ("Steering Committee"), comprised of representatives of each Implementing Institution, responsible for strategic oversight and guidance under the Program, all under terms and conditions acceptable to the Bank

Sections and Description

Section I.A. 1 (b): Ensure that each Implementing Institution will appoint, by not later than three months from the Date of Effectiveness, the focal points under terms satisfactory to the Bank, to monitor and oversee the implementation of the Program, including social and environmental requirements of the Program, if applicable.

Sections and Description

Section III.A: The Borrower, through the MoH, shall furnish to the Bank each Program Report not later than forty five (45) days after the end of each calendar semester, covering the calendar semester.

Sections and Description

Section III.B. 1 (a): No later than four months after the Effective Date, or such later date as agreed by the Bank, appoint/select and thereafter maintain, throughout the implementation of the Program, one or more independent verification agents, as needed, with qualifications and experience and under term of reference acceptable to the Bank to verify the data and other evidence supporting the achievement of one or more DLIs/DLRs

Sections and Description

Section I.B of the Schedule 2: The Borrower, through the MoH and the Other Implementing Institutions, shall carry out the Program Action Plan, or cause the Program Action Plan to be carried out, in accordance with the schedule set out in the said Program Action Plan in a manner satisfactory to the Bank.

Conditions

TASK TEAM

Bank Staff

Name	Role	Specialization	Unit
Huihui Wang	Team Leader(ADM Responsible)	Senior Health Economist	HECHN
Ana Holt	Team Leader	Health Specialist	HHNGE
Elena Corman	Procurement Specialist(ADM Responsible)	Procurement Specialist	EECRU

Elena Carmen Calin	Procurement Specialist	Procurement Specialist	EECRU
Anneliese Viorela Voinea	Financial Management Specialist(ADM Responsible)	Financial Management Specialist	EECG2
Cesar Niculescu	Environmental Specialist(ADM Responsible)	Senior Environment Specialist	SCAEN
Kristine Schwebach	Social Specialist(ADM Responsible)	Senior Social Development Specialsit	SCASO
Adanna Deborah Ugochi Chukwuma	Team Member	Health Specialist	HECHN
Alexandra Calin	Team Member	Operations Analyst	ECCRO
Andreea Silvia Florescu	Team Member	Program Assistant	ECCRO
Carlos Marcelo Bortman	Team Member	Lead Health Specialist	HLCHN
Catalin Pauna	Team Member	Senior Ecnomist	EECM2
Cristina Marilena Sorina Petcu	Team Member	Health Specialist	HECHN
Daria Goldstein	Team Member	Lead Counsel	LEGLE
Darjan Dragicevic	Team Member	Finance Analyst	WFACS
Harika Masud	Social Specialist	Social Development Specialist	SCASO
Iryna Postolovska	Team Member	Economist	HECHN
Johanne Angers	Team Member	Senior Operations Officer	HECHN
Luis M. Schwarz	Team Member	Senior Finance Officer	WFACS
Maria Lourdes Quiogue Kasilag	Team Member	Paralegal	LEGLE
Moses Sabuni Wasike	Team Member	Lead Financial Management Specialist	EECG2
Olena Doroshenko	Team Member	Health Specialist	HECHN
Zinaida Korableva	Team Member	Program Assistant	HECHN
Zlatan Sabic	Team Member	Senior Operations Officer	HECHN

Extended Team

Name	Title	Organization	Location
Flaviu Petean	Social Development	Consultant	Bucharest,Romania
Luka Voncina	Pharmaceutical policy expert	Consultant	Zagreb,Croatia

Radu Comsa	Health economist	Consultant	Bucharest,Romania
Tihomir Strizrep	Health Finance Management	Consultant	Zagreb,Croatia

ROMANIA
ROMANIA HEALTH PROGRAM FOR RESULTS

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I. STRATEGIC CONTEXT

A. Country Context

1. **Romania is an upper-middle-income country with a gross national income per capita of US$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 because of low fertility and high premature mortality, as well as high levels of migration. This has resulted in a population with a relatively old demographic structure. The old age dependency ratio – that is, the number of people aged 65 and over as a share of the working age population – is 27 percent.

2. **Romania's membership in the European Union (EU) has triggered an important positive socioeconomic and political transformation in the country.** Since joining the EU in 2007, Romania 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, enabling 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.

3. **Following parliamentary elections in December 2016, Romania is governed by a coalition 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, 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 have taken office since the December 2016 elections – which has affected the predictability of policymaking and the investment climate.

4. **Despite political volatility, Romania enjoys high rates of economic growth, but with widening macroeconomic imbalances.** Romania's economy grew by 7 percent in 2017 and 4.1 percent in 2018, driven by consumption, investment, and exports. The information and communication technology (ICT) 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 labor shortages for both skilled and unskilled jobs. In 2017 the Government promoted a series of procyclical fiscal measures, mainly 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 by the end of 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[1] 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 adverse effects on domestic

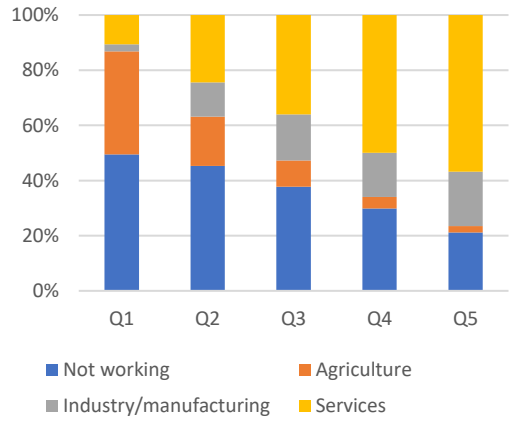
[1] Source: Ministry of Public Finance (MoPF).

growth and investment, which could be exacerbated by the uncertainty in fiscal policy and the tightening labor market. The partial decoupling of real wage growth and productivity could also affect Romania's competitiveness, adding upward pressures on the current account deficit.

5. **Economic growth has reduced poverty, although poverty rates remain higher in rural areas than in urban areas.** In line with robust economic growth, increased private consumption, and labor market improvements, the country's poverty rate (using the poverty line of US$5.50/day, 2011 purchasing power parity), which peaked at nearly 32 percent in 2012, is estimated to have declined to 22.3 percent in 2018, from 25.6 percent in 2015. The incomes of the bottom 40 percent of the population were boosted by employment gains in sectors with a large share of low-skilled workers (Figure 1). 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 that occurred between 2010 and 2016. Although poverty has declined in both rural and urban areas since 2014, in 2016 poverty rates in rural areas remained six times higher than those in cities and just over twice as high as those in towns and suburbs.

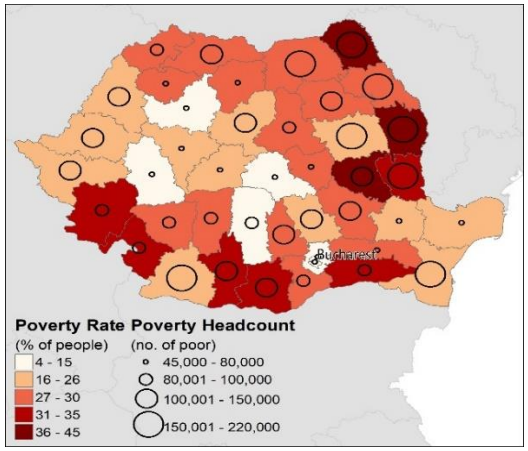
6. **Although Romania has made progress, its continuing large social and spatial disparities in inclusion present a significant development challenge.** The country's incomplete structural transformation is associated with an uneven spatial distribution of opportunities: 45 percent of the population 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; in some counties in the North-East region, the poverty rate is more than 10 times higher than in Bucharest (see Figure 2).

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.

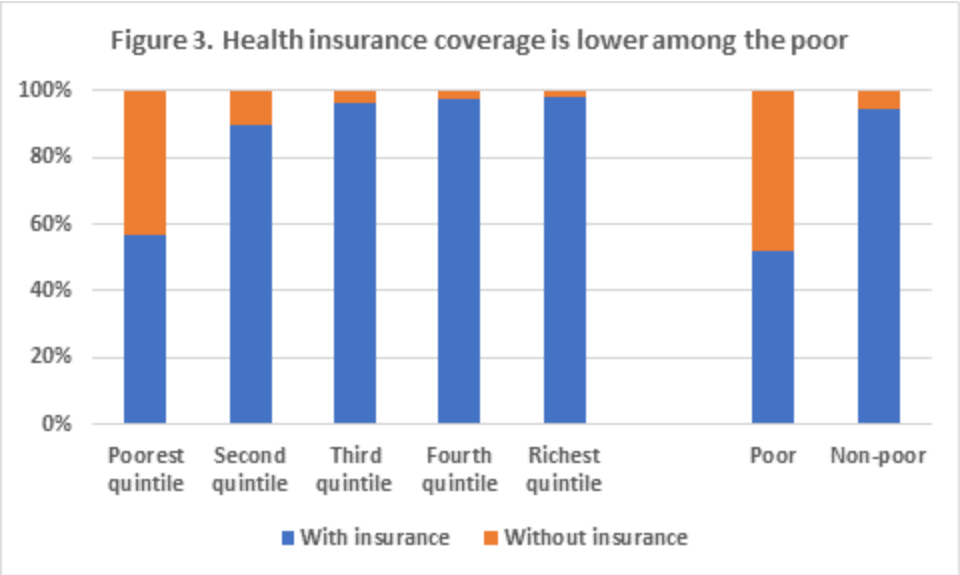
Figure 2. Romania is characterized by wide disparities in income.



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

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 social and regional disparities, and fiscal policies have failed to counter high levels of inequality. Health insurance coverage,

for example, is much lower among the poor compared with the non-poor (52 vs. 94 percent)[2] as shown in Figure 3. To counter the consequences of a population that is shrinking and aging—largely because of the external migration of working-age people—Romania urgently needs 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, triggering a virtuous cycle of inclusive growth and development.



8. **The 2015-2020 Government Strategy on Social Inclusion and Poverty Reduction acknowledges the need for tailored social services targeting vulnerable groups.** The Government's strategy defines vulnerable groups irrespective of poverty levels, as they face other challenges to social service access. The main categories of vulnerable groups it identifies are poor people, children, youth deprived of parental care and support, lone or dependent elderly people, Roma, persons with disabilities, people living in marginalized communities, and other vulnerable groups.[3] In 2013, these categories covered 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. The strategy noted that vulnerable groups require targeted interventions to increase their social and economic participation.

9. **Despite significant progress, Romania's institutions remain weak and hinder progress in building an inclusive society, promoting growth, and strengthening human capital.** Disparities in economic opportunity, poverty, and access to essential services across the country are most pronounced between urban and rural areas. Lack of access to essential services for some segments of the population reinforces the notion of "two Romanias" – one urban, dynamic, and united with the EU; the other rural, poor, and isolated. While de jure Romania has adequate structures in place, de facto implementation of key governance functions and legislation is poor. Political instability and the frequent turnover of ministers results in limited continuity and implementation of policies, while weak coordination between government levels and agencies undermines the efficiency of public financing. Underfinancing of social

[2] Source: 2016 Household Budget Survey, Romania. The poor are those at-risk of poverty, with income below 60 percent of the median equivalized income.
[3] 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.

sectors, such as health and education, results in poor quality of services and prevents Romania from achieving its human capital potential.

10. **To boost human capital—a central driver of sustainable growth and poverty reduction—Romania has made substantial progress in improving health outcomes over the last two decades, but challenges remain**. Between 1990 and 2016, life expectancy in Romania 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. 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 the country in 67th place out of 157 countries surveyed. This indicates that a child born in Romania today will only be 60 percent as productive as an adult as he/she would be with a complete education and in full health.

B. Sectoral and Institutional Context

11. **Health services in Romania are delivered through a complex network of public and private providers.** Box 1 presents brief definitions of the types of care and related providers. Most health services (including Primary Health Care (PHC), specialist care, inpatient care and palliative care) are contracted by the National Health Insurance House (NHIH), while community health care and emergency care are financed through the Ministry of Health's budget.

Box 1. Brief Definitions of Different Types of Care

Community health care: At the community level, 1528 community health nurses and 484 Roma health mediators are employed by Local Public Administration Authorities, and are involved in health education, surveillance of infectious diseases, and follow-up of treatment initiated in primary or specialist health care. Community health care providers refer to both community health nurses and Roma health mediators.

Primary health care: Primary health care and family medicine are used interchangeably in Romanian context. It involves basic, rather than specialized services, for most adult and childhood conditions, including diagnosis, treatment, and follow-up. There are 12,185 family physicians working in private family medicine practices (mostly solo practices).

Specialist care: Care is provided within a specific area of medicine, in inpatient and ambulatory settings *, including 3125 outpatient providers and over 560 hospitals.

Inpatient care: Medical treatment that is provided in a hospital or other facility and requires at least one overnight stay. There are 6.3 beds per 1,000 in Romania. About 96 percent of inpatient hospital beds belong to public hospitals, which are increasingly under the responsibility of the local public administration authorities.

Emergency care: Emergency medical attention given to an individual by hospital emergency units or pre-hospital teams (ambulance teams).

Palliative care: Specialized medical care for people living with a serious illness, provided in both ambulatory and inpatient settings.

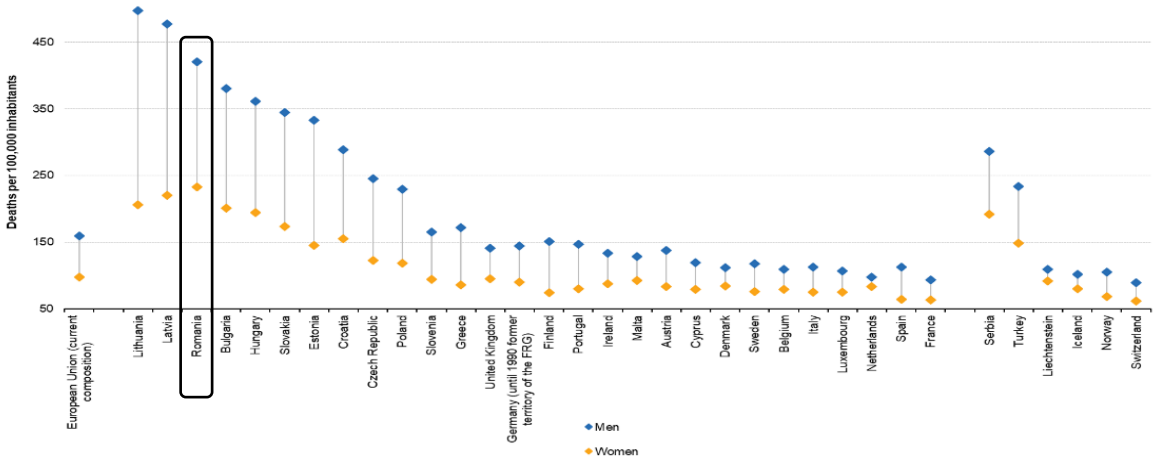
* Ambulatory settings include medical centers, polyclinics, physician offices, centers for diagnosis and treatment, and hospital outpatient departments. Except for hospital outpatient departments, other ambulatory settings are mostly private.

12. **Despite significant progress since joining the EU, Romania lags on health outcomes and service utilization.** While health outcomes have improved over the past two decades, they remain below the EU average. Healthy life expectancies in Romania—57.9 years for women and 58.6 years for men—are lower than the EU averages of 61.5 years and 61.4 years for women and men, respectively. Furthermore, national averages hide subnational disparities 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.[4] Vaccination rates have declined and are significantly below EU averages. In 2017, 87 percent of children in Romania received at least one dose of the measles vaccines before age one, compared to the EU average of 94 percent. Diabetes mellitus is a significant contributor to the burden of disease among adults. The number of years lived in disability, attributable to diabetes, increased by 10.4 percent between 2007 and 2017, more than for any other single disease in Romania.[5] Romania's rate of amenable mortality, that is mortality preventable through access to essential health services and public health interventions, is the highest in the EU for women and the third highest for men (Figure 4), signaling opportunities for improving

[4] National Institute of Statistics. Romania. 2015.
[5] Institute of Health Metrics and Evaluation, Romania, 2017. *http://www.healthdata.org/romania*

health outcomes through higher access to health services. Moreover, early deaths from preventable diseases and their complications are concentrated in the poorest 40 percent of the population.

Figure 4. Amenable Mortality Rates in EU Countries in 2015



Source: Eurostat.

Spending on Health

13. **Poor health outcomes and low service utilization are a function of low and inefficient health spending.** Despite a growing trend in the past, Romania spends less than 5 percent of GDP on health care, compared to an average of about 10 percent in the rest of the EU. Public spending constitutes 78 percent of current health expenditure, and 80 percent of it is pooled by the NHIH, the purchasing agency for health services. Only 0.3 percent of health spending is funded through voluntary private insurance.[6] The Public Expenditure Review conducted in 2017 identified major sources of inefficiency in health spending. First, health spending is skewed toward hospitals rather than PHC, which is a cost-effective means of service provision in EU countries with lower rates of amenable mortality. The NHIH spends 55 percent of expenditures to inpatient care, and only 6 percent to PHC. Second, decentralized procurement of medicines and medical devices, and limited implementation of innovative pharmaceutical policies, represent missed opportunities for efficiency gains. Between 2006 and 2017, expenditure on medicines and supplies accounted for 37.5 percent of health spending, more than double the EU average. In addition, the state budget transfers to the NHIH—which have averaged US$500 million annually over the past five years—are used predominantly to cover deficits in the National Health Insurance Fund (NHIF), creating disincentives for the NHIH to operate efficiently.

14. **With a publicly funded health sector, the Government needs to introduce efficiency discipline in managing public expenditure so that health outcomes will be improved in a financially sustainable manner.** Even though Romanian spending is at the low end among EU countries, global experiences prove that it is essential to put in place efficiency enhancement mechanisms first. If hospitals or health insurance funds are guaranteed to be bailed out when they have deficit, there will be no motivation to control cost and cut deficit. Resulting burden on the national budget leads to countries' fiscal inability to cover the

[6] Eurostat, 2015.

vulnerable groups as they should. An efficient system that ensures funds are not wasted will improve the sector's financial sustainability and facilitate increase in the sector share through reprioritization during the medium and long term. Health spending is normally driven up by an ageing population, increased prevalence of chronic diseases, rising prices of inputs and technology development. The total public health spending in Romania has increased from US$7.0 billion to US$10.6 billion in nominal terms (or 51 percent increase) between 2015 and 2018. Savings from efficiency improvement, therefore, are expected to slow down the growth of health spending, rather than reduce it. Global experience and country analysis indicate that efficiency can be enhanced through the following ways: redirecting expenditures from hospitals to PHC; decentralizing procurement of medical products; revising pharmaceutical measures; and addressing institutional challenges (i.e., lack of coordination and accountability).

15. **Significant gains in efficiency could be made by redirecting expenditures from hospitals toward PHC.** Family physicians have a gatekeeping role in Romania, but bypassing them is allowed for urgent or emergency conditions. However, because of both supply- and demand-side challenges (see Box 2 and Figure 5), PHC coverage is low among the underserved populations that includes a) the uninsured and the poor; and b) people living in underserved communities[7]; many patients delay seeking care or choose emergency services and specialists for care that could be provided in PHC settings. Furthermore, even for patients who have access to PHC, the effectiveness or quality of such services can be poor, so that health outcomes are suboptimal (Box 3). Bypassing PHC misses many opportunities for prevention and cost-effective management. In 2013, the number of PHC contacts per person per year in Romania was 4.8, lower than the EU average of 6.9.[8] The cost of these inefficiencies is high. In 2018, at least US$400 million, or approximately 10 percent of hospital spending, could have been avoided through effective PHC. Hospital expenditure has been a major driver for the insurance fund's deficit that demands the state's bailout. By redirecting expenditures from hospitals toward PHC, growth in hospital expenditure is expected to slow down as preventable hospital admissions will be avoided, and hospital resources will focus on complex cases that truly need medical attention from hospitals.

16. **To address challenges to access to PHC faced by underserved populations, the Government needs to expand legal entitlements and public financing for health while adopting community-based models that can address social barriers faced by vulnerable groups.** Legal entitlements or mandates that enshrine access to a pre-defined package of health care are a pre-requisite for addressing barriers to access. While necessary, global experience in health reform suggests that legal provisions are insufficient in the face of financial and social barriers to health care access. As health shocks are largely unpredictable at the individual level, reducing the reliance on direct, out-of-pocket payments for these unpredictable shocks among the uninsured is necessary to improve access to care. Countries that have made the most progress on access to care have often implemented mandatory contributions for people who can afford to pay and progressively increased other domestic resource mobilization for health for those who are unable to pay. Global experience in reducing inequities in access to care suggest that it is important to

[7] "Underserved Communities" means communes in the Borrower's territory that have more than 6 percent of their population living in census sectors that are marginalized in human capital, employment and living conditions. A census sector is considered marginalized if their index for human capital, employment and living conditions is below the national benchmark value. The list of these underserved communities, totaling 802 in 2016, is available in "The Atlas of Rural Marginalized Areas and of Local Human Development in Romania" published in 2016. The density of family physicians in underserved communities is 20 percent lower than national average.

[8] World Health Organization. European Health Information Gateway. January 2018.

integrate efforts to address social and financial determinants. In this regard, community-based models of care can facilitate health education and offer opportunities to address cultural norms that prevent the use of care that is otherwise legally, physically and financially accessible. Thus, access to care can be enhanced by legal mandates to grant the rights to an appropriate package of care to the population, increased public financing to cover the package of care and eliminate out-of-pocket payments, and community-based models that address cultural and other social barriers to care.

Box 2. Challenges to Access to PHC Faced by Underserved Populations

Underserved populations refer to 1) the uninsured and the poor; and 2) people living in underserved communities. Vulnerable groups (defined in paragraph 8), such as Roma population, are overrepresented in both categories. Underserved populations face supply side and/or demand side barriers as follows:

- **Supply side.** Residents in rural and remote areas are more likely to face **physical barriers** to health care access because there are few or no family physicians in these locations. Up to 90 percent of localities lacking a family physician are rural.

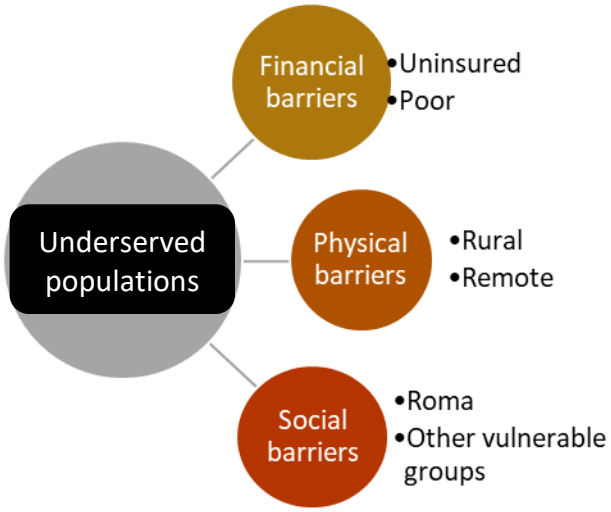
- **Demand side. Financial barriers** arise because of lack of health insurance, predominantly among informal workers, those who lack identity cards, and unemployed people who are not registered for social benefits. An estimated 2 million people do not have health insurance, hence access to basic package of PHC services. More than 60 percent of them are poor; 86 percent belong to the bottom 40 percent of the income distribution. However, even when insured, the poor may also face financial difficulty in accessing the care they need because of the copayments required for medication.

- **Demand side.** Vulnerable groups, including the Roma, also face **social barriers** to health care access, because their knowledge about benefits related to health services and their understanding of how to navigate the health system are limited.

- Among **vulnerable groups,** financial, physical, and social barriers often overlap. For example, 50 percent of Roma are not insured, and 9 percent are not registered with a family physician, compared to 14 percent and 4.5 percent in the general population.

- Roma women are less likely to see a family physician in the event of ill-health owing to social barriers (cultural norms around health seeking and household roles) and physical barriers (distance from the facility). These differences mirror broader gender disparities in health care access in Romania: while only 8.2 percent of men reportedly face financial and physical barriers to health care access, compared to 12.5 percent of women.

Figure 5. Barriers to Access to Health Services Faced by Underserved Populations



Box 3. Barriers to PHC Effectiveness

Effectiveness of PHC services is compromised by the limited scope of care provided by family physicians and the way they are being paid, resulting in underuse of these services.

- **Scope of care.** Clinical guidelines do not allow family physicians to initiate care for several ambulatory care sensitive conditions, including diabetes, asthma, chronic obstructive pulmonary disease, psychiatric conditions, and chronic pain. The scope of PHC has been reduced over the past decades: between 1993 and 2012, the probability of a primary care physician referring minor technical procedures to a specialist increased by 20 percent. For example, Diabetes Mellitus can be appropriately diagnosed, treated, and followed-up at the PHC level, with referrals to relevant specialists for complications as needed, as is the norm in strong health systems in high-income countries. However, the 2016 Country Profile for Romania revealed that PHC does not have basic medicines and technologies needed to manage Diabetes effectively, including prescriptions (for metformin, sulphonylurea, and insulin), HbA1c test, and urine strips for glucose and ketone measurement. As a result, family physicians are bypassed by patients seeking care directly from diabetologists or from emergency services for preventable complications at significantly higher costs to the system.

- **Provider payment methods.** Family physicians are paid on the basis of capitation (a fixed rate per capita) and fee-for-service (a price schedule for service activities). The best practice is to fully adjust capitation rate by disease risk, so that providers do not reject high risk group; at the same payment level, high risk group brings less income to providers due to their frequent use of care. However, in Romania capitation rate is adjusted for age only, and requires further adjustment for other determinants of disease risk such as gender and historical utilization patterns. Moreover, the volume of claims reimbursed on a fee-for-service basis, including preventive and case management services, is capped at 20 services per day, resulting in the undersupply of these services. Performance-based payments for quality or service coverage targets are implemented to some extent but not sufficiently.

17. **Decentralized procurement of drugs and medical devices by health care facilities presents a missed opportunity for economies of scale and efficiency gains.** Currently, over 350 public hospitals individually procure almost all medicines, medical supplies, and medical devices. This leads to a lack of standardization and increases the amount of administrative procurement activity. Information on the numerous procurement processes, including tendered prices, is not routinely shared through formal channels between hospitals or with the Ministry of Health (MoH) to inform procurement practice. The weak public procurement system prevents the Government from making the most effective use of public funds. Initial analyses point to substantial differences between unit prices of identical goods in individual hospitals, so that there are ample opportunities for savings. In 2017, EUR 1.3 billion expenditure on medical products could have benefited from centralized procurement. If all hospitals implement centralized procurement of medical products, it can lead to annual savings of US$ 300 million. Previous

efforts to expand centralized procurement (e.g., developing annual plans for centralized procurement in the MoH) were compromised by limited institutional capacity and faced sustainability challenges.

18. **Although innovative pharmaceutical policies have been adopted to improve the efficiency of the health system, their implementation is limited.** Romania has introduced some of the best global practices in pharmaceutical policy, including external reference pricing (ERP)[9], health technology assessment (HTA)[10], clawback taxes[11], and managed entry agreements (MEAs)[12], but their design and implementation require substantial adjustments to ensure value for money. Price referencing is not regularly recalculated[13], and the HTA does not consider the cost-effectiveness of medicines in the Romanian context. Moreover, it appears that the introduction of regulatory measures to control prices has disproportionately affected some of the old and very cheap generics, which the pharmaceutical companies have withdrawn from the market because they are no longer profitable. There are also concerns that the lower prices of some medicines in Romania compared to other EU countries may lead to parallel exports, jeopardizing access to certain innovative medicines. The number of medicines under MEAs, approximately 30 in 2018, is much lower than in other countries in the region. Strengthening and updating of the existing pharmaceutical policies would put Romania in line with the EU and neighbouring countries and significantly strengthen efficiency in spending on medicines.

Institutional Factors

19. **In addition to the broader challenge of socioeconomic inclusion, institutional factors underlie the barriers to access and drivers of inefficiency in the health system:** fragmentation in institutional coordination, misalignment of incentives in public financing relative to the goals of access and efficiency, and limited implementation capacity in key institutions. A review of health care reform experiences[14] in Europe reveals that other countries in the region with stronger health systems than Romania, invested in addressing structural problems in health service delivery[15]. These investments essentially address the institutional challenges that have been identified as constraints to expanding access and increasing efficiency in Romania – miscoordination, misaligned incentives, and gaps in implementation capacity.

[9] External reference pricing, also known as international reference pricing, refers to the practice of using the price of a pharmaceutical product (generally ex-manufacturer price, or other common point within the distribution chain) in one or several countries to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country. Reference may be made to single-source or multisource supply products.
[10] Health technology assessment is the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences, and aimed mainly at informing decision making regarding health technologies.
[11] Clawback tax is the amount that pharmaceutical companies have to return to the state when public spending on drugs exceeds the amount budgeted for.
[12] Managed entry agreements are contractual agreements between the marketing authorization holder and health care payers that enable access to a health technology subject to specified conditions.
[13] Prices are recalculated annually by the MoH according to article. 3 d) of the Rules on calculation and procedure of approval of the maximum prices of medicinal products for human use by the Order of the Minister of Health No. 368/2017.
[14] Institute of Medicine (US). Changing the Health Care System: Models from Here and Abroad. Washington (DC): National Academies Press (US); 1994. Health Care Reform: The European Experience. Available from: https://www.ncbi.nlm.nih.gov/books/NBK231468/
[15] These investments include adopting policy instruments to shift care from hospitals to primary care (such as incentive-based physician payment systems and need-based planning), using management information systems to monitor and reward performance, and promoting efficiency.

20. **Strengthening coordination among multiple agencies will improve:**

- **the design and implementation of policies for better access to care.** At the national level, the MoH is responsible for defining the general objectives and regulatory framework of the health system, while the NHIH manages the NHIF, through which health services are reimbursed. Coordination challenges at the institutional level are also seen at the service delivery level. The implementation of community health care requires coordination among the MoH who pays personnel; the local authorities who employ the personnel and provide for operating costs; district public health authorities (DPHAs) who supervise service delivery and family physicians, who ensure continuity of care between PHC and community health care. While in principle, community health nurses and Roma health mediators, who provide community health care, should coordinate with family physicians, only 20 percent of family physicians report regular meetings with community health personnel.[16] There are no official protocols for community health care, for coordination with family physicians, or for supervision by DPHAs.

- **efficiency in health spending.** The MoH funds preventive programs, the NHIH is responsible for curative care, and the Ministry of Public Finance (MoPF) oversees the management of health care financing. In practice, the state budget transfer to the MoH is mainly based on agreed line items (e.g., administrative, wages, capital investment, ambulance services) and historical trends, without explicit links to sectoral priorities. Local authorities are responsible for providing PHC facility operating spaces, funding operating costs, and supplementing personnel costs for community health care, but are often excluded from national health strategy. The implementation of community health care requires coordination among the MoH and local authorities.

21. **Fragmentation of information, uneven quality of data, and limited use of data for decision-making hinder the transparency and accountability of the health system.** Although large amounts of data are collected, they are not visible to all stakeholders in the health system, and health data analysis at the national level is incomplete and inefficient. The NHIH databases, although rich in information, are mostly related to the core business of insurance and are not easily available to the MoH and other stakeholders. The quality of data from providers and institutions is inconsistent. Data can be incomplete, unstructured, and non-standardized and could be electronically accessible. As the National Health Strategy recognized, there is no systemic data governance framework in place to address data quality and efficient exchange between data producers and consumers. The MoH lacks the stewardship capacity to deal with the fragmentation of health information and to coordinate across agencies. No agency or MoH unit is responsible for improvements in data governance and management within the health system and with other sectors. The lack of central medical data exchange services and the limited coordination of provider information systems present significant institutional and technical challenges for the introduction of patient-centered health care models in which services are coordinated across providers and levels of care. Although most providers do have some sort of computerized information system, the lack of a data governance standardization platform prohibits the efficient introduction of performance

[16] WHO. 2012. Evaluation of the Structure and Provision of Primary Care in Romania: a Survey-based Project.

indicators and quality assurance mechanisms, which are needed for performance-based payment methods.

22. **The public financing system creates incentives that are inconsistent with reducing inefficiencies and disparities in access to care.** Recognizing the inefficiency of a system of service delivery that is heavily skewed toward inpatient care, the Government of Romania (GoR) has identified PHC as a central component of the National Health Strategy 2014-2020. However, the allocation of NHIH budget to PHC has remained flat, around 6 percent, since 2012. NHIH mostly uses its annual state budget transfers to fill the deficit in NHIF, rather than to achieve service delivery results, so it has no incentive to operate efficiently. As Box 3 explained, the effectiveness of PHC is limited by the way family physicians are paid by NHIH; family physicians have no obligations or financial incentives to improve service conditions, as local authorities own the PHC facilities that are underfunded. The status of family medicine practices as small private businesses also makes it difficult for them to access public funding for improving supply conditions.

23. **While some reforms have been introduced to improve the governance and accountability of public financing, the roles and responsibilities of implementing agencies are not clearly defined, and their capacities are limited.** The delegation of some regulatory functions to newly established agencies is a step in the right direction, but its success will require substantial capacity building and clear delineation of functions. The National Authority for Quality Management in Health Care, established in 2015, cannot assess the quality of facilities in the absence of quality indicators. The National Agency for Medicines and Medical Devices relies on an ineffective HTA methodology that does not consider the cost-effectiveness of medicines in the Romanian context. Although a centralized procurement agency – the National Office for Centralized Procurement (ONAC) – was recently established, it does not yet have the mandate to procure goods and services for the health sector. The under-staffing of Government institutions, an indication of a mismatch between stated government priorities and resources allocation, continues to present significant challenges: for example, the Social Inclusion Unit within the MoH that is tasked with the development of community health programs has only one staff.

24. **Efficiency gains and access to services by underserved groups can be achieved only by addressing the institutional challenges that hinder effective implementation of the country's strategies and policies.** The National Health Strategy aims to restructure the inefficient pyramid of services, gradually ensure wider coverage of the population's health needs through the provision of services at the foundation of the system (community health care services, health care services provided by family physicians, and specialized ambulatory care), and reduce costs. The Strategy identifies cross-cutting solutions that would improve the sustainability and predictability of health financing to ensure access to quality care and financial protection for the population. The vision of enhanced PHC, however, has yet to materialize. Implementation of the Strategy is hindered by institutional constraints, such as poor coordination, lack of commitment to results and value for money, and limited institutional capacity. Concerted efforts are needed to achieve long-term policy goals.

C. Relationship to the CAS/CPF and Rationale for Use of Instrument

25. **The Country Partnership Framework (CPF) for Romania covers a five-year period, 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 to 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 toward 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 technical assistance and lending instruments for Bank support. The Bank and the IFC will pursue focused interventions, with clear indicators to show progress and mobilize support for further reform. In addition, the CPF proposes selectivity filters for all World Bank Group (WBG) operations. Besides the explicit goal of strengthening Romania's institutions, WBG financing would be assessed using the following three filters: (a) benefitting the poorest and most vulnerable, including Roma; (b) maximizing finance for development, including catalyzing private investment or other sources of funding (such as better absorption of EU funds); and/or (c) contributing to regional and global public goods.

26. **The proposed Program for Results (PforR) operation will contribute to the CPF's goal of an inclusive Romania by helping the country to achieve universal PHC coverage.** It will help ensure that no resident in Romania is unable to access PHC, through which more than 90 percent of health issues can be solved if delivered effectively. Achieving universal PHC coverage is aligned with the first area of focus for the Bank's support under the CPF, "to ensure equal opportunities for all," and with its second objective, "to improve access to modern health care," particularly for the poor and vulnerable. Table 1 shows how this proposed operation meets the CPF filters.

Table 1. Applicability of CPF Filters to the Proposed Operation

	Romania CPF filters	How filters are met by the proposed operation
Core WBG criterion	**Strengthen Romania's institutions in the health sector**	Addressing key institutional challenges, including fragmentation in institutional setup, misalignment of incentives embedded in public financing system, lack of transparency in monitoring, and limited institutional capacity in implementing policies (see paras. 13-25).
Additional IBRD criteria	**1. Benefit the poorest and most vulnerable, including Roma**	Specific focus on improving PHC coverage among underserved populations in Romania through interventions on both supply and demand side, including (a) expanding the provision of health insurance coverage for PHC services to the entire population of Romania, with special outreach to vulnerable groups including the Roma; and (b) improving access to community health care and PHC in underserved communities.
	2. Catalyze other sources of funding (such as better absorption of EU funds)	Government examining options for using EU grant funds for the implementation of activities to achieve the proposed DLIs. In addition, resources for implementation support may be considered from a potential reimbursable advisory services (RAS) operation to be funded by the EU or a cofinancing mechanism with the EU for which a Bank-executed trust fund would be established to provide the necessary external technical assistance and other key capacity-building activities.

27. **Building on the recently conducted Public Expenditure Review, the proposed operation will support the Government in introducing discipline in managing public expenditure and turning budget expenditure into an effective policy tool, ensuring that Romania is getting the most "bang for the buck."** The Bank financing will leverage its impact on both the entire Program expenditure and sector expenditure by targeting major changes in use of public funds: a) state budget transfer to NHIH (about US$500 million a year) shifts from fulfilling hospital deficit to providing PHC coverage of the uninsured; b) NHIH expenditure (about US$10 billion a year) breaks old pattern of underfunding the most cost-effective PHC sector, and detects inefficiencies on the basis of improved data governance system with an estimated saving of roughly 7.5 percent a year; c) Implementation of centralized procurement and pharmaceutical measures not only yields some immediate savings, but also builds a foundation for long-term savings estimated at US$300 million a year .

28. **The proposed PforR operation will be a pioneering platform to drive for results by removing institutional constraints and building stronger institutions.** The focus on results has drawn different institutions (e.g., MoPF, MoH, and NHIH) to work together, which has been clearly demonstrated throughout the preparation process of this operation. This is a breakthrough in aligning sector stewardship (MoH) and resource management (MoPF and NHIH). By aligning incentives, strengthening institutions, and improving accountability in the use of funds, the Program will help to ensure the long-term sustainability of public health financing. This operation will accumulate useful experiences for other sectors in Romania and/or other similar countries to apply a similar approach, particularly for other countries facing similar challenges of providing access to services from hard to reach populations in resources constrained environments.

29. **The proposed operation will contribute to achieving both World Bank's twin goals—to end extreme poverty and promote shared prosperity** (that is, sustainably increase the well-being of the poorer segments of society): it aims to increase the coverage of PHC services for underserved populations and to improve the efficiency of public health spending to gain the best value for public financing. Two million people (86 percent of whom represent the bottom 40 percent of the income distribution) will directly benefit from this operation by gaining access to the basic package of PHC. By rebalancing the hospital-centric system toward effective PHC, the proposed operation will greatly help equalize opportunities of improving health care and outcomes across the country, because PHC is deemed the most equitable way of providing health care compared with other types of care such as specialist care, emergency and inpatient care.

30. **As the proposed operation aims at increasing the access to and effectiveness of PHC services, it will contribute to reducing mortality and morbidity in Romania thus improving Romania's human capital, and such experience can benefit other countries facing similar challenges in their human capital improvement.** Recognizing the urgent global need for additional investments in human capital, in 2017 the WBG launched the Human Capital Project[17], which leverages advocacy, measurement, and analytical work to inform strategic policies to build human capital through investments in health, education, social

[17] 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 he/she was born. One of the proxies of the health component of the Human Capital Index measures adult survival rates, capturing 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.

protection, and labor. The proposed operation will be an integral element of the country's effort to improve human capital index, which is 0.60 and much lower than the predicted value for its income level. Moreover, the EU-funded Primary Health Care Activity Monitor for Europe Project, which evaluated the strength of primary care structures and service delivery processes in 31 countries, indicates that Romania faces significant challenges relative to other countries in the region, with respect to PHC effectiveness[18]. It also suggests that lessons from this Program will be useful for other countries facing challenges in these dimensions.

31. **The World Bank's involvement in the proposed PforR builds on the capacity and expertise the Government has developed in recent years, and it complements support under the ongoing project**. Since 1991, the World Bank has been a key partner in Romania, working on reforms and strengthening the health sector[19]. In the areas of centralized procurement and effective implementation of pharmaceutical measures, the proposed PforR provides support for Romania to continue benefiting from global best-practice and improve sector efficiency. Enhancing PHC complements support under other projects that are aimed at improving access to and the quality of hospital services such as specialist care, inpatient care and emergency care. Romania has been trying to consolidate its hospital network to improve efficiency but encountered challenges, which have proved that only with a strong PHC system, it is possible to have hospitals focus on complex cases that require specialized expert interventions.

32. **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**. This operation—Romania's first PforR—is proposing several major changes compared to ongoing and preceding operations. Most importantly, to allow for a focused approach and ensure the best chance for success, it will target a small number of carefully selected areas in support of the Government's program. In addition, use of the PforR instrument will encourage the client to adopt a results-oriented approach.

33. **The PforR instrument is appropriate for the proposed operation because it focuses on results while addressing the main constraints to their achievement**. The PforR instrument brings together different stakeholders to achieve a common objective over the course of its preparation and, more importantly, its implementation. By focusing on results rather than inputs, the PforR allows flexibility to innovate. It also responds to the GoR's demand for using a results-based approach to its investments. The use of country systems, with attention to system strengthening and institutional capacity building, will enhance the Program's development impact and sustainability and will support efficiency gains in the Government's program over time. The PforR will allow for improvements, as necessary, in the implementation of the Government's own technical, fiduciary, and environment and social systems.

[18] Kringos D, Boerma W, Bourgueil Y, et al. The Strength of Primary Care in Europe: An International Comparative Study. Br J Gen Pract. 2013;63(616):e742 – e750. doi:10.3399/bjgp13X674422

[19] 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, which increased access to, and improved the quality of, maternal, rural, and emergency health care services; (d) a DPL-DDO; and (e) the ongoing Health Sector Reform Project, which aims at improving access to and the quality of hospital services. The World Bank also supported the sector through technical assistance and is currently leading the health sector dialogue between the Government and international financing institutions.

Lastly, the PforR instrument encourages collaboration with potential partners in development around a common results framework.

II. PROGRAM DESCRIPTION

A. Government program

34. **The EU's cohesion policy aims to strengthen economic and social cohesion by reducing disparities in the level of development between regions.** The policy focuses on key areas that will help the EU face up to the challenges of the 21st century and remain globally competitive. As the EU's main investment policy, it defines investment priorities of EU funds. About one-third of the EU budget is allocated for the implementation of the cohesion policy. The cohesion policy framework is established for a period of seven years. The current period covers the years 2014-2020 and the next period for years 2021-2027. Promoting equal access to health care for a more inclusive Europe has consistently been the priority of EU's cohesion policy.

35. **Romania's National Health Strategy is developed in two phases: 2014-2020 and 2021-2027, in alignment with the EU cohesion policy.** The National Health Strategy (NHS) promotes social inclusion and introduces discipline in managing public financing, as health services are a critical factor in equalizing opportunities and the health sector budget accounts for a non-trivial 10 percent of the total Government budget.

36. **Overall, the NHS has identified eight main areas**. Seven areas focus on ensuring access to specific types of care: public health, community health care, primary health care, specialist care, inpatient care, emergency care and palliative care. The eighth area focuses on cross-cutting measures for health system strengthening, including implementation of health financing, human resource, service quality improvement and pharmaceutical policies, use of modern information technology in health sector, and institutional strengthening (Table 2).

Table 2. Care-Specific Areas and Cross-Cutting Measures in the National Health Strategy

<table>
<tr><td colspan="7">Areas 1-7 (Care-specific). Ensuring access to:</td></tr>
<tr><td>1. Public health</td><td>2.Community health care</td><td>3.Primary health care</td><td>4.Specialist care</td><td>5.Inpatient care</td><td>6.Emergency care</td><td>7.Palliative care</td></tr>
<tr><td colspan="7">Area 8. Cross-cutting measures for health system strengthening:
Implementation of health financing policies for better efficiency and financial sustainability
Accelerating the use of modern information technology or eHealth
Implementation of health human resource policies
Development and implementation of evidence-based pharmaceutical policies
Improvement of service quality
Building administrative capacities</td></tr>
</table>

B. PforR Program Scope

37. **The boundary for the PforR within the NHS has several dimensions.** First, it will focus on community health care and PHC among the seven care specific areas, and all the cross-cutting measures to the extent that they are related to community health care and PHC, as well as efficiency improvement of health expenditure (areas 2, 3 and 8 in Table 2). Focusing the Program resources on these areas will contribute to achieving universal coverage of PHC and increasing the efficiency of public financing in the health system. Second, the Program will have national coverage, but its most intense efforts to expand PHC coverage will be focused on reducing the challenges to health care use by underserved populations.

38. **Focusing on community health care and PHC is justified on several grounds.** In countries that have high coverage of services and good health outcomes, PHC tends to have a central role, with comprehensive care for most conditions provided by the family physician. Strengthening PHC in Romania is a necessary condition for improving access to services and increasing the efficiency of the health system; PHC reaches the largest share of the population and can help shift patients out of hospitals for better efficiency in resource use. Community health nurses and Roma health mediators, who facilitate linkages between underserved populations and family physicians, are essential to addressing physical and social barriers to access to care. While other types of care in the seven care-specific areas may contribute to health outcomes, access, and efficiency, they are covered by the ongoing Health Reform Project (Loan No. 8362-RO) that provides support to hospitals.

39. **The cross-cutting areas of the Government program are included in the PfoR because they address critical drivers of inefficiency identified in the Public Expenditure Review.** Therefore, the PfoR will support activities that improve the implementation of innovative pharmaceutical policies that have the potential to increase cost containment and the predictability of expenditures in the system. Likewise, the Program will support efforts to develop a health information system that facilitates collaboration across institutions and provides data on health expenditures to enable decision-makers to reduce intentional and unintentional inefficiencies in the health system. The PforR will not address the full array of issues identified under the NHS in these cross-cutting areas. For example, efforts to improve human resources for health in hospital service delivery, while important, are outside the Program focus on PHC and critical drivers of inefficiency.

40. **The proposed Program scope is informed by the findings of analytical work and the experiences of previous engagements, and defined by the country's demand and application of the CPF filters.** Analytical work (e.g., the SCD and PER) shows that Romania's health sector, financed mostly by public funds, is underfunded and inefficient, and is not effectively delivering services for the poorest and most vulnerable people, including Roma. Furthermore, previous engagements have shown that sound technical solutions are often left not implemented or are unsustainable because of inherent institutional constraints. The Government requested the Bank's support in expanding access to basic services for the entire population, particularly the uninsured and underserved, including Roma. As noted in Section I.C (Relationship to the CAS/CPF and Rationale for Use of Instrument), the proposed operation meets the core WBG engagement filter and two additional IBRD financing criteria.

41. **The proposed Program focuses on three results areas in which the Government requested the Bank's support and where the Bank's engagment is likely to make a signficant impact**.

Results area 1: Improving PHC coverage for underserved populations

42. This results area aims to improve PHC coverage for underserved people by addressing the physical, financial, and social challenges they face.

- To address physical challenges related to access to PHC, the Program will expand community health care and strengthen its collaboration with PHC. The National Health Strategy has identified community health care as a cost-effective means of providing access to essential services in rural areas and for underserved populations. The MoH will provide funding for local authorities to hire community health nurses and Roma health mediators, if required, for delivery of community health care. These community health care providers will conduct household visits to promote health and specific preventive interventions, develop resident rosters and identify those with high disease risks, promote the demand of health services when needed, and support community-based interventions. All these activities will promote early detection, improve treatment compliance, and increase health care use, thus leading to improvement in health outcomes.

- Guidelines will be developed to guide and standardize the daily work of community health workers (including both community health nurses and Roma health mediators). A template agreement is being developed for collaboration between public community health care and private PHC providers. The agreement will define specific steps for information exchange between community health care providers and PHC providers working in the same areas. Through such information exchange, community health care providers will inform family physicians about specific health situations of individuals included in their rosters, and support family physicians in reaching out to patients that require follow up. Community health care providers will be trained to ensure their compliance with the protocols. To improve the governance of community health care and PHC, the MoH will strengthen the existing unit to ensure the strategic planning at the institutional level for primary and community health care services and to improve the supervision of implementation, in partnership with DPHAs.

- To address social challenges faced by vulnerable groups, the targeted communities (including marginalized communities) will receive health education and support in navigating the health system, particularly PHC. As part of the communities, community health nurses and Roma health mediators will map out specific social challenges and help address them. As needed, primary care providers and community nurses in these communities will also be trained in working effectively with different cultures and ethnic minorities.

- To address financial challenges to PHC, the Government recently announced an initiative to provide the basic package of PHC to the uninsured in Romania. This will entail amending the health law to extend this benefit to the uninsured. In addition, state budgets and the NHIH's framework contract[20] with family physicians will be revised to reflect the cost of providing this

[20] "Framework Contract" means the legal document, approved by the Borrower, defining the health service package and the terms and conditions of their provision, including PHC services, to be provided within the Borrower's social health insurance system. Introduction of new groups of beneficiaries (e.g., basic package of PHC for the uninsured) will require change in the law. However, changes to the specific contents of services and specific parameters of provider payment mechanisms (e.g., fee

benefit. Furthermore, public campaigns will be conducted to make the population aware of the benefit to which they are entitled. Their awareness of the new benefit will be monitored, and grievance mechanisms will be strengthened to facilitate people's access to PHC services.

Results area 2: Rebalancing the hospital-centric system toward effective PHC

43. This results area aims to rebalance the hospital-centric system toward effective PHC by addressing the underlying institutional challenges: chronic underinvestment in PHC, the misalignment of incentives that is embedded in NHIH's provider payment mechanisms, and regulatory restrictions on the scope of PHC services. The Government plans a set of initiatives to make PHC comprehensive, widely accessible, and effective.

44. One initiative will revise the package of services in PHC to expand the number of services, including prescriptions for exams and medications to control the most prevalent noncommunicable diseases (NCDs) and increase the supply of preventive services for adults and children such as regular check-ups. In consultation with physician associations, the MoH will modify clinical guidelines to expand the scope of services in PHC to include initiation and coordination of care for some medical conditions such as diabetes mellitus, asthma, chronic obstructive pulmonary diseases, psychiatric conditions, and chronic pain, including prescription of related medication and the required diagnostic tests. The basic package of PHC will be updated to reflect these normative changes.

45. To increase the supply of PHC, the NHIH also aims to revise provider payment mechanisms, incentivizing family physicians to improve effectiveness of services. Specifically, NHIH will reimburse family physicians for providing additional services—for example, to enable them to initiate treatment of diabetes mellitus. It will also use a combination of mechanisms such as capitation (adjusted by age and gender), fee-for-service, and performance-based payment (payment made when pre-agreed performance criteria are achieved), and will adjust specific payment terms (e.g., rate of capitation, threshold for fee-for-service volume) to reflect global experiences and country context. With respect to performance-based payments, family physicians will be rewarded for attaining service coverage targets (e.g. vaccination rate of 90 percent for all children under-five on the list) and delivering effective care (e.g. bonuses for adherence to clinical guidelines for annual preventive checks for adults above 40).

46. Chronic underinvestment in PHC will be addressed through a two-pronged approach. First, the allocation of NHIH budget to PHC will be substantially increased during the next four years as the expanded scope of and access to PHC increase its use. This will greatly improve the funds inflow for family medicine practices. Second, a de minimis aid[21] scheme will be established to provide grants to facilitate the establishment of family medicine practices in areas where they are not available. It will also provide interest-free loans for practices to improve the quality of care, such as acquiring necessary equipment,

level and caps on volume of claims reimbursed) can take place through its annual updating process. Framework contract is updated and signed annually.

[21] De minimis aid means: "aid granted to a single undertaking over a given period of time that does not exceed a certain fixed amount" from public funds as defined by the Commission Regulation (EU) No. 1407/2013 of December 18, 2013.

training, or transportation and conducting minor refurbishment. The de minimis aid scheme will be first piloted and then expanded to about 20 percent of family medicine practices.

Results area 3: Improving health expenditure efficiency by addressing critical cost drivers

47. This results area aims to increase the efficiency of health expenditure by addressing critical cost drivers, including high spending on pharmaceuticals, devices and supplies and inefficient spending that can be detected through effective use of information.

48. To better control spending on pharmaceuticals and supplies, the Program will focus on more effective implementation of centralized procurement and pharmaceutical policies. This will entail refining the current policies (set out in Emergency Ordinance no. 71/2012, which notes that other European countries that implemented centralized procurement realized price reductions of 10 to 30 percent) and strengthening institutional capacity to implement them. Other proposed actions include modifying costing methodologies, setting health services prices by category of service providers, increasing the transparency of public spending using annual reports prepared by the NHIH and MoH, using risk-sharing mechanisms and cost-volume regulations for all new high-cost drugs, and revising the positive drug lists to ensure cost-effectiveness.

49. Under the Program, improvements in health information management are envisioned to ensure standardization, and interoperability of the existing subsystems, to facilitate access to information and enable evidence-based decision-making, including commitment controls. The application of state-of-the-art data analytics will help identify and prevent inefficient spending in many areas—for example, unnecessary care (referrals, visits, laboratory tests, etc.), failure to adhere to best practices, duplication of services, non-optimized drug prescriptions (e.g., less use of generics than expected), non-optimal use of infrastructure and medical equipment, low workforce productivity, detectable high-cost centers (e.g., population with high number of readmissions, over-prescribing centers), errors (e.g., coding, claimed services not connectable to medical conditions), and frauds.

50. **The budget for the Government program over the next four years is estimated at US$5.1 billion, of which IBRD financing would be US$557 million, or 11 percent of the program budget.** The specific expenditure categories included in the Program are goods and services, the wage bill, and capital expenditures. The activities under the Program will be funded from the budgets of the NHIH, MoH, and MoPF. For the NHIH, the Program will pertain to expenditures for family medicine services and NHIH administration. For MoH, the Program will relate to expenditure items dealing with community health care, including medical units in schools, data management, medicines policy, administration of related

activities, and the de minimis aid scheme for family physicians. In addition, the Program will include the portion of the MoPF budget that is related to ONAC.

Table 3. Program Financing

Source	Amount (US$ million)	Percentage of total
Counterpart funding	4,530.0	89
International Bank for Reconstruction and Development (IBRD)	557.2	11
Total Program financing	**5,087.2**	**100**

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

51. The proposed 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 challenges.

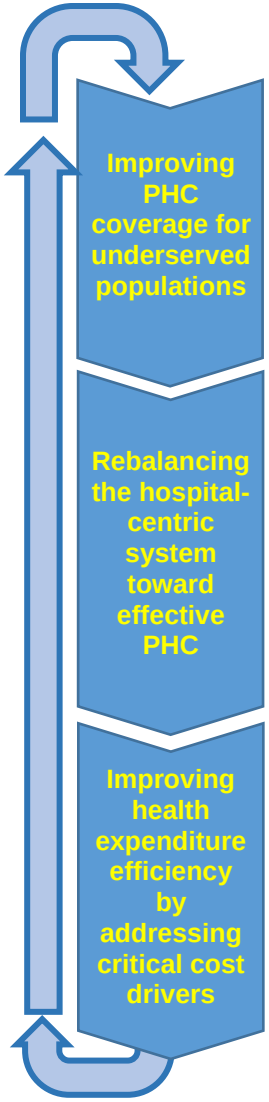
52. **Four PDO indicators have been identified to measure progress in the three results areas:**

- **PDO indicator 1**: Number of the uninsured in Romania who are registered with family physicians and entitled to receive the basic package of PHC services (Results area 1).
- **PDO indicator 2**: Percentage of adults (40 years old and above) receiving annual medical check-ups[22] from family physicians (Results area 2).
- **PDO indicator 3**: Share of the National Health Insurance Fund annual budget allocated to primary health care (Results area 2).
- **PDO indicator 4**: Proportion of the supplies and devices for emergency medical services (in value) procured under framework agreements by the National Office for Centralized Procurement (Results area 3).

53. **The proposed Program aims to achieve its PDO by addressing institutional constraints that hinder access and efficiency.** Theories of change for each Result Area are presented in Figure 6 below. In addition, Figure 11 in Annex 3 provides a graphical presentation of the detailed linkage between institutional challenges, health system barriers and the Program.

[22] Annual Medical Checkup means preventive checkup consultations for asymptomatic adults to assess the risk of illness and case-management consultations to evaluate newly diagnosed adult patients and actively monitor their conditions, carried out yearly by family physicians based on the provisions of the framework contract. (The conditions included in case-management consultations are hypertension, dyslipidemia, diabetes type 2, asthma, COPD are chronic kidney disease).

Figure 6. Theory of Change



	Actions	Institutional Factors
Improving PHC coverage for underserved populations	• Provision of demand-side financial incentives for the population to seek care early at PHC by granting everyone basic package of PHC • Addressing supply-side limitations and cultural barriers to access by strengthening community health care and their collaboration with PHC	• Shifting away from financing deficits towards program-based budgeting (aimed at covering the cost of the basic package of PHC for the uninsured) • Facilitating institutional linkages among the MoH, local authorities, and family physicians to implement community health care in collaboration with primary care in underserved authorities
Rebalancing the hospital-centric system toward effective PHC	• Enhancing PHC providers' (i.e., family physicians') ability to deliver quality care through grants and loans under de minimis aid scheme • Increasing the allocation for PHC within NHIH budget • Changing the way PHC providers are paid by insurance to encourage provision of preventive care and management of non-communicable diseases • Expanding the scope of services that can be provided by them so that care can be shifted away from specialists	• Providing PHC providers access to government or market financing for the first time • Prioritizing PHC not only in government policy document, but also in budget allocation • Realigning incentives embedded in service delivery and financing and motivating family physicians to provide more and better services
Improving health expenditure efficiency by addressing critical cost drivers	• Detecting and preventing inefficient spending through better data governance • Reducing inefficiency resulting from high spending on pharmaceuticals, medical supplies and devices through strengthening centralized procurement and implementation of pharmaceutical policies	• Building foundations for long-term reforms and more substantial savings in the future • Promoting evidence-based decision making through increased information sharing across key institutions • Consolidating institutional structures of public procurement, building ONAC's capacity and promoting collaboration between MoH, Ministry of Interior, NHIH and ONAC. • Building institutional capacity and effective implementation of pharmaceutical policies

D. Disbursement-Linked Indicators and Verification Protocols

54. **In this section we describe the Disbursement-Linked Indicators by results area, reflecting the critical institutional challenges that must be addressed to improve access to PHC and efficiency in the health system**. Verification will rely on existing systems—both Government databases and agencies where reporting is confirmed as sound, as well as surveys designed to help the system conduct checks and balances for the future. Verification process will involve confirming changes in regulatory and legislative documents, reviewing system reports from established databases, and conducting sample checks. The verification protocol for the DLIs (both verification entity and verification process) is described in detail in Annex 2.

Results area 1: Improving coverage for underserved populations

DLI 1: Access to the basic package of PHC services among the uninsured.

55. **Rationale.** At least 11 percent of Romania's population are not covered by the social health insurance system. The minimum benefits package these people can access at the PHC level is narrow, resulting in overuse of expensive emergency services for non-urgent and non-emergency conditions. Thus, the lack of health insurance presents a financial barrier to PHC access and increases the overall costs of the health system. In addition, the state budget transfers to the NHIH—which have averaged US$500 million annually over the past five years—are used predominantly to cover deficits in the NHIF, creating disincentives for the NHIH to operate efficiently. This DLI aims to support the shift from input-based to results-based financing, facilitating improvements in the efficiency and predictability of expenditures in the Romanian health system, while addressing demand-side financial barriers to health care access.

56. **Description.** The Government will revise the Health Reform Law to grant universal access to the basic package at the PHC level. These legislative changes will be translated into modifications of the NHIH framework contract with providers, enabling family physicians to provide a uniform package of services to all Romanian residents, regardless of their health insurance status. State budget transfers to the NHIF will be made annually to finance a uniform basic package for PHC for the uninsured. An estimated 2 million uninsured people will be enabled to receive services on the basic package list for PHC at no cost. The Government may need technical assistance in revising the basic package for universal access to PHC, including benefit package defining and costing, and expenditure projections.

DLI 2: Number of underserved communities receiving public community health care in collaboration with primary health care providers.

57. **Rationale.** Difficulties in collaboration between health providers and agencies involved in the provision of basic health services present supply-side barriers to access in underserved communities. A total of 439 local public administration authorities that face supply-side barriers to PHC access are considered underserved. Only 1.5 percent of urban communities and 6.9 percent of rural communities meet the requirement for community health nurses.[23] The local authority administration is expected to facilitate collaboration between community health workers and family physicians to promote access to

[23] To link residents of underserved communities to PHC, there should be one community health nurse per 500 persons and one Roma health mediator per 700 self-identifying Roma.

PHC; however, only 20 percent of family physicians report regular meetings with community health personnel and 18 percent report regular meetings with local authorities. This DLI aims to leverage partnerships among the MoH, local authorities, and largely private family physicians to address these supply-side barriers to PHC use in underserved communities. This DLI will also contribute to promoting knowledge and awareness on climate change risks to the communities, particularly the underserved, by increased outreach of community health workers.

58. **Description.** The MoH will develop and adopt methodological guidelines and household monitoring instruments for community health care, and template agreements for collaboration between community health care and PHC providers. Strategic planning to close supply-side barriers to PHC access will be informed by community needs assessments that characterize population health needs in underserved local authorities. The MoH and the local authority will hire and train community health nurses and will support them in providing health promotion services in at least 300 local authorities, facilitating linkages to PHC where needed. In communities with up to 700 self-identifying Roma, when needed, a Roma health mediator will also be hired, trained, and supported by the MoH and local authority to ensure the registration of vulnerable groups in PHC. The MoH may require technical assistance to develop guidelines for collaboration between community and primary care, assessment of community needs, supervision of care, and training to be provided to primary care providers and community health workers in working effectively with different cultures and ethnic minorities, as needed.

Results area 2: Rebalancing the hospital-centric system toward effective PHC

DLI 3: Share of the NHIH budget allocated to primary health care.

59. **Rationale.** The hospital-centric nature of the system is reflected in the relative underfunding of PHC. While 54 percent of annual health expenditure is on hospital care in Romania, relative to 40 percent in the EU, only 6.5 percent is spent on family medicine. The framework contract between NHIH and providers is tailored to budget classifications based on different line items, without orientation toward service delivery results. This DLI aims to support the MoH's efforts to reorient the health system toward PHC by adjusting incentives for service provision and increasing overall funding for PHC. This DLI will contribute to supporting resilience of the population to adverse climate-related events or conditions because, by expanding the volume and scope of services in PHC and bringing PHC closer to people, access to information on preventive measures on conditions related to climate change events will be enhanced (e.g., primary physicians will educate on prevention and protection measures during extreme weather conditions such as dehydration, sun exposure avoidance).

60. **Description.** With the rise in the scope and supply of PHC services, the share of the NHIH budget allocated to family medicine will increase from the current level of 6.5 percent to 10 percent by the end of the Program. NHIH is expected to need technical assistance to support the revision of clinical guidelines to expand the scope and supply of PHC services, and of the framework contract to expand the provider payment mechanisms used by NHIH (adjusting capitation and fees for service, and introducing

performance-based payment).

DLI 4: Number of family medicine practices receiving grants and loans for the purpose of increasing and improving the supply of primary health care services.

61. **Rationale.** The supply and quality of PHC are constrained by chronic underinvestment in family medicine and lack of collaboration across the institutions involved in its administration. Funding constraints faced by primary care physicians have negative implications for the structural quality of care, that is the availability of infrastructure, equipment, trained staff, supplies, and other inputs for care. In a recent assessment of care for diabetes mellitus, basic tests for case management could not be accessed in PHC, including urine strips for glucose measurement and oral glucose tolerance tests.[24] As 96 percent of family medicine practices are privately owned by individuals, traditional ways of accessing finance through the public sector and commercial financial institutions are infeasible. Incentivizing capital investments in PHC through the public sector requires coordination across national-level agencies on policies and regulation and between the national and district authorities on implementation modalities. Local authorities regulate the sale, lease, or rental of private assets, including infrastructure for PHC. However, the MoPF oversees health care financing, and the MoH defines the regulatory framework for PHC. This DLI aims to address the financial and coordination barriers to incentivizing an increase in the supply and quality of PHC.

62. **Description.** Through routine monitoring systems, the MoH and DPHAs regularly assess structural quality of facilities, including infrastructure, equipment, staff training, which also help determine needs for improvement. The MoPF and the MoH will then set up a de minimis aid scheme to fund capital investments in family medicine, including repairs and small refurbishing of facilities, equipment, training, transport, and other eligible expenditures defined by the assessment. The de minimis aid scheme will come into force through legislation that specifies the criteria for awards of grants or loans[25], and implementation guidelines. Family medicine practices applying for grants or loans will need to have a minimum of five years agreement for using infrastructure of local authorities (sale, concession, or lease) to ensure their continued presence in the community after being awarded by the scheme. Loans will be available for all family physicians who have an active contract with NHIH. Grants will be used to incentivize family physicians to start practice in remote areas. The MoH will call for proposals from family physicians, evaluate proposals and communicate with family physicians on the awarding of funds. These loans and grants are envisioned to be EUR 35,000 on average, with a maximum amount of EUR 50,000. The MoH may need technical assistance for technical design of the de minimis aid scheme including needs assessment, development of operational guidelines, and arrangements ensuring accountability in using grants and loans.

63. This DLI will also promote climate smart infrastructures and inclusion of energy efficiency measures in the refurbishing of health facilities in accordance with the European Climate Change Programme (Paris Agreement of 2015). The guidelines for implementation of the de minimis aid scheme

[24] WHO. 2016. Diabetes country profile: Romania.
[25] At the rate of 11 percent, ten-year loans will be provided to family physicians with interests covered by The MoPF.

will incorporate EU standards for health services, including energy efficiency updates and appropriate waste management.

DLI 5: Scope and effectiveness of PHC traced through the share of diabetes medication initiated by PHC providers and the proportion of adults (40+) receiving annual medical check-ups.

64. **Rationale.** This is a tracer indicator to demonstrate increased scope and effectiveness of PHC as the result of Program implementation. A commonly used diabetes medication, metformin, is chosen to monitor drug regimen initiation at PHC level. There are clear guidelines on how this medication should be prescribed, which will help prevent potential ambiguity of the reported results and unjustified prescription.

65. **Description.** Because of the expanded scope of PHC, the percentage of family physicians who initiate metformin prescriptions for diabetes mellitus type 2 (currently zero) will increase to an estimated 20 percent. In addition, with more funds allocated to family medicine and provider payment mechanisms revised, the proportion of adults receiving annual medical check-ups (currently negligible) will increase to 20 percent.

Results area 3: Improving health expenditure efficiency by addressing critical cost drivers.

DLI 6: Efficiency of NHIH expenditure improved through data-driven decision-making process.

66. **Rationale.** Lack of centralized data exchange platforms and mechanisms for accountability in the use of health financing lead to inefficiencies in health spending. The NHIH data system, which captures 67 percent of total health expenditure, has limited mechanisms to identify and prevent the provision of unnecessary services or detect errors in claims and fraud. The disconnect between the NHIH data system and the MoH (including services provided through community health care and the national health programs on prevention) also prevents the review of health expenditure and utilization patterns across the whole system. Lack of a data governance standardization platform limits communication between systems and prevents the introduction of quality assurance mechanisms to hold providers accountable for performance. This DLI will support the development of data governance framework and building IT systems that enable the identification and reduction of ineffective health expenditures and promote performance management in service provision. It will also improve epidemiological surveillance, detecting changes in incidence, mortality, and the geographic ranges of health outcomes.

67. **Description.** An inter-institutional agreement for data governance will be developed and implemented, strengthening the stewardship role of the MoH in overseeing the efficient, reliable, complete, and timely collection and reporting of data for decision-making via centralized platforms. The NHIH will develop and implement adaptive algorithms for service delivery reporting from health care providers and use the e-prescription system to improve detection of unnecessary service provision, errors in claims, and fraud. An interoperable system will also be developed to connect data from the NHIH, MoH and providers, enabling the application of advanced algorithms to further identify and reduce inefficient spending. Reducing losses due to inefficient spending[26] will reduce projected total health expenditure by

[26] "Inefficient spending" in the context of DLI 6 means spending that is detectable by data analytics as non-optimal, e.g. unnecessary care (referrals, visits, laboratory tests, etc.), non-adherence to best practices, duplication of services, non-optimized drugs prescriptions (e.g. lesser

the NHIH by 2.5 percent. Technical assistance will be required to design and implement an upgraded system platform for the interoperable data system.

DLI 7: Efficiency of expenditure improved through implementation of centralized procurement.

68. **Rationale.** In Romania over 350 public hospitals individually procure most medicines, medical supplies, and medical devices, missing opportunities to leverage economies of scale and increase l efficiency. Substantial differences between the unit prices of identical goods across hospitals indicate that centralized procurement presents an opportunity for cost savings from the EUR 1.3 billion spending on medical products. The duplication of administrative procurement activities across hospitals also creates inefficiency. ONAC does not carry out centralized procurement in the health sector, because it lacks both the legal mandate and experience. This DLI will facilitate collaboration between relevant agencies to address legislative and capacity barriers to centralized procurement in the health sector by ONAC.

69. **Description.** Procurement legislation will be amended to give ONAC the legal mandate to undertake centralized procurement in the health sector and to specify mechanisms for the coordinated provision of technical specifications for medical supplies and devices through the MoH and other agencies. ONAC will first carry out pooled procurement of selected standardized products, including other standardized products for which ONAC already has the mandate, and for which publicly owned hospitals lack framework agreements. ONAC will then undertake centralized procurement of at least 60 medical supplies and devices for emergency medical services, using technical specifications provided by the Ministry of Interior. Finally, selected medical supplies and devices[27] will be procured centrally for publicly owned hospitals contracted through the District Health Insurance Houses. As a result of the economies of scale, publicly-owned hospital expenditures on medical supplies and devices procured centrally are expected to achieve the savings of at least 5 percent. Technical assistance may be needed to support ONAC in launching and implementing centralized procurement.

70. This DLI will support centralized procurement of medical supplies and devices using climate smart approaches to reduce the carbon footprint embedded in manufacturing processes. Furthermore, consolidating procurement of these goods will significantly reduce the carbon footprint by increasing the efficiency of the procurement process.

DLI 8: Pharmaceutical measures revised for better efficiency.

71. **Rationale.** Adjustments in pharmaceutical regulation are needed to reduce costs while ensuring the availability of medicines. Pharmaceutical products are a significant cost driver in Romania: between 2006 and 2017, medicines and medical supplies accounted for 37.5 percent of health spending. Price referencing is sporadically implemented every five to six years, and HTAs do not consider the cost-

use of generics than expected), non-optimal use of infrastructure and medical equipment, low workforce productivity, detectable high cost centers (e.g. population with high number of readmissions, over-prescribing centers, etc.), errors (e.g. coding, claimed services not connectable to medical conditions) and fraud.

[27] Medical supplies and devices is a term covering a broad range of commonly used medical products, varying from syringes, needles, bandages, to stents, etc. Procurement of supplies and devices for emergency medical units is under the shared mandate of the Ministry of Interior and the Ministry of Health and covers only emergency services. Procurement of medical supplies and devices for publicly owned hospitals is under the mandate of the Ministry of Health, which will provide technical specifications for ONAC to centrally procure for all publicly owned hospitals.

effectiveness of medicines in the Romanian context. Furthermore, in many cases, MEAs are not used to facilitate the introduction of innovative medicines. The number of medicines under MEAs—approximately 30 in 2018—is much lower than in other countries in the region. This DLI will support changes in pharmaceutical policy to ensure regular price referencing, improvement of the HTA methodology, and increase in the uses of MEAs, facilitating access to medicines while ensuring efficiency gains.

72. **Description.** The pricing process for medicines will be completed annually and published on the MoH website, and the list of reference prices calculated on the basis of the prices set by the MoH will be published on the NHIH webpage. The National Agency for Medicines and Medical Devices will revise the HTA methodology for including new drugs on the positive list to take into account the cost-effectiveness of medication in the Romanian context. The MoH will increase the number of drugs with conditioned entry into the list of medicines reimbursed from the NHIH, such that a cumulative 50 percent of newly listed patented drugs will be introduced in the positive list through the revised HTA methodology and reimbursed by the NHIH, subject to MEAs. Technical assistance will be needed in developing and implementing the HTA methodology and in revising the drug list.

III. PROGRAM IMPLEMENTATION

A. Institutional and Implementation Arrangements

73. **Program implementation will be supervised at the national level using existing institutions and supervision practices.** The MoH will provide overall oversight of the Program, facilitate strategic decision-making, and ensure cross-agency coordination during Program implementation. For this purpose, a Steering Committee, headed by the General Secretary of the MoH and comprising representatives of the MoH, MoPF, and the NHIH, will be established to provide strategic oversight and guidance during Program implementation. The Steering Committee will meet at a minimum every quarter during Program implementation. A Program Coordinator will serve as the secretary to the Steering Committee (prepare the minutes, organize the meetings, and provide relevant documents to the Committee). The Program Coordinator will also provide support in the day-to-day implementation of the relevant DLRs related to the results areas, liaise with the World Bank on all matters pertaining to the Program, and submit evidence on the achievement of DLRs to the World Bank in accordance with the verification protocol (More details on roles and responsibilities among the various implementing entities are provided in Annex 8.)

74. **The MoPF, MoH, and NHIH will be jointly responsible for the national-level day-to-day supervision, technical guidance, and actual implementation of the Program.** Within each entity, a team of three to four key staff members will be designated as focal points. They will be responsible for supervising Program implementation according to their areas of competence and ensuring timely coordination with the relevant departments within each entity that are responsible for the implementation of the activities to achieve the DLRs. They will work in close collaboration with the Program Coordinator of the MoH. At a minimum, the following supervisory teams will be established: (a) MoPF: authorized representatives of the General Directorate of International Financial Relations, Directorate of Analysis and Streamlining of Public Spending, and ONAC (responsible for achievement of DLI 7 in collaboration with other agencies, including MoPF, MoH, Ministry of Interior, NHIH); (b) MoH: authorized representatives of the General Secretary, of the General Directorate of Medical Assistance and Public Health, General Directorate of Procurement, Informatization and Patrimony, National Agency of

Drugs and Medical Devices, and Institute of Public Health; (c) NHIH: authorized representatives of the Chief Medical Doctor's Office, Contracts with Health Providers Directorate, Legal Department, Economic Department, and IT Department, Control and Antifraud Department, and Financial Management Department. These supervisory teams are expected to work in close collaboration to ensure timely achievement of the Program DLRs.

75. **Sub-national level**. The Local Public Administration Authorities coordinated by the Ministry of Regional Development and Public Administration, and the DPHAs coordinated by the Ministry of Health, will be involved in the implementation of community health care and of the de minimis aid scheme. Under the Emergency Ordinance 18/2017, the DPHAs will supervise the implementation of community health care at the local level, including collaboration with family physicians. The DPHAs will also be responsible for monitoring and evaluation of activities under the responsibility of the Local Public Administration Authorities, community health nurses, and Roma health mediators. The Local Authorities are tasked, under the same Ordinance, with providing work space and funding operational costs of Community Health Nurses and Roma Health Mediators. The protocols to guide these functions will be supported through the Program. Within the de minimis aid scheme, family physicians will be expected to enter into agreements with Local Authorities to refurbish primary health care facilities provided by the Local Authorities as needed. In accordance with the scheme implementation guidelines to be developed, the DPHAs might be involved in assessing the eligibility of the applications by family physicians for financial support from the scheme and monitor the implementation of the scheme.

Table 4. National Level Key Oversight and Operational Bodies

Bodies				
	Responsibility	**Ministry of Public Finance**	**Ministry of Health**	**National Health Insurance House**
Steering Committee	Provide overall oversight of the Program, facilitate strategic decision-making, and ensure cross-agency coordination during Program implementation	Representatives of the MoPF	General Secretary (Chair) and other key representatives	Representatives of NHIH
Focal points	Provide supervision and technical guidance and oversee the implementation of the Program. Ensure timely coordination with the relevant departments within each entity that are responsible for the implementation of the activities to achieve the DLIs/DLRs. Work closely with the Program Coordinator of the MoH	Authorized representatives of the General Directorates of International Financial Relations, Budget and Finance; Directorate of Analysis and Streamlining of Public Spending; and ONAC	Authorized representatives of the General Secretary Office, General Directorate of Medical Assistance and Public Health; General Directorate of Procurement, Informatization and Patrimony, National Agency of Drugs and Medical Devices; and Institute of Public Health	Authorized representatives of the Chief Medical Doctor Office, Contracts with Health Providers Directorate; Legal Department; Economic Department; IT Department; Control and Antifraud Department; Financial Management Department

Bodies				
	Responsibility	Ministry of Public Finance	Ministry of Health	National Health Insurance House
Program Coordinator	Secretariat to the Steering Committee. Day-to-day implementation and support for the achievement of the DLRs. Liaises with the World Bank on all matters pertaining to the Program. Submits, as relevant, evidence on achievement of DLIs/DLRs to the World Bank in accordance with verification protocol	Supports the Program Coordinator of the MoH, as required Coordinates the preparation of periodic financial reports and Program audits for onward submission to the Program Coordinator of the MoH, who is responsible for transmitting the documents to the Bank	Program coordinator for the results areas	Supports the Program Coordinator of the MoH, as required

B. Results Monitoring and Evaluation

76. **The country's routine data reporting system is robust enough to be used for monitoring purpose.** There are two main routine health data reporting system in the country: health statistics from the National Institute of Public Health and those from the NHIH. The National Institute of Public Health regional directorates (Regional Centers for Public Health) routinely collect medical and administrative data from providers; the data are then aggregated at the national level. Reporting on communicable diseases is managed under a different department of the MoH and has online reporting. The NHIH collects primary care data from about 11,000 PHC facilities. The data related to insurance reimbursement payments (changes in empanelment, visits, services, referrals, etc.) are collected monthly by the NHIH Integrated Unique Informatics System (SIUI) and are reliable, detailed, and fully electronic. In addition to payment data, primary care providers provide medical data to the central Electronic Health Record (EHR) system of the NHIH. The NHIH also has detailed reporting from the e-prescription system. In addition to these two major routine data reporting systems, the software package for community health care reporting provides detailed data and indicators on community health care, such as nurses' visits. NHIH databases (mostly, SIUI, EHR and e-prescription) and the community health care database will be used to monitor progress related to community health care and PHC (Results Areas 1 and 2). These systems will be strengthened as needed to enhance the timeliness and quality of the data.

77. **The Program Coordinator of the MoH will be responsible for the timely collection of all documentation about Program implementation progress.** The Program Coordinator will ensure that the institutions and agencies responsible for each DLI have documented and verified progress on these indicators. The Program Coordinator will also consolidate all Program activity and fiduciary reports as required, review them, and prepare a twice-yearly progress report. The progress report will include

information on achievement of the Program indicators, highlighting bottlenecks and proposed corrective measures. The MoH will submit the monitoring data and progress reports to the Bank twice each year.

78. **To monitor the progress and impact of the major reform agendas embedded in the Program, policy analysis activities may be included in the results monitoring framework.** The proposed Program addresses major reform areas: provider payment mechanisms, drug pricing and reimbursement policies, increased resource allocation for primary care, de minimis aid scheme for improving service delivery conditions, and extension of the primary care benefit package to the uninsured. Systematic policy analysis will help the Government monitor both the expected impacts and unintended consequences of these major reforms. Examples of policy analyses include periodic public expenditure reviews that examine public spending and its equity and efficiency, periodic primary care system assessments (based on existing tools) to review the status of primary care practice and its coordination with other providers, and periodic patient experience surveys on the use of primary and community health care.

C. Disbursement Arrangements

79. Program funding will be based on the achievement of disbursement-linked results (DLRs) as part of the respective DLI and as certified in accordance with the independent verification protocol. Program funds will flow from the World Bank Loan account to the MoPF's EUR-nominated foreign account at the National Bank of Romania, upon achievement of DLIs and their DLRs verification, satisfactory to the Bank. These funds will be used in accordance with the public debt law. MoPF may withdraw up to EUR 25 million based on the achievement of agreed prior results (prior to the signing of the legal agreement).. MoPF may withdraw up to EUR 25 million based on the achievement of agreed prior results (prior to the signing of the legal agreement).

80. Advance from the Loan. An Advance from the Loan amount will be available using a revolving fund mechanism under which an amount of up to EUR 50 million can be requested provided that the needs and justifications for the said advance are provided to the Bank, and such needs and justifications are deemed acceptable. The Bank will require that the Borrower refunds, no later than six months after the legal agreement closing date, any advances (or portion of advances) if the DLIs have not been met (or have been only partially met) by the PforR Program Closing Date.

D. Capacity Building

81. **As part of technical assessment, the following areas have been identified for capacity building and institutional strengthening:** (a) technical assistance (TA) for the country's readiness to make regular state budget transfers for the uninsured to receive basic package, including cost estimation and expenditure projection; (b) TA for revising provider payment mechanisms related to PHC based on global experience; (c) TA for designing best-practice de minimis aid scheme for PHC providers, including strengthening the government's verification system for results and accountability; (d) TA to conduct surveys among family medicine practices on supply conditions and experiences of Program interventions and carry out household surveys on patients' insurance coverage, knowledge of their entitlements, and care-seeking experiences with PHC providers and community health care workers; (e) capacity building for MoH and local public health authorities to supervise community health care and PHC; (f) capacity building for the National Agency for Medicines and Medical Devices, MoH and NHIH to implement various

pharmaceutical policies; (g) capacity building for MoH, MoF and NHIH to monitor and evaluate implementation of policies related to PHC and efficiency of health spending through surveys and analytical work; and (h) capacity building for MoH and NHIH to improve data governance and development of interoperable data system.

82. **As part of the fiduciary assessment, the following areas have been identified for capacity building and institutional strengthening:** (a) TA for the establishment of a medical supplies procurement function in ONAC, including automated procurement processing functions, and credible mechanisms for ongoing specialized supplies specifications support by the MoH; (b) TA for the establishment and functioning of performance-based payments in health services at the NHIH; (c) TA for the establishment and functioning of a de minimis aid scheme at the MoH, including the system of internal controls, performance monitoring, and oversight; (d) capacity enhancement support to the Romanian Court of Accounts (RCoA) to effectively audit program activities; (e) TA for improved financial and procurement planning and budgeting at all levels of proposed program activities; and (f) capacity building to support the revised medical supplies pricing and reimbursement mechanisms envisaged under the Program, including capacity to effectively monitor their continued efficacy and take timely remedial actions.

83. **Implementation support** will be provided for all necessary external TA and other key capacity-building activities through a combination of different sources. First, preparation of RAS is underway to enable the Bank to provide enhanced implementation support and capacity building activities upon the Government's request, with focus on the areas of health financing or social health insurance, PHC, pharmaceutical policies and centralized procurement and surveys. Second, the Government is planning to apply to the Structural Reform Support Service fund for specific TA activity (e.g., Public Expenditure Review) during the upcoming cycle that starts in October 2019. Third, the ongoing Health Sector Reform Project will be used to secure TA activities that are needed by the Government, in the event the RAS is delayed. The first set of TA include: (a) estimating the financial needs related to providing the basic package of PHC to the uninsured; (b) revising provider payment mechanisms for PHC providers; (c) developing HTA methodology; and (d) developing a Health Data Management Strategy. These activities fit under Component 2 of the Program, improving public health sector governance and stewardship, and is estimated to cost approximately US$ 1 million.

84. **The verification process will use the government system as well as surveys designed to help strengthen the system checks and balances for the future**. This will help institutionalize and support the government efforts to have accurate and transparent data. TA may be needed for survey design and initial implementation. Independent of the source of the TA, the surveys are owned and executed by the government and will be the basis for the verifications of achievement of the DLRs.

85. Depending on the nature of the task, capacity-building activities can take the form of just-in-time TA, knowledge and experience exchange with other countries, or long-term advisory support.

IV.ASSESSMENT SUMMARY

A. Technical (Including Program Economic Evaluation)

Program's Strategic Relevance and Technical Soundness of the Approach

86. **The Program is aligned with recommendations from the European Council on structural and institutional reforms to promote responsible fiscal policymaking, social inclusion, and population health.** These recommendations focus on the need to address institutional challenges to universal health coverage: overall low funding, inefficient use of health resources in the health sector, and hospital-centric service delivery.[28] The Council also recommended a focus on responsible fiscal policy, promoting social inclusion, and strengthening of public procurement to promote efficiency. In keeping with this focus, the Government's National Health Strategy (2014-2020) aims to address significant system and institutional challenges to health care access and efficiency in Romania**.** The Program interventions will alleviate financial barriers arising from exclusion from insurance coverage; reduce geographic and sociocultural barriers to access to PHC in underserved populations; address the chronic underinvestment in PHC quality and misalignment of provider incentives with quality and efficiency; eliminate barriers to the institutional-level coordination required to improve PHC supply and quality; and address critical cost drivers in the system, including inefficient pharmaceutical policies and lack of strategic use of health information for service purchasing and cost containment.

87. **The Program objectives are also aligned with the World Bank's twin goals of reducing poverty and boosting shared prosperity.** The Program will address the key challenges to achieving the twin goals that were identified in the SCD, including the functioning of public institutions and the quality of governance. The Program also contributes to the CPF FY18-FY23 goal of an inclusive Romania, through interventions that reduce disparities in access to PHC, with a focus on underserved areas. The Program is further aligned with the CPF filters of strengthening Romania's institutions in the health sector; benefitting the poorest and most vulnerable, including the Roma population; and catalyzing other sources of funding (such as better absorption of EU funds). Achieving universal primary health coverage is in alignment with the first area of focus for the Bank's support under the CPF, "to ensure equal opportunities for all," and its second objective, "to improve access to modern health care," particularly for the poor and vulnerable.

88. **Investing in PHC is a cost-effective means of boosting stocks of human capital, through evidence-based management of NCDs that will result in higher labor productivity.** A high burden of NCDs leads to premature death and loss of productivity from ill-health. By increasing the supply and effectiveness of PHC, including in underserved areas that also bear a higher burden of NCDs, the operation will contribute toward reducing mortality and morbidity from chronic diseases. Reducing the burden of diseases will facilitate higher labor productivity for the working population and improved quality of life overall.

89. **There is a clear justification for support from the World Bank to strengthen PHC and boost the efficiency of the health system.** Investing in PHC generates positive externalities, as a healthy and

[28] European Commission. 2018. Council Recommendation on the 2018 National Reform Programme of Romania and Delivering a Council Opinion on the 2018 Convergence Programme of Romania.

productive workforce faciliates economic growth that benefits society in ways that are not captured by individiual transactions in the health sector. However, in Romania PHC is underfunded and resources are distributed inequitably, in favor of urban areas and high-income groups. Improvements in health system efficiency can expand fiscal space for PHC. Thus there is a rationale for the Government to invest in strengthening PHC and boosting health system efficiency. However, persistent institutional challenges—poor coordination, misaligned incentives, and limited capacity for implementation—have prevented prior investments from addressing service delivery challenges. The Bank is uniquely qualified to provide cross-sectoral support to improve PHC access and efficiency by addressing key institutional challenges, drawing on its expertise and global experience in health service delivery, IT, and governance. By addressing critical institutional and health system drivers of disparities in access to health care and fiscal inefficiency, the proposed Program will help Romania achieve a healthy and inclusive society.

90. **Reviews of reform experiences in improving the coverage of essential health services and the efficiency of the health sector indicate a central role for strong public institutions in addressing service delivery challenges.** In health systems with underfunded primary care, the capacity to raise sufficient revenues is essential to the provision of a comprehensive package of services to the population. By actively purchasing services, and using strong information systems, countries can implement measures to ensure that providers act in the interests of the population, promoting access, quality, and efficiency. Medical and financial audits, rewards for performance, and sanctions for fraud and errors can promote accountability and improve efficiency. In addition, capacities for convening, negotiating, consensus-building, and interagency collaboration are needed for health sector decision-making, including harmonizing benefit packages, defining payment methods, and ensuring access to medicines and other health care.

91. **Global experience on the importance of strong public institutions for universal health coverage is particularly salient in the Romanian context, where key institutional challenges have stalled previous reforms.**[29] The programs in the 2011 and 2013 Stand-By Arrangements between the Government of Romania and the IMF included commitments to shift service delivery from hospitals to PHC, allocate resources toward primary care, and monitor hospital budget execution. However, funding levels for primary care remained flat as the higher financial flows to family medicine were not tied to specific service delivery results; the deficits due to lack of expenditure commitment controls persisted in the absence of health information systems that could incentivize transparency and accountability; and health services remain hospital-centric because of the misaligned incentives embedded in the framework contract and clinical guidelines. The Country Partnership Strategy for FY14-17 also included an objective of improved health service delivery, including the introduction of additional roles and payment methods for family physicians. However, these changes were not made, partly because of poor coordination among the MoH, physician associations, and the NHIH. Finally, the Second Fiscal Effectiveness and Growth development policy loan included a prior action focused on implementing centralized procurement in the health sector. However, the newly created ONAC lacked the mandate or technical capacity to undertake centralized procurement of medical products, and there were no mechanisms for collaboration between the ONAC, MoH, and other agencies for implementation. As a result, limited centralized procurement through the

[29] Tangcharoensathien, Viroj, and David B. Evans. 2013. "Beyond Clinical Skills: Key Capacities Needed for Universal Health Coverage": 801-801A.

MoH was introduced. Addressing critical institutional challenges is thus a necessary step toward increasing access to PHC and improving health sector efficiency in Romania.

92. **There is relatively strong evidence regarding the effectiveness of financial incentives in encouraging the establishment of family medicine practices and influencing the geographic distribution of family physicians.** Bärnighausen and Bloom analyzed programs that offered financial incentives, including loans, to health workers to set up primary care practices in Japan, Canada, and New Zealand.[30] They found that these incentives attracted a significant number of health workers to underserved areas. In Canada, an increase in reimbursements for general practitioners in rural and underserved areas and reduced reimbursements for areas with oversupply reduced geographical disparities in primary care provision.[31] In France, interest-free loans from local and national authorities were successful in encouraging physicians to set up practices in rural areas.[32] Given the significant cost of setting up new family medicine practices in Romania, the introduction of a scheme that finances these costs – small facility repairs, equipment, and training – may facilitate the increase in supply of primary care, including in underserved areas.

93. **Expanded access to insurance has been implemented in other contexts to eliminate financial barriers to health care use.** A 2016 systematic review of the global literature on the association between financial coverage of health services and utilization, concluded that health insurance significantly increases utilization, and thus access to care.[33] The only experimental evidence on the impacts of health insurance coverage available is for the populations in the United States. Findings from a randomized controlled trial indicate that access to insurance leads to substantial increases in the use of primary and preventive care, lower out-of-pocket medical expenditures, and better self-reported health.[34] The same experiment also found a higher likelihood of early diagnosis of and adherence to prescribed therapy for diabetes mellitus when service users were insured.[35] While hospitalizations and the use of emergency care may also increase in the short term, strengthening emergency care triage systems and instituting PHC's gatekeeping function can prevent this effect.[36] The inclusion of the uninsured population of Romania in the basic package will increase PHC use while reducing expensive hospital care use, boosting health care access and making efficiency gains to the health system.

94. **Payment mechanisms promote realignments in service delivery by shaping the incentive structure for health care providers.** Capitation payments create incentives to provide care more efficiently and contain costs; however, to function well, they must be adjusted for the expected health

[30]Bärnighausen T and Bloom DE. 2009. Financial Incentives for Return of Service in Underserved Areas: A Systematic Review. BMC Health Services Research: 9:86 (available via www.biomedcentral.com).
[31] Wilson NW, Couper ID, De Vries E, Reid S, Fish T, Marais BJ. 2009. A Critical Review of Interventions to Redress the Inequitable Distribution of Healthcare Professionals to Rural and Remote Areas. *Rural and Remote Health* 9: 1060. (Online)
[32] Bruguière M-T. 2011. Rapport d'information, fait au nom de la délegation aux collectivités territoriales et à la décentralisation, sur les territoires et la santé. French Senate document nr. 600, 14 June.
[33] Nosratnejad S, Shami E Health Insurance and The Utilization of Health Care: A Systematic Review. *BMJ Open* 2017; 7: bmjopen-2016-015415.70. doi: 10.1136/bmjopen-2016-015415.70
[34] Finkelstein, Amy, et al. 2012. "The Oregon Health Insurance Experiment: Evidence from the First Year. *The Quarterly Journal of Economics* 127.3: 1057-1106.
[35] Baicker, Katherine, et al. 2013. "The Oregon Experiment—Effects of Medicaid on Clinical Outcomes. *New England Journal of Medicine* 368.18: 1713-1722.
[36] Van den Heede, Koen, and Carine Van de Voorde. 2016. "Interventions to reduce emergency department utilisation: A review of reviews. *Health Policy* 120.12 (2016): 1337-1349.

needs of patients to prevent risk selection. Fee-for-service reimbursements encourage providers to increase the units of the rewarded services and may lead to unnecessary utilization and increased costs. Given the constraint placed on primary care delivery in Romania by the caps for fee-for-service reimbursements introduced to contain costs, performance-based financing will be introduced. This model, which ties reimbursements to specific output and outcome targets rather than inputs, has proven successful in improving quality while containing costs in both low-income countries (such as Rwanda and Uganda) and higher-income settings (including Croatia, Estonia, and the United Kingdom).[37]

95. **Improvements in the supply of family physicians and the incentives for effective care in Romania must be accompanied by an expanded scope of service.** Comparative studies of primary care in Europe have concluded that in the stronger health systems in the region, primary care serves as the main entry point to the rest of the health care system, coordinates care for the patient within the system, and monitors diagnosis, treatment, prevention, and follow-up for most illnesses.[38] Relative to other countries in the EU, including Bulgaria, primary care in Romania is significantly less comprehensive in terms of the scope of services family physicians can provide.[39] Modifying clinical pathways to enable family physicians to initiate care for most chronic diseases, including diabetes mellitus and asthma, will improve the effectiveness of care and efficiency in the health system by reducing the use of expensive inpatient care.

96. **Systematic reviews examining community health programs worldwide have found that they are effective at service delivery related to health promotion and other preventive care.**[40] With minimal training in clinical service delivery, lay health workers have been found to increase immunization uptake among children, reduce child morbidity from common illnesses, promote exclusive breastfeeding, and improve adherence to treatment, including for tuberculosis. The UK's National Health Service has a key role for multidisciplinary primary care in managing chronic illnesses. Nurses are paid by local authorities to provide care at home for specific groups, sharing responsibility for patient care with the physician. Systematic reviews of similar models conclude that nurses can effectively increase health knowledge and positively influence health-seeking behavior; these findings are consistent with the objective of promoting PHC access in Romania through community health nurses.

97. **Centralized procurement of medical products can provide significant cost savings and increase health system efficiency.** In 2016, the MoH approved a centralized procurement plan for antibiotics and oncology medication that successfully reduced the average price of drugs. In Romania, centralized procurement of 31 antibiotics and 11 oncology drugs, representing 15 percent of total public spending on medication, led to a reduction in the average price of drugs from RON 22.2 in 2015 to RON 20.0 in 2017. Centralized procurement has been undertaken for vaccines, tuberculosis and HIV medication, HIV ELISA

[37] Eldridge, Cynthia, and Natasha Palmer. 2009. "Performance-based Payment: Some Reflections on the Discourse, Evidence and Unanswered Questions. *Health Policy and Planning* 24.3: 160-166. Hindle, Don, and Karolina Kalanj. "New General Practitioner Payment Formula in Croatia: Is It Consistent with Worldwide Trends? *Croatian Medical Journal* 45.5 (2004): 604-610. European Health Observatory. 2014. Paying for Performance in Health Care: Implications for Health System Performance and Accountability.

[38] Kringos, Dionne et al. 2013. "The Strength of Primary Care in Europe: An International Comparative Study. *British Journal of General Practice: the Journal of the Royal College of General Practitioners* vol. 63,616: e742-50.

[39] Ibid.

[40] Gilmore, Brynne, and Eilish McAuliffe. 2013. "Effectiveness of Community Health Workers Delivering Preventive Interventions for Maternal and Child Health in Low- and Middle-Income Countries: A Systematic Review. *BMC Public Health* 13.1: 847.

tests, contraceptives, powdered milk, implantable medical devices, and fuel. However, there is room to expand the range of products and the volume of medical purchases subject to centralized procurement. The total expenditures for medical products amenable to centralized procurement were estimated at US$1.3 billion in 2017. There is significant evidence[41] that centralized procurement can achieve cost savings by creating economies of scale and improving purchasing power. It is estimated that Romania can save US$300 million each year if all hospitals implement centralized procurement of medical products.

98. **There is strong evidence that systemic investments in electronic health lead to increased efficiency, significant monetary savings, and implementation of informed policies.**[42] Most middle- and higher-income countries strive to use electronic health records to improve health care quality, patient safety, and health system performance monitoring.[43] Patient-centered health care built around modern and efficient PHC requires robust data and communication mechanisms that enable provider-to-provider communication and empower patients for stronger engagement. Furthermore, the linkage of health care use and financial information through integrated financial management information systems can support the management of health sector financial operations and improve public financial management and cost containment.

99. **Pharmaceutical policies that are aligned to ensure transparency, access to medicines, and cost containment can be powerful tools for promoting fiscal efficiency.** Clawback taxes are effective at preventing budget overshooting, and they increase the predictability of public pharmaceutical spending. Countries such as France, Germany, Italy, and Portugal have reported substantial savings due to clawback policies. Most countries that implement such policies have exemptions for generic medicines, an approach that could benefit Romania, given the indications that older and cheaper generics are being priced out of the market. Regarding HTA, a review of the top 50 medicines by expenditure in Romania found substantial scope for potential savings through delisting medicines that are ineffective for their indications or for which superior, better-value alternatives are available. For example, estimated savings related to bevacizumab amounted to EUR 18.9 million per year. HTA can be an effective tool for controlling expenditure in the health sector and ensuring that resources are spent on interventions that provide the best value. Finally, MEAs can enable access to innovative medicines while controlling cost escalation. However, in scaling up cost-volume and cost-volume-results contracts, there is a need to balance concerns about confidentiality of agreements with budget transparency.

[41] Some countries have benchmarked the prices obtained through framework agreements with the standard prices in the price lists of suppliers. This benchmarking indicates savings of around 20-50 percent (Denmark, France, Hungary, Italy). In some systems, the assessment of additional savings has been made in terms of savings on transaction costs. A research in Sweden has shown that all transaction costs have decreased for about EUR 50 million on the annual level due to the centralized procurement system. Finland estimates that savings that come out of centralized procurement range between EUR 100 – 150 million annually. Association Aven in Italian region Emilia Romagna stated that they made savings of 45 percent for pharmaceuticals and 20 percent for medical supplies through centralized procurement in 2008. The savings consist of both lower prices and reduced transaction costs.

[42] Bartlett C, Boehncke K, Johnstone-Burt A, Wallace V. 2010. Optimising eHealth Value: Using an Investment Model to Build a Foundation for Program Success. PwC.

[43] OECD. 2013. Strengthening Health Information Infrastructure for Health Care Quality Governance.

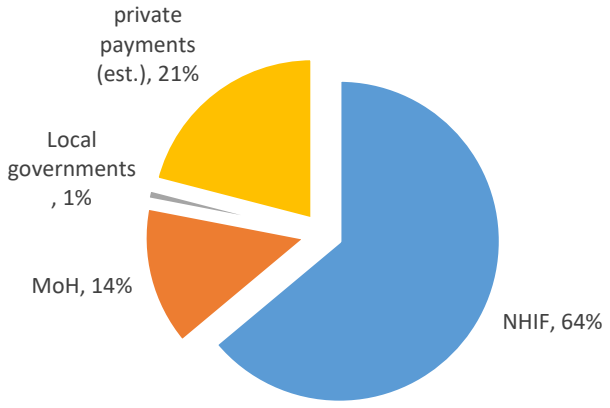
The Program Expenditure Framework

100. **In Romania public financing pays for around 80 percent of health care services.** Health care expenditure has averaged 5 to 5.5 percent of GDP over the last 10 years. Public funding is complemented by private payments, which consist of out-of-pocket payments and voluntary health insurance. Figure 7 shows the major funding sources in 2018.

101. **Despite the country's fiscal situation, public spending on health care has been growing over time, both in absolute terms and as a share of GDP** (Figure 8). NHIH and MoH expenditure on health services rose from around 3.7 percent of GDP in 2015 to 4.3 percent in 2018, and the Government estimates that it will reach 4.5 percent of GDP in 2019. In absolute figures, the revenues[44] of the NHIH rose from around US$5,829 million in 2015 to US$8,912 million in 2018 and are projected to reach US$9,795 million in 2019. In 2018, around 80 percent of NHIF revenues came from health insurance contributions. These were complemented by revenues from the clawback tax (around 9 percent of the total), from transfers from the state budget of around 5.7 percent, and from other smaller sources.

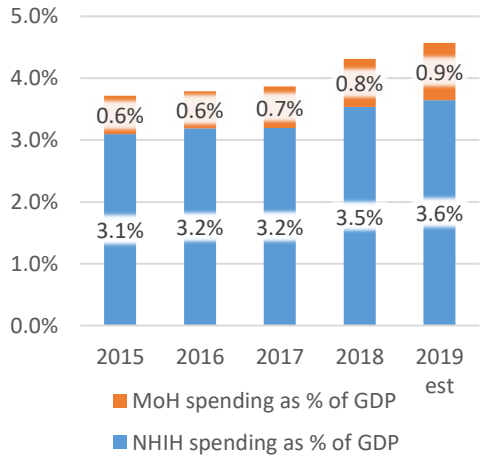
102. **The above growing trend is likely to continue during Program implementation.** NHIH revenue, mostly from social insurance contribution, has grown by a nominal 12 percent each year from 2015 to 2018. It is projected to continue to grow by another 10 percent in 2019 and at a similar pace throughout the implementation of the Program. This growth rate is significantly higher than the projected economic growth rate, 3 percent based on World Bank data.

Figure 7. Health Care Financing in Romania by Sources, 2018



Sources: MoF, Eurostat. Private payments were estimated using Eurostat data for 2012–16

Figure 8. NHIH and MoH Expenditure as % of GDP 2015-2019



Sources: MoF. 2019 figures are based on the budget approved by Parliament.

103. **The Government budget of the Program is funded through the MoH, NHIH, and MoPF (ONAC) and is estimated at US$4,530 million over four years (2020-2023).** The Bank will provide a financial

[44] In current US$, using the average RON/US$ exchange rate of the relevant year.

contribution to the GoR program of US$557.2 million equivalent as part of the Program. As a share in total Government expenditure, the program will grow from 0.9 to 1.3 percent from 2020 to 2023. The expenditure program is based on the work plans and activities within the Program boundary (see Annex 3 for details). More than 86 percent of the Program financing supports delivery of primary care to the entire population of Romania, including the uninsured. Table 5 presents the expenditure items included for each agency by economic classification.

104. **Around 86 percent of the Program expenditure will be implemented by the NHIH through the NHIF** (Table 5). The NHIF is the predominant source of funding for family medicine and for the administration of the NHIH, which will be involved in developing and implementing regulations concerning PHC. The MoH will finance community health care and family medicine investments through a de minimis aid scheme that will support the rehabilitation and equipping of family medicine practices. The MoH contribution to community health care includes the wage bill for the unit overseeing community and primary care. The MoPF will finance expenditures related to the functioning of ONAC.[45] The actions related to regulations on pricing and reimbursement of medicines will be funded through the MoH and NHIH budgets. Finally, interventions to develop data-driven decision-making will be financed from the MoH and NHIH budgets.

Table 5. Estimated Four-Year Budget of the Program, by Implementation Agency and Expenditure Category

Agency/item	2020	2021	2022	2023	2020-2023	% of Program
NHIF	**724**	**899**	**1,046**	**1,244**	**3,914**	**86.4%**
Wage bill	9	10	10	11	40	0.9%
Goods & services*	715	890	1,035	1,221	3,861	85.2%
Capital	-	-	-	13	13	0.3%
MoH	**136**	**142**	**157**	**174**	**609**	**13.4%**
Wage bill	136	139	143	146	564	12.5%
goods & services	0	1	3	2	6	0.1%
transfers	-	2	12	20	34	0.7%
capital	-	0	-	5	5	0.1%
MoF	**2**	**2**	**2**	**2**	**7**	**0.1%**
Wage bill	1	1	1	1	5	0.1%
goods & services	0	0	0	0	2	0.0%
Total	**862**	**1,043**	**1,204**	**1,420**	**4,530**	**100.0%**

Source: WBG Staff computations based on NHIH, MoH and MoF data. Values in million US$.
**This includes state budget transfer for the uninsured to receive basic package of PHC services and NHIH's budget allocation to PHC for the insured.*

105. **The Program is not expected to impose any significant burden on the state budget.** Achievement of Program results will depend on: 1) better use of existing budget for PHC, community care and

[45] The cost of goods subject to ONAC centralized procurement will be financed from the budgets of the beneficiary institutions, e.g., public hospitals.

administration, about 82 percent of total Program expenditure; 2) increased allocation for PHC through re-prioritization of the NHIH overall budget, about 11 percent; and 3) additional budget increase for new activities, such as state budget transfers for the uninsured, additional allocation for community care, establishment of state-aid scheme and health data integration, about 7 percent. Such additional budget requirements translate into less than 1 percent of total public financing in health sector during the Program period, imposing a negligible impact on the total government budget.

106. **Moreover, the Program is expected to have some positive impact on the country's fiscal situation.** Specifically, a reduction is foreseen in the need for state budget on emergency care and state transfer to NHIH that fulfills the deficit. In the past years, on average US$500 million each year were transferred to NHIH to fulfill the deficit that is largely driven by hospital expenditure. With the Program interventions, 2.5 percent of NHIH expenditure (DLI 6) will be saved due to better use of information to detect inefficient spending, which means US$250 million a year. Furthermore, about US$400 million of inpatient care spending can be avoided through enhanced PHC. And annual savings of US$100 million can be initially achieved through implementing centralized procurement for medical supplies and devices, then about US$300 million each year if centralized procurement is implemented for all medical products. All together this will significantly reduce the likelihood of NHIH running deficit and hence the need for state budget transfer related to it.

107. **The program's financial sustainability is ensured by the existing fiscal and budgetary arrangements, as well as Program interventions.** First, NHIH's key role in financing the Program ensures high funding predictability for the Program, consistent with the country's Medium-Term Fiscal Framework. In addition, the state budget recurrent revenues are also projected on a stable growth trajectory, which ensures predictability for the state budget-funded share of the Program. As a result, the Program expenditure will account for around 10 percent of the total public financing for health sector. Second, the Program locks in the funding for key reform areas through the adoption of regulatory changes and revision of budget law, thus minimizing the risk of withdrawing financial inputs within state budget or NHIH budget after the Program closes.

Economic Rationale

108. **There is a strong economic rationale for investing in the implementation of the National Health Strategy, and the Government's continued effort to strengthen primary care services and improve the efficiency of public spending, as the Program proposes.** The Strategy recognizes the need for sustainable financing of the health sector and proposes an action plan to increase health sector efficiency through cost control, sustainable growth of public funding for health, and a regulatory framework that stimulates private sector funding for health and does not compromise financial protection for the poor. The additional resources provided by the Program will help increase access to and the effectiveness of PHC and will generate efficiency gains from further development of centralized procurement in health care; development of e-health systems integrating community, primary, and secondary care; and improvements in the pricing of and reimbursement for medicines. Because all these areas are a primary responsibility of Government institutions, the Program can help improve the efficiency of Government spending. The anticipated increased financing of the Program will require 0.1 percent of GDP compared with the baseline expenditures for the program of 0.3 percent of GDP in 2019. Such costs are feasible,

given the important priorities that the Program will support and the improvements in health outcomes and fiscal space that are expected to result from it.

109. **Actions taken through the Program will yield direct economic benefit through** increased efficiency in health spending (by reduction of unnecessary referrals for specialized outpatient care and of avoidable emergency visits and hospital admissions for both insured and uninsured populations, and by the more streamlined procurement of medication and consumables); improved health status (due to premature deaths and disability-adjusted life-years—DALYs—averted through improved access to and quality of primary care and improved prevention and management of diseases); and improved equity (by increasing access to PHC). In addition, spillover effects from strengthened purchasing and data systems can be expected to generate substantial benefits across the health system.

110. **A cost-benefit analysis was conducted, focusing on long-term benefit of this Program such as improved health status and reduced pharmaceutical spending.** The full cost of the Program was assumed to be distributed across 2020-2023 as if all Government funding is available and the Bank's contribution is fully executed (all DLIs achieved). Benefits were estimated from the literature, or similar WBG investments, and projected out to 2034. The combined net present value of the Program from both analyses is estimated to be US$4,721 million. The combined benefit-cost ratio for the Program is estimated at 2.07, and the internal rate of return at 26 percent (Table 6) under conservative estimates for the potential reductions in DALYs from Program's interventions.

Table 6. Summary of Economic Benefit of the Program

	Baseline scenario	Low scenario	High scenario
Benefit cost ratio	2.07	1.75	3.15
Internal rate of return	26%	23%	99%
Net present value, US$ million	4,721	3,392	9,306

111. **Technical assessment has concluded that the implementation of the proposed PforR operation is subject to substantial risk in the following areas:** 1) governance: weak governance in community health care and their collaboration with PHC needs to be strengthened; 2) regulation: amendment of regulations during the first year is critical for several major result, because it will ensure that the implementation entities have legal basis and sufficient implementation time; and 3) monitoring and evaluation: lack of monitoring and evaluation framework to assess the impact of the Program that goes beyond reporting of operational progress, e.g., the impact of the initiative that grants the uninsured access to the basic package of PHC services, PHC benefit awareness and PHC utilization.

B. Fiduciary

112. **The Program fiduciary systems are adequate** to support the Program and provide overall reasonable assurance that the Program financing proceeds will be used for the intended purposes, with due attention to the principles of economy, efficiency, effectiveness, transparency, and accountability, subject to the implementation of fiduciary actions defined in the PAP. The Program fiduciary responsibilities will be carried out by the MoH, NHIH, and ONAC (for their parts of the Program) and will

be coordinated by the MoH for the overall Program. The fiduciary risk rating is Substantial. The main findings of the assessment are outlined in the following paragraphs, and in greater detail in Annex 4

113. **There is overall adequate planning and budgeting capacity at both the MoH and the NHIH**. The MoPF has established robust arrangements for annual budgeting and allocation of resources, including well-established and -applied timelines. Entities exercise strict control over spending, with good short-term predictability of funding and close to 100 percent budget execution rates. In the MoH and NHIH, expenditures incurred by subordinate spending units are monitored through the submission of monthly, quarterly, and annual reports, which are usually timely and of satisfactory quality. The budgets of NHIH and MoH are structured on programs tailored to the functional budget classification.

114. **Program-based budgeting is under development in Romania,** including in health care, and is not yet sufficiently reliable to be used in relation to the expenditure projected in the operation. Deployment of an Institutional Strategic Plan for the health sector, proposed by the Bank in 2018 under a technical assistance project, is expected to complement ongoing efforts.

115. **Although there is overall an adequate level of budget execution in the sector, inconsistent revenue flows to the exchequer and shifting strategic priorities present risks of underfunding and delayed allocations that could adversely affect the Program budget.** Delays and shortfalls in budgetary allocations for some of the more substantial Program expenses (i.e., increased coverage of primary care, development of the e-health system, and the de minimis aid scheme) may impair achievement of the intended results. To mitigate this risk, it is proposed that the sustainability of financing for the Program will be monitored, and any financing gaps will be discussed with the main stakeholders as part of the Bank's implementation support and supervision.

116. **The MoH and NHIH have overall acceptable procurement planning and processing capacity.** Adequate procurement planning and execution are actively enforced by the ANAP, which is the main regulatory body for public procurement. Each agency elaborates an annual procurement strategy (above defined thresholds) and annual procurement plans, as well as a contracting strategy for each procurement activity to be launched. ONAC will follow the same practices once it becomes operational for the health sector. Procurement units at the MoH and NHIH are well established and have adequate planning and implementation capacity, including for centralized procurement for subordinate units. The assessment identified opportunities for process improvements, including (a) establishment of electronic platforms for collating user needs, and (b) improved packaging. As ONAC has recently been established, it requires extensive capacity building support to establish an electronic platform to be used to collate and consolidate procurement requests, monitor the implementation of framework agreements, and communicate with contracting authorities. Proposed capacity-building support is included in the PAP.

117. Although procurement planning and processing capacities are generally adequate, there are capacity gaps. The following issues have been identified at the MoH: (a) long tendering processes, generally nine months and longer, for a competitive procedure; (b) frequent cancellation of tenders or blockages of the tendering process if complaints are received; (c) limited technical capacities to develop technical specifications and otherwise provide support during the evaluation and clarifications process; and (d) difficulty in identifying and maintaining the same technical experts (who are generally doctors) throughout the procurement cycle, starting from the development of the technical specification and

ending with the contract award. In addition, even though the Procurement Unit is well staffed, the procurement function is carried out by three staff, making it difficult to undertake additional work or even cope with the current workload. At the NHIH, a major share of financing under the Program relates to IT infrastructure (development of various electronic platforms, software, and hardware), and the nature of these contracts could be challenging, given the existing capacities and lack of experience with contracts of such value and complexity. Similar support will be required to help ONAC carry out its proposed mandate, including building technical competencies to conduct specialized procurement in the health sector. Proposed capacity-building support is included in the PAP.

118. **All public procurement processes are performed using an electronic platform.** The e-procurement system was first introduced in 2007, and an improved version was launched in April 2018 (http://sicap-prod.e-licitatie.ro/pub). All contracting authorities are required to conduct their public procurement through the e-procurement system, irrespective of values and procedures applied.

119. **Adequate contract management arrangements are in place.** Legal provisions regarding contract execution are supplemented by relevant guidance and templates that are adapted to the specific needs of each contracting authority. At MoH and NHIH, requesting technical departments are responsible for monitoring the implementation of contracts for the institutions operational needs. For centralized procurement, the Procurement Unit of the MoH concludes framework agreements in the name of the final beneficiaries, who are then responsible for concluding and managing the subsequent contracts. After the framework agreement is signed with the successful tenderers, the agreement, tender documents, and technical and financial offers are sent to the beneficiaries to conclude and sign the subsequent contracts in accordance with their individual procurement plan and allocated budget. The management of subsequent contracts is the responsibility of each public health institution. An issue identified during the assessment at MoH and NHIH is that limited data are available at the central level on contract implementation (implementation progress, quantities supplied, payments made).

120. **The Program will finance the procurement of goods and services whose procurement are not expected to require the mandatory review of the Bank's Operational Procurement Review Committee.** The Program is defined to cover community health care, primary care, and policy reforms related to cost control. Therefore, most of the Program expenditures are related to services provided by family physicians contracted by NHIH and recurrent expenditures, including wages, goods and services, and capital investments incurred by MoH, NHIH, and ONAC in Program-related areas. In addition to regular operating costs, implementing agencies will require TA and certain up-front investments to implement the agreed milestones and achieve the DLIs. Some activities will be implemented with the existing resources of the agencies, including external support. A review of projected expenditures indicates that the size of the contracts will be small to medium.

121. **Robust transparency and complaints-handling mechanisms are in place.** The new e-procurement system is in line with the national legislation and EU Directives. The system publishes procurement plans, bidding opportunities, and contract awards and allows public authorities to procure goods, works, and services electronically and economic operators to submit bids and proposals electronically. Law 101/2016 on remedies transposes the relevant EU Directive and provides for an independent complaint review mechanism, which has been in place since 2006. The National Council for Solving Complaints (CNSC) is an independent body established with the mandate to guarantee effective

remedies for complaints in public procurement. CNSC's decisions can be challenged in the Appeal Courts. The establishment of CNSC does not preclude the right of any of the parties to address their cause directly to the courts. An assessment of arrangements and system performance found that it takes considerably longer to solve complaints in the health sector than in other sectors, affecting the duration and outcomes of tendering.

122. Romania's debarment procedures are embedded in legislation that obligates contracting authorities to exclude from the procurement process tenderers that have been convicted for participating in criminal acts, corruption and fraud, terrorism, money laundering or terrorist financing, child labor, or other forms of human trafficking. At the same time, contracting authorities are required to exclude tenderers that did not fulfill their obligations or have been involved in unlawful matters, such as not paying taxes or social security contributions, or in conflict of interest, that did not fulfill their contractual obligations, or that have been in collusion or made false declarations, and so on. However, no lists of debarred companies are maintained.

123. **For the Program accounting and financial reporting, the Bank will rely on the existing Government accounting and financial reporting arrangements.** All Program entities prepare several quarterly and annual financial statements of satisfactory quality. The three entities involved in Program implementation will continue to reflect the expenses incurred for the Program through the existing systems. A review of financial reporting and auditing compliance by MoH and NHIH confirms that adequate capacity exists. For the purposes of annual financial reporting and auditing, the Program expenditures will be collated at the level of the MoH by the Program coordinator and a set of Program financial statements will be subject to independent audit

124. **Internal controls are well established in the Program entities.** There are clear written procedures for authorizations, segregation of duties, reconciliations, and so on, covering expenditure and financial management, as well as procurement responsibilities. Strict ex-ante and detective controls are imposed by the legislation and internal regulations, particularly over budget execution, but they are often rather bureaucratic and do not necessarily endorse a risk-based value-for-money approach. As an EU member, Romania is part of the Public Internal Financial Control agenda, and there are plans to further strengthen this area. Internal audit and control and antifraud functions are well represented at MoH and NHIH, with good capacity and work programs, procedures and tools, and a reasonable coverage of the sector, given its complexity and fragmentation. The strategy for consolidation of public administration 2014-2020 recognizes among other objectives the need to increase the use of internal controls standards and strengthen the internal audit capacity at both central and local levels.

125. **The de minimis aid scheme envisaged under the Program will support the establishment of new PHC practices in communes that are classified as underserved and the improvement in the supply of PHC services.** The type of financing (grant or subsidized interest loan) and implementation arrangements are still to be decided. A Government decision will be issued in this respect in the first year of the Program, when the first call is expected to be launched.

126. **Arrangements for similar de minimis aid schemes managed by the MoPF are sufficiently robust and reliable.** Several types of de minimis aid schemes are implemented in Romania (including one targeting public hospitals under local authorities), and information on them and the applicable regulatory

frameworks is published on the Competition Council`s dedicated website. There is comprehensive EU and national legislation that regulates de minimis aid schemes, and monitoring is exercised at different levels such as the MoPF and the Competition Council.

127. **Minimum quality standards for the eligible activities and fiduciary aspects will be defined before the scheme is launched.** The Bank will review proposed arrangements, signal any weaknesses in the proposed design, and work with the counterparts to ensure adequate implementation arrangements, including for the fiduciary aspects. The Program will provide technical support to develop the capacity required for the design and implementation of fiduciary arrangements, including a system of internal controls and oversight, and this area will be monitored under the PAP.

128. **Program financial statements will be audited annually by an auditor acceptable to the Bank.** The Romanian Court of Accounts (RCoA) is presently undertaking a comprehensive institutional reform and capacity building effort, under a separately-funded initiative. This support is intended to strengthen the technical capacity of the Court to fully adopt a risk-based approach and methodology consistent with the International Organization of Supreme Audit Institutions (INTOSAI) standards and practices. It is intended that as that capacity is attained, the Court may be engaged to audit the Program financial statements. In the interim, this assessment proposes engaging a private sector firm under terms of reference acceptable to the Bank.

129. **Audited financial statements of the Program will be presented to the Bank within 12 months**[46] **after the end of each reporting period, and at the end of the Program**. The borrower will disclose the audit reports for the Program and the entities within one month of their receipt from the auditors and acceptance by the Bank, by posting the reports on the MoH and NHIH websites. Following the formal receipt of these reports, the Bank will make them publicly available according to the World Bank Policy on Access to Information.

130. **The Bank's Anticorruption Guidelines will be applicable to the Program**. The Program shall be subject to the Bank's Guidelines on Preventing and Combating Fraud and Corruption in Program-for-Results Financing, dated February 1, 2012 and revised July 10, 2015, which require that Borrowers ensure that any person or entity debarred or suspended by the Bank is not awarded a contract under or otherwise allowed to participate in the Program during the period of such debarment or suspension. Participation, however, does not include the performance under contracts entered into or other engagements that began prior to the date of the Loan Agreement. The list of such debarred firms and individuals can be found on the following website: www.worldbank.org/debarr. The compliance with this requirement will be checked through the Program's audit of the financial statements. A memorandum of understanding (MoU) between the Romanian Prosecutor's Office attached to the High Court of Cassation and Justice, the National Anticorruption Directorate (DNA) and the Bank's Integrity Vice Presidency (INT), signed on December 8, 2014 is in force. In this MoU, the parties commit to cooperate with each other on matters of mutual interest within the scope of their mandates. The terms of this MoU will be applicable to the Program. The DNA has proven to be an effective institution in the past decade, with a notable track record

[46] The 12-month submission period for the audited financial statements of the Program is proposed considering the workload requirements of the RCoA.

of non-partisan investigations and prosecutions into allegations of corruption at the highest levels of politics, the judiciary and other sectors, including health.

131. Program financial statements auditing arrangements will require that all notable matters requiring to be reported to the Bank are included in the management letter.

132. **Fiduciary risk mitigation measures are proposed in the PAP (Annex 6).** Fiduciary risk is assessed as Substantial; the main issues and proposed remedial actions are summarized in Section E below.

133. **The Program proposes to introduce several new funding and procurement management initiatives for which technical assistance for capacity building and improved performance is envisaged**. Areas assessed as requiring this assistance are summarized under Section III.D (Capacity Building) above.

134. **Program implementation support**. During Program implementation, the Bank's fiduciary team will (a) review implementation progress and work with the task teams to examine the achievement of Program results, legal covenants, and PAP requirements that are of a fiduciary nature; (b) help the borrower resolve implementation issues and provide institutional support; (c) monitor the performance of fiduciary systems and audit reports, including the implementation of the PAP; and (d) monitor changes in fiduciary risks to the Program and, as relevant, compliance with the fiduciary provisions of legal covenants.

C. Environmental and Social

135. The Environmental and Social Systems Assessment (ESSA) for this Program was undertaken to: 1) assess Romania's systems for managing environmental and social effects that are associated with the proposed set of investments related to this Program; and 2) the GoR's institutional capacity to plan, monitor and report on environmental and social management measures as part of this Program's implementation. The ESSA took into consideration the requirements of the Program-for-Results Financing Policy and Directive. Its findings are intended to ensure that this Program is implemented in a manner that maximizes potential environmental and social benefits and avoids, minimizes or mitigates adverse environmental and social impacts and risks. This assessment also informs the preparation of the PAP that the GoR is expected to use to bridge any significant gaps in existing environmental and social management systems in line with the six core sustainability principles of the PforR.

Environmental System

136. **The Program itself does not have explicit environmental management objectives**. The ESSA finds the country's existing legal and regulatory frameworks for environmental management to be relevant to the activities supported under the Program and consistent with the World Bank's PforR Policy and Directive. The results areas identified under the Program and the corresponding DLIs do not recommend activities and or actions that will have significant adverse impacts on the environment that are sensitive, diverse, or unprecedented. The average daily and monthly quantity of medical waste will not be significantly increased and the existing disposal infrastructure for medical waste has sufficient capacity to take these additional quantities. However, for the newly created PHC facilities under this Program in rural

and remote areas the existence of medical waste collection contracts with specialized sanitary operators should be confirmed.

137. Romania has comprehensive legislation on environmental protection that is fully aligned with the EU legislation, and the assessment confirmed the general adequacy of the environmental systems and of the institutional and legal framework for medical waste management at the PHC level. There is in place a medical waste management system, and a regular verification of the effectiveness and performance of internal medical waste management. As the Program will not support any new investments in construction or major rehabilitation works, this assessment does not include other environmental issues such as potential impacts of civil works, energy conservation, as well as environmental legacy in the case of closing any buildings.

138. The general adequacy of the environmental systems, of institutional and legal framework for medical waste management at the PHC level, was confirmed during the assessment. The medical waste system, medical waste management plans, and contracts of the family practices with authorized sanitary operators are practiced in all areas within the health sector in Romania. In the rural and remote areas largely addressed under this Program, the PHC services need to consider the continuous implementation of the mandatory legal regulations for medical waste management in order to avoid potential risks of inappropriate disposal in non-authorized landfills.

139. Key issues identified by the Environmental System Assessment as potentially sensitive are not connected with any further capacity building and may be addressed through the continuous enforcement of the specific regulatory framework issued by the MoH. The relevant implementation of environmental actions is defined in the PAP.

Social System

140. The Program is expected to generate substantial social benefits, particularly through its efforts to improve PHC coverage for underserved populations including the uninsured and the poor and people living in localities that lack a family physician or in rural localities with a low density of family physicians.

141. The Program will achieve this by expanding community health care and strengthen its collaboration with PHC to address physical barriers hindering access to PHC, particularly since the National Health Strategy has identified community health care as a cost-effective means of providing access to essential services in rural areas and for underserved populations. To address social barriers faced by vulnerable groups, the targeted communities (including marginalized communities) will receive health education and support in navigating the health system, particularly PHC. As part of the communities, community health nurses and Roma health mediators will identify specific social barriers and help address them. To address financial barriers to PHC, the Government recently announced an initiative to provide the basic package of PHC to the uninsured in Romania. This will entail amending the health law to extend this benefit to the uninsured. In addition, state budgets and the NHIH framework contract with family physicians will be revised to reflect the cost of providing this benefit.

142. *Gender.* This Program intends to contribute towards reducing the gender gap in access to primary health care. It builds on the 2018 Romania Gender Assessment[47] and the findings of the Environmental and Social Systems Assessment (ESSA) that has been conducted for this Program. The 2016 *Eurostat* report and the 2016 *Health Systems in Transition* report for Romania indicate that 12.5 percent of women in Romania face barriers in health care access due to cost, travel time, or waiting lists, compared to 8.2 percent of men. Moreover, Roma women are less likely to seek health care from family physicians than Roma men, in a large part due to social barriers (particularly, cultural norms on seeking health care and household roles)[48].

143. The Program's interventions will contribute towards addressing financial, physical and social challenges to improve access to PHC services. It will support the Government to provide basic PHC services to uninsured persons who have hitherto refrained from seeking PHC services due to financial constraints. These basic PHC services will include, among others, essential antenatal and other health services for women. In keeping with norms in other EU countries with strong health systems, the Government is committing to ensuring access to a broader package of services at the PHC level for the entire population, regardless of insurance status. Moreover, since 70 percent of family physicians in Romania are female, the ability to register with primary health care physicians without insurance coverage will make it easier for Roma women to seek health care without concerns about routing traditional norms by consulting male family physicians. Finally, the Program's efforts to strengthen community health care will serve to improve health care access for females. In particular, household visits conducted by community health care providers will improve access for Roma women who traditionally do not venture to seek medical care outside the home unaccompanied, as well as other Romanian women who reside in remote and less accessible locations.

144. The results of the Program's activities to increase PHC coverage for underserved populations will be monitored through the results indicators for PDO 1 (number of uninsured in Romania who are registered with family physicians and entitled to receive the basic package of PHC services) and PDO 2 (number of adults aged 40+ years receiving annual medical check-ups from family physicians). Gender disaggregated data that will be compiled and reported for these indicators will enable the Government to monitor and compare the access of men and women to PHC services and note any differences in gap between genders, including PHC services offered under the basic package to women (e.g., antenatal and other maternal health care) and men (e.g., chronic diseases detection).

145. The Program's interventions to improve access to PHC services is also likely to have a positive impact on health outcomes for women and men, the status of which is described in paragraph 12.

146. *Citizen Engagement*. There are a range of existing citizen engagement mechanisms in the health sector. Some of these mechanisms include a complaint management system and avenues for consultations; the engagement of Patients Associations[49] in monitoring the implementation of framework contracts between the NHIH and health providers; and activities of NGOs related to areas such as increasing awareness of health initiatives and community health care. The Program will use

[47] World Bank Group. 2018. "Romania Gender Assessment". June.
http://documents.worldbank.org/curated/en/252801528141456395/Romania-gender-assessment
[48] National Institute of Statistics. Romania. 2015.
[49] *http://caspa.ro/home/*, visited on 5 April 2019

communication tools, as may be relevant, and will build upon and improve the accessibility and inclusivity of selected citizen engagement mechanisms at the community level.

147. From the social development standpoint, two core ESSA principles are relevant to this Program: *(i) Core Principle 1: General Principle of Environmental and Social Management;*[50] and (ii) *Core Principle 5: Due consideration to be given to the needs or concerns of vulnerable groups*[51]*. Core Principle 4: Land Acquisition*[52] is not relevant in this case since there is no land acquisition and therefore no impact on private assets or livelihoods is expected. This Program will only support minor refurbishment of existing facilities (e.g. small repairs of existing facilities such as painting, flooring, sealing windows, fixing doors).

148. The ESSA findings confirm that the GoR current system of managing the social aspects of the Romania Health Program for Results has several strengths: a strong legal framework for improving equitable and inclusive access to PHC services; institutional mechanisms for various stakeholders to relay their perspectives on the Program's design, including national and local level complaint procedures; and a Roma Health Mediator program that has a high potential for scale-up.

149. At the same time, there are potential bottlenecks that could hinder the access of underserved populations to PHC. Firstly, many vulnerable groups, including but not limited to Roma, may not be able to use family physicians since they do not have ID cards and or birth certificates and, thus, are not able to register themselves for family care. Secondly, they have a disincentive to seek PHC services due to alleged perceptions of disrespect, cultural insensitivity etc. on the part of service providers. Thirdly, access to family physicians may become even more constrained for elderly and disabled people, particularly in remote and rural areas, as the workload of family physicians significantly increases because of the Program. Fourthly, many of the currently under-served population, especially those who are illiterate or based in remote rural areas, may remain unaware of the improved coverage and scope of basic benefits now available to them and may not seek PHC services as a result. They may also remain unaware of existing feedback and or grievance mechanisms that they can use to report whether their access to PHC services has improved or not.

150. The Program is designed to mitigate several of these risks. The Program's expansion of community health care and strengthening its collaboration with PHC will be helpful to improve access to community health care (CHC) and PHC services for underserved groups. The MoH will hire community health nurses and Roma health mediators and deploy them to communities to provide community-based interventions. Protocols and guidelines will be developed to guide their daily work and collaboration with family physicians, and trainings will be provided to ensure their compliance with the protocols. These measures will make CHC more accessible and or attractive to vulnerable groups, including Roma by: (i) increasing the ratio of community health nurses and Roma health mediators to community members so that they can provide community health care more readily and regularly; and (ii) improving the quality and effectiveness of the work performed by community healthcare workers since they would now be based

[50] This core principle aims to promote environmental and social sustainability in Program design; avoid, minimize, or mitigate adverse impacts, and promote informed decision-making relating to the Program's environmental and social impacts.
[51] This core principle aims to give due consideration to the cultural appropriateness of, and equitable access to, Program benefits, giving special attention to the rights and interests of the Indigenous Peoples and to the needs or concerns of vulnerable groups.
[52] This core principle aims to manage land acquisition and loss of access to natural resources in a way that avoids or minimizes displacement, and assist affected people in improving, or at the minimum restoring, their livelihoods and living standards.

on formalized standards and protocols. As part of its effort to improve collaboration between CHC and PHC and to facilitate access to PHC, targeted communities will receive health education and support from community nurses and Roma health mediators in navigating the health system, particularly PHC.

151. To help allay some of the disincentives to seek PHC services due to alleged perceptions of disrespect, cultural insensitivity etc., primary care providers and community nurses will be trained in working effectively with different cultures and ethnic minorities, as needed. Strategic planning to overcome supply-side barriers to PHC access will be informed by community needs assessments and combined with the mobilization of additional community health personnel. Both will also help to address any potential instances of constrained access to PHC for elderly and disabled people in remote or hard to reach locations due to the increased workload of family physicians. Finally, to increase awareness of the expanded insurance coverage and PHC services that are available, the Program will include public outreach efforts and monitor the level of awareness of the population in this regard.

152. *Consultation and disclosure of the ESSA Report***.** The ESSA report was prepared in consultation with several stakeholders including the implementing agencies and other public institutions, NGOs, municipal authorities, family physicians, community health nurses and health mediators. The World Bank team also convened a consultation with the Roma Sounding Board on March 28, 2019[53]. The final draft of the ESSA report was presented in a workshop during the appraisal on June 25, 2019 with the participation of the MoH, NHIH, MoPF and representatives of other groups including: the Sanitas Federation in Romania, the National Association for the Protection of Patients, and ADCIA Botosani and the Danrom Association Roma organizations. Comments on the draft report were shared by the Federation of Associations of Family Physicians' Employers and the Cluj School of Public Health. The participants endorsed the findings of the draft ESSA report, while emphasizing issues such as increased collaboration between PHC providers and community health care workers to improve primary healthcare access for underserved groups, conducting community needs assessments, and monitoring the results of the Program's interventions. The draft ESSA report was finalized upon consideration of the feedback provided.

153. Prior to organizing the workshop, English and Romanian versions of the draft ESSA report were posted on the website of the World Bank's Country Office for Romania on June 17, 2019. The final ESSA report was disclosed on the World Bank's website on August 15, 2019.

D. Climate Co-Benefits

Exposure

154. Romania is highly vulnerable to the impacts of climate change—droughts, high temperatures, heat waves, heavy precipitation, landslides, earthquakes, and floods. Droughts may become more frequent in some areas because of decreased river runoff and increased demand for and consumption of water due to economic development and population growth. The most common natural disasters—heavy rainstorms, mudslides, landslides, earthquakes, and extreme weather—have resulted in significant

[53] Please refer to the 'Summary Environmental and Social Systems Assessment' in Annex 5 for further details on consultations.

physical, social, and financial impacts over recent decades. Increases in the annual average temperature are expected to be in the range of 0.5-1.5°C by 2029, and 2.0-5.0°C by 2099.

155. 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. Program activities could be affected by river floods and earthquakes, causing destruction to health facilities and further disturbing the already limited access to health services.

Impact of Climate Change on Health

156. The strong increase in the frequency of extremely high values for summer thermal stress since the mid-1980s indicates an increased risk to human health during the summer months in Romania. Heat waves lead to a short-term increase in the number of deaths or the aggravation of certain chronic conditions (especially the cardiovascular and respiratory ones). Longer summers lead to increases exposure to UV radiation, with direct effects on skin health (skin cancer), and the stress on agriculture may influence nutritional status, especially that of the poor population and children.

157. Although Romania has well-established public policies to promote public health, it is still not sufficiently prepared to deal with the range of problems stemming from climate change. It also lacks a climate-smart approach in the health sector. Health has been identified as one of the most vulnerable sectors in the country, and improved access to health care, particularly for vulnerable groups, is one of the adaptation measures to reduce vulnerability to climate change. The low overall enrollment with a PHC practice—particularly among vulnerable groups and in rural areas—and the limited access to technology make it more difficult to monitor disease outbreaks and warn vulnerable populations. In spite of the country's significant risk of exposure to natural events, the levels of awareness, basic education, and protective measures provided by PHC services are still insufficient.

Climate Adaptation Measures Supported by the Program

158. Through DLI 1, DLI 2, DLI 3, and DLI 6, the Program will increase access to health services to the residents of Romania, which is critical in case of climate-change-induced natural disasters or epidemics of diseases exacerbated by climate change. This increased access will particularly benefit vulnerable groups such as the elderly, the disabled, children, women, ethnic minorities, and those on low incomes.

- By expanding access to PHC services to the entire population, *DLI 1* (EUR 75 million) will increase preparedness for extreme weather conditions and help prevent deaths due to heat waves and the aggravation of chronic conditions (such as cardiovascular disease and respiratory diseases). Consequently, it will strengthen resilience through community access to PHC services and increased utilization of health care.

- As part of the community health care provided under *DLI 2* (EUR 75 million), community health workers will educate the population on climate issues and will make first aid readily available to the population in case of extreme climate-related events (such as flooding and earthquake) in underserved areas. By promoting institutional coordination in the sector, the Program will help the Government's response to climate events and enhance emergency preparedness.

- *DLI 3* (EUR 75 million) will expand scope and services for PHC by increasing its budget. This will contribute to supporting resilience to climate change events of the overall population, which will have greater access to adequate information and care, including climate-related conditions.

- The establishment of an interoperable health data system under *DLI 6* (EUR 50 million) will allow epidemiological surveillance, which can provide early detection of changes in incidence, mortality and geographic range of health outcomes associated with climate change[54] and the development of methodologies to forecast major health problems related to climate change effects.

Climate Mitigation Measures Supported by the Program

159. Through DLIs 4 and 7, the Program will support measures to mitigate climate change events.

- *DLI 4* (EUR 75 million) will support expenditures on facility rehabilitation and equipment in accordance with the EU standards, encouraging Romanian family physicians to improve climate-smart infrastructures and integrate energy efficiency measures in refurbishing health facilities. This incentive will support expenditures on facility rehabilitation and equipment in accordance with the EU standards in respect of the Paris Agreement of 2015 and EU Directive 2010/31/EU on the requirements for health facilities and services, particularly in relation to the energy efficiency updates and appropriate waste management, which has been translated into the Romanian Law 121/2014 that defines the energy efficiency requirements and requirements to withstand various climate change impacts. Abiding by the Directive is mandatory for all EU member states, including Romania. Adhering to defined norms and standards will, therefore, be mandatory for all beneficiaries of grants/loans.Consequently, the Program will help reduce carbon dioxide (CO 2) emission caused by the sector and improve energy efficiency, which is in line with the strategy of the European Climate Change Programme.

- *DLI 7* (EUR 50 million) will support the centralized procurement of medical supplies and devices, using a climate-smart approach to reduce the carbon footprint of manufacturing processes by ensuring adherence to the EU Directive 2014/24/EU on the following conditions to be included within the procurement processes: a) environmental requirements to be included in technical specifications (Article 23(3)b); b) award decisions and specifications to be based on criteria required by eco-labels (Article 23(6)); c) social and environmental conditions to be included in performance of contracts (Article 26); d) bidders and their suppliers have to demonstrate compliance with environmental obligations (Article 27); e) bidders have to show that they can perform a contract in accordance with environmental management measures (Articles 48(2)f and 50), and f) environmental characteristics can be included in award criteria (Article 53). Furthermore, consolidating procurement of these goods for as many as 300 hospitals would significantly reduce carbon footprint by increasing efficiency of the procurement process.

E. Risk Assessment

[54] Climate change and adaptation of the health sector: The case of infectious diseases. Confalonieri, Menezes, and de Souza. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4720270/*

160. **The overall risk is considered Substantial.** The most significant area of risk is related to the Government's institutional capacity for implementation and sustainability. Other substantial risks include political and governance, macroeconomic, technical design, social, and fiduciary aspects.

161. **Political and governance (Substantial).** Presidential elections, scheduled for the end of 2019, and parliamentary elections, likely to take place at end-2020, may divert policymakers' attention away from reforms and delay the implementation of the reform agenda supported by the PforR. This risk is exacerbated by the high political volatility of recent years, with a high turnover of ministers and other key decision-makers. Vested interests in the health sector may also undermine the implementation of some reforms. These risks are partly mitigated by the Government's strong support for the reforms promoted by the Program and the leadership shown by the Ministers of Health and Finance during the preparation of the Program. Senior civil servants in the two ministries and in the NHIH support the reforms and have taken the lead in articulating the scope and content of the Program. The restructuring and modernization of the health system enjoys strong bipartisan support in Parliament and among key stakeholders and ordinary citizens, who are discontent with the level of access to and quality of some medical services.

162. **Macroeconomic (Substantial).** A substantial worsening of global economic conditions would adversely affect Romania's economy, with negative consequences for the timely implementation of the reform agenda. While Romania has been enjoying high growth rates in the last few years, macroeconomic imbalances are widening, but remain manageable. Increases in public wages and in pensions in the past two years have triggered pressures on the budget, but the Government has reaffirmed its commitment to maintain a budget deficit below 3 percent of GDP. Nevertheless, a new pension law approved by the Parliament in June 2019, granting generous pension increases during the period 2020-2022, compounds the budgetary pressures. This decision risks pushing the budget deficit to above 3 percent of GDP in 2020 and beyond in the absence of compensatory fiscal measures. Romania's public debt is among the lowest in the EU, but a negative shock to the global economy or a significant slowdown of growth in the Euro area, Romania's main trade partner, would affect Romania's economic performance. Nevertheless, the reforms implemented with the support of this Program remain a priority for the Government, which should be able to ensure the appropriate fiscal space for implementation. Measures to improve spending efficiency and achieve savings are key areas of the Program. The Government is looking at options for using EU funds, which are budget-neutral, for the implementation of activities to achieve the proposed DLIs.

163. **Technical design of Program (Substantial).** The results areas prioritize evidence-based interventions to address bottlenecks to increasing the scope of and access to PHC services and improving the efficiency of the public health sector. However, challenges may arise from the technical design. In the absence of a carefully constructed incentive structure, there is a potential for perverse incentives that may exacerbate existing urban-rural disparities in access to family medicine and fail to correct the undersupply of preventive and case management services. To mitigate this risk, the Program aims to differentiate incentives in ways that appropriately account for provider behavior and informed by extensive consultations with physicians' associations. Romania's decentralized political structure means that for the success of the de minimis aid program it is critical to engage the local public administration authorities, who in most cases are responsible for providing premises to family medicine practices. The PforR aims to introduce a regulation that facilitates agreements with local authorities to mitigate the risk to the de minimis aid scheme. The design of the PforR is focused on addressing supply-side barriers to

care and removing financial barriers through improving insurance coverage. However, for challenges such as uptake of screening, other significant demand-side barriers such as cultural factors also affect some groups. The involvement of community health nurses will help address various demand-side barriers to PHC use.

164. In addition, some milestones and activities are logically interrelated in terms of sequencing. To ensure smooth implementation, it will be necessary to carefully map out all implementation arrangements and steps in detail and encourage close coordination among teams working on separate DLIs (or activities).

165. **Institutional capacity for implementation and sustainability (High).** The biggest lesson learned from past and ongoing engagements in Romania is that the implementation capacity of the MoH remains low, and MoPF/ONAC is newly established. The NHIH is deemed to have better capacity, and its county-level branches can help with implementation on the ground. Nevertheless, the current institutional setup leads to fragmentation and inefficiencies and is focused on inputs rather than results. Moving from the input-based model to a PforR—the first in Romania—represents a significant change in accountability and exposes Government counterparts to the risk of not receiving funding if the DLIs are not achieved. To mitigate these risks, an implementation support and capacity building plan will be elaborated under the ongoing Health Sector Reform Project. Additional resources may be considered from a potential RAS to provide the necessary external TA and other key capacity-building activities. Moreover, a Steering Committee, chaired by the General Secretary of the Ministry of Health, will be established to provide oversight of the Program and improve coordination among the key entities. A Program Coordinator will also be appointed to ensure the day-to-day implementation of the relevant milestones related to the DLIs. This Coordinator will be supported by a team of three to four key staff, designated as focal points, who will be responsible for supervising the implementation of the Program and ensuring timely coordination with the relevant departments that are responsible for the activities to support the achievement of the DLIs and DLRs.

166. **Social (Substantial).** The social risk is considered substantial due to potential bottlenecks that could hinder the access of underserved populations to PHC. Firstly, many vulnerable groups, including but not limited to Roma, may not be able to use family physicians if they do not have ID cards and or birth certificates and thus are not able to register themselves for family care. Secondly, they may have a disincentive to seek PHC services due to alleged perceptions of disrespect, cultural insensitivity etc. on the part of service providers. Thirdly, access to family physicians may become even more constrained for elderly and disabled people, particularly in remote and rural areas, as the workload of family physicians increases because of the Program. Fourthly, many of the currently underserved population, especially those who are illiterate or based in remote rural areas, may remain unaware of the improved coverage and scope of basic benefits now available to them and may not seek PHC services as a result. They may also remain unaware of existing feedback and or grievance mechanisms that they can use to report whether their access to PHC services has improved or not. The proposed mitigation measures are presented in paragraph 25 of Annex 5 (Summary of the Environmental and Social Systems Assessement).

167. **Fiduciary (Substantial).** The Program fiduciary risk is deemed to be substantial based on the following risks identified during the fiduciary assessment: (a) Risk of insufficient and or delayed financing of Program activities by the MoPF (considering the increased envelope needed for certain results areas

and the systemic budgetary constraints); (b) Capacity constraints in the oversight of primary and community health care staffing and related expenses by MoH and NHIH; (c) Potential weaknesses in internal controls and oversight of the de minimis aid scheme for family physicians; (d) Potential weaknesses in internal controls and oversight of the performance-based financing mechanism for family physicians at NHIH; (d) Potential delays in preparation and audit of the Program financial statements (considering the multiple stakeholders); (e) Complexity of arrangements for: (i) pricing and reimbursement of medicines; and (ii) clawback tax calculation and management by the MoPF, through the National Agency for Fiscal Administration; (f) The Romanian Court of Accounts (RCoA) may not have enough capacity and experience in auditing the new activities proposed under the Program; (f) ONAC is newly established and has not yet developed requisite capacity to perform the full range of procurement activities, including of specialized medical supplies and devices; (g) Lack of electronic platforms to collect and consolidate the procurement needs of beneficiaries delays the preparation of the tenders and unnecessarily increases the level of effort of personnel managing the procurement process; (h) Limited experience with IT procurement might delay the procurement process and affect its quality and outcome. The proposed mitigation measures to address these risks are presented in Table 18 of Annex 4 (Summary of the Fiduciary Systems Assessment).

ANNEX 1. RESULTS FRAMEWORK MATRIX

Results Framework
COUNTRY: Romania
Romania Health Program for Results

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 challenges.

Program Development Objective Indicators by Objectives/Outcomes

Indicator Name	DLI	Baseline	Intermediate Targets			End Target
			1	2	3	
To increase the coverage of primary health care for underserved populations						
Number of the uninsured in Romania who are registered with family physicians and entitled to receive the basic package of PHC services (disaggregated by gender) (Number)	DLI 1	0.00	0.00	0.00	500,000.00	2,000,000.00
Percentage of adults (40 years old and above) receiving annual medical check-ups from family physicians (disaggregated by gender) (Percentage)	DLI 5	1.00	1.00	1.00	10.00	20.00

Indicator Name	DLI	Baseline	Intermediate Targets			End Target
			1	2	3	
To improve the efficiency of health spending						
Percentage of National Health Insurance House's annual budget allocated to PHC (Percentage)	DLI 3	6.50	6.50	8.00	9.00	10.00
Proportion of the supplies and devices for emergency medical services (in value) procured under framework agreements by the National Office for Centralized Procurement (Percentage)	DLI 7	0.00		30.00		50.00

Intermediate Results Indicator by Results Areas

Indicator Name	DLI	Baseline	Intermediate Targets			End Target
			1	2	3	
Improving coverage for underserved population						
Number of underserved communities covered by community health care in collaboration with PHC (Number)	DLI 2	0.00	0.00	50.00	150.00	300.00
Difference between the counties with the highest and lowest coverages of children who have received one dose of measles vaccination at 12 months old (Text)		48.6% Highest coverage: 100% Lowest coverage: 51.4%	47%	45%	43%	41%
Percentage of uninsured who are aware they are entitled to receive the same PHC basic benefit package as the insured (Text)		Not applicable because they are not entitled yet			60%	90%
Number of community health care workers (community health nurses and Roma health mediators) trained (Number)		0.00	0.00	1,500.00	2,000.00	2,000.00
Percentage of women living in communities covered by community health care receiving at least one annual visit from a community health care provider (Percentage)		0.00	0.00	10%	40%	70%
Hospital-centric health system rebalanced towards effective primary care						
Percentage of metformin prescriptions initiated at the PHC level (Percentage)		0.00	0.00	10.00	20.00	30.00
Number of family physicians	DLI 4	0.00	0.00	340.00	2,000.00	2,500.00

Indicator Name	DLI	Baseline	Intermediate Targets			End Target
			1	2	3	
receiving grants and loans to improve the supply of PHC (Number)						
Number of family doctors incentivized through grants to improve supply of PHC in underserved areas (Number)		0.00	0.00	60.00	300.00	400.00
Number of communication tools applied for universal access to PHC, de minimis aid scheme, and framework contract modification (Number)		0.00	3.00	6.00	9.00	12.00
Number of public expenditure reviews conducted (Number)		0.00	1.00		1.00	3.00
Improving fiscal efficiency by addressing cristical cost drivers						
Percentage change in claims detected as unacceptable (unnecessary care, non-optimized laboratory tests, intentional or unintentional errors, …) (Percentage)	DLI 6	0.00				0.00
PHC claims (Percentage)		0.00	0.00	10.00	20.00	20.00
Hospital claims (Percentage)		0.00	0.00	5.00	10.00	20.00
Laboratory tests (Percentage)		0.00	0.00	10.00	20.00	30.00
Percentage of healthcare providers that automatically share data to the central EHR (Percentage)		0.00				0.00
PHC practices (Percentage)		0.00	0.00	0.00	30.00	90.00
Hospitals (Percentage)		0.00	0.00	0.00	10.00	60.00

Indicator Name	DLI	Baseline	Intermediate Targets			End Target
			1	2	3	
Community health care information system upgraded to share data with the EHR (Yes/No)		No	No	No	Yes	Yes
Annual international price comparisons for all medicines with registered shortages in Romania (Yes/No)		No	Yes	Yes	Yes	Yes
Management Entry Agreement signed for 50% of newly assessed patented drugs with conditional entry decision through HTA methodology (Percentage)	DLI 8	0.00	0.00	0.00	30.00	50.00
Clawback tax regulation revised to improve access to cost-effective drugs (Text)		Clawback tax not revised			Clawback tax revised	Clawback tax revised
Revision of the list of drugs reimbursed by NHIH (Text)		List of drugs reimbursed by HNIH not revised using updated HTA methodology / HTA Methodology not updated	No	List of drugs reimbursed by NHIH revised		List of drugs reimbursed by NHIH revised

Monitoring & Evaluation Plan: PDO Indicators					
Indicator Name	**Definition/Description**	**Frequency**	**Datasource**	**Methodology for Data Collection**	**Responsibility for Data Collection**
Number of the uninsured in Romania who are registered with family physicians and entitled to receive the basic package of PHC services (disaggregated by gender)	Number of uninsured in Romania who are registered with family physicians and entitled to receive the same PHC basic benefit package as for the insured population.	Annual	NHIH	NHIH database	NHIH
Percentage of adults (40 years old and above) receiving annual medical check-ups from family physicians (disaggregated by gender)	Definition and content of annual medical check-up will be revised and finalized through the modification of framework contract to ensure most cost-effective preventive interventions. Numerator: Number of adults (40+) receiving annual medical check-up as defined in the PAD during a given year (if one person receives both preventive check up and case management during the same year, it will only be counted once). Denominator: Total number of adults (40+) registered with family	Annual	Numerator from NHIH; denominator from census	NHIH claims, reports and data with age group breakdown	NHIH

	physicians to receive basic package during the same year as for the numerator.				
Percentage of National Health Insurance House's annual budget allocated to PHC	Numerator: annual NHIH budget for service delivery allocated to family medicine Denominator: total NHIH budget for service delivery allocated to goods and services and transfers	Annual	NHIH budget	Copy of NHIH detailed budget submitted to the World Bank	NHIH
Proportion of the supplies and devices for emergency medical services (in value) procured under framework agreements by the National Office for Centralized Procurement	Numerator: value of supplies and devices for emergency services procured under framework agreement in a given year Denominator: total value of supplies and devices used for emergency services in a given year	Annual	ONAC, MoI	ONAC procurement records, MoI reports	MoH

Monitoring & Evaluation Plan: Intermediate Results Indicators					
Indicator Name	**Definition/Description**	**Frequency**	**Datasource**	**Methodology for Data Collection**	**Responsibility for Data Collection**
Number of underserved communities covered by community health care in collaboration with PHC	The standards for implementation of community health care in collaboration with PHC providers will be specified in the developed guidelines. Community health nurses will be hired, trained, and supported by the MoH to provide health promotion services based on the standards define by the MoH, to provide services according to the protocols to at least 300 local authorities, and facilitate linkages to primary health care where needed. In communities with up to 700 self-identifying Roma, a Roma health mediator will also be hired (at the request of the community), trained, and supported by the Ministry of Health and local authority to ensure registration of vulnerable	Annual	MoH	Progress report by MoH	MoH

	groups in primary health care.				
Difference between the counties with the highest and lowest coverages of children who have received one dose of measles vaccination at 12 months old	This indicator serves as a proxy for access to care among underserved population. Vaccination coverage for MMR (1 dose) at 12 months (%) is routinely estimated by National Institute of Public Health at county level based on survey data	Annual	National Institute of Public Health	Annual reports	MoH
Percentage of uninsured who are aware they are entitled to receive the same PHC basic benefit package as the insured	This indicator measures population's awareness to their entitled benefit. Surveys will be conducted to estimate the awareness of the uninsured population to their new entitlement to free PHC services		MoH	Community nurses reports and PHC registry	MoH
Number of community health care workers (community health nurses and Roma health mediators) trained	Community health workers (community health nurses and Roma health mediators) will be trained on the new guidelines, and households survey tools developed and adopted for	Annual	MoH	Training report	MoH

	community health care in collaboration with PHC family physicians.				
Percentage of women living in communities covered by community health care receiving at least one annual visit from a community health care provider	This indicator measures women's access to community health care. Numerator: Women residing in communities covered by community health care receiving at least one annual visit from a community health care provider Denominator: Women residing in communities covered by community health care	Annual	Electronic system for community health care (AMCMSR)	Report from the electronic system for community health care (AMCMSR)	MoH
Percentage of metformin prescriptions initiated at the PHC level	Numerator: number of metformin initiations by family medicine physicians in a given year Denominator: Number of total metformin initiations recorded in the e-prescription system in a given year	Annual	NHIH prescription database	Reports from NHIH e-prescription database	NHIH
Number of family physicians receiving grants and loans to improve the supply of PHC	Number of family doctors receiving grants or loans under the de minimis aid scheme based on implementation manual	Annual	MoPF	Contracts for grants/loans	MoPF

Number of family doctors incentivized through grants to improve supply of PHC in underserved areas	Number of family doctors in underserved areas receiving grants under the de minimis aid scheme based on implementation manual	Annual	MoPF	Contracts for grants	MoPF
Number of communication tools applied for universal access to PHC, de minimis aid scheme, and framework contract modification	Actions will be carried out to raise awareness about the new reforms. At least 1 action per year will be conducted on each of the following initiatives: universal access to PHC, de minimis aid scheme, and framework contract modification (3 actions per year).	Annual	MoH/NHIH	Communication tool materials submitted to the World Bank	MoH/NHIH
Number of public expenditure reviews conducted	To examine patterns of public expenditure, as well as equity and efficiency of public expenditure in health sector	Three times during Program period	MoPF	Public expenditure review reports	MoPF
Percentage change in claims detected as unacceptable (unnecessary care, non-optimized laboratory tests, intentional or unintentional errors, …)	The upgraded NHIH systems support enhanced data quality assessment for improving the use of resources analyses, costing trends, and support detection of unnecessary care, non-optimized laboratory tests,	Annual	System reports from integrated NHIH management system showing the detected cases of	Data from NHIH database	NHIH

	intentional or unintentional errors , and other cases of inefficient spending. The upgraded systems will deploy automatic algorithms for electronic check-ups and reviews. This indicator measures the effectiveness of these upgrades. The data from 2019 will be used as the reference point. Numerator: (Percentage of discovered unacceptable cases) – (Percentage of discovered unacceptable cases in 2019) by type of service; Denominator: Percentage of discovered unacceptable cases in 2019 by type of service		inefficient spending in healthcare claims (PHC, hospitals, and laboratory tests claims)		
PHC claims	Numerator: (Percentage of discovered unacceptable cases) – (Percentage of discovered unacceptable cases in 2019) for PHC claims; Denominator: Percentage of discovered unacceptable cases in 2019	Annual	System reports from integrated NHIH management system showing the detected	Data from NHIH database	NHIH

	for PHC claims		cases of inefficient spending in health care claims for PHC services.		
Hospital claims	Numerator: (Percentage of discovered unacceptable cases) – (Percentage of discovered unacceptable cases in 2019) for hospital claims; Denominator: Percentage of discovered unacceptable cases in 2019 for hospital claims.	Annual	System reports from integrated NHIH management system showing the detected cases of inefficient spending in health care claims for hospital services.	Data from NHIH database	NHIH
Laboratory tests	Numerator: (Percentage of discovered unacceptable cases) – (Percentage of discovered unacceptable cases in 2019) for laboratory test claims; Denominator: Percentage of discovered unacceptable cases in 2019 for	Annual	System reports from integrated NHIH management system showing the detected cases of	Data from NHIH database	NHIH

	laboratory tests claims.		inefficient spending in health care claims for laboratory tests.		
Percentage of healthcare providers that automatically share data to the central EHR	The NHIH EHR will be re-designed to become National EHR. It will allow at least: (i) data exchange with any system, (ii) Master Patient Index (MPI) for data consolidation, (iii) clinical data repository, including data on prescriptions and referrals, (iv) document repository, (v) digital imaging repository, (vi) document repository, (vii) patient self-managed data repository. The design will build on existing NHIH EHR and consolidated standardization framework. This indicator measures the use of the EHR. As a proxy, the percentage of PHC practices and hospitals that share data to the EHR will	Annual	The EHR system	The EHR databases will be checked to identify the data resources	MoH

	be used.				
PHC practices	This indicator measures the use of the EHR. As a proxy, the percentage of PHC practices that share data to the EHR will be used.	Annual	The EHR system	The EHR databases will be checked to identify the data sources.	MoH
Hospitals	This indicator measures the use of the EHR. As a proxy, the percentage of hospitals that share data to the EHR will be used.	Annual	The EHR system	The EHR databases will be checked to identify the data resources.	MoH
Community health care information system upgraded to share data with the EHR	The community care information system is upgraded to be used by nurses in daily work and share data with the central EHR	Annual	The EHR system	The EHR databases will be checked to identify the data shared by the community care information system	MoH
Annual international price comparisons for all medicines with registered shortages in Romania	The list of reference prices calculated based on the prices set by the Ministry of Health will be published on the National Health Insurance House web page	Annual	NHIH website	Link to the published report	NHIH
Management Entry Agreement signed for 50% of newly assessed patented drugs with conditional entry decision through HTA methodology	The Ministry of Health will increase the number of drugs with conditioned entry into the list of medicines reimbursed from the National Health Insurance House. This indicator measures the	Annual	NHIH MEA contracts	MoH Drug Agency will provide the results of the HTA evaluation; NHIH will provide the MEA contract numbers	NHIH

	cumulative share of newly-listed patented drugs introduced in the positive list through the revised health technology assessment methodology and reimbursed by the National Health Insurance House subject to managed entry agreements. Numerator: Number of patented drugs introduced in the positive list through new HTA methodology subject to MEA Denominator: Total number of patented drugs introduced in the positive list through new HTA methodology				
Clawback tax regulation revised to improve access to cost-effective drugs	The MoH/MoPF will revise clawback tax in accordance with applicable national legal framework to mitigate negative impact to the lowest cost generic products.	Once (third year of implement ation)	MoH	Official Gazette	MoH
Revision of the list of drugs reimbursed by NHIH	The National Agency for Medicines and Medical Devices will revise the	Once (Second year of	MoH/NHIH		

	positive list of drugs using newly developed HTA methodology incorporating cost-effectiveness of medication in Romania	implement ation)			

ANNEX 2. Disbursement Linked Indicators, Disbursement Arrangements and Verification Protocols

Disbursement Linked Indicators Matrix				
DLI 1	Access to the basic package of PHC services among the uninsured			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (EUR)**	**As % of Total Financing Amount**
Outcome	Yes	Text	75,000,000.00	
Period	**Value**		**Allocated Amount (EUR)**	**Formula**
Baseline	About 2 million uninsured do not have access to the basic package of PHC services			
Prior Results			0.00	
Year 1	Health Reform Law 95/2006 amended to provide basic package of PHC services at free to the uninsured		20,000,000.00	
Year 2	Annual Budget Law and Medium Expenditure Framework reflect the amended Health Reform Law 95/2006 to finance the basic package of PHC services for the uninsured		20,000,000.00	
Year 3			0.00	
Year 4	At least 2 million uninsured registered with PHC providers (family physicians) to receive the basic package of PHC services		35,000,000.00	See Formula under Description of DLI

DLI 2	Number of underserved communities receiving public community health care in collaboration with PHC providers			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (EUR)**	**As % of Total Financing Amount**
Outcome	Yes	Text	75,000,000.00	
Period	**Value**		**Allocated Amount (EUR)**	**Formula**
Baseline	Community health services not in collaboration with PHC services			
Prior Results			0.00	
Year 1	Methodological guidelines and household monitoring instruments for community health care, and template agreements for collaboration between community health care and PHC developed and adopted by the MoH		24,000,000.00	
Year 2			0.00	
Year 3			0.00	
Year 4	300 underserved communities providing public community health in collaboration with PHC providers		51,000,000.00	See Formula under Description of DLI

DLI 3	Share of the NHIH budget allocated to primary health care			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (EUR)**	**As % of Total Financing Amount**
Output	Yes	Text	75,000,000.00	
Period	**Value**		**Allocated Amount (EUR)**	**Formula**

Baseline	a) Share of the NHIH budget allocated to family medicine is 6.5%; b)Provider payment mechanisms for PHC providers limits effectiveness of PHC provision; c) Limited scope of PHC		
Prior Results		0.00	
Year 1	Framework contract is modified to increase the effectiveness of PHC through a) Revised provider payment mechanisms; and b) Expanded scope of services allowed at PHC	20,000,000.00	
Year 2	Share of the NHIH budget allocated to PHC is at least 8%	20,000,000.00	
Year 3		0.00	
Year 4	Share of the NHIF budget allocated to PHC is 10%	35,000,000.00	See Formula under Description of DLI

DLI 4	Number of family medicine practices receiving grants and loans for the purpose of increasing and improving the supply of PHC services			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (EUR)**	**As % of Total Financing Amount**
Process	Yes	Text	75,000,000.00	
Period	**Value**		**Allocated Amount (EUR)**	**Formula**
Baseline	Family medicine practices lack capacity (equipment, supplies, skills) to provide quality care, especially in underserved areas.			

Prior Results		0.00	
Year 1	Government regulations adopted to establish a de minimis aid scheme and proposals received within the first 30 days evaluated by MoH	15,000,000.00	
Year 2	At least 60 grants and at least 340 loans awarded to family medicine practices	20,000,000.00	
Year 3	240 grants agreements and 1360 loans agreements signed with family medicine practices	40,000,000.00	See Formula under Description of DLI
Year 4		0.00	

DLI 5	Scope and effectiveness of PHC traced through the share of diabetes medication initiated by PHC providers and proportion of adults (40+) receiving annual medical check up			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (EUR)**	**As % of Total Financing Amount**
Outcome	Yes	Text	50,000,000.00	
Period	**Value**		**Allocated Amount (EUR)**	**Formula**
Baseline	a) Initiation of diabetes medication at the PHC level is 0%; b) Number of adults (40+) receiving annual medical check-ups is 1%			
Prior Results			0.00	
Year 1			0.00	
Year 2			0.00	

Year 3	a) 10% of metformin prescription (a commonly used diabetes medication) initiated by PHC providers; b)10% of adults (40+) receiving annual medical check ups by PHC providers	20,000,000.00	EUR 10 million for a) and EUR 10 million for b)
Year 4	a) 20% of metformin prescription (a commonly used diabetes medication) initiated by PHC providers; b) 20% of adults (40+) receiving annual medical check ups by PHC providers	30,000,000.00	See Formula under Description of DLI

DLI 6	Efficiency of NHIH expenditure improved through data-driven decision making process			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (EUR)**	**As % of Total Financing Amount**
Outcome	No	Text	50,000,000.00	0.00
Period	**Value**		**Allocated Amount (EUR)**	**Formula**
Baseline	0% (current level of avoiding unnecessary expenditures used as baseline)			
Prior Results			0.00	
Year 1			0.00	
Year 2	a) Health Data Management Strategy approved by MoH, and institutional arrangements implemented as defined in the said Strategy; b) Integrated management system in NHIH upgraded to allow improved detection of inefficient spending on claims management in PHC and hospital care, and e-prescription.		25,000,000.00	

Year 3		0.00	
Year 4	a) An inter-operable system connects data between PHC providers, NHIH and MoH, to provide regular data cross-checks and inefficient spending data analytics; b).Efficiency of health spending increased by avoiding inefficient NHIH expenditures in an amount equivalent to 2.5% of total projected annual NHIH expenditures	25,000,000.00	

DLI 7	Efficiency of expenditure improved through implementation of centralized procurement			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (EUR)**	**As % of Total Financing Amount**
Outcome	No	Text	50,000,000.00	
Period	**Value**		**Allocated Amount (EUR)**	**Formula**
Baseline	National Office for Centralized Procurement (ONAC) not operational and not mandated to work in health sector			
Prior Results	Legal framework is adopted to authorize ONAC to carry out centralized procurement for the health sector and establish the institutional responsibilities of the MoH, including relationship with ONAC and relevant entities		10,000,000.00	
Year 1	Framework agreements between ONAC and suppliers signed for 60 medical supplies and devices for emergency medical services		10,000,000.00	
Year 2			0.00	

Year 3	Framework Agreements between ONAC and suppliers signed for minimum of 60 medical supplies and devices for publicly owned hospitals and savings through economies of scale in procurement that are equivalent to 5% of estimated value of selected 60 medical supplies and devices based on the published market prices	30,000,000.00	
Year 4		0.00	

DLI 8	Pharmaceutical measures revised for better efficiency			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (EUR)**	**As % of Total Financing Amount**
Outcome	No	Text	50,000,000.00	
Period	**Value**		**Allocated Amount (EUR)**	**Formula**
Baseline	Shortcoming of existing pharmaceutical policy: a) External reference pricing for pharmaceutical carried out sporadically b) List of drugs reimbursed based on outdated health technology assessment (HTA) methodology c) Great potential to expand use of Management Entry Agreements (MEA)			
Prior Results	MoH approved the new HTA methodology for inclusion of new drugs to the list of drugs		15,000,000.00	
Year 1	Annual recalculated prices for medication published on the MoH website and annual list of reference prices published on the NHIH website		15,000,000.00	

Year 2		0.00	
Year 3		0.00	
Year 4	MEA signed by NHIH and market authorization holders for 50% of newly assessed patented drugs with the conditional entry decision using the new HTA methodology	20,000,000.00	

Verification Protocol Table: Disbursement Linked Indicators	
DLI 1	Access to the basic package of PHC services among the uninsured
Description	Year 4: Formula: EUR 35 million divided by 2 million multiplied by actual number of uninsured registered with PHC providers (family physicians) to receive the basic package of PHC services, up to a maximum amount of EUR 35 million. This DLI aims to support the shift from input-based to results-based financing, facilitating improvements in the efficiency and predictability of expenditures in the Romanian health system, while addressing demand-side financial barriers to health care access. Year 1: The Health Reform Law 95/2006 will be amended to provide the basic package of PHC services to the uninsured at free. Year 2: Annual budget law and medium expenditure framework will reflect the amended Health Reform Law 95/2006 to finance the coverage of basic package of PHC services among the uninsured. Year 4: Two million uninsured people will be registered with family physician to receive the basic package of PHC services.
Data source/ Agency	Year 1:Official Gazette from MoH and MoPF; Year 2: Official Gazette from MoH and NHIH; Year 4: NHIH reports on the number of people registered with family physicians for basic package of PHC
Verification Entity	Independent Verification Entity (IVA)
Procedure	Year 1: IVA will confirm that the amendment of the law grants free access to basic package of PHC services to the uninsured. Year 2: IVA will confirm that budget allocation for projected expenditure for the revised basic benefit package for the uninsured to be transferred to NHIH is approved by the budget Law and reflected in the medium expenditure framework.. Year 4: IVA will confirm that the NHIH reports include 2 million uninsured population that are registered and there is claim of PHC services among this group.

DLI 2	Number of underserved communities receiving public community health care in collaboration with PHC providers
Description	Year 4: Formula: EUR 51 million divided by 300 multiplied by actual number of communities providing public community health in collaboration with PHC, up to a maximum amount of EUR 51 million. This DLI aims to improve the effectiveness of community health services and leverage partnerships between public provision of community health care and largely private family physicians to address supply-side barriers to PHC in underserved communities. Year 1: The MoH will develop and adopt methodological guidelines and household monitoring instruments for community health care, and template agreements for collaboration between community health care and PHC providers. The methodological guidelines and template agreements will specify the scope of work of community health nurses, Roma health mediators, and family physicians in the continuum of care between community and PHC, the technical standards for each procedure, and mechanisms for collaboration (between community healthcare and PHC) and supervision by the DPHAs. The household monitoring instrument will also include standardized evaluation of health risks for each household in the geographical area of each community nurse. Year 4: The agreements for collaboration between community health care and PHC providers will be signed. Community health nurses will be hired, trained, and supported by the MoH to provide health promotion services based on the standards define by the MoH, to provide services according to the guidelines to at least 300 local authorities that meet the criteria of underserved communities defined in the PAD, and facilitate linkages to PHC per the collaboration agreement signed. In communities with up to 700 self-identifying Roma, a Roma health mediator will also be hired (at the request of the community), trained, and supported by the MoH and local authority to ensure registration of vulnerable groups to receive PHC services.
Data source/ Agency	Year 1: Ministerial order/MoH Year 4: existing electronic system for community health care (AMCMSR) from MoH
Verification Entity	IVA
Procedure	Year 1 (Development of standards): Methodological guidelines and household monitoring instruments for community health care, and template agreements for collaboration between community health care and PHC providers developed and adopted by the MoH. The IVA will confirm the issuance of Ministerial order. Year 4 (300 communities): The IVA will confirm, using the existing electronic system for community health care (AMCMSR), the number of localities that have community services in place and reporting, including for each locality: a) the number of community health nurses and Roma health mediators working in the area; b) the number of agreements for collaboration signed; c) summary reports on the number of services delivered (household visits, communication with PHC providers and referrals to PHC providers) per month; and d) supervision reports prepared by the DPHA. The verification protocol will

	include spot checks/surveys to be conducted with technical support to confirm the results achieved to complement and validate system generated data.
DLI 3	Share of the NHIH budget allocated to primary health care
Description	Year 4: Formula: EUR 17.5 million multiplied by percentage points of the share of NHIH budget above 8% allocated to family medicine, up to a maximum amount of EUR 35 million (percentage points of the share of NHIH budget should be rounded to the first decimal digit (e.g., 9.7%). This DLI aims to support efforts by the Ministry of Health to reorient the health system towards primary health care, by adjusting the incentives for service provision through revision of clinical guidelines and provider payment mechanisms and increasing overall funding for primary health care. Negotiations between the NHIH and the family physicians association will continue as currently is the case, and the framework contract will then be approved by the NHIH Board and MoH. Year 1: Milestone a) Provider payment mechanisms for family physicians will be modified to incentivize an increase in the scope and supply of primary health care services. Specifically, capitation methods will also be adjusted for gender, the threshold on the volume of services reimbursed through fee-for-services will be increased, performance-based payment mechanisms for attaining service coverage targets and quality will be introduced, and family physicians will be reimbursed for services introduced through the revision of clinical guidelines (e.g., initiation and coordination for chronic diseases care). Milestone b): Relevant regulations will be modified by the Ministry of Health in consultation with physician associations to expand the scope of services in primary health care to include initiation and coordination of care for diabetes mellitus and cervical cancer and other such as chronic obstructive pulmonary diseases, psychiatric conditions, and chronic pain, including prescription of related medication and the required diagnostic tests. These normative changes will be translated to regulation through the framework contract. Year 2: The share of the NHIH budget allocated to family medicine is at least 8%. Numerator: annual NHIH budget for service delivery allocated to family medicine . Denominator: total NHIH budget for service delivery allocated to goods and services and transfers in the same year as for the numerator. Year 4: The hare of the NHIH budget allocated to family medicine is 10% by Year 4. Numerator: annual NHIH budget for service delivery allocated to family medicine. Denominator: total NHIH budget for service delivery allocated to goods and services and transfers in the same year as the numerator.
Data source/ Agency	Year 1: Official Gazette from MoH and NHIH Year 2: Official Gazette/NHIH Year 4: Official Gazette/NHIH
Verification Entity	IVA
Procedure	Year 1: IVA will confirm that the revised framework contract reflects changes in provider payment mechanisms and

	reimbursement for expanded scope of PHC as described in the PAD. Year 2: The IVA will assess the official gazette documenting legislation on the budget for NHIH to confirm that the allocated amount for family medicine is at least 8% of the total NHIH budget. Year 4: The IVA will assess the official gazette documenting legislation on the budget for NHIH to confirm that the allocated amount for family medicine is 10% of the total NHIH budget.
DLI 4	Number of family medicine practices receiving grants and loans for the purpose of increasing and improving the supply of PHC services
Description	Year 3: Formula: EUR 42,000 multiplied by actual number of grants + EUR 22,000 multiplied by the number of loans up to 1360, up to a maximum amount of EUR 40 million. This DLI aims to address the financial and coordination barriers to incentivizing increase in the supply and quality of primary health care in Romania. Year 1: Government regulations establishing the de minimis aid scheme are in place and first group of proposals (received within 30 days) are evaluated. The guidelines for the scheme will include operational procedures of the scheme (e.g., criteria for awarding grants and loans, guidelines for evaluation of proposals, procedures for assessment of service conditions, reporting requirements for beneficiaries on use of funds, and field-inspection by designated entity on fund use). The Evaluation report for the first group of proposals will be consistent with the scheme guidelines. Year 2: At least 60 grants and 340 loans are awarded. Year 3: 240 additional grants and 1360 additional loans agreements are signed with family medicine practices.
Data source/ Agency	Year 1: Official Gazette; evaluation report of the first group of proposals. Year 2: Copy of communication sent to the applicants on the result of the evaluation. Year 3: Summary report of contracts signed.
Verification Entity	IVA
Procedure	Year 1 (regulations passed/scheme established): The IVA will confirm that government regulations establishing the state aid scheme have been issued and first group of proposals have been evaluated and following the scheme guidelines. Year 2: The IVA will confirm that the summary report includes at least 60 grants and 340 loans. Notifications of the result of the evaluation have been sent to the applicants. Year 3: The IVA will confirm that the summary report includes contracts for the 240 grants and 1360 loans (excluding those that have already been awarded in Year 2). The verification protocol will include spot checks, to be conducted with technical support, with beneficiaries against the routine reports submitted by beneficiaries and regular field-inspection reports, with technical support when needed.

DLI 5	Scope and effectiveness of PHC traced through the share of diabetes medication initiated by PHC providers and proportion of adults (40+) receiving annual medical check up
Description	Year 4: Formula: EUR 15 million divided by 10 and multiplied by (percentage of metformin prescription initiated by PHC providers minus 10 percentage points) up to EUR 15 million for (a) and EUR 15 million divided by 10 and multiplied by (percentage adults (40+) receiving annual medical check-ups minus 10 percentage points) up to EUR 15 million for (b). This DLI serves as a tracer indicator for increased scope and improved effectiveness of PHC services. Years 3 and 4: the total allocation of EUR 50 M is divided equally between result related to metformin (EUR 25 M) and annual check up (EUR 25 M); Year 3: a) Due to the expansion of the scope of primary health care, the percentage of metformin prescriptions for Diabetes Mellitus Type 2 initiated by family physicians will increase to 10%. Numerator: number of metformin regimen initiation by family medicine physicians in a given 12 months period. Denominator: total number of metformin regimen initiations in the same 12 months as for the numerator. b) The NHIH will revisit the scope of preventive check-ups for asymptomatic adults, ensuring its focus on most cost-effective preventive interventions and revise the framework contract accordingly. The result will be estimated based on the following: Numerator: number of adults (40+) receiving annual medical check-ups as defined in the PAD during a given year (if a person receives both preventive check-up and case management during the same year, it will only be counted once). Denominator: number of adults (40+) registered with family physicians to receive basic package during the same year as for the numerator. Year 4: a) same as for Year 3, but the target is 20%; b) same as for Year 3, but the target is 20%.
Data source/ Agency	Year 3: Existing e-prescription system/NHIH system reports Year 4: Existing e-prescription system/NHIH system reports
Verification Entity	IVA
Procedure	Years 3 and year 4: The IVA will confirm that the existing system reports include the numerator, the denominator and the share as defined. The IVA will also confirm that mechanisms for reviewing and checking reported data in the system are in place (such as outliers, unexplained changes in patterns, mismatching) and actions are taken to address the identified inconsistencies based on related evidence.
DLI 6	Efficiency of NHIH expenditure improved through data-driven decision making process
Description	This DLI will support efforts to build IT systems that will enable improved legal, financial, organizational and data analytics capacity to improve policy decisions for identifying and reducing inefficient health expenditure and promoting performance management in service provision. “Inefficient health expenditures" means spending that is detectable by data analytics as

	non-optimal. For instance, unnecessary care (referrals, visits, laboratory tests, etc.), non-adherence to best practices, duplication of services, non-optimized laboratory tests, non-optimal use of infrastructure and medical equipment, low workforce productivity, detectable high cost centers such as high readmissions, over-prescribing centers, etc., and errors, including coding, claimed services not connectable to medical conditions, and frauds. Year 2: a) A Health Data Management Strategy is developed and aims at increasing the stewardship role of the Ministry of Health in overseeing the efficient, reliable, complete, and timely collection and reporting of data for decision-making via centralized systems. A stakeholders' agreement in the form of a policy paper will define as a minimum: (i) a single vision of IT domain in health, including consolidation and coordination of current systems and projects already underway at NHIH and MoH, (ii) overall future architecture of health data management and eHealth systems and their interaction, (iii) institutional arrangements on improved data governance and responsibilities for the implementation of the Strategy, and (iv) action plan, including sources of investments and sustainable systems' development and maintenance. Year 4: a) The advanced methodology and algorithms for identifying inefficient spending are expanded by using data analytics and cross-check on the connected data among NHIH, MoH and providers. An inter-operable system that connects data among NHIH, MoH, and providers (based on Government Cloud support) is established to allow: - integration of key central systems (expanded national EHR, key registries such as HR registry, NHIH core systems, ePrescription, eReferrals), providers' systems (PHC, hospitals, pharmacies, laboratories) and community care information system; - interaction between the systems based on interoperability standards, and data and registers models according to the EU recommendations; - Integrated Health Management Information System (HMIS) as a Business Intelligence (BI) and data analytics tool that allows consolidation of administrative and financial data, implements data cross-checks and smart analytics aimed at reducing losses caused by inefficient spending and provides analytical reporting on healthcare system resources (human resources, facilities, etc.) and key performance indicators (KPIs). - The National Health Data Observatory as a data warehouse and data reporting/analytics tool that identifies health data consumers, data sets and data sources, consolidates public health data sets and registries, provides key national healthcare system indicators, including key national reporting indicators to EU, WHO, … (NOTE: The HMIS and Observatory can be implemented as one technical system, but with distinctive features). b) The MoH, NHIH and IPH will use improved methodology and algorithms to utilize new tools and information available, including blended methods of monitoring and evaluation (automatic with the combination of manual/classic audit), improvements of the definition of data sets to be provided by providers, legal consolidation of data on healthcare systems resources, etc. To improve legal, financial, organizational and data analytics capacity to make better policies and decisions, thus increasing the efficiency of the healthcare system by avoiding unnecessary NHIH expenditures.

Data source/ Agency	Year 2: a) Official Gazette and collaboration protocols/MoH documenting: (i) the adoption of Health Data Management Strategy, (ii) implementation of the institutional arrangements in accordance with the Strategy (establishment of a Strategy implementation unit, and agreed institutional responsibilities of the MoH, NHIH, PHI and other stakeholders), (iii) establishment of standardization and software certification mechanisms. b) System reports from integrated NHIH management system showing the detected cases of inefficient spending in healthcare claims (PHC and hospitals) and from ePrescriptions/NHIH. Year 4: a) System reports from central registries, National EHR, NHIH core systems, ePrescription, eReferrals, community health care information system, HMIS and Health Data Observatory that show system utilization and data exchange between systems/MoH, NHIH and IPH. b) The report on calculated NHIH expenditure reduction due to improved data management in the last 12 months. Projected NHIH expenditure (based on trend from the period 2014-2020) will be compared with actual NHIH expenditure to estimate expenditures avoided by reducing losses (MoH and NHIH).
Verification Entity	IVA
Procedure	Year 2: a) The IVA will confirm the Official Gazette and collaboration protocols include i) the adoption of Health Data Management Strategy, (ii) implementation of the institutional arrangements in accordance with the Strategy (establishment of a Strategy implementation unit, and agreed institutional responsibilities of the MoH, NHIH, PHI and other stakeholders), (iii) establishment of standardization and software certification mechanisms. b) The IVA will confirm that system reports from the integrated NHIH management system show detection of cases of inefficient spending in health care claims and from ePrescriptions. Year 4: a) The MoH, NHIH and IPH will provide system reports from central registries, National EHR, NHIH core systems, ePrescription, eReferrals, community health care information system, HMIS and Health Data Observatory. The IVA will confirm the reports include: (i) level of systems implementation, (ii) level of systems usage, (iii) mapping of data exchange between the systems, and (iv) effectiveness of systems' support to business processes. b) The IVA will confirm that the methodology for projecting expenditures and calculating expenditure reduction as an outcome of improved data management is used by NHIH.
DLI 7	Efficiency of expenditure improved through implementation of centralized procurement
Description	This DLI will facilitate coordination between relevant agencies to address legislative and capacity barriers to centralized procurement in the health sector by the National Office for Centralized Procurement. As a result, gains of at least 5% in

	expenditure in medical supplies and devices from economies of scale will be achieved. Prior result: ,t legislation will be amended to mandate the National Office for Centralized Procurement to undertake centralized procurement for the health sector. The legislation will also specify institutional responsibilities of ONAC, MoH and other relevant entities (e.g., Ministry of Internal Affairs and hospitals), as well as their collaboration mechanisms.. Year 1: The National Office for Centralized Procurement conclude at least 60 framework agreements with suppliers for medical supplies and devices for emergency medical services, using technical specifications provided by the Ministry of Interior. Year 3: a) The National Office for Centralized Procurement will conclude framework agreements for at least 60 medical supplies and devices for publicly owned hospitals contracted with the HNIH, using technical specifications provided by the Ministry of Health. b) Concluded framework agreement value of medical supplies and devices procured for publicly owned hospitals by ONAC will be compared with the estimated value resulting from published market price for corresponding medical supplies and devices in same calendar year to calculate expenditure avoided through economies of scale in procurement.
Data source/ Agency	Prior result: Official Gazette/MoPF Year 1: E-procurement system/ONAC Year 3: E-procurement system/ONAC/MoPF
Verification Entity	IVA
Procedure	Prior result: The IVA will confirm the Official Gazette reflects the results described above. Year 1: The IVA will confirm that the snapshots provided by the ONAC includes signed framework agreements for 60 medical supplies and devices for emergency medical services. Year 3: a) The IVA will confirm that the snapshots provided by the ONAC include signed framework agreements for 60 medical supplies and devices for publicly owned hospitals. b) The IVA will confirm that the weighted average 5% reduction is based on projected expenditure and the difference between the estimated value resulting from published market price and procured price in line with the Law 98/2016, Directive 24 of 2014, for 60 selected products.
DLI 8	Pharmaceutical measures revised for better efficiency
Description	This DLI will support changes in pharmaceutical policy to ensure regular implementation of price referencing, improvement of the health technology assessment methodology, and the increase in implementation of managed entry agreements facilitating access to medicines while ensuring efficiency gains. Prior result 1: The National Agency for Medicines and Medical Devices will revise the health technology assessment methodology for inclusion of new drugs on the positive list to incorporate cost-effectiveness of medication in Romania. Year 1: To improve transparency and accountability, the pricing process for medicines will be completed annually and published on the Ministry of Health website, while the list of

	reference prices calculated based on the prices set by the Ministry of Health will be published on the National Health Insurance House web page. Year 4: The Ministry of Health will increase the number of MEA signed for drugs with conditioned entry into the list of medicines reimbursed from the National Health Insurance House. Cumulative of 50% of newly-listed patented drugs with conditional entry decision will be introduced in the positive list through the revised health technology assessment methodology and reimbursed by the National Health Insurance House subject to concluded MEAs. Numerator: newly-listed patented drugs with conditional entry decision, introduced in the positive list through the revised health technology assessment methodology and reimbursed by the National Health Insurance House, for which MEA have been concluded between the NHIH and market authorization holders; Denominator: all newly-listed patented drugs with conditional entry decision introduced in the positive list through the revised health technology assessment methodology and reimbursed by the National Health Insurance House; Time period: Cumulative as of the year 2.
Data source/ Agency	PR: Official Gazette/MoH/NHIH Year 1: Website, MoH and NHIH Year 4: Contracts, NHIH
Verification Entity	IVA
Procedure	Prior Result: IVA will confirm that the official gazette reflecting legislation documenting the adoption of the new HTA methodology. Year 1: IVA will confirm that the MoH Website includes description of pricing process for medication and NHIH website including list of reference prices endorsed by independent experts in this field. Year 4: IVA will confirm theist of registration numbers of contracts for newly-listed patented drugs subject to MEA, the list of newly assessed patented drugs with the conditional entry, and the share as defined above.

ANNEX 3. (SUMMARY) TECHNICAL ASSESSMENT

COUNTRY : Romania
Romania Health Program for Results

A. Government program ("program")

1. **The EU's cohesion policy aims to strengthen economic and social cohesion by reducing disparities in the level of development between regions.** The policy focuses on key areas which will help the EU face up to the challenges of the 21st century and remain globally competitive. As the EU's main investment policy, it defines investment priorities of EU funds. About one-third of the EU budget is allocated for implementation of the cohesion policy. The cohesion policy framework is established for a period of seven years: 2021-2027. Promoting equal access to health care for a more inclusive Europe has consistently been the priority of EU's cohesion policy.

2. **In alignment with EU's cohesion policy's implementation in the health sector of Romania, National Health Strategy (NHS) is developed in two phases: 2014-2020 and post-2020.** The National Health Strategy promotes social inclusion and introduces discipline in managing public financing, as health services are a critical factor in equalizing opportunities and the health sector budget accounts for a non-trivial 10 percent of the total Government budget.

3. **Overall, the NHS has identified eight main areas**. Seven areas focus on issues related to specific types of services: public health, community health care, primary health care, specialist care, inpatient care, emergency care and palliative care. The eighth area focuses on cross-cutting measures for health system strengthening, including implementation of health financing, human resource, service quality improvement and pharmaceutical policies, use of modern information technology in health sector, and institutional strengthening (Table 7).

Table 7. Care-Specific Areas and Cross-Cutting Measures in the National Health Strategy

Areas 1-7: Care-specific						
1. Public health	2.Community health care	3.Primary health care	4.Specialist care	5.Inpatient care	6.Emergency care	7.Palliative care
Area 8. Cross-cutting measures for health system strengthening: • Implementation of health financing policies for better efficiency and financial sustainability • Accelerating the use of modern information technology or eHealth • Implementation of health human resource policies • Development and implementation of evidence-based pharmaceutical policies • Improvement of service quality • Building administrative capacities						

B. PforR Program Scope

4. **The boundary for the PforR within the National Health Strategy has several dimensions.** First, it will focus on community health care and PHC among the seven care specific areas, and all the cross-cutting measures to the extent that they are related to community health care and PHC, as well as efficiency improvement of health expenditure (areas 2, 3 and 8 in Table 7). Focusing the Program resources on these areas will contribute to achieving universal coverage of PHC and increasing the efficiency of public financing in the health system. Second, the Program will have national coverage, but its most intense efforts to expand PHC coverage will be in reducing the constraints to health care use by underserved populations.

5. **Focusing on community health care and PHC is justified on several grounds.** In countries that have high coverage of services and good health outcomes, PHC tends to have a central role, with comprehensive care for most conditions provided by the family physician. Strengthening PHC in Romania is a necessary condition for improving access to services and increasing the efficiency of the health system; PHC reaches the largest share of the population and can help shift patients out of hospitals for better efficiency in resource use. Community health nurses and Roma health mediators, who facilitate linkages between underserved populations and family physicians, are essential to addressing physical and social challenges to access to care. While other types of care in the seven care-specific areas may contribute to health outcomes, access, and efficiency, they are covered by the ongoing Health Reform Project (Loan No. 8362-RO) that provide support to hospitals.

6. **The cross-cutting areas of the Government program are included in the PfoR because they address critical drivers of inefficiency identified in the Public Expenditure Review.** Therefore, the PfoR will support activities that improve the implementation of innovative pharmaceutical policies that have the potential to increase cost containment and the predictability of expenditures in the system. Likewise, the Program will support efforts to develop a health information system that facilitates collaboration across institutions and provides data on health expenditures to enable decision-makers to reduce intentional and unintentional inefficiencies in the health system. The PforR will not address the full array of issues identified under the NHS in these cross-cutting areas. For example, efforts to improve human resources for health in hospital service delivery, while important, are outside the Program focus on PHC and critical drivers of inefficiency.

7. **The proposed Program scope is informed by the findings of analytical work and the experiences of previous engagements, and defined by the country's demand and application of the CPF filters.** Analytical work (e.g., the SCD and PER) show that Romania's health sector, financed mostly by public funds, is underfunded and inefficient, and is not effectively delivering services for the poorest and most vulnerable peopple, including Roma. Furthermore, previous engagements have shown that sound technical solutions are often left not implemented or are unsustainable because of inherent institutional challenges. The Government requested the Bank's support in expanding access to basic services for the entire population, particularly the uninsured and underserved, including Roma. As noted in Section I.C (Relationship to the CAS/CPF and Rationale for Use of Instrument), the proposed operation meets the core WBG engagement filter and two additional IBRD financing criteria.

8. **The proposed Program focuses on three results areas in which the Government requested the Bank's support and where the Bank's engagment is likely to make a signficant impact**.

Results area 1: Improving PHC coverage for underserved populations

9. This results area aims to improve PHC coverage for underserved people by addressing the physical, financial, and social challenges they face.

- To address physical challenges related to access to PHC, the Program will expand community health care and strengthen its collaboration with PHC. The National Health Strategy has identified community health care as a cost-effective means of providing access to essential services in rural areas and for underserved populations. The MoH will provide funding for local authorities to hire community health nurses and Roma health mediators, if required, for delivery of community health care. These community health care providers will conduct household visits to promote health and specific preventive interventions, develop resident rosters and identify those with high disease risks, promote the demand of health services when needed, and support community-based interventions. All these activities will promote early detection, improve treatment compliance, and increase health care use, thus leading to improvement in health outcomes.

- Guidelines will be developed to guide and standardize the daily work of community health workers (including both community health nurses and Roma health mediators). A template agreement is being developed for collaboration between public community health care and PHC providers who are private. The agreement will define specific steps for information exchange between community health care providers and PHC providers working in the same areas. Through such information exchange, community health care providers will inform family physicians about specific health situations of individuals included in their rosters, and support family physicians in reaching out patients that require follow up. Community health care providers will be trained to ensure their compliance with the protocols. To improve the governance of community health care and PHC, the MoH will strengthen a unit to ensure the strategic planning at the institutional level for primary and community health care services and to improve the supervision of implementation, in partnership with DPHAs.

- To address social challenges faced by vulnerable groups, the targeted communities (including marginalized communities) will receive health education and support in navigating the health system, particularly PHC. As part of the communities, community health nurses and Roma health mediators will map out specific social challenges and help address them. As needed, primary care providers and community nurses in these communities will also be trained in working effectively with different cultures and ethnic minorities.

- To address financial challenges to PHC, the Government recently announced an initiative to provide the basic package of PHC to the uninsured in Romania. This will entail amending the health law to extend this benefit to the uninsured. In addition, state budgets and the NHIH's framework contract[55] with family physicians will be revised to reflect the cost of providing this

[55] Framework contract is governed by Health Reform Law 95/2006 and defines types of services covered by the insurance and provider payment mechanisms that apply to different providers for a given group of beneficiaries. Introduction of new groups

benefit. Furthermore, public campaigns will be conducted to make the population aware of the benefit to which they are entitled. Their awareness of the new benefit will be monitored, and grievance mechanisms will be strengthened to facilitate people's access to PHC services.

Results area 2: Rebalancing the hospital-centric system toward effective PHC

10. This results area aims to rebalance the hospital-centric system toward effective PHC by addressing the underlying institutional challenges: chronic underinvestment in PHC, the misalignment of incentives that is embedded in NHIH's provider payment mechanisms, and regulatory restrictions on the scope of PHC services. The Government plans a set of initiatives to make PHC comprehensive, widely accessible, and effective.

11. One initiative will revise the package of services in PHC to expand the number of services, including prescriptions for exams and medications to control the most prevalent noncommunicable diseases (NCDs) and increase the supply of preventive services for adults and children such as regular check-ups. In consultation with physician associations, the MoH will modify clinical guidelines to expand the scope of services in PHC to include initiation and coordination of care for some medical conditions such as diabetes mellitus, asthma, chronic obstructive pulmonary diseases, psychiatric conditions, and chronic pain, including prescription of related medication and the required diagnostic tests. The basic package of PHC will be updated to reflect these normative changes that will be available for both the insured and uninsured.

12. To increase the supply of PHC, the NHIH also aims to revise provider payment mechanisms, incentivizing family physicians to improve effectiveness of services. Specifically, NHIH will reimburse family physicians to provide services—for example, to enable them to initiate treatment of Diabetes Mellitus. It will also use a combination of mechanisms such as capitation (adjusted by age and gender), fee-for-service, and performance-based payment (payment made when pre-agreed performance criteria are achieved), and will adjust specific payment terms (e.g., rate of capitation, threshold for fee-for-service volume) to reflect global experiences and country context. With respect to performance-based payments, family physicians will be rewarded for attaining service coverage targets (e.g. vaccination rate of 90 percent for all children under-five on the list) and delivering effective care (e.g. bonuses for adherence to clinical guidelines for annual preventive checks for adults above 40 years).

13. Chronic underinvestment in PHC will be addressed through a two-pronged approach. First, the allocation of NHIH budget to PHC will be substantially increased during the next four years as the expanded scope of and access to PHC increase its use. This will greatly improve the funds inflow for family medicine practices. Second, a de minimis aid[56] scheme will be established to provide grants to facilitate the establishment of family medicine practices in areas where they are not available. It will also provide interest-free loans for practices to improve the quality of care, such as acquiring necessary equipment,

of beneficiaries (e.g., basic package of PHC for the uninsured) will require change in the law. However, changes to the specific contents of services and specific parameters of provider payment mechanisms (e.g., fee level and caps on volume of claims reimbursed) can take place through its annual updating process. Framework contract is updated and signed annually.

[56] de minimis aid means: "aid granted to a single undertaking over a given period of time that does not exceed a certain fixed amount" from public funds as defined by the Commission Regulation (EU) No. 1407/2013 of December 18, 2013.

training, or transportation and conducting minor refurbishment. The de minimis aid scheme will be first piloted and then expanded to about 20 percent of family medicine practices.

Results area 3: Improving health expenditure efficiency by addressing critical cost drivers

14. This results area aims to increase the efficiency of health expenditure by addressing critical cost drivers, including high spending on pharmaceuticals, devices and supplies and inefficient spending that can be detected through effective use of information.

15. To better control spending on pharmaceuticals and supplies, the Program will focus on more effective implementation of centralized procurement and pharmaceutical policies. This will entail refining the current policies (set out in Emergency Ordinance no. 71/2012, which notes that other European countries that implemented centralized procurement realized price reductions of 10-30 percent) and strengthening institutional capacity to implement them. Other proposed actions include modifying costing methodologies, setting health services prices by category of service providers, increasing the transparency of public spending using annual reports prepared by the NHIH and MoH, using risk-sharing mechanisms and cost-volume regulations for all new high-cost drugs, and revising the positive drug lists to ensure cost-effectiveness.

16. Under the Program, improvements in health information management are envisioned to ensure standardization, and interoperability of the existing subsystems, to facilitate access to information and enable evidence-based decision-making, including commitment controls. The application of state-of-the-art data analytics will help identify and prevent inefficient spending in many areas—for example, unnecessary care (referrals, visits, laboratory tests, etc.), failure to adhere to best practices, duplication of services, non-optimized drug prescriptions (e.g., less use of generics than expected), non-optimal use of infrastructure and medical equipment, low workforce productivity, detectable high-cost centers (e.g., population with high number of readmissions, over-prescribing centers), errors (e.g., coding, claimed services not connectable to medical conditions), and frauds.

17. **The budget for the Government program over the next four years is estimated at US$5.1 billion, of which IBRD financing would be US$557 million, or 11 percent of the program budget.** The specific expenditure categories included in the Program are goods and services, the wage bill, and capital expenditures. The activities under the Program will be funded from the budgets of the NHIH, MoH, and MoPF. For the NHIH, the Program will pertain to expenditures for family medicine services and NHIH administration. For MoH, the Program will relate to expenditure items dealing with community health

care, PHC, and administration of related activities. In addition, the Program will include the portion of the MoPF budget that is related to ONAC.

Table 8. Program Financing

Source	Amount (US$ million)	Percentage of total
Counterpart funding	4,530.0	89
International Bank for Reconstruction and Development (IBRD)	557.2	11
Total Program financing	**5,087.2**	**100**

Program's Strategic Relevance and Technical Soundness of the Approach

18. **The Program is aligned with recommendations from the European Council on structural and institutional reforms to promote responsible fiscal policy-making, social inclusion and population health.** These recommendations focus on the need to address institutional challenges to universal health coverage, including overall low funding, inefficient use of health resources in the health sector and hospital-centric service delivery. [57] The Council also recommended a focus on responsible fiscal policy, promoting social inclusion, and strengthening of public procurement to promote efficiency. In keeping with this focus, the Government's National Health Strategy (2014-2020) aims to address significant health system and institutional challenges to health care access and efficiency in the Romanian health sector overall**.** The Program interventions will alleviate financial barriers arising from exclusion from insurance coverage; reduce geographical and sociocultural barriers in access to PHC in underserved populations; address the chronic underinvestment in PHC quality and misalignment of provider incentives with quality and efficiency; eliminate barriers to institutional-level coordination required for improvement of PHC supply and quality; and address critical cost drivers in the system including inefficient pharmaceutical policies and lack of strategic use of health information for service purchasing and cost containment.

19. **The Program objectives are also aligned with the World Bank's twin goals of reducing poverty and boosting shared prosperity in Romania and globally.** The Program will address key challenges to achieving the twin goals identified in the Systematic Country Diagnostic, including the functioning of public institutions and the quality of governance. The Program also contributes to the Country Partnership Framework FY18-FY23 goal of an inclusive Romania, through the implementation of interventions that reduce disparities in access to primary health care, with a priority focus on underserved areas. Achieving universal primary health coverage is in alignment with the first area of focus for Bank's support under the CPF, "to ensure equal opportunities for all", and its second objective, "to improve access to modern health care", particularly for the poor and vulnerable.

20. **Investing in PHC is a cost-effective means of boosting stocks of human capital, through evidence-based management of non-communicable diseases (NCDs) and the resulting improvements in labor productivity.** A high burden of NCDs leads to premature death and loss of productivity from

57 European Commission. Council recommendation on the 2018 National Reform Programme of Romania and delivering a Council opinion on the 2018 Convergence Programme of Romania. 2018.

absenteeism and presenteeism. Increasing the supply and effectiveness of PHC, including in underserved areas that also bear a higher burden of NCDs, the operation will contribute towards reducing mortality and morbidity from chronic diseases. Reducing the burden of diseases will facilitate higher labor productivity for the working population and improved quality of life overall.

21. **There is a clear justification for support from the World Bank to strengthen PHC and boost health system efficiency.** Investing in PHC generates positive externalities, as a healthy and productive work force faciliates economic growth that benefits society in ways that are not captured by individiual transactions in the health sector. However, PHC is underfunded in Romania and resources are distributed inequitably, in favor of urban areas and high-income groups. Improvements in health system efficiency can further expand fiscal space for PHC. This provides a rationale for investments in strengthening PHC and boosting health system efficiency by the Government. However, persistent institutional challenges due to poor coordination, misaligned incentives, and limited capacity for implementation, have prevented prior investments from addressing service delivery challenges. The Bank is uniquely qualified to provide cross-sectoral support to improve PHC and efficiency by addressing key institutional challenges, drawing on expertise and global experience in health service delivery, IT, and governance. The proposed Program, which addresses critical institutional and health system drivers of disparities in health care access and fiscal inefficiency, will help Romania achieve a healthy and inclusive society.

22. **Reviews of reform experiences in improving coverage of essential health services and efficiency of the health sector indicate a central role for strong public institutions in addressing service delivery challenges.** The capacity to raise sufficient revenues is essential to the provision of a comprehensive package of services to the population, in health systems with underfunded primary care. Through active purchasing of services, using strong information systems, countries can implement measures to ensure providers act in the interests of the population, promoting access, quality, and efficiency. In addition, medical and financial audits, rewards for performance, and sanctions for fraud and errors, can promote accountability and improve efficiency. In addition, capacities for convening, negotiating, consensus-building, and interagency collaboration are needed for health sector decision-making, including harmonizing benefit packages, defining payment methods, and ensuring access to medicines and other health care.

23. **Global experience on the importance of strong public institutions for universal health coverage is particularly salient in the Romanian context where the key institutional challenges to health care access and effficiency, including poor coordination, misaligned incentives, and low implementation capacity have stalled previous reforms.**[58] The programs in the 2011 and 2013 stand-by arrangements between the Government of Romania and the International Monetary Fund, included commitments to shift service delivery from hospitals to primary health care, allocate resources towards primary care, and monitor hospital budget execution. However, funding levels for primary care remained flat as the higher financial flows to family medicine were not tied to specific service delivery results; the deficits due to lack of expenditure commitment controls persisted in the absence of health information systems that incentivize transparency and accountability; and the hospital-centric nature of health services remains given the misaligned incentives embedded in the framework contract and clinical guidelines. The Country Partnership Strategy for FY14-17 also included an objective of improved health service delivery, including

[58] Tangcharoensathien, Viroj, and David B. Evans. 2013. "Beyond Clinical Skills: Key Capacities Needed for Universal Health Coverage.": 801-801A.

the introduction of additional roles and payment methods for family physicians. However, the roles and payment of family physicians were not modified, in part due to poor coordination between the MoH, physician associations, and the NHIH. Finally, the second fiscal effectiveness and growth development policy loan included a prior action focused on implementing centralized procurement in the health sector. However, the newly-created ONAC lacked the mandate or technical capacity to undertake centralized procurement of medical products and the mechanisms for coordination between the ONAC, MoH, and other agencies for implementation were non-existent. As a result, there was limited introduction of centralized procurement through the MoH. Addressing critical institutional challenges is thus a necessary step towards increasing access to primary health care and improving health sector efficiency in Romania.

24. **There is relatively strong evidence regarding the effectiveness of financial incentives in encouraging the establishment of family medicine practices and influencing the geographic distribution of family physicians.** Bärnighausen et al. analyzed programmes that offered financial incentives, including loans, to health workers to set up primary care practices in Japan, Canada, and New Zealand.[59] They found that these incentives also attracted a significant number of health workers to underserved areas. In Canada, an increase in reimbursements for general practitioners in rural and underserved areas and reduced reimbursements for areas with oversupply reduced geographical disparities in primary care provision. [60] In France, interest-free loans from local and national authorities were successful in encouraging the setup of practices in rural areas.[61] Given the significant cost of refurbishing PHC practices in Romania, the introduction of a scheme that finances these costs – small facility repairs, equipment, and training – may facilitate the increase in supply of primary care, including in underserved areas.

25. **Expanded access to insurance has been implemented in other contexts to eliminate financial barriers to health care use.** A 2016 systematic review of the global literature on the association between financial coverage of health services and utilization, concluded that health insurance significantly increases utilization, and thus access to care.[62] The only experimental evidence on the impacts of health insurance coverage have been conducted on populations in the United States. Findings from a randomized controlled trial indicate that access to insurance leads to substantial increases in the use of primary and preventive care, lower out-of-pocket medical expenditures, and better self-reported health.[63] The same experiment also found a higher likelihood of early diagnosis of and adherence to prescribed therapy for diabetes mellitus when service users were insured.[64] While hospitalizations and the use of emergency care may also increase in the short term, strengthening emergency care triage systems and instituting PHC's gatekeeping function can prevent this effect.[65] The inclusion of the uninsured population of

[59]Bärnighausen T & Bloom DE. 2009. Financial Incentives for Return of Service in Underserved Areas: A Systematic Review. BMC Health Services Research, 9:86 (available via www.biomedcentral.com).
[60] Wilson NW, Couper ID, De Vries E, Reid S, Fish T, Marais BJ. 2009. A Critical Review of Interventions to Redress the Inequitable Distribution of Healthcare Professional to Rural and Remote Areas. Rural and Remote Health 9: 1060. (Online).
[61] Bruguière M-T. 2011. Rapport d'information, fait au nom de la délegation aux collectivités territoriales et à la décentralisation, sur les territoires et la santé. French Senate document nr. 600, 14 June.
[62] Nosratnejad S, Shami E. 2016. Health Insurance and The Utilization of Health Care: A Systematic Review. *BMJ Open* 2017; 7: bmjopen-015415.70. doi: 10.1136/bmjopen-015415.70
[63] Finkelstein, Amy, et al. 2012. "The Oregon Health Insurance Experiment: Evidence from the First Year. *The Quarterly Journal of Economics* 127.3: 1057-1106.
[64] Baicker, Katherine, et al. 2013. "The Oregon Experiment—Effects of Medicaid on Clinical Outcomes. *New England Journal of Medicine* 368.18: 1713-1722.
[65] Van den Heede, Koen, and Carine Van de Voorde. 2016. "Interventions to Reduce Emergency Department Utilisation: A Review of Reviews. *Health Policy* 120.12: 1337-1349.

Romania in the basic package will increase PHC use while reducing expensive hospital care use, boosting health care access and making efficiency gains to the health system.

26. **Payment mechanisms provoke realignments in service delivery by shaping the incentive structure for health care providers.** Capitation payments create incentives to provide care more efficiently and contain costs. However, to function well, capitation payments must be adjusted for the expected health needs of patients to prevent risk selection. On the other hand, fee-for-service reimbursements encourage providers to increase the units of the rewarded services and may lead to unnecessary utilization and increase costs. Given the constraint placed on primary care delivery in Romania by the caps for fee-for-service reimbursements introduced to encourage cost containment, performance-based financing will be introduced. This model, which ties reimbursements to specific output and outcome targets rather than inputs, has proven successful in improving quality while containing costs in low-income countries (such as Rwanda and Uganda) as well as higher income settings (including Croatia, Estonia, and United Kingdom).[66, 67, 68]

27. **Improving the supply of family physicians and the incentives for effective care in Romania must be accompanied by an expanded service scope.** Comparative studies of primary care in Europe have concluded that stronger health systems in the region have a central role for primary care provision. In these health systems, primary care is the main entry point to rest of the health care system, coordinates care for the patient within the system, and monitors diagnosis, treatment, prevention and follow-up for most illnesses. [69] Relative to other countries in the EU, including Bulgaria, primary care in Romania is significantly less comprehensive in terms of the scope of services family physicians can provide.[70] Modifying clinical pathways to enable family physicians to initiate care for most chronic diseases, including diabetes mellitus and asthma will improve the effectiveness of care and efficiency in the health system by reducing expensive inpatient care use.

28. **Systematic reviews examining community health programmes worldwide have found that these cadres are effective at service delivery related to health promotion and other preventive care.[71]** With minimal training in clinical service delivery, lay health workers have been found to increase immunization uptake among children, reduce child morbidity from common illnesses, promote exclusive breastfeeding, and improve adherence to treatment, including for tuberculosis. The National Health Service in the United Kingdom has a key role for multidisciplinary primary care in managing chronic illnesses. Nurses are paid by local authorities to provide care at home for specific groups and share responsibility for patient care with the physician. Systematic reviews of similar models conclude that

[66] Eldridge, Cynthia, and Natasha Palmer. "Performance-based payment: some reflections on the discourse, evidence and unanswered questions." Health policy and planning 24.3 (2009): 160-166.
[67] Hindle, Don, and Karolina Kalanj. "New general practitioner payment formula in Croatia: is it consistent with worldwide trends?" Croatian medical journal 45.5 (2004): 604-610.
[68] European Health Observatory. Paying for performance in health care: implications for health system performance and accountability. 2014.
[69] Kringos, Dionne et al. “The strength of primary care in Europe: an international comparative study” British journal of general practice: the journal of the Royal College of General Practitioners vol. 63,616 (2013): e742-50.
[70] Kringos, Dionne et al. “The strength of primary care in Europe: an international comparative study” British journal of general practice: the journal of the Royal College of General Practitioners vol. 63,616 (2013): e742-50.
[71] Gilmore, Brynne, and Eilish McAuliffe. "Effectiveness of community health workers delivering preventive interventions for maternal and child health in low-and middle-income countries: a systematic review." BMC public health 13.1 (2013): 847.

nurses can effectively impact health knowledge and positively influence health-seeking behaviour, consistent with the objective of promoting PHC access in Romania through community health nurses.

29. **Centralized procurement of medical products can provide significant cost savings and increase health system efficiency.** In 2016, the MoH approved a centralized procurement plan for antibiotics and oncology medication which was successful in reducing the average price of drugs. Centralized procurement in Romania of 31 antibiotics and 11 oncology drugs, representing 15 per cent of total public spending on medication, led to a reduction in the average price of drugs from RON 22.2 in 2015 to RON 20.0 in 2017. Centralized procurement has been undertaken for vaccines, tuberculosis and HIV medication, HIV ELISA tests, contraceptives, powdered milk, and implantable medical devices, and fuel. However, there is room to expand the range of products and volume of medical purchases subject to centralized procurement. The total expenditures for medical products amenable to centralized procurement was estimated at US$ 1.3 billion in 2017. There is significant evidence[72] that centralized procurement can achieve cost savings by creating economies of scale and improving purchasing power. It is estimated that Romania can yield US$300 million saving each year if all hospitals implement centralized procurement of medical products.

30. **There is strong evidence that systemic investments in electronic health can contribute to increased efficiency, significant monetary savings and implementation of informed policies.** [73] Most middle- and higher-income countries strive for the use of electronic health records to improve healthcare quality, patient safety, and health system performance monitoring.[74] Integrated, patient-centered health care built around modern and efficient PHC requires robust data and communication mechanisms that will enable provider-to-provider communication and empower patients for stronger engagement. Furthermore, the linkage of health care use and financial information through integrated financial management information systems, can support the management of health sector financial operations, improve public financial management and cost containment.

31. **Pharmaceutical policies aligned to ensure transparency, access to medicines, and cost containment can be powerful tools for promoting fiscal efficiency.** Clawback taxes are effective at preventing budget overshooting and increase the predictability of public pharmaceutical spending. Several countries, such as Germany, France, Italy and Portugal, have reported substantial savings due to clawback policies. Most countries that implement such policies have exemptions for generic medicines, which is indicated in Romania given the indications that older and cheaper generics are being priced out of the market. Regarding HTA, a review of the top 50 medicines by expenditure in Romania found substantial scope for potential savings through delisting medicines that are ineffective for their indications

[72] Some countries have benchmarked the prices obtained through framework agreements with the standard prices in the price lists of suppliers. This benchmarking indicates savings of around 20-50 percent (Denmark, France, Hungary, Italy). In some systems, the assessment of additional savings has been made in terms of savings on transaction costs. A research in Sweden has shown that all transaction costs have decreased for about EUR 50 million on the annual level due to the centralized procurement system. Finland estimates that savings that come out of centralized procurement range between EUR 100 – 150 million annually. Association Aven in Italian region Emilia Romagna stated that they made savings of 45 percent for pharmaceuticals and 20 percent for medical supplies through centralized procurement in 2008. The savings consist of both lower prices and reduced transaction costs.

[73] Bartlett C, Boehncke K, Johnstone-Burt A, Wallace V. Optimising eHealth value: using an investment model to build a foundation for program success. PwC. 2010.

[74] Strengthening Health Information Infrastructure for Health Care Quality Governance, OECD, 2013.

or for which superior, better value alternatives are available. For example, estimated savings related to bevacizumab amounted to EUR 18.9 million per annum. HTA can be a central tool for the control of expenditure in the health sector and to ensure that resources are spent on interventions that provide the best value. Finally, through MEAs, access to innovative medicines can be enabled while controlling cost escalation. However, in scaling up cost-volume and cost-volume-result contracts, there is a need to balance concerns regarding confidentiality of agreements with transparency of budgets.

C. Program Expenditure Framework

32. The following will: (1) provide a brief overview of public healthcare expenditure in Romania, which approximately estimates the expenditure of the government program, National Health Strategy 2014-2020; as well as its principal sources of financing, intermediary agencies that manage the public healthcare budget – National Health Insurance Fund (NHIF) and the Ministry of Health (MoH) – and their budget programs as specified in the 2018 budget execution and 2019 approved budget; (2) assess the government program budget performance, including the intermediary agencies that manage the public healthcare budget – National Health Insurance Fund (NHIF) and the Ministry of Health (MoH) – and their budget programs as specified in the 2018 budget execution and 2019 approved budget; and (3) analyze the Program ("P") expenditures in view of the planned budget appropriations and forecast laid down in the Government Medium-Term Budget Framework (MTBF) for 2019-2021.

Government Health Expenditure in Romania

33. **Romania's public expenditure in healthcare (Government program, GP) has been growing rapidly in recent years.** Although it has varied historically below 4 percent of GDP, its share has been growing in recent years following successive rounds of pay rises for health sector employees. Between 2014 and 2018 it grew faster than both GDP and total Government expenditure with a compound annual growth rate of 12 percent. As a result, by 2018 the share of the GP increased to 4.3 percent of GDP and 13 percent of total Government expenditure. In 2018, total public expenditure in health has exceeded 41,000 million lei, or US$ 10,000 million. Based on the past trend and forecast laid down in MTEF, it is estimated that the total public health expenditure for the Program period 2020-2023 will be US$ 55,437 million.

Table 9: Yearly estimated values of Government Program

	2020	2021	2022	2023	2020-2023
Government program (million lei)	48,051	55,259	57,494	60,944	221,748
Government program (million euro)	10,401	12,013	12,553	13,307	48,206
Government program (million US$)	12,013	13,815	14,373	15,236	55,437

Source: Ministry of Finance, WB team estimates.
Note: Government Program estimates includes only National Health Insurance Fund and Ministry of Health consolidated expenditure, not local budgets.
Note: For data outside the MTEF (2019-2022) or estimates visibly astray from past trends, such as the case of MoH forecast expenditure 2019-2022, a CAGR of 6 percent was used. The value is deemed conservative in the light of past growth (2014-2018).

34. **Public expenditure on healthcare in Romania stems from three main sources.** By far, the biggest source of expenditure is the NHIF, which is mainly funded from social health insurance contributions. The

NHIF accounts for more than three-quarters of all public healthcare expenditure. The state budget is funding more than 20 percent of public healthcare expenditure, including budget allocated to MoH and subsidies to the NHIF. Local budgets cover the remaining 1 percent of expenditure.

Table 10: Share of public expenditures on health by budget source

	2017	2018 preliminary	2019 plan
NHIF (%)	73%	76%	76%
state budget (%)	26%	23%	23%
local governments (%)	1%	1%	1%
public HC expenditure (%)	100%	100%	100%
public HC expenditure (mil. lei)	33,624	41,248	47,665
public HC expenditure (mil. euro)	7,374	8,870	10,207
public HC expenditure (mil. USD)	8,406	10,312	11,916
public HC expenditure (% of GDP)	3.9%	4.3%	4.6%

Source of data: Ministry of Finance.
Note: public HC expenditure represents the Government program ("p").
Note: the share of the state budget includes subsidies to the NHIF; the share of NHIF is net of state budget subsidies.

35. **Corresponding to the financing sources, the two main institutions that manage public healthcare expenditure are the National Health Insurance House and the Ministry of Health**. The NHIH is the single payer in the social health insurance system and is managing 82 percent of total Government healthcare budget, including both NHIF contribution and state budget transfer. It buys services, medicines and devices from approximately 25,000 providers. The MoH, which spends 17 percent of total, is responsible for stewardship in the healthcare system, but also implements public health interventions and preventive National Health Programs, funds emergency services and other specific expenditure items, such as resident physicians' wage-bill and capital improvements in public health infrastructure.

36. **More than 80 percent of NHIF revenues are made of health insurance contributions.** Health insurance contributions from employees and self-employed made for 84 percent of the NHIF revenues in 2018. They were supplemented by revenues from the clawback tax on medicines (10 percent) and state budget subsidies (6 percent). The latter are calculated to offset the NHIF deficit. Supported by Romania's recent high economic growth rates, revenues from health insurance contributions also posted a strong performance, in correlation with the growth in wages and labor force. Between 2014-2018 they increased by 14.4 percent annually. For 2019-2022, the medium-term expenditure framework (MTEF) envisages a growth rate of 11.7 percent annually, with net revenue to the NHIF set to reach US$9,900 million, in 2022, up from US$8,100 million, in 2019. However, the WB estimates are more conservative, pointing to a 9 percent CAGR over the same period, based on the official forecasts for labor force and average gross wages.

Government Program Budget Performance

37. **For budget formulation, execution and reporting, a uniform budget classification is used for all levels of the budget system** that ensures the unification of the forms of budget statistics and comparability with international practice. The budget classification is part of the Chart of Accounts used for the bookkeeping of operations on the execution of budgets and economic activities of budgetary institutions in the general government sector. The budget classifications are in line with the basic principles of the GFSM 2001. The composition of budget appropriations and budget execution is organized based on economic and functional classification.

38. **The fiscal responsibility law allows for flexibility in adjusting the budget through maximum two amendments in the second half of a budget year**. In-year reallocations of budgetary appropriations between items of the economic classification of expenditures are permitted also in the second half of the year. In-year reallocations of budgetary appropriations between institutions within the limits of one administrator of budgetary funds are permitted within the limits of quarterly appropriations.

39. **The budget statements distinguish three key concepts** when it comes to budget approval and execution:

(i) "Initial appropriations," or originally approved budget, that is stated in the yearly budget law approved by the Parliament, usually in December of the preceding year;
(ii) "Definitive appropriations," or the budget that is rectified during the course of the year and is usually approved by the Government through Government Ordinance, based on a mandate from Parliament; and
(iii) "Effected payments," or the actual expenditure.

40. **Comparing "definitive" with "initial appropriations" reveals how much short-term predictability one could obtain with the budget that is originally approved.** In most cases the budget rectifications have added to the initial appropriations. While variations of the NHIF initial budget were lower and rather limited, those related to the MoH budget were wider and bi-directional. The same is true for budget appropriations on NHIF's family medicine versus MoH's community care. In the latter case, the significant growth in 2017 following in-year rectifications is due to pay rises enacted during that year.

Table 11. Short-term predictability of the healthcare budget, 2016 – 2018 (%)

final budget vs. plan	Government program	NHIF – total	MoH - total	NHIF family medicine	MoH community care
2016	100.6%	101.4%	98.0%	103.3%	70.4%
2017	103.1%	102.2%	106.2%	100.0%	130.8%
2018 (prelim.)	104.8%	103.5%	109.6%	105.8%	107.8%

Notes:

a. This indicator measures the share of the rectified budget in the originally planned budget for the year in question. Source of data: Ministry of Finance, NHIH.

b. MoH family medicine and MoH community care are presented in the table as two major budget line items that contribute to Program expenditure framework.

41. **Comparing "effected payments" with "definitive appropriations" reveals that the budget execution rate is high for both NHIF and MoH.** Within NHIF, expenditure on family medicine services is executed close to 99 percent. Likewise, MoH's community care expenditure is executed close to 100 percent[75]. In 2018, the rectified budget for community care was exceeded by the actual payments following a reallocation of appropriations from a budget item within the same budget chapter.

Table 12. Execution rate of the healthcare budget, 2016 – 2018 (%)

Year	Government Program	NHIF – total	MoH - total	NHIF family medicine	MoH community care
2016	95.6%	97.7%	87.9%	99.1%	98.8%
2017	99.1%	99.6%	97.5%	98.6%	98.7%
2018 (prelim.)	99.2%	99.7%	97.5%	99.3%	104.2%

Source of data: Ministry of Finance.

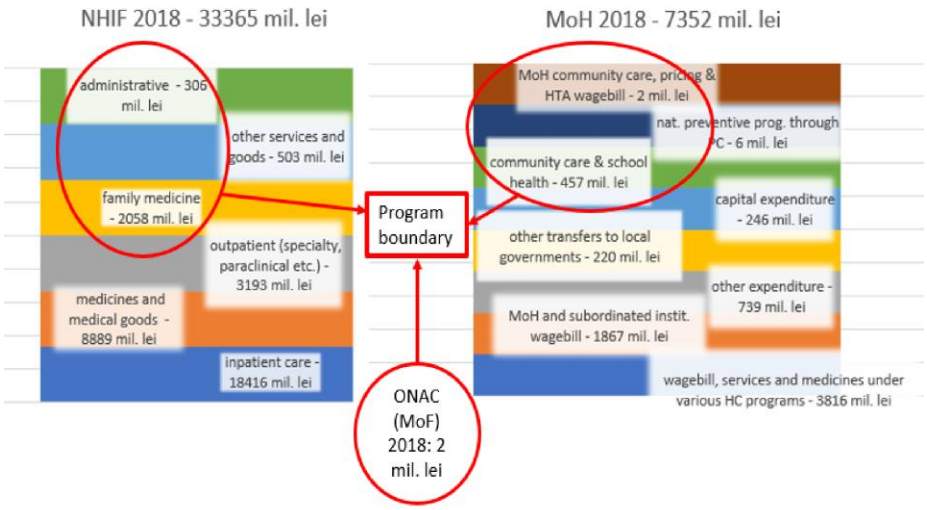
Note: MoH family medicine and MoH community care are presented in the table as two major budget line items that contribute to Program expenditure framework.

Mapping the Program expenditures

42. **Classification of health sector budget by expenditure function allows the definition of the boundary for the Program ("P") expenditure framework.** The Program envisages interventions in primary care, reimbursed medicines, centralized procurement and e-health systems, which will be funded from the budgets of the National Health Insurance Fund, the Ministry of Health and the Ministry of Finance. In the case of the NHIF, the Program will pertain to expenditure with family medicine services and with the Fund's administration by the NHIH. In the case of MoH, the Program will relate to expenditure items dealing with community care, including school health units, the de minimis aid scheme for investment support to family physicians, pricing and HTA of medicines and MoH administration for related policy making and program management. For the MoF budget, the Program will include the administration of the National Office for Centralized Procurement (ONAC). Additionally, expenditure on e-health systems will be split between the NHIH and MoH, based on assigned activities. All these expenditure programs mark the boundary of the Program.

[75] In community care, appropriations are transferred to local budgets where community nurses and roma mediators work. They are employees of local governments, while the Ministry of Health is funding their wagebill via the above transfers.

Figure 9: Government budgets in healthcare (government program) and Program boundary, 2018



Source: Ministry of Finance, National Health Insurance House, Ministry of Health.
Note: MoH and subordinated units wage bill includes the expenditure for MoH at central and county level and for ambulance services.
Note: NHIF expenditure does not include sick-leave allowances, which classify as social assistance expenditure.

43. **The estimation of Program expenditure items uses the budget classification and information from budget statements, the responsible institutions and regulations on public sector pay**. The administration costs calculated in the Program for NHIH were based on the budget statements for 2017 and 2018 and forecast using a 6 percent CAGR. They include wage bill and goods & services for the central office of the National Health Insurance House, which is involved in planning and regulating primary care services. Likewise, ONAC administrative expenditure were estimated based on the wage bill and goods & services reported for 2018. The administration costs related to MoH include the wage bill associated with the departments responsible for community care, medicines prices and HTA and rely on data from MoH on the current number and future needs of personnel. Data on average pay was estimated based on the provisions of the Public Sector Unitary Pay Law. The cost of family medicine services was projected based on the Government's commitment to increase the share of family medicine in NHIF expenditure to 10 percent. Consequently, annual increments were added to the 6 percent share budgeted for 2019, based on the agreed action plan. The growth will accommodate the expenditure related to primary care services to uninsured population. The estimate of the de minimis aid scheme costs included the subsidies for interest rates, as well as grants to physicians in underserved areas, using an average grant and loan value of US$40,000 and the targets the Government committed to by 2023. The data management interventions' costs were estimated by activity using expert assessment based on previous experience.

Table 13. Expenditure items used to estimate Program budget and calculation method

Expenditure item	Budget classification	Calculation 2020-2023	Source
NHIH administration costs	Wage bill, goods & services	Forecast using a 6% cagr, based on 2017-2018 expenditure	NHIH budget statements

Expenditure item	Budget classification	Calculation 2020-2023	Source
MoH specialized units running costs	Wage bill	Positions and estimated annual average wage (cagr 6%)	MoH, unitary pay law
ONAC running costs	Wage bill, goods & services	Forecast using a 6% cagr, based on 2018 expenditure	ONAC, unitary pay law
Community nurses' running costs	Wage bill	Forecast using a 6% cagr, based on 2019 expenditure	2019 state budget law
Family medicine services	Goods & services	Gradual increase from 7.1% (2019) to 10% (2023)	2019 state budget law
Family medicine cost of services for uninsured	Goods & services	Included in the family medicine expenditure above	
Data management integration	Goods & services, capital	Cost per activity	Expert estimates
De minimis aid scheme supporting primary health care services	Transfers to lenders	Interest rate subsidy	Expert estimates based on average value of loan (US$ 40,000), interest rates and a 3-year grace period; Estimated value of grants is also US$40,000

44. **As shown in table 14, the most important contribution to the Program budget is made by the National Health Insurance Fund.** By 2023, it will have exceeded to 86 percent of total expenditure, most of which is related to the purchase of family medicine services. Until 2018, family medicine allocation from the NHIF has grown nominally, but it remained around 6 percent of the total Fund's healthcare expenditure. The 2019 state budget law draft envisages a growth in family medicine funding which will raise its share to 7 percent to NHIF expenditure. The interventions planned with a view to expanding access to services and the scope of the basic service package, coupled with the overhaul of the payment systems, are set to increase the share of primary care from 7 to 10 percent by 2023, in line with the Government's commitment. The main MoH contribution to the program budget is related to community care (13 percent of the Program budget). The MoH's main contributions to the program budget are related to community care and the de minimis state aid scheme for family physicians (13.4 percent of the Program budget).

45. **Most of the Program's expenditure is made of goods & services.** Total NHIH contribution to the Program relies on goods and services, but it also includes wage bill for the Fund's administration (at central level) and capital expenditure (for data management infrastructure). The MoH contribution is distributed between wage bill (community care and medicines policy-making administration), goods & services (data

management software), transfers (de minimis state aid scheme), and capital (data management infrastructure). The MoPF contribution is made of ONAC administration (wage bill and goods & services).

Table 14. Breakdown of Program expenditure by budget source and item 2020-2023 (mil. lei & %)

Agency/item	2020	2021	2022	2023	2020-2023	% of Program
NHIF	**724**	**899**	**1,046**	**1,244**	**3,914**	**86.4%**
Wagebill	9	10	10	11	40	0.9%
Goods & services*	715	890	1,035	1,221	3,861	85.2%
Capital	-	-	-	13	13	0.3%
MoH	**136**	**142**	**157**	**174**	**609**	**13.4%**
Wage bill	136	139	143	146	564	12.5%
goods & services	0	1	3	2	6	0.1%
transfers	-	2	12	20	34	0.7%
capital	-	0	-	5	5	0.1%
MoF	**2**	**2**	**2**	**2**	**7**	**0.1%**
Wage bill	1	1	1	1	5	0.1%
goods & servicesP	0	0	0	0	2	0.0%
Total	**862**	**1,043**	**1,204**	**1,420**	**4,530**	**100.0%**

Source of data: MoPF, MoH and NHIH, WB calculations.
Note 1: data reflects only the expenditures related to the Program not the entire budgets of the respective institutions.
Note 2: in the case of NHIH, the expenditure referred as goods & services includes family physicians services purchased by the NHIH based on the framework contract provisions; in the case of MoH, the expenditure within goods & services refers to data management, which are subject to public procurement.

46. **The value of the Program throughout 2020-2023 will add up to RON 18.1 billion (EUR 3.94 billion/US$ 4.53 billion) from government sources, and US$ 5.1 billion together with Bank financing**. Total government expenditure pertaining to the Program is expected to grow incrementally, as the interventions foreseen in primary care will be rolled out nationally. As a share in total Government expenditure, the program will grow from 0.9 to 1.3 percent from 2020 to 2023.

47. **The Program is not expected to impose any significant burden on the state budget.** Achievement of Program results will depend on: 1) better use of existing budget for PHC, community care and administration, about 82 percent of total Program expenditure; 2) increased allocation for PHC through re-prioritization of the NHIH overall budget, about 11 percent; and 3) additional budget increase for new activities such as state budget transfers for the uninsured, additional allocation for community care, establishment of de minimis aid scheme and health data integration, about 7 percent. Such additional budget requirements translate into less than 1 percent of total public financing in health sector during the Program period, imposing a negligible impact on the total government budget.

48. **Moreover, the Program is expected to have some positive impact on the country's fiscal situation.** Specifically, reduction is foreseen in the need for state budget on emergency care and state transfer to NHIH that fulfills the deficit. In the past years, on average US$500 million each year were transferred to NHIH to fulfill the deficit that is largely driven by hospital expenditure. With the Program

interventions, 2.5 percent of NHIH expenditure (DLI 6) will be saved due to better use of information to detect inefficient spending, which means US$250 million a year. Furthermore, about US$400 million inpatient care spending can be saved through enhanced PHC. This will significantly reduce the likelihood of NHIH running deficit and hence the need for state budget transfer related to it.

49. **The program's financial sustainability is ensured by the existing fiscal and budgetary arrangements, as well as Program interventions.** First, NHIH's key role in financing the Program ensures high funding predictability for the Program, consistent with the country's Medium-Term Fiscal Framework. NHIH revenue, mostly from social insurance contribution, has grown by a nominal 12 percent each year from 2015 to 2018. It is projected to continue to grow by another 10 percent in 2019 and at a similar pace throughout the implementation of the Program. In addition, the state budget recurrent revenues are also projected on a stable growth trajectory, around 6 percent annually up to 2023, which ensures predictability for the state budget-funded share of the Program. As a result, the Program expenditure will account for around 10 percent of the total public financing for health sector. Second, the Program locks in key reform areas through adoption of regulatory changes and revision of budget law, thus minimize the risk of withdrawing financial inputs within state budget or NHIH budget after the Program closes.

D. Economic Justification of the Program

50. **There is a strong economic rationale for investing in strengthening PHC as proposed by the Program.** The Program is intended to support continued effort of the government to strengthen the primary care services and improve efficiency of public spending. The Strategy recognizes the need for sustainable financing of the health sector and proposes an action plan to increase health sector efficiency through cost control and sustainable growth of public funding for health. The additional resources provided by the Program will generate efficiency gains from further development of centralized procurement on healthcare, data-driven systems for decision-making, and improvements to pharmaceutical policy.

51. **Taking action through the Program can be expected to tackle these issues and yield direct economic benefit through** increased efficiency in health spending (by reduction of unnecessary referrals for specialized outpatient care, of avoidable emergency visits and hospital admissions for both insured and uninsured population, the more streamlined procurement of medication and consumables); improved health status (due to averting premature deaths and disability-adjusted life years (DALYs) through improved access and quality of primary care, improved prevention and management of NCDs, and improved management of chronic diseases such as diabetes); and, improved equity (by preventing the use of more expensive emergency care services and improved health outcomes). In addition, spillover effects from strengthening purchasing of services for cost containment can be expected to generate substantial benefits across the health system.

52. **An economic analysis was conducted to estimate the costs and benefits of the Program.** The economic analysis focused on estimating long-term benefits of the Program, including the returns to improved health status and reduced pharmaceutical spending. These two analyses are then combined to give a single net present value (NPV) of the proposed investment. Costs were calculated in US$ and health benefits were estimated in terms of disability-adjusted life years (DALYs). The analysis draws on an

extensive review of data from Romania and the international literature. It also relies on several assumptions, in line with previous economic analyses conducted for World Bank projects in the Romanian health sector supporting similar interventions.

53. **The costs of the Program are mostly determined by the expenditures of the National Health Insurance House as explained in the Program Expenditure Framework**. The Bank financing of the Program will help increase the share of the expenditures of the NHIH allocated to the health care and other critical activities that will support achievement of the Program's DLIs. For the cost-benefit analysis, costs for medicines and medical goods are also included to estimate efficiency gains in the second area. The investment to the Program will amount to a total of US$ 5.1 billion. Total expenditure pertaining to the Program is expected to grow incrementally, as the interventions foreseen in primary care will be rolled out nationally. The contribution from the Bank will be absorbed by the total cost of the Program (Table 15).

Table 15: Total expenditures associated with the implementation of the Program

Program expenditures (million US$)	2020	2021	2022	2023	2020-2023
Government funding of the Program	863.0	1,043.0	1,204.0	1,420.0	4,530.0
Bank contribution, approximated allocation	143.8	94.7	100.3	218.4	557.2
Total cost of the Program	1006.8	1137.7	1304.3	1420.0	5,087.2

54. **The monetary value of the Program's health gains was modelled by estimating the potential impact on the burden of chronic diseases.** The benefits attributable to the Program were measured by comparing the situation with the Program to the continuation of an existing activities. In the absence of the program, the DALYs associated with chronic diseases were projected using an average annual change in DALYs between 2010-2017. The interventions of the Program ware estimated to produce additional benefits by helping avert more DALYs than the interpolated trend.

55. **The cost-benefits of the Program were calculated for a 15-year period (2020-2034) using three scenarios (baseline, lower impact and higher impact).** The assumptions used in the cost-benefit analysis are summarized in Table 16.

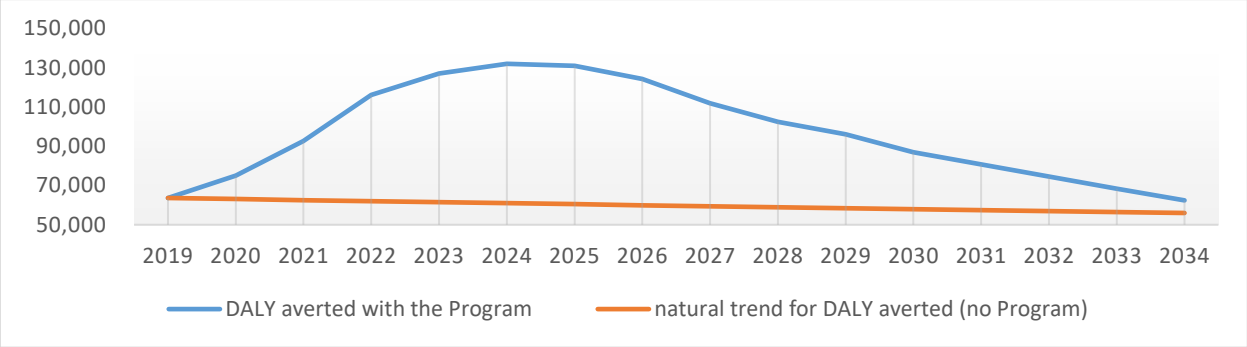
Table 16: Key inputs and assumptions used for the cost-benefit analysis

Key Inputs	Baseline Scenario Assumptions	Sensitivity Analysis	
		Low scenario	High Scenario
Monetary value of DALY	1 x GDP per capita	1 x GDP per capita	1.5 x GDP per capita
Discount rate of the monetary value of future health benefits	3%	5%	3%
Basic discount rate	5.7% (2.7% inflation; 3%-time value of money)	4.5%	6.5%

Key Inputs	Baseline Scenario Assumptions	Sensitivity Analysis	
		Low scenario	High Scenario
Benefits of interventions in terms of DALYs averted	*Increasing access and effectiveness of primary health care*: total 10% reduction in DALYs related to chronic diseases *(excluding DALY related to diabetes type 2)* over 15 years	Same as in the baseline	Same as in the baseline
	Increase of metformin prescriptions at primary care level: up to 0.5% annual reduction in DALYs related to diabetes type 2	Same as in the baseline	Same as in the baseline
Pharmaceutical savings from Centralized procurement for health sector and revised policy measures	5% reduction in government spending on pharmaceuticals starting in 2021	2% reduction in government spending on pharmaceuticals starting in 2021	7% reduction in government spending on pharmaceuticals starting in 2021

56. Under the default scenario, the program is estimated to prevent a total of 589,837 DALYs due to better detection, prevention and management of chronic diseases, as shown in Figure 10, between 2020 and 2034, compared to the counterfactual scenario.

Figure 10: DALYs due to chronic diseases averted compared to counterfactual scenario, by year



57. **The total expenditures for medical products amenable to centralized procurement was estimated at US$1,265 million in 2017.** We also estimated potential savings from the implementation of the centralized procurement and revised pricing and reimbursement mechanisms. Using the expected inflation rates and the assumptions about the potential 5 percent reduction in government spending on pharmaceuticals, we estimated the potential efficiency gains of the Program in the second area and included the generated savings to the total monetized value of the benefits.

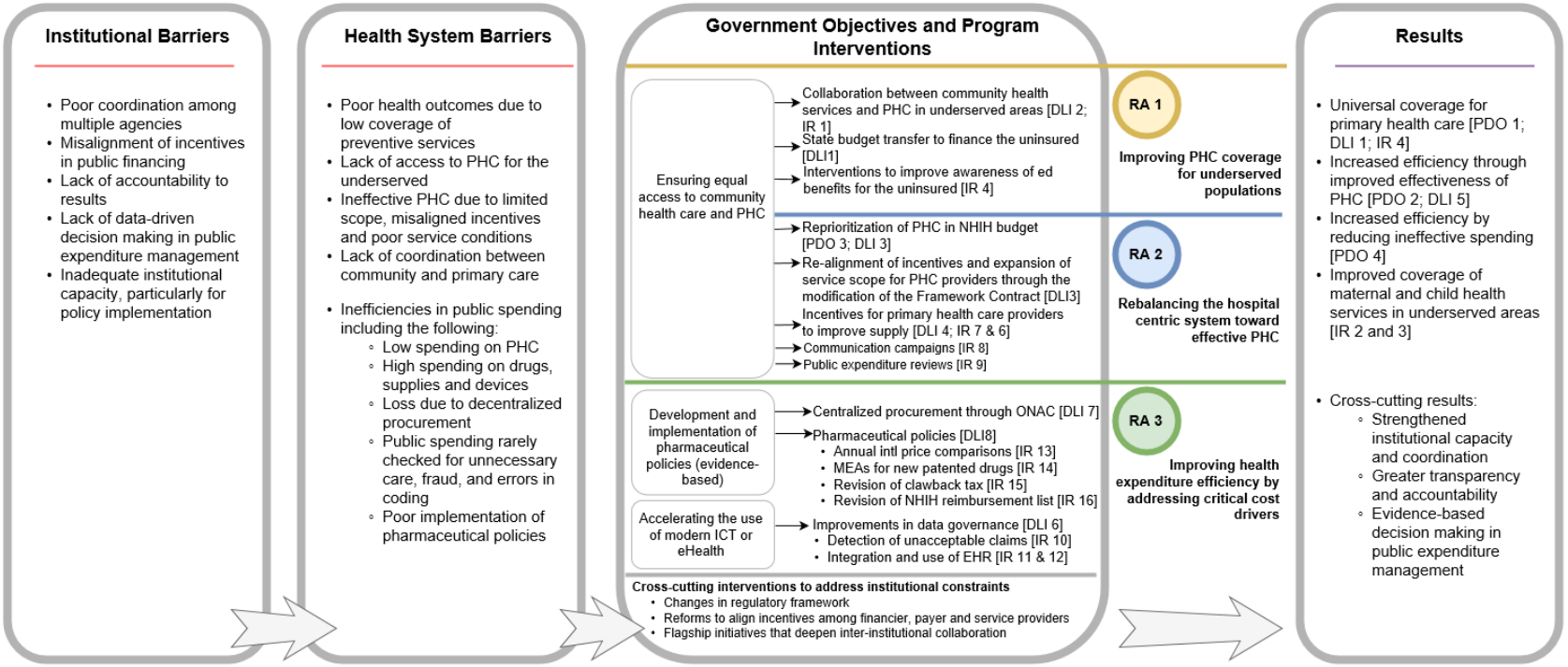
58. **The received benefits from implementation of the Program are more than 2 times larger than the total investment.** Under the baseline scenario, the benefit cost ratio (BCR) is 2.07; internal rate of return (IRR) is 26 percent, and the net present value (NPV) of the Program is US$4,721 million. The sensitivity analysis shows relatively sustainable results in terms of the economic indicators. Table 17 presents the results of the economic analysis.

Table 17: Results of the economic analysis: benefit cost ratio, internal rate of return, net present value

	Baseline scenario	Low scenario	High scenario
Benefit cost ratio	2.07	1.75	3.15
Internal rate of return	26%	23%	99%
Net present value, US$ million	4,721	3,392	9,306

59. **It is important to note that results are likely to be conservative.** Only the direct health benefits and efficiency gains are estimated, and indirect costs, such as those related to lost productivity, are not included. We also did not include the potential effects related to the decreased hospitalization rates and less frequent use of the emergency care because of strengthening the primary care service delivery. Our estimations, therefore, for the potential reductions in DALYs and reallocation of spending, are quite conservative.

Figure 11. Detailed linkage between institutional challenges, health system barriers and the Program



ANNEX 4. (SUMMARY) FIDUCIARY SYSTEMS ASSESSMENT

COUNTRY : Romania
Romania Health Program for Results

1. A Fiduciary System Assessment (FSA) was carried out in accordance with the Bank Policy and Directive on Program-for-Results Financing. It evaluated the fiduciary systems pertaining to the Romania Health Program-for-Results (PforR) Program. The integrated fiduciary assessment comprised assessment of the fiduciary arrangements, performance and risks relating to the Program's procurement; financial management; and governance and anticorruption activities. The objective of the assessment was to provide reference that could be used to monitor fiduciary system performance during the implementation of the Program, as well as to identify actions, as relevant, to enhance the performance of the systems.

2. **The Program's financial management and procurement systems and institutions provide reasonable assurance that the financing under the Program is used for intended purposes, with due regard to the principles of economy, efficiency, effectiveness, transparency and accountability**. The FSA aimed to review the capacity of the implementing agencies on their ability to (a) record, control, and manage all Program resources and produce timely, understandable, relevant and reliable information for the Borrower and the World Bank; (b) follow good procurement practices based on the applicable legislative framework and using procurement performance indicators with focus on outcomes to support the PDO and mitigate risks associated with the Program and the implementing agencies; and (c) ensure that implementation arrangements are adequate and risks related to fraud and corruption as well as complaints handling mechanism is reasonably mitigated by the existing framework. The FSA includes a summary of key risks and respective mitigation measures, together with institutional strengthening actions reflected in the Program Action Plan (PAP).

3. **The Program's Fiduciary risk rating is substantial**. The analysis was based on various assessments and activities carried out by the Bank as part of the ongoing Reimbursable Advisory Services (RAS) Agreement on the Support to the Implementation of the Public Procurement Strategy and the RAS for Assessing the Public Procurement System, which is under preparation; the Bank's assessment of the systemic causes of delays and inefficiencies in the preparation and implementation of Bank-financed investment projects; the Bank's knowledge of the health sector (including fiduciary performance of the ongoing Health Sector Reform project implemented by MoH) and country public financial management systems, reviews of external audit findings as well as the results of field visits implemented within the assessment frames. The main contributing factors to the substantial level of fiduciary risk are summarized in the following table. Key issues and proposed remedial actions are also outlined in the PAP (Annex 6).

Table 18: Fiduciary issues and mitigation measures

Issues	Proposed mitigation measures
Financial Management	
Risk of insufficient and/or delayed financing of Program activities by the MoPF (considering the increased envelope needed for certain results areas and the systemic budgetary constraints)	While the relevant sector legislation would be revised to accommodate the proposed changes, the operation envisages to earmark transfers to NHIH to cover for additional costs and for increasing predictability of funding. Proposed monitoring arrangements are reflected in the PAP

Issues	Proposed mitigation measures
	and the Program's implementation support and supervision plan.
Capacity challenges in the oversight of primary and community health care staffing and related expenses by MoH and NHIH	The Program finances activities to enhance the quality of monitoring. (i.e., upgrading and integrating health systems, including automatic data cross-checks and error and fraud detection tools, public disclosure of relevant data, establishment of a unit for governance of primary and community health care in the MoH, revision of clinical protocols and care pathways, etc.) The proposed revisions in the framework contract to expand the scope of primary care services and revise the payment mechanisms should be duly reflected in the NHIH`s internal procedures and communicated to fiduciary staff. As part of implementation support and supervision, the Bank will monitor the continuing efficacy of the implementing entities' capacity to oversee and monitor performance.
Potential weaknesses in internal controls and oversight of the de minimis aid scheme for family physicians	Technical assistance for establishing the scheme, including a system of internal controls, performance monitoring and oversight is reflected in the PAP.
Potential weaknesses in internal controls and oversight of the performance-based financing mechanism for family physicians at NHIH	Technical assistance for establishing the mechanism, including a system of internal controls, performance monitoring and oversight is reflected in the PAP. The Bank will monitor the continuing efficacy of the implementing entities' capacity as part of implementation support and supervision.
Potential delays in preparation and audit of the Program financial statements (considering the multiple stakeholders) by MoH.	Program coordination arrangements will include centralised preparation of Program financial statements as reflected in the PAP.
Complexity of arrangements for: (i) pricing and reimbursement of medicines; and (ii) clawback tax calculation and management by the NHIH and MoPF.	Technical assistance for establishing the mechanism, including a system of internal controls, performance monitoring and oversight is reflected in the PAP. The Bank will monitor the continuing efficacy of the implementing entities' capacity as part of implementation support and supervision. To improve transparency and accountability, the MoH and NHIH pricing process for medicines will be completed and published on their respective websites annually. Any notifications received on the pricing process will be duly tackled and outcome of investigations made public.
The Romanian Court of Accounts (RCoA) may not have enough capacity and experience in auditing the new activities proposed under the Program	RCoA is presently undertaking comprehensive institutional reform and capacity building effort, under a separately-funded initiative. It is intended that as that capacity is attained, the RCoA may be engaged to audit the Program financial statements. In the interim, this assessment

Issues	Proposed mitigation measures
	proposes engaging a private sector firm under terms of reference acceptable to the Bank. RCoA capacity will be monitored annually as reflected in the PAP.
Procurement	
ONAC is newly established and has not yet developed requisite capacity to perform the full range of procurement activities, including of specialized medical supplies and equipment.	Technical assistance to build capacity including establishing systems and resources for efficient and effective performance. Establishment of mechanisms for ongoing specialized supplies' procurement support by the MoH.
Lack of electronic platforms to collect and consolidate the procurement needs of beneficiaries delays the preparation of the tenders and unnecessarily increases the level of effort of personnel managing the procurement process.	Complete the initiated development of the proposed electronic platform.
Limited experience with IT procurement might delay the procurement process and affect its quality and outcome.	Enhance the IT expertise through technical assistance programs and/or employ specialists in the area.

Program Planning and Budgeting

4. **Overall, there is adequate planning and budgeting capacity at respective implementing entities and a clear annual budgeting cycle**. Romania scores well on the Open Budget Index Survey (its 2017 Open Budget Index score is 75 out of 100). The Government's budget planning cycle commences in May of each year with all public institutions submitting their funding proposals to the MoPF. Proposals are generally based upon historical spending patterns, rather than endorsing a forward-looking strategic approach. Following discussions with line ministries, MoPF ultimately decides respective institutions` budgets, which are then formalized in an annual law passed by Parliament. There is strict control exercised by entities over spending, with good short-term predictability over funding and close to 100 percent budget execution rates. There are clear bottom-up processes and reliable systems for reporting of expenditures on a monthly, quarterly and yearly basis.

5. **Government's budget classification system is comprehensive including administrative, economic and functional classifications and with the ability to produce consistent data according to international standards**. The budgets of NHIH and MoH are structured on programs tailored to the functional budget classification. Program-based budgeting is under development, including in healthcare, and not yet sufficiently reliable to be used in relation to the expenditure projected in the operation. Deployment of an Institutional Strategic Plan (ISP) by MoH was proposed by the Bank in 2018 under a technical assistance project. Over a four-year life-cycle, the ISP strategic objectives and budgetary programs were projected to add up to 187 billion RON, with annual allocations rising from 40,6 billion RON in 2018 to 52,5 billion RON by 2021.

6. **Consistent and timely availability of resources for Program activities is a risk**. Potential delayed and/or limited budgetary allocations for some of the more substantial Program expenses (i.e. de

minimis aid scheme, increased coverage of primary care, development of e-health system) may impair achievement of the intended results. To mitigate this risk, sustained adequacy of financing for the Program will be monitored by the Bank as part of implementation support and supervision.

Procurement Arrangements

7. Procurement under the Program will be carried out by: (i) MoH through its Procurement, Patrimony and IT Direction Unit (hereinafter "Procurement Unit of the MoH") which is also responsible for centralized procurement in the health sector; (ii) NHIH through its Public Procurement Unit within the Logistics, Patrimony and Public Procurement Directorate; and (iii) ONAC which is subordinated to the MoPF. All institutions use the country e-procurement system to conduct public procurement. The procurement functions of respective Program implementing agencies are currently established as follows:

- The Procurement Unit of the MoH is responsible for procurement of products/services required for the MoH's functioning and for centralized procurement for health units nationally.
- The Procurement Unit of the NHIH is responsible for procurement of products/services required for the NHIH functioning and for the county Health Insurance Houses at the local level.
- ONAC is responsible for centralized procurement of commonly used items for all government institutions excluding specialized procurement for the health sector, an activity to be introduced under the Program.

8. While the Procurement Units within the MoH and the NHIH are well-established and fully functional, ONAC was established in May 2018 with the mandate to conduct centralized procurement on behalf of all central government institutions of selected categories of goods/services except for health sector products for which a centralized procurement unit is already in place at the MoH. Staffing commenced with the appointment of the President of ONAC by the Prime Minister (Decision No 270/2018). ONAC initiated the first procurement in March 2019. ONAC has 36 staff, comprising 10 managerial/administrative staff and 26 procurement staff.

Procurement Planning

9. Adequate procurement planning and execution are actively enforced by ANAP through the legal provisions, transposing the requirements at EU level, and the Web-based Guide available at www.achizitiipublice.gov.ro. All contracting authorities are required to elaborate an annual procurement strategy (above defined thresholds) and annual procurement plan, as well as a contracting strategy for each procedure to be launched. The same procedures are adopted by all contracting authorities, including the Program implementing agencies.

10. Procurement Plans (PPs) of implementing agencies are normally published on their websites (*www.ms.ro, www.cnas.ro* and *www.onac.gov.ro*). Generally, the PPs provide the following information: description of the activity, CPV code, cost estimates, selection method, and planned timeline. Public procurement legislation requires that an extract of the annual PP is published every 6 months highlighting procurement activities above the EU thresholds. However, no such extracts are available on the website of the MoH and NHIH given that the planned procurement activities are below these thresholds. PPs are updated once the annual budget is approved in line with the approved amounts for investments. Subsequent updates of the PP are done whenever necessary throughout the year.

11. Summary analysis of the Procurement Plan of the MoH (2018) observes: (i) the default selection method is open tender resulting in either a public procurement contract or a framework agreement for activities within the threshold defined in the Public Procurement Law; (ii) procurement of vaccines and medical devices have the largest share of expenditures in the PP; (iii) small value procurement is generally limited to procurement for the institutional functioning and simplified procedures are applied for these; (iv) for larger value contracts for supply of medical products, the estimated duration of the tender ranges between six months to one year starting with tender launching and ending with contract award; (v) PP include an annex with the list of all planned very small value contracts awarded under direct contracting procedures.

12. Summary analysis of the Procurement Plan of the NHIH (2018) observes: (i) the default selection method is open tender resulting in framework agreements for activities within the threshold defined in the Public Procurement Law; (ii) application of simplified procedures for small value of contracts; (iii) most of the activities are limited to procurement for institutional functioning; and (iv) generally the estimated duration of tenders is adequate given that simplified procedures apply and these do not normally envisage lengthy processes.

Issues identified during the assessment are summarized as follows, with proposed remedial actions outlined in the PAP (Annex 6):

a) MoH has not established an electronic platform to facilitate the collation and consolidation of data on subordinated institutions' needs. Information is currently maintained on Excel spreadsheet files and shared by email;
b) At MoH, the packaging of contracts is generally done by "one-product one-lot" in order to (i) avoid block delays of entire tender packages when complaints are received, or the unit is otherwise unable to complete the evaluation and make the award for a particular lot, and (ii) avoid complaints from potential bidders relating to particular grouping of products perceived as restricting competition;
c) While NHIH conducts the centralized procurement of goods and services for the NHIH and its subordinated units, information is not currently available nor published on its website;
d) ONAC is not yet sufficiently established and currently has limited capacities to conduct procurement and has not yet established clear working arrangements with public health institutions as envisaged under the Program; and
e) At ONAC, an electronic platform to be used for the collation and consolidation of procurement requests, monitoring implementation of framework agreements and communication with contracting authorities is still under development;

Procurement Processing

13. **Preparation of bidding documents and technical specifications.** Standard Bidding Documents have been developed by ANAP and are available on their website: www.anap.gov.ro. In practice, each technical department within the institution assesses the needs and submits the data to the Procurement Department which collects and consolidates the data. Technical input (technical specifications, terms of references) is provided by the relevant technical departments. The persons involved in the preparation of TSs are doctors and other experts depending on the nature of products/services to be procured. The

preparation of technical specifications and the bidding documents is a lengthy process and often takes significant time to accumulate basic information, as it involves numerous consultations with the public institutions for which the joint procurement is conducted and with the business community. The technical experts that have prepared the technical specifications usually participate later on in the evaluation process.

14. Procurement Units are generally not involved in the preparation of the technical aspects of the bidding documents. They are responsible for the tendering phase, overall guidance through the procurement process and development of the annual PP.

Opening and evaluation of bids

15. Tenders are opened in public and minutes of public opening are prepared in a form and content as defined in the legislation. A copy of the minutes is made available to all authorized representatives of the tenderers. Evaluation is done in accordance with the evaluation and qualification criteria in the tender documents and is carried out by an evaluation committee.

16. The e-procurement system was first introduced in 2007 with an improved version launched in April 2018 (http://sicap-prod.e-licitatie.ro/pub). Information on tenders launched before April 2018 can still be retrieved from the old system for data analysis purposes. The current system publishes procurement plans, bidding opportunities and contract awards. The platform represents an electronic infrastructure which offers the public authorities of Romania the possibility to procure goods, works and services through electronic means and the economic operators the possibility to submit bids/proposals. It has a user-friendly interface, offers structured data which can be easily retrieved by any user and advance search function. The system brought more transparency in public procurement. In 2018, about 35,354 procurement procedures were conducted with a total value of 139,718,293 RON.

17. Issues identified during the assessment are summarized as follows, with proposed remedial actions outlined in the PAP (Annex 6):

a) At the MoH: (i) long tendering processes, generally nine months and longer, for a competitive procedure; (ii) frequent cancellation of tenders or blockages of the tendering process due to complaints; (iii) limited technical capacities to develop technical specifications and otherwise provide support during the evaluation/clarifications process; (iv) difficulty in identifying and maintaining the same technical experts (who are generally doctors) throughout the procurement cycle, starting from the development of the technical specification and ending with the contract award; and (v) even though the Procurement Unit is well staffed, procurement function is carried out by three staff, thus making it difficult to undertake additional work or even cope with the current workload.
b) Given its current mandate, ONAC does not have the required technical competencies to conduct procurement in the health sector;
c) At the NHIH, a major share of financing will be related to IT infrastructure (development of various electronic platforms, software, and possibly hardware) and the nature of these contracts could be challenging, as the NHIH has limited experience with such procurement.

Contract Management

18. **Legal provisions regarding contract execution are supplemented by relevant guidance and templates which are adapted to the specific needs of each contracting authority**. At MoH and NHIH, the template for the contract conditions, which include the obligations for both parties, are published together with the tender documents for each procurement launched. Payment deadlines are set in accordance with Law 72/2013, and clearly mentioned in the contract conditions. Similar deadlines are established for both procurement contracts and framework agreements. MoH generally opts for payment of invoices within 60 days after their receipt, following the acceptance of the goods or services, whereas NHIH prefers to pay within 30 days. Contract conditions also provide for specific delays in case the set deadlines are unjustifiably not met, generally 0.1 percent. The requesting technical departments are responsible for monitoring the implementation of contracts for operational needs of the institution. Contracts are generally implemented according to the agreed conditions and payments are made within the established deadlines. The requesting technical departments are responsible for monitoring the implementation of contracts for operational needs of the institution. For centralized procurement, the Procurement Unit of the MoH concludes framework agreements in the name of the final beneficiaries who are then responsible for concluding and managing the subsequent contracts. After the framework agreement is signed with the successful tenderers, the agreement, tender documents, technical and financial offers are sent to the beneficiaries to conclude and sign the subsequent contracts in accordance with their individual procurement plan and allocated budget. Management of subsequent contracts is within the responsibility of respective public health institutions.

19. An issue identified during the assessment at MoH and NHIH is limited data available at the central level on contract implementation (implementation progress, quantities supplied, payments made). The proposed remedial action is outlined in the PAP (Annex 6).

Procurable Items

20. **Procurement Profile of the Program:** The Program is defined to cover community health care, primary care and policy reforms related to cost control. Therefore, most of the Program expenditures are related to services provided by family medicine physicians contracted by NHIH and recurrent expenditures including wages, goods and services and capital investments incurred by MoH, NHIH and ONAC in program-related areas. In addition to the regular operating costs, implementing agencies will require TA and certain upfront investments needed to implement the agreed milestones and achieve the DLIs. Some activities will be implemented with the existing resources within the agencies, including external support.

21. The size of contracts is envisaged to be small to medium and as such, the Program will not finance contracts which would require the mandatory review by the Bank's OPRC. The current procurement portfolio of IAs routinely comprises small-value goods and services. An exception to these is the large-value contracts for vaccines, medicines and/or medical devices procured centrally by the MoH. However, these contracts are financed from the beneficiary institutions budgets (for example: public hospitals) through the subsequent agreements signed between the institution and the supplier. The MoH is only managing the procurement process up to the contract award and up to the signing of the framework agreement. At the same time, over the period of 2018 – 2019, the largest procurement managed by the MoH was estimated at RON 136 million (USD 32 million equivalent) which is considerably below the OPRC

threshold for Substantial risk. While the largest procurement managed by the NHIH for the same period was estimated at RON 7.5 million (USD 2 million equivalent). No tenders have been launched by ONAC as of end of March 2019. However, both in the case of the MoH and ONAC, once it becomes functional and undertakes centralized procurement of health products, there could potentially be procurement activities the value of which may fall within the OPRC threshold. However, such contracts are beyond the boundaries of the proposed PforR operation.

Transparency and Complaints Handling

22. A new e-procurement system was launched in April 2018 (http://sicap-prod.e-licitatie.ro/pub), developed by the Agency for Digital Agenda of Romania in line with the national legislation and EU Directives. The system publishes the procurement plans, bidding opportunities and contract awards. The platform represents an electronic infrastructure which offers the public authorities of Romania the possibility to procure goods, works and services through electronic means and the economic operators the possibility to submit bids/proposals. It has a user-friendly interface, offers structured data which can be easily retrieved by any user and advance search function. The system brought more transparency in this area and generated savings of public funds throughout the procurement cycle.

23. The Law 101/2016 on remedies transposes the relevant EU Directive and provides for an independent complaint review mechanism which has been in place since 2006. The National Council for Solving Complaints (CNSC) is an independent body established with the mandate to guarantee effective remedies for complaints in public procurement. CNSC's decisions can be challenged in the Appeal Courts. The establishment of CNSC does not preclude the right of any of the parties to address their cause directly to the courts.

24. In 2017, 4782 complaints [data for 2018 is not available] were submitted and analyzed by CNSC (about 18 percent of the total number of procurement procedures), registering an increase compared with 2016 due to the increase in the number of procurement procedures initiated in the e-procurement system. The complaints generally contest the result of the evaluation process (about 83 percent), particularly with regards to the rejection of bids. A total of 3494 decisions were issued by CNSC, with 66percent of the complaints being rejected. 19 percent of the decisions were contested at the competent Appeal Court and in the case of about 97 percent of the complaints, the Court confirmed the ruling issued by CNSC. The average duration for solving complaints is 29 days. However, the general feedback is that duration of solving complaints in the health sector is considerably longer. This has a direct impact on the duration of the tender and its outcome (cancelled lots/tenders).

25. **Debarment procedures:** Romania's debarment procedures are embedded in legislation that obligates contracting authorities to exclude from the procurement process tenderers that have been convicted for participation in a criminal organization, corruption and fraud, terrorism, money laundering or terrorist financing, child labor or other forms of trafficking in human being. At the same time, contracting authorities are required to exclude tenderers that did not fulfil their obligations relating to the payment of taxes or social security contributions, taxes to the state budget, is in conflict of interest or did not fulfil their contractual obligations, for collusion or false declarations etc. However, no lists of debarred companies are maintained.

Program Accounting and Financial Reporting

26. **The Program uses a comprehensive accounting and reporting framework and reliable tools**. Expenses incurred for achieving the Program results will be accounted in line with the national legislation in force, which includes detailed methodologies and instructions issued by MoPF. There is a unified chart of account for the central and local government units. Since 2006, 11 IPSAS (International Public Sector Accounting Standards) accrual accounting standards have been adopted. As an important step towards faster and better collection of data, a national commitment and reporting system (Forexebug) was rolled-out in the public administration in 2017. Key changes triggered by the implementation of this new reporting system are (i) the development of Treasury cash accounts of revenues and expenses at COFOG 2 level- respectively, chapter, sub-chapter and paragraph for revenues and expenses, and as per economic classification at the level of title, article and line item for expenses; (ii) control of payments vs. commitments in the Treasury; (iii) transmittal to MoPF by each public institution of a standard analytical trial balance; and (iv) elimination of consolidation of financial statements at the level of secondary, respectively primary credit holders. Starting with 2019, financial statements will be submitted only electronically, permitting efficient preparation of Program financial statements.

27. **All Program entities prepare several quarterly and annual financial statements of satisfactory quality**. There include, inter alia: a balance sheet that shows assets and liabilities, the patrimonial results account, cash flow statement, the budget execution accounts showing all transactions made in the current period, annexes to the financial statements and explanatory notes. The three entities involved in Program implementation will continue to reflect the expenses incurred for the Program as per the framework in force, in the existing systems. These costs should be easily identifiable at any moment and proper analytical accounting records should be maintained in this regard at the level of each entity. Program expenses will be quantified during the yearly state audit and reflected in a note to each entity`s financial statements.

28. **For the purposes of annual financial reporting and auditing, the Program expenditures will be collated at the level of the MoH by the Program coordinator and a set of Program financial statements subject to independent audit.** A review of financial reporting and auditing compliance by MoH and NHIH confirms that adequate capacity exists. The Program financial audit will include in its scope the expenditures incurred for the activities envisaged under the Program (wages of relevant staff, purchase of software, hardware, consulting services, training, etc.) as funded from the budgets of the MoH, MoPF (including ONAC), and NHIH. These should be presented in a note in the separate audit reports produced for each entity. The scope of the financial audit will include the review of the relevant work and findings of the entities internal audit function.

The de minimis aid Scheme and Performance-Based Financing

29. A de minimis aid scheme and a performance-based financing mechanism are envisaged under the Program to incentivize family medicine. This will support the establishment of new family medicine practices in 329 local government units which are classified as underserved. The type of financing (grant or subsidized interest loan) and implementation arrangements are still to be decided. A Government Decision will be issued in this respect in the first year of the Program, when the first call is expected to be launched.

30. **Existing arrangements for similar de minimis aid schemes managed by the MoPF are sufficiently robust and reliable and would be considered for the design of the proposed instrument**. There are several types of de minimis aid schemes implemented in Romania (including one in the health sector for financing procurement of medical devices by the public health hospitals in the subordination of the Timis local authority) and information on the ongoing ones and applicable regulatory framework is published on the Competition Council`s dedicated website. There is a comprehensive EU and national legislation that regulates de minimis aid schemes, and monitoring is exercised at different levels such as MoPF and Competition Council.

31. **The minimum quality standards for the eligible activities and fiduciary aspects will be developed and provided to the Bank before the launch of the scheme.** The Bank will review proposed arrangements and signal any weaknesses in the proposed design and work with the counterparts to ensure adequate implementation arrangements, including fiduciary aspects. Technical support for required capacity for the design and implementation of fiduciary arrangements, including a system of internal controls and oversight is proposed to be supported under the Program and will be monitored under the PAP.

Program Treasury Management and Funds Flow

32. The Treasury Single Account (TSA) framework is clearly designed and well-functioning. Program implementing entities operate with sub-accounts of the main TSA. Program expenses will be budgeted and channeled through the existing budgetary system, according to the national legislation in force. Budget resources are made available to the agencies which are responsible to manage expenditures in accordance with the monthly, quarterly and yearly limits and ceilings imposed by the MoPF. A tight control is exercised over credit releases through the combination of quarterly cash limits and monthly credit openings. The Treasury Information System can produce budget execution reports on a cash basis in almost real time. The recently-introduced Forexebug also contributed to more effective scrutiny over commitments and payments, as mentioned above.

33. NHIH administers NHIF (which ensures about 75 percent of the sector financing) and is responsible for planning and purchasing, through its county branches, health services from both public and private hospitals, laboratories, pharmacies, ambulatory care specialists, GPs etc. NHIH's treasury management and funds flow mechanisms are assessed as reliable and sufficiently robust based on a review of their internal control and oversight arrangements, together with a review of findings of the latest independent audit reports.

Internal Controls and Internal Audit

34. Romania, as an EU member is part of Public Internal Financial Control (PIFC) agenda and there are plans to further strengthen this area. The strategy for consolidation of public administration 2014-2020 recognizes among other objectives the need to increase the use of internal controls standards and strengthen the internal audit capacity at both central and local level.

35. **Internal controls are well established in the entities in the scope of the Program**. There are clear written procedures for authorizations, segregation of duties, reconciliations etc. covering expenditure and

financial management, as well as procurement responsibilities. There are strict ex-ante and detective controls imposed by the legislation and internal regulations, particularly over the budget execution, but often rather bureaucratic and not necessarily endorsing a risk-based value-for-money approach.

36. Internal audit function complemented by other oversight departments such as control, integrity and antifraud at the level of MoH and NHIH is well-regulated, but its effectiveness is impaired by capacity constraints. It has a well-formulated legislative framework established through Law 672/2002 which defines its scope as covering the broader areas of strategic decisions, regulation development, coordination, control, evaluation, and reporting. Internal audit looks into areas such as budgeting, accounting and reporting, public procurement, HR, IT, legal aspects, EU funds and other specific functions and should cover them every three years. Compliance and quality are monitored by the MoPF Central Harmonization Unit of Public Internal Audit (CHUPIA), with entities being subject to its review (or of the superior budgetary unit) at least once every five years. The RCoA also receives on a yearly basis a report on the internal audit activities carried out from public entities and considers the findings in its work.

37. The internal audit function is well-organized in the implementing agencies (except in ONAC, as mentioned below) but there are challenges in terms of staffing and skills development, scope of audit work programs, and proper follow-up on findings. In practice, although it complies with legislation, it is still dominated to a large extent by compliance-focused audit engagement missions and is not yet fully endorsing a longer-term, risk-based planning method of internal auditing. MoH`s internal audit function is perceived as good practice by the RCoA in terms of coverage of different types of activities. Each year the NHIH`s internal audit evaluates the activities of various central departments (such as medical services; pharmaceuticals, clawback and cost-volume contracts; control and antifraud etc.) and of a representative sample of subordinated county insurance houses. ONAC is subject to MoPF`s internal audit which has adequate capacity and has included it in its strategic multi-year work plan.

38. In light with the expanded scope of activities to be introduced by the Program, this assessment proposes a need to evaluate and continually monitor the technical capacity of the MoH and the NHIH to effectively oversee the continuing efficacy of internal controls and oversight over Program resources. Capacity needs will be supported by the Program and monitored by the Bank as part of implementation support and supervision.

Program Audit

39. The Bank is presently engaging with the Romanian Court of Accounts (RCoA) on an institutional reform and capacity building effort, under a separately-funded initiative. This support is intended at strengthening the technical capacity of the Court to fully adopt a risk-based approach and methodology consistent with the INTOSAI standards and practices. It is intended that as that capacity is attained, the Court will be engaged to audit the Program financial statements. In the interim, this assessment proposes engaging a private sector firm under terms of reference acceptable to the Bank. Audited program financial statements will be required to be submitted to the Bank within 12 months following the end of the financial year.

40. RCoA has audited timely and satisfactorily the public entities involved in the program, with the exception of the recently-created ONAC. It has also conducted several performance audits in the health

sector (such as on various national health programs). It has issued a qualified-except for opinion, with an emphasis of matter paragraph on the 2017 financial statements of both MoH and NHIH. In the case of MoH, the audit revealed issues such as double-accounted expenses, medical equipment purchased but put in operation after payment, inaccurate recording of consumption of vaccines, etc. The audit of the NHIH noted irregularities pertaining to the reimbursement of medicines and health services under the contracts concluded between the country insurance houses and providers, and partial implementation of the internal control managerial standards.

Governance and Anticorruption

41. **The Bank's Anticorruption Guidelines will be applicable to the Program**. The Program shall be subject to the Bank's Guidelines on Preventing and Combating Fraud and Corruption in Program-for-Results Financing, dated February 1, 2012 and revised July 10, 2015, which require that Borrowers ensure that any person or entity debarred or suspended by the Bank is not awarded a contract under or otherwise allowed to participate in the Program during the period of such debarment or suspension. Participation, however, does not include the performance under contracts entered into or other engagements which began prior to the date of the Loan Agreement. The list of such debarred firms and individuals can be found on the following website: *www.worldbank.org/debarr*. The compliance with this requirement will be checked through the Program's audit. A memorandum of understanding (MoU) entered between the Romanian Prosecutor's Office attached to the High Court of Cassation and Justice, the National Anticorruption Directorate (DNA) and the Bank's Integrity Vice Presidency (INT), signed on December 8, 2014 is in force. In this MoU, the parties commit to cooperate with each other on matters of mutual interest within the scope of their mandates. The terms of this MoU will be applicable to the Program.

42. Corruption is still acknowledged as an issue in the public sector and is generally more prominent in the health sector. According to the 2018 Transparency International's Corruption Perception Index, Romania was ranked 61st in the list of 180 countries. Despite some improvements, Romania has marked a decrease in government effectiveness, regulatory quality, and control of corruption in the past few years (WGI data: 2013-2017). After the adoption of the National Anticorruption Strategy for 2016-2020, several actions have been endorsed specifically for the health sector (such as increasing efficiency and transparency of use of funding, strengthening accountability mechanisms, etc.) and measures have been taken to implement them, with uneven success. Specific arrangements were discussed and agreed during Program appraisal.

43. **Romania's anti-corruption agency has requisite capacity**. The DNA is the national agency tasked with preventing, investigating and prosecuting corruption-related offenses. The DNA is headed by a Chief-Prosecutor and 2 deputies, nominated by the Minister of Justice and appointed by the President of Romania. The Chief-Prosecutor of the Directorate is subordinated to the General-Prosecutor of the Prosecutor's Office attached to the High Court of Cassation and Justice. The DNA has in recent years established an impressive track record in terms of solving high and medium level corruption cases.

44. The 2014 Anti-Corruption Report of the European Commission highlighted the Romanian DNA as one of 5 examples of good practices in anti-corruption agencies across the EU observing a notable track record of non-partisan investigations and prosecutions into allegations of corruption at the highest levels of politics, the judiciary and other sectors, including Health. In the past seven years, DNA has indicted over

4,700 defendants. 90.25 percent of its indictments were confirmed through final court decisions. Nearly 1,500 defendants were convicted through final court decisions, almost half of them holding very high-level positions. While recognizing important progress achieved in certain areas, the latest EC MCV report issued in November 2018 signals the substantial pressure exercised over the independence of judiciary, including on DNA, which may reverse the anticorruption reform.

Fiduciary Risk

45. Fiduciary risk assessment and mitigation measures are proposed in the PAP (Annex 6). Risk is assessed as Substantial with the main issues and proposed remedial actions summarized in the Risk Assessment (Section D of the PAD) and in the Table 18 above.

Technical capacity building support

46. The Program proposes to introduce several new funding and procurement management initiatives for which TA for capacity building and improved performance is envisaged. Areas assessed as requiring this assistance are summarized under Section III.D (Capacity Building) of the PAD.

Implementation Support

47. During the Program implementation, the Bank's fiduciary team will: (i) review implementation progress and work with the task teams to examine the achievement of Program results and/or legal covenants/PAP that are of a fiduciary nature; (ii) support the Borrower to resolve implementation issues and provide institutional support; (iii) monitor the performance of fiduciary systems and audit reports, including the implementation of the PAP; and (iv) monitor changes in fiduciary risks to the Program and, as relevant, compliance with the fiduciary provisions of legal covenants capacity building. More specifically the Bank fiduciary team will:

- Monitor changes in fiduciary risks of the Program and compliance with the fiduciary provisions of the legal covenant relating to timely availability to the MoH and NHIH of Program funds by the MoPF.
- Monitor the continuing efficacy of the implementing entities' internal controls and oversight capacity for the expanded scope of primary care, revised pricing and reimbursement mechanisms and claw-back tax calculation.
- Monitor the Program financial statements preparation process.
- Review the Program annual financial and procurement audit reports and management letters and monitor the implementation of audit recommendations.
- Monitor and provide institutional procurement and financial management capacity building support as needed.

ANNEX 5. SUMMARY ENVIRONMENTAL AND SOCIAL SYSTEMS ASSESSMENT

COUNTRY : Romania
Romania Health Program for Results

1. The Environmental and Social Systems Assessment (ESSA) for this Program was undertaken to: 1) assess Romania's systems for managing environmental and social effects that are associated with the proposed set of investments related to this Program; and 2) the GoR's institutional capacity to plan, monitor and report on environmental and social management measures as part of this Program's implementation. Its findings are intended to ensure that this Program is implemented in a manner that maximizes potential environmental and social benefits and avoids, minimizes or mitigates adverse environmental and social impacts and risks. This assessment also informed the preparation of the Program Action Plan (PAP) that the GoR is expected to use to bridge any significant gaps in existing environmental and social management systems in line with the six core sustainability principles of the PforR.

2. The methodology for the preparation of this ESSA Report included 1) a desk review of existing information and data sources; and 2) consultations with various stakeholders. The desk review included a thorough analysis of national policies, legal requirements and institutional arrangements in the fields of health care, social assistance, social inclusion of vulnerable groups and environment. Extensive consultations were carried out with the main Program implementing agencies, the MoH, MoPF, and NHIH. Other institutions that were consulted during the process included: the National Institute for Public Health, The National School for Public Health at Babes Bolyai University, the National School for Public Health, Management and Training in Healthcare, Ministry of Social Justice, College of Physicians in Romania, National Society for Family Physicians, County Public Health Directorates, the National Association for the Protection of Patients, the Coalition of Associations working with Chronic Disease Patients (19 NGOs), the Renasterea Foundation for Women's Health, the E-Romja Association for Roma women rights and other Roma NGOs. Municipalities, family physician practices, community health nurses and health mediators were also consulted during site visits in the following rural and urban communities in disadvantaged and underserved areas in the south-east of Romania: Tandarei, Barbulesti, Ceamurila, Jurilovca, Kogalniceanu, Crisan, Mila 23, Caraorman, Sfantu Gheorghe. The ESSA team also convened a consultation with the Roma Sounding Board on March 28, 2019 (9 Roma organizations were present at the meeting: Roma Educational Fund, Danrom, CRIS, Roma Centre for Health Policies - Sastipen, Resource Centre for Roma Communities, Romani CRISS, NevoParudimos, Botosani Roma Marginalized Association) in relation to the Program's outcomes.

3. Among the six core principles that guide the ESSA analysis as per Operational Policy/Bank Procedure (OP/BP) 9.00 on Program for Results Financing, three are considered relevant for the Romania Health PforR:

   Core Principle 1: Environmental and Social Management procedures and processes aim to (i) promote environmental and social sustainability in Program design; (ii) avoid, minimize, or mitigate adverse impacts; and (iii) promote informed decision-making related to the Program's environmental and social impacts.

Core Principle 3: Public and Worker Safety. Environmental and social procedures and processes aim to protect public and worker safety against the potential risks associated with exposure to toxic chemicals, hazardous wastes, and other dangerous materials under the Program.

Core Principle 5: Due consideration to be given to the needs or concerns of vulnerable groups. This gives attention to vulnerable and disadvantaged groups, including, as relevant, the poor, the disabled, women and children, the elderly, or marginalized ethnic groups. If necessary, special measures are taken to promote equitable access to the Program benefits.

Core Principle 4 on Land Acquisition is not applicable to this Program because there will be no land acquisition and therefore no impact on private assets and livelihoods. The Program will only support minor refurbishment of existing facilities, including small repairs of existing facilities such as painting, flooring, sealing windows and fixing doors.

Environmental System

4. Implementation and enforcement of environmental regulations were assessed through the lenses of the institutional and inter-links point of view. The ESSA included roles and responsibilities of the ministries, governmental organizations, local authorities, agencies, institutions and institutes, other bodies and family medicine practices.

5. There is a common and convergent approach between the ministries and other central governmental authorities on health and environmental sectors based on specific strategies and policies developed by each of these authorities. The Ministry of Environment is leading the preparation of environmental regulations, including the allocation of specific responsibilities to other authorities with roles and attributions related to environmental sectors. The actual Governmental structure includes also the Ministry of Waters and Forests in charge of water resource management.

6. Another important authority is represented by the General Inspectorate for Emergency Situations within the Ministry of Internal Affairs, which coordinates at the national level all emergency prevention and management activities, ensures and coordinates human, material, financial and other resources, including first aid and emergency medical assistance within the emergency units and emergency departments. These are the main relevant entities with major authority on environment and public health reactive and preventive actions. In addition, there are other operational institutional structures - national administrations, institutes with scientific, procedural, monitoring and reporting roles and activities. Among these the most relevant are the National Administration for Meteorology and the National Institute for Public Health.

7. The roles and responsibilities for environmental protection and climate change adaptation in relation to health-related activities are set in the different strategic documents, including: National Strategy for Health 2014-2020, National Strategy on Climate Change and Economic Growth Based on Low Carbon Emissions 2016-2020, National Waste Management Plan, among others.

8. Overall, the Program is likely to have positive environmental and public health impacts to the health

sector. Benefits include improved overall access to quality and efficient PHC services, including in underserved areas. The environmental system assessment conducted during preparation identified the general adequacy of the environmental institutional and legal framework for medical waste management at the PHC level, as well as the need to increase the role of PHC in preparing and responding to climate change related threats to human health.

9. ESSA identified two main environmental areas relevant to the scope of the proposed PforR: 1) medical waste management; and 2) public health and medical primary care within the context of the adaptation to climate change effects.

Medical waste management

10. The main environmental sensitivity in the health system is the management of medical wastes. There is a scientific debate on the priority of co-incineration against other alternative technologies for medical waste. About 20,000 tons of medical wastes are generated yearly in Romania by the state and private health care/treatment units, representing about 3 percent of all hazardous waste generated nationwide. Out of these, the PHC units performing medical activities generate on average less than 300 kg of hazardous waste per year. Selective collection, specialized transport and treatment and neutralization complex systems are in place and functional. The Program risks on dealing with medical waste management are reasonably covered by the existing systems but will require continuous effort to address the challenges emerging from the enforcement of the specific regulatory framework to all PHC services, as stipulated in the technical norms. Community nurses perform limited medical procedures and thus generate limited amounts of medical waste. There is no service specifically dedicated to community health care, and the medical waste from nurses' activities enter into the selective collection system of family physician. Considering the potential increase in waste management, this practice could continue based on the existing contracts of family practices with authorized sanitary operators.

11. The main environmental sensitivity in the health sector, and in particular the fields of primary and community health care is related to the management of medical waste. Risks associated with this section include:

- Actual limited level of knowledge on prevention and/or mitigation in relation to the generation of medical waste at the level of the primary and community health care;
- The current implementation of the regulations in the field of medical wastes management at the PHC level in the rural areas is not fully effective; and
- The potential risks related to inappropriate disposal of hazardous and non-hazardous waste in non-authorized places, especially in rural, remote areas.

Adaptation of health system to climate change

12. Romania has well established public policies to promote human health but is still not sufficiently prepared to deal with the range of problems associated to the consequences of climate change. Climate change and the increased incidents of extreme weather events (heat waves, droughts, floods,

storms etc.) require an increased in the level of knowledge of the population with regards to the need to adapt human health in general, and vulnerable groups in particular. Despite a significant risk of exposure to such natural events for the vulnerable groups mainly, but also to the affected communities at large, the levels of awareness, basic education and protective measures provided by the PHC services are still insufficient and need more focused actions.

13. Key issues identified by the Environmental System Assessment, including risk mitigation and capacity building could be addressed through the implementation of environmental actions as defined in the PAP. In line with this provision, preventive actions have been proposed to strengthen the capacity to react in the case such weather events – development at national level of detection, surveillance and response systems for all events and risks related to the public health, including strategic stocks of critical supplies, trained personnel and a mechanism of institutional coordination and partnerships between the public and private sectors.

14. Extreme weather events, such as floods, storms, heat waves and drought can lead to severe consequences for the population, and in particular for the most vulnerable groups that are far more exposed due to poor housing and limited engagement with alert systems. In addition, threats arising from extreme events can be aggravated by the healthcare system, which may have weaknesses not only in terms of early warning and alertness, but also in its ability to respond. The consequences of disasters require a rapid and well-coordinated response to protect the health of affected communities.

15. The adaptation measures will depend on local or regional characteristics such as the availability of resources, the profiles of vulnerability, the patterns of exposure to hazards, the capacity of decision makers to use the information available and the public perception of the problem. Development of early warning systems for epidemics, especially after extreme hydro-meteorological events, such as storms and floods are critical as outbreaks of water-associated, water-borne and mosquito born infections are commonly reported after these events.

16. To ensure that communities and healthcare facilities are prepared for impacts of climate change, including natural disasters and flooding, PHC providers, family doctors and nurses can work with local and state health departments and healthcare facilities to ensure that disaster preparedness plan and training are in place in the event of disruption in community infrastructure or health services. As an example, nurses can further facilitate the development of climate adaptation plans and action plans for extreme temperature events to ensure that people have access to necessary care. Nurses should effectively communicate with patients, colleagues, policy makers, and the public in conveying messages on how climate change affects health. Key issues identified by the Environmental System Assessment, including risk mitigation/capacity building, would be addressed through the implementation of environmental and social actions as defined in the PAP.

Recommendations to mitigate Environmental Risks

Necessary Measures:

- Develop inter-agencies cooperation at central and local levels to address the adaptation to climate change and to adjacent extreme weather events;
- Develop reactive and preventive procedures and guidelines for PHC system with regard to

common and shared responsibilities for environment and public health, in relation with the two identified priorities: adaptation to climate change effects and medical waste management;

Useful Measures:

- Increase the level of knowledge on prevention and/or mitigation in relation to the generation of medical waste at the level of the primary and community care;
- Develop management of medical wastes at the PHC level in the rural areas which are largely targeted by the Program, with the aim to mitigate the potential risks related to inappropriate disposal of hazardous and non-hazardous waste;
- Update contracts with authorized sanitary operators for collection and appropriate disposal of each category of medical wastes, especially at the level of the PHC in the rural areas which are largely considered by the Program.

Social System

17. Since there is no overarching social framework or system that is applicable to Romania's healthcare sector, the description of the 'social system' for this Program is based on an analysis of legislative and institutional arrangements for the health sector (including PHC) that is overlaid by the GoR's cross sectoral priority to improve the social inclusion of vulnerable groups.

18. The ESSA analysis concludes that Romania has a robust legal and institutional framework vis-à-vis Patient's Rights. The rights outlined in the European Charter of Patients' Rights are included in Romanian legislation, including those for: preventive measures, free choice, respect for patients' time, observance of quality standards, safety, innovation, avoidance of unnecessary suffering and pain, personalized treatment and complaints and compensation. Moreover, the National Health Strategy 2014-2020 provides a national vision on health care services provision, which focuses on gradually ensuring a wider coverage of the population's health needs through health services that are provided at the foundation of the system (community health care services, health care services provided by the family doctor and specialized ambulatory care). The ESSA review also confirms that there are well established transparency and feedback mechanisms as part of Romania's healthcare system. Information on statutory benefits, medical errors and patients' access to medical records is stipulated by law. Patients have the option to submit feedback through the complaint management systems of the College of Physicians, the MoH and the DPHAs and/or patient surveys that are implemented by DHIHs based on MoH order 146/2015.

19. The ESSA's review of laws and frameworks for social inclusion also confirm the GoR's substantive efforts towards combating discrimination for vulnerable groups in all walks of life, including provision of healthcare services. This includes the stipulations of Government Ordinance (GO) 137/2000 regarding the prevention and the punishment of all forms of discrimination, and the establishment of the National Council for Combating Discrimination. It also confirms that several actions supported by the broader scope of this Program are aligned with priorities outlined by the Strategy of the Government of Romania for the Inclusion of Romanian Citizens belonging to Roma Minority for 2015-2020. These include: (i) informing residents of Romania belonging to the Roma minority on their right to the minimal health service package designed for persons not covered by the health insurance

system; (ii) increasing the share of the Roma people receiving primary healthcare services; and (iii) monitoring access of the Roma people uninsured with the minimal healthcare service package.

20. The ESSA analysis confirms that the Roma Health Mediator (RHM) Program has demonstrated potential for scale-up. The RHM program is characterized by strong leadership from Romani Criss - a Roma NGO, with ongoing cooperation with the GoR that has enabled the institutionalization of the Roma Health Mediator program. Except for the past few years, the program has grown steadily with increasing numbers of trained and employed RHMs.

21. It also finds that there is precedent for administering periodic surveys in the health sector bodes well for the development of a standardized monitoring approach for integrated primary care. For example, findings of the 2016 study on Quality and Costs of Primary Care in Europe study for Romania confirmed family physicians' willingness to widen the scope of their activities and their readiness to improve the way in which they are contributing to the goals of the Romanian health care system. In addition, surveys applied at the level of the population are a mandatory feature at the level of each District Health Insurance House (DHIH). Each year, the DHIHs apply a survey to a sample of the population to assess the level of satisfaction with medical service providers and assess the level of knowledge of beneficiaries, in relation to their rights and services made available to them. On the other hand, findings of the ESSA analysis also attest to weaknesses with regard to social aspects of this Program, including:

- **Limited efforts to make information available to vulnerable and underserved groups in accessible formats (e.g. in the form of brochures or posters)**. In the absence of such efforts, there may be challenges for persons who are unfamiliar with technical or legal terms to understand their rights and entitlements with regard to accessing PHC services, persons who may not have access to the internet in remote areas, or for blind persons who may wish to seek information on primary healthcare in braille. Moreover, the level of awareness of procedural aspects and value chains of various GRMs in the health sector appears to be limited, particularly among more remote communities and vulnerable groups.
- **Social disincentives for underserved groups to register with family care physicians**. These include alleged perceptions of discriminatory conduct (such as longer wait times) and limited appreciation by medical service providers of some of the cultural concepts, beliefs and attitudes that influence incentives to seek primary healthcare services.
- **Lack of access to ID cards for some members of underserved and vulnerable communities**. In the absence of ID cards, even hitherto uninsured persons who have an interest in seeking PHC services would be unable to register with their family physicians and to gain access to PHC.
- **In specific rural and remote areas where there is already a shortage of family physicians, their increased workload may serve as a deterrent for accommodating field visits**. This could have a debilitating impact on elderly/disabled patients with limited mobility and the ability to access the PHC facility.

Evaluation of social risks

22. The ESSA findings also confirm some social risks for this Program due to potential bottlenecks that could hinder the access of underserved populations to PHC. Firstly, many vulnerable groups, including but not limited to Roma, may not be able to use family physicians since they do not have ID cards

and/or birth certificates and thus are not able to register themselves for family care. Secondly, they have a disincentive to seek PHC services that could stem from: i) concepts, beliefs and attitudes of the Roma towards health, health behavior and disease (e.g. some values, like notions of purity and impurity, are widespread among the Roma, and may explain the avoidance of contact with particular materials or individuals); and ii) discriminatory practices on the part of doctors and other medical practitioners towards Roma, including having to wait much longer than non-Roma to receive services and getting less information about treatment, are reported as a major deterrent from seeking medical help, particularly for minor health issues. Thirdly, access to family physicians may become even more constrained for elderly/disabled people, particularly in remote and rural areas, as the workload of family physicians significantly increases because of the Program. Fourthly, many of the currently under-served population, especially those who are illiterate or based in remote rural areas, may remain unaware of the improved coverage and scope of basic benefits now available to them and may not seek PHC services as a result. They may also remain unaware of existing feedback/grievance mechanisms that they can use to report whether their access to PHC services has improved or not.

23. The Program is designed to mitigate several of these risks. The Program's expansion of community health care and strengthening its collaboration with PHC will be helpful to improve access to community health care (CHC) and PHC services for underserved groups. The MoH will hire community health nurses and Roma health mediators and deploy them to communities to provide community-based interventions. Protocols and guidelines will be developed to guide their daily work and collaboration with family physicians, and trainings will be provided to ensure their compliance with the protocols. These measures will make CHC more accessible and/or attractive to vulnerable groups, including Roma by: i) increasing the ratio of community health nurses and Roma health mediators to community members so that they can provide community health care more readily and regularly and ii) improving the quality and effectiveness of the work performed by community healthcare workers since they would now be based on formalized standards and protocols. As part of its effort to improve collaboration between CHC and PHC and to facilitate access to PHC, targeted communities will receive health education and support from community nurses and Roma health mediators in navigating the health system, particularly PHC.

24. To help allay some of the disincentives to seek PHC services due to alleged perceptions of disrespect, cultural insensitivity etc., primary care providers and community nurses will be trained in working effectively with different cultures and ethnic minorities, as needed. Strategic planning to close supply-side barriers to PHC access that are informed by community needs assessments, combined with the mobilization of additional community health personnel will also help to abate any potential instances of constrained access to PHC for elderly/disabled people in remote or hard to reach locations due to the increased workload of family physicians. Finally, to increase awareness regarding expanded insurance coverage and PHC services that are available to them the Program will include public outreach efforts and monitor the level of awareness of the population in this regard.

25. Recommended actions: The following list reflects the proposed actions aimed at mitigating the social risks that have been identified and maximizing the Program's benefits: 1) public outreach efforts are tailored to meet the information and communication needs of target audiences to increase awareness among the population regarding the benefits to which they are entitled, and about the feedback mechanisms that they can use; 2) information regarding PHC sector is made available in accessible

formats to increase awareness of the insurance coverage and scope of services included in the basic healthcare package on an ongoing basis beyond the initial thrust of public outreach efforts; 3) instituting periodic monitoring of the uptake of PHC services and the perceptions of beneficiaries to identify changes in the number of beneficiaries registered with their primary healthcare providers, as well as any other challenges with regard to their accessibility to PHC services; and 4) monitor the number of potential patients that social workers have helped to acquire IDs for their registration with family physicians is monitored so that it can serve as an incentive for community health workers to help persons who are contending with this issue.

Consultative process in the formulation of the ESSA

26. Extensive consultations were undertaken with the main Program implementing agencies, the Ministry of Health, the Ministry of Finance and the National Health Insurance House. Other institutions that were consulted during the process included: the National Institute for Public Health, The National School for Public Health at Babes Bolyai University, the National School for Public Health, Management and Training in Healthcare, Ministry of Social Justice, College of Physicians in Romania, National Society for Family Physicians, County Public Health Directorates, the National Association for the Protection of Patients, the Coalition of Associations working with Chronic Disease Patients (19 NGOs), the Renasterea Foundation for Women's Health, the E-Romja Association for Roma women rights and other Roma NGOs. Municipalities, family physician practices, community health nurses and health mediators were also consulted during site visits in the following rural and urban communities in disadvantaged and underserved areas in the south-east of Romania: Tandarei, Barbulesti, Ceamurila, Jurilovca, Kogalniceanu, Crisan, Mila 23, Caraorman, Sfantu Gheorghe.

27. The ESSA team also convened a consultation with the Roma Sounding Board[76] on March 28, 2019 (9 Roma organizations were present at the meeting: Roma Educational Fund, Danrom, CRIS, Roma Centre for Health Policies - Sastipen, Resource Centre for Roma Communities, Romani CRISS, NevoParudimos, Botosani Roma Marginalized Association) in relation to the Program's outcomes. The final draft of the ESSA report was presented in a workshop during Program appraisal on June 25, 2019 with the participation of the MoH, NHIH, MoPF and representatives of other groups. Prior to organizing the workshop, the English and Romanian versions of the draft ESSA report were posted on the website of the World Bank's Country Office for Romania on June 17, 2019.

28. The final draft of the ESSA report was presented in a workshop during the Program appraisal on June 25, 2019 with the participation of the MoH, NHIH, MoPF and representatives of other groups, including: the Sanitas Federation in Romania, the National Association for the Protection of Patients, ADCIA Botosani and Danrom Association. Comments on the draft report were shared by the Federation of Associations of Family Physicians' Employers and the Cluj School of Public Health. The participants endorsed the findings of the draft ESSA report, while emphasizing issues such as increased collaboration between PHC providers and community health care workers to improve primary healthcare access for underserved groups, conducting community needs assessments and monitoring the results of the Program's interventions. The draft ESSA report was finalized upon consideration of the feedback provided.

29. The final ESSA report was disclosed on the World Bank's website on August 15, 2019.

[76] This was established in 2017 at the level of the World Bank office in Romania.

ANNEX 6. PROGRAM ACTION PLAN

Action Description	Source	DLI#	Responsibility	Timing		Completion Measurement
Sufficient allocation of Program funding in the budget and timely remittance of financing to implementing entities	Fiduciary Systems		MoPF	Recurrent	Continuous	Program funding consistent with annual workplans.
Strengthen the enforcement of the existing regulations for medical waste management to handle, collect, record, store, decontaminate, transport and disposal of waste by developing/updating/revising internal procedures and guidelines at PHC	Environmental and Social Systems		MoH	Other	First 2 years of Program implementation	Analysis of MoH internal regulations norms for implementing the procedures for reactive and preventive identified priorities for medical waste management confirmed
Strengthen the capacity to adapt, prevent and react to extreme weather events by developing/updating/revising internal procedures and guidelines at PHC	Environmental and Social Systems		MoH	Other	First 2 years of Program implementation	Analysis of MoH internal regulations/norms for implementing the procedures for reactive and preventive identified priorities for adaptation to climate change effects confirmed
Develop and implement existing communication tools, as may be relevant, to increase public awareness of Program initiatives in consultation with the World Bank	Environmental and Social Systems		MoH, NIPH, CSO, other	Other	Second and third years of Program implementation	Findings on the level of public awareness regarding access to basic services package for uninsured
Strengthening a unit of the MoH to ensure integration at the institutional level of strategic	Technical		MoH	Due Date	31-Mar-2020	A ministerial order will be issued to specify the unit staffing, job descriptions and qualifications, overall institutional mandate, and

planning for primary and community health care services						operational budget.
Determining the benefit package for PHC, including the currently uninsured	Technical		MoH, NHIH, MoPF	Due Date	30-Jun-2020	Benefit package for PHC determined and incorporated in the Health Care Law 95/2006.
Issuing government decision and Joint Ministerial Order to establish the state-aid scheme	Technical		MoH, MoPF	Due Date	31-Dec-2019	Government Decision and Joint Ministerial Order (MoH & MoPF) define the criteria, scope and tools for application for grants or loans of up to EUR 50,000.
Conducting public expenditure review based on defined scope of work	Technical		MoPF	Other	At least 2 times during Program period	PER conducted and results analyzed and used for decision making
Maintain records of and track the number of patients, on a sample basis, whom community health workers have referred to acquire IDs for their registration with family physicians	Environmental and Social Systems		NHIH, MoH, MoSPJ	Recurrent	Yearly	Reporting by community health workers on the number of patients who have been referred by community health workers to acquire an ID for their registration with family physicians
Adequate arrangements and technical capacity to prepare Program financial statements and have them timely audited	Fiduciary Systems		MoH	Recurrent	Continuous	Timely preparation and audit of Program financial statements.
Technical assistance for the establishment of centralized procurement of medical supplies – including systems and staffing	Fiduciary Systems		MoH/MoPF/ONAC	Other	First year of Program implementation	Report on completed review and implementation of report's recommendations – included in annual progress report
Technical assistance for the establishment and maintenance of electronic platforms for collation of	Fiduciary Systems		MoH/MoPF/ONAC	Due Date	30-Dec-2022	Report on system functionalities and roll-out data, including information on capacity building of actual and potential users – included in annual progress report.

procurement needs of implementing entities to support timely centralized procurement						
Ensuring fund availability for grants under the de minimis aid scheme	Technical		MoPF	Due Date	31-Mar-2020	Sufficient funds available under the state-aid scheme to achieve Program targets.
Adequate technical capacity to develop and implement de minimis aid scheme and performance-based financing mechanism	Fiduciary Systems		MoPF, MoH	Recurrent	Continuous	Effective systems of internal control and oversight established and maintained - evidenced in annual progress and audit reports.
Conducting training of community nurses and Roma mediators on public community health care in collaboration with PHC providers	Technical		MoH	Other	Year 2 of Program implementation	Training conducted and evaluation report from training participants available.

ANNEX 7. IMPLEMENTATION SUPPORT PLAN

COUNTRY : Romania
Romania Health Program for Results

1. The Implementation Support Plan is in line with the Bank's PforR operational guidelines. The Borrower is responsible for the implementation of all Program activities in support of achievement of the agreed DLIs, as well as of elimination of inefficiencies/bottlenecks identified in the social, environment and fiduciary assessments. The Bank will tailor implementation support in technical, fiduciary, environmental and social aspects to ensure the following:

(a) Provide technical advice to the implementation of the PAP, the achievement of DLIs and elimination of other social, fiduciary or governance- related bottlenecks relevant to the Program;
(b) Review the Program implementation progress, review program progress reports and such other relevant information;
(c) Advise and review documentation prior to serving as evidence for the fulfillment of DLRs as may be appropriate (e.g., revision of Framework Contract with PHC service providers);
(d) Monitor health system performance with an emphasis on the Program result areas and monitoring compliance with legal agreements, keep records of risks and propose remedy actions to improve Program performance, if and as needed;
(e) Provide support in resolving any operational issues pertaining to the Program, including review of grievance redress mechanisms;
(f) Monitor the performance of fiduciary systems, potential changes in fiduciary risks of the Program, and the Program's performance in terms of timely availability of financing to the ONAC, MoH, and NHIH;
(g) Monitor the Program financial statement preparation process and assist the Borrower as necessary;
(h) Review the Program annual financial and procurement audit reports and management letters, discuss with the Borrower and monitor the implementation of the auditor's recommendation;
(i) Based on the information provided by the audit reports, assess and analyze changes in fiduciary performance of the Program and propose remedial actions, as needed;
(j) Review the MoPF (including ONAC), MoH, and NHIH internal audit annual plans, terms of reference and the scope of the audit at PHC facilities. Review the annual internal audit reports and discuss with the Borrower the auditors' finding and recommendations as well as the necessary actions to address the observations and implement the recommendations;
(k) Monitor and help the Borrower as needed with institutional fiduciary capacity building. In particular:
- review implementation progress and achievement of Program results, including effectiveness and quality of procurement planning, timeliness and competitiveness of the procurement processes;
- provide support for implementation issues and institutional capacity building, as releant;
- monitor the performance of the fiduciary systems and audits, as well as compliance with fiduciary provisions of the legal covenants and the PAP.

2. The following major categories of support are envisioned:

(a) **Implementation support, capacity building, and training relating to the result areas and DLIs:** some DLIs have initial milestones that require intensive upfront support from Bank staff and consultants. Examples of required expertise and experience include developing technical specifications for several online platforms, content development for online training material, areas relating to the revisions of the benefit package and the drug list (such as evidence-based medicine, health technology assessment, and budget impact analysis), development of procedure classification for PHC, and developing reporting templates for quality care online dashboard;

(b) **Supervision of operation, technical and fiduciary review:** supervision will be conducted on a regular basis. Given the fiduciary weaknesses in the Program system, the fiduciary support will be more extensive than for a regular Bank operation (or Investment Project Financing instrument).

Table 19. Main focus of implementation support

Time	Focus	Skills needed	Resource estimate*	Partner role
First 12 months	Program Operations Manual Technical specifications (TS) for quality data platform and CPD platform Developing Health Data Management Strategy Revision of benefit package and drug list Provider payment Drug price control measures Fiduciary/budget planning Environment and Social Systems Patient experience perspective	Operation, planning, M&E Health information system/e-Health/IT NCD Strategic purchasing Health economics Costing of services Pharmaceuticals Quality assurance governance Fiduciary Environment and Social Systems Citizen engagement expertise	Three visits of the core team to: (1) Develop the Program Operations Manual and train on PforR implementation; (2) Launch the PforR and start TA on technical areas; (3) Supervise and provide implementation supports. TA support as needed by specialty areas	EU to participate in supervision visits, provide inputs in their areas of expertise and coordinate activities.
12-48 months	Program operation Process monitoring and evaluation Content development for online continuing medical education Electronic health standardization Technical specifications (TS) for health information systems Data reporting, QOC measuring Clinical guideline/protocol revision Procedure classification for PHC	Operation, planning, M&E Health information system/e-Health/IT Expert in content development (focused on PHC and community health care) Strategic purchasing Health economics Costing of services Expertise in evidence-based medicine Pharmaceuticals Quality assurance governance Fiduciary	Regular supervision visits TA support as needed by specialty areas	EU to participate in supervision visits, provide inputs in their areas of expertise and coordinate activities.

Time	Focus	Skills needed	Resource estimate*	Partner role
	Fiduciary/budget planning Environment and Social Systems Patient experience perspective	Environment and Social Systems Citizen engagement expertise		
Mid-term review	Assessment of Program achievement at mid-term; Potential restructuring	Operation, M&E Program evaluation Fiduciary, environmental and social systems expertise	Conduct mid-term assessment	EU to provide inputs at the mid-term review workshop

*Total resources needed estimated at US$0.4 million per fiscal year.

3. The World Bank core task team will include the task team leader(s) (health specialist and/or economist), operations officer, technical specialist (economist and/or health specialist), procurement, financial management, environmental and social systems specialists. Some team members are based in the country or region to provide prompt support and follow up on implementation of the Program. Expertise from the Health, Nutrition, and Population Global Practice, as well as from other practices will be drawn upon as needed.

Table 20. Task team skills mix requirements for implementation support (per year)

Skills needed	Number of staff weeks	Number of trips	Comments
Senior economist (task team leader)	16	3-4	Headquarters-based
Health specialist	22		Country based
Senior operation officer	10	3	Headquarters-based
Quality of care and service delivery expert	12	3-4	Headquarters-based
Health economist/strategic purchasing	12	3-4	Headquarters-based
E-health and health information system expert	4	1	Headquarters-based
Technical consultants	As required	As required	International and in-country
Procurement specialist	5		Based in the region
Financial management specialist	5	2	Country based
Lead Financial management specialist	2	2	Headquarters-based
Environment specialist	2	2	Country based
Social specialist	2	2	Headquarters-based or country based

ANNEX 8: ROLES AND RESPONSIBILITIES WITH RESPECT TO THE DLIs

Disbursement-linked Indicators (DLI)		Responsibilities of Entities and Institutions							
		Health Facilities	Local Public Administration	MoH/Department of Community and Primary Health Care	MoH/Budget Department	MoH/Procurement and HTA Departments	NHIH (also District Health Insurance House DHIH)	MoPF/Budget Department	MoPF/ONAC
DLI #1	**Access to the basic package of PHC services among the uninsured**			MoH, with the MoPF and NHIH, to define the scope of the basic benefit package for uninsured people in primary care within the Law 95/2006. A joint order of the MoH and NHIH will be released to enact the by-laws of the revised framework contract.				Ensure appropriate budget allocation to cover the population	
DLI #2	**Number of underserved communities receiving public community health care in collaboration with PHC providers** [77]		Signed agreements with the MoH to implement community health care in collaboration with primary care in the selected local public administration units.	Develop the protocols and tools for implementation of collaboration between primary and community care; Develop ToR, including staffing profiles, for a primary and Social Inclusion Unit in the MoH.					
DLI #3	**Share of the NHIH budget allocated to PHC**			Adjust the clinical pathways and guidelines to expand the scope of PHC services, including amending diabetic guidelines; A joint order with NHIH to enact the by-laws of the revised			Revise FC to incentivize effective PHC and expanded scope of services, including modification of fee-for-services (FFS) mechanism, improve risk-adjusted capitation, introduction of		

[77] The Local Public Administration Authorities, under the coordination of the Ministry of Regional Development and Public Administration, and the DPHAs, under the coordination of the Ministry of Health, will be involved in the implementation of community health care and of the de minimis aid scheme. Under the framework of Emergency Ordinance 18/2017, the DPHAs will supervise the implementation of community health care at the local level, including collaboration with family physicians. The DPHAs will also be responsible for monitoring and evaluation of activities under the responsibility of Local Public Administration Authorities, Community Health Nurses, and Roma Health Mediators.

				framework contract.			performance-based payments; and increase budget allocated to family medicine. Translate changes in clinical guidelines into the framework contract.		
DLI #4	**Number of family medicine practices receiving grants and loans for the purpose of increasing and improving the supply of PHC services** [78]	Submit proposals to the MoH in accordance with the regulatory framework for the de minimis aid scheme	To facilitate the sale, (5-year) concession or lease of family medicine cabinets.	MoPF and MoH to co-initiate a draft Government Decision and provide regulatory framework to precisely defining the de minimis aid scheme and technical guidelines (eligibility criteria, flow of funds); Make call for proposals from family medicine physicians; Approve proposals according to adopted Government Decision	To finance proposals according to the regulatory framework for the de minimis aid scheme			MoPF , through its relevant departments,MoH and NHIH to issue government decision for the minimis aid and provide regulatory documents to define de minimis aid To transfer budget to MoH	
DLI #5	**Scope and effectiveness of PHC traced through the share of diabetes medication initiation by PHC providers and proportion of adults (40+) receiving annual medical check-ups**						E-prescription system of the NHIH will provide data on the reimbursement by volume for metformin by provider type. The NHIH will revise the scope of regular check-up, incentivize family physicians to provide more annual medical		

78 The Local Public Administration Authorities are tasked, under the framework of Emergency Ordinance 18/2017, in providing work space and funding of operational costs of Community Health Nurses and Roma Health Mediators. The protocols to guide these functions will be supported through the Program. Within the de minimis aid scheme, family physicians will be expected to enter into agreements with Local Authorities to refurbish primary health care facilities provided by the Local Authorities as needed. In accordance with the scheme implementation manual, the DPHAs will also assess the eligibility of the applications by family physicians for financial support from the scheme and monitor the investments in primary health care practices at the local level.

							check-ups and report levels of check-ups		
DLI #6	**Efficiency of NHIH expenditure improved through data-driven decision-making process**			To develop Health Data Management Strategy To develop institutional arrangements on improved data governance and responsibilities for the implementation of the Health Data Management Strategy. Establish software systems certification mechanisms. To develop fundamental registries (as on-line services) To upgrade community health care information system To implement Heath Data Observatory (in IPH). To use improved methodology and algorithms to make better policies and decisions, thus increasing the efficiency of the healthcare system by avoiding unnecessary NHIH expenditures.			To upgrade core NHIH systems To develop and implement adaptive algorithms for analysis of service delivery (including claims) EHR implemented. To implement/upgrade and integrate key central systems (EHR, e-Prescription, e-Referrals, patients' portal) To implement Integrated Health Management Information System (HMIS) To use improved methodology and algorithms to make better policies and decisions, thus increasing the efficiency of the healthcare system by avoiding unnecessary NHIH expenditures.		To use improved methodology and algorithms to make better policies and decisions, thus increasing the efficiency of the healthcare system by avoiding unnecessary NHIH expenditures.
DLI #7	**Efficiency of expenditure improved through implementation of centralized procurement**	Hospitals provide quantities of required standardized goods to MoH. EMS departments provide quantities of medical supplies and		MoH to send an agreed list of items to procure and set the internal procedures to collect and transmit the data.		MoH provides technical specifications for medical supplies and devices and or Terms of Reference for bidding/ selection process by ONAC. MoH collects needs (medical supplies and devices) from EMS department and			MoPF and MoH will develop an Emergency Ordinance allowing ONAC to implement centralized procurement for the health sector. ONAC conducts

		devices for EMS to MoH.				publicly-owned hospitals. Ministry of Interior provides technical specifications for medical supplies and devices for EMS departments for the bidding/ selection process by ONAC.			procurement based on the list of items, including the needs and quantities, technical specifications for medical products and devices and Terms of Reference for bidding/ selection process from MoH MoPF completes staffing of ONAC
DLI #8	**Pharmaceutical measures revised for better efficiency**			Two revisions of the list of medicines based on HTA department recommendations. Annual implementation and publishing on web site of international price comparisons.	Revised regulation on the differentiated clawback tax.	Revision of HTA methodology; Agency for Medicines HTA department – HTA to result in two revisions of the lists of medicine	Annual implementation and publishing on web site of reference pricing. Managed entry agreements for patented medicines		

ANNEX 9: MAP OF ROMANIA